

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                                             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|----------------------------|------------------------------------------------------------------|-----------------|--------------|----------------|
| 29-May-2012                                                                                | 8505242                  | EXPEDITED (15-DAY) | N                  | OT              | US-JNJFOC-20120404439      |                                                                  |                 | Male         | USA            |
| <u>Preferred Term</u>                                                                      | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                                               | <u>Duration</u> | <u>Mfr</u>   |                |
| Cerebrovascular Accident; Hypertension; Muscle Spasticity; Musculoskeletal Stiffness; Pain | Tramadol Hydrochloride   |                    |                    | S               | Unknown                    |                                                                  |                 | Not Reported |                |
|                                                                                            | Wellbutrin               |                    |                    | S               | Oral                       |                                                                  |                 | Not Reported |                |
|                                                                                            | Lexapro                  |                    |                    | S               | Unknown                    |                                                                  |                 | Not Reported |                |
|                                                                                            | Cymbalta                 |                    |                    | S               | Oral                       |                                                                  |                 | Not Reported |                |
|                                                                                            | Unspecified Ingredient   |                    |                    | S               | Unknown                    |                                                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                                             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-May-2012                                                                                | 8583113                  | EXPEDITED (15-DAY) | Y                  | OT              | IT-JNJFOC-20120515989      |                                                                  | 77 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                                      | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                                               | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypotension; Intentional Overdose; Intentional Self-Injury; Tachycardia                    | Risperdal                |                    |                    | S               | Oral                       |                                                                  |                 | Not Reported |                |
|                                                                                            | Lorazepam                |                    |                    | S               | Oral                       |                                                                  |                 | Not Reported |                |
|                                                                                            | Metformin Hydrochloride  |                    |                    | S               | Oral                       |                                                                  |                 | Not Reported |                |
|                                                                                            | Lyrica                   |                    |                    | S               | Oral                       |                                                                  |                 | Not Reported |                |
|                                                                                            | Escitalopram Oxalate     |                    |                    | S               | Oral                       |                                                                  |                 | Not Reported |                |
|                                                                                            | Flurazepam Hydrochloride |                    |                    | S               | Oral                       |                                                                  |                 | Not Reported |                |
|                                                                                            | Levothyroxine Sodium     |                    |                    | S               | Oral                       |                                                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                                             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-May-2012                                                                                | 8583594                  | EXPEDITED (15-DAY) | Y                  | HO, OT          | AU-ASTRAZENECA-2012SE32165 |                                                                  | < 1 DAY         | Male         | AUS            |
| <u>Preferred Term</u>                                                                      | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                                               | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Withdrawal Syndrome Neonatal; Meconium Abnormal                                       | Seroquel Xr              |                    |                    | S               | Transplacental             | 75-100 Mg Daily Started Pre-Pregnancy And Stopped After Delivery |                 | Astrazeneca  |                |
|                                                                                            | Lexapro                  |                    |                    | S               | Transplacental             | 20mg Daily Started At                                            |                 | Not Reported |                |

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|                                                      |   |                |                                                                   |              |
|------------------------------------------------------|---|----------------|-------------------------------------------------------------------|--------------|
| Dextroamphetamine                                    | S | Transplacental | 16/40 Weeks And Stopped After Delivery                            | Not Reported |
| Dexamethasone                                        | C | Transplacental | 10mg As Required Started Pre-Pregnancy Until 35/40 Weeks          | Not Reported |
| Aminobenzoic Acid\Biotin\Choline\Folic Acid\Inositol | C | Transplacental | 10mg As Required Started Pre-Pregnancy And Stopped At 35/40 Weeks | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-May-2012              | 8583794       | EXPEDITED (15-DAY) | Y                  | OT              | AT-ROCHE-1071795     |                      | 28 YR      | Male       | AUT            |

| <u>Preferred Term</u>   | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Extrapyramidal Disorder | Rivotril                |              |            | S           |              | Dose Reduced       |                 | Not Reported |
|                         | Rivotril                |              |            | S           |              |                    |                 | Not Reported |
|                         | Cipralex                |              |            | S           |              |                    |                 | Not Reported |
|                         | Haldol                  |              |            | S           |              | Dose Increased     |                 | Not Reported |
|                         | Haldol                  |              |            | S           |              | Dose Reduced       |                 | Not Reported |
|                         | Haldol                  |              |            | S           |              |                    |                 | Not Reported |
|                         | Lyrica                  |              |            | S           |              |                    |                 | Not Reported |
|                         | Lyrica                  |              |            | S           |              |                    |                 | Not Reported |
|                         | Mianserin Hydrochloride |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-May-2012              | 8584185       | EXPEDITED (15-DAY) | Y                  | OT              | IN-WATSON-2012-08513 |                      | 67 YR      | Male       | IND            |

| <u>Preferred Term</u>       | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------|----------------------|--------------|------------|-------------|--------------|--------------------------|-----------------|--------------|
| Drug Interaction; Hypomania | Clonazepam           |              |            | S           | Unknown      | 0.5 Mg, Daily At Bedtime |                 | Watson       |
|                             | Escitalopram Oxalate |              |            | S           | Unknown      | 10 Mg, Daily             |                 | Not Reported |

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| <u>FDA Received Date</u>                                                                             | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 29-May-2012                                                                                          | 8584787                 | EXPEDITED (15-DAY) | Y                  | OT              | US-FRI-1000030783    |                      | 49 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Gastrointestinal Inflammation; Nausea; Vomiting                                                      | Lexapro                 |                    |                    | S               |                      | 20 Mg                |                 | Forest       |                |
|                                                                                                      | Lexapro                 |                    |                    | S               |                      |                      | 10 YR           | Forest       |                |
| <u>FDA Received Date</u>                                                                             | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-May-2012                                                                                          | 8584813                 | EXPEDITED (15-DAY) | Y                  | OT              | FR-FRI-1000030819    |                      | 66 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Middle Insomnia; Night Sweats                                                                        | Escitalopram Oxalate    |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                                                                                      | Metformin Hydrochloride |                    |                    | C               | Oral                 | 1700 Mg              |                 | Not Reported |                |
|                                                                                                      | Olmotec                 |                    |                    | C               | Oral                 | 10 Mg                |                 | Not Reported |                |
|                                                                                                      | Fenofibrate             |                    |                    | C               | Oral                 | 200 Gbq              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                             | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-May-2012                                                                                          | 8585901                 | EXPEDITED (15-DAY) | Y                  | HO              | AU-FRI-1000030789    |                      | 23 YR           | Female       | AUS            |
| <u>Preferred Term</u>                                                                                | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Breast Discharge; Breast Pain; Breast Swelling; Depression; Galactorrhoea; Psychomotor Hyperactivity | Lexapro                 |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                             | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-May-2012                                                                                          | 8600368                 | DIRECT             | N                  |                 |                      |                      | 59 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Asthenia;                                                                                   | Escitalopram Oxalate    |                    |                    | S               | Oral                 | 10 Mgs Bid Po        |                 | Mylan        |                |

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Depression; Product  
Substitution Issue; Tremor

| <u>FDA Received Date</u>             | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------|----------------------|--------------------|--------------------|-----------------|------------------------------------------|----------------------|-----------------|--------------|----------------|
| 31-May-2012                          | 7860434              | EXPEDITED (15-DAY) | Y                  | OT              | CA-FRI-1000022159                        |                      |                 | Female       | CAN            |
| <u>Preferred Term</u>                | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Mood Swings;<br>Overdose | Escitalopram Oxalate |                    |                    | S               | Oral                                     | 30 Mg                |                 | Forest       |                |
|                                      | Remicade             |                    |                    | S               | Intravenous (not<br>otherwise specified) | 5.3571 Mg            |                 | Not Reported |                |

| <u>FDA Received Date</u>             | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 31-May-2012                          | 8569953                | EXPEDITED (15-DAY) | Y                  | HO, LT          | ES-FRI-1000030586    |                      | 73 YR           | Female       | ESP            |
| <u>Preferred Term</u>                | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypercreatinaemia;<br>Rhabdomyolysis | Escitalopram Oxalate   |                    |                    | S               | Oral                 | 5 Mg                 |                 | Forest       |                |
|                                      | Depakene               |                    |                    | S               | Oral                 | 400 Mg               |                 | Not Reported |                |
|                                      | Pantoprazole           |                    |                    | S               | Oral                 | 40 Mg                |                 | Not Reported |                |
|                                      | Fluvastatin            |                    |                    | S               | Oral                 | 80 Mg                |                 | Not Reported |                |
|                                      | Tramadol Hydrochloride |                    |                    | S               | Oral                 | 150 Mg               |                 | Not Reported |                |
|                                      | Ultracet               |                    |                    | S               | Oral                 | 3 Df                 |                 | Not Reported |                |

| <u>FDA Received Date</u>                                 | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| 31-May-2012                                              | 8585914              | EXPEDITED (15-DAY) |                    | DE, OT          | US-PFIZER INC-<br>2010001738 |                      | 49 YR           | Female       | USA            |
| <u>Preferred Term</u>                                    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Completed<br>Suicide; Respiratory Arrest | Citalopram           |                    |                    | S               | Oral                         | Unk                  |                 | Not Reported |                |
|                                                          | Escitalopram Oxalate |                    |                    | S               | Oral                         | Unk                  |                 | Not Reported |                |
|                                                          | Venlafaxine Hcl      |                    |                    | S               | Oral                         | Unk                  |                 | Pfizer       |                |
|                                                          | Ethanol              |                    |                    | S               | Oral                         | Unk                  |                 | Not Reported |                |



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| <u>FDA Received Date</u>                                                                                                                                                                                    | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|-----------------|----------------|
| 31-May-2012                                                                                                                                                                                                 | 8588592                  | EXPEDITED (15-DAY) | Y                  | DE, HO, OT      | US-GLAXOSMITHKLINE-B0803431A |                      | 29 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                       | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Areflexia; Completed Suicide; Gastrointestinal Sounds Abnormal; Hypotension; Hypoxic-Ischaemic Encephalopathy; Overdose; Peripheral Coldness; Pulseless Electrical Activity; Pupil Fixed; Sinus Tachycardia | Bupropion                |                    |                    | S               | Unknown                      |                      |                 | Glaxosmithkline |                |
|                                                                                                                                                                                                             | Quetiapine               |                    |                    | S               | Unknown                      |                      |                 | Glaxosmithkline |                |
|                                                                                                                                                                                                             | Escitalopram Oxalate     |                    |                    | S               | Unknown                      |                      |                 | Glaxosmithkline |                |
|                                                                                                                                                                                                             | Ibuprofen                |                    |                    | S               | Unknown                      |                      |                 | Glaxosmithkline |                |
|                                                                                                                                                                                                             | Desvenlafaxine Succinate |                    |                    | S               | Unknown                      |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                                                                                                    | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 31-May-2012                                                                                                                                                                                                 | 8588723                  | EXPEDITED (15-DAY) | N                  | CA              | US-FRI-1000030913            |                      | < 1 DAY         | Male            | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                       | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Coarctation Of The Aorta                                                                                                                                                                                    | Lexapro                  |                    |                    | S               | Transplacental               |                      |                 | Forest          |                |
| <u>FDA Received Date</u>                                                                                                                                                                                    | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 31-May-2012                                                                                                                                                                                                 | 8588777                  | EXPEDITED (15-DAY) | N                  | CA              | US-FRI-1000030911            |                      | < 1 DAY         | Male            | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                       | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Atrial Septal Defect; Patent Ductus Arteriosus                                                                                                                                                              | Lexapro                  |                    |                    | S               | Transplacental               |                      |                 | Forest          |                |
| <u>FDA Received Date</u>                                                                                                                                                                                    | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 31-May-2012                                                                                                                                                                                                 | 8588813                  | EXPEDITED (15-DAY) | N                  | CA              | US-FRI-1000030909            |                      | < 1 DAY         | Male            | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                       | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Hypoplastic Left Heart                                                                                                                                                                                      | Lexapro                  |                    |                    | S               | Transplacental               |                      |                 | Forest          |                |

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Syndrome

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 31-May-2012                       | 8588830                | EXPEDITED (15-DAY)        | N                           | DE                       | US-FRI-1000030907             |                               | < 1 DAY             | Male                | USA                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Cardiac Disorder               | Lexapro                 |                       |                     | S                    | Transplacental        |                             |                          | Forest              |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 31-May-2012                       | 8588848                | EXPEDITED (15-DAY)        | N                           | CA                       | US-FRI-1000030855             |                               | < 1 DAY             | Female              | USA                     |

| <a href="#">Preferred Term</a>                                   | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|------------------------------------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Hypoplastic Left Heart Syndrome; Maternal Drugs Affecting Foetus | Lexapro                 |                       |                     | S                    | Transplacental        |                             |                          | Forest              |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 31-May-2012                       | 8588882                | EXPEDITED (15-DAY)        | N                           | CA                       | US-FRI-1000030901             |                               | < 1 DAY             | Male                | USA                     |

| <a href="#">Preferred Term</a>  | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|---------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Hypoplastic Left Heart Syndrome | Lexapro                 |                       |                     | S                    | Transplacental        |                             |                          | Forest              |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 31-May-2012                       | 8589063                | EXPEDITED (15-DAY)        | N                           | CA                       | US-FRI-1000030863             |                               | < 1 DAY             | Male                | USA                     |

| <a href="#">Preferred Term</a>  | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|---------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Hypoplastic Left Heart Syndrome | Lexapro                 |                       |                     | S                    | Transplacental        |                             |                          | Forest              |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 31-May-2012                       | 8589156                | EXPEDITED (15-DAY)        | Y                           | OT                       | CA-FRI-1000022122             |                               | 28 YR               | Male                | CAN                     |

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| <u>Preferred Term</u>                                                                                      | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Headache; Nausea; Overdose; Photophobia; Vision Blurred                                                    | Escitalopram Oxalate |                    |                    | S               | Oral                 | 30 Mg                |                 | Forest       |                |
|                                                                                                            | Wellbutrin XI        |                    |                    | S               | Oral                 | 150 Mg               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-May-2012                                                                                                | 8589269              | EXPEDITED (15-DAY) | N                  | CA              | US-FRI-1000030899    |                      | < 1 DAY         | Male         | USA            |
| <u>Preferred Term</u>                                                                                      | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aortic Valve Prolapse; Congenital Aortic Valve Incompetence; Ventricular Septal Defect                     | Lexapro              |                    |                    | S               | Transplacental       |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-May-2012                                                                                                | 8589373              | EXPEDITED (15-DAY) | N                  | CA              | US-FRI-1000030895    |                      | < 1 DAY         | Female       | USA            |
| <u>Preferred Term</u>                                                                                      | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrial Septal Defect; Patent Ductus Arteriosus; Pulmonary Artery Stenosis Congenital                       | Lexapro              |                    |                    | S               | Transplacental       |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-May-2012                                                                                                | 8589448              | EXPEDITED (15-DAY) | N                  | CA              | US-FRI-1000030877    |                      | < 1 DAY         | Male         | USA            |
| <u>Preferred Term</u>                                                                                      | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bicuspid Aortic Valve; Coarctation Of The Aorta; Hypoplastic Left Heart Syndrome; Patent Ductus Arteriosus | Lexapro              |                    |                    | S               | Transplacental       |                      |                 | Forest       |                |

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| <a href="#">FDA Received Date</a>                                                                                                       | <a href="#">Case #</a>             | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a>          | <a href="#">Country</a> |
|-----------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|------------------------------|-------------------------|
| 31-May-2012                                                                                                                             | 8589483                            | EXPEDITED (15-DAY)        | N                           | CA                       | US-FRI-1000030865             |                               | < 1 DAY                  | Female                       | USA                     |
| <a href="#">Preferred Term</a>                                                                                                          | <a href="#">Product</a>            | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a>          |                         |
| Heart Disease Congenital                                                                                                                | Lexapro                            |                           |                             | S                        | Transplacental                |                               |                          | Forest                       |                         |
| <a href="#">FDA Received Date</a>                                                                                                       | <a href="#">Case #</a>             | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a>          | <a href="#">Country</a> |
| 31-May-2012                                                                                                                             | 8589522                            | EXPEDITED (15-DAY)        | N                           | CA                       | US-FRI-1000030867             |                               | < 1 DAY                  | Male                         | USA                     |
| <a href="#">Preferred Term</a>                                                                                                          | <a href="#">Product</a>            | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a>          |                         |
| Coarctation Of The Aorta                                                                                                                | Lexapro                            |                           |                             | S                        | Transplacental                |                               |                          | Forest                       |                         |
| <a href="#">FDA Received Date</a>                                                                                                       | <a href="#">Case #</a>             | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a>          | <a href="#">Country</a> |
| 31-May-2012                                                                                                                             | 8589549                            | EXPEDITED (15-DAY)        | N                           | CA                       | US-FRI-1000030869             |                               | < 1 DAY                  | Male                         | USA                     |
| <a href="#">Preferred Term</a>                                                                                                          | <a href="#">Product</a>            | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a>          |                         |
| Atrial Septal Defect;<br>Fallot'S Tetralogy;<br>Pulmonary Artery Stenosis<br>Congenital; Ventricular<br>Septal Defect                   | Lexapro                            |                           |                             | S                        | Transplacental                |                               |                          | Forest                       |                         |
| <a href="#">FDA Received Date</a>                                                                                                       | <a href="#">Case #</a>             | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a>          | <a href="#">Country</a> |
| 31-May-2012                                                                                                                             | 8607666                            | DIRECT                    | Y                           |                          |                               |                               | 60 YR                    | Male                         | USA                     |
| <a href="#">Preferred Term</a>                                                                                                          | <a href="#">Product</a>            | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a>          |                         |
| Anal Incontinence;<br>Chromatopsia; Dyspnoea;<br>Hyperthermia; Loss Of<br>Consciousness; Serotonin<br>Syndrome; Urinary<br>Incontinence | Trazodone Hydrochloride<br>Lexapro |                           |                             | S<br>S                   |                               |                               |                          | Not Reported<br>Not Reported |                         |

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| <a href="#">FDA Received Date</a>                                   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|---------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 31-May-2012                                                         | 8610405                 | DIRECT                    | Y                           |                          |                               |                               | 31 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                      | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Agitation; Insomnia;<br>Product Substitution Issue;<br>Restlessness | Escitalopram Oxalate    |                           |                             | S                        |                               | 10mg Qd                       |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 01-Jun-2012                                                         | 8554387                 | EXPEDITED (15-DAY)        | Y                           | OT                       | US-FRI-1000030398             |                               | 38 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>                                      | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Abdominal Pain Upper;                                               | Escitalopram Oxalate    |                           |                             | S                        |                               | 5 Mg                          |                          | Forest              |                         |
| Anxiety; Arthralgia;                                                | Humira                  |                           |                             | S                        |                               | 40 Mg/0.8 MI Pen/2weeks       |                          | Not Reported        |                         |
| Burning Sensation;                                                  | Xanax                   |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
| Choking Sensation;                                                  |                         |                           |                             |                          |                               |                               |                          |                     |                         |
| Dizziness; Drug                                                     |                         |                           |                             |                          |                               |                               |                          |                     |                         |
| Ineffective; Dyspnoea; Eye                                          |                         |                           |                             |                          |                               |                               |                          |                     |                         |
| Swelling; Headache;                                                 |                         |                           |                             |                          |                               |                               |                          |                     |                         |
| Nausea; Neck Pain; Panic                                            |                         |                           |                             |                          |                               |                               |                          |                     |                         |
| Attack; Pharyngeal                                                  |                         |                           |                             |                          |                               |                               |                          |                     |                         |
| Oedema; Pruritus;                                                   |                         |                           |                             |                          |                               |                               |                          |                     |                         |
| Psoriasis; Swelling Face;                                           |                         |                           |                             |                          |                               |                               |                          |                     |                         |
| Swollen Tongue                                                      |                         |                           |                             |                          |                               |                               |                          |                     |                         |
| <a href="#">FDA Received Date</a>                                   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 01-Jun-2012                                                         | 8590463                 | EXPEDITED (15-DAY)        | N                           | CA                       | US-FRI-1000030871             |                               | < 1 DAY                  | Female              | USA                     |
| <a href="#">Preferred Term</a>                                      | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Atrial Septal Defect                                                | Lexapro                 |                           |                             | S                        | Transplacental                |                               |                          | Forest              |                         |
| <a href="#">FDA Received Date</a>                                   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 01-Jun-2012                                                         | 8590486                 | EXPEDITED (15-DAY)        | N                           | CA                       | US-FRI-1000030873             |                               | < 1 DAY                  | Male                | USA                     |

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| <u>Preferred Term</u>                                                                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
|-------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| Fallot'S Tetralogy                                                                        | Lexapro        |                    |                    | S               | Transplacental       |                      |                 | Forest     |                |
| <u>FDA Received Date</u>                                                                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 01-Jun-2012                                                                               | 8590651        | EXPEDITED (15-DAY) | N                  | CA              | US-FRI-1000030875    |                      | < 1 DAY         | Male       | USA            |
| <u>Preferred Term</u>                                                                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Atrial Septal Defect;<br>Maternal Drugs Affecting<br>Foetus; Ventricular Septal<br>Defect | Lexapro        |                    |                    | S               | Transplacental       |                      |                 | Forest     |                |
| <u>FDA Received Date</u>                                                                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 01-Jun-2012                                                                               | 8590756        | EXPEDITED (15-DAY) | N                  | CA              | US-FRI-1000030879    |                      | < 1 DAY         | Male       | USA            |
| <u>Preferred Term</u>                                                                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Transposition Of The<br>Great Vessels                                                     | Lexapro        |                    |                    | S               | Transplacental       |                      |                 | Forest     |                |
| <u>FDA Received Date</u>                                                                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 01-Jun-2012                                                                               | 8590881        | EXPEDITED (15-DAY) | N                  | CA              | US-FRI-1000030881    |                      | < 1 DAY         | Male       | USA            |
| <u>Preferred Term</u>                                                                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Ventricular Septal Defect                                                                 | Lexapro        |                    |                    | S               | Transplacental       |                      |                 | Forest     |                |
| <u>FDA Received Date</u>                                                                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 01-Jun-2012                                                                               | 8590950        | EXPEDITED (15-DAY) | N                  | CA              | US-FRI-1000030883    |                      | < 1 DAY         | Male       | USA            |
| <u>Preferred Term</u>                                                                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Atrioventricular Septal<br>Defect; Ventricular Septal<br>Defect                           | Lexapro        |                    |                    | S               | Transplacental       |                      |                 | Forest     |                |

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| <u>FDA Received Date</u>                                                                                                          | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 01-Jun-2012                                                                                                                       | 8590951        | EXPEDITED (15-DAY) | N                  | DE              | US-FRI-1000030885    |                      |                 | Male       | USA            |
| <u>Preferred Term</u>                                                                                                             | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Cardiac Disorder                                                                                                                  | Lexapro        |                    |                    | S               | Transplacental       |                      |                 | Forest     |                |
| <u>FDA Received Date</u>                                                                                                          | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 01-Jun-2012                                                                                                                       | 8590979        | EXPEDITED (15-DAY) | N                  | CA              | US-FRI-1000030887    |                      | < 1 DAY         | Male       | USA            |
| <u>Preferred Term</u>                                                                                                             | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Atrial Septal Defect;<br>Patent Ductus Arteriosus;<br>Ventricular Septal Defect                                                   | Lexapro        |                    |                    | S               | Transplacental       |                      |                 | Forest     |                |
| <u>FDA Received Date</u>                                                                                                          | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 01-Jun-2012                                                                                                                       | 8591063        | EXPEDITED (15-DAY) | N                  | CA              | US-FRI-1000030889    |                      | < 1 DAY         | Male       | USA            |
| <u>Preferred Term</u>                                                                                                             | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Transposition Of The<br>Great Vessels                                                                                             | Lexapro        |                    |                    | S               | Transplacental       |                      |                 | Forest     |                |
| <u>FDA Received Date</u>                                                                                                          | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 01-Jun-2012                                                                                                                       | 8591174        | EXPEDITED (15-DAY) | N                  | CA              | US-FRI-1000030891    |                      | < 1 DAY         | Female     | USA            |
| <u>Preferred Term</u>                                                                                                             | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Double Outlet Right<br>Ventricle; Fallot'S<br>Tetralogy; Pulmonary<br>Artery Stenosis<br>Congenital; Ventricular<br>Septal Defect | Lexapro        |                    |                    | S               | Transplacental       |                      |                 | Forest     |                |

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| <a href="#">FDA Received Date</a>                                   | <a href="#">Case #</a>         | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>  | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a>    | <a href="#">Country</a> |
|---------------------------------------------------------------------|--------------------------------|---------------------------|-----------------------------|--------------------------|--------------------------------|-------------------------------|--------------------------|------------------------|-------------------------|
| 01-Jun-2012                                                         | 8591214                        | EXPEDITED (15-DAY)        | N                           | CA                       | US-FRI-1000030893              |                               | < 1 DAY                  | Male                   | USA                     |
| <a href="#">Preferred Term</a>                                      | <a href="#">Product</a>        | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>          | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a>    |                         |
| Fallot'S Tetralogy                                                  | Lexapro                        |                           |                             | S                        | Transplacental                 |                               |                          | Forest                 |                         |
| <a href="#">FDA Received Date</a>                                   | <a href="#">Case #</a>         | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>  | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a>    | <a href="#">Country</a> |
| 01-Jun-2012                                                         | 8591244                        | EXPEDITED (15-DAY)        | N                           | CA                       | US-FRI-1000030903              |                               | < 1 DAY                  | Male                   | USA                     |
| <a href="#">Preferred Term</a>                                      | <a href="#">Product</a>        | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>          | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a>    |                         |
| Maternal Drugs Affecting Foetus; Transposition Of The Great Vessels | Lexapro                        |                           |                             | S                        | Transplacental                 |                               |                          | Forest                 |                         |
| <a href="#">FDA Received Date</a>                                   | <a href="#">Case #</a>         | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>  | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a>    | <a href="#">Country</a> |
| 01-Jun-2012                                                         | 8610741                        | DIRECT                    | Y                           | DE, OT                   |                                |                               | 23 YR                    | Male                   | USA                     |
| <a href="#">Preferred Term</a>                                      | <a href="#">Product</a>        | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>          | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a>    |                         |
| Completed Suicide; Gun Shot Wound; Product Substitution Issue       | Escitalopram Oxalate           |                           |                             | S                        | Oral                           | 20mg Qday Po                  | 10 DAY                   | Not Reported           |                         |
| <a href="#">FDA Received Date</a>                                   | <a href="#">Case #</a>         | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>  | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a>    | <a href="#">Country</a> |
| 04-Jun-2012                                                         | 8447525                        | EXPEDITED (15-DAY)        | Y                           | CA                       | FR-FRI-1000028867              |                               | < 1 DAY                  | Female                 | FRA                     |
| <a href="#">Preferred Term</a>                                      | <a href="#">Product</a>        | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>          | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a>    |                         |
| Foetal Exposure During Pregnancy; Gaze Palsy; Tremor                | Escitalopram Oxalate<br>Zoloft |                           |                             | S<br>C                   | Transplacental<br>Transmammary | 10 Mg                         |                          | Forest<br>Not Reported |                         |
| <a href="#">FDA Received Date</a>                                   | <a href="#">Case #</a>         | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>  | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a>    | <a href="#">Country</a> |
| 04-Jun-2012                                                         | 8514716                        | EXPEDITED (15-DAY)        | Y                           | HO, OT                   | CH-FRI-1000029760              |                               |                          | Female                 | CHE                     |



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| <u>Preferred Term</u>                                                                                                                     | <u>Product</u>                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------|--------------------|--------------------|-----------------|-----------------------|-------------------------------|-----------------|--------------|----------------|
| Chest Discomfort;<br>Myalgia; Paraesthesia;<br>Visual Impairment                                                                          | Escitalopram Oxalate                     |                    |                    | S               |                       | 20 Mg                         |                 | Forest       |                |
|                                                                                                                                           | Trazodone Hydrochloride                  |                    |                    | S               |                       |                               |                 | Not Reported |                |
|                                                                                                                                           | Bactrim                                  |                    |                    | S               |                       |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                  | <u>Case #</u>                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Jun-2012                                                                                                                               | 8577075                                  | NON-EXPEDITED      | Y                  | HO              | FR-JNJFOC-20120513760 |                               | 84 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                     | <u>Product</u>                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Seizure                                                                                                                 | Tramadol Hydrochloride And Acetaminophen |                    |                    | S               | Oral                  |                               |                 | Not Reported |                |
|                                                                                                                                           | Lorazepam                                |                    |                    | C               | Unknown               |                               |                 | Not Reported |                |
|                                                                                                                                           | Crestor                                  |                    |                    | C               | Unknown               |                               |                 | Not Reported |                |
|                                                                                                                                           | Cytomel                                  |                    |                    | C               | Unknown               |                               |                 | Not Reported |                |
|                                                                                                                                           | Alendronate Sodium                       |                    |                    | C               | Unknown               |                               |                 | Not Reported |                |
|                                                                                                                                           | Hydrochlorothiazide\Valsartan            |                    |                    | C               | Unknown               |                               |                 | Not Reported |                |
|                                                                                                                                           | Tenormin                                 |                    |                    | C               | Unknown               |                               |                 | Not Reported |                |
|                                                                                                                                           | Aspirin                                  |                    |                    | C               | Unknown               |                               |                 | Not Reported |                |
|                                                                                                                                           | Escitalopram Oxalate                     |                    |                    | S               | Oral                  |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                  | <u>Case #</u>                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Jun-2012                                                                                                                               | 8595187                                  | EXPEDITED (15-DAY) | Y                  | HO, LT          | FR-FRI-1000030975     |                               | 26 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                     | <u>Product</u>                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Cardio-Respiratory Arrest;<br>Generalised Tonic-Clonic Seizure; Hypokalaemia;<br>Leukocytosis; Overdose;<br>Serotonin Syndrome | Escitalopram Oxalate                     |                    |                    | S               | Oral                  | 10 Mg                         |                 | Forest       |                |
|                                                                                                                                           | Escitalopram Oxalate                     |                    |                    | S               |                       | Overdose With An Unknown Dose |                 | Forest       |                |
|                                                                                                                                           | Valium                                   |                    |                    | C               | Oral                  |                               |                 | Not Reported |                |
|                                                                                                                                           | Methadone Hydrochloride                  |                    |                    | C               |                       |                               |                 | Not Reported |                |

# FDA Adverse Event Reporting System

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| <u>FDA Received Date</u>                                                                                                                                                                                     | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|--------------------------------|------------------------------------|-----------------|--------------|----------------|
| 04-Jun-2012                                                                                                                                                                                                  | 8595289                  | EXPEDITED (15-DAY) | Y                  | HO              | FR-FRI-1000030979              |                                    | 63 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                                        | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Disinhibition; Suicide Attempt                                                                                                                                                                               | Escitalopram Oxalate     |                    |                    | S               | Oral                           | 10 Mg                              |                 | Forest       |                |
|                                                                                                                                                                                                              | Telmisartan              |                    |                    | C               | Oral                           | 40 Mg                              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                     | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Jun-2012                                                                                                                                                                                                  | 7183450                  | EXPEDITED (15-DAY) | Y                  | OT              | US-PFIZER INC-US-WYE-H11366009 |                                    | 74 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                        | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Ageusia; Constipation; Decreased Appetite; Diarrhoea; Drug Ineffective; Dry Mouth; Dyskinesia; Muscle Twitching; Nightmare; Suicidal Ideation; Suicide Attempt; Therapeutic Product Effect Decreased; Tremor | Effexor Xr               |                    |                    | S               | Oral                           | 75 Mg, 1x/Day                      |                 | Pfizer       |                |
|                                                                                                                                                                                                              | Pristiq Extended Release |                    |                    | S               | Oral                           | 50.0 Mg, 1x/Day                    |                 | Pfizer       |                |
|                                                                                                                                                                                                              | Pristiq Extended Release |                    |                    | S               | Oral                           | Patient Tried Taking Half A Tablet |                 | Pfizer       |                |
|                                                                                                                                                                                                              | Doxepin Hydrochloride    |                    |                    | S               |                                | Unk                                |                 | Pfizer       |                |
|                                                                                                                                                                                                              | Zoloft                   |                    |                    | S               |                                | Unk                                |                 | Pfizer       |                |
|                                                                                                                                                                                                              | Mirtazapine              |                    |                    | S               |                                | Unk                                |                 | Not Reported |                |
|                                                                                                                                                                                                              | Paroxetine               |                    |                    | S               |                                | Unk                                |                 | Unknown      |                |
|                                                                                                                                                                                                              | Trazodone Hydrochloride  |                    |                    | S               |                                | Unk                                |                 | Not Reported |                |
|                                                                                                                                                                                                              | Wellbutrin               |                    |                    | S               |                                | Unk                                |                 | Not Reported |                |
|                                                                                                                                                                                                              | Zyprexa                  |                    |                    | S               |                                | Unk                                |                 | Not Reported |                |
|                                                                                                                                                                                                              | Seroquel                 |                    |                    | S               |                                | Unk                                |                 | Not Reported |                |
|                                                                                                                                                                                                              | Lexapro                  |                    |                    | S               |                                | Unk                                |                 | Not Reported |                |
|                                                                                                                                                                                                              | Cymbalta                 |                    |                    | S               |                                | Unk                                |                 | Not Reported |                |
|                                                                                                                                                                                                              | Paxil                    |                    |                    | S               |                                | Unk                                |                 | Not Reported |                |
|                                                                                                                                                                                                              | Prozac                   |                    |                    | S               |                                | Unk                                |                 | Not Reported |                |
|                                                                                                                                                                                                              | Depakote                 |                    |                    | S               |                                | Unk                                |                 | Not Reported |                |
|                                                                                                                                                                                                              | One-A-Day Nos            |                    |                    | C               |                                |                                    |                 | Not Reported |                |
|                                                                                                                                                                                                              | Fish Oil, Hydrogenated   |                    |                    | C               |                                |                                    |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                            | <u>Case #</u>                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------|------------------------------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| 05-Jun-2012                                                         | 8557252                                  | EXPEDITED (15-DAY) | Y                  | HO, LT          | ES-ABBOTT-12P-144-0933953-00 |                      | 73 YR           | Female       | ESP            |
| <u>Preferred Term</u>                                               | <u>Product</u>                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypercreatininaemia;<br>Rhabdomyolysis                              | Depakene                                 |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                                     | Pantoprazole                             |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                                     | Fluvastatin                              |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                                     | Tramadol Hydrochloride                   |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                                     | Escitalopram Oxalate                     |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                                     | Tramadol Hydrochloride And Acetaminophen |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                            | <u>Case #</u>                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Jun-2012                                                         | 8565703                                  | EXPEDITED (15-DAY) | Y                  | HO              | IT-PFIZER INC-2012117653     |                      | 28 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                               | <u>Product</u>                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bradykinesia;<br>Bradyphrenia;<br>Hypotension; Intentional Overdose | Xanax                                    |                    |                    | S               | Oral                         | 1 Mg, Unk            |                 | Pfizer       |                |
|                                                                     | Xanax                                    |                    |                    | S               |                              | 6 Df, Unk            |                 | Pfizer       |                |
|                                                                     | Escitalopram Oxalate                     |                    |                    | S               | Oral                         | 10 Mg, Unk           |                 | Not Reported |                |
|                                                                     | Bromazepam                               |                    |                    | S               | Oral                         | 20 Df, Unk           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                            | <u>Case #</u>                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Jun-2012                                                         | 8598598                                  | NON-EXPEDITED      | Y                  | OT              | US-FRI-1000030775            |                      | 50 YR           | Female       | USA            |
| <u>Preferred Term</u>                                               | <u>Product</u>                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Candida Infection                                                   | Lexapro                                  |                    |                    | S               | Oral                         |                      |                 | Forest       |                |
|                                                                     | Bystolic                                 |                    |                    | C               |                              |                      |                 | Not Reported |                |
|                                                                     | Synthroid                                |                    |                    | C               |                              |                      |                 | Not Reported |                |

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| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 05-Jun-2012              | 8600191       | EXPEDITED (15-DAY) | N                  | OT              | US-PFIZER INC-2012131172 |                      | 45 YR      | Female     | USA            |

| <u>Preferred Term</u>      | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Glucose Increased;   | Pristiq Extended Release |              |            | S           |              | 100 Mg, Unk        |                 | Pfizer       |
| Blood Triglycerides        | Pristiq Extended Release |              |            | S           |              |                    |                 | Pfizer       |
| Increased; Cognitive       | Pristiq Extended Release |              |            | S           |              |                    |                 | Pfizer       |
| Disorder; Dizziness; Drug  | Effexor Xr               |              |            | S           |              | Unk                |                 | Pfizer       |
| Ineffective; Fluid         | Xanax                    |              |            | S           |              | Unk                |                 | Pfizer       |
| Retention; Hallucination;  | Lexapro                  |              |            | S           |              | Unk                |                 | Not Reported |
| High Density Lipoprotein   | Prozac                   |              |            | S           |              | Unk                |                 | Not Reported |
| Increased; Low Density     | Wellbutrin               |              |            | S           |              | Unk                |                 | Not Reported |
| Lipoprotein Increased;     | Cymbalta                 |              |            | S           |              | Unk                |                 | Not Reported |
| Migraine; Nausea; Suicidal | Lisinopril               |              |            | C           |              | 10 Mg, Unk         |                 | Not Reported |
| Ideation; Swelling; Weight |                          |              |            |             |              |                    |                 |              |
| Increased                  |                          |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Jun-2012              | 8619106       | DIRECT           | N                  |                 |                      |                      | 78 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                           | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Chills; Dizziness; Feeling Of Body Temperature Change; Insomnia; Nausea; Stress | Escitalopram Oxalate |              |            | S           |              | 1 Day              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------------------|----------------------|------------|------------|----------------|
| 06-Jun-2012              | 8574879       | EXPEDITED (15-DAY) | N                  | HO, OT          | CH-BRISTOL-MYERS SQUIBB COMPANY-16586323 |                      | 57 YR      | Female     | CHE            |

| <u>Preferred Term</u>                                  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                     | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------------------------------------------|-----------------|--------------|
| Electrocardiogram Qt Prolonged; Hypokalaemia; Overdose | Abilify        |              |            | S           | Oral         | 1 Df : 30-45mg,Since Months Until 20feb12;Dose Reduced |                 | Not Reported |

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|               |   |      |                                       |              |
|---------------|---|------|---------------------------------------|--------------|
| Risperdal     | S | Oral | On 21feb12-06mar12,15mg               | Not Reported |
| Ciprallex     | S | Oral | 1 Df : 1/4/6 Mg                       | Not Reported |
| Furosemide    | S | Oral | 1 Df: 10/20mg                         | Not Reported |
| Beloc-Zok     | S | Oral | 1df : 40/20mg,Dose Reduced On 02mar12 | Not Reported |
| Gliclazide    | C | Oral |                                       | Not Reported |
| Cardioaspirin | C | Oral |                                       | Not Reported |
| Dipiperon     | C | Oral | 1 Df : 60/40mg                        | Not Reported |
| Deroxat       | C | Oral | 1 Df : 20/10mg                        | Not Reported |
| Allopurinol   | C | Oral |                                       | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Jun-2012              | 8621544       | EXPEDITED (15-DAY) | N                  |                 | 2012P1023882         |                      | 38 YR      | Female     | USA            |

| <u>Preferred Term</u>                    | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Dizziness Postural;<br>Tinnitus; Vertigo | Rifampin             |              |            | S           | Oral         | 600 Mg;Qd;Oral     |                 | Not Reported |
|                                          | Escitalopram Oxalate |              |            | S           |              | 2.5 Mg; Qd         |                 | Not Reported |
|                                          | Lexapro              |              |            | C           |              |                    |                 | Not Reported |
|                                          | Vitamins             |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Jun-2012              | 8622524       | DIRECT           | N                  | HO, LT, OT      |                      |                      | 67 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                        | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Fall; Head Injury;<br>Hyperhidrosis; Loss Of<br>Consciousness; Muscular<br>Weakness; Palpitations;<br>Product Substitution Issue;<br>Syncope | Escitalopram Oxalate |              |            | S           | Oral         | One Tab Daily Po   | 3 DAY           | Not Reported |

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| <u>FDA Received Date</u>                                                                                                                                                | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|----------------------|----------------|
| 06-Jun-2012                                                                                                                                                             | 8623471                         | DIRECT             | N                  |                 |                      |                      |                 | Unknown              | USA            |
| <u>Preferred Term</u>                                                                                                                                                   | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Abnormal Dreams;<br>Agitation; Anger; Anxiety;<br>Blood Pressure Increased;<br>Hyperacusis; Insomnia;<br>Product Substitution Issue;<br>Pruritus Generalised;<br>Stress | Lexapro<br>Escitalopram Oxalate |                    |                    | S<br>C          |                      |                      |                 | Teva<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 07-Jun-2012                                                                                                                                                             | 8603685                         | EXPEDITED (15-DAY) | N                  | CA              | US-FRI-1000030965    |                      | < 1 DAY         | Female               | USA            |
| <u>Preferred Term</u>                                                                                                                                                   | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Maternal Drugs Affecting<br>Foetus; Ventricular Septal<br>Defect                                                                                                        | Lexapro                         |                    |                    | S               | Transplacental       |                      |                 | Forest               |                |
| <u>FDA Received Date</u>                                                                                                                                                | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 07-Jun-2012                                                                                                                                                             | 8603696                         | EXPEDITED (15-DAY) | N                  | CA              | US-FRI-1000030967    |                      |                 | Female               | USA            |
| <u>Preferred Term</u>                                                                                                                                                   | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Craniosynostosis                                                                                                                                                        | Lexapro                         |                    |                    | S               | Transplacental       |                      |                 | Forest               |                |
| <u>FDA Received Date</u>                                                                                                                                                | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 07-Jun-2012                                                                                                                                                             | 8603812                         | EXPEDITED (15-DAY) | N                  | CA              | US-FRI-1000030969    |                      |                 | Female               | USA            |
| <u>Preferred Term</u>                                                                                                                                                   | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Craniosynostosis                                                                                                                                                        | Lexapro                         |                    |                    | S               | Transplacental       |                      |                 | Forest               |                |

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

| <u>FDA Received Date</u>                                                                        | <u>Case #</u>                                                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u>         | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>                                       | <u>Country</u> |
|-------------------------------------------------------------------------------------------------|----------------------------------------------------------------|--------------------|--------------------|------------------|------------------------------|---------------------------------|-----------------|--------------------------------------------------|----------------|
| 07-Jun-2012                                                                                     | 8622513                                                        | DIRECT             | N                  |                  |                              |                                 | 52 YR           | Female                                           | USA            |
| <u>Preferred Term</u>                                                                           | <u>Product</u>                                                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>                 | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>                                       |                |
| Bruxism; Dysstasia;<br>Fungal Infection;<br>Palpitations; Product<br>Substitution Issue; Tremor | Escitalopram Oxalate                                           |                    |                    | S                |                              | Am .5 1; Pm .10 1               |                 | Mylan                                            |                |
| <u>FDA Received Date</u>                                                                        | <u>Case #</u>                                                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u>         | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>                                       | <u>Country</u> |
| 07-Jun-2012                                                                                     | 8627732                                                        | DIRECT             | Y                  | OT               |                              |                                 | 50 YR           | Female                                           | USA            |
| <u>Preferred Term</u>                                                                           | <u>Product</u>                                                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>                 | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>                                       |                |
| Loss Of Libido; Product<br>Substitution Issue                                                   | Escitalopram                                                   |                    |                    | S                | Oral                         | 1 Tab Daily By Mouth 1<br>Month | 1 MTH           | Not Reported                                     |                |
| <u>FDA Received Date</u>                                                                        | <u>Case #</u>                                                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u>         | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>                                       | <u>Country</u> |
| 07-Jun-2012                                                                                     | 8635044                                                        | DIRECT             | Y                  | OT               |                              |                                 | 40 YR           | Female                                           | USA            |
| <u>Preferred Term</u>                                                                           | <u>Product</u>                                                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>                 | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>                                       |                |
| Headache; Nausea;<br>Tremor                                                                     | Citalopram<br>Lexapro                                          |                    |                    | S<br>S           | Oral                         | 20 Mg Daily Oral                |                 | Forest<br>Not Reported                           |                |
| <u>FDA Received Date</u>                                                                        | <u>Case #</u>                                                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u>         | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>                                       | <u>Country</u> |
| 08-Jun-2012                                                                                     | 8578943                                                        | EXPEDITED (15-DAY) | Y                  | HO               | IT-FRI-1000030682            |                                 | 28 YR           | Female                                           | ITA            |
| <u>Preferred Term</u>                                                                           | <u>Product</u>                                                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>                 | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>                                       |                |
| Bradykinesia;<br>Bradyphrenia;<br>Hypotension; Intentional<br>Overdose                          | Escitalopram Oxalate<br>Escitalopram Oxalate<br>Xanax<br>Xanax |                    |                    | S<br>S<br>S<br>S | Oral<br>Oral<br>Oral<br>Oral | <br>28 Tablets<br><br>6 Tablets |                 | Forest<br>Forest<br>Not Reported<br>Not Reported |                |

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

|                                            |                |                    |                    |                 |                      |                      |                 |              |                |
|--------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Bromazepam                                 |                |                    | S                  | Oral            | 20 Tablets           |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Jun-2012                                | 8605324        | EXPEDITED (15-DAY) | N                  | HO              | US-FRI-1000030988    |                      | 23 YR           | Male         | USA            |
| <u>Preferred Term</u>                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Agitation;<br>Physical Assault | Lexapro        |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                            | Lexapro        |                    |                    | S               | Oral                 | 20 Mg                |                 | Forest       |                |
|                                            | Risperdal      |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Jun-2012                                | 8605803        | EXPEDITED (15-DAY) | N                  | CA              | US-FRI-1000030999    |                      | < 1 DAY         | Male         | USA            |
| <u>Preferred Term</u>                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Talipes                                    | Lexapro        |                    |                    | S               | Transplacental       |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Jun-2012                                | 8606101        | EXPEDITED (15-DAY) | N                  | CA              | US-FRI-1000031051    |                      |                 | Male         | USA            |
| <u>Preferred Term</u>                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Craniosynostosis                           | Lexapro        |                    |                    | S               | Transplacental       |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Jun-2012                                | 8527423        | EXPEDITED (15-DAY) | Y                  | HO, OT          | JP-FRI-1000029975    |                      | 67 YR           | Female       | JPN            |
| <u>Preferred Term</u>                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hepatic Function<br>Abnormal; Jaundice     | Lexapro        |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                            | Phenobarbital  |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |
|                                            | Bromisoval     |                    |                    | C               | Oral                 | 0.3 Mg               |                 | Not Reported |                |
|                                            | Alprazolam     |                    |                    | C               | Oral                 | 1.2 Mg               |                 | Not Reported |                |



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

|                              |   |      |        |              |
|------------------------------|---|------|--------|--------------|
| Sulpiride                    | C | Oral | 150 Mg | Not Reported |
| Hange-Koboku-To              | C | Oral | 3 Df   | Not Reported |
| Flunitrazepam                | C | Oral | 2 Mg   | Not Reported |
| Chlorpromazine Hydrochloride | C | Oral |        | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Jun-2012              | 8537218       | EXPEDITED (15-DAY) | N                  | OT              | US-FRI-1000029754    |                      | 16 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                           | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Anxiety; Homicidal Ideation; Hyperhidrosis; Insomnia; Obsessive-Compulsive Disorder; Off Label Use; Panic Reaction; Suicidal Ideation; Vomiting | Escitalopram Oxalate |              |            | S           |              | 20 Mg              |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 11-Jun-2012              | 8608078       | EXPEDITED (15-DAY) | Y                  | OT              | CH-PFIZER INC-2012135720 |                      | 37 YR      | Female     | CHE            |

| <u>Preferred Term</u>                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Caesarean Section; Failed Forceps Delivery | Vibramycin     |              |            | S           |              | 50 Mg, 1x/Day      | 54 DAY          | Pfizer       |
|                                            | Ciprallex      |              |            | S           |              | 2 Df, 1x/Day       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Jun-2012              | 8608969       | EXPEDITED (15-DAY) | Y                  | HO              | IT-FRI-1000031140    |                      | 47 YR      | Female     | ITA            |

| <u>Preferred Term</u>       | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------|----------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Intentional Overdose; Sopor | Citalopram           |              |            | S           |              | Overdose Took 28 Tablets At Once |                 | Forest       |
|                             | Escitalopram Oxalate |              |            | S           |              | Overdose Took 14 Tablets At Once |                 | Forest       |
|                             | Alprazolam           |              |            | S           |              | Overdose Took 19 Tablets         |                 | Not Reported |

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

At Once

| <u>FDA Received Date</u>      | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------|-----------------------------|--------------------|--------------------|-----------------|----------------------------|-------------------------------|-----------------|--------------|----------------|
| 11-Jun-2012                   | 8608989                     | EXPEDITED (15-DAY) | Y                  | DS              | AU-FRI-1000031167          |                               | 63 YR           | Male         | AUS            |
| <u>Preferred Term</u>         | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Overdose; Withdrawal Syndrome | Lexapro                     |                    |                    | S               | Oral                       | Overdose 40 Mg - Downtitrated |                 | Forest       |                |
|                               | Prothiaden                  |                    |                    | C               |                            | 100 Mg                        |                 | Not Reported |                |
| <u>FDA Received Date</u>      | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Jun-2012                   | 8609014                     | EXPEDITED (15-DAY) | Y                  | HO              | FR-FRI-1000031168          |                               | 87 YR           | Female       | FRA            |
| <u>Preferred Term</u>         | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Toxic Encephalopathy          | Escitalopram Oxalate        |                    |                    | S               | Oral                       | 20 Mg                         |                 | Forest       |                |
|                               | Rocephin                    |                    |                    | C               | Subcutaneous               |                               |                 | Not Reported |                |
|                               | Tramadol Hydrochloride      |                    |                    | C               |                            |                               |                 | Not Reported |                |
|                               | Amitriptyline Hydrochloride |                    |                    | C               |                            |                               |                 | Not Reported |                |
|                               | Rivotril                    |                    |                    | C               |                            |                               |                 | Not Reported |                |
|                               | Tegretol                    |                    |                    | C               |                            |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>      | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Jun-2012                   | 7751556                     | EXPEDITED (15-DAY) |                    | DE              | US-PFIZER INC-2011002730   |                               | 61 YR           | Male         | USA            |
| <u>Preferred Term</u>         | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide             | Verapamil Hcl               |                    |                    | S               |                            |                               |                 | Pfizer       |                |
|                               | Alprazolam                  |                    |                    | S               |                            |                               |                 | Pfizer       |                |
|                               | Doxepin Hcl                 |                    |                    | S               |                            |                               |                 | Pfizer       |                |
|                               | Escitalopram Oxalate        |                    |                    | S               |                            |                               |                 | Not Reported |                |
|                               | Cyclobenzaprine             |                    |                    | S               |                            |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>      | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Jun-2012                   | 7772305                     | EXPEDITED (15-DAY) | Y                  | DE              | US-PFIZER INC-2011US-41275 |                               | 61 YR           | Male         | USA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u> | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Verapamil Hydrochloride       |              |            | S           | Oral         | Unk                |                 | Pfizer       |
|                       | Escitalopram Oxalate          |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                       | Cyclobenzaprine Hydrochloride |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                       | Doxepin                       |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                       | Alprazolam                    |              |            | S           | Oral         | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Jun-2012              | 8536309       | EXPEDITED (15-DAY) | Y                  | OT              | JP-FRI-1000030085    |                      | 44 YR      | Female     | JPN            |

| <u>Preferred Term</u> | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anaphylactic Shock    | Lexapro                  |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                       | Biperiden Hydrochloride  |              |            | S           | Oral         | 3 Mg               |                 | Not Reported |
|                       | Etizolam                 |              |            | C           | Oral         |                    |                 | Not Reported |
|                       | Bromazepam               |              |            | C           | Oral         |                    |                 | Not Reported |
|                       | Estazolam                |              |            | C           | Oral         | 2 Mg               |                 | Not Reported |
|                       | Etizolam                 |              |            | C           | Oral         | 3 Mg               |                 | Not Reported |
|                       | Paxil                    |              |            | C           | Oral         | 20 Mg              |                 | Not Reported |
|                       | Yoryacool                |              |            | C           | Oral         | 160 Mg             |                 | Not Reported |
|                       | Loxoprofen Sodium        |              |            | C           | Oral         | 60 Mg              |                 | Not Reported |
|                       | Manidipine Hydrochloride |              |            | C           | Oral         | 10 Mg              |                 | Not Reported |
|                       | Amoxapine                |              |            | C           | Oral         | 75 Mg              |                 | Not Reported |
|                       | Amoxapine                |              |            | C           | Oral         | 75 Mg              |                 | Not Reported |
|                       | Magnesium Oxide          |              |            | C           | Oral         | 1980 Mg            |                 | Not Reported |
|                       | Brotizolam               |              |            | C           | Oral         | 0.25 Mg            |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 12-Jun-2012              | 8610187       | EXPEDITED (15-DAY) | Y                  | HO              | FR-PFIZER INC-2012135490 |                      | 25 YR      | Female     | FRA            |

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

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

|                 |                      |   |  |  |                   |  |  |              |
|-----------------|----------------------|---|--|--|-------------------|--|--|--------------|
| Drug Resistance | Effexor Xr           | S |  |  |                   |  |  | Pfizer       |
|                 | Cyamemazine          | S |  |  | Unk               |  |  | Not Reported |
|                 | Escitalopram Oxalate | S |  |  | Unk               |  |  | Not Reported |
|                 | Valium               | S |  |  | 25 Mg, 3x/Day     |  |  | Not Reported |
|                 | Opium Tincture       | S |  |  | 10 Mg, 2 Or 3xday |  |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Jun-2012              | 8612446       | EXPEDITED (15-DAY) | Y                  | CA, OT          | BE-FRI-1000031220    |                      |            | Male       | BEL            |

| <u>Preferred Term</u>                                                                                                                 | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|----------------|--------------------|-----------------|------------|
| Developmental Delay;<br>Dyspnoea; Foetal<br>Exposure During<br>Pregnancy; Neonatal<br>Disorder; Neonatal<br>Hypoxia; Neonatal Seizure | Escitalopram Oxalate |              |            | S           | Transplacental |                    |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Jun-2012              | 8613098       | EXPEDITED (15-DAY) | N                  | CA              | US-FRI-1000031170    |                      |            | Male       | USA            |

| <u>Preferred Term</u>                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|------------|
| Atrial Septal Defect;<br>Cardiac Aneurysm | Lexapro        |              |            | S           | Transplacental |                    |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Jun-2012              | 8613397       | EXPEDITED (15-DAY) | Y                  | OT              | US-FRI-1000025991    |                      |            | Male       | USA            |

| <u>Preferred Term</u>          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Depression Suicidal;<br>Stress | Lexapro        |              |            | S           |              |                    |                 | Forest       |
|                                | Effexor        |              |            | S           |              |                    |                 | Not Reported |
|                                | Ambien         |              |            | S           |              |                    |                 | Not Reported |
|                                | Zyprexa        |              |            | S           |              |                    |                 | Not Reported |
|                                | Wellbutrin     |              |            | S           |              | 600 Mg             |                 | Not Reported |
|                                | Adderall       |              |            | S           |              |                    |                 | Not Reported |

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

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Jun-2012              | 8635571       | EXPEDITED (15-DAY) | Y                  | OT              | AUR-APL-2012-02573   |                      | 33 YR      | Female     | USA            |

| <u>Preferred Term</u>       | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------|---------------------------|--------------|------------|-------------|--------------|-----------------------------------|-----------------|--------------|
| Anxiety; Crying;            | Citalopram Hydrobromide   |              |            | S           |              | (20 Mg,1 D)                       |                 | Not Reported |
| Decreased Appetite;         | Mirtazapine (Mirtazapine) |              |            | S           |              | (15 Mg,At Bed Time)               |                 | Not Reported |
| Dyspnoea; Emotional         | Escitalopram Oxalate      |              |            | S           |              | (10 Mg,1 D) ; (30 Mg,1 D) ;14 DAY |                 | Not Reported |
| Disorder; Increased         |                           |              |            |             |              | (45 Mg,1 D) ; (30 Mg,1 D) ;       |                 |              |
| Appetite; Maternal          |                           |              |            |             |              | (45 Mg,1 D)                       |                 |              |
| Exposure During             |                           |              |            |             |              | (10 Mg,1 D) ; (30 Mg,1 D) ;       |                 |              |
| Pregnancy; Palpitations;    |                           |              |            |             |              | (45 Mg,1 D) ; (30 Mg,1 D) ;       |                 |              |
| Panic Attack; Poor Quality  |                           |              |            |             |              | (45 Mg,1 D)                       |                 |              |
| Sleep; Thinking Abnormal;   |                           |              |            |             |              | (10 Mg,1 D) ; (30 Mg,1 D) ;28 DAY |                 |              |
| Urinary Hesitation; Urinary |                           |              |            |             |              | (45 Mg,1 D) ; (30 Mg,1 D) ;       |                 |              |
| Retention; Weight           |                           |              |            |             |              | (45 Mg,1 D)                       |                 |              |
| Increased                   |                           |              |            |             |              | (10 Mg,1 D) ; (30 Mg,1 D) ;       |                 |              |
|                             |                           |              |            |             |              | (45 Mg,1 D) ; (30 Mg,1 D) ;       |                 |              |
|                             |                           |              |            |             |              | (45 Mg,1 D)                       |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Jun-2012              | 8468683       | EXPEDITED (15-DAY) |                    | OT              | RO-FRI-1000029134    |                      |            | Male       | ROM            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Aggression; Homicide  | Escitalopram Oxalate |              |            | S           |              |                    |                 | Forest       |
|                       | Xanax                |              |            | S           |              |                    |                 | Not Reported |
|                       | Bromazepam           |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Jun-2012              | 8573521       | EXPEDITED (15-DAY) |                    | HO              | US-ROCHE-1066504     |                      | 28 YR      | Female     | USA            |

| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|----------------|--------------|------------|-------------|--------------|-------------------------|-----------------|--------------|
| Abdominal Pain;          | Pegasys        |              |            | S           | Subcutaneous |                         |                 | Not Reported |
| Depression; Dyspnoea;    | Copegus        |              |            | S           |              | 600 Mg In Every Morning |                 | Not Reported |
| Mania; Nausea;           |                |              |            |             |              | And 400 Mg In Every     |                 |              |
| Pancreatic Cyst; Urinary |                |              |            |             |              |                         |                 |              |

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

|                 |                      |   |      |  |         |       |  |  |              |
|-----------------|----------------------|---|------|--|---------|-------|--|--|--------------|
| Tract Infection |                      |   |      |  | Evening |       |  |  |              |
|                 | Alisporivir          | S | Oral |  |         |       |  |  | Not Reported |
|                 | Escitalopram Oxalate | S | Oral |  |         | 3 DAY |  |  | Not Reported |
|                 | Escitalopram Oxalate | S |      |  |         | 3 DAY |  |  | Not Reported |
|                 | Escitalopram Oxalate | S | Oral |  |         |       |  |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Jun-2012              | 8578011       | EXPEDITED (15-DAY) |                    | HO              | US-FRI-1000030703    |                      | 41 YR      | Female     | USA            |

| <u>Preferred Term</u>                  | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Diabetic Ketoacidosis;<br>Pancreatitis | Escitalopram Oxalate   |              |            | S           | Oral         | 20 Mg              |                 | Forest       |
|                                        | Unspecified Ingredient |              |            | S           | Oral         | 2 Mg               |                 | Not Reported |
|                                        | Lipitor                |              |            | C           |              |                    |                 | Not Reported |
|                                        | Advil                  |              |            | C           |              |                    |                 | Not Reported |
|                                        | Tums                   |              |            | C           |              |                    |                 | Not Reported |
|                                        | Lantus                 |              |            | C           |              |                    |                 | Not Reported |
|                                        | Humalog                |              |            | C           |              |                    |                 | Not Reported |
|                                        | Lisinopril             |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Jun-2012              | 8635091       | DIRECT           | Y                  | OT              |                      |                      | 45 YR      | Female     | USA            |

| <u>Preferred Term</u>                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Therapeutic Product Effect<br>Decreased | Lexapro        |              |            | S           | Oral         | One Po Qd          |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Jun-2012              | 8605276       | EXPEDITED (15-DAY) | Y                  | OT              | CY-FRI-1000031102    |                      | 68 YR      | Female     | CYP            |

| <u>Preferred Term</u>                  | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Oedema Peripheral;<br>Pulmonary Oedema | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                        | Levothyroxine Sodium |              |            | C           |              | 75 Mg              |                 | Not Reported |
|                                        | Antihypertensives    |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                                          | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 15-Jun-2012                                                                                                                                                                                                                       | 8618150                 | EXPEDITED (15-DAY) | Y                  | LT              | CH-FRI-1000031397    |                      |                 | Female       | CHE            |
| <u>Preferred Term</u>                                                                                                                                                                                                             | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Haemorrhagic Disorder                                                                                                                                                                                                             | Escitalopram Oxalate    |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                                                                                                                                                                                                                   | Ginseng, North American |                    |                    | S               | Oral                 | 60 Mg                |                 | Not Reported |                |
|                                                                                                                                                                                                                                   | Calcimagon D3           |                    |                    | C               | Oral                 | 1000 Mg              |                 | Not Reported |                |
|                                                                                                                                                                                                                                   | Zopiclone               |                    |                    | C               | Oral                 | 7.5 Mg               |                 | Not Reported |                |
|                                                                                                                                                                                                                                   | Omeprazole              |                    |                    | C               | Oral                 | 40 Mg                |                 | Not Reported |                |
|                                                                                                                                                                                                                                   | Dafalgan                |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                          | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Jun-2012                                                                                                                                                                                                                       | 8618228                 | EXPEDITED (15-DAY) | Y                  | HO              | FR-FRI-1000031408    |                      |                 | Male         | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                                                             | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Impulsive Behaviour                                                                                                                                                                                                               | Escitalopram Oxalate    |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                                                                                                                                                                                                                   | Oxazepam                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                   | Baclofen                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                   | Zopiclone               |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                          | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Jun-2012                                                                                                                                                                                                                       | 8636240                 | DIRECT             | N                  | LT, OT          |                      |                      | 65 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                             | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain Upper;<br>Aggression; Anxiety;<br>Asthenia; Blood Pressure<br>Fluctuation; Chest Pain;<br>Constipation; Crying;<br>Dizziness; Eating<br>Disorder; Fatigue; Gait<br>Disturbance; Headache;<br>Heart Rate Increased; | Escitalopram Oxalate    |                    |                    | S               | Oral                 | 1 Pill 1 A Day Oral  |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Hostility; Hyperhidrosis;  
Insomnia; Irritability;  
Nausea; Pyrexia;  
Restlessness; Tremor;  
Unevaluable Event;  
Vertigo; Vomiting

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Jun-2012              | 8636794       | DIRECT           | Y                  | OT              |                      |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                                             | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                         | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------------------------------|-----------------|--------------|
| Condition Aggravated;<br>Crying; Depression;<br>Feeling Abnormal;<br>Irritability | Escitalopram Oxalate |              |            | S           | Oral         | 20 Mg 1 Tab Qd Oral 3 To<br>4 Weeks Of Use |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Jun-2012              | 8619769       | EXPEDITED (15-DAY) | N                  | CA              | US-FRI-1000031354    |                      |            | Male       | USA            |

| <u>Preferred Term</u>                                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|------------|
| Congenital Anomaly;<br>Craniosynostosis;<br>Developmental Delay | Lexapro        |              |            | S           | Transplacental |                    |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Jun-2012              | 8620520       | EXPEDITED (15-DAY) | Y                  | HO              | CA-FRI-1000027127    |                      | 25 YR      | Female     | CAN            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Seizure               | Escitalopram Oxalate |              |            | S           | Oral         |                    |                 | Forest       |
|                       | Amitriptyline        |              |            | S           | Oral         | 10 Mg              |                 | Not Reported |
|                       | Mavik                |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Docusate Sodium      |              |            | C           |              |                    |                 | Not Reported |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                           | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 18-Jun-2012                                                        | 8620544                  | EXPEDITED (15-DAY) | Y                  | OT              | CA-FRI-1000027141    |                      | 26 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                              | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Nervousness; Peripheral Coldness; Pruritus; Skin Burning Sensation | Escitalopram Oxalate     |                    |                    | S               | Oral                 |                      |                 | Forest       |                |
|                                                                    | Escitalopram Oxalate     |                    |                    | S               |                      |                      |                 | Forest       |                |
|                                                                    | Mirtazapine              |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                    | Mirtazapine              |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                    | Birth Control Pill       |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                           | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Jun-2012                                                        | 8620578                  | EXPEDITED (15-DAY) | Y                  | OT              | JP-FRI-1000031432    |                      | 47 YR           | Male         | JPN            |
| <u>Preferred Term</u>                                              | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Chills; Dyspnoea; Tremor                                           | Lexapro                  |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                                                    | Lexapro                  |                    |                    | S               |                      | 20 Mg                |                 | Forest       |                |
|                                                                    | Lorazepam                |                    |                    | C               |                      | 1.5 Mg               |                 | Not Reported |                |
|                                                                    | Ethyl Loflazepate        |                    |                    | C               |                      | 2 Mg                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                           | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Jun-2012                                                        | 8622366                  | EXPEDITED (15-DAY) | Y                  | OT              | US-FRI-1000031238    |                      | 45 YR           | Female       | USA            |
| <u>Preferred Term</u>                                              | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Discomfort;                                              | Lexapro                  |                    |                    | S               |                      |                      |                 | Forest       |                |
| Blood Glucose Increased;                                           | Pristiq Extended Release |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Blood Triglycerides                                                | Pristiq Extended Release |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Increased; Dizziness;                                              | Pristiq Extended Release |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Drug Ineffective; Fluid                                            | Effexor Xr               |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Retention; Hallucination;                                          | Xanax                    |                    |                    | S               |                      |                      |                 | Not Reported |                |
| High Density Lipoprotein                                           | Prozac                   |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Increased; Low Density                                             | Wellbutrin               |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Lipoprotein Increased;                                             | Cymbalta                 |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Migraine; Nausea; Suicidal                                         | Lisinopril               |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Ideation; Swelling;                                                |                          |                    |                    |                 |                      |                      |                 |              |                |

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

Thinking Abnormal;  
Weight Increased

| <u>FDA Received Date</u>                                                               | <u>Case #</u>                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------|------------------------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------------------------|-----------------|--------------|----------------|
| 19-Jun-2012                                                                            | 8622672                                  | EXPEDITED (15-DAY) | Y                  | HO              | FR-FRI-1000031427         |                                        | 42 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                  | <u>Product</u>                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Ischaemic Stroke                                                                       | Escitalopram Oxalate                     |                    |                    | S               | Oral                      | 10 Mg                                  |                 | Forest       |                |
| <u>FDA Received Date</u>                                                               | <u>Case #</u>                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Jun-2012                                                                            | 8622946                                  | EXPEDITED (15-DAY) | Y                  | HO              | CA-FRI-1000022231         |                                        |                 | Female       | CAN            |
| <u>Preferred Term</u>                                                                  | <u>Product</u>                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Eye Swelling; Generalised Erythema; Pruritus Generalised; Urticaria; Visual Impairment | Escitalopram Oxalate                     |                    |                    | S               | Oral                      | 5 Mg                                   |                 | Forest       |                |
|                                                                                        | Escitalopram Oxalate                     |                    |                    | S               | Oral                      | 10 Mg                                  |                 | Forest       |                |
|                                                                                        | Macrobid                                 |                    |                    | S               | Oral                      | 200 Mg                                 |                 | Not Reported |                |
|                                                                                        | Desogestrel And Ethinyl Estradiol        |                    |                    | C               | Oral                      |                                        |                 | Not Reported |                |
|                                                                                        | Tramadol Hydrochloride And Acetaminophen |                    |                    | C               | Oral                      | 325 Mg Acetaminophen, 37.5 Mg Tramadol |                 | Not Reported |                |
|                                                                                        | Tylenol With Codeine                     |                    |                    | C               | Oral                      |                                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                               | <u>Case #</u>                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Jun-2012                                                                            | 8623043                                  | EXPEDITED (15-DAY) | Y                  | HO              | FR-MYLANLABS-2012S1011695 |                                        | 88 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                  | <u>Product</u>                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Hyponatraemia; Serotonin Syndrome                                    | Escitalopram Oxalate                     |                    |                    | S               | Unknown                   | 5 Mg/Day                               |                 | Mylan        |                |
|                                                                                        | Levothyroxine Sodium                     |                    |                    | C               | Unknown                   |                                        |                 | Not Reported |                |
|                                                                                        | Travoprost                               |                    |                    | C               | Unknown                   |                                        |                 | Not Reported |                |
|                                                                                        | Timolol Maleate                          |                    |                    | C               | Unknown                   |                                        |                 | Not Reported |                |
|                                                                                        | Loramyc                                  |                    |                    | S               |                           | 50 Mg/Day                              |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                              | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------|-----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 19-Jun-2012                                                                                           | 8638068               | DIRECT             | Y                  |                 |                      |                      | 45 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                 | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Disturbance In Attention; Fatigue; Initial Insomnia; Mood Altered; Pruritus; Sleep Disorder | Escitalopram Oxalate  |                    |                    | S               | Oral                 | 1 1/2 Tablet Qd Oral |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                              | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Jun-2012                                                                                           | 8474501               | EXPEDITED (15-DAY) | Y                  | HO              | BE-FRI-1000029132    |                      | 62 YR           | Female       | BEL            |
| <u>Preferred Term</u>                                                                                 | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Arrhythmia; Dizziness; Tachycardia; Ventricular Tachycardia                                           | Escitalopram Oxalate  |                    |                    | S               | Oral                 | 15 Mg                |                 | Forest       |                |
|                                                                                                       | Escitalopram Oxalate  |                    |                    | S               | Oral                 | 15 Mg                |                 | Forest       |                |
|                                                                                                       | Flupentixol           |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                       | Prothiaden            |                    |                    | C               | Oral                 | 75 Mg                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                              | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Jun-2012                                                                                           | 8488082               | EXPEDITED (15-DAY) | Y                  | LT              | FR-FRI-1000028584    |                      |                 | Female       | FRA            |
| <u>Preferred Term</u>                                                                                 | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bradycardia                                                                                           | Escitalopram Oxalate  |                    |                    | S               | Oral                 | 20 Mg                |                 | Forest       |                |
|                                                                                                       | Escitalopram Oxalate  |                    |                    | S               |                      |                      |                 | Forest       |                |
|                                                                                                       | Sotalol Hydrochloride |                    |                    | S               | Oral                 | 80 Mg                |                 | Not Reported |                |
|                                                                                                       | Sotalol Hydrochloride |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                              | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Jun-2012                                                                                           | 8623987               | EXPEDITED (15-DAY) | Y                  | HO              | CA-FRI-1000027368    |                      | 19 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                                                                 | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

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

|                                                                                                                                                     |                                   |   |      |                         |       |              |
|-----------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|---|------|-------------------------|-------|--------------|
| Blood Potassium Increased; Eye Swelling; Generalised Erythema; Pruritus Generalised; Urticaria; Visual Impairment; White Blood Cell Count Increased | Escitalopram Oxalate              | S | Oral | 0.5 Df                  | 9 DAY | Forest       |
|                                                                                                                                                     | Escitalopram Oxalate              | S | Oral | 1 Df                    | 9 DAY | Not Reported |
|                                                                                                                                                     | Escitalopram Oxalate              | S | Oral | 1 Df                    | 9 DAY | Forest       |
|                                                                                                                                                     | Macrobid                          | S | Oral | 200 Mg                  | 9 DAY | Not Reported |
|                                                                                                                                                     | Tramadol Hydrochloride            | C |      | Daily Dose Not Reported |       | Not Reported |
|                                                                                                                                                     | Desogestrel And Ethinyl Estradiol | C | Oral | Daily Dose Not Reported |       | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Jun-2012              | 8624119       | EXPEDITED (15-DAY) | Y                  | LT              | CA-FRI-1000027130    |                      | 36 YR      | Female     | CAN            |

| <u>Preferred Term</u>                                                                                                                                                                             | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Abnormal Dreams; Aggression; Confusional State; Decreased Appetite; Disturbance In Attention; Fatigue; Hyperacusis; Nervous System Disorder; Pollakiuria; Somnolence; Suicidal Ideation; Tinnitus | Escitalopram Oxalate |              |            | S           | Oral         |                    | 4 DAY           | Forest     |
|                                                                                                                                                                                                   | Escitalopram Oxalate |              |            | S           |              |                    | 4 DAY           | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Jun-2012              | 8627018       | EXPEDITED (15-DAY) | Y                  | HO              | FR-FRI-1000031513    |                      | 55 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Seizure               | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg              |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Jun-2012              | 8642755       | DIRECT           | N                  | OT              |                      |                      | 58 YR      | Female     | USA            |

| <u>Preferred Term</u>                        | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u> |
|----------------------------------------------|----------------------|--------------|------------|-------------|--------------|---------------------|-----------------|------------|
| Drug Ineffective; Product Substitution Issue | Escitalopram Oxalate |              |            | S           | Oral         | 20 Mg Once A Day Po |                 | Mylan      |

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

|                    |   |              |
|--------------------|---|--------------|
| Prilosec           | C | Not Reported |
| Hydrochlorothizide | C | Not Reported |
| Amlodipine         | C | Not Reported |
| Besylate           | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Jun-2012              | 8645183       | DIRECT           | N                  |                 |                      |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>                                                                                               | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Glucose Decreased;<br>Dizziness; Fear;<br>Hyperventilation; Nausea;<br>Product Substitution Issue;<br>Syncope | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg Each Day Po  | 2 DAY           | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 21-Jun-2012              | 7460252       | EXPEDITED (15-DAY) | N                  | DE              | US-MYLANLABS-2010S1011460 |                      | 50 YR      | Female     | USA            |

| <u>Preferred Term</u>                                        | <u>Product</u>                                     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>             | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------|----------------------------------------------------|--------------|------------|-------------|--------------------------|--------------------|-----------------|--------------|
| Overdose; Respiratory Depression; Toxicity To Various Agents | Fentanyl Transdermal System                        |              |            | S           | Transdermal              | Change Q3d         |                 | Mylan        |
|                                                              | Nortriptyline Hydrochloride                        |              |            | S           |                          |                    |                 | Not Reported |
|                                                              | Lexapro                                            |              |            | S           |                          |                    |                 | Not Reported |
|                                                              | Diphenhydramine                                    |              |            | S           |                          |                    |                 | Not Reported |
|                                                              | Symbicort                                          |              |            | C           | Respiratory (inhalation) |                    |                 | Not Reported |
|                                                              | Advair Diskus                                      |              |            | C           |                          |                    |                 | Not Reported |
|                                                              | Diazepam                                           |              |            | C           |                          | Every 8 Hours      |                 | Not Reported |
|                                                              | Diovan                                             |              |            | C           |                          |                    |                 | Not Reported |
|                                                              | Plavix                                             |              |            | C           |                          |                    |                 | Not Reported |
|                                                              | Lyrca                                              |              |            | C           |                          |                    |                 | Not Reported |
|                                                              | Ibuprofen                                          |              |            | C           |                          | Every 4-6 Hours    |                 | Not Reported |
|                                                              | Nexium                                             |              |            | C           |                          |                    |                 | Not Reported |
|                                                              | Metformin Hydrochloride                            |              |            | C           |                          |                    |                 | Not Reported |
|                                                              | Glycol Salicylate\Menthol\Methyl Salicylate\Thymol |              |            | C           |                          |                    |                 | Not Reported |

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

| <u>FDA Received Date</u>                                                                                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 21-Jun-2012                                                                                                           | 8541119        | EXPEDITED (15-DAY) | Y                  | HO, OT          | US-PFIZER INC-2012104183 |                      | 51 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Depression; Malaise; Mental Disorder                                                                         | Xanax Xr       |                    |                    | S               | Oral                     | 1 Mg, 3x/Day         |                 | Pfizer       |                |
|                                                                                                                       | Xanax Xr       |                    |                    | S               |                          |                      |                 | Pfizer       |                |
|                                                                                                                       | Xanax Xr       |                    |                    | S               |                          |                      |                 | Pfizer       |                |
|                                                                                                                       | Xanax Xr       |                    |                    | S               |                          |                      |                 | Pfizer       |                |
|                                                                                                                       | Lexapro        |                    |                    | S               |                          | 20 Mg, Unk           |                 | Not Reported |                |
|                                                                                                                       | Lexapro        |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Jun-2012                                                                                                           | 8628946        | EXPEDITED (15-DAY) | N                  | HO              | US-FRI-1000031418        |                      | 96 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Homicidal Ideation; Off Label Use; Suicidal Ideation                                                                  | Lexapro        |                    |                    | S               | Oral                     | 5 Mg                 |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Jun-2012                                                                                                           | 8629283        | EXPEDITED (15-DAY) | N                  | CA              | US-FRI-1000031368        |                      | < 1 DAY         | Female       | USA            |
| <u>Preferred Term</u>                                                                                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrial Septal Defect; Bicuspid Aortic Valve; Congenital Anomaly; Pulmonary Artery Stenosis; Ventricular Septal Defect | Lexapro        |                    |                    | S               | Transplacental           |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Jun-2012                                                                                                           | 8650703        | DIRECT             |                    | OT              |                          |                      | 42 YR           | Male         | USA            |

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

| <u>Preferred Term</u>                                                                                                               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Blood Glucose Fluctuation; Confusional State; Disorientation; Headache; Muscular Weakness; Musculoskeletal Pain; Pain In Extremity  | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10mg Once Daily Po   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Jun-2012                                                                                                                         | 8630348              | EXPEDITED (15-DAY) | Y                  | HO              | JP-FRI-1000031510    |                      | 69 YR           | Female       | JPN            |
| <u>Preferred Term</u>                                                                                                               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Pneumonia Aspiration; Vomiting                                                                                                      | Lexapro              |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                                                                                                                     | Lexapro              |                    |                    | S               | Oral                 | 20 Mg                |                 | Forest       |                |
|                                                                                                                                     | Remeron              |                    |                    | C               | Oral                 | 45 Mg                |                 | Not Reported |                |
|                                                                                                                                     | Ethyl Loflazepate    |                    |                    | C               | Oral                 | 45 Mg                |                 | Not Reported |                |
|                                                                                                                                     | Lansoprazole         |                    |                    | C               | Oral                 | 15 Mg                |                 | Not Reported |                |
|                                                                                                                                     | Urapidil             |                    |                    | C               | Oral                 | 60 Mg                |                 | Not Reported |                |
|                                                                                                                                     | Magnesium Oxide      |                    |                    | C               | Oral                 | 2640 Mg              |                 | Not Reported |                |
|                                                                                                                                     | Estazolam            |                    |                    | C               | Oral                 | 4 Mg                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Jun-2012                                                                                                                         | 8648194              | DIRECT             | Y                  | OT              |                      |                      | 44 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State; Heart Rate Increased; Hyperhidrosis; Hypertension; Musculoskeletal Stiffness; Product Substitution Issue; Tremor | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg 1 Per Day Po   | 3 DAY           | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 25-Jun-2012              | 8546091       | NON-EXPEDITED    | Y                  |                 | US-PFIZER INC-2012104197 |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                                               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abdominal Discomfort; Anxiety; Drug Intolerance; Fatigue; Feeling Abnormal; Malaise | Xanax Xr       |              |            | S           | Oral         | 1 Mg, 3x/Day       |                 | Pfizer       |
|                                                                                     | Xanax Xr       |              |            | S           |              |                    |                 | Pfizer       |
|                                                                                     | Xanax Xr       |              |            | S           |              |                    |                 | Pfizer       |
|                                                                                     | Alprazolam     |              |            | S           | Oral         | Unk                |                 | Pfizer       |
|                                                                                     | Alprazolam     |              |            | S           | Oral         | 1 Mg, 3x/Day       |                 | Pfizer       |
|                                                                                     | Alprazolam     |              |            | S           |              |                    |                 | Pfizer       |
|                                                                                     | Lexapro        |              |            | S           |              | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 25-Jun-2012              | 8632244       | EXPEDITED (15-DAY) | Y                  | LT              | CH-JNJFOC-20120610001 |                      | 25 YR      | Male       | CHE            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Suicide Attempt       | Risperdal      |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Risperdal      |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Risperdal      |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Risperdal      |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Risperdal      |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Cipralext      |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Lorazepam      |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Lorazepam      |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Lorazepam      |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Lorazepam      |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Seroquel       |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Jun-2012              | 8645533       | DIRECT           |                    |                 |                      |                      |            | Female     | USA            |



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

| <u>Preferred Term</u>                                                                                                           | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Product Substitution Issue                                                                                                      | Lexapro                   |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                        | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Jun-2012                                                                                                                     | 8647885                   | DIRECT             | N                  | OT              |                      |                      | 43 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                           | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Dyspepsia; Insomnia; Product Substitution Issue                                                                        | Escitalopram Oxalate      |                    |                    | S               | Oral                 | 10 Mg Day Po         |                 | Teva         |                |
| <u>FDA Received Date</u>                                                                                                        | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Jun-2012                                                                                                                     | 8648259                   | DIRECT             | N                  | HO, LT, OT      |                      |                      | 57 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                           | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bedridden; Blood Pressure Increased; Depression; Dizziness; Headache; Nausea; Product Quality Issue; Product Substitution Issue | Escitalopram Oxalate      |                    |                    | S               | Oral                 | 1 Daily Po           |                 | Mylan        |                |
| <u>FDA Received Date</u>                                                                                                        | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Jun-2012                                                                                                                     | 8246434                   | EXPEDITED (15-DAY) | Y                  | DE, HO, OT      | 2011SP051883         |                      | 72 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                           | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Hypertrophy;                                                                                                            | Mirtazapine               |                    |                    | S               | Oral                 | 30 Mg;Qd;Po          |                 | Not Reported |                |
| Depressed Level Of Consciousness; Fall;                                                                                         | Cipralext                 |                    |                    | S               | Oral                 | 30 Mg;Qd;Po          |                 | Not Reported |                |
| Hepatic Cirrhosis;                                                                                                              | Lithium Citrate           |                    |                    | S               | Oral                 | Po                   |                 | Not Reported |                |
| Humerus Fracture;                                                                                                               | Ziprasidone Hydrochloride |                    |                    | S               | Oral                 | 40 Mg;Bid;Po         |                 | Not Reported |                |
| Hyperventilation; Internal Fixation Of Fracture;                                                                                | Alprazolam                |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Lactic Acidosis; Lacunar Infarction; Multiple Organ Dysfunction Syndrome;                                                       | Potassium Chloride        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                 | Ferro Duretter            |                    |                    | C               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Neuroleptic Malignant  
Syndrome; Organ Failure;  
Renal Failure;  
Rhabdomyolysis

| <u>FDA Received Date</u>         | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------|-----------------|--------------------|--------------------|-----------------|------------------------------|----------------------------------------|-----------------|--------------|----------------|
| 26-Jun-2012                      | 8346578         | EXPEDITED (15-DAY) | Y                  | HO              | CA-ABBOTT-12P-028-0893310-00 |                                        | 25 YR           | Female       | CAN            |
| <u>Preferred Term</u>            | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Seizure                          | Mavik           |                    |                    | S               | Oral                         | Daily Dose & Frequency<br>Not Reported |                 | Not Reported |                |
|                                  | Cipralex        |                    |                    | S               | Oral                         | Daily Dose & Frequency<br>Not Reported |                 | Not Reported |                |
|                                  | Amitriptyline   |                    |                    | S               | Unknown                      |                                        |                 | Not Reported |                |
|                                  | Docusate Sodium |                    |                    | C               |                              | Daily Dose & Frequency<br>Not Reported |                 | Not Reported |                |
| <u>FDA Received Date</u>         | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Jun-2012                      | 8634441         | EXPEDITED (15-DAY) | Y                  | LT              | CH-ASTRAZENECA-2012SE30626   |                                        | 25 YR           | Male         | CHE            |
| <u>Preferred Term</u>            | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Joint Injury; Suicide<br>Attempt | Seroquel        |                    |                    | S               | Oral                         |                                        | 1 DAY           | Zeneca       |                |
|                                  | Risperdal       |                    |                    | S               | Oral                         |                                        | 14 DAY          | Not Reported |                |
|                                  | Risperdal       |                    |                    | S               | Oral                         |                                        | 9 DAY           | Not Reported |                |
|                                  | Risperdal       |                    |                    | S               | Oral                         |                                        | 18 DAY          | Not Reported |                |
|                                  | Risperdal       |                    |                    | S               | Oral                         |                                        | 13 DAY          | Not Reported |                |
|                                  | Risperdal       |                    |                    | S               | Oral                         |                                        | 9 DAY           | Not Reported |                |
|                                  | Cipralex        |                    |                    | S               | Oral                         |                                        |                 | Not Reported |                |
|                                  | Lorazepam       |                    |                    | S               | Oral                         |                                        | 1 DAY           | Not Reported |                |
|                                  | Lorazepam       |                    |                    | S               | Oral                         |                                        | 1 DAY           | Not Reported |                |
|                                  | Lorazepam       |                    |                    | S               | Oral                         |                                        | 1 DAY           | Not Reported |                |
|                                  | Lorazepam       |                    |                    | S               | Oral                         |                                        | 20 DAY          | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Jun-2012              | 8636767       | EXPEDITED (15-DAY) | Y                  | HO              | US-FRI-1000031496    |                      | 79 YR      | Female     | USA            |

| <u>Preferred Term</u>                                               | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                             | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------|-------------------------|--------------|------------|-------------|------------------------------------------|--------------------|-----------------|--------------|
| Anaemia; Dehydration;<br>Drug Ineffective; Mental<br>Status Changes | Lexapro                 |              |            | S           | Oral                                     | 10 Mg              |                 | Forest       |
|                                                                     | Namenda                 |              |            | S           | Oral                                     | 20 Mg              |                 | Forest       |
|                                                                     | Bapineuzumab            |              |            | S           | Intravenous (not<br>otherwise specified) |                    |                 | Not Reported |
|                                                                     | Baby Aspirin            |              |            | C           | Oral                                     | 81mg               |                 | Not Reported |
|                                                                     | Omeprazole              |              |            | C           | Oral                                     | 20 Mg              |                 | Not Reported |
|                                                                     | Metformin Hydrochloride |              |            | C           | Oral                                     | 1000 Mg            |                 | Not Reported |
|                                                                     | Simvastatin             |              |            | C           | Oral                                     | 40 Mg              |                 | Not Reported |
|                                                                     | Ramipril                |              |            | C           | Oral                                     | 2.5 Mg             |                 | Not Reported |
|                                                                     | Exelon Patch            |              |            | C           | Transdermal                              | 9.5 Mg             |                 | Not Reported |
|                                                                     | Centrum                 |              |            | C           | Oral                                     | 1 Dosage Forms     |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Jun-2012              | 8636986       | EXPEDITED (15-DAY) | Y                  | OT              | JP-FRI-1000031578    |                      | 20 YR      | Female     | JPN            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Visual Acuity Reduced | Lexapro        |              |            | S           | Oral         | 20 Mg              |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Jun-2012              | 8651519       | DIRECT           | N                  |                 |                      |                      | 42 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                       | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Drug Ineffective;<br>Dysphagia; Panic Attack;<br>Product Substitution Issue | Escitalopram Oxalate |              |            | S           | Oral         | 7.5mg Qd Po        | 3 WEEK          | Teva       |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                             | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|--------------------------------------------------|-----------------|------------|----------------|
| 26-Jun-2012                                                                                                                | 8652497              | DIRECT             |                    |                 |                      |                                                  | 27 YR           | Female     | USA            |
| <u>Preferred Term</u>                                                                                                      | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                               | <u>Duration</u> | <u>Mfr</u> |                |
| Anxiety; Condition Aggravated; Panic Attack; Product Substitution Issue                                                    | Escitalopram Oxalate |                    |                    | S               |                      | 10 Mg, Daily, Oral 047<br>10 Mg, Daily, Oral 047 | 3 WEEK          | Mylan      |                |
|                                                                                                                            | Escitalopram Oxalate |                    |                    | S               | Oral                 | 20 Mg, Daily, Oral. 047                          | 4 WEEK          | Mylan      |                |
| <u>FDA Received Date</u>                                                                                                   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                             | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 27-Jun-2012                                                                                                                | 8637779              | EXPEDITED (15-DAY) | N                  | OT              | US-TEVA-344867USA    |                                                  |                 | Unknown    | USA            |
| <u>Preferred Term</u>                                                                                                      | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                               | <u>Duration</u> | <u>Mfr</u> |                |
| Dizziness; Fall; Head Injury; Hyperhidrosis; Joint Injury; Loss Of Consciousness; Muscular Weakness; Palpitations; Syncope | Escitalopram Oxalate |                    |                    | S               |                      |                                                  |                 | Ivax       |                |
| <u>FDA Received Date</u>                                                                                                   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                             | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 27-Jun-2012                                                                                                                | 8638433              | EXPEDITED (15-DAY) | Y                  | OT              | FR-FRI-1000036602    |                                                  | 69 YR           | Male       | FRA            |
| <u>Preferred Term</u>                                                                                                      | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                               | <u>Duration</u> | <u>Mfr</u> |                |
| Fall; Rib Fracture; Speech Disorder; Vertigo                                                                               | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg                                            |                 | Forest     |                |
| <u>FDA Received Date</u>                                                                                                   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                             | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 27-Jun-2012                                                                                                                | 8639708              | EXPEDITED (15-DAY) | N                  | OT              | US-FRI-1000031555    |                                                  | < 1 DAY         | Male       | USA            |
| <u>Preferred Term</u>                                                                                                      | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                               | <u>Duration</u> | <u>Mfr</u> |                |
| Atrial Septal Defect; Ventricular Septal Defect                                                                            | Lexapro              |                    |                    | S               | Transplacental       |                                                  |                 | Forest     |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                              | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|----------------------|----------------------------|-----------------|--------------|----------------|
| 27-Jun-2012                                                                                                           | 8654794                   | DIRECT             | N                  | HO, LT, OT      |                      |                            |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                                                                 | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Blood Pressure Increased; Feeling Abnormal; Insomnia                                                         | Escitalopram Oxalate      |                    |                    | S               |                      | 1x Day                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                              | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Jun-2012                                                                                                           | 8654955                   | DIRECT             |                    |                 |                      |                            | 48 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                 | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Drug Ineffective; Product Substitution Issue                                                                 | Escitalopram Oxalate      |                    |                    | S               | Oral                 | Escitalopram 20mg 1/D Oral |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                              | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Jun-2012                                                                                                           | 8657794                   | DIRECT             | N                  | OT              |                      |                            | 61 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                 | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Anxiety; Loss Of Personal Independence In Daily Activities; Product Substitution Issue; Suicidal Ideation | Escitalopram Oxalate      |                    |                    | S               | Oral                 | 10mg Once A Day Po         |                 | Teva         |                |
| <u>FDA Received Date</u>                                                                                              | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Jun-2012                                                                                                           | 8325434                   | EXPEDITED (15-DAY) | Y                  | DE              | DK-WATSON-2011-22664 |                            | 72 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                 | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Hypertrophy; Dyspnoea; Fall; Hepatic Cirrhosis; Humerus Fracture; Hypertension; Internal Fixation Of          | Mirtazapine               |                    |                    | S               | Oral                 | 30 Mg, Daily               |                 | Watson       |                |
|                                                                                                                       | Ziprasidone Hydrochloride |                    |                    | S               | Oral                 | 40 Mg, Bid                 |                 | Not Reported |                |
|                                                                                                                       | Lithium Citrate           |                    |                    | S               | Oral                 | 6 Mmol, Unk                |                 | Not Reported |                |

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

|                                                                                                                                                     |                                                                                                                            |                                 |                                            |                                                                     |                                                                                              |
|-----------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------|---------------------------------|--------------------------------------------|---------------------------------------------------------------------|----------------------------------------------------------------------------------------------|
| Fracture; Lactic Acidosis;<br>Lacunar Infarction;<br>Neuroleptic Malignant<br>Syndrome; Organ Failure;<br>Pyrexia; Renal Failure;<br>Rhabdomyolysis | Cipralext<br>Fragmin<br>Bendroflumethiazide\Potassium<br>Chloride<br>Amlodipine Actavis<br>Alprazolam<br>Ferrous Succinate | S<br>C<br>C<br>C<br>C<br>C<br>C | Oral<br><br><br><br><br>Unknown<br>Unknown | 30 Mg, Daily<br>Unk<br>Unk<br>Unk<br>0.5 Mg, Daily<br>100 Mg, Daily | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |
|-----------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------|---------------------------------|--------------------------------------------|---------------------------------------------------------------------|----------------------------------------------------------------------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 28-Jun-2012              | 8591302              | EXPEDITED (15-DAY) | Y                  | OT              | IT-FRI-1000030456    |                      | 43 YR           | Female       | ITA            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Gingival Bleeding        | Escitalopram Oxalate |                    |                    | S               | Oral                 | 8 Df                 |                 | Forest       |                |
|                          | Lithium              |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                           | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|----------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 28-Jun-2012                                                                                        | 8640875        | EXPEDITED (15-DAY) | N                  | CA              | US-FRI-1000031557    |                      | < 1 DAY         | Male       | USA            |
| <u>Preferred Term</u>                                                                              | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Atrial Septal Defect;<br>Maternal Drugs Affecting<br>Foetus; Transposition Of<br>The Great Vessels | Lexapro        |                    |                    | S               | Transplacental       |                      |                 | Forest     |                |

| <u>FDA Received Date</u>       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 28-Jun-2012                    | 8641063        | EXPEDITED (15-DAY) | N                  | OT              | US-FRI-1000031559    |                      | < 1 DAY         | Male       | USA            |
| <u>Preferred Term</u>          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Congenital Anomaly;<br>Talipes | Lexapro        |                    |                    | S               | Transplacental       |                      |                 | Forest     |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

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| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Jun-2012              | 8642002       | EXPEDITED (15-DAY) |                    | OT              | DE-FRI-1000036596    |                      |            | Female     | DEU            |

| <u>Preferred Term</u>                                                | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                              | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------|---------------------------|--------------|------------|-------------|--------------|-------------------------------------------------|-----------------|--------------|
| Galactorrhoea;<br>Hyperhidrosis;<br>Potentiating Drug<br>Interaction | Escitalopram Oxalate      |              |            | S           | Oral         | 10 Mg                                           |                 | Forest       |
|                                                                      | Fexofenadine Hcl          |              |            | C           | Oral         | 240 Mg                                          |                 | Not Reported |
|                                                                      | Fexofenadine Hcl          |              |            | C           | Oral         | 120 Mg                                          |                 | Not Reported |
|                                                                      | Yaz                       |              |            | C           | Oral         | 0.02 Mg Ethinylestradiol /<br>3 Mg Drospirenone |                 | Not Reported |
|                                                                      | Escitalopram Oxalate      |              |            | S           | Oral         | 20 Mg                                           |                 | Not Reported |
|                                                                      | Escitalopram Oxalate      |              |            | S           | Oral         | 10 Mg                                           |                 | Not Reported |
|                                                                      | Venlafaxine Hydrochloride |              |            | S           | Oral         | 75 Mg                                           |                 | Not Reported |
|                                                                      | Venlafaxine Hydrochloride |              |            | S           | Oral         | 150 Mg                                          |                 | Not Reported |
|                                                                      | Pipamperone Hydrochloride |              |            | S           | Oral         | 40 Mg                                           |                 | Not Reported |
|                                                                      | Pipamperone Hydrochloride |              |            | S           | Oral         | 40 Mg                                           |                 | Not Reported |
|                                                                      | Pipamperone Hydrochloride |              |            | S           | Oral         | 20 Mg                                           |                 | Not Reported |
|                                                                      | Pipamperone Hydrochloride |              |            | S           | Oral         | 40 Mg                                           |                 | Not Reported |
|                                                                      | Pipamperone Hydrochloride |              |            | S           | Oral         | 20 Mg                                           |                 | Not Reported |
|                                                                      | Pipamperone Hydrochloride |              |            | S           | Oral         | 40 Mg                                           |                 | Not Reported |
|                                                                      | Pipamperone Hydrochloride |              |            | S           | Oral         | 80 Mg                                           |                 | Not Reported |
|                                                                      | Pipamperone Hydrochloride |              |            | S           | Oral         | 160 Mg                                          |                 | Not Reported |
|                                                                      | Pipamperone Hydrochloride |              |            | S           | Oral         | 80 Mg                                           |                 | Not Reported |
|                                                                      | Pipamperone Hydrochloride |              |            | S           | Oral         | 40 Mg                                           |                 | Not Reported |
|                                                                      | Pipamperone Hydrochloride |              |            | S           | Oral         | 80 Mg                                           |                 | Not Reported |
|                                                                      | Pipamperone Hydrochloride |              |            | S           | Oral         | 40 Mg                                           |                 | Not Reported |
|                                                                      | Pipamperone Hydrochloride |              |            | S           | Oral         | 80 Mg                                           |                 | Not Reported |
| Pipamperone Hydrochloride                                            |                           |              | S          | Oral        | 40 Mg        |                                                 | Not Reported    |              |
| Pipamperone Hydrochloride                                            |                           |              | S          | Oral        | 80 Mg        |                                                 | Not Reported    |              |
| Pipamperone Hydrochloride                                            |                           |              | S          | Oral        | 40 Mg        |                                                 | Not Reported    |              |

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

|                                                           |                      |                    |                    |                 |                                          |                           |                 |              |                |
|-----------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|------------------------------------------|---------------------------|-----------------|--------------|----------------|
| Pipamperone Hydrochloride                                 |                      |                    | S                  | Oral            | 40 Mg                                    |                           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Jun-2012                                               | 8659613              | DIRECT             | Y                  |                 |                                          |                           | 23 YR           | Female       | USA            |
| <u>Preferred Term</u>                                     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |                |
| Fatigue; Product Substitution Issue; Sedation; Somnolence | Escitalopram Oxalate |                    |                    | S               | Oral                                     | 20mg One Am Po            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Jun-2012                                               | 8661088              | DIRECT             |                    | HO              |                                          |                           |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |                |
| Autonomic Nervous System Imbalance; Seizure               | Lexapro              |                    |                    | S               |                                          | 1 Pill 1 A Day For 4 Days |                 | Not Reported |                |
| <u>FDA Received Date</u>                                  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Jun-2012                                               | 8644075              | EXPEDITED (15-DAY) | Y                  | LT              | ID-BRISTOL-MYERS SQUIBB COMPANY-16713042 |                           | 17 YR           | Male         | IDN            |
| <u>Preferred Term</u>                                     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |                |
| Stevens-Johnson Syndrome                                  | Abilify              |                    |                    | S               | Oral                                     |                           | 3 DAY           | Not Reported |                |
|                                                           | Abilify              |                    |                    | S               | Oral                                     |                           | 3 DAY           | Not Reported |                |
|                                                           | Cipralext            |                    |                    | S               |                                          |                           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Jul-2012                                               | 8646214              | EXPEDITED (15-DAY) | Y                  | HO              | FR-FRI-1000036776                        |                           | 49 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |                |
| Cerebral Haematoma                                        | Escitalopram Oxalate |                    |                    | S               | Oral                                     |                           |                 | Forest       |                |
|                                                           | Abilify              |                    |                    | S               | Oral                                     |                           |                 | Not Reported |                |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

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| <u>FDA Received Date</u>   | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------|-----------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 02-Jul-2012                | 8646519                     | EXPEDITED (15-DAY) | Y                  | DS, HO          | FR-FRI-1000014090    |                      | 58 YR           | Female       | FRA            |
| <u>Preferred Term</u>      | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Tolosa-Hunt Syndrome       | Escitalopram Oxalate        |                    |                    | S               | Oral                 |                      |                 | Forest       |                |
|                            | Influenza Virus Vaccine Nos |                    |                    | S               | Intramuscular        |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>   | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Jul-2012                | 8646537                     | EXPEDITED (15-DAY) | Y                  | HO              | FR-FRI-1000036710    |                      | 82 YR           | Female       | FRA            |
| <u>Preferred Term</u>      | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Distension;      | Escitalopram Oxalate        |                    |                    | S               | Oral                 | 5 Mg                 |                 | Forest       |                |
| Ascites; Drug Interaction; | Coumadin                    |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Dyspnoea;                  | Esidrex                     |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Hyponatraemia;             | Tahor                       |                    |                    | C               |                      |                      |                 | Not Reported |                |
| International Normalised   |                             |                    |                    |                 |                      |                      |                 |              |                |
| Ratio Increased; Nausea;   |                             |                    |                    |                 |                      |                      |                 |              |                |
| Oedema Peripheral;         |                             |                    |                    |                 |                      |                      |                 |              |                |
| Weight Increased           |                             |                    |                    |                 |                      |                      |                 |              |                |
| <u>FDA Received Date</u>   | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Jul-2012                | 8646541                     | EXPEDITED (15-DAY) | Y                  | OT              | TR-FRI-1000036773    |                      | 92 YR           | Female       | TUR            |
| <u>Preferred Term</u>      | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Diabetes Insipidus; Fall   | Escitalopram Oxalate        |                    |                    | S               | Oral                 | 5 Mg                 |                 | Forest       |                |
|                            | Memantine                   |                    |                    | S               | Oral                 | 5 Mg                 |                 | Forest       |                |
|                            | Desyrel                     |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                            | Sertraline Hydrochloride    |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                            | Xanax                       |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>   | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Jul-2012                | 8662826                     | DIRECT             | N                  | LT              |                      |                      | 45 YR           | Female       | USA            |

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| <u>Preferred Term</u>                            | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
|--------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------|-----------------|--------------|----------------|
| Product Substitution Issue;<br>Suicidal Ideation | Escitalopram Oxalate    |                    |                    | S               | Oral                 | 20 Mg 1 Day Po          |                 | Teva         |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Jul-2012                                      | 8647879                 | EXPEDITED (15-DAY) | Y                  | LT              | FR-FRI-1000036771    |                         | 97 YR           | Female       | FRA            |
| <u>Preferred Term</u>                            | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrioventricular Block<br>Complete               | Escitalopram Oxalate    |                    |                    | S               | Oral                 | 10 Mg                   |                 | Forest       |                |
|                                                  | Escitalopram Oxalate    |                    |                    | S               | Oral                 | 20 Mg                   |                 | Not Reported |                |
|                                                  | Mianserin               |                    |                    | S               | Oral                 | 10 Mg                   |                 | Not Reported |                |
|                                                  | Crestor                 |                    |                    | C               |                      |                         |                 | Not Reported |                |
|                                                  | Ramipril                |                    |                    | C               |                      |                         |                 | Not Reported |                |
|                                                  | Kardegic                |                    |                    | C               |                      |                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Jul-2012                                      | 8647890                 | EXPEDITED (15-DAY) | Y                  | OT              | CA-FRI-1000036772    |                         |                 | Male         | CAN            |
| <u>Preferred Term</u>                            | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest                                   | Escitalopram Oxalate    |                    |                    | S               | Oral                 | Daily Dose Not Reported |                 | Forest       |                |
|                                                  | Methadone Hydrochloride |                    |                    | C               |                      | Daily Dose Not Reported |                 | Not Reported |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Jul-2012                                      | 8648687                 | EXPEDITED (15-DAY) | Y                  | DE              | FR-FRI-1000025231    |                         | 53 YR           | Male         | FRA            |
| <u>Preferred Term</u>                            | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Hyperhidrosis              | Escitalopram Oxalate    |                    |                    | S               |                      | 10 Mg                   |                 | Forest       |                |
|                                                  | Escitalopram Oxalate    |                    |                    | S               |                      | 10 Mg                   |                 | Forest       |                |
|                                                  | Alprazolam              |                    |                    | C               | Oral                 | 0.375 Mg                |                 | Not Reported |                |
|                                                  | Theralene               |                    |                    | C               | Oral                 | 10 Df                   |                 | Not Reported |                |

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

| <u>FDA Received Date</u>                                                                                   | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>     | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|----------------|----------------|
| 03-Jul-2012                                                                                                | 8648757                   | EXPEDITED (15-DAY) | N                  | CA              | US-FRI-1000036707    |                      | < 1 DAY         | Male           | USA            |
| <u>Preferred Term</u>                                                                                      | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>     |                |
| Hydrocephalus; Spina Bifida                                                                                | Lexapro                   |                    |                    | S               | Transplacental       |                      |                 | Forest         |                |
| <u>FDA Received Date</u>                                                                                   | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>     | <u>Country</u> |
| 03-Jul-2012                                                                                                | 8664267                   | DIRECT             | N                  | OT              |                      |                      | 37 YR           | Female         | USA            |
| <u>Preferred Term</u>                                                                                      | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>     |                |
| Insomnia; Mood Swings; Nausea; Panic Attack; Product Substitution Issue; Unevaluable Event; Vision Blurred | Escitalopram Oxalate      |                    |                    | S               | Oral                 | 25 Mg 1/Day Po       |                 | Teva           |                |
| <u>FDA Received Date</u>                                                                                   | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>     | <u>Country</u> |
| 05-Jul-2012                                                                                                | 8247522                   | EXPEDITED (15-DAY) | Y                  | DE, HO, OT      | 2011MA016018         |                      | 72 YR           | Female         | DNK            |
| <u>Preferred Term</u>                                                                                      | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>     |                |
| Acute Kidney Injury;                                                                                       | Mirtazapine               |                    |                    | S               | Oral                 | 30 Mg;Qd;Po          |                 | Purepac        |                |
| Cardiac Hypertrophy;                                                                                       | Mirtazapine               |                    |                    | S               | Oral                 | 30 Mg;Qd;Po          |                 | Actavis Totowa |                |
| Constipation; Dialysis;                                                                                    | Ziprasidone Hydrochloride |                    |                    | S               | Oral                 | 40 Mg;Bid;Po         |                 | Not Reported   |                |
| Dyspnoea; Fall; Hepatic                                                                                    | Lithium Citrate           |                    |                    | S               | Oral                 | 6 Mmol;Unk;Po        |                 | Not Reported   |                |
| Cirrhosis; Humerus                                                                                         | Cipralext                 |                    |                    | S               | Oral                 | 30 Mg;Qd;Po          |                 | Not Reported   |                |
| Fracture; Hypertension;                                                                                    | Ferro Curetter            |                    |                    | C               |                      |                      |                 | Not Reported   |                |
| Infarction; Lactic Acidosis;                                                                               | Centy Med                 |                    |                    | C               |                      |                      |                 | Not Reported   |                |
| Lacunar Infarction; Liver                                                                                  | Kalimklorid               |                    |                    | C               |                      |                      |                 | Not Reported   |                |
| Disorder; Multiple Organ                                                                                   | Alprazolam                |                    |                    | C               |                      |                      |                 | Not Reported   |                |
| Dysfunction Syndrome;                                                                                      |                           |                    |                    |                 |                      |                      |                 |                |                |
| Myocardial Necrosis                                                                                        |                           |                    |                    |                 |                      |                      |                 |                |                |
| Marker Increased;                                                                                          |                           |                    |                    |                 |                      |                      |                 |                |                |
| Neuroleptic Malignant                                                                                      |                           |                    |                    |                 |                      |                      |                 |                |                |
| Syndrome; Polydipsia;                                                                                      |                           |                    |                    |                 |                      |                      |                 |                |                |
| Post Procedural                                                                                            |                           |                    |                    |                 |                      |                      |                 |                |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Complication;  
Rhabdomyolysis; Urinary  
Tract Infection

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 05-Jul-2012              | 8612752       | NON-EXPEDITED    | N                  |                 | US-PFIZER INC-<br>2012139829 |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Hypersensitivity | Lyrica                  |              |            | S           |              | Unk                |                 | Pfizer       |
|                       | Atarax                  |              |            | S           |              | Unk                |                 | Pfizer       |
|                       | Bystolic                |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Trazodone Hydrochloride |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Elavil                  |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Lexapro                 |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Wellbutrin              |              |            | S           |              | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 05-Jul-2012              | 8650472       | NON-EXPEDITED    | Y                  |                 | US-PFIZER INC-<br>2012157422 |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Feeling Drunk         | Lyrica                    |              |            | S           |              | Unk                |                 | Pfizer       |
|                       | Hydroxyzine Hydrochloride |              |            | S           |              | Unk                |                 | Pfizer       |
|                       | Lexapro                   |              |            | S           |              | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|------------|------------|----------------|
| 05-Jul-2012              | 8650586       | EXPEDITED (15-DAY) | Y                  | OT              | FR-ASTRAZENECA-<br>2012SE43878 |                      | 61 YR      | Male       | FRA            |

| <u>Preferred Term</u>                       | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Prolactin Increased;<br>Gynaecomastia | Inexium              |              |            | S           | Oral         |                    |                 | Astrazeneca  |
|                                             | Escitalopram Oxalate |              |            | S           | Oral         |                    | 14 MTH          | Not Reported |
|                                             | Escitalopram Oxalate |              |            | S           | Oral         |                    | 128 DAY         | Not Reported |

# FDA Adverse Event Reporting System

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| <a href="#">FDA Received Date</a>                                                                                                                                                                           | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 05-Jul-2012                                                                                                                                                                                                 | 8650979                 | EXPEDITED (15-DAY)        | N                           | CA                       | US-FRI-1000036768             |                               | < 1 DAY                  | Male                | USA                     |
| <a href="#">Preferred Term</a>                                                                                                                                                                              | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Arnold-Chiari Malformation; Congenital Anomaly; Spina Bifida                                                                                                                                                | Lexapro                 |                           |                             | S                        | Transplacental                |                               |                          | Forest              |                         |
| <a href="#">FDA Received Date</a>                                                                                                                                                                           | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 05-Jul-2012                                                                                                                                                                                                 | 8666057                 | DIRECT                    | Y                           | HO                       |                               |                               | 55 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                                                                                                                                              | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Dyspnoea; Hyponatraemia; Wheezing                                                                                                                                                                           | Lexapro                 |                           |                             | S                        | Oral                          | One Tablet Daily Po           |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                                                                                                           | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 05-Jul-2012                                                                                                                                                                                                 | 8667695                 | DIRECT                    |                             | OT                       |                               |                               | 23 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                                                                                                                                              | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Anxiety; Blood Pressure Increased; Condition Aggravated; Decreased Appetite; Depression; Dysphagia; Fatigue; Feeling Abnormal; Impaired Work Ability; Nausea; Product Substitution Issue; Visual Impairment | Escitalopram Oxalate    |                           |                             | S                        | Oral                          | 10mg Daily Po                 |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                                                                                                           | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 06-Jul-2012                                                                                                                                                                                                 | 8597140                 | EXPEDITED (15-DAY)        | Y                           | HO                       | BE-FRI-1000030976             |                               | 38 YR                    | Male                | BEL                     |
| <a href="#">Preferred Term</a>                                                                                                                                                                              | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |

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|         |                      |   |      |      |                        |
|---------|----------------------|---|------|------|------------------------|
| Seizure | Escitalopram Oxalate | S | Oral | 5 Mg | Forest                 |
|         | Escitalopram Oxalate | S |      |      |                        |
|         | Symbicort            | C |      |      | Forest<br>Not Reported |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 06-Jul-2012                       | 8651858                | NON-EXPEDITED             | N                           |                          | US-FRI-1000036800             |                               | 55 YR               | Female              | USA                     |

| <a href="#">Preferred Term</a>                    | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|---------------------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Crying; Depression;<br>Irritability; Paraesthesia | Lexapro                 |                       |                     | S                    | Oral                  | 10 Mg                       |                          | Forest              |
|                                                   | Lexapro                 |                       |                     | S                    | Oral                  | 20 Mg                       |                          | Forest              |
|                                                   | Clonidine               |                       |                     | C                    |                       |                             |                          | Not Reported        |
|                                                   | Potassium               |                       |                     | C                    |                       |                             |                          | Not Reported        |
|                                                   | Vitamin B1              |                       |                     | C                    |                       |                             |                          | Not Reported        |
|                                                   | Folic Acid              |                       |                     | C                    |                       |                             |                          | Not Reported        |
|                                                   | Losartan Potassium      |                       |                     | C                    |                       |                             |                          | Not Reported        |
|                                                   | Suboxone                |                       |                     | C                    |                       |                             |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 06-Jul-2012                       | 8651886                | NON-EXPEDITED             | Y                           |                          | US-FRI-1000036806             |                               |                     | Male                | USA                     |

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

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 06-Jul-2012                       | 8651898                | EXPEDITED (15-DAY)        | Y                           | HO                       | FR-FRI-1000036847             |                               | 78 YR               | Female              | FRA                     |

| <a href="#">Preferred Term</a>             | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Loss Of Consciousness;<br>Weight Decreased | Escitalopram Oxalate    |                       |                     | S                    | Oral                  | 20 Mg                       |                          | Forest              |
|                                            | Victoza                 |                       |                     | S                    | Subcutaneous          | 3 MI                        |                          | Not Reported        |
|                                            | Simvastatin             |                       |                     | S                    | Oral                  | 20 Mg                       |                          | Not Reported        |
|                                            | Gliclazide              |                       |                     | S                    | Oral                  | 60 Mg                       |                          | Not Reported        |
|                                            | Metformin Hydrochloride |                       |                     | S                    | Oral                  | 2550 Mg                     |                          | Not Reported        |

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| <u>FDA Received Date</u>                                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 06-Jul-2012                                                    | 8652038              | EXPEDITED (15-DAY) | Y                  | OT              | FR-FRI-1000026421     |                      |                 | Female       | FRA            |
| <u>Preferred Term</u>                                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Dependence;<br>Withdrawal Syndrome                        | Escitalopram Oxalate |                    |                    | S               | Oral                  | 5 Mg                 |                 | Forest       |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Jul-2012                                                    | 8652881              | EXPEDITED (15-DAY) | Y                  | OT              | IT-JNJFOC-20120700191 |                      | 44 YR           | Male         | ITA            |
| <u>Preferred Term</u>                                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Overdose;<br>Intentional Self-Injury;<br>Sopor     | Haldol               |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                | Haldol               |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                | Zyprexa              |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                | Escitalopram Oxalate |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Jul-2012                                                    | 8667589              | DIRECT             | N                  |                 |                       |                      | 44 YR           | Female       | USA            |
| <u>Preferred Term</u>                                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State;<br>Dizziness; Product<br>Substitution Issue | Escitalopram Oxalate |                    |                    | S               | Oral                  | 2.5ml Once A Day Po  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Jul-2012                                                    | 8667693              | DIRECT             | Y                  |                 |                       |                      | 29 YR           | Female       | USA            |
| <u>Preferred Term</u>                                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Galactorrhoea; Product<br>Substitution Issue                   | Escitalopram Oxalate |                    |                    | S               | Oral                  | 15 Mg Daily Po       |                 | Teva         |                |

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| <u>FDA Received Date</u> | <u>Case #</u>                                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|---------------------------------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------|-----------------|--------------|----------------|
| 06-Jul-2012              | 8682058                                           | EXPEDITED (15-DAY) | Y                  | OT              | 2012155287           |                               | 67 YR           | Female       | CHE            |
| <u>Preferred Term</u>    | <u>Product</u>                                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Pneumonia Bacterial      | Methotrexate                                      |                    |                    | S               | Oral                 | 1 Df, 1x/Day, Oral            |                 | Not Reported |                |
|                          | Fragmin                                           |                    |                    | S               | Subcutaneous         | 5000 Iu, 1x/Day, Subcutaneous |                 | Not Reported |                |
|                          | Ibuprofen                                         |                    |                    | S               | Oral                 | 1 Df Per Day, Oral            |                 | Not Reported |                |
|                          | Prednisone                                        |                    |                    | S               | Oral                 | 10 Mg, 1x/Day, Oral           |                 | Not Reported |                |
|                          | Cipralex                                          |                    |                    | S               | Oral                 | 10 Mg, 1x/Day, Oral           |                 | Not Reported |                |
|                          | Ramipril                                          |                    |                    | C               |                      |                               |                 | Not Reported |                |
|                          | Pantozol (Pantoprazole Sodium)                    |                    |                    | C               |                      |                               |                 | Not Reported |                |
|                          | Calcimagon-D3 (Calcium Carbonate, Colecalciferol) |                    |                    | C               |                      |                               |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>                                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Jul-2012              | 8654733                                           | EXPEDITED (15-DAY) | Y                  | HO              | IT-FRI-1000036861    |                               | 84 YR           | Male         | ITA            |
| <u>Preferred Term</u>    | <u>Product</u>                                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrioventricular Block   | Escitalopram Oxalate                              |                    |                    | S               | Oral                 | 10 Mg                         |                 | Forest       |                |
|                          | Escitalopram Oxalate                              |                    |                    | S               |                      |                               | 5 YR            | Forest       |                |
|                          | Zyprexa                                           |                    |                    | S               | Oral                 | 2.5 Mg                        |                 | Not Reported |                |
|                          | Zyprexa                                           |                    |                    | S               |                      |                               |                 | Not Reported |                |
|                          | Bisoprolol Fumarate                               |                    |                    | C               | Oral                 | 2.5 Mg                        |                 | Not Reported |                |
|                          | Diazepam                                          |                    |                    | C               | Oral                 | 0.5                           |                 | Not Reported |                |
|                          | Triatec Hct 5mg+25mg Compresse                    |                    |                    | C               | Oral                 |                               |                 | Not Reported |                |
|                          | Triatec Compresse                                 |                    |                    | C               | Oral                 | 5 Mg                          |                 | Not Reported |                |
|                          | Pravastatin Sodium                                |                    |                    | C               | Oral                 | 20 Mg                         |                 | Not Reported |                |
|                          | Clopidogrel Bisulfate                             |                    |                    | C               | Oral                 | 75 Mg                         |                 | Not Reported |                |



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| <u>FDA Received Date</u>                                                                                               | <u>Case #</u>                               | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>                             | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|------------------|--------------------|-----------------|----------------------|-----------------------------|-----------------|----------------------------------------|----------------|
| 09-Jul-2012                                                                                                            | 8670084                                     | DIRECT           | Y                  |                 |                      |                             |                 | Female                                 | USA            |
| <u>Preferred Term</u>                                                                                                  | <u>Product</u>                              | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>                             |                |
| Decreased Appetite; Drug Ineffective; Fatigue; Feeling Abnormal; Movement Disorder                                     | Lexapro<br>Estradiol<br>Vitamin B12 1000 Mg |                  |                    | S<br>C<br>C     |                      |                             |                 | Forest<br>Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                                               | <u>Case #</u>                               | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>                             | <u>Country</u> |
| 09-Jul-2012                                                                                                            | 8671705                                     | DIRECT           | N                  |                 |                      |                             |                 | Unknown                                | USA            |
| <u>Preferred Term</u>                                                                                                  | <u>Product</u>                              | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>                             |                |
| Drug Ineffective; Product Substitution Issue                                                                           | Lexapro                                     |                  |                    | S               | Oral                 | 10 Mg Once Po Qd            |                 | Not Reported                           |                |
| <u>FDA Received Date</u>                                                                                               | <u>Case #</u>                               | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>                             | <u>Country</u> |
| 09-Jul-2012                                                                                                            | 8671863                                     | DIRECT           | Y                  | OT              |                      |                             | 62 YR           | Male                                   | USA            |
| <u>Preferred Term</u>                                                                                                  | <u>Product</u>                              | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>                             |                |
| Drug Ineffective; Product Substitution Issue                                                                           | Escitalopram Oxalate                        |                  |                    | S               | Oral                 | 10 Mg Once Daily P.O (Oral) |                 | Mylan                                  |                |
| <u>FDA Received Date</u>                                                                                               | <u>Case #</u>                               | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>                             | <u>Country</u> |
| 09-Jul-2012                                                                                                            | 8673906                                     | DIRECT           |                    |                 |                      |                             | 87 YR           | Male                                   | USA            |
| <u>Preferred Term</u>                                                                                                  | <u>Product</u>                              | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>                             |                |
| Agitation; Disorientation; Fall; Inappropriate Antidiuretic Hormone Secretion; Medication Error; Mental Status Changes | Lexapro                                     |                  |                    | S               |                      |                             |                 | Not Reported                           |                |

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| <u>FDA Received Date</u>                   | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 09-Jul-2012                                | 8673975                     | DIRECT             |                    |                 |                      |                      | 18 YR           | Unknown      | USA            |
| <u>Preferred Term</u>                      | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Intercepted Product<br>Dispensing Error    | Lisinopril                  |                    |                    | S               |                      | 10 Mg                |                 | Not Reported |                |
|                                            | Lexapro                     |                    |                    | S               |                      | 10 Mg                |                 | Not Reported |                |
| <u>FDA Received Date</u>                   | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Jul-2012                                | 9204308                     | NON-EXPEDITED      |                    |                 | 2012HGS-003392       |                      | 44 YR           | Female       | USA            |
| <u>Preferred Term</u>                      | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Fatigue;<br>Hypotension; Nausea | Benlysta                    |                    |                    | S               | Intravenous drip     | 1 In 28 D            |                 | Not Reported |                |
|                                            | Hyzaar                      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                            | Losartan                    |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                            | Clobetasol Propionate       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                            | Plaquenil                   |                    |                    | C               |                      | 2 In 1 D             |                 | Not Reported |                |
|                                            | Prednisone                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                            | Synthroid                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                            | Vitamin D2 (Ergocalciferol) |                    |                    | C               |                      | 1 In 1 Wk            |                 | Not Reported |                |
|                                            | Amlodipine                  |                    |                    | C               |                      | Once                 |                 | Not Reported |                |
|                                            | Lexapro                     |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                   | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Jul-2012                                | 8648613                     | EXPEDITED (15-DAY) |                    | HO              | US-FRI-1000036747    |                      | 29 YR           | Female       | USA            |
| <u>Preferred Term</u>                      | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cholecystitis;<br>Cholelithiasis           | Lexapro                     |                    |                    | S               | Oral                 | 20 Mg                |                 | Forest       |                |
|                                            | Unspecified Ingredient      |                    |                    | S               | Oral                 | 3 Mg                 |                 | Not Reported |                |
|                                            | Yasmin                      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                            | Biotene                     |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                            | Zyrtec                      |                    |                    | C               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                     | <u>Case #</u>                                                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------|--------------------------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 10-Jul-2012                                  | 8658180                                                                  | EXPEDITED (15-DAY) | Y                  | OT              | FR-FRI-1000036928    |                      |                 | Female       | FRA            |
| <u>Preferred Term</u>                        | <u>Product</u>                                                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Psoriasis                                    | Escitalopram Oxalate                                                     |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                              | Escitalopram Oxalate                                                     |                    |                    | S               | Oral                 | 15 Mg                |                 | Forest       |                |
|                                              | Escitalopram Oxalate                                                     |                    |                    | S               | Oral                 | 20 Mg                |                 | Not Reported |                |
|                                              | Amitriptyline Hydrochloride                                              |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                              | Effexor                                                                  |                    |                    | S               |                      | 150 Mg               |                 | Not Reported |                |
|                                              | Prazepam                                                                 |                    |                    | C               | Oral                 | 10 Mg As Needed      |                 | Not Reported |                |
| <u>FDA Received Date</u>                     | <u>Case #</u>                                                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Jul-2012                                  | 8658815                                                                  | EXPEDITED (15-DAY) | Y                  | DE              | JP-FRI-1000036917    |                      |                 | Male         | JPN            |
| <u>Preferred Term</u>                        | <u>Product</u>                                                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Death                                        | Lexapro                                                                  |                    |                    | S               | Oral                 |                      |                 | Forest       |                |
|                                              | Adalat                                                                   |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |
|                                              | Brotizolam                                                               |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |
|                                              | Neurotrophin Neurotrophin(An Extract Obtained From Inflammatory Rabbit S |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |
|                                              | Nicorandil                                                               |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                     | <u>Case #</u>                                                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Jul-2012                                  | 8673970                                                                  | DIRECT             | Y                  |                 |                      |                      | 63 YR           | Female       | USA            |
| <u>Preferred Term</u>                        | <u>Product</u>                                                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective; Product Substitution Issue | Lexapro                                                                  |                    |                    | S               | Oral                 | Lexapro 10mg Qd Oral |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <a href="#">FDA Received Date</a>                                                  | <a href="#">Case #</a>         | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|------------------------------------------------------------------------------------|--------------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 10-Jul-2012                                                                        | 8674043                        | DIRECT                    | Y                           | OT                       |                               |                               | 83 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                     | <a href="#">Product</a>        | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Hot Flush                                                                          | Escitalopram Oxalate           |                           |                             | S                        |                               | 20 Mg One Qd Po               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                  | <a href="#">Case #</a>         | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 11-Jul-2012                                                                        | 8660829                        | EXPEDITED (15-DAY)        | Y                           | HO                       | AU-FRI-1000036940             |                               | < 1 DAY                  | Male                | AUS                     |
| <a href="#">Preferred Term</a>                                                     | <a href="#">Product</a>        | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy                | Lexapro                        |                           |                             | S                        | Transplacental                | 20 Mg                         |                          | Forest              |                         |
|                                                                                    | Dexamphetamine                 |                           |                             | C                        | Transplacental                | 20 Mg                         |                          | Not Reported        |                         |
|                                                                                    | Quetiapine                     |                           |                             | C                        | Transplacental                | 75 Mg                         |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                  | <a href="#">Case #</a>         | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 11-Jul-2012                                                                        | 8660837                        | EXPEDITED (15-DAY)        | Y                           | DE                       | FR-FRI-1000036935             |                               | 52 YR                    | Male                | FRA                     |
| <a href="#">Preferred Term</a>                                                     | <a href="#">Product</a>        | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Myocardial Infarction                                                              | Escitalopram Oxalate           |                           |                             | S                        | Oral                          | 5 Mg                          |                          | Forest              |                         |
|                                                                                    | Tahor                          |                           |                             | C                        |                               | 10 Mg                         |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                  | <a href="#">Case #</a>         | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 11-Jul-2012                                                                        | 8661061                        | EXPEDITED (15-DAY)        | Y                           | HO                       | CH-ROCHE-1082216              |                               | 67 YR                    | Female              | CHE                     |
| <a href="#">Preferred Term</a>                                                     | <a href="#">Product</a>        | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Blood Loss Anaemia; Enterocolitis Haemorrhagic; Lower Gastrointestinal Haemorrhage | Methotrexate                   |                           |                             | S                        | Oral                          | Drug Withdrawn                |                          | Not Reported        |                         |
|                                                                                    | Ramipril                       |                           |                             | C                        | Oral                          |                               |                          | Not Reported        |                         |
|                                                                                    | Pantozol (Pantoprazole Sodium) |                           |                             | C                        | Oral                          |                               |                          | Not Reported        |                         |
|                                                                                    | Calcimagon-D3                  |                           |                             | C                        | Oral                          |                               |                          | Not Reported        |                         |

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

|  |            |   |                                       |                      |              |
|--|------------|---|---------------------------------------|----------------------|--------------|
|  | Rocephin   | S | Intravenous (not otherwise specified) | Drug Withdrawn       | Not Reported |
|  | Ibuprofen  | S | Oral                                  | Drug Withdrawn       | Not Reported |
|  | Prednisone | S | Oral                                  | Dose Not Changed     | Not Reported |
|  | Klacid     | S | Oral                                  | Reported As 'Kalcid' | Not Reported |
|  | Fragmin    | S | Subcutaneous                          |                      | Not Reported |
|  | Cipraxel   | S | Oral                                  | Dose Not Changed     | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Jul-2012              | 8608982       | EXPEDITED (15-DAY) | Y                  | OT              | NO-FRI-1000031157    |                      | 19 YR      | Female     | NOR            |

| <u>Preferred Term</u>                 | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Binge Eating; Intentional Self-Injury | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg              |                 | Forest     |
|                                       | Escitalopram Oxalate |              |            | S           | Oral         | 20                 |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Jul-2012              | 8642140       | EXPEDITED (15-DAY) |                    | HO, OT          | DE-FRI-1000036605    |                      |            | Male       | DEU            |

| <u>Preferred Term</u>                                                                           | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Akathisia; Blood Thyroid Stimulating Hormone Decreased; Delirium; Potentiating Drug Interaction | Escitalopram Oxalate |              |            | S           | Oral         | 20 Mg              |                 | Forest       |
|                                                                                                 | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg              |                 | Not Reported |
|                                                                                                 | Remergil             |              |            | S           | Oral         | 30 Mg              |                 | Not Reported |
|                                                                                                 | Remergil             |              |            | S           | Oral         | 15 Mg              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                               | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------------------------------------|----------------------|------------|------------|----------------|
| 12-Jul-2012              | 8662137       | NON-EXPEDITED    |                    |                 | US-MUTUAL PHARMACEUTICAL COMPANY, INC.-IMPR2011000 |                      | 59 YR      | Male       | USA            |

| <u>Preferred Term</u>                      | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--------------------------------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Abnormal Dreams; Anxiety; Depression; Drug | Imipramine Hydrochloride |              |            | S           | Oral         |                    |                 | Mutual     |

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

|                                                                      |                          |   |      |              |
|----------------------------------------------------------------------|--------------------------|---|------|--------------|
| Ineffective; Drug<br>Withdrawal Syndrome;<br>Headache; Off Label Use | Imipramine Hydrochloride | S | Oral | Mutual       |
|                                                                      | Imipramine Hydrochloride | S | Oral | Mutual       |
|                                                                      | Imipramine Hydrochloride | S |      | Mutual       |
|                                                                      | Lexapro                  | S | Oral | Not Reported |
|                                                                      | Lexapro                  | S |      | Not Reported |
|                                                                      | Clonazepam               | C | Oral | Not Reported |
|                                                                      | Benazepril               | C | Oral | Not Reported |

| <u>FDA Received Date</u>                                                                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| 12-Jul-2012                                                                                      | 8662320              | EXPEDITED (15-DAY) | Y                  | LT, OT          | US-ASTRAZENECA-2012SE47031 |                      | 29 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Brain Injury; Cardiac Arrest; Haemodynamic Instability; Hypotension; Overdose; Sinus Tachycardia | Quetiapine           |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                                                                  | Escitalopram Oxalate |                    |                    | S               |                            |                      |                 | Not Reported |                |
|                                                                                                  | Desvenlafaxine       |                    |                    | S               |                            |                      |                 | Not Reported |                |
|                                                                                                  | Bupropion            |                    |                    | S               |                            |                      |                 | Not Reported |                |
|                                                                                                  | Ibuprofen            |                    |                    | S               |                            |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 12-Jul-2012              | 8662900              | EXPEDITED (15-DAY) | Y                  | LT              | IT-FRI-1000006445    |                      | 60 YR           | Female       | ITA            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cerebral Haemorrhage     | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                          | Valsartan            |                    |                    | S               | Oral                 | 80 Mg                |                 | Not Reported |                |
|                          | Rosuvastatin Calcium |                    |                    | C               | Oral                 | 10 Mg                |                 | Not Reported |                |
|                          | Levothyroxine        |                    |                    | C               | Oral                 | 50 Mcg               |                 | Not Reported |                |
|                          | Phenobarbital        |                    |                    | C               | Oral                 | 100 Mg               |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 12-Jul-2012              | 8677612        | DIRECT           | N                  | DS              |                      |                      | 39 YR           | Female     | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

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

|                                                                                         |                    |        |              |                                      |                              |
|-----------------------------------------------------------------------------------------|--------------------|--------|--------------|--------------------------------------|------------------------------|
| Akathisia; Dysphemia;<br>Gait Disturbance; Muscle<br>Twitching; Speech<br>Disorder; Tic | Abilify<br>Lexapro | S<br>S | Oral<br>Oral | Po Couple Months<br>Po Couple Months | Not Reported<br>Not Reported |
|-----------------------------------------------------------------------------------------|--------------------|--------|--------------|--------------------------------------|------------------------------|

| <u>FDA Received Date</u>       | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------|----------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 12-Jul-2012                    | 8677647              | DIRECT           | Y                  | OT              |                      |                      | 34 YR           | Female       | USA            |
| <u>Preferred Term</u>          | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Headache;<br>Nausea | Escitalopram Oxalate |                  |                    | S               | Oral                 | 10 Mg, 1 Day, Po     |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                                                           | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 12-Jul-2012                                                                                                                                                                        | 8678001              | DIRECT           | N                  | HO              |                      |                      | 39 YR           | Female     | USA            |
| <u>Preferred Term</u>                                                                                                                                                              | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Anxiety; Asthenia; Blood<br>Pressure Increased;<br>Chills; Feeling Of Body<br>Temperature Change;<br>Hyperhidrosis;<br>Hypoaesthesia;<br>Palpitations; Panic Attack;<br>Somnolence | Escitalopram Oxalate |                  |                    | S               | Oral                 | 20 Mg Daily Po       |                 | Mylan      |                |

| <u>FDA Received Date</u>                                                                                                                                                                                 | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 13-Jul-2012                                                                                                                                                                                              | 8680557              | DIRECT           | N                  | OT              |                      |                      | 45 YR           | Female     | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                    | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Anhedonia; Decreased<br>Interest; Disturbance In<br>Attention; Dizziness;<br>Fatigue; Feeling<br>Abnormal; Feeling Hot;<br>Heart Rate Increased;<br>Nausea; Panic Attack;<br>Product Substitution Issue; | Escitalopram Oxalate |                  |                    | S               |                      | 5 Mg, Daily          |                 | Mylan      |                |

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

Therapeutic Product Effect  
Decreased; Treatment  
Noncompliance; Tremor

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Jul-2012              | 8665840       | EXPEDITED (15-DAY) | Y                  | CA, DE          | IL-FRI-1000037046    |                      |            | Unknown    | ISR            |

| <u>Preferred Term</u>                        | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|----------------------------------------------|----------------------|--------------|------------|-------------|----------------|--------------------|-----------------|------------|
| Foetal Exposure During Pregnancy; Stillbirth | Escitalopram Oxalate |              |            | S           | Transplacental | 10 Mg              |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Jul-2012              | 8666764       | EXPEDITED (15-DAY) | Y                  | HO              | FR-FRI-1000037090    |                      | 88 YR      | Female     | FRA            |

| <u>Preferred Term</u>            | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                          | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------|---------------------------|--------------|------------|-------------|---------------------------------------|--------------------|-----------------|--------------|
| Generalised Tonic-Clonic Seizure | Escitalopram Oxalate      |              |            | S           | Oral                                  | 5 Mg               |                 | Forest       |
|                                  | Imipenem And Cilastatin   |              |            | S           | Intravenous (not otherwise specified) | 1 Df               |                 | Not Reported |
|                                  | Lasix                     |              |            | C           |                                       | Not Reported       |                 | Not Reported |
|                                  | Aspirin                   |              |            | C           |                                       | Not Reported       |                 | Not Reported |
|                                  | Cacit [Calcium Carbonate] |              |            | C           |                                       | Not Reported       |                 | Not Reported |
|                                  | Inexium                   |              |            | C           |                                       | Not Reported       |                 | Not Reported |
|                                  | Tahor                     |              |            | C           |                                       | Not Reported       |                 | Not Reported |
|                                  | Ramipril                  |              |            | C           |                                       | Not Reported       |                 | Not Reported |
|                                  | Epoetin Beta              |              |            | C           |                                       | Not Reported       |                 | Not Reported |
|                                  | Bisoprolol Fumarate       |              |            | C           |                                       | Not Reported       |                 | Not Reported |
|                                  | Corvasal (Molsidomine)    |              |            | C           |                                       | Not Reported       |                 | Not Reported |
|                                  | Diffu K                   |              |            | C           |                                       | Not Reported       |                 | Not Reported |
|                                  | Amlodipine Besylate       |              |            | C           |                                       | Not Reported       |                 | Not Reported |
|                                  | Miconazole                |              |            | C           |                                       | Not Reported       |                 | Not Reported |
|                                  | Urbanyl                   |              |            | C           |                                       | Not Reported       |                 | Not Reported |



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

|                                                                                                                                | Ferrous Sulfate           |                    | C                  |                 |                      | Not Reported                                                |                 | Not Reported |                |
|--------------------------------------------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------------------------------------|-----------------|--------------|----------------|
|                                                                                                                                | Lantus                    |                    | C                  |                 |                      | Not Reported                                                |                 | Not Reported |                |
|                                                                                                                                | Cosopt                    |                    | C                  |                 |                      | Not Reported                                                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                       | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Jul-2012                                                                                                                    | 8683673                   | DIRECT             | Y                  | OT              |                      |                                                             | 52 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                          | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Dizziness;<br>Drug Withdrawal<br>Syndrome; Product Dose<br>Omission; Product<br>Substitution Issue;<br>Tearfulness | Escitalopram Oxalate      |                    |                    | S               | Oral                 | 1/2 Tab Bid Po                                              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                       | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Jul-2012                                                                                                                    | 8324602                   | EXPEDITED (15-DAY) | Y                  | OT              | GER/UKI/11/0018623   |                                                             | 22 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                          | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Disease<br>Recurrence; Disturbance<br>In Social Behaviour;<br>Oculogyric Crisis                                       | Risperidone (Risperidone) |                    |                    | S               | Oral                 | Oral ; 1.5 Mg, 1 In 1 D,<br>Oral ;1.5 Mg, 1 In 1 D,<br>Oral | 167 DAY         | Not Reported |                |
|                                                                                                                                |                           |                    |                    |                 | Oral                 | Oral ; 1.5 Mg, 1 In 1 D,<br>Oral ;1.5 Mg, 1 In 1 D,<br>Oral |                 |              |                |
|                                                                                                                                |                           |                    |                    |                 | Oral                 | Oral ; 1.5 Mg, 1 In 1 D,<br>Oral ;1.5 Mg, 1 In 1 D,<br>Oral |                 |              |                |
|                                                                                                                                | Cipralext                 |                    |                    | S               | Oral                 | 10 Mg, 1 In 1 D, Oral ; 10<br>Mg, 2 In 1 D, Oral            |                 | Not Reported |                |
|                                                                                                                                |                           |                    |                    |                 | Oral                 | 10 Mg, 1 In 1 D, Oral ; 10<br>Mg, 2 In 1 D, Oral            |                 |              |                |
|                                                                                                                                | Orphenadrine Citrate      |                    |                    | C               |                      |                                                             |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Jul-2012              | 8639288       | EXPEDITED (15-DAY) | Y                  | DE, HO, LT      | JP-FRI-1000036599    |                      | 66 YR      | Female     | JPN            |

| <u>Preferred Term</u>                     | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Altered State Of Consciousness; Pneumonia | Lexapro                 |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                           | Promazine Hydrochloride |              |            | C           | Oral         |                    |                 | Not Reported |
|                                           | Nesina                  |              |            | C           | Oral         | 25 Mg              |                 | Not Reported |
|                                           | Lansoprazole            |              |            | C           | Oral         |                    |                 | Not Reported |
|                                           | Etizolam                |              |            | C           | Oral         | 1 Mg               |                 | Not Reported |
|                                           | Flunitrazepam           |              |            | C           | Oral         | 2 Mg               |                 | Not Reported |
|                                           | Trazodone Hydrochloride |              |            | C           | Oral         | 50 Mg              |                 | Not Reported |
|                                           | Clonazepam              |              |            | C           | Oral         | 0.5 Mg             |                 | Not Reported |
|                                           | Bayaspirin              |              |            | C           | Oral         | 100 Mg             |                 | Not Reported |
|                                           | Metformin Hydrochloride |              |            | C           | Oral         | 750 Mg             |                 | Not Reported |
|                                           | Mirtazapine             |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Jul-2012              | 8665832       | EXPEDITED (15-DAY) | Y                  | CA, HO          | IL-FRI-1000037031    |                      | 32 YR      | Female     | ISR            |

| <u>Preferred Term</u>     | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Polyhydramnios; Pregnancy | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg              |                 | Forest     |
|                           | Escitalopram Oxalate |              |            | S           |              |                    |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------|----------------------|------------|------------|----------------|
| 17-Jul-2012              | 8667399       | EXPEDITED (15-DAY) | N                  | HO, OT          | FR-GENZYME-FLUD-1001514 |                      | 56 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                                                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|-----------------------|-----------------|--------------|
| Alanine Aminotransferase Increased; Atrial Fibrillation; Blood Creatinine Increased; | Fludara        |              |            | S           | Unknown      | 80 Mg, Unk, Cycle 1   | 3 DAY           | Genzyme      |
|                                                                                      | Fludara        |              |            | S           | Unknown      | 80 Mg, Qd, Cycle 2    | 3 DAY           | Genzyme      |
|                                                                                      | Mabthera       |              |            | S           | Unknown      | 755 Mg, Once, Cycle 1 | 1 DAY           | Not Reported |

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|                            |                                  |   |         |                        |       |              |
|----------------------------|----------------------------------|---|---------|------------------------|-------|--------------|
| Cardiac Murmur;            | Mabthera                         | S | Unknown | 1000 Mg, Once, Cycle 2 | 1 DAY | Not Reported |
| Diarrhoea; Headache;       | Endoxan                          | S | Unknown | 500 Mg, Qd, Cycle 1    | 3 DAY | Not Reported |
| Hypotension; Leukopenia;   | Endoxan                          | S | Unknown | 400 Mg, Qd, Cycle 2    | 3 DAY | Not Reported |
| Muscle Spasms;             | Escitalopram Oxalate             | S | Unknown | 10 Mg, Qd, 1 Pill      |       | Not Reported |
| Neutropenia; Oedema        | Calcifediol                      | S | Unknown | 15 Mg/100ml (3 Drps/D) |       | Not Reported |
| Peripheral; Pyrexia; Rash; | Unspecified Ingredient           | S | Unknown | Unk                    |       | Not Reported |
| Vertigo; Vomiting          | Magnesium Pidolate               | S | Unknown | Unk                    |       | Not Reported |
|                            | Blueberry Leaf Extract\Vitamin A | S | Unknown | 100 Mg, Unk            |       | Not Reported |
|                            | Bactrim                          | S | Unknown | Unk                    |       | Not Reported |
|                            | Valacyclovir Hydrochloride       | S | Unknown | 500 Mg, Unk            |       | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Jul-2012              | 8668283       | EXPEDITED (15-DAY) | Y                  | CA, DE          | CA-ROCHE-1085008     |                      |            | Female     | CAN            |

| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Limb Reduction Defect;   | Tamiflu        |              |            | S           | Transplacental |                    |                 | Not Reported |
| Maternal Exposure Timing | Cipralex       |              |            | S           | Transplacental |                    |                 | Not Reported |
| Unspecified              | Diclectin      |              |            | S           | Unknown        |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Jul-2012              | 8684757       | DIRECT           |                    |                 |                      |                      |            | Unknown    | USA            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Intercepted Product   | Escitalopram Oxalate |              |            | S           | Oral         | 20 Mg Po Daily     |                 | Not Reported |
| Dispensing Error;     | Amlodipine           |              |            | S           |              |                    |                 | Not Reported |
| Medication Error      | Benazepril           |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 18-Jul-2012              | 8058801       | EXPEDITED (15-DAY) | N                  | HO              | AU-GLAXOSMITHKLINE-B0735398A |                      | 21 YR      | Female     | AUS            |

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

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

|                                             |                      |   |                                       |                   |                 |
|---------------------------------------------|----------------------|---|---------------------------------------|-------------------|-----------------|
| Malaise; Maternal Exposure During Pregnancy | Zofran               | S | Unknown                               |                   | Glaxosmithkline |
|                                             | Zofran               | S | Intravenous (not otherwise specified) |                   | Glaxosmithkline |
|                                             | Zofran               | S | Unknown                               |                   | Glaxosmithkline |
|                                             | Maxolon              | S | Unknown                               |                   | Glaxosmithkline |
|                                             | Ventolin             | S | Unknown                               | 2puff As Required | Glaxosmithkline |
|                                             | Escitalopram Oxalate | S | Unknown                               | 10g Unknown       | Glaxosmithkline |

| <u>FDA Received Date</u>                        | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| 18-Jul-2012                                     | 8670371              | EXPEDITED (15-DAY) | N                  | OT              | FR-ASTRAZENECA-2012SE48023 |                      | 62 YR           | Male         | FRA            |
| <u>Preferred Term</u>                           | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Chest Discomfort; Drug Interaction; Tachycardia | Tenormin             |                    |                    | S               | Oral                       |                      |                 | Zeneca       |                |
|                                                 | Hydrocortisone       |                    |                    | C               |                            |                      |                 | Not Reported |                |
|                                                 | Flecainide Acetate   |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                 | Escitalopram Oxalate |                    |                    | S               | Oral                       |                      | 8 DAY           | Not Reported |                |
|                                                 | Escitalopram Oxalate |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|----------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 18-Jul-2012                                              | 8671443        | EXPEDITED (15-DAY) | N                  | CA              | US-FRI-1000036985    |                      | < 1 DAY         | Male       | USA            |
| <u>Preferred Term</u>                                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Cleft Lip; Congenital Anomaly; Ventricular Septal Defect | Lexapro        |                    |                    | S               | Transplacental       |                      |                 | Forest     |                |

| <u>FDA Received Date</u>                  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|-------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 18-Jul-2012                               | 8671753              | EXPEDITED (15-DAY) | Y                  | OT              | GB-FRI-1000021144    |                      | 22 YR           | Female     | GBR            |
| <u>Preferred Term</u>                     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Anxiety; Disturbance In Social Behaviour; | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest     |                |

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|                   |                      |   |      |                                             |              |
|-------------------|----------------------|---|------|---------------------------------------------|--------------|
| Oculogyric Crisis | Escitalopram Oxalate | S | Oral | 20 Mg                                       | Forest       |
|                   | Escitalopram Oxalate | S | Oral | Dose Reduced                                | Forest       |
|                   | Risperidone          | S | Oral | Variable Doses Between 0.25mg And 1mg Daily | Not Reported |
|                   | Risperidone          | S | Oral | 1.5 Mg                                      | Not Reported |
|                   | Orphenadrine Citrate | C |      | 150 Mg                                      | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Jul-2012              | 8671914       | EXPEDITED (15-DAY) | Y                  | HO              | FR-FRI-1000037171    |                      | 49 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hepatitis             | Escitalopram Oxalate   |              |            | S           | Oral         | 15 Mg              |                 | Forest       |
|                       | Acetaminophen          |              |            | S           | Oral         | 4 G                |                 | Not Reported |
|                       | Ketoprofen             |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Tramadol Hydrochloride |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Triflucan              |              |            | C           | Oral         | 100 Mg             |                 | Not Reported |
|                       | Fungizone              |              |            | C           | Buccal       |                    |                 | Not Reported |
|                       | Cyamemazine            |              |            | C           | Oral         | 20 Df              |                 | Not Reported |
|                       | Valium                 |              |            | C           | Oral         | 45 Df              |                 | Not Reported |
|                       | Lovenox                |              |            | C           | Subcutaneous | 0.4 MI             |                 | Not Reported |
|                       | Diclofenac Sodium      |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Jul-2012              | 8696220       | DIRECT           | N                  | LT              |                      |                      |            | Female     | USA            |

| <u>Preferred Term</u>                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Cholesterol Increased; Hypertension | Lexapro        |              |            | S           |              |                    | 3 MTH           | Not Reported |
|                                           | Cymbalta       |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Jul-2012              | 8696548       | DIRECT           | Y                  |                 |                      |                      | 36 YR      | Female     | USA            |

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

| <u>Preferred Term</u>                                                                                       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------------------|-----------------|--------------|----------------|
| Appetite Disorder; Nausea; Product Substitution Issue; Sleep Disorder; Therapeutic Product Effect Decreased | Escitalopram Oxalate |                    |                    | S               |                      |                                  |                 | Mylan        |                |
| <u>FDA Received Date</u>                                                                                    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Jul-2012                                                                                                 | 8696607              | DIRECT             | Y                  |                 |                      |                                  | 29 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective; Product Substitution Issue; Tremor                                                        | Escitalopram Oxalate |                    |                    | S               |                      |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Jul-2012                                                                                                 | 8488077              | EXPEDITED (15-DAY) | Y                  | HO              | AU-FRI-1000029481    |                                  | 63 YR           | Female       | AUS            |
| <u>Preferred Term</u>                                                                                       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Epistaxis; Overdose                                                                                         | Lexapro              |                    |                    | S               | Oral                 | Prescribed Overdose: 50 Mg Daily |                 | Forest       |                |
|                                                                                                             | Oxazepam             |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                             | Mirtazapine          |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                             | Lorazepam            |                    |                    | C               |                      |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Jul-2012                                                                                                 | 8552600              | EXPEDITED (15-DAY) | Y                  | OT              | GB-FRI-1000030317    |                                  |                 | Female       | GBR            |
| <u>Preferred Term</u>                                                                                       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Antiphospholipid Antibodies; Coagulation Time Prolonged; Haemorrhage                                        | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg                            |                 | Forest       |                |
|                                                                                                             | Aripiprazole         |                    |                    | C               |                      |                                  |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                   | <u>Case #</u>                                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>                           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------|-----------------------------------------------|--------------------|--------------------|-----------------|------------------------------------------|------------------------------------------------|-----------------|--------------|----------------|
| 19-Jul-2012                                                                | 8659035                                       | EXPEDITED (15-DAY) | Y                  | HO              | CH-ABBOTT-12P-151-0954432-00             |                                                | 68 YR           | Female       | CHE            |
| <u>Preferred Term</u>                                                      | <u>Product</u>                                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>                             | <u>Duration</u> | <u>Mfr</u>   |                |
| Anaemia; Enterocolitis<br>Haemorrhagic;<br>Gastrointestinal<br>Haemorrhage | Klacid                                        |                    |                    | S               | Oral                                     |                                                |                 | Not Reported |                |
|                                                                            | Ibuprofen                                     |                    |                    | S               | Oral                                     |                                                |                 | Not Reported |                |
|                                                                            | Cipralex                                      |                    |                    | S               |                                          |                                                |                 | Not Reported |                |
|                                                                            | Prednisone                                    |                    |                    | S               | Oral                                     |                                                |                 | Not Reported |                |
|                                                                            | Methotrexate                                  |                    |                    | S               | Oral                                     |                                                |                 | Not Reported |                |
|                                                                            | Rocephin                                      |                    |                    | S               | Intravenous (not<br>otherwise specified) |                                                |                 | Not Reported |                |
|                                                                            | Calcium Carbonate                             |                    |                    | C               | Oral                                     |                                                |                 | Not Reported |                |
|                                                                            | Ramipril                                      |                    |                    | C               | Oral                                     |                                                |                 | Not Reported |                |
|                                                                            | Pantozol (Switzerland)                        |                    |                    | C               | Oral                                     |                                                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                   | <u>Case #</u>                                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>                           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Jul-2012                                                                | 8661501                                       | EXPEDITED (15-DAY) | Y                  | OT              | JP-PFIZER INC-2012165348                 |                                                |                 | Unknown      | JPN            |
| <u>Preferred Term</u>                                                      | <u>Product</u>                                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>                             | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyperventilation; Oxygen<br>Saturation Decreased                           | Atarax                                        |                    |                    | S               | Intramuscular                            |                                                |                 | Pfizer       |                |
|                                                                            | Zoloft                                        |                    |                    | S               | Oral                                     |                                                |                 | Pfizer       |                |
|                                                                            | Lexapro                                       |                    |                    | S               | Oral                                     |                                                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                   | <u>Case #</u>                                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>                           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Jul-2012                                                                | 8672863                                       | EXPEDITED (15-DAY) | Y                  | HO              | NO-FRI-1000037139                        |                                                | 78 YR           | Female       | NOR            |
| <u>Preferred Term</u>                                                      | <u>Product</u>                                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>                             | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;<br>Headache;<br>Hyponatraemia; Vomiting                  | Escitalopram Oxalate                          |                    |                    | S               | Oral                                     | 10 Mg                                          |                 | Forest       |                |
|                                                                            | Losartan Potassium And<br>Hydrochlorothiazide |                    |                    | S               | Oral                                     | 50 Mg Losartan, 12.5 Mg<br>Hydrochlorothiazide |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                      |   |      |           |              |
|----------------------|---|------|-----------|--------------|
| Metoprolol Succinate | C | Oral | 25 Mg     | Not Reported |
| Nexium               | C | Oral | 20 Mg     | Not Reported |
| Marevan              | C | Oral | 2.1429 Mg | Not Reported |
| Simvastatin          | C |      | 40 Mg     | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Jul-2012              | 8673775       | EXPEDITED (15-DAY) | Y                  | OT              | FR-FRI-1000037213    |                      | 25 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Epilepsy              | Escitalopram Oxalate    |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                       | Escitalopram Oxalate    |              |            | S           | Oral         | 5 Mg               |                 | Not Reported |
|                       | Rivotril                |              |            | C           |              |                    |                 | Not Reported |
|                       | Alprazolam              |              |            | C           |              |                    |                 | Not Reported |
|                       | Urbanyl                 |              |            | C           |              |                    |                 | Not Reported |
|                       | Mianserin Hydrochloride |              |            | C           |              |                    |                 | Not Reported |
|                       | Depakene                |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Jul-2012              | 8697148       | DIRECT           | Y                  | OT              |                      |                      | 37 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                               | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Gastrointestinal<br>Haemorrhage;<br>Gastrointestinal Pain;<br>Nausea; Product<br>Substitution Issue | Escitalopram Oxalate |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Teva       |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Jul-2012              | 8698251       | DIRECT           | Y                  | OT              |                      |                      | 34 YR      | Female     | USA            |

| <u>Preferred Term</u>          | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Dizziness; Headache;<br>Nausea | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg 1 Day Po     |                 | Not Reported |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| 20-Jul-2012                                                                                      | 8675193              | EXPEDITED (15-DAY) | Y                  | HO, LT          | FR-ASTRAZENECA-2012SE49208 |                      | 56 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Myocardial Infarction                                                                            | Quetiapine Fumarate  |                    |                    | S               | Oral                       |                      |                 | Zeneca       |                |
|                                                                                                  | Cyamemazine          |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                                                                  | Escitalopram Oxalate |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Jul-2012                                                                                      | 8675657              | EXPEDITED (15-DAY) | Y                  | HO              | PHHY2012PL061187           |                      | 75 YR           | Male         | POL            |
| <u>Preferred Term</u>                                                                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Serotonin Syndrome                                                                               | Ondansetron          |                    |                    | S               | Oral                       | 24 Mg, Daily         | 19 DAY          | Novartis     |                |
|                                                                                                  | Fentanyl             |                    |                    | S               | Transdermal                | 50 Ug, Daily         | 19 DAY          | Not Reported |                |
|                                                                                                  | Escitalopram Oxalate |                    |                    | S               | Oral                       | 10 Mg, Daily         | 19 DAY          | Not Reported |                |
| <u>FDA Received Date</u>                                                                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Jul-2012                                                                                      | 8676162              | EXPEDITED (15-DAY) | Y                  | HO              | CH-FRI-1000037260          |                      |                 | Female       | CHE            |
| <u>Preferred Term</u>                                                                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Gastrointestinal<br>Haemorrhage;<br>Haematemesis;<br>International Normalised<br>Ratio Increased | Escitalopram Oxalate |                    |                    | S               | Oral                       | 10 Mg                |                 | Forest       |                |
|                                                                                                  | Aspirin Cardio       |                    |                    | S               | Oral                       | 100 Mg               |                 | Not Reported |                |
|                                                                                                  | Aspirin Cardio       |                    |                    | S               | Oral                       | 100 Mg               |                 | Not Reported |                |
|                                                                                                  | Plavix               |                    |                    | S               | Oral                       | 75 Mg                |                 | Not Reported |                |
|                                                                                                  | Plavix               |                    |                    | S               | Oral                       | 75 Mg                |                 | Not Reported |                |
|                                                                                                  | Torem                |                    |                    | S               | Oral                       | 10 Mg                |                 | Not Reported |                |
|                                                                                                  | Marcumar             |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                                                                  | Pravastatin          |                    |                    | C               | Oral                       | 20 Mg                |                 | Not Reported |                |
|                                                                                                  | Beloc-Zok            |                    |                    | C               | Oral                       | 50 Mg                |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|               |   |      |       |              |
|---------------|---|------|-------|--------------|
| Zestril       | C | Oral | 20 Mg | Not Reported |
| Calcimagon D3 | C | Oral | 2 Df  | Not Reported |
| Nexium        | C | Oral | 40 Mg | Not Reported |
| Seroquel      | C | Oral | 25 Mg | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 23-Jul-2012              | 8315332       | EXPEDITED (15-DAY) | Y                  | OT              | GB-MYLANLABS-2011S1024644 |                      | 21 YR      | Female     | GBR            |

| <u>Preferred Term</u>                             | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abnormal Behaviour;<br>Anxiety; Oculogyric Crisis | Risperidone          |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                   | Risperidone          |              |            | S           |              |                    |                 | Not Reported |
|                                                   | Risperidone          |              |            | S           |              |                    |                 | Not Reported |
|                                                   | Cipralelex           |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                   | Cipralelex           |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                   | Orphenadrine Citrate |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Jul-2012              | 8527375       | EXPEDITED (15-DAY) | Y                  | OT              | CH-FRI-1000029945    |                      |            | Male       | CHE            |

| <u>Preferred Term</u>                | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Haematoma; Urogenital<br>Haemorrhage | Escitalopram Oxalate |              |            | S           |              |                    |                 | Forest       |
|                                      | Escitalopram Oxalate |              |            | S           |              |                    |                 | Forest       |
|                                      | Diclofenac           |              |            | C           |              |                    |                 | Not Reported |
|                                      | Ibuprofen            |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Jul-2012              | 8589161       | EXPEDITED (15-DAY) | Y                  | HO              | CH-TEVA-339949ISR    |                      | 89 YR      | Female     | CHE            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hyponatraemia         | Ibuprofen      |              |            | S           | Oral         | 1200 Milligram;    |                 | Ivax         |
|                       | Omeprazole     |              |            | S           | Oral         | 40 Milligram;      |                 | Not Reported |
|                       | Cipralelex     |              |            | S           | Oral         | 10 Milligram;      |                 | Not Reported |

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

|                   |   |      |                 |              |
|-------------------|---|------|-----------------|--------------|
| Zopiclone         | C | Oral | 7.5 Milligram;  | Not Reported |
| Orlistat          | C | Oral | 1 Dosage Forms; | Not Reported |
| Dafalgan          | C | Oral |                 | Not Reported |
| Calcium Carbonate | C | Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Jul-2012              | 8671769       | EXPEDITED (15-DAY) | Y                  | OT              | JP-FRI-1000037172    |                      | 50 YR      | Female     | JPN            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Seizure               | Lexapro        |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                       | Lexapro        |              |            | S           | Oral         | 5 Mg               |                 | Forest       |
|                       | Zoloft         |              |            | C           | Oral         | 50 Mg              |                 | Not Reported |
|                       | Zoloft         |              |            | C           | Oral         | 75 Mg              |                 | Not Reported |
|                       | Zoloft         |              |            | C           | Oral         | 100 Mg             |                 | Not Reported |
|                       | Zoloft         |              |            | C           | Oral         | 50 Mg              |                 | Not Reported |
|                       | Zoloft         |              |            | C           | Oral         | 25 Mg              |                 | Not Reported |
|                       | Sulpiride      |              |            | C           | Oral         | 150 Mg             |                 | Not Reported |
|                       | Sulpiride      |              |            | C           | Oral         | 100 Mg             |                 | Not Reported |
|                       | Sulpiride      |              |            | C           | Oral         | 75 Mg              |                 | Not Reported |
|                       | Sulpiride      |              |            | C           | Oral         | 50 Mg              |                 | Not Reported |
|                       | Palgin         |              |            | C           | Oral         | 0.5 Mg             |                 | Not Reported |
|                       | Myslee         |              |            | C           | Oral         | 10 Mg              |                 | Not Reported |
|                       | Flunitrazepam  |              |            | C           | Oral         | 2 Mg               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Jul-2012              | 8676238       | EXPEDITED (15-DAY) | Y                  | HO              | FR-FRI-1000037263    |                      | 51 YR      | Female     | FRA            |

| <u>Preferred Term</u>                 | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abnormal Behaviour;<br>Hyponatraemia; | Escitalopram Oxalate |              |            | S           | Oral         | 20 Mg              |                 | Forest       |
|                                       | Fluoxetine Hcl       |              |            | S           | Oral         |                    |                 | Not Reported |

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

Inappropriate Antidiuretic  
Hormone Secretion

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Jul-2012              | 8678750       | EXPEDITED (15-DAY) | Y                  | CA              | DE-FRI-1000037278    |                      |            | Male       | DEU            |

| <u>Preferred Term</u>                                                                                                                                        | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Caesarean Section;<br>Congenital Central<br>Nervous System Anomaly;<br>Foetal Exposure During<br>Pregnancy; Foetal Heart<br>Rate Deceleration<br>Abnormality | Escitalopram Oxalate     |              |            | S           | Transplacental |                    |                 | Forest       |
|                                                                                                                                                              | Paroxetine Hydrochloride |              |            | C           | Transplacental | 20 Mg              |                 | Not Reported |
|                                                                                                                                                              | Ibuprofen                |              |            | C           | Transplacental |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Jul-2012              | 8678777       | EXPEDITED (15-DAY) | Y                  | HO              | NL-FRI-1000037259    |                      | 45 YR      | Female     | NLD            |

| <u>Preferred Term</u> | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Jaw Fracture          | Lexapro           |              |            | S           | Oral         | 18 Mg              |                 | Forest       |
|                       | Ethinyl Estradiol |              |            | C           | Oral         |                    |                 | Not Reported |
|                       | Fexofenadine      |              |            | C           | Oral         | 270 Mg             |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Jul-2012              | 8702550       | DIRECT           | N                  | OT              |                      |                      | 31 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                 | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Abnormal Behaviour;<br>Depression; Disease<br>Recurrence; Panic Attack;<br>Product Substitution Issue | Escitalopram Oxalate |              |            | S           | Oral         | 1 Daily Po         |                 | Teva       |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Jul-2012              | 8680277       | NON-EXPEDITED    | N                  |                 | US-BAYER-2012-073352 |                      |            | Male       | USA            |

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

| <u>Preferred Term</u>                                             | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|------------------------------|-------------------------------------|-----------------|--------------|----------------|
| Therapeutic Response<br>Unexpected                                | Levitra              |                    |                    | S               |                              | Unk                                 |                 | Jenapharm    |                |
|                                                                   | Lexapro              |                    |                    | S               |                              | Unk                                 |                 | Not Reported |                |
|                                                                   | Adderall Xr          |                    |                    | S               |                              | Unk                                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                          | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Jul-2012                                                       | 8680426              | EXPEDITED (15-DAY) | Y                  | OT              | CA-ABBOTT-12P-028-0956883-00 |                                     |                 | Unknown      | CAN            |
| <u>Preferred Term</u>                                             | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Apgar Score Low; Foetal Exposure During Pregnancy; Normal Newborn | Ciprallex            |                    |                    | S               | Transplacental               |                                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                          | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Jul-2012                                                       | 8680474              | EXPEDITED (15-DAY) | Y                  | OT              | GB-WATSON-2012-12432         |                                     | 22 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                             | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Disturbance In Social Behaviour; Oculogyric Crisis       | Risperidone          |                    |                    | S               | Oral                         | 1.5 Mg, Daily                       |                 | Watson       |                |
|                                                                   | Risperidone          |                    |                    | S               | Oral                         | 1.5 Mg, Daily                       | 84 DAY          | Watson       |                |
|                                                                   | Risperidone          |                    |                    | S               | Oral                         | 0.25mg-1.5mg Daily, (Variable Dose) | 85 DAY          | Watson       |                |
|                                                                   | Ciprallex            |                    |                    | S               | Oral                         | 20mg Daily                          | 142 DAY         | Not Reported |                |
|                                                                   | Ciprallex            |                    |                    | S               | Oral                         | 10 Mg, Daily                        | 36 DAY          | Not Reported |                |
|                                                                   | Orphenadrine Citrate |                    |                    | C               | Unknown                      | 50 Mg, Tid                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                          | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Jul-2012                                                       | 8708151              | DIRECT             | Y                  | OT              |                              |                                     | 54 YR           | Female       | USA            |
| <u>Preferred Term</u>                                             | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Headache; Hyperhidrosis; Malaise                       | Escitalopram Oxalate |                    |                    | S               | Oral                         | Once Tab Qd Po                      |                 | Teva         |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|            |   |              |
|------------|---|--------------|
| Coumadin   | C | Not Reported |
| Inderal    | C | Not Reported |
| Testoretic | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|------------|------------|----------------|
| 25-Jul-2012              | 8683122       | EXPEDITED (15-DAY) | Y                  | HO              | CH-SANOFI-AVENTIS-2012SA051306 |                      | 76 YR      | Female     | CHE            |

| <u>Preferred Term</u>                                                                                                       | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction;<br>Haematemesis;<br>International Normalised<br>Ratio Increased; Upper<br>Gastrointestinal<br>Haemorrhage | Marcumar             |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                             | Beloc-Zok            |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                                             | Zestril              |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                                             | Torseamide           |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                                             | Pravastatin          |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                                             | Calcimagon-D3        |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                                             | Nexium               |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                                             | Seroquel             |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                                             | Clopidogrel          |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                             | Aspirin Cardio       |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                             | Escitalopram Oxalate |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Jul-2012              | 8709227       | DIRECT           | Y                  | LT              |                      |                      | 46 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                 | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Asthenia; Depression;<br>Paresis; Product<br>Substitution Issue;<br>Suicidal Ideation | Escitalopram Oxalate |              |            | S           |              |                    |                 | Mylan      |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Jul-2012              | 8708994       | DIRECT           | Y                  | OT              |                      |                      | 46 YR      | Female     | USA            |

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

| <u>Preferred Term</u>                                                                                                                                | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
|------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|------------------------------|-----------------|--------------|----------------|
| Affective Disorder;<br>Anxiety; Insomnia;<br>Irritability; Panic Attack;<br>Product Substitution Issue                                               | Escitalopram Oxalate   |                    |                    | S               | Oral                 | 10 Mg Once Q Afternoon<br>Po |                 | Teva         |                |
|                                                                                                                                                      | Escitalopram Oxalate   |                    |                    | S               | Oral                 | 20 Mg Once Q Hs Po           |                 | Teva         |                |
| <u>FDA Received Date</u>                                                                                                                             | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Jul-2012                                                                                                                                          | 8687373                | EXPEDITED (15-DAY) | Y                  | OT              | US-FRI-1000037225    |                              |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Feeling<br>Abnormal; Unevaluable<br>Event                                                                                                   | Lexapro                |                    |                    | S               |                      |                              |                 | Forest       |                |
|                                                                                                                                                      | Ramipril               |                    |                    | C               |                      |                              |                 | Not Reported |                |
|                                                                                                                                                      | Estradiol              |                    |                    | C               |                      |                              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                             | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Jul-2012                                                                                                                                          | 8687590                | EXPEDITED (15-DAY) | Y                  | HO              | FR-FRI-1000037352    |                              | 63 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                                | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;<br>Hyperreflexia;<br>Tachycardia; Tremor                                                                                           | Escitalopram Oxalate   |                    |                    | S               | Oral                 | 10 Mg                        |                 | Forest       |                |
|                                                                                                                                                      | Escitalopram Oxalate   |                    |                    | S               | Oral                 |                              |                 | Forest       |                |
|                                                                                                                                                      | Tramadol Hydrochloride |                    |                    | S               | Oral                 |                              |                 | Not Reported |                |
|                                                                                                                                                      | Haldol                 |                    |                    | S               | Oral                 | 20 Mg/MI                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                             | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Jul-2012                                                                                                                                          | 8688810                | EXPEDITED (15-DAY) | Y                  | HO              | FR-FRI-1000036862    |                              | 59 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                                                                | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Depersonalisation/Dereali<br>sation Disorder;<br>Depressed Mood; Flight<br>Of Ideas; Logorrhoea;<br>Restlessness; Suicidal<br>Ideation; Tachyphrenia | Escitalopram Oxalate   |                    |                    | S               | Oral                 | 10 Mg                        |                 | Forest       |                |
|                                                                                                                                                      | Escitalopram Oxalate   |                    |                    | S               | Oral                 | 15 Mg                        |                 | Forest       |                |
|                                                                                                                                                      | Plavix                 |                    |                    | C               | Oral                 | 75 Mg                        |                 | Not Reported |                |
|                                                                                                                                                      | Oxazepam               |                    |                    | C               | Oral                 | 50 Mg                        |                 | Not Reported |                |

# FDA Adverse Event Reporting System

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### Detailed Report

| <u>FDA Received Date</u>                                                                       | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------|--------------------------|------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| 27-Jul-2012                                                                                    | 8690526                  | NON-EXPEDITED    | N                  | OT              | US-ASTRAZENECA-2012SE18514 |                      | 48 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                          | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective; Insomnia; Mood Swings; Paranoia; Suicidal Ideation                           | Seroquel                 |                  |                    | S               | Oral                       |                      |                 | Zeneca       |                |
|                                                                                                | Seroquel                 |                  |                    | S               | Oral                       |                      |                 | Zeneca       |                |
|                                                                                                | Pristiq Extended Release |                  |                    | S               |                            |                      |                 | Not Reported |                |
|                                                                                                | Wellbutrin               |                  |                    | S               |                            |                      |                 | Not Reported |                |
|                                                                                                | Lexapro                  |                  |                    | S               |                            |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                       | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Jul-2012                                                                                    | 8710335                  | DIRECT           | Y                  |                 |                            |                      | 43 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                          | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depressive Symptom; Disease Recurrence; Drug Intolerance; Product Substitution Issue; Sedation | Lexapro                  |                  |                    | S               | Oral                       | 40 Mg Lexapro Qd Po  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                       | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Jul-2012                                                                                    | 8712867                  | DIRECT           | N                  | LT, OT          |                            |                      | 43 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                          | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Feeling Abnormal; Suicidal Ideation; Thought Blocking; Vitamin D                               | Lexapro                  |                  |                    | S               | Oral                       | 10 Mg Once A Day, Po | 1 WEEK          | Forest       |                |
| <u>FDA Received Date</u>                                                                       | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Jul-2012                                                                                    | 8714126                  | DIRECT           | N                  | RI              |                            |                      | 76 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                          | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective; Muscular                                                                     | Escitalopram Oxalate     |                  |                    | S               | Oral                       | 40mg Daily Po        |                 | Teva         |                |



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

Weakness; Product  
Substitution Issue;  
Somnolence

| <a href="#">FDA Received Date</a>                                                                        | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a>   | <a href="#">Country</a> |
|----------------------------------------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|-----------------------|-------------------------|
| 28-Jul-2012                                                                                              | 8690801                 | EXPEDITED (15-DAY)        |                             | OT                       | GB-009507513-2011SP001131     |                               | 35 YR                    | Unknown               | GBR                     |
| <a href="#">Preferred Term</a>                                                                           | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a>   |                         |
| Facial Paralysis                                                                                         | Zispin<br>Escitalopram  |                           |                             | S<br>S                   |                               |                               |                          | Merck<br>Not Reported |                         |
| <a href="#">FDA Received Date</a>                                                                        | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a>   | <a href="#">Country</a> |
| 30-Jul-2012                                                                                              | 8441197                 | EXPEDITED (15-DAY)        | N                           | HO                       | US-FRI-1000028731             |                               | 14 YR                    | Female                | USA                     |
| <a href="#">Preferred Term</a>                                                                           | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a>   |                         |
| Depression; Fatigue;<br>Intentional Self-Injury; Off<br>Label Use; Suicidal<br>Ideation; Suicide Attempt | Lexapro                 |                           |                             | S                        | Oral                          | 5 Mg                          |                          | Forest                |                         |
|                                                                                                          | Lexapro                 |                           |                             | S                        | Oral                          | 10 Mg                         |                          | Forest                |                         |
|                                                                                                          | Lexapro                 |                           |                             | S                        |                               | 5 Mg                          |                          | Forest                |                         |
| <a href="#">FDA Received Date</a>                                                                        | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a>   | <a href="#">Country</a> |
| 30-Jul-2012                                                                                              | 8691054                 | EXPEDITED (15-DAY)        | Y                           | HO                       | FR-JNJFOC-20120711229         |                               | 63 YR                    | Female                | FRA                     |
| <a href="#">Preferred Term</a>                                                                           | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a>   |                         |
| Drug Interaction;<br>Hyperreflexia;<br>Tachycardia; Tremor                                               | Haldol                  |                           |                             | S                        | Oral                          |                               |                          | Not Reported          |                         |
|                                                                                                          | Escitalopram Oxalate    |                           |                             | S                        | Oral                          |                               |                          | Not Reported          |                         |
|                                                                                                          | Escitalopram Oxalate    |                           |                             | S                        | Oral                          |                               |                          | Not Reported          |                         |
|                                                                                                          | Tramadol Hydrochloride  |                           |                             | S                        | Oral                          |                               |                          | Not Reported          |                         |
| <a href="#">FDA Received Date</a>                                                                        | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a>   | <a href="#">Country</a> |
| 30-Jul-2012                                                                                              | 8691445                 | NON-EXPEDITED             | Y                           |                          | US-PFIZER INC-2012180587      |                               |                          | Unknown               | USA                     |
| <a href="#">Preferred Term</a>                                                                           | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a>   |                         |

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

|                        |                                         |   |     |              |
|------------------------|-----------------------------------------|---|-----|--------------|
| Abdominal Discomfort;  | Bextra                                  | S | Unk | Pfizer       |
| Drug Hypersensitivity; | Fluoxetine Hcl                          | S | Unk | Not Reported |
| Pain                   | Lexapro                                 | S | Unk | Not Reported |
|                        | Amiloride Hcl W/<br>Hydrochlorothiazide | S | Unk | Not Reported |
|                        | Bupropion                               | S | Unk | Not Reported |
|                        | Dicloxacillin Sodium                    | S | Unk | Not Reported |
|                        | Vicodin                                 | S | Unk | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Jul-2012              | 8693356       | EXPEDITED (15-DAY) | Y                  | HO, LT          | CH-FRI-1000037408    |                      |            | Male       | CHE            |

  

| <u>Preferred Term</u>                                                                | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------|-----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Acute Kidney Injury; Blood Loss Anaemia; Lower Gastrointestinal Haemorrhage; Melaena | Escitalopram Oxalate        |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                                                                      | Escitalopram Oxalate        |              |            | S           |              |                    |                 | Forest       |
|                                                                                      | Remeron                     |              |            | S           | Oral         | 30 Mg              |                 | Not Reported |
|                                                                                      | Remeron                     |              |            | S           |              |                    |                 | Not Reported |
|                                                                                      | Plavix                      |              |            | S           | Oral         | 75 Mg              |                 | Not Reported |
|                                                                                      | Aspirin Cardio              |              |            | S           | Oral         | 100 Mg             |                 | Not Reported |
|                                                                                      | Aspirin Cardio              |              |            | S           | Oral         | 100 Mg             |                 | Not Reported |
|                                                                                      | Glucophage                  |              |            | S           | Oral         | 850 Mg             |                 | Not Reported |
|                                                                                      | Diclofenac Epolamine        |              |            | S           | Other        |                    |                 | Not Reported |
|                                                                                      | Concor                      |              |            | C           | Oral         | 10 Mg              |                 | Not Reported |
|                                                                                      | Triatec Comp 2.5 Mg/12.5 Mg |              |            | C           | Oral         | 2.5 Mg             |                 | Not Reported |
|                                                                                      | Sortis                      |              |            | C           | Oral         | 40 Mg              |                 | Not Reported |
|                                                                                      | Seroquel                    |              |            | C           | Oral         | 100 Mg             |                 | Not Reported |
|                                                                                      | Lantus                      |              |            | C           | Subcutaneous | 4 Iu               |                 | Not Reported |
|                                                                                      | Tamsulosin Hydrochloride    |              |            | C           | Oral         | 400 Mcg            |                 | Not Reported |
|                                                                                      | Haldol                      |              |            | C           | Oral         |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 31-Jul-2012                                                                                                            | 8569801              | EXPEDITED (15-DAY) | Y                  | OT              | FR-FRI-1000030544    |                      | 60 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Rectal Haemorrhage                                                                                                     | Escitalopram Oxalate |                    |                    | S               | Oral                 | 5 Mg                 |                 | Forest       |                |
|                                                                                                                        | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-Jul-2012                                                                                                            | 8651153              | EXPEDITED (15-DAY) | N                  | CA              | US-FRI-1000036740    |                      | < 1 DAY         | Male         | USA            |
| <u>Preferred Term</u>                                                                                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Double Outlet Right Ventricle; Pulmonary Valve Stenosis; Transposition Of The Great Vessels; Ventricular Septal Defect | Lexapro              |                    |                    | S               | Transplacental       |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-Jul-2012                                                                                                            | 8674205              | EXPEDITED (15-DAY) | Y                  | OT              | JP-FRI-1000037220    |                      | 33 YR           | Male         | JPN            |
| <u>Preferred Term</u>                                                                                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Activation Syndrome                                                                                                    | Lexapro              |                    |                    | S               | Oral                 | 20 Mg                |                 | Forest       |                |
|                                                                                                                        | Lexapro              |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                                                                                                        | Vegetamin-B          |                    |                    | C               | Oral                 | 1 Df                 |                 | Not Reported |                |
|                                                                                                                        | Flunitrazepam        |                    |                    | C               | Oral                 | 2 Mg                 |                 | Not Reported |                |
|                                                                                                                        | Etizolam             |                    |                    | C               | Oral                 | 1 Mg                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-Jul-2012                                                                                                            | 8695221              | EXPEDITED (15-DAY) | Y                  | HO              | SE-FRI-1000037480    |                      | 51 YR           | Male         | SWE            |
| <u>Preferred Term</u>                                                                                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

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

|                                 |                      |   |      |                  |              |
|---------------------------------|----------------------|---|------|------------------|--------------|
| Arrhythmia; Atrial Fibrillation | Escitalopram Oxalate | S | Oral | 20 Mg            | Forest       |
|                                 | Escitalopram Oxalate | S |      |                  |              |
|                                 | Metoprolol           | C |      |                  |              |
|                                 | Oxazepam             | C |      |                  |              |
|                                 |                      |   |      | 50 Mg            | Not Reported |
|                                 |                      |   |      | 10-30 Mg Per Day | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-Jul-2012              | 8730571       | EXPEDITED (15-DAY) | Y                  | OT              | 2012070133           |                      | 55 YR      | Female     | CAN            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                                                   | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|------------------------------------------------------------------------------------------------------|-----------------|--------------|
| Anxiety; Asthenia; Balance Disorder; Diarrhoea; Disorientation; Disturbance In Attention; Dizziness; Drug Interaction; Dyspnoea; Euphoric Mood; Gait Disturbance; Hallucination; Headache; Hypopnoea; Muscle Spasms; Palpitations; Pulse Pressure Increased; Somnolence; Urinary Tract Infection; Vomiting | Cesamet        |              |            | S           | Oral         | (0.25 Mg), Oral                                                                                      |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                            | Baclofen       |              |            | S           |              | 60 Mg (20 Mg,3 In 1 D)                                                                               |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                            | Buprenorphine  |              |            | S           | Transdermal  | 240 Mcg(10mcg,1 In 1 Hr),360 Mcg(15mcg,1 In 1 Hr),480 Mcg (20mcg,1 In 1 Hr),120 Mcg (5 Mcg,1 In 1 Hr |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                            | Cipralext      |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D),Oral                                                                         |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                            | Clonazepam     |              |            | S           | Oral         | 3 Mg (1 Mg,3 In 1 D), Oral                                                                           |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                            |                |              |            |             |              |                                                                                                      |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Aug-2012              | 8470615       | EXPEDITED (15-DAY) | Y                  | OT              | JP-FRI-1000029233    |                      | 25 YR      | Female     | JPN            |

| <u>Preferred Term</u>                               | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Dysphonia; Fear; Seizure; Tremor; Vomiting | Lexapro                   |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                                     | Rilmazafone Hydrochloride |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Aug-2012              | 8651924       | EXPEDITED (15-DAY) | Y                  | OT              | FR-FRI-1000036842    |                      | 61 YR      | Male       | FRA            |

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

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

|                                             |                      |   |      |       |              |
|---------------------------------------------|----------------------|---|------|-------|--------------|
| Blood Prolactin Increased;<br>Gynaecomastia | Escitalopram Oxalate | S | Oral | 10 Mg | Forest       |
|                                             | Inexium              | C | Oral | 40 Mg | Not Reported |
|                                             | Prazepam             | C | Oral | 5 Mg  | Not Reported |

| <u>FDA Received Date</u>                                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------|----------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 01-Aug-2012                                               | 8691538        | EXPEDITED (15-DAY) | N                  | OT              | US-PFIZER INC-2011102419 |                      |                 | Male         | USA            |
| <u>Preferred Term</u>                                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective; Drug Withdrawal Syndrome;               | Chantix        |                    |                    | S               |                          | 0.5 Mg, Daily        |                 | Pfizer       |                |
| Ejaculation Failure;                                      | Chantix        |                    |                    | S               |                          | Unk                  |                 | Pfizer       |                |
| Insomnia; Loss Of Libido;                                 | Chantix        |                    |                    | S               |                          | 1 Mg, 2x/Day         |                 | Pfizer       |                |
| Pollakiuria; Suicidal Ideation; Thirst; Urinary Retention | Geodon         |                    |                    | S               |                          | 40 Mg, 2x/Day        |                 | Pfizer       |                |
|                                                           | Abilify        |                    |                    | S               |                          | 10 Mg, Daily         |                 | Not Reported |                |
|                                                           | Abilify        |                    |                    | S               |                          | 15 Mg, Daily         |                 | Not Reported |                |
|                                                           | Lexapro        |                    |                    | S               |                          | 10 Mg, Unk           |                 | Not Reported |                |
|                                                           | Xanax          |                    |                    | C               |                          | Unk                  |                 | Not Reported |                |

| <u>FDA Received Date</u>                                     | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------|----------------|------------------|--------------------|-----------------|--------------------------|-------------------------------------|-----------------|--------------|----------------|
| 01-Aug-2012                                                  | 8696346        | NON-EXPEDITED    | N                  | OT              | US-PFIZER INC-2012182500 |                                     |                 | Male         | USA            |
| <u>Preferred Term</u>                                        | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Depression;                                         | Geodon         |                  |                    | S               | Oral                     | 40 Mg In Morning And 80 Mg At Night |                 | Pfizer       |                |
| Fatigue; Hypersensitivity; Muscle Rigidity; Weight Increased | Geodon         |                  |                    | S               | Oral                     | 80 Mg In Morning And 80 Mg At Night |                 | Pfizer       |                |
|                                                              | Geodon         |                  |                    | S               | Oral                     | 80 Mg At Night And 20 Mg In Morning |                 | Pfizer       |                |
|                                                              | Lexapro        |                  |                    | S               |                          | 5 Mg, Daily                         |                 | Not Reported |                |
|                                                              | Lexapro        |                  |                    | S               |                          | 10 Mg, Daily                        |                 | Not Reported |                |
|                                                              | Lexapro        |                  |                    | S               |                          | 20 Mg, Daily                        |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|          |   |      |                                           |              |
|----------|---|------|-------------------------------------------|--------------|
| Lexapro  | S | Oral | 5 Mg, Daily                               | Not Reported |
| Depakote | S |      | 500 Mg In Morning And<br>1000 Mg At Night | Not Reported |
| Ritalin  | C |      | Unk                                       | Not Reported |
| Seroquel | C |      | 200 Mg, Daily                             | Not Reported |
| Lamictal | C |      | 100 Or 200 Mg Daily                       | Not Reported |
| Ambien   | C |      | Unk                                       | Not Reported |

| <u>FDA Received Date</u>                                                                                           | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------------------------|-----------------|----------------------|----------------|
| 01-Aug-2012                                                                                                        | 8696529                  | EXPEDITED (15-DAY) | Y                  | HO, LT          | CH-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>16802985 |                                        | 74 YR           | Male                 | CHE            |
| <u>Preferred Term</u>                                                                                              | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>           |                |
| Acute Kidney Injury; Blood<br>Loss Anaemia; Drug<br>Interaction; Lower<br>Gastrointestinal<br>Haemorrhage; Melaena | Glucophage               |                    |                    | S               | Oral                                            |                                        |                 | Bristol Myers Squibb |                |
|                                                                                                                    | Remeron                  |                    |                    | S               | Oral                                            |                                        |                 | Not Reported         |                |
|                                                                                                                    | Flector                  |                    |                    | S               | Subcutaneous                                    |                                        |                 | Not Reported         |                |
|                                                                                                                    | Concor                   |                    |                    | C               | Oral                                            |                                        |                 | Not Reported         |                |
|                                                                                                                    | Ramipril                 |                    |                    | C               | Oral                                            |                                        |                 | Not Reported         |                |
|                                                                                                                    | Sortis                   |                    |                    | C               | Oral                                            |                                        |                 | Not Reported         |                |
|                                                                                                                    | Seroquel                 |                    |                    | C               |                                                 |                                        |                 | Not Reported         |                |
|                                                                                                                    | Lantus                   |                    |                    | C               | Subcutaneous                                    |                                        |                 | Not Reported         |                |
|                                                                                                                    | Tamsulosin Hydrochloride |                    |                    | C               | Oral                                            |                                        |                 | Not Reported         |                |
|                                                                                                                    | Haldol                   |                    |                    | C               | Oral                                            |                                        |                 | Not Reported         |                |
|                                                                                                                    | Plavix                   |                    |                    | S               | Oral                                            |                                        |                 | Sanofi Aventis       |                |
|                                                                                                                    | Aspirin Cardio           |                    |                    | S               | Oral                                            | Interruoted:11may12<br>Resumed:21may12 |                 | Not Reported         |                |
|                                                                                                                    | Cipralexx                |                    |                    | S               | Oral                                            |                                        |                 | Not Reported         |                |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 01-Aug-2012                       | 8697918                 | EXPEDITED (15-DAY)        | Y                           | HO                       | FR-FRI-1000037516             |                               | 82 YR                    | Female              | FRA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |

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

|                                                                                          |                      |   |      |       |        |
|------------------------------------------------------------------------------------------|----------------------|---|------|-------|--------|
| Electrocardiogram Qt Prolonged; Loss Of Consciousness; Orthostatic Hypotension; Vomiting | Escitalopram Oxalate | S | Oral | 10 Mg | Forest |
|------------------------------------------------------------------------------------------|----------------------|---|------|-------|--------|

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 01-Aug-2012                       | 8718188                | DIRECT                    | N                           | OT                       |                               |                               | 56 YR               | Female              | USA                     |

| <a href="#">Preferred Term</a>                                                                                                                | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|-----------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Anxiety; Condition Aggravated; Feeling Of Despair; Irritable Bowel Syndrome; Product Substitution Issue; Therapeutic Product Effect Decreased | Escitalopram Oxalate    |                       |                     | S                    | Oral                  | 10 Mg Daily Po              |                          | Teva                |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 01-Aug-2012                       | 8726010                | DIRECT                    | Y                           |                          |                               |                               | 48 YR               | Male                | USA                     |

| <a href="#">Preferred Term</a>                  | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|-------------------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Product Substitution Issue; Screaming; Vomiting | Lexapro                 |                       |                     | S                    | Oral                  | 20 Mg 1 Po Ad               |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 03-Aug-2012                       | 8662848                | EXPEDITED (15-DAY)        | Y                           | DE, LT                   | IT-FRI-1000036934             |                               | 42 YR               | Male                | ITA                     |

| <a href="#">Preferred Term</a>                   | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Cardiac Arrest; Drug Abuse; Intentional Overdose | Escitalopram Oxalate    |                       |                     | S                    | Oral                  | 1 Posological Unit          |                          | Forest              |
|                                                  | Lormetazepam            |                       |                     | S                    | Oral                  | 150 Posological Units       |                          | Not Reported        |
|                                                  | Olanzapine              |                       |                     | S                    | Oral                  | 1 Posological Unit          |                          | Not Reported        |
|                                                  | Brotizolam              |                       |                     | S                    | Oral                  | 1 Posological Unit          |                          | Not Reported        |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                       | <u>Case #</u>                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------|---------------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 03-Aug-2012                                                                                    | 8707190                                     | EXPEDITED (15-DAY) | Y                  | HO              | FR-FRI-1000037217    |                      | 86 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                          | <u>Product</u>                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Electrocardiogram Qt Prolonged; Injury; Off Label Use; Syncope                                 | Escitalopram Oxalate                        |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                                                                                | Escitalopram Oxalate                        |                    |                    | S               | Oral                 | 15 Mg                |                 | Forest       |                |
|                                                                                                | Pantoprazole                                |                    |                    | C               | Oral                 | 20 Mg                |                 | Not Reported |                |
|                                                                                                | Simvastatin                                 |                    |                    | C               | Oral                 | 40 Mg                |                 | Not Reported |                |
|                                                                                                | Zopiclone                                   |                    |                    | C               | Oral                 | 7.5 Mg               |                 | Not Reported |                |
|                                                                                                | Cefpodoxime Proxetil                        |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                | Solupred (Prednisolone Sodium Metazoate)    |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                | Derinox (Naphazoline Nitrate)\Prednisolone) |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                | Acetaminophen                               |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                       | <u>Case #</u>                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Aug-2012                                                                                    | 8707202                                     | EXPEDITED (15-DAY) | N                  | CA              | US-FRI-1000037474    |                      | < 1 DAY         | Female       | USA            |
| <u>Preferred Term</u>                                                                          | <u>Product</u>                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hydrocephalus; Maternal Drugs Affecting Foetus; Microcephaly; Oculoauriculovertebral Dysplasia | Lexapro                                     |                    |                    | S               | Transplacental       |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                       | <u>Case #</u>                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Aug-2012                                                                                    | 8728705                                     | DIRECT             | N                  | OT              |                      |                      | 36 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                          | <u>Product</u>                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Chest Pain; Crying; Depression; Disturbance In Attention; Feeling                              | Escitalopram Oxalate                        |                    |                    | S               | Oral                 | 20 Mg 1 X Day Po     |                 | Mylan        |                |



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

Abnormal; Hypertension;  
Insomnia; Intentional Self-  
Injury; Palpitations;  
Performance Status  
Decreased; Product  
Substitution Issue;  
Suicidal Ideation

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Aug-2012              | 8476913       | EXPEDITED (15-DAY) | Y                  | HO, OT          | JP-FRI-1000029337    |                      | 49 YR      | Female     | JPN            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Abdominal Discomfort;<br>Abdominal Pain; Alanine<br>Aminotransferase<br>Increased; Aspartate<br>Aminotransferase<br>Increased; Blood Pressure<br>Increased; Blood Uric Acid<br>Increased; Diarrhoea;<br>Electrocardiogram<br>Abnormal; Epistaxis; Face<br>Oedema; Gamma-<br>Glutamyltransferase<br>Increased; Hyperhidrosis;<br>Malaise; Musculoskeletal<br>Stiffness; Myalgia;<br>Nausea; Oliguria;<br>Photophobia; Pollakiuria;<br>Urinary Retention; Visual<br>Acuity Reduced; Vomiting;<br>Weight Increased | Lexapro        |              |            | S           | Oral         |                    |                 | Forest     |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 06-Aug-2012                       | 8634688                 | EXPEDITED (15-DAY)        | Y                           | OT                       | PHHY2012CA044960              |                               | 41 YR                    | Female              | CAN                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Abdominal Discomfort;             | Diclofenac              |                           |                             | S                        |                               | Unk Ukn, Prn                  |                          | Novartis            |                         |

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

|                                     |               |   |      |  |            |        |  |              |
|-------------------------------------|---------------|---|------|--|------------|--------|--|--------------|
| Abnormal Sensation In               | Gabapentin    | C |      |  |            |        |  | Not Reported |
| Eye; Drug Interaction;              | Water Pills   | C |      |  |            |        |  | Not Reported |
| Dyspnoea; Eye Swelling;             | Baclofen      | C |      |  |            |        |  | Not Reported |
| Fatigue; Headache;                  | Nexium        | C |      |  |            |        |  | Not Reported |
| Lymphocyte Count                    | Tylenol       | C |      |  |            |        |  | Not Reported |
| Decreased; Multiple                 | Vesicare      | C |      |  |            |        |  | Not Reported |
| Sclerosis Relapse;                  | Amitriptyline | C |      |  |            |        |  | Not Reported |
| Muscular Weakness;                  | Clonazepam    | C |      |  |            |        |  | Not Reported |
| Nausea; Neutropenia;                | Gilenya       | S | Oral |  | 0.5 Mg, Qd | 29 DAY |  | Not Reported |
| Pyrexia; Vision Blurred;            | Cipraxel      | S |      |  |            |        |  | Not Reported |
| White Blood Cell Count<br>Decreased |               |   |      |  |            |        |  |              |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 06-Aug-2012              | 8731369        | DIRECT           | N                  | HO              |                      |                      | 70 YR           | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrial Fibrillation      | Lexapro        |                  |                    | S               | Oral                 | 10mg 1/Day Po        |                 | Not Reported |                |
|                          | Pristiq        |                  |                    | S               | Oral                 | 50mg 1/Day Po        |                 | Not Reported |                |
|                          | Tenormin       |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Pradaxa        |                  |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                       | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------|----------------------|------------------|--------------------|-----------------|----------------------|--------------------------------------|-----------------|--------------|----------------|
| 06-Aug-2012                                                    | 8736513              | DIRECT           | Y                  | OT              |                      |                                      | 30 YR           | Female       | POL            |
| <u>Preferred Term</u>                                          | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Blood Test<br>Abnormal; Erythropenia;<br>Neutropenia | Escitalopram Oxalate |                  |                    | S               | Oral<br>Oral         | 10mg 1per Day Po<br>10mg 1per Day Po |                 | Not Reported |                |

| <u>FDA Received Date</u>                 | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 07-Aug-2012                              | 8502751              | EXPEDITED (15-DAY) | Y                  | DS, HO, LT      | CA-FRI-1000029697    |                      | 50 YR           | Male         | CAN            |
| <u>Preferred Term</u>                    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Bipolar<br>Disorder; Cardiac | Escitalopram Oxalate |                    |                    | S               |                      |                      |                 | Forest       |                |
|                                          | Cymbalta             |                    |                    | S               |                      |                      |                 | Not Reported |                |

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

|                               |                            |   |              |
|-------------------------------|----------------------------|---|--------------|
| Disorder; Condition           | Cymbalta                   | S | Not Reported |
| Aggravated; Confusional State | Clonazepam                 | C | Not Reported |
|                               | Kemadrin                   | C | Not Reported |
|                               | Pantoloc                   | C | Not Reported |
|                               | Procyclidine Hydrochloride | C | Not Reported |
|                               | Rivotril                   | C | Not Reported |
|                               | Teva-Pantoprazole          | C | Not Reported |
|                               | Topiramate                 | C | Not Reported |
|                               | Zyprexa                    | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Aug-2012              | 8503631       | EXPEDITED (15-DAY) | Y                  | HO              | CA-FRI-1000029696    |                      | 57 YR      | Male       | CAN            |

| <u>Preferred Term</u>                                                                                                                                   | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Asthenia; Blood Pressure Increased; Condition Aggravated; Decreased Appetite; Dizziness; Fatigue; Insomnia; Muscle Spasms; Nausea; Palpitations; Tremor | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                                                                                                                                         | Escitalopram Oxalate |              |            | S           | Oral         | 5 Mg               |                 | Forest       |
|                                                                                                                                                         | Asa                  |              |            | C           |              | 80 Mg              |                 | Not Reported |
|                                                                                                                                                         | Hydrochlorothiazide  |              |            | C           |              | 12.5 Mg            |                 | Not Reported |
|                                                                                                                                                         | Prilosec             |              |            | C           |              | 20 Mg              |                 | Not Reported |
|                                                                                                                                                         | Monopril             |              |            | C           |              | 20 Mg              |                 | Not Reported |
|                                                                                                                                                         | Viagra               |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Aug-2012              | 8503836       | EXPEDITED (15-DAY) | Y                  | LT              | CA-FRI-1000029685    |                      | 28 YR      | Unknown    | CAN            |

| <u>Preferred Term</u>                                                                 | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Crying; Depression; Hallucinations, Mixed; Self-Injurious Ideation; Suicidal Ideation | Escitalopram Oxalate |              |            | S           |              |                    |                 | Forest     |
|                                                                                       | Escitalopram Oxalate |              |            | S           |              |                    |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Aug-2012              | 8506747       | EXPEDITED (15-DAY) | Y                  | OT              | CA-FRI-1000029716    |                      | 55 YR      | Female     | CAN            |

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

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

|                                                                                      |                                |   |             |                 |              |
|--------------------------------------------------------------------------------------|--------------------------------|---|-------------|-----------------|--------------|
| Anxiety; Asthenia; Balance Disorder; Diarrhoea; Disorientation;                      | Escitalopram Oxalate           | S | Oral        | 20 Mg           | Forest       |
| Disturbance In Attention; Dizziness; Drug Interaction; Dyspnoea; Euphoric Mood; Gait | Baclofen                       | S |             | 60 Mg As Needed | Not Reported |
| Disturbance; Hallucination; Headache; Hypopnoea; Muscle Spasms;                      | Butrans                        | S | Transdermal | 480 ½G          | Not Reported |
| Palpitations; Pulse Pressure Increased;                                              | Butrans                        | S | Transdermal | 360 ½G          | Not Reported |
| Somnolence; Urinary Tract Infection; Vomiting                                        | Butrans                        | S | Transdermal | 240 ½G          | Not Reported |
|                                                                                      | Butrans                        | S | Transdermal | 120 ½G          | Not Reported |
|                                                                                      | Butrans                        | S | Transdermal | 480 ½G          | Not Reported |
|                                                                                      | Cesamet                        | S | Oral        | 0.5 Mg          | Not Reported |
|                                                                                      | Clonazepam                     | S | Oral        | 3 Mg            | Not Reported |
|                                                                                      | Ciprofloxacin Extended-Release | C | Oral        | 1000 Mg         | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Aug-2012              | 8514777       | EXPEDITED (15-DAY) | Y                  | DS, HO, OT      | CA-FRI-1000029770    |                      |            | Male       | CAN            |

| <u>Preferred Term</u>                                                                                                                                                           | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Diarrhoea Neonatal; Extrapyramidal Disorder; Foetal Exposure During Pregnancy; Hypertonia Neonatal; Neonatal Tachypnoea; Poor Quality Sleep; Selective Eating Disorder; Trismus | Escitalopram Oxalate        |              |            | S           | Transplacental | 20 Mg              |                 | Forest       |
|                                                                                                                                                                                 | Benzotropine Mesylate       |              |            | S           | Transplacental | 1.5 Mg             |                 | Not Reported |
|                                                                                                                                                                                 | Gabapentin                  |              |            | S           | Transplacental | 1800 Mg            |                 | Not Reported |
|                                                                                                                                                                                 | Methadone Hydrochloride     |              |            | S           | Transplacental | 70 Mg              |                 | Not Reported |
|                                                                                                                                                                                 | Nortriptyline Hydrochloride |              |            | S           | Transplacental | 20 Mg              |                 | Not Reported |
|                                                                                                                                                                                 | Rabeprazole                 |              |            | S           | Transplacental | 40 Mg              |                 | Not Reported |
|                                                                                                                                                                                 | Seroquel                    |              |            | S           | Transplacental | 100 Mg             |                 | Not Reported |
|                                                                                                                                                                                 | Seroquel Xr                 |              |            | S           | Transplacental | 300 Mg             |                 | Not Reported |
|                                                                                                                                                                                 | Zopiclone                   |              |            | S           | Transplacental | 7.5 Mg             |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Aug-2012              | 8712183       | EXPEDITED (15-DAY) | Y                  | LT              | FR-FRI-1000037589    |                      | 15 YR      | Female     | FRA            |

| <u>Preferred Term</u>      | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|----------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Disinhibition; Intentional | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg              |                 | Forest     |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Self-Injury; Off Label Use;  
Suicidal Ideation

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Aug-2012              | 8729243       | DIRECT           | Y                  | HO              |                      |                      | 35 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                         | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|-------------------------------------|-----------------|--------------|
| Drug Interaction;<br>Hyperhidrosis; Movement<br>Disorder; Restlessness;<br>Serotonin Syndrome;<br>Tachycardia | Metaxalone           |              |            | S           | Oral         | 800 Mg Twice Oral 047               |                 | Not Reported |
|                                                                                                               | Escitalopram Oxalate |              |            | S           | Oral         | 20 Mg Daily Oral 047<br>Many Months |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Aug-2012              | 8730603       | DIRECT           | Y                  | OT              |                      |                      | 61 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Affective Disorder;<br>Diarrhoea; Drug<br>Intolerance; Mental<br>Disorder; Oedema<br>Peripheral; Product<br>Substitution Issue; Renal<br>Impairment | Lexapro        |              |            | S           |              |                    |                 | Mylan      |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Aug-2012              | 8731023       | EXPEDITED (15-DAY) | Y                  | OT              | 2012AP002219         |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                  | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|---------------------|-----------------|--------------|
| Anxiety Disorder; Blunted<br>Affect; Crying; Decreased<br>Appetite; Dyspnoea;<br>Increased Appetite;<br>Maternal Exposure During<br>Pregnancy; Merycism; Off<br>Label Use; Palpitations;<br>Panic Attack; Poor Quality | Citalopram Hydrobromide |              |            | S           |              | 20 Mg, Qd           |                 | Not Reported |
|                                                                                                                                                                                                                        | Mirtazapine             |              |            | S           |              | 15;30;45 Mg, Hs, Qd |                 | Not Reported |
|                                                                                                                                                                                                                        | Escitalopram Oxalate    |              |            | S           |              | 10 Mg, Qd           |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Sleep; Urinary Retention;  
Weight Increased

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Aug-2012              | 8731409       | DIRECT           | N                  | DS              |                      |                      |            | Male       | USA            |

| <u>Preferred Term</u>                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Exposure Via Father;<br>Heart Disease Congenital | Lexapro        |              |            | S           | Oral         | 10 Mg 1x Day Oral  |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 08-Aug-2012              | 8650960       | EXPEDITED (15-DAY) | Y                  |                 | US-JNJFOC-20120603399 |                      | 58 YR      | Female     | USA            |

| <u>Preferred Term</u>  | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------|--------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Depression; Somnolence | Invega             |              |            | S           | Oral         |                    |                 | Not Reported |
|                        | Invega             |              |            | S           | Oral         |                    |                 | Not Reported |
|                        | Invega             |              |            | S           | Oral         |                    |                 | Not Reported |
|                        | Lexapro            |              |            | S           | Oral         |                    |                 | Not Reported |
|                        | Xanax              |              |            | C           | Oral         |                    |                 | Not Reported |
|                        | Gabapentin         |              |            | C           | Oral         |                    |                 | Not Reported |
|                        | Unknown Medication |              |            | C           | Unknown      |                    |                 | Not Reported |
|                        | Abilify            |              |            | C           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Aug-2012              | 8731783       | DIRECT           | Y                  |                 |                      |                      | 14 YR      | Female     | USA            |

| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |
|------------------------|----------------|--------------|------------|-------------|--------------|------------------------|-----------------|--------------|
| Dyskinesia; Gaze Palsy | Lexapro        |              |            | S           | Oral         | 1 1/2 Pills Per Day Po |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Aug-2012              | 8658814       | EXPEDITED (15-DAY) | Y                  | HO              | CH-FRI-1000036918    |                      |            | Female     | CHE            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                                   | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|-----------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|------------------------------------------|----------------------|-----------------|--------------|----------------|
| Anaemia; Enterocolitis<br>Haemorrhagic;<br>Gastrointestinal<br>Haemorrhage              | Escitalopram Oxalate   |                    |                    | S               | Oral                                     | 10 Mg                |                 | Forest       |                |
|                                                                                         | Ibuprofen              |                    |                    | S               | Oral                                     |                      |                 | Not Reported |                |
|                                                                                         | Prednisone             |                    |                    | S               | Oral                                     | 10 Mg                |                 | Not Reported |                |
|                                                                                         | Methotrexate           |                    |                    | S               | Oral                                     |                      |                 | Not Reported |                |
|                                                                                         | Klacid                 |                    |                    | S               | Oral                                     | 1000 Mg              |                 | Not Reported |                |
|                                                                                         | Rocephin               |                    |                    | S               | Intravenous (not<br>otherwise specified) | 2 G                  |                 | Not Reported |                |
|                                                                                         | Fragmin                |                    |                    | S               | Subcutaneous                             | 5000 Iu              |                 | Not Reported |                |
|                                                                                         | Calcimagon D3          |                    |                    | C               | Oral                                     |                      |                 | Not Reported |                |
|                                                                                         | Ramipril               |                    |                    | C               | Oral                                     | 5 Mg                 |                 | Not Reported |                |
|                                                                                         | Pantozol (Switzerland) |                    |                    | C               | Oral                                     | 20 Mg                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Aug-2012                                                                             | 8678734                | EXPEDITED (15-DAY) | Y                  | OT              | FR-FRI-1000037257                        |                      | 57 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                   | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Panic Attack;<br>Presyncope                                                    | Escitalopram Oxalate   |                    |                    | S               | Oral                                     | 10 Mg                |                 | Forest       |                |
|                                                                                         | Previscan (Fluindione) |                    |                    | C               |                                          |                      |                 | Not Reported |                |
|                                                                                         | Kerlone                |                    |                    | C               |                                          | 1 Df                 |                 | Not Reported |                |
|                                                                                         | Atacand                |                    |                    | C               |                                          | 8 Mg                 |                 | Not Reported |                |
|                                                                                         | Beta Blocking Agent    |                    |                    | C               |                                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Aug-2012                                                                             | 8696832                | EXPEDITED (15-DAY) | Y                  | HO              | CH-PFIZER INC-<br>2012184320             |                      | 73 YR           | Male         | CHE            |
| <u>Preferred Term</u>                                                                   | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Acute Kidney Injury; Blood<br>Loss Anaemia;<br>Gastrointestinal<br>Haemorrhage; Melaena | Flector                |                    |                    | S               | Topical                                  | Unk                  |                 | Pfizer       |                |
|                                                                                         | Plavix                 |                    |                    | S               | Oral                                     | 75 Mg, Daily         | 382 DAY         | Not Reported |                |
|                                                                                         | Aspirin Cardio         |                    |                    | S               | Oral                                     | 100 Mg Daily         | 392 DAY         | Not Reported |                |

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

|                              |   |              |                      |              |
|------------------------------|---|--------------|----------------------|--------------|
| Aspirin Cardio               | S | Oral         | 100 Mg, 1x/Day       | Not Reported |
| Cipralex                     | S | Oral         | 10 Mg Daily          | Not Reported |
| Remeron                      | S | Oral         | 30 Mg Daily          | Not Reported |
| Glucophage                   | S | Oral         | 850 Mg Daily         | Not Reported |
| Concor                       | C | Oral         | 10 Mg Daily          | Not Reported |
| Hydrochlorothiazide\Ramipril | C | Oral         | 2.5 Mg/12.5 Mg Daily | Not Reported |
| Sortis                       | C | Oral         | 40 Mg Daily          | Not Reported |
| Lantus                       | C | Subcutaneous | 4 Iu Daily           | Not Reported |
| Tamsulosin Hydrochloride     | C | Oral         | 400 Ug, Daily        | Not Reported |
| Haldol                       | C |              | Unk                  | Not Reported |
| Seroquel                     | C | Oral         | 25 Mg, 4x/Day        | Not Reported |

| <u>FDA Received Date</u>                                                      | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| 09-Aug-2012                                                                   | 8715439              | EXPEDITED (15-DAY) | Y                  | HO              | US-ASTRAZENECA-2012SE53980 |                      | 20 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                         | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Overdose;<br>Intentional Product<br>Misuse; Serotonin<br>Syndrome | Quetiapine           |                    |                    | S               | Oral                       |                      |                 | Zeneca       |                |
|                                                                               | Quetiapine           |                    |                    | S               | Oral                       |                      |                 | Zeneca       |                |
|                                                                               | Escitalopram Oxalate |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                                               | Escitalopram Oxalate |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                                               | Escitalopram Oxalate |                    |                    | S               | Oral                       | Overdose             |                 | Not Reported |                |
|                                                                               | Escitalopram Oxalate |                    |                    | S               | Oral                       | Overdose             |                 | Not Reported |                |
|                                                                               | Percocet             |                    |                    | S               |                            |                      |                 | Not Reported |                |
|                                                                               | Percocet             |                    |                    | S               |                            |                      |                 | Not Reported |                |
|                                                                               | Clonazepam           |                    |                    | S               |                            |                      |                 | Not Reported |                |
|                                                                               | Clonazepam           |                    |                    | S               |                            |                      |                 | Not Reported |                |
|                                                                               | Cocaine              |                    |                    | S               |                            |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|------------|----------------|
| 10-Aug-2012              | 8652208        | EXPEDITED (15-DAY) | Y                  | HO              | CH-ABBOTT-12P-151-0950492-00 |                      | 68 YR           | Female     | CHE            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                           |                        |   |                                       |              |
|---------------------------|------------------------|---|---------------------------------------|--------------|
| Back Pain; Blood Loss     | Methotrexate           | S | Oral                                  | Not Reported |
| Anaemia;                  | Ramipril               | C | Oral                                  | Not Reported |
| Cytomegalovirus Test      | Pantozol (Switzerland) | C | Oral                                  | Not Reported |
| Positive; Diverticulitis; | Calcium Carbonate      | C | Oral                                  | Not Reported |
| Enterocolitis             | Tramadol Hydrochloride | C |                                       | Not Reported |
| Haemorrhagic;             | Klacid                 | S | Oral                                  | Not Reported |
| Gastrointestinal          | Ibuprofen              | S | Oral                                  | Not Reported |
| Inflammation;             | Cipralex               | S | Oral                                  | Not Reported |
| Haemorrhoids; Lower       | Prednisone             | S | Oral                                  | Not Reported |
| Gastrointestinal          | Rocephin               | S | Intravenous (not otherwise specified) | Not Reported |
| Haemorrhage               | Fragmin                | S | Subcutaneous                          | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Aug-2012              | 8675915       | EXPEDITED (15-DAY) | Y                  | HO              | PHHY2012FR061967     |                      | 81 YR      | Male       | FRA            |

| <u>Preferred Term</u>     | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Aphasia; Asthenia;        | Leponex              |              |            | S           | Oral         | 1 Df, Daily        |                 | Novartis     |
| Cerebrovascular Accident; | Exelon Patch         |              |            | S           | Transdermal  | 1 Df, Daily        |                 | Not Reported |
| Hemiplegia                | Oxybutynin           |              |            | S           |              | 2 Df, Daily        |                 | Not Reported |
|                           | Escitalopram Oxalate |              |            | S           |              | 1 Df, Daily        |                 | Not Reported |
|                           | Benserazide\Levodopa |              |            | S           |              | 4 Df, Daily        |                 | Not Reported |
|                           | Modopar              |              |            | S           |              | 1 Df, Daily        |                 | Not Reported |
|                           | Aspirin              |              |            | C           |              | 1 Df, Daily        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Aug-2012              | 8717403       | EXPEDITED (15-DAY) | Y                  | HO              | CN-FRI-1000037657    |                      | 29 YR      | Female     | CHN            |

| <u>Preferred Term</u>                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Alanine Aminotransferase Increased; Aspartate | Lexapro        |              |            | S           | Oral         | 10 Mg              |                 | Forest     |

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

|                                      |                        |   |      |             |              |
|--------------------------------------|------------------------|---|------|-------------|--------------|
| Aminotransferase Increased; Jaundice | Jingwu Capsules        | C | Oral | 18 Capsules | Not Reported |
|                                      | Tongtian Oral Solution | C | Oral | 30 MI       | Not Reported |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 10-Aug-2012                       | 8717456                | EXPEDITED (15-DAY)        | Y                           | OT                       | IT-FRI-1000037711             |                               | 77 YR               | Female              | ITA                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Medication Error; Sopor        | Escitalopram Oxalate    |                       |                     | S                    | Oral                  | 20 Mg                       |                          | Forest              |
|                                | Reminyl                 |                       |                     | S                    | Oral                  | 12 Mg                       |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 10-Aug-2012                       | 8717561                | EXPEDITED (15-DAY)        | N                           | OT                       | US-FRI-1000037666             |                               |                     | Female              | USA                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Systemic Lupus Erythematosus   | Escitalopram Oxalate    |                       |                     | S                    |                       |                             |                          | Forest              |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 13-Aug-2012                       | 8677278                | EXPEDITED (15-DAY)        | N                           | OT                       | US-JNJFOC-20120706102         |                               | 74 YR               | Male                | USA                     |

| <a href="#">Preferred Term</a>         | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|----------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Confusional State;                     | Zytiga                  |                       |                     | S                    | Oral                  |                             |                          | Not Reported        |
| Depression; Dizziness;                 | Lexapro                 |                       |                     | S                    | Oral                  |                             |                          | Not Reported        |
| Dyspnoea Exertional;                   | Lexapro                 |                       |                     | S                    | Oral                  |                             |                          | Not Reported        |
| Fatigue; Fear; Headache;               | Prednisone              |                       |                     | S                    | Oral                  |                             |                          | Not Reported        |
| Hypersomnia;                           | Prednisone              |                       |                     | S                    | Oral                  |                             |                          | Not Reported        |
| Hypokinesia; Muscular Weakness; Oedema |                         |                       |                     | S                    | Oral                  |                             |                          | Not Reported        |
| Peripheral; Pain; Weight Increased     |                         |                       |                     |                      |                       |                             |                          |                     |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 13-Aug-2012                       | 8715090                | EXPEDITED (15-DAY)        | Y                           | HO, LT                   | IT-ASTRAZENECA-2012SE54601    |                               | 33 YR               | Male                | ITA                     |

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

| <u>Preferred Term</u>                                                                                                               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| Hyperthermia; Suicide Attempt                                                                                                       | Seroquel             |                    |                    | S               | Oral                       |                      | 123 DAY         | Zeneca       |                |
|                                                                                                                                     | Ciprallex            |                    |                    | S               | Oral                       |                      | 123 DAY         | Not Reported |                |
|                                                                                                                                     | Depakene             |                    |                    | S               | Oral                       |                      | 123 DAY         | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Aug-2012                                                                                                                         | 8743022              | DIRECT             | N                  | OT              |                            |                      | 30 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Affective Disorder; Cardiac Disorder; Chest Pain; Diarrhoea; Fatigue; Nausea; Product Substitution Issue; Somnolence                | Escitalopram Oxalate |                    |                    | S               | Oral                       | 20 Mg Once Daily Po  | 8 DAY           | Mylan        |                |
| <u>FDA Received Date</u>                                                                                                            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Aug-2012                                                                                                                         | 7923108              | EXPEDITED (15-DAY) |                    | OT              | US-ASTRAZENECA-2010SE21304 |                      | 68 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Breast Cancer Female; Gastrooesophageal Reflux Disease; Meniscus Injury; Pain In Extremity; Panic Attack; Thyroid Disorder | Nexium               |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                                                                                                     | Crestor              |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                                                                                                     | Synthroid            |                    |                    | S               | Unknown                    |                      |                 | Not Reported |                |
|                                                                                                                                     | Lexapro              |                    |                    | S               | Unknown                    |                      |                 | Not Reported |                |
|                                                                                                                                     | Arimidex             |                    |                    | C               |                            |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Aug-2012                                                                                                                         | 8658256              | EXPEDITED (15-DAY) | Y                  | HO, OT          | JP-FRI-1000036745          |                      | 68 YR           | Female       | JPN            |
| <u>Preferred Term</u>                                                                                                               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Activation Syndrome; Blood Pressure Increased;                                                                                      | Lexapro              |                    |                    | S               | Oral                       | 10 Mg                |                 | Forest       |                |
|                                                                                                                                     | Amoxapine            |                    |                    | C               |                            |                      |                 | Not Reported |                |

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

| Hyperhidrosis;<br>Palpitations; Tremor                                                                                       | Other Ssris<br>Ludiomil |                    | C<br>C             |                 |                      | Oral                              |                 | Not Reported<br>Not Reported |                |
|------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|-----------------------------------|-----------------|------------------------------|----------------|
| <u>FDA Received Date</u>                                                                                                     | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 14-Aug-2012                                                                                                                  | 8723197                 | EXPEDITED (15-DAY) | Y                  | OT              | GB-FRI-1000037739    |                                   | 40 YR           | Male                         | GBR            |
| <u>Preferred Term</u>                                                                                                        | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>                   |                |
| Anxiety;<br>Depersonalisation/Dereali<br>sation Disorder;<br>Depression; Derealisation;<br>Dissociation                      | Escitalopram Oxalate    |                    |                    | S               | Oral                 |                                   |                 | Forest                       |                |
| <u>FDA Received Date</u>                                                                                                     | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 14-Aug-2012                                                                                                                  | 8723202                 | EXPEDITED (15-DAY) | Y                  | HO              | FR-FRI-1000037746    |                                   | 19 YR           | Female                       | FRA            |
| <u>Preferred Term</u>                                                                                                        | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>                   |                |
| Dystonia; Overdose;<br>Ventricular Extrasystoles                                                                             | Escitalopram Oxalate    |                    |                    | S               | Oral                 | One Intake Of 10 Tab. Of<br>10 Mg |                 | Forest                       |                |
|                                                                                                                              | Orap                    |                    |                    | S               | Oral                 | One Intake Of 10 Tab. Of<br>1 Mg  |                 | Not Reported                 |                |
|                                                                                                                              | Paroxetine              |                    |                    | S               | Oral                 | One Intake Of 2 Tab. Of<br>20 Mg  |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                                                                                                     | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 14-Aug-2012                                                                                                                  | 8723436                 | EXPEDITED (15-DAY) | N                  | OT              | US-FRI-1000037812    |                                   | 79 YR           | Female                       | USA            |
| <u>Preferred Term</u>                                                                                                        | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>                   |                |
| Crying; Drug Interaction;<br>Hallucination, Auditory;<br>Hallucination, Visual;<br>Somnolence; Toxicity To<br>Various Agents | Lexapro                 |                    |                    | S               | Oral                 | 20 Mg                             |                 | Forest                       |                |
|                                                                                                                              | Oxycontin               |                    |                    | S               |                      |                                   |                 | Not Reported                 |                |
|                                                                                                                              | Oxycontin               |                    |                    | S               |                      | 40 Mg Every 8 Hours As<br>Needed  |                 | Not Reported                 |                |
|                                                                                                                              | Morphine                |                    |                    | S               |                      |                                   |                 | Not Reported                 |                |

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|                                                                                                                                                                                        | Lunesta                  |                    | S                  |                 | 3 Mg                   |                      | Not Reported    |              |                |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|------------------------|----------------------|-----------------|--------------|----------------|
|                                                                                                                                                                                        | Vicodin                  |                    | C                  |                 | As Needed              |                      | Not Reported    |              |                |
| <u>FDA Received Date</u>                                                                                                                                                               | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Aug-2012                                                                                                                                                                            | 8723492                  | EXPEDITED (15-DAY) | Y                  | OT              | FR-GILEAD-2012-0059552 |                      | 26 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Pruritus; Rash                                                                                                                                                                         | Truvada                  |                    |                    | S               | Oral                   | 1 Df, Qd             | 27 DAY          | Gilead       |                |
|                                                                                                                                                                                        | Prezista                 |                    |                    | S               | Oral                   | 300 Mg, Qd           | 11 DAY          | Not Reported |                |
|                                                                                                                                                                                        | Escitalopram Oxalate     |                    |                    | S               | Oral                   | 1 Df, Qd             |                 | Not Reported |                |
|                                                                                                                                                                                        | Norvir                   |                    |                    | C               | Oral                   | 1 Df, Qd             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                               | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Aug-2012                                                                                                                                                                            | 8739441                  | EXPEDITED (15-DAY) | Y                  | OT              | 2012AP002296           |                      | 28 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State; Drug Screen False Positive; Focal Dyscognitive Seizures; Intentional Overdose; Intentional Product Misuse; Postictal State; Tachycardia; Toxicity To Various Agents | Tramadol Hydrochloride   |                    |                    | S               |                        |                      |                 | Not Reported |                |
|                                                                                                                                                                                        | Omeprazole               |                    |                    | S               |                        |                      |                 | Not Reported |                |
|                                                                                                                                                                                        | Escitalopram Oxalate     |                    |                    | S               |                        |                      |                 | Not Reported |                |
|                                                                                                                                                                                        | Naproxen                 |                    |                    | S               |                        |                      |                 | Not Reported |                |
|                                                                                                                                                                                        | Cyclobenzaprine          |                    |                    | S               |                        |                      |                 | Not Reported |                |
|                                                                                                                                                                                        |                          |                    |                    |                 |                        |                      |                 |              |                |
| <u>FDA Received Date</u>                                                                                                                                                               | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Aug-2012                                                                                                                                                                            | 8749139                  | DIRECT             | N                  | OT              |                        |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                                                                                                                                  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Diarrhoea                                                                                                                                                                              | Lexapro                  |                    |                    | S               | Oral                   | 10 Mg, 1xday, Po     | 6 WEEK          | Forest       |                |
|                                                                                                                                                                                        | Pristiq Extended Release |                    |                    | C               |                        |                      |                 | Not Reported |                |
|                                                                                                                                                                                        | Zoloft                   |                    |                    | C               |                        |                      |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                         | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 15-Aug-2012                                                                                                                                                                                                                                                                                      | 8747201                | DIRECT             | Y                  |                 |                      |                      | 55 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                            | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Pruritus Generalised                                                                                                                                                                                                                                                                             | Escitalopram           |                    |                    | S               | Oral                 | 20mg Qd Po           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                         | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Aug-2012                                                                                                                                                                                                                                                                                      | 8527753                | EXPEDITED (15-DAY) | Y                  | HO, OT          | DE-FRI-1000029976    |                      | 55 YR           | Male         | DEU            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                            | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Blood Bilirubin Increased; Chromaturia; Gamma-Glutamyltransferase Increased; Jaundice; Off Label Use; Protein Total Decreased; Serum Ferritin Increased; Transaminases Increased | Escitalopram Oxalate   |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                                                                                                                                                                                                                                                                                  | Unspecified Ingredient |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                         | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Aug-2012                                                                                                                                                                                                                                                                                      | 8633890                | EXPEDITED (15-DAY) | Y                  | OT              | FR-FRI-1000031589    |                      | 71 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                            | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Generalised Tonic-Clonic Seizure                                                                                                                                                                                                                                                                 | Escitalopram Oxalate   |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                                                                                                                                                                                                                                                                                  | Amlodipine Besylate    |                    |                    | C               | Oral                 | 10 Mg                |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                  | Bisoprolol Fumarate    |                    |                    | C               | Oral                 | 7.5 Mg               |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                  | Zocor                  |                    |                    | C               | Oral                 | 20 Mg                |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                  | Coaprovel              |                    |                    | C               | Oral                 | 150 Mg               |                 | Not Reported |                |

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|                                                    | Oxazepam                 | C                  | Oral               | 200 Mg          |                          | Not Reported              |                 |              |                |
|----------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|--------------------------|---------------------------|-----------------|--------------|----------------|
|                                                    | Depakene                 | C                  | Oral               | 1000 Mg         |                          | Not Reported              |                 |              |                |
| <u>FDA Received Date</u>                           | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Aug-2012                                        | 8686829                  | NON-EXPEDITED      | Y                  |                 | US-PFIZER INC-2012181543 |                           | 50 YR           | Female       | USA            |
| <u>Preferred Term</u>                              | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |                |
| Nausea                                             | Pristiq Extended Release |                    |                    | S               | Oral                     | 50 Mg, 1x/Day, At Bedtime |                 | Pfizer       |                |
|                                                    | Pristiq Extended Release |                    |                    | S               | Oral                     | Unk                       |                 | Pfizer       |                |
|                                                    | Lexapro                  |                    |                    | S               |                          | Unk                       |                 | Not Reported |                |
|                                                    | Effexor                  |                    |                    | C               |                          | Unk                       | 14 DAY          | Not Reported |                |
|                                                    | Levothyroxine            |                    |                    | C               |                          | 75 Ug, Unk                |                 | Not Reported |                |
| <u>FDA Received Date</u>                           | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Aug-2012                                        | 8698844                  | EXPEDITED (15-DAY) | Y                  | HO, OT          | DE-FRI-1000037522        |                           |                 | Female       | DEU            |
| <u>Preferred Term</u>                              | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyponatraemia;<br>Potentiating Drug<br>Interaction | Escitalopram Oxalate     |                    |                    | S               | Oral                     | 5 Mg                      |                 | Forest       |                |
|                                                    | Escitalopram Oxalate     |                    |                    | S               | Oral                     | 10 Mg                     |                 | Not Reported |                |
|                                                    | Escitalopram Oxalate     |                    |                    | S               | Oral                     | 15 Mg                     |                 | Not Reported |                |
|                                                    | Escitalopram Oxalate     |                    |                    | S               | Oral                     | 20 Mg                     |                 | Forest       |                |
|                                                    | Escitalopram Oxalate     |                    |                    | S               | Oral                     | 10 Mg                     |                 | Not Reported |                |
|                                                    | Remergil                 |                    |                    | S               | Oral                     | 30 Mg                     |                 | Not Reported |                |
|                                                    | Remergil                 |                    |                    | S               | Oral                     | 45 Mg                     |                 | Not Reported |                |
|                                                    | Remergil                 |                    |                    | S               | Oral                     | 30 Mg                     |                 | Not Reported |                |
|                                                    | Nexium                   |                    |                    | S               | Oral                     | 20 Mg                     |                 | Not Reported |                |
|                                                    | Seroquel                 |                    |                    | S               | Oral                     | 50 Mg                     |                 | Not Reported |                |
|                                                    | Lamotrigine              |                    |                    | C               | Oral                     | 25 Mg                     |                 | Not Reported |                |
|                                                    | Lamotrigine              |                    |                    | C               | Oral                     | 50 Mg                     |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                                                                             | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 16-Aug-2012                                                                                                                          | 8727469                 | EXPEDITED (15-DAY) | Y                  | HO, OT          | FR-FRI-1000037778    |                      |                 | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Headache; Nausea; Suicidal Ideation; Suicide Attempt; Swelling; Weight Increased                                                     | Escitalopram Oxalate    |                    |                    | S               | Oral                 | 1 Df                 |                 | Forest       |                |
|                                                                                                                                      | Escitalopram Oxalate    |                    |                    | S               |                      | 2 Df                 |                 | Not Reported |                |
|                                                                                                                                      | Questran                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                      | Aldactazine             |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                      | Levothyrox              |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                             | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Aug-2012                                                                                                                          | 8727630                 | EXPEDITED (15-DAY) | Y                  | OT              | IT-FRI-1000037807    |                      | 81 YR           | Male         | ITA            |
| <u>Preferred Term</u>                                                                                                                | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Presyncope                                                                                                                           | Escitalopram Oxalate    |                    |                    | S               | Oral                 | 1 Df                 |                 | Forest       |                |
|                                                                                                                                      | Donepezil Hydrochloride |                    |                    | S               | Oral                 | 5 Mg                 |                 | Not Reported |                |
|                                                                                                                                      | Allopurinol             |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                      | Pantoprazole            |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                      | Peridon                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                      | Cardioaspirin           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                      | Esapent                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                             | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Aug-2012                                                                                                                          | 8748166                 | DIRECT             | N                  | OT              |                      |                      | 58 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Emotional Disorder; Hypersomnia; Impaired Work Ability; Memory Impairment; Polydipsia; Product Substitution Issue; Suicidal Ideation | Escitalopram Oxalate    |                    |                    | S               |                      |                      |                 | Mylan        |                |



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| <u>FDA Received Date</u>                                   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 17-Aug-2012                                                | 8749345              | DIRECT             | Y                  | OT              |                      |                      | 23 YR           | Male         | USA            |
| <u>Preferred Term</u>                                      | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Disease Recurrence; Product Substitution Issue | Escitalopram Oxalate |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Aug-2012                                                | 8695619              | EXPEDITED (15-DAY) | Y                  | HO, LT          | FR-FRI-1000037437    |                      | 58 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                      | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Brain Oedema; Hyponatraemia; Serotonin Syndrome            | Escitalopram Oxalate |                    |                    | S               | Oral                 | 20 Mg                |                 | Forest       |                |
|                                                            | Anafranil            |                    |                    | S               | Oral                 | 75 Mg                |                 | Not Reported |                |
|                                                            | Lormetazepam         |                    |                    | C               | Oral                 | 1 Df At Bedtime      |                 | Not Reported |                |
|                                                            | Pravastatin          |                    |                    | C               | Oral                 | 20 Mg                |                 | Not Reported |                |
|                                                            | Lorazepam            |                    |                    | C               | Oral                 | 2.5 Mg               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Aug-2012                                                | 8732110              | EXPEDITED (15-DAY) | Y                  | HO              | FR-FRI-1000037846    |                      | 93 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                      | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Hyponatraemia                            | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                                            | Aldactazine          |                    |                    | S               | Oral                 | 1 Df                 |                 | Not Reported |                |
|                                                            | Cordarone            |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |
|                                                            | Levothyrox           |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |
|                                                            | Vitamin B12          |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |
|                                                            | Sterogyl             |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                            | Lercanidipine        |                    |                    | C               |                      |                      |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                                                    | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|-----------------|----------------|
| 20-Aug-2012                                                                                                 | 8732303                  | EXPEDITED (15-DAY) | Y                  | OT              | US-GLAXOSMITHKLINE-A0989918A |                      | 34 YR           | Male            | USA            |
| <u>Preferred Term</u>                                                                                       | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Anxiety; Blindness; Cardiac Disorder; Dizziness; Gait Inability; Palpitations; Vertigo; Withdrawal Syndrome | Paxil                    |                    |                    | S               | Oral                         |                      |                 | Glaxosmithkline |                |
|                                                                                                             | Lexapro                  |                    |                    | S               | Unknown                      |                      |                 | Not Reported    |                |
|                                                                                                             | Alprazolam               |                    |                    | S               | Oral                         |                      |                 | Glaxosmithkline |                |
|                                                                                                             | Sertraline Hydrochloride |                    |                    | S               | Oral                         | 50mg Per Day         | 3 WEEK          | Not Reported    |                |
|                                                                                                             | Zoloft                   |                    |                    | S               | Oral                         | 50mg Per Day         |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                    | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 20-Aug-2012                                                                                                 | 8732629                  | EXPEDITED (15-DAY) | Y                  | HO              | FR-FRI-1000037877            |                      | 81 YR           | Male            | FRA            |
| <u>Preferred Term</u>                                                                                       | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Ischaemic Stroke                                                                                            | Escitalopram Oxalate     |                    |                    | S               | Oral                         | 10 Mg                |                 | Forest          |                |
|                                                                                                             | Leponex                  |                    |                    | S               | Oral                         | 25 Mg                |                 | Not Reported    |                |
|                                                                                                             | Modopar                  |                    |                    | S               | Oral                         | 4 Df                 |                 | Not Reported    |                |
|                                                                                                             | Modopar                  |                    |                    | S               | Oral                         | 100mg / 25mg         |                 | Not Reported    |                |
|                                                                                                             | Exelon                   |                    |                    | S               | Other                        | 1 Df                 |                 | Not Reported    |                |
|                                                                                                             | Oxybutynin               |                    |                    | S               | Oral                         | 2 Df                 |                 | Not Reported    |                |
|                                                                                                             | Aspirin                  |                    |                    | C               |                              | 1 Df                 |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                    | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 20-Aug-2012                                                                                                 | 8732983                  | EXPEDITED (15-DAY) | Y                  | LT              | FR-FRI-1000037894            |                      | 26 YR           | Male            | FRA            |
| <u>Preferred Term</u>                                                                                       | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Disinhibition                                                                                               | Escitalopram Oxalate     |                    |                    | S               |                              |                      |                 | Forest          |                |
|                                                                                                             | Ludomil                  |                    |                    | S               | Oral                         | 75 Mg                |                 | Not Reported    |                |
|                                                                                                             | Fentanyl                 |                    |                    | S               | Oral                         |                      |                 | Not Reported    |                |

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

|                                          |                      |                    |                    |                 |                      |                        |                 |              |                |
|------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|------------------------|-----------------|--------------|----------------|
| Alcohol                                  |                      |                    | S                  |                 |                      | Not Reported           |                 |              |                |
| <u>FDA Received Date</u>                 | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Aug-2012                              | 8732984              | EXPEDITED (15-DAY) | Y                  | OT              | FR-FRI-1000037869    |                        | 26 YR           | Male         | FRA            |
| <u>Preferred Term</u>                    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Pruritus; Rash                           | Escitalopram Oxalate |                    |                    | S               | Oral                 | 1 Df                   |                 | Forest       |                |
|                                          | Prezista             |                    |                    | S               | Oral                 | 300 Mg                 |                 | Not Reported |                |
|                                          | Truvada              |                    |                    | S               | Oral                 | 200 Mg/245 Mg          |                 | Not Reported |                |
|                                          | Norvir               |                    |                    | C               | Oral                 | 1 Df                   |                 | Not Reported |                |
| <u>FDA Received Date</u>                 | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Aug-2012                              | 8749165              | DIRECT             | Y                  | OT              |                      |                        |                 | Unknown      | USA            |
| <u>Preferred Term</u>                    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Electrocardiogram Qt Prolonged; Tinnitus | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg Qd Po 5 Mg Qd Po |                 | Mylan        |                |
|                                          |                      |                    |                    |                 | Oral                 | 10 Mg Qd Po 5 Mg Qd Po |                 |              |                |
| <u>FDA Received Date</u>                 | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Aug-2012                              | 8721237              | EXPEDITED (15-DAY) | Y                  | HO              | IT-FRI-1000024740    |                        | 35 YR           | Male         | ITA            |
| <u>Preferred Term</u>                    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyperthermia; Suicide Attempt            | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg                  |                 | Forest       |                |
|                                          | Seroquel             |                    |                    | S               | Oral                 | 600 Mg                 |                 | Not Reported |                |
|                                          | Depakene             |                    |                    | S               | Oral                 | 900 Mg                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                 | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Aug-2012                              | 8734304              | EXPEDITED (15-DAY) | N                  | CA, HO          | US-FRI-1000037934    |                        | < 1 DAY         | Female       | USA            |
| <u>Preferred Term</u>                    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Congenital Cardiovascular                | Lexapro              |                    |                    | S               | Transplacental       |                        |                 | Forest       |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Anomaly; Failure To Thrive; Premature Baby; Respiratory Syncytial Virus Infection; Underweight; Vomiting

| <a href="#">FDA Received Date</a>                                                                                                                            | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 21-Aug-2012                                                                                                                                                  | 8734576                 | EXPEDITED (15-DAY)        | N                           | CA                       | US-FRI-1000037912             |                               | < 1 DAY                  | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                                                                                               | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Atrial Septal Defect; Cleft Palate; Congenital Anomaly; Lung Disorder                                                                                        | Lexapro                 |                           |                             | S                        | Transplacental                |                               |                          | Forest              |                         |
| <a href="#">FDA Received Date</a>                                                                                                                            | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 21-Aug-2012                                                                                                                                                  | 8734664                 | EXPEDITED (15-DAY)        | N                           | HO                       | US-PURDUE-USA-2012-0091484    |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                                                                                               | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Abdominal Pain Upper; Cardiac Disorder; Headache; Inadequate Analgesia; Nausea; Pain; Somnolence; Unevaluable Event                                          | Oxycontin               |                           |                             | S                        | Oral                          | 80 Mg, Unk                    |                          | Purdue              |                         |
|                                                                                                                                                              | Lexapro                 |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
|                                                                                                                                                              | Alprazolam              |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
|                                                                                                                                                              | Roxicodone              |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
|                                                                                                                                                              | Unspecified Ingredient  |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                                                            | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 21-Aug-2012                                                                                                                                                  | 8734673                 | EXPEDITED (15-DAY)        | Y                           | HO                       | PHHY2012CA069982              |                               | 25 YR                    | Female              | CAN                     |
| <a href="#">Preferred Term</a>                                                                                                                               | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Coma; Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Hypocalcaemia; Hypokalaemia; Hypotension; Intentional Overdose; Pulse Absent; | Amitriptyline           |                           |                             | S                        |                               |                               |                          | Novartis            |                         |
|                                                                                                                                                              | Fluoxetine Hcl          |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
|                                                                                                                                                              | Escitalopram Oxalate    |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
|                                                                                                                                                              | Olanzapine              |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
|                                                                                                                                                              | Quetiapine              |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
|                                                                                                                                                              | Gabapentin              |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Suicide Attempt;  
Tachycardia

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 21-Aug-2012              | 8734832       | NON-EXPEDITED    | N                  |                 | US-ASTRAZENECA-2012SE56818 |                      |            | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                          | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Extrasystoles;<br>Formication; Hallucination,<br>Auditory; Memory<br>Impairment; Mental<br>Impairment; Paranoia;<br>Thinking Abnormal | Seroquel Xr             |              |            | S           | Oral         |                    |                 | Astrazeneca  |
|                                                                                                                                                | Seroquel Xr             |              |            | S           | Oral         |                    |                 | Astrazeneca  |
|                                                                                                                                                | Clonazepam              |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                | Clonazepam              |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                | Trazodone Hydrochloride |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                | Trazodone Hydrochloride |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                | Escitalopram Oxalate    |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                | Escitalopram Oxalate    |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Aug-2012              | 8734973       | EXPEDITED (15-DAY) | Y                  | HO              | FR-FRI-1000025993    |                      | 49 YR      | Female     | FRA            |

| <u>Preferred Term</u>                   | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Hypotension; Malaise;<br>Pruritus; Rash | Escitalopram Oxalate |              |            | S           |              |                    |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Aug-2012              | 8735008       | EXPEDITED (15-DAY) | Y                  | HO, LT          | CH-FRI-1000037808    |                      |            | Female     | CHE            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Subdural Haematoma    | Escitalopram Oxalate |              |            | S           | Oral         | 20 Mg              |                 | Forest       |
|                       | Marcumar             |              |            | S           | Oral         | 3 Mg               |                 | Not Reported |
|                       | Budesonide           |              |            | C           | Oral         | 6 Mg               |                 | Not Reported |
|                       | Calcium Sandoz Ff    |              |            | C           | Oral         | 500 Mg             |                 | Not Reported |
|                       | Vi-De 3              |              |            | C           |              | 12.8571 Gtt        |                 | Not Reported |
|                       | Concor               |              |            | C           | Oral         | 1.25 Mg            |                 | Not Reported |

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

|                        |   |      |                 |              |
|------------------------|---|------|-----------------|--------------|
| Movicol                | C | Oral |                 | Not Reported |
| Oxycontin              | C | Oral | 30 Mg           | Not Reported |
| Torseamide             | C | Oral | 20 Mg           | Not Reported |
| Pantozol (Switzerland) | C | Oral | 40 Mg           | Not Reported |
| Seroquel               | C | Oral | 62.5 Mg         | Not Reported |
| Lorazepam              | C |      | 1 Mg, As Needed | Not Reported |

| <u>FDA Received Date</u>                                                                        | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|-------------------------------------------------------------------------------------------------|----------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 21-Aug-2012                                                                                     | 8749192              | DIRECT           | N                  | DS, OT          |                      |                      | 40 YR           | Female     | USA            |
| <u>Preferred Term</u>                                                                           | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Anxiety; Depression;<br>Economic Problem;<br>Product Substitution Issue;<br>Withdrawal Syndrome | Venlafaxine          |                  |                    | S               | Oral                 | 450 Mg, Daily, Po    |                 | Teva       |                |
|                                                                                                 | Escitalopram Oxalate |                  |                    | S               | Oral                 | 40 Mg, Daily, Po     |                 | Teva       |                |

| <u>FDA Received Date</u>                                                                                                | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------|----------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 21-Aug-2012                                                                                                             | 8749364              | DIRECT           |                    | OT              |                      |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>                                                                                                   | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Anxiety; Condition<br>Aggravated; Depression;<br>Drug Ineffective;<br>Emotional Distress;<br>Product Substitution Issue | Escitalopram Oxalate |                  |                    | S               |                      |                      |                 | Teva       |                |

| <u>FDA Received Date</u>                                | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 21-Aug-2012                                             | 8761637        | EXPEDITED (15-DAY) |                    | HO, OT          | AUR-APL-2012-03481   |                      | 20 YR           | Male         | USA            |
| <u>Preferred Term</u>                                   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain;<br>Depressed Mood;                      | Escitalopram   |                    |                    | S               | Oral                 | 1d                   |                 | Not Reported |                |
| Incorrect Route Of Product<br>Administration; Lethargy; | Quetiapine     |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                         | Clonazepam     |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |

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

|                                                                                                                |                   |   |      |              |
|----------------------------------------------------------------------------------------------------------------|-------------------|---|------|--------------|
| Mental Status Changes;<br>Oxygen Saturation<br>Decreased; Respiratory<br>Rate Decreased;<br>Serotonin Syndrome | Cocaine (Cocaine) | S | Oral | Not Reported |
|                                                                                                                | Percocet          | S | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Aug-2012              | 8571827       | EXPEDITED (15-DAY) | Y                  | HO              | CH-FRI-1000030602    |                      |            | Female     | CHE            |

| <u>Preferred Term</u>                                                                                | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                             | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------|-----------------------------|--------------|------------|-------------|------------------------------------------|--------------------|-----------------|--------------|
| Delirium; Encephalopathy;<br>Extrapyramidal Disorder;<br>Hyperkinesia; Tardive<br>Dyskinesia; Tremor | Escitalopram Oxalate        |              |            | S           | Oral                                     | 10 Mg              |                 | Forest       |
|                                                                                                      | Escitalopram Oxalate        |              |            | S           |                                          | 10 Mg              |                 | Forest       |
|                                                                                                      | Zyprexa                     |              |            | S           | Oral                                     | 2.5 Mg             |                 | Not Reported |
|                                                                                                      | Zolpidem                    |              |            | S           | Oral                                     | 10 Mg              |                 | Not Reported |
|                                                                                                      | Levofloxacin                |              |            | C           | Oral                                     |                    |                 | Not Reported |
|                                                                                                      | Sintrom                     |              |            | C           | Oral                                     |                    |                 | Not Reported |
|                                                                                                      | Sintrom                     |              |            | C           |                                          |                    |                 | Not Reported |
|                                                                                                      | Cordarone                   |              |            | C           | Oral                                     | 100 Mg             |                 | Not Reported |
|                                                                                                      | Cordarone                   |              |            | C           |                                          |                    |                 | Not Reported |
|                                                                                                      | Euthyrox                    |              |            | C           | Oral                                     | 0.075 Mg           |                 | Not Reported |
|                                                                                                      | Tenormin                    |              |            | C           | Oral                                     | 25 Mg              |                 | Not Reported |
|                                                                                                      | Nitroglycerin               |              |            | C           | Oral                                     |                    |                 | Not Reported |
|                                                                                                      | Dafalgan                    |              |            | C           | Intravenous (not<br>otherwise specified) |                    |                 | Not Reported |
|                                                                                                      | Rocephin                    |              |            | C           | Intravenous (not<br>otherwise specified) | 2 G                |                 | Not Reported |
|                                                                                                      | Piperacillin And Tazobactam |              |            | C           |                                          |                    |                 | Not Reported |
|                                                                                                      | Pamidronate Disodium        |              |            | C           |                                          |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Aug-2012              | 8612466       | EXPEDITED (15-DAY) | Y                  | DE, HO          | NL-FRI-1000031250    |                      | 53 YR      | Male       | NLD            |

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

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

|                                       |                      |   |      |           |              |
|---------------------------------------|----------------------|---|------|-----------|--------------|
| Circulatory Collapse;<br>Sudden Death | Lexapro              | S | Oral | 20 Mg     | Forest       |
|                                       | Omeprazole           | C | Oral | 40 Mg     | Not Reported |
|                                       | Zocor                | C | Oral | 40 Mg     | Not Reported |
|                                       | Leponex              | C | Oral | 50 Mg     | Not Reported |
|                                       | Leponex              | C | Oral |           | Not Reported |
|                                       | Oxazepam             | C | Oral |           | Not Reported |
|                                       | Ascal                | C |      | 100 Mg    | Not Reported |
|                                       | Slow-K               | C | Oral |           | Not Reported |
|                                       | Vitamin B-Complex    | C |      |           | Not Reported |
|                                       | Aspirin\Dipyridamole | C |      | 25/200 Mg | Not Reported |
|                                       | Ramipril             | C | Oral |           | Not Reported |
|                                       | Ascal Cardio Brisper | C | Oral |           | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 22-Aug-2012              | 8735653       | EXPEDITED (15-DAY) | Y                  | HO, OT          | US-JNJFOC-20120805291 |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>                                | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Agranulocytosis; Drug Interaction;<br>Rhabdomyolysis | Risperidone         |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                      | Haloperidol Lactate |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                      | Fentanyl            |              |            | S           | Transdermal  |                    |                 | Not Reported |
|                                                      | Zetia               |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                      | Tricor              |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                      | Lipitor             |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                      | Thorazine           |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                      | Seroquel            |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                      | Zyprexa             |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                      | Geodon              |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                      | Abilify             |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                      | Ativan              |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                      | Klonopin            |              |            | S           | Unknown      |                    |                 | Not Reported |



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

|                     |   |         |              |
|---------------------|---|---------|--------------|
| Cogentin            | S | Unknown | Not Reported |
| Lexapro             | S | Unknown | Not Reported |
| Citalopram          | S | Unknown | Not Reported |
| Phenelzine          | S | Unknown | Not Reported |
| Depakote            | S | Unknown | Not Reported |
| Aricept             | S | Unknown | Not Reported |
| Colchicine          | S | Unknown | Not Reported |
| Daptomycin          | S | Unknown | Not Reported |
| Unasyn              | S | Unknown | Not Reported |
| Ziagen              | S | Unknown | Not Reported |
| Valcyte             | S | Unknown | Not Reported |
| Clofarabine         | S | Unknown | Not Reported |
| Cyclophosphamide    | S | Unknown | Not Reported |
| Prednisone          | S | Unknown | Not Reported |
| Prograf             | S | Unknown | Not Reported |
| Aldesleukin         | S | Unknown | Not Reported |
| Rapamycin           | S | Unknown | Not Reported |
| Aspirin             | S | Unknown | Not Reported |
| Crestor             | S | Unknown | Not Reported |
| Hydrochlorothiazide | S | Unknown | Not Reported |
| Penicillin          | S | Unknown | Not Reported |
| Zosyn               | S | Unknown | Not Reported |
| Keflex              | S | Unknown | Not Reported |
| Ceftriaxone         | S | Unknown | Not Reported |
| Bactrim             | S | Unknown | Not Reported |
| Dilantin            | S | Unknown | Not Reported |
| Neurontin           | S | Unknown | Not Reported |
| Tegretol            | S | Unknown | Not Reported |
| Azathioprine Sodium | S | Unknown | Not Reported |

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

|               |   |         |              |
|---------------|---|---------|--------------|
| Sulfasalazine | S | Unknown | Not Reported |
| Plavix        | S | Unknown | Not Reported |
| Simvastatin   | S | Unknown | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Aug-2012              | 8750012       | DIRECT           | Y                  |                 |                      |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                                  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Product Substitution Issue;<br>Therapeutic Product Effect<br>Decreased | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Aug-2012              | 8750062       | DIRECT           | Y                  |                 |                      |                      | 54 YR      | Female     | USA            |

| <u>Preferred Term</u>                      | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Abdominal Pain Upper;<br>Diarrhoea; Nausea | Escitalopram Oxalate |              |            | S           | Oral         | 20mg 1 Qd Oral     |                 | Teva       |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Aug-2012              | 8675060       | EXPEDITED (15-DAY) | Y                  |                 | JP-FRI-1000037056    |                      | 20 YR      | Female     | JPN            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Activation Syndrome   | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg              |                 | Forest     |
|                       | Escitalopram Oxalate |              |            | S           |              |                    |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 23-Aug-2012              | 8725673       | EXPEDITED (15-DAY) | Y                  | HO              | IT-ABBOTT-11P-083-0865555-00 |                      | 35 YR      | Male       | ITA            |

| <u>Preferred Term</u>         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hyperthermia; Suicide Attempt | Valproic Acid  |              |            | S           | Oral         |                    |                 | Not Reported |
|                               | Cipralext      |              |            | S           | Oral         |                    |                 | Not Reported |

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

|                                                                                            |                             |                    |                    |                 |                                |                      |                 |              |                |
|--------------------------------------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|-----------------|--------------|----------------|
| Seroquel                                                                                   |                             |                    | S                  |                 | Oral                           |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                   | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Aug-2012                                                                                | 8739793                     | EXPEDITED (15-DAY) | Y                  | OT              | AU-AMGEN-AUSSP2012052346       |                      | 53 YR           | Unknown      | AUS            |
| <u>Preferred Term</u>                                                                      | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Nausea; Orthostatic Hypotension                                                 | Cinacalcet Hydrochloride    |                    |                    | S               |                                | Unk                  |                 | Amgen        |                |
|                                                                                            | Escitalopram Oxalate        |                    |                    | S               |                                | 10 Mg, Qd            | 3 DAY           | Not Reported |                |
|                                                                                            | Lercanidipine               |                    |                    | S               |                                | 10 Mg, Qd            |                 | Not Reported |                |
|                                                                                            | Telmisartan                 |                    |                    | S               |                                | 40 Mg, Unk           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                   | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Aug-2012                                                                                | 8750210                     | DIRECT             | Y                  | OT              |                                |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                      | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Blood Pressure Increased; Dysphagia; Product Substitution Issue; Throat Tightness | Escitalopram Oxalate        |                    |                    | S               | Oral                           | 1.5 Tabs, Daily, Po  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                   | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Aug-2012                                                                                | 8634243                     | EXPEDITED (15-DAY) | N                  | OT              | TR-US-EMD SERONO, INC.-7122142 |                      |                 | Female       | TUR            |
| <u>Preferred Term</u>                                                                      | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Test Abnormal; Cholelithiasis; Hepatic Enzyme Increased                              | Rebif                       |                    |                    | S               | Subcutaneous                   |                      |                 | Not Reported |                |
|                                                                                            | Rebif                       |                    |                    | S               |                                |                      |                 | Not Reported |                |
|                                                                                            | Spasmex (Trospium Chloride) |                    |                    | S               | Oral                           |                      |                 | Not Reported |                |
|                                                                                            | Famotidine                  |                    |                    | S               | Oral                           |                      |                 | Not Reported |                |
|                                                                                            | Cipralext                   |                    |                    | S               | Oral                           |                      |                 | Not Reported |                |
|                                                                                            | Aspirin                     |                    |                    | S               | Oral                           |                      |                 | Not Reported |                |
|                                                                                            | Levothyroxine Sodium        |                    |                    | S               | Oral                           |                      | 4 YR            | Not Reported |                |

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

| Tegretol                                                                                                           |                                    |                    | S                  |                 | Oral                 |                      | Not Reported    |              |                |
|--------------------------------------------------------------------------------------------------------------------|------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| <u>FDA Received Date</u>                                                                                           | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Aug-2012                                                                                                        | 8743441                            | EXPEDITED (15-DAY) | Y                  | OT              | FR-FRI-1000038117    |                      | 41 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                              | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Withdrawal Syndrome                                                                                                | Escitalopram Oxalate               |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                                                                                                    | Escitalopram Oxalate               |                    |                    | S               | Oral                 | 5 Mg                 |                 | Forest       |                |
|                                                                                                                    | Escitalopram Oxalate               |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                    | Xanax                              |                    |                    | C               | Oral                 | 3 Df                 |                 | Not Reported |                |
|                                                                                                                    | Stilnox                            |                    |                    | C               | Oral                 | Not Regular Intake   |                 | Not Reported |                |
|                                                                                                                    | Theralene                          |                    |                    | C               | Oral                 | 15 To 20 Drops       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                           | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Aug-2012                                                                                                        | 8743446                            | EXPEDITED (15-DAY) | Y                  | CA              | FR-FRI-1000038120    |                      | < 1 DAY         | Male         | FRA            |
| <u>Preferred Term</u>                                                                                              | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypospadias; Maternal Exposure During Pregnancy                                                                    | Escitalopram Oxalate               |                    |                    | S               | Transplacental       |                      |                 | Forest       |                |
|                                                                                                                    | Aceprometazine Maleate\Meprobamate |                    |                    | S               | Transplacental       |                      |                 | Not Reported |                |
|                                                                                                                    | Prazepam                           |                    |                    | S               | Transplacental       |                      |                 | Not Reported |                |
|                                                                                                                    | Atarax                             |                    |                    | S               | Transplacental       |                      |                 | Not Reported |                |
|                                                                                                                    |                                    |                    |                    |                 |                      |                      |                 |              |                |
| <u>FDA Received Date</u>                                                                                           | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Aug-2012                                                                                                        | 8750297                            | DIRECT             | N                  | HO              |                      |                      | 34 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                              | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Coordination Abnormal; Disturbance In Attention; Dizziness; Dystonia; Headache; Heart Rate Increased; Hot | Lexapro                            |                    |                    | S               | Oral                 | 10 Mg Oral           | 12 HR           | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Flush; Incoherent;  
Nausea; Serotonin  
Syndrome; Syncope;  
Visual Impairment

| <u>FDA Received Date</u>                                                                                                     | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| 24-Aug-2012                                                                                                                  | 8750456              | DIRECT             | Y                  | RI              |                              |                      | 21 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                        | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Fatigue; Headache;<br>Irritability; Nausea;<br>Product Substitution Issue;<br>Tremor; Vomiting                               | Escitalopram Oxalate |                    |                    | S               | Oral                         | 20mg Daily Oral      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                     | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Aug-2012                                                                                                                  | 8746431              | EXPEDITED (15-DAY) | N                  | OT              | 2012SP002348                 |                      | 79 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                        | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Crying; Drug Interaction;<br>Hallucination, Auditory;<br>Hallucination, Visual;<br>Somnolence; Toxicity To<br>Various Agents | Lunesta              |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                                                                                              | Lexapro              |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                                                                                                                              | Oxycontin            |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                                                                                                                              | Oxycontin            |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                                                                                                                              | Morphine             |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                                                                                                                              | Vicodin              |                    |                    | C               |                              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                     | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Aug-2012                                                                                                                  | 8746685              | EXPEDITED (15-DAY) | N                  | HO              | US-PFIZER INC-<br>2012207156 |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                        | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Disorder;<br>Headache; Pain;<br>Somnolence                                                                           | Alprazolam           |                    |                    | S               |                              | 80 Mg, Unk           |                 | Pfizer       |                |
|                                                                                                                              | Roxicodone           |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                                                                                                                              | Lexapro              |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                                                                                                                              | Oxycontin            |                    |                    | S               |                              |                      |                 | Not Reported |                |

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

| <u>FDA Received Date</u>                                                        | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|-----------------------------|-----------------|--------------|----------------|
| 27-Aug-2012                                                                     | 8748741                | EXPEDITED (15-DAY) | Y                  | OT              | IT-FRI-1000038157    |                             | 62 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                           | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Balance Disorder;<br>Circulatory Collapse;<br>Nausea; Vision Blurred            | Escitalopram Oxalate   |                    |                    | S               | Oral                 |                             |                 | Forest       |                |
|                                                                                 | Prazepam               |                    |                    | C               |                      |                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                        | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Aug-2012                                                                     | 8683835                | EXPEDITED (15-DAY) |                    | DE              | DE-FRI-1000037256    |                             | 29 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                                           | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Death; Overdose                                                         | Escitalopram           |                    |                    | S               | Oral                 | Suspected Overdose (260 Mg) |                 | Forest       |                |
|                                                                                 | Escitalopram           |                    |                    | S               | Oral                 | 20 Mg                       |                 | Forest       |                |
|                                                                                 | Escitalopram           |                    |                    | S               | Oral                 | 20 Mg                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                        | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Aug-2012                                                                     | 8757567                | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000038156    |                             | 90 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                           | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Anaemia; International Normalised Ratio Increased; Overdose; Subdural Haematoma | Escitalopram           |                    |                    | S               | Oral                 | 5 Mg                        |                 | Forest       |                |
|                                                                                 | Previscan (Fluindione) |                    |                    | S               | Oral                 | 0.25 Df                     |                 | Not Reported |                |
|                                                                                 | Previscan              |                    |                    | S               |                      | Fluindione Overdose Nos     |                 | Not Reported |                |
|                                                                                 | Atorvastatine          |                    |                    | C               |                      | 10 Mg                       |                 | Not Reported |                |
|                                                                                 | Mediatsensyl           |                    |                    | C               |                      |                             |                 | Not Reported |                |
|                                                                                 | Furosemide             |                    |                    | C               |                      |                             |                 | Not Reported |                |
|                                                                                 | Coaprovel              |                    |                    | C               |                      |                             |                 | Not Reported |                |
|                                                                                 | Celiprolol             |                    |                    | C               |                      |                             |                 | Not Reported |                |
|                                                                                 | Forlax                 |                    |                    | C               |                      |                             |                 | Not Reported |                |
|                                                                                 | Ixprim                 |                    |                    | C               |                      |                             |                 | Not Reported |                |
|                                                                                 | Kaleorid               |                    |                    | C               |                      |                             |                 | Not Reported |                |

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

| <u>FDA Received Date</u>                                                             | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 28-Aug-2012                                                                          | 8760251        | DIRECT           | Y                  |                 |                      |                      | 59 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Drug Intolerance; Dry Mouth; Headache; Nausea; Product Substitution Issue | Escitalopram   |                  |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                      | Crestor        |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                      | Spironolactone |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                      | Catapres       |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                      | Tumicelex      |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                      | Singulair      |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                      | Premarin       |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                      | Zyrtec         |                  |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                            | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------|----------------|------------------|--------------------|-----------------|---------------------------------------|----------------------|-----------------|--------------|----------------|
| 28-Aug-2012                                         | 8760603        | DIRECT           |                    | OT              |                                       |                      | 43 YR           | Female       | USA            |
| <u>Preferred Term</u>                               | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Product Substitution Issue; Social Problem | Escitalopram   |                  |                    | S               | Intravenous (not otherwise specified) |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                                                                               | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 28-Aug-2012                                                                                                                                                                                            | 8780355                     | EXPEDITED (15-DAY) | Y                  | HO, OT          | 2012AP002523         |                      | 25 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                                                                                                                                                                  | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiotoxicity; Coma; Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Haemodynamic Instability; Hypocalcaemia; Hypokalaemia; Hypotension; Intentional Overdose; Pulse Absent; | Amitriptyline               |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                        | Fluoxetine                  |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                        | Olanzapine (Olanzapine)     |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                        | Quetiapine                  |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                        | Gabapentin (Gabapentin)     |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                        | Escitalopram                |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                        | Fluoxetine (Fluoxetine)     |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                        | Escitalopram (Escitalopram) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                        | Olanzapine (Olanzapine)     |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                        | Quetiapine (Quetiapine)     |                    |                    | C               |                      |                      |                 | Not Reported |                |

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

|                                                                                                                                                                                          |                        |                         |                    |                 |                                                               |                      |                 |                      |                |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|-------------------------|--------------------|-----------------|---------------------------------------------------------------|----------------------|-----------------|----------------------|----------------|
| Suicidal Ideation;<br>Tachycardia                                                                                                                                                        |                        | Gabapentin (Gabapentin) |                    | C               |                                                               | Not Reported         |                 |                      |                |
| <u>FDA Received Date</u>                                                                                                                                                                 | <u>Case #</u>          | <u>Case Type</u>        | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 29-Aug-2012                                                                                                                                                                              | 8345946                | EXPEDITED (15-DAY)      |                    | DE, HO          | BE-B.I.<br>PHARMACEUTICALS,I<br>NC./RIDGEFIELD-2012-<br>BL-00 |                      | 94 YR           | Male                 | BEL            |
| <u>Preferred Term</u>                                                                                                                                                                    | <u>Product</u>         | <u>Comp.</u>            | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Atrial Fibrillation; Cerebral<br>Haemangioma; Cerebral<br>Haemorrhage;<br>Confusional State;<br>Depression; Drug<br>Interaction; Escherichia<br>Infection; Fall;<br>Hypokalaemia; Sepsis | Pradaxa                |                         |                    | S               |                                                               | 220 Mg               |                 | Boehringer Ingelheim |                |
|                                                                                                                                                                                          | Escitalopram           |                         |                    | S               |                                                               |                      |                 | Not Reported         |                |
|                                                                                                                                                                                          | Mirtazapine            |                         |                    | S               |                                                               |                      |                 | Not Reported         |                |
|                                                                                                                                                                                          | Lasix                  |                         |                    | S               | Oral                                                          | 60 Mg                |                 | Not Reported         |                |
|                                                                                                                                                                                          | Ranitidine             |                         |                    | C               |                                                               |                      |                 | Not Reported         |                |
|                                                                                                                                                                                          | Loramet                |                         |                    | C               |                                                               |                      |                 | Not Reported         |                |
|                                                                                                                                                                                          | Emconcor               |                         |                    | C               |                                                               |                      |                 | Not Reported         |                |
|                                                                                                                                                                                          | Perfusion              |                         |                    | C               |                                                               |                      |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                                                                                                                                 | <u>Case #</u>          | <u>Case Type</u>        | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 29-Aug-2012                                                                                                                                                                              | 8759582                | EXPEDITED (15-DAY)      |                    | OT              | US-FRI-1000038138                                             |                      |                 | Female               | USA            |
| <u>Preferred Term</u>                                                                                                                                                                    | <u>Product</u>         | <u>Comp.</u>            | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Cardiac Disorder;<br>Headache; Pain;<br>Somnolence                                                                                                                                       | Lexapro                |                         |                    | S               |                                                               |                      |                 | Forest               |                |
|                                                                                                                                                                                          | Oxycontin              |                         |                    | S               |                                                               | 80 Mg                |                 | Not Reported         |                |
|                                                                                                                                                                                          | Alprazolam             |                         |                    | S               |                                                               |                      |                 | Not Reported         |                |
|                                                                                                                                                                                          | Roxicodone             |                         |                    | S               |                                                               |                      |                 | Not Reported         |                |
|                                                                                                                                                                                          | Unspecified Ingredient |                         |                    | S               |                                                               |                      |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                                                                                                                                 | <u>Case #</u>          | <u>Case Type</u>        | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 29-Aug-2012                                                                                                                                                                              | 8762410                | NON-EXPEDITED           |                    |                 | US-PFIZER INC-<br>2012210339                                  |                      | 77 YR           | Unknown              | USA            |
| <u>Preferred Term</u>                                                                                                                                                                    | <u>Product</u>         | <u>Comp.</u>            | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Drug Hypersensitivity                                                                                                                                                                    | Neosporin              |                         |                    | S               |                                                               | Unk                  |                 | Pfizer               |                |
|                                                                                                                                                                                          | Lexapro                |                         |                    | S               |                                                               | Unk                  |                 | Not Reported         |                |



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

|                                                                                          | Monopril       |                    | S                  |                 | Unk                       |                      |                 |              | Not Reported   |
|------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
|                                                                                          | Zestoretic     |                    | S                  |                 | Unk                       |                      |                 |              | Not Reported   |
| <u>FDA Received Date</u>                                                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Aug-2012                                                                              | 8762503        | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2012211188  |                      | 81 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity                                                                    | Celebrex       |                    |                    | S               |                           | Unk                  |                 | Pfizer       |                |
|                                                                                          | Codeine        |                    |                    | S               |                           | Unk                  |                 | Not Reported |                |
|                                                                                          | Lexapro        |                    |                    | S               |                           | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Aug-2012                                                                              | 8760934        | EXPEDITED (15-DAY) |                    | HO, OT          | US-FRI-1000038136         |                      | 44 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anger; Crying; Feeling Abnormal; Impaired Driving Ability; Somnolence; Suicidal Ideation | Lexapro        |                    |                    | S               |                           |                      |                 | Forest       |                |
|                                                                                          | Lexapro        |                    |                    | S               |                           |                      |                 | Forest       |                |
|                                                                                          | Topamax        |                    |                    | C               |                           |                      |                 | Not Reported |                |
|                                                                                          | Soma           |                    |                    | C               |                           |                      |                 | Not Reported |                |
|                                                                                          | Hydrocodone    |                    |                    | C               |                           |                      |                 | Not Reported |                |
|                                                                                          | Detrol         |                    |                    | C               |                           |                      |                 | Not Reported |                |
|                                                                                          | Provigil       |                    |                    | C               |                           |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Aug-2012                                                                              | 8761076        | EXPEDITED (15-DAY) |                    | CA, DE          | US-FRI-1000038192         |                      | < 1 DAY         | Male         | USA            |
| <u>Preferred Term</u>                                                                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Congenital Anomaly; Hypoplastic Left Heart Syndrome                                      | Lexapro        |                    |                    | S               | Transplacental            |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Aug-2012                                                                              | 8762328        | EXPEDITED (15-DAY) |                    | DE, HO          | BE-B.I. PHARMACEUTICALS,I |                      | 94 YR           | Male         | BEL            |

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

NC./RIDGEFIELD-2011-  
BL-00

| <u>Preferred Term</u>                                                                                                                                               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------|
| Atrial Fibrillation; Cerebral Haemangioma; Cerebral Haemorrhage; Confusional State; Depression; Drug Interaction; Escherichia Infection; Fall; Hypokalaemia; Sepsis | Pradaxa        |              |            | S           |              | 220 Mg             |                 | Boehringer Ingelheim |
|                                                                                                                                                                     | Escitalopram   |              |            | S           |              |                    |                 | Not Reported         |
|                                                                                                                                                                     | Mirtazapine    |              |            | S           |              |                    |                 | Not Reported         |
|                                                                                                                                                                     | Lasix          |              |            | S           | Oral         | 60 Mg              |                 | Not Reported         |
|                                                                                                                                                                     | Ranitidine     |              |            | C           |              |                    |                 | Not Reported         |
|                                                                                                                                                                     | Loramet        |              |            | C           |              |                    |                 | Not Reported         |
|                                                                                                                                                                     | Emconcor       |              |            | C           |              |                    |                 | Not Reported         |
|                                                                                                                                                                     | Perfusion      |              |            | C           |              |                    |                 | Not Reported         |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Aug-2012              | 8762927       | DIRECT           |                    | OT              |                      |                      | 18 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                                                                              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Apathy; Drug Withdrawal Syndrome; Educational Problem; Homicidal Ideation; Memory Impairment; Mood Swings; Panic Attack; Psychotic Disorder; Shoplifting; Social Problem; Suicidal Ideation; Theft | Lexapro        |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Aug-2012              | 8762936       | DIRECT           |                    |                 |                      |                      | 42 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|---------------------|-----------------|--------------|
| Arthralgia; Cheilitis; Dyspnoea; Heart Rate Irregular; Insomnia; Reaction To Excipient; | Lexapro        |              |            | S           | Oral         | 20 Mg Once A Day Po |                 | Not Reported |

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

Scratch; Therapy  
Cessation; Urticaria

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-Aug-2012              | 8646536       | EXPEDITED (15-DAY) |                    | HO              | FI-FRI-1000036744    |                      |            | Female     | FIN            |

| <u>Preferred Term</u>                                          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Deafness Unilateral;<br>Nausea; Vertigo; Vertigo<br>Positional | Escitalopram   |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                                                | Escitalopram   |              |            | S           | Oral         | 5 Mg               |                 | Forest       |
|                                                                | Escitalopram   |              |            | S           | Oral         | 10 Mg              |                 | Not Reported |
|                                                                | Atacand        |              |            | S           | Oral         | 8 Mg               |                 | Not Reported |
|                                                                | Aciclovir      |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                | Progynova      |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                | Nexium         |              |            | C           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-Aug-2012              | 8764255       | EXPEDITED (15-DAY) |                    | OT              | VE-FRI-1000038254    |                      | 25 YR      | Female     | VEN            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Scleroderma           | Lexapro        |              |            | S           | Oral         | 2 Mg               |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-Aug-2012              | 8764454       | EXPEDITED (15-DAY) |                    | CA, DE          | US-FRI-1000027276    |                      |            | Unknown    | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|------------|
| Spina Bifida          | Lexapro        |              |            | S           | Transplacental | 20 Mg              |                 | Forest     |
|                       | Lexapro        |              |            | S           |                |                    |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-Aug-2012              | 8780050       | DIRECT           | Y                  |                 |                      |                      | 14 YR      | Female     | USA            |

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

| <u>Preferred Term</u>                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Fatigue; Product Substitution Issue      | Lexapro        |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Sep-2012                              | 8766833        | EXPEDITED (15-DAY) |                    | OT              | DE-FRI-1000021654    |                      |                 | Female       | DEU            |
| <u>Preferred Term</u>                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Electrocardiogram Qt Prolonged           | Escitalopram   |                    |                    | S               | Oral                 | 5 Mg                 |                 | Forest       |                |
| <u>FDA Received Date</u>                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Sep-2012                              | 8767559        | EXPEDITED (15-DAY) |                    | OT              | NO-FRI-1000038256    |                      |                 | Female       | NOR            |
| <u>Preferred Term</u>                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Apathy; Balance Disorder;                | Escitalopram   |                    |                    | S               |                      | 40 Mg                |                 | Forest       |                |
| Burning Sensation;                       | Escitalopram   |                    |                    | S               |                      | 20 Mg                |                 | Forest       |                |
| Decreased Appetite;                      | Escitalopram   |                    |                    | S               |                      | 5 Mg                 |                 | Not Reported |                |
| Medication Error; Memory                 | Imovane        |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Impairment; Mobility                     | Marevan        |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Decreased; Neurological                  |                |                    |                    |                 |                      |                      |                 | Not Reported |                |
| Symptom; Pain;                           |                |                    |                    |                 |                      |                      |                 | Not Reported |                |
| Prescribed Overdose                      |                |                    |                    |                 |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Sep-2012                              | 8780208        | DIRECT             | Y                  |                 |                      |                      | 17 YR           | Female       | USA            |
| <u>Preferred Term</u>                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Irritability; Product Substitution Issue | Escitalopram   |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Sep-2012                              | 8768401        | EXPEDITED (15-DAY) |                    | OT              | HU-ROCHE-1111384     |                      | 53 YR           | Female       | HUN            |

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

| <u>Preferred Term</u>                                                      | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Aortic Valve Incompetence; Left Atrial Enlargement; Sinus Node Dysfunction | Clonazepam           |              |            | S           | Unknown      | Dose: 1-1-2 Mg     |                 | Not Reported |
|                                                                            | Clonazepam           |              |            | S           | Unknown      | Dose: 0.5-0.5-3 Mg |                 | Not Reported |
|                                                                            | Quetiapine Fumarate  |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                            | Carbamazepine        |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                            | Escitalopram         |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                            | Lithium Carbonate    |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                            | Lithium Carbonate    |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                            | Clonazepam           |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                            | Atorvastatin         |              |            | C           |              |                    |                 | Not Reported |
|                                                                            | Levothyroxin         |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                            | Ketoconazole         |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                            | Amiloride            |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                            | Hydrochlorothiazide  |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                            | Acetylsalicylic Acid |              |            | C           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Sep-2012              | 8771147       | EXPEDITED (15-DAY) |                    | OT              | JP-FRI-1000038347    |                      | 72 YR      | Male       | JPN            |

| <u>Preferred Term</u> | <u>Product</u>   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Seizure               | Lexapro          |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                       | Sermion          |              |            | C           | Oral         | 15 Mg              |                 | Not Reported |
|                       | Depas (Etizolam) |              |            | C           | Oral         | 0.5 Mg             |                 | Not Reported |
|                       | Depas            |              |            | C           | Oral         | 1 Mg               |                 | Not Reported |
|                       | Etisedan         |              |            | C           | Oral         | 1 Mg               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Sep-2012              | 8771155       | EXPEDITED (15-DAY) |                    | LT              | JP-FRI-1000038270    |                      | 33 YR      | Male       | JPN            |

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

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|                                             |            |   |      |        |              |
|---------------------------------------------|------------|---|------|--------|--------------|
| Drug-Induced Liver Injury;<br>Off Label Use | Lexapro    | S | Oral | 10 Mg  | Forest       |
|                                             | Lexotan    | C | Oral | 4 Mg   | Not Reported |
|                                             | Rebamipide | C | Oral | 300 Mg | Not Reported |
|                                             | Urso       | C | Oral | 300 Mg | Not Reported |
|                                             | Tapizol    | C | Oral | 30 Mg  | Not Reported |
|                                             | Medetax    | C | Oral |        | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Sep-2012              | 8771483       | EXPEDITED (15-DAY) |                    | HO              | AU-FRI-1000038311    |                      | 66 YR      | Female     | AUS            |

| <u>Preferred Term</u>              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Bradycardia; Loss Of Consciousness | Escitalopram   |              |            | S           | Oral         | 5 Mg               |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Sep-2012              | 8717455       | EXPEDITED (15-DAY) |                    | LT              | JP-FRI-1000037712    |                      | 63 YR      | Male       | JPN            |

| <u>Preferred Term</u>                           | <u>Product</u>                                       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------|------------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Activation Syndrome;<br>Delusion; Hallucination | Lexapro                                              |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                                 | Lexapro                                              |              |            | S           | Oral         | 20 Mg              |                 | Forest       |
|                                                 | Lexapro                                              |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                                 | Remeron                                              |              |            | S           | Oral         | 45 Mg              |                 | Not Reported |
|                                                 | Zyprexa                                              |              |            | C           | Oral         | 2.5 Mg             |                 | Not Reported |
|                                                 | Zyprexa                                              |              |            | C           | Oral         | 5 Mg               |                 | Not Reported |
|                                                 | Zyprexa                                              |              |            | C           | Oral         | 7.5 Mg             |                 | Not Reported |
|                                                 | Zyprexa                                              |              |            | C           | Oral         | 10 Mg              |                 | Not Reported |
|                                                 | Meilax                                               |              |            | C           | Oral         | 2 Mg               |                 | Not Reported |
|                                                 | Solanax                                              |              |            | C           | Oral         | 0.4 Mg             |                 | Not Reported |
|                                                 | Amlodin Od                                           |              |            | C           | Oral         | 5 Mg               |                 | Not Reported |
|                                                 | Glycyron (Ammonium Glycyrrhizate)\Glycine\ Racemethi |              |            | C           | Oral         |                    |                 | Not Reported |

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

online)

| <a href="#">FDA Received Date</a>                                      | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 06-Sep-2012                                                            | 8784686                 | DIRECT                    |                             | OT                       |                               |                               | 61 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                         | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Anger; Anger; Product Substitution Issue; Sleep Disorder; Sleep Terror | Lexapro                 |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                      | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 07-Sep-2012                                                            | 8773336                 | EXPEDITED (15-DAY)        |                             | DE                       | AU-FRI-1000038423             |                               | 34 YR                    | Female              | AUS                     |
| <a href="#">Preferred Term</a>                                         | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Overdose                                                               | Lexapro                 |                           |                             | S                        | Oral                          |                               |                          | Forest              |                         |
|                                                                        | Lexapro                 |                           |                             | S                        | Oral                          | Overdose: Unknown Dose        |                          | Forest              |                         |
|                                                                        | Olanzapine              |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
|                                                                        | Olanzapine              |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
|                                                                        | Oxazepam                |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
|                                                                        | Oxazepam                |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
|                                                                        | Temazepam               |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
|                                                                        | Temazepam               |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                      | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 07-Sep-2012                                                            | 8789202                 | DIRECT                    |                             |                          |                               |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>                                         | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Ineffective; Product Quality Issue                                | Escitalopram            |                           |                             | S                        | Oral                          |                               |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>                                      | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 10-Sep-2012                                                            | 7878648                 | EXPEDITED (15-DAY)        |                             | HO                       | US-ASTRAZENECA-2011SE11145    |                               | 59 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                         | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |

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|                                                                                          |                |   |                             |         |              |
|------------------------------------------------------------------------------------------|----------------|---|-----------------------------|---------|--------------|
| Arthralgia; Back Disorder;<br>Crying; Dysphonia;<br>Dyspnoea; Gait<br>Disturbance;       | Symbicort Pmdi | S | Respiratory<br>(inhalation) | Unknown | Not Reported |
| Gastrooesophageal Reflux<br>Disease; Hypoaesthesia;<br>Hypoaesthesia;                    | Nexium         | S | Oral                        |         | Not Reported |
| Incontinence; Malaise;<br>Malaise; Muscle Spasms;                                        | Crestor        | S | Oral                        |         | Not Reported |
| Nausea; Nervousness;<br>Product Dose Omission;<br>Sensation Of Foreign<br>Body; Vomiting | Lexapro        | S | Unknown                     |         | Not Reported |
|                                                                                          | Lexapro        | S | Unknown                     | Generic | Not Reported |
|                                                                                          | Pristiq        | C |                             |         | Not Reported |
|                                                                                          | Actinel        | C |                             |         | Not Reported |
|                                                                                          | Osteoforte     | C |                             |         | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Sep-2012              | 8789606       | DIRECT           | Y                  |                 |                      |                      | 53 YR      | Female     | USA            |

| <u>Preferred Term</u>         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------|----------------|--------------|------------|-------------|--------------|-----------------------|-----------------|--------------|
| Panic Attack;<br>Paraesthesia | Doxycycline    |              |            | S           | Oral         |                       |                 | Not Reported |
|                               | Lexapro        |              |            | S           | Oral         | 1/2 Dose Approx 12/04 |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Sep-2012              | 8742965       | EXPEDITED (15-DAY) |                    | LT              | JP-FRI-1000037753    |                      | 34 YR      | Male       | JPN            |

| <u>Preferred Term</u>                                                                                                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Activation Syndrome;<br>Delirium; Dizziness;<br>Insomnia; Memory<br>Impairment; Nausea;<br>Palpitations; Suicide<br>Attempt | Escitalopram   |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                                                                                                             | Solanax        |              |            | C           | Oral         | 0.4 Mg             |                 | Not Reported |
|                                                                                                                             | Huscode        |              |            | C           | Oral         | 9 Dosage Forms     |                 | Not Reported |
|                                                                                                                             | Geninax        |              |            | C           | Oral         | 400 Mg             |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Sep-2012              | 8767567       | EXPEDITED (15-DAY) |                    | OT              | IT-FRI-1000038299    |                      | 36 YR      | Female     | ITA            |

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



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

|                                         |              |   |      |        |              |
|-----------------------------------------|--------------|---|------|--------|--------------|
| Loss Of Consciousness;<br>Off Label Use | Escitalopram | S | Oral | 20 Mg  | Forest       |
|                                         | Largactil    | S | Oral | 150 Mg | Not Reported |
|                                         | Tegretol     | C | Oral | 800 Mg | Not Reported |
|                                         | Seroquel     | C | Oral | 300 Mg | Not Reported |
|                                         | Lendormin    | C | Oral |        | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 11-Sep-2012              | 8770943       | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-<br>2012212509 |                      | 57 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                              | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abnormal Dreams;<br>Asthenia; Diarrhoea; Drug<br>Ineffective; Hyperhidrosis;<br>Insomnia; Nausea;<br>Nervousness; Palpitations;<br>Panic Disorder; Parosmia;<br>Retching; Weight<br>Decreased; Weight<br>Increased | Pristiq              |              |            | S           |              | Unk                |                 | Pfizer       |
|                                                                                                                                                                                                                    | Pristiq              |              |            | S           |              | 50 Mg, 1x/Day      |                 | Pfizer       |
|                                                                                                                                                                                                                    | Effexor              |              |            | S           |              | Unk                |                 | Pfizer       |
|                                                                                                                                                                                                                    | Viibryd              |              |            | S           | Oral         | 10 Mg, 1x/Day      |                 | Not Reported |
|                                                                                                                                                                                                                    | Viibryd              |              |            | S           | Oral         | 20 Mg, 1x/Day      |                 | Not Reported |
|                                                                                                                                                                                                                    | Citalopram           |              |            | S           |              | 20 Mg, 1x/Day      |                 | Not Reported |
|                                                                                                                                                                                                                    | Lexapro              |              |            | S           |              | Unk                |                 | Not Reported |
|                                                                                                                                                                                                                    | Celexa               |              |            | C           |              | Unk                |                 | Not Reported |
|                                                                                                                                                                                                                    | Wellbutrin           |              |            | C           |              | Unk                |                 | Not Reported |
|                                                                                                                                                                                                                    | Abilify              |              |            | C           |              | Unk                |                 | Not Reported |
|                                                                                                                                                                                                                    | Levothyroxine Sodium |              |            | C           |              | 75 Ug, 1x/Day      |                 | Not Reported |
|                                                                                                                                                                                                                    | Glucosamine          |              |            | C           |              | Unk                |                 | Not Reported |
|                                                                                                                                                                                                                    | Chondroitin          |              |            | C           |              | Unk                |                 | Not Reported |
|                                                                                                                                                                                                                    | Fish Oil             |              |            | C           |              | Unk                |                 | Not Reported |
|                                                                                                                                                                                                                    | Baby Aspirin         |              |            | C           |              | Unk, As Needed     |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 11-Sep-2012              | 8777064       | EXPEDITED (15-DAY) |                    | OT              | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>16863078 |                      | 20 YR      | Male       | USA            |

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

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|                                                                                                                                                                    |                    |   |                                                                                                                   |              |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|---|-------------------------------------------------------------------------------------------------------------------|--------------|
| Abnormal Behaviour;<br>Depression; Expired<br>Product Administered;<br>Feeling Jittery; Mania;<br>Muscle Twitching; Wrong<br>Technique In Product<br>Usage Process | Abilify Tabs 10 Mg | S | Feb12:5mg/D,2d69670,Ex<br>p:Mr15;10mg:0f596898a,E<br>xpmy12;10mg:0f60008a.E<br>xpjl12,2.5mg<br>1df:1/2tabso(10mg) | Not Reported |
|                                                                                                                                                                    | Lithium            | S |                                                                                                                   | Not Reported |
|                                                                                                                                                                    | Escitalopram       | S |                                                                                                                   | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Sep-2012              | 8777496       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000038452    |                      | 59 YR      | Female     | FRA            |

| <u>Preferred Term</u>                | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Eczema; Photosensitivity<br>Reaction | Escitalopram            |              |            | S           |              | 1 Df On Request    |                 | Forest       |
|                                      | Ketum                   |              |            | S           | Cutaneous    | 1 Df On Request    |                 | Not Reported |
|                                      | Toplexil (Oxomemazine)  |              |            | S           |              | 1 Df On Request    |                 | Not Reported |
|                                      | Pyostacine              |              |            | C           |              | 3000 Mg            |                 | Not Reported |
|                                      | Solupred (Prednisolone) |              |            | C           |              |                    |                 | Not Reported |
|                                      | Diprosone               |              |            | C           |              |                    |                 | Not Reported |
|                                      | Orbenine                |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Sep-2012              | 8777677       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000038449    |                      | 79 YR      | Female     | FRA            |

| <u>Preferred Term</u>             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Pruritus; Rash Maculo-<br>Papular | Escitalopram   |              |            | S           | Oral         | 5 Mg               |                 | Forest       |
|                                   | Dalacine       |              |            | S           | Oral         | 2700 Mg            |                 | Not Reported |
|                                   | Oflocet        |              |            | C           | Oral         | 600 Mg             |                 | Not Reported |
|                                   | Lovenox        |              |            | C           | Subcutaneous |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Sep-2012              | 8673889       | EXPEDITED (15-DAY) |                    |                 | FR-FRI-1000037215    |                      | 20 YR      | Female     | FRA            |

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

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

|                                         |              |   |      |       |              |
|-----------------------------------------|--------------|---|------|-------|--------------|
| Haematoma; Menorrhagia;<br>Metrorrhagia | Escitalopram | S | Oral | 10 Mg | Forest       |
|                                         | Escitalopram | S | Oral | 5 Mg  | Forest       |
|                                         | Varnoline    | C | Oral | 1 Df  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Sep-2012              | 8778661       | EXPEDITED (15-DAY) |                    | OT              | CA-FRI-1000038509    |                      |            | Female     | CAN            |

| <u>Preferred Term</u>                                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Choking; Dry Mouth; Dry Throat; Dysphagia; Panic Reaction | Escitalopram   |              |            | S           | Oral         | 15 Mg              |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Sep-2012              | 8790508       | DIRECT           |                    | OT              |                      |                      | 72 YR      | Female     | USA            |

| <u>Preferred Term</u>                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Anxiety; Panic Attack; Product Substitution Issue | Escitalopram   |              |            | S           | Oral         | 20mg Per Day Po    |                 | Teva       |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 13-Sep-2012              | 8780695       | EXPEDITED (15-DAY) |                    | HO              | CH-ASTRAZENECA-2012SE69865 |                      | 84 YR      | Female     | CHE            |

| <u>Preferred Term</u>                                                                                                      | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------|-------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Colitis;<br>Gastroesophageal Reflux Disease; Haematemesis; Hiatus Hernia; Hypochromic Anaemia; Intestinal Ulcer; Pneumonia | Sequase                       |              |            | S           | Oral         |                    |                 | Zeneca       |
|                                                                                                                            | Cipralext                     |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                            | Tilur                         |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                            | Novalgine (Metamizole Sodium) |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                                            | Calcimagon D3                 |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                                            | Omezol                        |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                                            | Lithium Aspartate             |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                                            | Neurontin                     |              |            | C           | Oral         |                    |                 | Not Reported |

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

|                                                                        |                |                    |                    |                 |                      |                      |                 |              |                |
|------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
|                                                                        | Requip         | C                  | Oral               |                 |                      |                      |                 | Not Reported |                |
|                                                                        | Madopar        | C                  | Oral               |                 |                      |                      |                 | Not Reported |                |
|                                                                        | Detrusitol     | C                  | Oral               |                 |                      |                      |                 | Not Reported |                |
|                                                                        | Motilium       | C                  | Oral               |                 |                      |                      |                 | Not Reported |                |
|                                                                        | Euthyrox       | C                  | Oral               |                 |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Sep-2012                                                            | 8784319        | EXPEDITED (15-DAY) |                    | OT              | JP-FRI-1000025531    |                      | 25 YR           | Male         | JPN            |
| <u>Preferred Term</u>                                                  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Altered State Of Consciousness; Seizure                                | Lexapro        |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
| <u>FDA Received Date</u>                                               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Sep-2012                                                            | 8790925        | DIRECT             |                    | OT              |                      |                      | 54 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Feeling Jittery; Nausea; Unevaluable Event; Vomiting                   | Escitalopram   |                    |                    | S               | Oral                 | 20mg Qd Po           |                 | Mylan        |                |
|                                                                        | Omeprazole     |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                        | Monelukast     |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                        | Loratidine     |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                        | Simvastatin    |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                        | Doxycycline    |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                        | Ativan         |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Sep-2012                                                            | 8790933        | DIRECT             |                    | OT              |                      |                      | 30 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Maternal Exposure Timing                                   | Escitalopram   |                    |                    | S               | Oral                 |                      |                 | Teva         |                |
| Unspecified; Panic Attack; Pregnancy; Product Substitution Issue; Rash | Escitalopram   |                    |                    | S               | Oral                 |                      |                 | Teva         |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                 | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| 14-Sep-2012                                                                                              | 8666160              | EXPEDITED (15-DAY) |                    | HO              | JP-ASTRAZENECA-2012SE47527   |                      | 39 YR           | Female       | FIN            |
| <u>Preferred Term</u>                                                                                    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Deafness Unilateral;<br>Nausea; Vertigo; Vertigo<br>Positional                                           | Atacand              |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                                                                          | Cipralelex           |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                                                                          | Cipralelex           |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                                                                          | Cipralelex           |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                                                                          | Aciclovir            |                    |                    | C               | Oral                         |                      |                 | Not Reported |                |
|                                                                                                          | Estradiol            |                    |                    | C               | Oral                         |                      |                 | Not Reported |                |
|                                                                                                          | Esomeprazole Sodium  |                    |                    | C               | Oral                         |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                 | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Sep-2012                                                                                              | 8771772              | EXPEDITED (15-DAY) |                    | HO, OT          | HU-ABBOTT-12P-076-0975861-00 |                      | 53 YR           | Female       | HUN            |
| <u>Preferred Term</u>                                                                                    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrial Fibrillation; Atrial<br>Tachycardia; Fatigue;<br>Palpitations; Sinus Arrest;<br>Sinus Bradycardia | Levothyroxine        |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                                                                                                          | Escitalopram         |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                                                                                                          | Quetiapine           |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                                                                                                          | Amiloride            |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                                                                                                          | Hydrochlorothiazide  |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                                                                                                          | Acetylsalicylic Acid |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                                                                                                          | Clonazepam           |                    |                    | S               |                              | 0.5-0.5-3 Mg         |                 | Not Reported |                |
|                                                                                                          | Clonazepam           |                    |                    | S               |                              | 1-1-2 Mg             |                 | Not Reported |                |
|                                                                                                          | Cinolazepam          |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                                                                                                          | Ketoconazole         |                    |                    | S               |                              | Intertrigo           |                 | Not Reported |                |
|                                                                                                          | Lithium Carbonate    |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                                                                                                          | Lithium Carbonate    |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                                                                                                          | Carbamazepine        |                    |                    | S               |                              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                 | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Sep-2012                                                                                              | 8791346              | DIRECT             |                    | LT, OT          |                              |                      | 89 YR           | Male         | USA            |

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

| <u>Preferred Term</u>                                                                                                                                                                               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                                              | <u>Duration</u> | <u>Mfr</u>   |                |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|--------------------------|-----------------------------------------------------------------|-----------------|--------------|----------------|
| Abnormal Behaviour;<br>Adjustment Disorder With<br>Depressed Mood;<br>Confusional State;<br>Imprisonment; Lethargy;<br>Malaise; Nausea; Physical<br>Assault; Suicidal Ideation;<br>Weight Decreased | Lexapro              |                    |                    | S               | Oral                     | From May 1st To May 8th<br>1st Time From June 8th<br>To June 30 |                 | Teva         |                |
|                                                                                                                                                                                                     | Namenda              |                    |                    | C               |                          |                                                                 |                 | Not Reported |                |
|                                                                                                                                                                                                     | Aricept              |                    |                    | C               |                          |                                                                 |                 | Not Reported |                |
|                                                                                                                                                                                                     | Axona Medical Food   |                    |                    | C               |                          |                                                                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                                            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Sep-2012                                                                                                                                                                                         | 8766627              | EXPEDITED (15-DAY) |                    | HO, OT          | HU-FRI-1000038249        |                                                                 | 53 YR           | Female       | HUN            |
| <u>Preferred Term</u>                                                                                                                                                                               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                                              | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrial Fibrillation; Atrial<br>Tachycardia; Fatigue;<br>Palpitations; Sinus Arrest;<br>Sinus Bradycardia                                                                                            | Escitalopram         |                    |                    | S               |                          |                                                                 |                 | Forest       |                |
|                                                                                                                                                                                                     | Lithium Carbonate    |                    |                    | S               |                          | 1000 Mg                                                         |                 | Not Reported |                |
|                                                                                                                                                                                                     | Quetiapine           |                    |                    | S               |                          | 200 Mg                                                          |                 | Not Reported |                |
|                                                                                                                                                                                                     | Amiloride            |                    |                    | S               |                          |                                                                 |                 | Not Reported |                |
|                                                                                                                                                                                                     | Hydrochlorothiazide  |                    |                    | S               |                          |                                                                 |                 | Not Reported |                |
|                                                                                                                                                                                                     | Acetylsalicylic Acid |                    |                    | S               |                          |                                                                 |                 | Not Reported |                |
|                                                                                                                                                                                                     | Levothyroxin         |                    |                    | S               |                          |                                                                 |                 | Not Reported |                |
|                                                                                                                                                                                                     | Clonazepam           |                    |                    | S               |                          | 0.5-0.5-3 Mg                                                    |                 | Not Reported |                |
|                                                                                                                                                                                                     | Cinolazepam          |                    |                    | S               |                          |                                                                 |                 | Not Reported |                |
|                                                                                                                                                                                                     | Ketoconazole         |                    |                    | S               |                          |                                                                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                                            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Sep-2012                                                                                                                                                                                         | 8792741              | EXPEDITED (15-DAY) |                    | HO              | FR-BAYER-2012-<br>094203 |                                                                 | 21 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                                              | <u>Duration</u> | <u>Mfr</u>   |                |
| Aplasia; Dyspnoea;<br>Ecchymosis;<br>Haemorrhagic Disorder;<br>Infection; Menorrhagia                                                                                                               | Yaz                  |                    |                    | S               | Oral                     | 1 Df, Qd                                                        |                 | Bayer        |                |
|                                                                                                                                                                                                     | Seroplex             |                    |                    | S               | Oral                     | Unk                                                             |                 | Not Reported |                |
|                                                                                                                                                                                                     | Xanax                |                    |                    | S               | Oral                     | Unk                                                             |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                        | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------------------------------------------------------------------------|-----------------|--------------|----------------|
| 18-Sep-2012                                     | 8799217        | DIRECT             | Y                  | OT              |                      |                                                                                        | 22 YR           | Female       | USA            |
| <u>Preferred Term</u>                           | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Movement Disorder                               | Sertraline     |                    |                    | S               | Oral                 | 50 - 100mg Daily Po<br>12/20/2011 - 8/20/12;<br>8/31/12 To Present But<br>Tapering Off |                 | Not Reported |                |
|                                                 | Escitalopram   |                    |                    | S               | Oral                 | 50 - 100mg Daily Po<br>12/20/2011 - 8/20/12;<br>8/31/12 To Present But<br>Tapering Off |                 | Not Reported |                |
|                                                 |                |                    |                    |                 |                      | 10mg Daily Po                                                                          |                 |              |                |
| <u>FDA Received Date</u>                        | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Sep-2012                                     | 8806331        | DIRECT             |                    | DS, LT          |                      |                                                                                        | 64 YR           | Female       | USA            |
| <u>Preferred Term</u>                           | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective; Product<br>Substitution Issue | Escitalopram   |                    |                    | S               |                      |                                                                                        |                 | Teva         |                |
| <u>FDA Received Date</u>                        | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Sep-2012                                     | 8709886        | EXPEDITED (15-DAY) |                    | OT              | JP-FRI-1000037584    |                                                                                        | 18 YR           | Female       | JPN            |
| <u>Preferred Term</u>                           | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Self-Injury;<br>Wound               | Lexapro        |                    |                    | S               | Oral                 | 20 Mg                                                                                  |                 | Forest       |                |
|                                                 | Cymbalta       |                    |                    | C               | Oral                 | 40 Mg                                                                                  |                 | Not Reported |                |
|                                                 | Lendormin D    |                    |                    | C               | Oral                 | 0.25 Mg                                                                                |                 | Not Reported |                |
|                                                 | Evamyl         |                    |                    | C               | Oral                 | 1 Mg                                                                                   |                 | Not Reported |                |
|                                                 | Abilify        |                    |                    | C               | Oral                 | 2 Mg                                                                                   |                 | Not Reported |                |
|                                                 | Halcion        |                    |                    | C               | Oral                 |                                                                                        |                 | Not Reported |                |
|                                                 | Somelin        |                    |                    | C               | Oral                 |                                                                                        |                 | Not Reported |                |

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

|                  |   |      |              |
|------------------|---|------|--------------|
| Solanax          | C | Oral | Not Reported |
| Depas (Etizolam) | C | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Sep-2012              | 8712210       | EXPEDITED (15-DAY) |                    | OT              | JP-FRI-1000037588    |                      | 19 YR      | Female     | JPN            |

| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Intentional Self-Injury | Lexapro        |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                         | Wypax          |              |            | C           | Oral         | 0.5 Mg             |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 19-Sep-2012              | 8796173       | EXPEDITED (15-DAY) |                    | HO              | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>16946972 |                      | 70 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                            | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|-------------------------------------------------------------------------------|-----------------|--------------|
| Fatigue; Feeling Abnormal; Knee Arthroplasty; Pain; Wrong Technique In Product Usage Process | Abilify        |              |            | S           |              | 20mg Abilify Tab In Half. Currently On 10 Mg Once Daily(By Breaking Half Tab) |                 | Not Reported |
|                                                                                              | Lexapro        |              |            | S           |              |                                                                               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 19-Sep-2012              | 8799481       | NON-EXPEDITED    |                    |                 | US-PFIZER INC-<br>2012230063 |                      | 48 YR      | Female     | USA            |

| <u>Preferred Term</u>                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Adverse Drug Reaction; Drug Ineffective | Effexor        |              |            | S           |              | Unk                |                 | Pfizer       |
|                                         | Trazodone Hcl  |              |            | S           |              | Unk                |                 | Unknown      |
|                                         | Paxil          |              |            | S           |              | Unk                |                 | Not Reported |
|                                         | Celexa         |              |            | S           |              | Unk                |                 | Not Reported |
|                                         | Lexapro        |              |            | S           |              | Unk                |                 | Not Reported |
|                                         | Prozac         |              |            | S           |              | Unk                |                 | Not Reported |
|                                         | Wellbutrin     |              |            | S           |              | Unk                |                 | Not Reported |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|--------------------------|----------------------------|-----------------|--------------|----------------|
| 20-Sep-2012                                                                                                                                                                                  | 7916136        | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2011089062 |                            | 56 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain Upper; Anxiety; Choking Sensation; Drug Ineffective; Drug Interaction; Energy Increased; Fatigue; Flatulence; Gastrooesophageal Reflux Disease; Insomnia; Malaise; Somnolence | Pristiq        |                    |                    | S               | Oral                     | 50 Mg, 1x/Day              |                 | Pfizer       |                |
|                                                                                                                                                                                              | Pristiq        |                    |                    | S               |                          | Unk                        |                 | Pfizer       |                |
|                                                                                                                                                                                              | Zoloft         |                    |                    | S               | Oral                     | Unk                        |                 | Pfizer       |                |
|                                                                                                                                                                                              | Alprazolam     |                    |                    | S               |                          |                            |                 | Pfizer       |                |
|                                                                                                                                                                                              | Lexapro        |                    |                    | S               |                          | Unk                        |                 | Not Reported |                |
|                                                                                                                                                                                              | Restoril       |                    |                    | S               |                          | Unk                        |                 | Not Reported |                |
|                                                                                                                                                                                              | Suboxone       |                    |                    | S               |                          |                            |                 | Not Reported |                |
|                                                                                                                                                                                              | Prilosec       |                    |                    | C               |                          | 20 (Units Unspecified), Qd |                 | Not Reported |                |
|                                                                                                                                                                                              | Valium         |                    |                    | C               |                          | 10 Mg, 3x/Day              |                 | Not Reported |                |
|                                                                                                                                                                                              | Trazodone      |                    |                    | C               |                          | 50 Mg, Hs (At Bedtime)     |                 | Not Reported |                |
|                                                                                                                                                                                              | Xanax          |                    |                    | C               |                          | Unk                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Sep-2012                                                                                                                                                                                  | 8742064        | EXPEDITED (15-DAY) |                    | OT              | IT-PFIZER INC-2012204441 |                            | 17 YR           | Male         | ITA            |
| <u>Preferred Term</u>                                                                                                                                                                        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>   |                |
| Off Label Use; Suicidal Ideation                                                                                                                                                             | Xanax          |                    |                    | S               | Oral                     | 0.5 Mg, Daily              |                 | Pfizer       |                |
|                                                                                                                                                                                              | Xanax          |                    |                    | S               | Oral                     | 1 Mg, Daily                |                 | Pfizer       |                |
|                                                                                                                                                                                              | Cipralex       |                    |                    | S               | Oral                     | 5 Mg, 1x/Day               |                 | Not Reported |                |
|                                                                                                                                                                                              | Cipralex       |                    |                    | S               | Oral                     | 10 Mg, 1x/Day              |                 | Not Reported |                |
|                                                                                                                                                                                              | Cipralex       |                    |                    | S               | Oral                     | 5 Mg, Daily                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Sep-2012                                                                                                                                                                                  | 8798385        | EXPEDITED (15-DAY) |                    | OT              | SE-FRI-1000038717        |                            | 18 YR           | Female       | SWE            |
| <u>Preferred Term</u>                                                                                                                                                                        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>   |                |

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

|                                                                            |              |   |      |                                                               |        |
|----------------------------------------------------------------------------|--------------|---|------|---------------------------------------------------------------|--------|
| Contusion; Menstruation<br>Delayed; Suicidal Ideation;<br>Weight Decreased | Escitalopram | S | Oral | 10 Mg                                                         | Forest |
|                                                                            | Escitalopram | S | Oral | 20 Mg Intermittently For<br>14-16 Days Per Menstrual<br>Cycle | Forest |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Sep-2012              | 8799242       | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000037555    |                      | 55 YR      | Male       | FRA            |

  

| <u>Preferred Term</u>                                                             | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------|-------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Disinhibition; Erectile<br>Dysfunction; Feeling<br>Abnormal; Suicidal<br>Ideation | Escitalopram      |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                                                                   | Antihypertensives |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Sep-2012              | 8799261       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000038754    |                      | 87 YR      | Male       | FRA            |

  

| <u>Preferred Term</u>                                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------|----------------|--------------|------------|-------------|--------------|-----------------------|-----------------|--------------|
| Abdominal Wall<br>Haematoma; Anaemia;<br>Thrombocytopenia | Escitalopram   |              |            | S           | Oral         |                       |                 | Forest       |
|                                                           | Calciparine    |              |            | S           | Subcutaneous | (0.4 MI) - 3 Df Daily |                 | Not Reported |
|                                                           | Kardegic       |              |            | S           | Oral         | 160 Mg                |                 | Not Reported |
|                                                           | Aprovel        |              |            | C           |              |                       |                 | Not Reported |
|                                                           | Trivastal      |              |            | C           |              |                       |                 | Not Reported |
|                                                           | Seresta        |              |            | C           |              |                       |                 | Not Reported |
|                                                           | Tanganil       |              |            | C           |              |                       |                 | Not Reported |
|                                                           | Cordarone      |              |            | C           |              |                       |                 | Not Reported |
|                                                           | Forlax         |              |            | C           |              |                       |                 | Not Reported |
|                                                           | Duphalac       |              |            | C           |              |                       |                 | Not Reported |
|                                                           | Eupressyl      |              |            | C           |              |                       |                 | Not Reported |
|                                                           | Bactrim        |              |            | C           |              |                       |                 | Not Reported |
|                                                           | Amlor          |              |            | C           |              |                       |                 | Not Reported |
|                                                           | Lasilix        |              |            | C           |              |                       |                 | Not Reported |
|                                                           | Lanzoprazole   |              |            | C           |              |                       |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

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| <u>FDA Received Date</u>                                                                                                                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| 20-Sep-2012                                                                                                                                                    | 8799281        | EXPEDITED (15-DAY) |                    | DS, HO, LT, OT  | DE-FRI-1000038760          |                      | < 1 DAY         | Female       | DEU            |
| <u>Preferred Term</u>                                                                                                                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cerebral Haemorrhage Neonatal; Foetal Exposure During Pregnancy; Haemangioma Of Liver; Hypotonia; Seizure; Small For Dates Baby; Subdural Haemorrhage Neonatal | Escitalopram   |                    |                    | S               | Transplacental             | 20 Mg                |                 | Forest       |                |
|                                                                                                                                                                | Escitalopram   |                    |                    | S               | Transplacental             | 10 Mg                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Sep-2012                                                                                                                                                    | 8801187        | NON-EXPEDITED      |                    |                 | US-009507513-1209USA005724 |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Behaviour; Insomnia; Weight Increased                                                                                                                 | Saphris        |                    |                    | S               | Oral                       |                      |                 | Merck        |                |
|                                                                                                                                                                | Fanapt         |                    |                    | S               | Oral                       | 8 Mg, Bid            |                 | Not Reported |                |
|                                                                                                                                                                | Lexapro        |                    |                    | S               |                            |                      |                 | Not Reported |                |
|                                                                                                                                                                | Seroquel       |                    |                    | S               |                            |                      |                 | Not Reported |                |
|                                                                                                                                                                | Risperidone    |                    |                    | S               |                            |                      |                 | Not Reported |                |
|                                                                                                                                                                | Pristiq        |                    |                    | C               |                            |                      |                 | Not Reported |                |
|                                                                                                                                                                | Effexor Xr     |                    |                    | C               |                            |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Sep-2012                                                                                                                                                    | 8777756        | EXPEDITED (15-DAY) |                    | OT              | PHHY2012FR078541           |                      | 64 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Concomitant Disease Progression; Depression; Dyskinesia; Restless Legs Syndrome; Suicidal Ideation                                                             | Femara         |                    |                    | S               |                            |                      |                 | Novartis     |                |
|                                                                                                                                                                | Seroplex       |                    |                    | S               |                            | 5 Mg, Daily          |                 | Not Reported |                |
|                                                                                                                                                                | Fenofibrate    |                    |                    | C               |                            |                      |                 | Not Reported |                |
|                                                                                                                                                                | Sevikar        |                    |                    | C               |                            |                      |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                                                  | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------|----------------------------------|--------------------|--------------------|-----------------|----------------------|--------------------------------|-----------------|--------------|----------------|
| 21-Sep-2012                                                                                               | 8801469                          | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000038842    |                                | 86 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                     | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyponatraemia; Seizure                                                                                    | Escitalopram                     |                    |                    | S               | Oral                 | 10 Mg                          |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                  | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Sep-2012                                                                                               | 8801911                          | EXPEDITED (15-DAY) |                    | HO              | NL-FRI-1000038756    |                                | 69 YR           | Female       | NLD            |
| <u>Preferred Term</u>                                                                                     | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain;<br>Abdominal Pain Upper;<br>Hyperhidrosis; Off Label<br>Use; Panic Attack;<br>Torticollis | Escitalopram                     |                    |                    | S               | Oral                 | 10 Mg                          |                 | Forest       |                |
|                                                                                                           | Propranolol                      |                    |                    | C               |                      | 80 Mg                          |                 | Not Reported |                |
|                                                                                                           | Salazopyrine                     |                    |                    | C               |                      | 1000 Mg                        |                 | Not Reported |                |
|                                                                                                           | Ulcogant                         |                    |                    | C               |                      | 3 Dosage Forms                 |                 | Not Reported |                |
|                                                                                                           | Ascal (Acetylsalicylate Calcium) |                    |                    | C               |                      | 80 Mg                          |                 | Not Reported |                |
|                                                                                                           | Esomeprazol                      |                    |                    | C               |                      | 80 Mg                          |                 | Not Reported |                |
|                                                                                                           | Naproxen                         |                    |                    | C               |                      |                                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                  | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Sep-2012                                                                                               | 8808703                          | DIRECT             | Y                  | OT              |                      |                                | 66 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                     | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Sexual Dysfunction                                                                                        | Lexapro                          |                    |                    | S               | Oral                 | Lexapro 5mg Once Daily<br>Oral | <1 WK           | Not Reported |                |
|                                                                                                           | Lipitor                          |                    |                    | C               |                      |                                |                 | Not Reported |                |
|                                                                                                           | Victoza                          |                    |                    | C               |                      |                                |                 | Not Reported |                |
|                                                                                                           | Metformin                        |                    |                    | C               |                      |                                |                 | Not Reported |                |
|                                                                                                           | Atenolol                         |                    |                    | C               |                      |                                |                 | Not Reported |                |
|                                                                                                           | Norvasc                          |                    |                    | C               |                      |                                |                 | Not Reported |                |
|                                                                                                           | Asa                              |                    |                    | C               |                      |                                |                 | Not Reported |                |
|                                                                                                           | Temazepam                        |                    |                    | C               |                      |                                |                 | Not Reported |                |
|                                                                                                           | Xolatan                          |                    |                    | C               |                      |                                |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                                                             | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|------------------------------|-----------------------|-----------------|--------------|----------------|
| 21-Sep-2012                                                                                                          | 8809034                   | DIRECT             |                    | OT              |                              |                       | 34 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Blood Pressure Increased; Feeling Abnormal; Headache; Nausea; Product Substitution Issue; Suicidal Ideation | Escitalopram              |                    |                    | S               | Oral                         |                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                             | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Sep-2012                                                                                                          | 8771504                   | EXPEDITED (15-DAY) |                    | HO              | FR-ABBOTT-12P-056-0932679-00 |                       |                 | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Dyskinesia                                                                                                           | Seroplex                  |                    |                    | S               | Oral                         |                       |                 | Not Reported |                |
|                                                                                                                      | Domperidone               |                    |                    | S               | Oral                         |                       |                 | Not Reported |                |
|                                                                                                                      | Azilect                   |                    |                    | C               | Oral                         |                       |                 | Not Reported |                |
|                                                                                                                      | Stalevo                   |                    |                    | C               | Oral                         | 100mg/25mg/200mg      |                 | Not Reported |                |
|                                                                                                                      | Requip                    |                    |                    | C               | Oral                         |                       |                 | Not Reported |                |
|                                                                                                                      | Stalevo                   |                    |                    | C               | Oral                         | 50mg/12.5mg/200mg Tid |                 | Not Reported |                |
|                                                                                                                      | Madopar                   |                    |                    | C               | Oral                         | 50mg/12.5mg           |                 | Not Reported |                |
|                                                                                                                      | Detensiel                 |                    |                    | C               | Oral                         |                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                             | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Sep-2012                                                                                                          | 8803948                   | EXPEDITED (15-DAY) |                    | HO              | FR-ABBOTT-12P-056-0970058-00 |                       | 93 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Decreased Appetite; Dehydration; Drug Interaction; Dyspnoea; General Physical Health                                 | Seroplex                  |                    |                    | S               | Oral                         |                       |                 | Not Reported |                |
|                                                                                                                      | Altizide W/Spironolactone |                    |                    | S               | Oral                         |                       |                 | Not Reported |                |
|                                                                                                                      | Cordarone                 |                    |                    | C               | Oral                         |                       |                 | Not Reported |                |

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|                                                             |             |   |      |              |
|-------------------------------------------------------------|-------------|---|------|--------------|
| Deterioration;<br>Hyponatraemia; Renal<br>Failure; Vomiting | Levothyrox  | C | Oral | Not Reported |
|                                                             | Vitamin B12 | C | Oral | Not Reported |
|                                                             | Sterogyl    | C |      | Not Reported |
|                                                             | Lercan      | C |      | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 23-Sep-2012              | 8803998       | EXPEDITED (15-DAY) |                    | HO              | FI-ABBOTT-12P-055-0952935-00 |                      | 39 YR      | Female     | FIN            |

| <u>Preferred Term</u>                                          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Deafness Unilateral;<br>Nausea; Vertigo; Vertigo<br>Positional | Cipralelex     |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                | Cipralelex     |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                | Cipralelex     |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                | Atacand        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                | Aciclovir      |              |            | C           | Oral         | A                  |                 | Not Reported |
|                                                                | Progynova      |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                | Nexium         |              |            | C           | Oral         | A                  |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 23-Sep-2012              | 8804453       | EXPEDITED (15-DAY) |                    | HO, OT          | CA-ABBOTT-12P-028-0976397-00 |                      | 58 YR      | Male       | CAN            |

| <u>Preferred Term</u>              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anger; Anxiety; Suicide<br>Attempt | Cipralelex     |              |            | S           | Oral         |                    |                 | Not Reported |
|                                    | Cipralelex     |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 24-Sep-2012              | 8775084       | EXPEDITED (15-DAY) |                    | DS, HO          | FR-JNJFOC-20120814881 |                      | 71 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cognitive Disorder;<br>Depression; Drug<br>Interaction; Extrapyrimalal<br>Disorder; Fall; General | Durogesic      |              |            | S           | Transdermal  |                    |                 | Not Reported |
|                                                                                                   | Seroplex       |              |            | S           | Oral         | 2 Tablets A Day    |                 | Not Reported |

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

|                                  |                  |   |         |           |              |
|----------------------------------|------------------|---|---------|-----------|--------------|
| Physical Health<br>Deterioration | Inexium          | S | Oral    | Long Term | Not Reported |
|                                  | Hydrocortisone   | C | Oral    | Long-Term | Not Reported |
|                                  | Levothyrox       | C | Oral    | Long-Term | Not Reported |
|                                  | Seresta          | C | Oral    | Long-Term | Not Reported |
|                                  | Zolpidem         | C | Oral    | Long-Term | Not Reported |
|                                  | Parkinane Lp     | C | Oral    |           | Not Reported |
|                                  | Movicol          | C | Unknown |           | Not Reported |
|                                  | Paraffin, Liquid | C | Unknown |           | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Sep-2012              | 8802930       | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000038751    |                      | < 1 DAY    | Female     | USA            |

| <u>Preferred Term</u>                                                                                                               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|------------|
| Atrial Septal Defect;<br>Coarctation Of The Aorta;<br>Congenital Anomaly;<br>Patent Ductus Arteriosus;<br>Ventricular Septal Defect | Lexapro        |              |            | S           | Transplacental |                    |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 24-Sep-2012              | 8804079       | EXPEDITED (15-DAY) |                    | OT              | IT-JNJFOC-20120906913 |                      | 48 YR      | Female     | ITA            |

| <u>Preferred Term</u>                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Intentional Overdose;<br>Intentional Self-Injury | Risperdal      |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Entact         |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 24-Sep-2012              | 8804618       | EXPEDITED (15-DAY) |                    | HO              | BE-ABBOTT-12P-013-0976211-00 |                      | 59 YR      | Female     | BEL            |

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

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

|              |   |      |                   |              |
|--------------|---|------|-------------------|--------------|
| Vitamin B    | C | Oral | 2 Tablets Per Day | Not Reported |
| Simvastatine | C | Oral |                   | Not Reported |
| Asaflow      | C | Oral |                   | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 24-Sep-2012              | 8804876       | EXPEDITED (15-DAY) |                    | HO, LT          | FR-ASTRAZENECA-2012SE73412 |                      | 89 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                                                        | <u>Product</u>                                                                                                      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction; Fall;<br>Head Injury;<br>Hyponatraemia;<br>Inappropriate Antidiuretic<br>Hormone Secretion | Hytacand                                                                                                            |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                              | Seroplex                                                                                                            |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                              | Risperdal                                                                                                           |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                              | Colchicine                                                                                                          |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                              | Codoliprane                                                                                                         |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                              | Tiapridal                                                                                                           |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                              | Transipeg (Polyethylene Glycol 3350\Potassium Chloride\Sodium Bicarbonate\Sodium Chloride\Sodium Sulfate Anhydrous) |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                              | Levophta                                                                                                            |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                              | Xanax                                                                                                               |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                              | Hemigoxine                                                                                                          |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                              | Inipomp                                                                                                             |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 25-Sep-2012              | 8783090       | NON-EXPEDITED    |                    |                 | US-ASTRAZENECA-2012SE70499 |                      | 38 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                           | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Adverse Event; Blood Pressure Increased; Confusional State; Drug Ineffective; Insomnia; Memory Impairment; Memory Impairment; Nasal Congestion; | Lexapro              |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                 | Lexapro              |              |            | S           | Oral         | Generic, Daily     |                 | Not Reported |
|                                                                                                                                                 | Metoprolol Succinate |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                 | Seroquel             |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                 | Seroquel             |              |            | S           | Oral         |                    |                 | Not Reported |



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

|              |                  |   |      |                |  |              |
|--------------|------------------|---|------|----------------|--|--------------|
| Restlessness | Seroquel         | S | Oral |                |  | Not Reported |
|              | Seroquel         | S | Oral |                |  | Not Reported |
|              | Seroquel         | S | Oral | Generic, Daily |  | Not Reported |
|              | Seroquel         | S | Oral | Generic, Daily |  | Not Reported |
|              | Fenofibrate      | C | Oral |                |  | Not Reported |
|              | Psychotropic Med | C |      |                |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Sep-2012              | 8808111       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000038879    |                      | 89 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                                                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|---------------------------|-----------------|--------------|
| Confusional State;<br>General Physical Health<br>Deterioration;<br>Hallucination, Visual | Escitalopram   |              |            | S           | Oral         | 20 Mg                     |                 | Forest       |
|                                                                                          | Risperdal      |              |            | S           | Oral         | 0.5 Mg                    |                 | Not Reported |
|                                                                                          | Durogesic      |              |            | S           | Transdermal  | 25 Mcg                    |                 | Not Reported |
|                                                                                          | Zolpidem       |              |            | S           | Oral         |                           |                 | Not Reported |
|                                                                                          | Rivotril       |              |            | S           | Oral         | 2.5 Mg/ML - 4 Drops Daily |                 | Not Reported |
|                                                                                          | Moduretic      |              |            | C           |              |                           |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Sep-2012              | 8737382       | EXPEDITED (15-DAY) |                    | OT              | US-FRI-1000037919    |                      | 58 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Affect Lability; Alcohol<br>Abuse; Emotional<br>Distress; Hypersomnia;<br>Memory Impairment;<br>Suicidal Ideation; Suicide<br>Attempt | Escitalopram   |              |            | S           | Oral         | 20 Mg              |                 | Forest       |
|                                                                                                                                       | Klonopin       |              |            | C           | Oral         | 2 Mg At Bedtime    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Sep-2012              | 8778651       | EXPEDITED (15-DAY) |                    | HO              | IT-FRI-1000038505    |                      | 37 YR      | Female     | ITA            |

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

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

Off Label Use; Seizure      Escitalopram      S      Oral      20 Mg      Forest

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 26-Sep-2012              | 8809085       | EXPEDITED (15-DAY) |                    | HO              | FR-JNJFOC-20120907475 |                      | 89 YR      | Male       | FRA            |

| <u>Preferred Term</u>               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Confusional State;<br>Hallucination | Risperdal      |              |            | S           | Oral         |                    |                 | Not Reported |
|                                     | Durogesic      |              |            | S           | Transdermal  |                    |                 | Not Reported |
|                                     | Seroplex       |              |            | S           | Oral         |                    |                 | Not Reported |
|                                     | Zolpidem       |              |            | S           | Oral         |                    |                 | Not Reported |
|                                     | Rivotril       |              |            | S           | Oral         | 2.5mg/MI           |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 26-Sep-2012              | 8809790       | EXPEDITED (15-DAY) |                    | HO              | HU-MYLANLABS-2012S1019430 |                      | 53 YR      | Female     | HUN            |

| <u>Preferred Term</u>                                                              | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Drug Interaction; Drug Interaction; Sinus Node Dysfunction; Sinus Node Dysfunction | Lithium              |              |            | S           | Unknown      |                                  |                 | Mylan        |
|                                                                                    | Lithium              |              |            | S           | Unknown      |                                  |                 | Mylan        |
|                                                                                    | Carbamazepine        |              |            | S           | Unknown      |                                  |                 | Not Reported |
|                                                                                    | Quetiapine           |              |            | S           | Unknown      |                                  |                 | Not Reported |
|                                                                                    | Escitalopram         |              |            | S           | Unknown      | 10mg (Frequency Not Stated)      |                 | Not Reported |
|                                                                                    | Ketoconazole         |              |            | S           | Unknown      |                                  |                 | Not Reported |
|                                                                                    | Atorvastatin         |              |            | C           | Unknown      | 40mg (Frequency Not Stated)      |                 | Not Reported |
|                                                                                    | Levothyroxine Sodium |              |            | C           | Unknown      | 150microg (Frequency Not Stated) |                 | Not Reported |
|                                                                                    | Clonazepam           |              |            | C           | Unknown      | 1-1-2mg (Frequency Not Stated)   |                 | Not Reported |
|                                                                                    | Cinolazepam          |              |            | C           | Unknown      | 40mg (Frequency Not Stated)      |                 | Not Reported |

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

|                     |   |         |                                    |              |
|---------------------|---|---------|------------------------------------|--------------|
| Amiloride           | C | Unknown | 5mg (Frequency Not Stated)         | Not Reported |
| Hydrochlorothiazide | C | Unknown | 50mg (Frequency Not Stated)        | Not Reported |
| Aspirin             | C | Unknown | 100mg (Frequency Not Stated)       | Not Reported |
| Clonazepam          | C | Unknown | 0.5-0.5-3mg (Frequency Not Stated) | Not Reported |

| <u>FDA Received Date</u>                                                | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 26-Sep-2012                                                             | 8809793        | EXPEDITED (15-DAY) |                    | HO, OT          | US-FRI-1000038823    |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Injection Site Erythema;<br>Off Label Use; Seizure;<br>Weight Decreased | Lexapro        |                    |                    | S               | Subcutaneous         |                      |                 | Forest       |                |
|                                                                         | Lexapro        |                    |                    | S               |                      |                      |                 | Forest       |                |
|                                                                         | Rebif          |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                         | Alcohol        |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                         | Acetaminophen  |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 26-Sep-2012              | 8809801        | EXPEDITED (15-DAY) |                    | HO, OT          | CA-FRI-1000038989    |                      | 19 YR           | Male       | CAN            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Seizure                  | Escitalopram   |                    |                    | S               | Oral                 | 20 Mg                |                 | Forest     |                |

| <u>FDA Received Date</u>                                                   | <u>Case #</u>             | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------|---------------------------|------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| 26-Sep-2012                                                                | 8810323                   | NON-EXPEDITED    |                    |                 | US-009507513-1209USA008841 |                      |                 | Male         | USA            |
| <u>Preferred Term</u>                                                      | <u>Product</u>            | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain Upper;<br>Back Pain; Drug Ineffective;<br>Pain In Extremity | Cozaar                    |                  |                    | S               | Oral                       |                      |                 | Merck        |                |
|                                                                            | Amlodipine                |                  |                    | S               |                            |                      |                 | Not Reported |                |
|                                                                            | Venlafaxine Hydrochloride |                  |                    | S               |                            |                      |                 | Not Reported |                |
|                                                                            | Lexapro                   |                  |                    | S               |                            |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                         | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| 26-Sep-2012                                                                                                                                                      | 8811832             | DIRECT             | Y                  |                 |                              |                      | 31 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                            | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Decreased Appetite;<br>Fatigue; Headache;<br>Irritability; Nausea;<br>Product Substitution Issue                                                                 | Escitalopram        |                    |                    | S               | Oral                         | 10mg 1 Po Qd         |                 | Teva         |                |
| <u>FDA Received Date</u>                                                                                                                                         | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Sep-2012                                                                                                                                                      | 8814097             | DIRECT             | Y                  |                 |                              |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                            | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective; Fatigue;<br>Sluggishness                                                                                                                       | Escitalopram        |                    |                    | S               | Oral                         | 30 Mg Daily Oral     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                         | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Sep-2012                                                                                                                                                      | 8470559             | EXPEDITED (15-DAY) |                    | OT              | JP-FRI-1000029225            |                      | 42 YR           | Female       | JPN            |
| <u>Preferred Term</u>                                                                                                                                            | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dystonia; Excessive Eye<br>Blinking; Facial Spasm;<br>Fear; Musculoskeletal<br>Stiffness; Nausea;<br>Seizure; Tardive<br>Dyskinesia; Tremor;<br>Tremor; Vomiting | Lexapro             |                    |                    | S               | Oral                         | 10 Mg                |                 | Forest       |                |
|                                                                                                                                                                  | Lexapro             |                    |                    | S               | Oral                         | 20 Mg                |                 | Forest       |                |
|                                                                                                                                                                  | Fluvoxamine Maleate |                    |                    | C               | Oral                         | 150 Mg               |                 | Not Reported |                |
|                                                                                                                                                                  | Evamyl              |                    |                    | C               | Oral                         | 2 Mg                 |                 | Not Reported |                |
|                                                                                                                                                                  | Brotizolam          |                    |                    | C               | Oral                         | 0.25 Mg              |                 | Not Reported |                |
|                                                                                                                                                                  | Estazolam           |                    |                    | C               | Oral                         | 2 Mg                 |                 | Not Reported |                |
|                                                                                                                                                                  | Horizon             |                    |                    | C               | Oral                         | 15 Mg                |                 | Not Reported |                |
|                                                                                                                                                                  | Rilyft              |                    |                    | C               | Oral                         | 10 Mg                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                         | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Sep-2012                                                                                                                                                      | 8738226             | NON-EXPEDITED      |                    |                 | US-PFIZER INC-<br>2012205320 |                      |                 | Male         | USA            |

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| <u>Preferred Term</u>                                                                                                                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
|--------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|-----------------------|--------------------------------|-----------------|--------------|----------------|
| Nervousness                                                                                                                                | Pristiq        |                    |                    | S               | Oral                  | 50 Mg, 1x/Day                  |                 | Pfizer       |                |
|                                                                                                                                            | Lexapro        |                    |                    | S               |                       | 20 Mg, Unk                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Sep-2012                                                                                                                                | 8812492        | EXPEDITED (15-DAY) |                    | HO              | US-TEVA-361271        | USA                            | 20 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Overdose;<br>Serotonin Syndrome                                                                                                | Clonazepam     |                    |                    | S               | Nasal                 | Multiple Crushed Tablets       |                 | Teva         |                |
|                                                                                                                                            | Clonazepam     |                    |                    | S               | Unknown               |                                |                 | Teva         |                |
|                                                                                                                                            | Escitalopram   |                    |                    | S               | Nasal                 | Multiple Crushed 20mg Tablets  |                 | Not Reported |                |
|                                                                                                                                            | Escitalopram   |                    |                    | S               | Unknown               | 20 Mg/D                        |                 | Not Reported |                |
|                                                                                                                                            | Quetiapine     |                    |                    | S               | Nasal                 | Multiple Crushed 100mg Tablets |                 | Not Reported |                |
|                                                                                                                                            | Quetiapine     |                    |                    | S               | Unknown               |                                |                 | Not Reported |                |
|                                                                                                                                            | Percocet       |                    |                    | S               | Nasal                 | Multiple Crushed Tablets       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Sep-2012                                                                                                                                | 8812528        | EXPEDITED (15-DAY) |                    | LT              | FR-JNJFOC-20120908608 |                                | 89 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Altered State Of Consciousness; Drug Interaction; Fall; Head Injury; Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion; Vomiting | Risperdal      |                    |                    | S               | Oral                  |                                |                 | Not Reported |                |
|                                                                                                                                            | Hytacand       |                    |                    | S               | Oral                  | 8/12.5 Mg                      |                 | Not Reported |                |
|                                                                                                                                            | Seroplex       |                    |                    | S               | Oral                  |                                |                 | Not Reported |                |
|                                                                                                                                            | Hemigoxine     |                    |                    | C               | Unknown               |                                |                 | Not Reported |                |
|                                                                                                                                            | Inipomp        |                    |                    | C               | Unknown               |                                |                 | Not Reported |                |
|                                                                                                                                            | Xanax          |                    |                    | C               | Unknown               |                                |                 | Not Reported |                |
|                                                                                                                                            | Colchicine     |                    |                    | C               | Unknown               |                                |                 | Not Reported |                |
|                                                                                                                                            | Codoliprane    |                    |                    | C               | Unknown               |                                |                 | Not Reported |                |

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|  |                                                                                                                     |   |         |              |
|--|---------------------------------------------------------------------------------------------------------------------|---|---------|--------------|
|  | Tiapridal                                                                                                           | C | Unknown | Not Reported |
|  | Transipeg (Polyethylene Glycol 3350\Potassium Chloride\Sodium Bicarbonate\Sodium Chloride\Sodium Sulfate Anhydrous) | C | Unknown | Not Reported |
|  | Levophta                                                                                                            | C | Unknown | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Sep-2012              | 8812648       | EXPEDITED (15-DAY) |                    | HO, OT          | PHHY2012US081766     |                      | 20 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Agitation; Anxiety; Body Temperature Increased;                                                       | Escitalopram   |              |            | S           |              | 20 Mg Per Day      |                 | Not Reported |
| Clonus; Communication Disorder; Confusional State; Disorientation;                                    | Escitalopram   |              |            | S           |              |                    |                 | Not Reported |
| Hyperhidrosis;                                                                                        | Clonazepam     |              |            | S           |              |                    |                 | Novartis     |
| Hyperreflexia; Hypopnoea;                                                                             | Quetiapine     |              |            | S           |              | 100 Mg, Unk        |                 | Not Reported |
| Intentional Overdose;                                                                                 | Cocaine        |              |            | S           |              |                    |                 | Not Reported |
| Lethargy; Mental Disorder; Muscle Rigidity;                                                           | Percocet       |              |            | S           |              |                    |                 | Not Reported |
| Respiratory Rate Decreased; Serotonin Syndrome; Tachycardia; Wrong Technique In Product Usage Process |                |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Sep-2012              | 8813611       | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000038987    |                      |            | Male       | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Drug Dependence       | Escitalopram   |              |            | S           |              | 20 Mg              |                 | Forest     |

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| <u>FDA Received Date</u>                                                              | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|--------------------------|--------------------------|-----------------|--------------|----------------|
| 27-Sep-2012                                                                           | 8816250                   | DIRECT             | Y                  | OT              |                          |                          | 63 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                 | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Feeling Hot; Hyperhidrosis; Insomnia                                       | Escitalopram              |                    |                    | S               | Oral                     | 10mg 1 Per Day Po        | 7 DAY           | Mylan        |                |
| <u>FDA Received Date</u>                                                              | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Sep-2012                                                                           | 8795815                   | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000038611        |                          | 73 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                 | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State; Dizziness; Lung Disorder; Overdose; Somnolence; Walking Disability | Escitalopram              |                    |                    | S               | Oral                     | 15 Mg                    |                 | Forest       |                |
|                                                                                       | Escitalopram              |                    |                    | S               | Oral                     |                          |                 | Not Reported |                |
|                                                                                       | Lepticur                  |                    |                    | S               | Oral                     | 30 Df                    |                 | Not Reported |                |
|                                                                                       | Lepticur                  |                    |                    | S               |                          | Overdose: Unknown Amount |                 | Not Reported |                |
|                                                                                       | Levothyrox                |                    |                    | C               | Oral                     | 75 Mcg                   |                 | Not Reported |                |
|                                                                                       | Alprazolam                |                    |                    | C               | Oral                     | 0.25 Mg                  |                 | Not Reported |                |
|                                                                                       | Zyprexa                   |                    |                    | C               | Oral                     | 1 Df                     |                 | Not Reported |                |
|                                                                                       | Inexium                   |                    |                    | C               |                          | 40 Mg                    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                              | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Sep-2012                                                                           | 8814085                   | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2012237511 |                          | 53 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                 | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain Upper; Drug Ineffective; Myalgia; Pain In Extremity                    | Amlodipine Besilate       |                    |                    | S               |                          | Unk                      |                 | Pfizer       |                |
|                                                                                       | Venlafaxine Hydrochloride |                    |                    | S               |                          | Unk                      |                 | Pfizer       |                |
|                                                                                       | Losartan                  |                    |                    | S               |                          | Unk                      |                 | Not Reported |                |
|                                                                                       | Lexapro                   |                    |                    | S               |                          | Unk                      |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                                                                                                          | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| 28-Sep-2012                                                                                                                                                       | 8814860             | EXPEDITED (15-DAY) |                    | CA, DE          | US-FRI-1000038907            |                      | < 1 DAY         | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                             | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Congenital Anomaly;<br>Ebstein'S Anomaly                                                                                                                          | Lexapro             |                    |                    | S               | Transplacental               |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                                                          | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Sep-2012                                                                                                                                                       | 8815086             | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000038912            |                      | < 1 DAY         | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                             | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrial Septal Defect;<br>Congenital Anomaly;<br>Fallot'S Tetralogy;<br>Pulmonary Artery Stenosis<br>Congenital; Ventricular<br>Septal Defect                      | Lexapro             |                    |                    | S               | Transplacental               |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                                                          | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Oct-2012                                                                                                                                                       | 8712245             | EXPEDITED (15-DAY) |                    | HO, OT          | FI-AMGEN-<br>FINSP2012048488 |                      | 67 YR           | Female       | FIN            |
| <u>Preferred Term</u>                                                                                                                                             | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anaemia; Aspartate<br>Aminotransferase<br>Increased; Blood Alkaline<br>Phosphatase Increased;<br>Blood Lactate<br>Dehydrogenase<br>Increased;<br>Thrombocytopenia | Xgeva               |                    |                    | S               | Subcutaneous                 | 120 Mg, Q4wk         |                 | Amgen        |                |
|                                                                                                                                                                   | Xgeva               |                    |                    | S               |                              |                      |                 | Amgen        |                |
|                                                                                                                                                                   | Ciprallex           |                    |                    | S               | Oral                         | 5 Mg, Qd             |                 | Not Reported |                |
|                                                                                                                                                                   | Specicor            |                    |                    | C               | Oral                         | 47.5 Mg, Bid         |                 | Not Reported |                |
|                                                                                                                                                                   | Faslodex /01503001/ |                    |                    | C               | Intramuscular                | 500 Mg, Q4wk         |                 | Not Reported |                |
|                                                                                                                                                                   | Faslodex /01503001/ |                    |                    | C               |                              |                      |                 | Not Reported |                |
|                                                                                                                                                                   | Oxycontin           |                    |                    | C               | Oral                         | 10 Mg, Bid           |                 | Not Reported |                |
|                                                                                                                                                                   | Lipcut              |                    |                    | C               | Oral                         | 40 Mg, Qd            |                 | Not Reported |                |



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| <u>FDA Received Date</u>                                               | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 01-Oct-2012                                                            | 8817933                | EXPEDITED (15-DAY) |                    | DS, LT          | FR-FRI-1000039067    |                      | 47 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                  | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State;<br>Hyponatraemia; Osmotic<br>Demyelination Syndrome | Escitalopram           |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                                                        | Olmetec                |                    |                    | S               | Oral                 | 10 Mg                |                 | Not Reported |                |
|                                                                        | Climaston              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                        | Levothyrox             |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                        | Previscan (Fluindione) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                        | Veratran               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                        | Calciparine            |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                        | Volibris               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                        | Revatio                |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                     | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|------------------------------|-------------------------------------|-----------------|--------------|----------------|
| 01-Oct-2012                                                                                  | 8818572              | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-<br>2012241917 |                                     | 53 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                        | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Cholesterol<br>Decreased; Drug<br>Ineffective; Infection<br>Protozoal; Pain; Paralysis | Effexor              |                    |                    | S               |                              | Unk                                 |                 | Pfizer       |                |
|                                                                                              | Xanax                |                    |                    | S               |                              | Unk, Daily As Needed                |                 | Pfizer       |                |
|                                                                                              | Escitalopram Oxalate |                    |                    | S               |                              | 40 Mg, Daily                        |                 | Not Reported |                |
|                                                                                              | Klonopin             |                    |                    | C               |                              | Half A Tablet Of 2mg Daily          |                 | Not Reported |                |
|                                                                                              | Klonopin             |                    |                    | C               |                              |                                     |                 | Not Reported |                |
|                                                                                              | Ritalin              |                    |                    | C               |                              | 20mg In Morning And<br>10mg At Noon |                 | Not Reported |                |
|                                                                                              | Ritalin              |                    |                    | C               |                              |                                     |                 | Not Reported |                |
|                                                                                              | Oxyir                |                    |                    | C               |                              | 5 Mg, As Needed                     |                 | Not Reported |                |
|                                                                                              | Oxyir                |                    |                    | C               |                              |                                     |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 01-Oct-2012              | 8819692        | EXPEDITED (15-DAY) |                    | HO              | FR-JNJFOC-<br>20120908635 |                      | 78 YR           | Female     | FRA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

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|                                        |                     |   |             |              |
|----------------------------------------|---------------------|---|-------------|--------------|
| Fall; Hyponatraemia;<br>Rhabdomyolysis | Durogesic           | S | Transdermal | Not Reported |
|                                        | Seroplex            | S | Oral        | Not Reported |
|                                        | Lexomil             | S | Oral        | Not Reported |
|                                        | Domperidone         | C | Unknown     | Not Reported |
|                                        | Calcium Vitamine D3 | C | Unknown     | Not Reported |
|                                        | Fosavance           | C | Unknown     | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 01-Oct-2012              | 8819742       | EXPEDITED (15-DAY) |                    | HO              | US-MYLANLABS-2012S1019540 |                      | 20 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------------------|-----------------|--------------|
| Incorrect Route Of Product Administration; Intentional Overdose; Mental Status Changes; Serotonin Syndrome | Escitalopram   |              |            | S           | Nasal        | Multiple Crushed 20mg Tablets  |                 | Not Reported |
|                                                                                                            | Escitalopram   |              |            | S           | Nasal        | Multiple Crushed 20mg Tablets  |                 | Not Reported |
|                                                                                                            | Escitalopram   |              |            | S           | Unknown      | 20 Mg/D                        |                 | Not Reported |
|                                                                                                            | Escitalopram   |              |            | S           | Unknown      | 20 Mg/D                        |                 | Not Reported |
|                                                                                                            | Quetiapine     |              |            | S           | Nasal        | Multiple Crushed 100mg Tablets |                 | Not Reported |
|                                                                                                            | Quetiapine     |              |            | S           | Nasal        | Multiple Crushed 100mg Tablets |                 | Not Reported |
|                                                                                                            | Quetiapine     |              |            | S           | Unknown      |                                |                 | Not Reported |
|                                                                                                            | Quetiapine     |              |            | S           | Unknown      |                                |                 | Not Reported |
|                                                                                                            | Clonazepam     |              |            | S           | Nasal        | Multiple Crushed Tablets       |                 | Mylan        |
|                                                                                                            | Clonazepam     |              |            | S           | Nasal        | Multiple Crushed Tablets       |                 | Mylan        |
|                                                                                                            | Clonazepam     |              |            | S           | Unknown      |                                |                 | Mylan        |
|                                                                                                            | Clonazepam     |              |            | S           | Unknown      |                                |                 | Mylan        |
|                                                                                                            | Percocet       |              |            | S           | Nasal        | Multiple Crushed Tablets       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Oct-2012              | 8819819       | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000039038    |                      | < 1 DAY    | Female     | USA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|---------------------------------|-----------------|--------------|----------------|
| Atrial Septal Defect; Cleft Palate; Congenital Anomaly; Diaphragmatic Hernia; Talipes | Lexapro        |                    |                    | S               | Transplacental       |                                 |                 | Forest       |                |
| <u>FDA Received Date</u>                                                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Oct-2012                                                                           | 8816834        | DIRECT             | Y                  | OT              |                      |                                 | 33 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Depression; Fatigue                                                          | Escitalopram   |                    |                    | S               | Oral                 | Escitalopram 20mg Once Daily Po |                 | Not Reported |                |
|                                                                                       | Citalopram     |                    |                    | S               | Oral                 | Citalopram 40mg Once Daily Po   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Oct-2012                                                                           | 8816835        | DIRECT             |                    | OT              |                      |                                 |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Headache; Hyperacusis; Migraine; Nausea; Photophobia; Unevaluable Event               | Escitalopram   |                    |                    | S               | Oral                 | 20 Mg 1 Tablet Daily By Mouth   |                 | Teva         |                |
| <u>FDA Received Date</u>                                                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Oct-2012                                                                           | 8820534        | EXPEDITED (15-DAY) |                    | LT              | FR-FRI-1000039069    |                                 | 89 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion         | Escitalopram   |                    |                    | S               | Oral                 | 10 Mg                           |                 | Forest       |                |
|                                                                                       | Hytacand       |                    |                    | S               | Oral                 | 8 Mg/12.5 Mg                    |                 | Not Reported |                |
|                                                                                       | Risperdal      |                    |                    | S               | Oral                 | 1 Mg                            |                 | Not Reported |                |
|                                                                                       | Colchicine     |                    |                    | C               |                      |                                 |                 | Not Reported |                |
|                                                                                       | Codoliprane    |                    |                    | C               |                      |                                 |                 | Not Reported |                |

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

|                                                                                                                     |   |              |
|---------------------------------------------------------------------------------------------------------------------|---|--------------|
| Tiapridal                                                                                                           | C | Not Reported |
| Transipeg (Polyethylene Glycol 3350\Potassium Chloride\Sodium Bicarbonate\Sodium Chloride\Sodium Sulfate Anhydrous) | C | Not Reported |
| Levophta                                                                                                            | C | Not Reported |
| Xanax                                                                                                               | C | Not Reported |
| Hemigoxine                                                                                                          | C | Not Reported |
| Inipomp                                                                                                             | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Oct-2012              | 8820680       | EXPEDITED (15-DAY) | HO                 |                 | CH-FRI-1000039071    |                      |            | Female     | CHE            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hepatocellular Injury | Escitalopram   |              |            | S           | Oral         | 5 Mg               |                 | Forest       |
|                       | Escitalopram   |              |            | S           |              |                    |                 | Forest       |
|                       | Dafalgan       |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Dafalgan       |              |            | S           |              |                    |                 | Not Reported |
|                       | Tebokan        |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Enalapril      |              |            | S           | Oral         | 10 Mg              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------------------|----------------------|------------|------------|----------------|
| 02-Oct-2012              | 8821152       | NON-EXPEDITED    |                    |                 | US-BRISTOL-MYERS SQUIBB COMPANY-16492332 |                      | 47 YR      | Female     | USA            |

| <u>Preferred Term</u>                          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                                                 | <u>Duration</u> | <u>Mfr</u>           |
|------------------------------------------------|----------------|--------------|------------|-------------|--------------|----------------------------------------------------------------------------------------------------|-----------------|----------------------|
| Heart Rate Increased;<br>Insomnia; Nervousness | Buspar         |              |            | S           |              |                                                                                                    |                 | Bristol Myers Squibb |
|                                                | Lexapro        |              |            | S           | Oral         | 5mg(27jun-2011),2.5mg 2 Times A Day,15mg,10mg,Dosing time Changed From Bedtime Morning On Mar 2012 |                 | Not Reported         |
|                                                | Lexapro        |              |            | S           | Oral         | 5mg(27jun-2011),2.5mg 2                                                                            |                 | Not Reported         |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Times A  
Day,15mg,10mg,Dosingti  
me Changed From  
Bedtime Morning On Mar  
2012

Prilosec

C

Not Reported

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------------------------------------|----------------------|------------|------------|----------------|
| 02-Oct-2012              | 8821174       | EXPEDITED (15-DAY) |                    | OT              | US-ROXANE<br>LABORATORIES, INC.-<br>2012-RO-01927RO |                      | 28 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                         | <u>Product</u>                                                                     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>                | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                                                                             |
|-----------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------|--------------|------------|----------------------------|--------------|--------------------|-----------------|----------------------------------------------------------------------------------------|
| Abortion Spontaneous;<br>Maternal Exposure During<br>Pregnancy;<br>Polyhydramnios; Stillbirth | Lithium Carbonate<br>Macrogol<br>Escitalopram<br>Synthroid<br>Heparin<br>Magnesium |              |            | S<br>S<br>S<br>S<br>S<br>S |              | 200 Mg             |                 | Roxane<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Oct-2012              | 8817172       | DIRECT           | Y                  |                 |                      |                      | 46 YR      | Female     | USA            |

| <u>Preferred Term</u>                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Drug Ineffective;<br>Stress | Escitalopram   |              |            | S           | Oral         | 20 Mg, 1 Qd Po     |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Oct-2012              | 8817173       | DIRECT           | Y                  | OT              |                      |                      | 32 YR      | Male       | USA            |

| <u>Preferred Term</u>                   | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Anxiety;<br>Headache; Insomnia | Escitalopram Oxalate |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Oct-2012              | 8823411       | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000039085    |                      |            | Male       | USA            |

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

| <u>Preferred Term</u>                                                                                                                                               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|-----------------------|-----------------|--------------|----------------|
| Hypospadias; Talipes                                                                                                                                                | Lexapro              |                    |                    | S               | Transplacental       |                       |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                                                            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Oct-2012                                                                                                                                                         | 8818829              | DIRECT             |                    | OT              |                      |                       | 21 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Disease Recurrence; Irritability; Panic Attack; Product Substitution Issue                                                                              | Escitalopram         |                    |                    | S               | Oral                 |                       |                 | Not Reported |                |
|                                                                                                                                                                     | Lamotrigine          |                    |                    | C               |                      |                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Oct-2012                                                                                                                                                         | 8825195              | EXPEDITED (15-DAY) |                    | OT              | US-TEVA-361072USA    |                       |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Adverse Event; Drug Dependence; Drug Intolerance; Drug Withdrawal Syndrome                                                                                          | Mirtazapine          |                    |                    | S               |                      | 15 Milligram Daily;   |                 | Teva         |                |
|                                                                                                                                                                     | Clonazepam           |                    |                    | S               |                      | .125 Milligram Daily; |                 | Not Reported |                |
|                                                                                                                                                                     | Escitalopram Oxalate |                    |                    | S               |                      | 10 Milligram Daily;   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Oct-2012                                                                                                                                                         | 8829898              | EXPEDITED (15-DAY) | Y                  | HO              | 2012AP003167         |                       | 20 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated; Depressed Mood; Incorrect Route Of Product Administration; Intentional Overdose; Serotonin Syndrome; Wrong Technique In Product Usage Process | Quetiapine Fumarate  |                    |                    | S               |                      |                       |                 | Not Reported |                |
|                                                                                                                                                                     | Clonazepam           |                    |                    | S               |                      |                       |                 | Not Reported |                |
|                                                                                                                                                                     | Escitalopram         |                    |                    | S               |                      |                       |                 | Not Reported |                |
|                                                                                                                                                                     | Percocet             |                    |                    | S               |                      |                       |                 | Not Reported |                |
|                                                                                                                                                                     | Cocaine              |                    |                    | S               |                      |                       |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>     | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|------------------------------|--------------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|-----------------------|-----------------|----------------------|----------------|
| 04-Oct-2012                  | 9227449                        | NON-EXPEDITED      |                    | OT              | PHEH2011US02520                                 |                       | 58 YR           | Female               | USA            |
| <u>Preferred Term</u>        | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>           |                |
| Application Site Burn;       | Estalis                        |                    |                    | S               | Transdermal                                     |                       |                 | Not Reported         |                |
| Application Site Irritation; | Climara (Estradiol)            |                    |                    | S               |                                                 |                       |                 | Not Reported         |                |
| Depression; Drug             | Lexapro (Escitalopram Oxalate) |                    |                    | S               |                                                 |                       |                 | Not Reported         |                |
| Ineffective; Hormone Level   | Diazepine ( No                 |                    |                    | C               |                                                 |                       |                 | Not Reported         |                |
| Abnormal; Pain In            | Ingredients/Substances)        |                    |                    |                 |                                                 |                       |                 |                      |                |
| Extremity; Vaginal           | Amlodipine ( Amlodipine)       |                    |                    | C               |                                                 |                       |                 | Not Reported         |                |
| Haemorrhage                  |                                |                    |                    |                 |                                                 |                       |                 |                      |                |
| <u>FDA Received Date</u>     | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 05-Oct-2012                  | 8771201                        | EXPEDITED (15-DAY) |                    | DE, HO, OT      | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>16879645 |                       | 55 YR           | Male                 | USA            |
| <u>Preferred Term</u>        | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>           |                |
| Clavicle Fracture;           | Abilify                        |                    |                    | S               | Oral                                            | Started Either 2 Or   |                 | Not Reported         |                |
| Dysphagia; Fall;             |                                |                    |                    |                 |                                                 | 5mg,Dose Increased To |                 |                      |                |
| Parkinsonism; Pneumonia      |                                |                    |                    |                 |                                                 | 10mg,Jul12            |                 |                      |                |
| Aspiration                   | Buspar                         |                    |                    | S               |                                                 |                       |                 | Bristol Myers Squibb |                |
|                              | Lexapro                        |                    |                    | S               |                                                 |                       |                 | Not Reported         |                |
|                              | Lexapro                        |                    |                    | S               |                                                 |                       |                 | Not Reported         |                |
|                              | Ambien                         |                    |                    | S               |                                                 | Qhs                   |                 | Not Reported         |                |
|                              | Lipitor                        |                    |                    | C               |                                                 |                       |                 | Not Reported         |                |
|                              | Allegra                        |                    |                    | C               |                                                 |                       |                 | Not Reported         |                |
|                              | Vitamin C                      |                    |                    | C               |                                                 |                       |                 | Not Reported         |                |
|                              | Vitamin D3                     |                    |                    | C               |                                                 |                       |                 | Not Reported         |                |
| <u>FDA Received Date</u>     | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 05-Oct-2012                  | 8823107                        | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000039056                               |                       |                 | Female               | USA            |
| <u>Preferred Term</u>        | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>           |                |
| Pulmonary Artery Stenosis    | Lexapro                        |                    |                    | S               | Transplacental                                  |                       |                 | Forest               |                |
| Congenital                   |                                |                    |                    |                 |                                                 |                       |                 |                      |                |

# FDA Adverse Event Reporting System

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### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                                  | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 05-Oct-2012                                                                                                                                                                                                               | 8829424                | DIRECT             | Y                  |                 |                      |                      | 46 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                     | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective                                                                                                                                                                                                          | Escitalopram           |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                  | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Oct-2012                                                                                                                                                                                                               | 8772502                | EXPEDITED (15-DAY) |                    | OT              | AU-FRI-1000038315    |                      | < 1 DAY         | Female       | AUS            |
| <u>Preferred Term</u>                                                                                                                                                                                                     | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Withdrawal Syndrome; Foetal Exposure During Pregnancy; Neonatal Respiratory Distress                                                                                                                                 | Lexapro                |                    |                    | S               | Transplacental       |                      |                 | Forest       |                |
|                                                                                                                                                                                                                           | Aripiprazole           |                    |                    | S               | Transplacental       | 10 Mg                |                 | Not Reported |                |
|                                                                                                                                                                                                                           | Breast Feeding Support |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                           | Fefol                  |                    |                    | C               | Transplacental       |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                  | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Oct-2012                                                                                                                                                                                                               | 8822409                | EXPEDITED (15-DAY) |                    | OT              | US-FRI-1000039092    |                      | 51 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                     | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Cold Sweat; Dizziness; Drug Ineffective; Ecg P Wave Inverted; Electrocardiogram T Wave Inversion; Fatigue; Flushing; Insomnia; Left Atrial Enlargement; Lipoma; Myalgia; Palpitations; Panic Attack; Tachycardia | Escitalopram           |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                                                                                                                                                                                                           | Klonopin               |                    |                    | C               |                      | As Needed            |                 | Not Reported |                |
|                                                                                                                                                                                                                           | Aspirin                |                    |                    | C               | Oral                 | 81 Mg                |                 | Not Reported |                |
|                                                                                                                                                                                                                           | Lipitor                |                    |                    | C               |                      | 10 Mg                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                  | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Oct-2012                                                                                                                                                                                                               | 8827698                | NON-EXPEDITED      |                    |                 | US-PFIZER INC-       |                      |                 | Female       | USA            |



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

2012244846

| <u>Preferred Term</u>                                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Dizziness; Drug Interaction; Headache; Insomnia; Nausea | Celebrex       |              |            | S           |              | Unk                |                 | Pfizer       |
|                                                         | Lexapro        |              |            | S           |              | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Oct-2012              | 8688656       | EXPEDITED (15-DAY) |                    | HO              | ES-FRI-1000037354    |                      | 79 YR      | Female     | ESP            |

| <u>Preferred Term</u>                                               | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction; Lower Gastrointestinal Haemorrhage; Off Label Use | Escitalopram        |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                                                     | Adiro               |              |            | S           | Oral         | 300 Mg             |                 | Not Reported |
|                                                                     | Paracetamol         |              |            | C           | Oral         | 3000 Mg            |                 | Not Reported |
|                                                                     | Pravastatin         |              |            | C           | Oral         | 20 Mg              |                 | Not Reported |
|                                                                     | Enalapril           |              |            | C           | Oral         | 5 Mg               |                 | Not Reported |
|                                                                     | Aricept / Donepezil |              |            | C           | Oral         | 10 Mg              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Oct-2012              | 8832534       | DIRECT           | Y                  | OT              |                      |                      | 25 YR      | Female     | USA            |

| <u>Preferred Term</u>                                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Depression; Insomnia; Product Substitution Issue | Lexapro        |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Oct-2012              | 8832550       | DIRECT           | Y                  | OT              |                      |                      | 40 YR      | Female     | USA            |

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

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                                                                                                                                                                                      |                |                    |                    |                 |                                                 |                                                                                       |                 |              |                |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|-------------------------------------------------|---------------------------------------------------------------------------------------|-----------------|--------------|----------------|
| Disturbance In Attention;<br>Headache; Mood Swings                                                                                                                                                                   |                | Escitalopram       | S                  | Oral            | 1.5 Tablet Oral                                 |                                                                                       | Not Reported    |              |                |
| <u>FDA Received Date</u>                                                                                                                                                                                             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                                                                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Oct-2012                                                                                                                                                                                                          | 8164861        | EXPEDITED (15-DAY) |                    | HO, OT          | FR-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>16113607 |                                                                                       | 49 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                                                | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                                                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Aphasia; Cerebral                                                                                                                                                                                                    | Abilify        |                    |                    | S               | Oral                                            |                                                                                       |                 | Not Reported |                |
| Haematoma;                                                                                                                                                                                                           | Abilify        |                    |                    | S               | Oral                                            |                                                                                       |                 | Not Reported |                |
| Cerebrovascular Accident;                                                                                                                                                                                            | Seroplex       |                    |                    | S               | Oral                                            | 1 Dosage Form: Scored<br>Film-Coated Tablet;<br>Escitalopram Oxalate 10<br>Mg         |                 | Not Reported |                |
| Fall; Hemiplegia                                                                                                                                                                                                     |                |                    |                    |                 |                                                 |                                                                                       |                 |              |                |
|                                                                                                                                                                                                                      | Parkinane      |                    |                    | S               | Oral                                            | 1 Dosage Form:<br>Extended-Release<br>Capsule; Trihexyphenidyl<br>Hydrochloride 5 Mg, |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                                                                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Oct-2012                                                                                                                                                                                                          | 8833954        | DIRECT             |                    | OT              |                                                 |                                                                                       | 36 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                                                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Depressed Mood;<br>Disease Recurrence; Drug<br>Ineffective; Fatigue;<br>Feeling Abnormal; Feeling<br>Abnormal; Headache;<br>Irritability; Lethargy;<br>Premenstrual Syndrome;<br>Product Substitution Issue | Escitalopram   |                    |                    | S               | Oral                                            | 5-10 Depends On Time<br>Month.                                                        | 3 MTH           | Mylan        |                |
| <u>FDA Received Date</u>                                                                                                                                                                                             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                                                                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Oct-2012                                                                                                                                                                                                          | 8837031        | EXPEDITED (15-DAY) |                    | HO              | USA/USA/12/0026136                              |                                                                                       | 20 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                                                    | <u>Duration</u> | <u>Mfr</u>   |                |

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

|                            |                     |   |              |
|----------------------------|---------------------|---|--------------|
| Abdominal Pain; Agitation; | Quetiapine Fumarate | S | Not Reported |
| Anxiety; Communication     | Escitalopram        | S | Not Reported |
| Disorder; Condition        | Clonazepam          | S | Not Reported |
| Aggravated; Depressed      | Percocet /00446701/ | S | Not Reported |
| Mood; Disorientation;      | Cocaine (Cocaine)   | S | Not Reported |
| Hyperhidrosis;             |                     |   |              |
| Hyperreflexia;             |                     |   |              |
| Hyperthermia;              |                     |   |              |
| Hypopnoea; Intentional     |                     |   |              |
| Overdose; Intentional      |                     |   |              |
| Product Use Issue;         |                     |   |              |
| Lethargy; Medication       |                     |   |              |
| Error; Mental Status       |                     |   |              |
| Changes; Muscle Rigidity;  |                     |   |              |
| Myoclonus; Oxygen          |                     |   |              |
| Saturation Decreased;      |                     |   |              |
| Serotonin Syndrome;        |                     |   |              |
| Tachycardia                |                     |   |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Oct-2012              | 8581554       | EXPEDITED (15-DAY) |                    | HO, LT          | ES-TEVA-338753ISR    |                      | 71 YR      | Male       | ESP            |

| <u>Preferred Term</u>       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------|----------------|--------------|------------|-------------|--------------|---------------------|-----------------|--------------|
| Drug Interaction; Epistaxis | Azilect        |              |            | S           | Oral         | 1 Milligram Daily;  |                 | Teva         |
|                             | Escitalopram   |              |            | S           | Oral         | 10 Milligram Daily; |                 | Not Reported |
|                             | Quetiapine     |              |            | S           | Oral         | 50 Milligram Daily; |                 | Not Reported |
|                             | Ripserdal Flas |              |            | S           | Oral         | 50 Microgram Daily; |                 | Not Reported |
|                             | Simvastatin    |              |            | C           | Oral         | 20 Milligram Daily; |                 | Not Reported |
|                             | Requip-Prolib  |              |            | C           | Oral         | 8 Milligram Daily;  |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Oct-2012              | 8835190       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000039317    |                      | 53 YR      | Male       | FRA            |

| <u>Preferred Term</u>                        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|----------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Balance Disorder;<br>Bradycardia; Dizziness; | Nebivolol      |              |            | S           | Oral         | 2.5 Mg             |                 | Forest     |

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

|                                  |             |   |                          |            |              |
|----------------------------------|-------------|---|--------------------------|------------|--------------|
| Lung Disorder; Visual Impairment | Isoptine    | S | Oral                     | 120 Mg     | Not Reported |
|                                  | Furosemide  | S | Oral                     | 50mg 20 Mg | Not Reported |
|                                  | Cozaar      | S | Oral                     | 100 Mg     | Not Reported |
|                                  | Kardegic    | S | Oral                     | 160 Mg     | Not Reported |
|                                  | Seroplex    | S | Oral                     | 20 Mg      | Not Reported |
|                                  | Metformin   | C | Oral                     |            | Not Reported |
|                                  | Symbicort   | C | Respiratory (inhalation) |            | Not Reported |
|                                  | Allopurinol | C | Oral                     |            | Not Reported |
|                                  | Atarax      | C |                          |            | Not Reported |

| <u>FDA Received Date</u>                                                                                                | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|------------------------------|-----------------|--------------|----------------|
| 11-Oct-2012                                                                                                             | 8837262        | DIRECT           | Y                  | OT              |                      |                              | 57 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Discomfort; Abdominal Distension; Diarrhoea; Headache; Hypersensitivity; Product Substitution Issue; Vomiting | Celexa         |                  |                    | S               | Oral                 | Celexa 20 Daily Po - Liquid  |                 | Not Reported |                |
|                                                                                                                         | Lexapro        |                  |                    | S               | Oral                 | Lexapro 20 Daily Po - Liquid |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------|---------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 11-Oct-2012                                                                                             | 8841714             | EXPEDITED (15-DAY) | Y                  | HO              | 2012SUN00116         |                      | 20 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                   | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain; Depressed Mood; Intentional Overdose; Intentional Product Use Issue; Serotonin Syndrome | Quetiapine Fumarate |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                         | Escitalopram        |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                         | Clonazepam          |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                         | Percocet            |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                         | Cocaine (Cocaine)   |                    |                    | S               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                      | <u>Case #</u>                                                         | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------|-----------------------------------------------------------------------|------------------|--------------------|-----------------|----------------------|-------------------------------|-----------------|--------------|----------------|
| 12-Oct-2012                                                                   | 7701555                                                               | NON-EXPEDITED    | N                  | HO              | 1000009544           |                               | 79 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                         | <u>Product</u>                                                        | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Blood Sodium Decreased; Fatigue; Feeling Abnormal; Gait Disturbance | Lexapro                                                               |                  |                    | S               | Oral                 | Oral                          |                 | Not Reported |                |
|                                                                               | High Blood Pressure Medication Nos (Antihypertensives)                |                  |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                               |                                                                       |                  |                    |                 |                      |                               |                 |              |                |
| <u>FDA Received Date</u>                                                      | <u>Case #</u>                                                         | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Oct-2012                                                                   | 8225873                                                               | NON-EXPEDITED    | Y                  | RI, OT          | 1000016212           |                               |                 | Female       | USA            |
| <u>Preferred Term</u>                                                         | <u>Product</u>                                                        | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Serotonin Syndrome                                                            | Lexapro                                                               |                  |                    | S               |                      |                               |                 | Not Reported |                |
|                                                                               | Zoloft                                                                |                  |                    | S               |                      |                               |                 | Not Reported |                |
|                                                                               | Wellbutrin                                                            |                  |                    | S               |                      |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                      | <u>Case #</u>                                                         | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Oct-2012                                                                   | 8226225                                                               | NON-EXPEDITED    | Y                  | RI, OT          | 1000021607           |                               | 63 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                         | <u>Product</u>                                                        | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Aplastic Anaemia                                                              | Lexapro                                                               |                  |                    | S               |                      | 10 Mg                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                      | <u>Case #</u>                                                         | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Oct-2012                                                                   | 8226263                                                               | NON-EXPEDITED    | N                  | RI, OT          | 1000022542           |                               | 57 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                         | <u>Product</u>                                                        | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Weight Increased                                                              | Lexapro                                                               |                  |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D), Oral | 1 DAY           | Not Reported |                |
|                                                                               | Prescription Pain Medications Nos (Prescription Pain Medications Nos) |                  |                    | S               |                      |                               |                 | Not Reported |                |
|                                                                               | Haldol (Haloperidol)                                                  |                  |                    | C               |                      |                               |                 | Not Reported |                |

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|                                                                                                                                                                                                                                                                |                |                    |                    |                 |                            |                                                |                 |              |                |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------------|------------------------------------------------|-----------------|--------------|----------------|
| Nexium (Esomeprazole)                                                                                                                                                                                                                                          |                |                    | C                  |                 |                            | Not Reported                                   |                 |              |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Oct-2012                                                                                                                                                                                                                                                    | 8815447        | EXPEDITED (15-DAY) |                    | OT              | FR-ASTRAZENECA-2012SE73307 |                                                | 36 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                             | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Urinary Retention                                                                                                                                                                                                                            | Xeroquel       |                    |                    | S               | Oral                       | Dose Progressively Increased To 300 Mg Per Day |                 | Astrazeneca  |                |
|                                                                                                                                                                                                                                                                | Seroplex       |                    |                    | S               | Oral                       |                                                |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                | Lexomil        |                    |                    | S               | Oral                       |                                                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Oct-2012                                                                                                                                                                                                                                                    | 8837635        | EXPEDITED (15-DAY) |                    | HO, OT          | IT-FRI-1000037407          |                                                | 44 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                             | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Overdose; Intentional Self-Injury; Sopor; Suicide Attempt                                                                                                                                                                                          | Escitalopram   |                    |                    | S               | Oral                       | Overdose: 300 Mg                               |                 | Forest       |                |
|                                                                                                                                                                                                                                                                | Lexotan        |                    |                    | C               | Oral                       | 50 Mg                                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Oct-2012                                                                                                                                                                                                                                                    | 8837885        | EXPEDITED (15-DAY) |                    | OT              | HR-PFIZER INC-2012251930   |                                                | 80 YR           | Male         | HRV            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                             | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Cholesterol Increased; Blood Uric Acid Increased; Constipation; Diarrhoea; Flatulence; Haematocrit Decreased; Haemoglobin Decreased; Muscle Atrophy; Muscle Spasms; Myalgia; Nail Discolouration; Nitrite Urine Present; Red Blood Cell Count Decreased; | Tritace        |                    |                    | S               | Oral                       | 2.5 Mg, 1x/Day                                 |                 | Pfizer       |                |
|                                                                                                                                                                                                                                                                | Controlloc     |                    |                    | S               | Oral                       | 20 Mg, 1x/Day                                  |                 | Pfizer       |                |
|                                                                                                                                                                                                                                                                | Aggrenox       |                    |                    | S               | Oral                       | 1 Df, 2x/Day                                   |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                | Teotard        |                    |                    | S               | Oral                       | 200 Mg, 1x/Day                                 |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                | Cipralext      |                    |                    | S               | Oral                       | 5 Mg, 1x/Day                                   |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                | Norprexanil    |                    |                    | S               | Oral                       | 1 Df, 1x/Day                                   |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                | Crestor        |                    |                    | S               | Oral                       | 20 Mg, 1x/Day                                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                | Lamisil        |                    |                    | C               | Topical                    | Unk                                            |                 | Not Reported |                |

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

|                    |                       |   |      |                |              |
|--------------------|-----------------------|---|------|----------------|--------------|
| Walking Disability | Eicosapentaenoic Acid | C | Oral | Unk            | Not Reported |
|                    | Pumpkin Oil           | C |      | Unk            | Not Reported |
|                    | Magnesium Citrate     | C | Oral | 300 Mg, 1x/Day | Not Reported |

| <u>FDA Received Date</u>                                                                    | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 12-Oct-2012                                                                                 | 8838284        | EXPEDITED (15-DAY) | CA                 |                 | US-FRI-1000039299    |                      | < 1 DAY         | Female     | USA            |
| <u>Preferred Term</u>                                                                       | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Congenital Anomaly;<br>Congenital Diaphragmatic<br>Hernia; Neonatal<br>Respiratory Distress | Lexapro        |                    |                    | S               | Transplacental       |                      |                 | Forest     |                |

| <u>FDA Received Date</u>                                                                     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|----------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 12-Oct-2012                                                                                  | 8838448        | EXPEDITED (15-DAY) | CA                 |                 | US-FRI-1000039305    |                      |                 | Male       | USA            |
| <u>Preferred Term</u>                                                                        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Aortic Stenosis; Atrial<br>Septal Defect; Congenital<br>Anomaly; Patent Ductus<br>Arteriosus | Lexapro        |                    |                    | S               | Transplacental       |                      |                 | Forest     |                |

| <u>FDA Received Date</u>                                                                                                                                                                                                                | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u>                                                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|--------------------------------|-----------------------------------------------------------------------------|-----------------|--------------|----------------|
| 12-Oct-2012                                                                                                                                                                                                                             | 8838655        | EXPEDITED (15-DAY) |                    | OT              | HR-ASTRAZENECA-<br>2012SE76972 |                                                                             |                 | Male         | HRV            |
| <u>Preferred Term</u>                                                                                                                                                                                                                   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>                                                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Cholesterol<br>Increased; Blood Uric Acid<br>Increased; Constipation;<br>Diarrhoea; Flatulence;<br>Haematocrit Decreased;<br>Haemoglobin Decreased;<br>Muscle Atrophy; Muscle<br>Spasms; Myalgia; Nail<br>Discolouration; Nitrite | Crestor        |                    |                    | S               | Oral                           |                                                                             |                 | Astrazeneca  |                |
|                                                                                                                                                                                                                                         | Aggrenox       |                    |                    | S               | Oral                           | 200 Mg Dipyridamole+ 25<br>Mg Acetylsalicylic Acid, 1<br>Df Two Times A Day |                 | Not Reported |                |
|                                                                                                                                                                                                                                         | Norprexanil    |                    |                    | S               | Oral                           | 5 Mg Perindopril + 5 Mg<br>Amlodipine Besilate 1 Df<br>Every Day            |                 | Not Reported |                |

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

|                                                                   |                          |   |         |        |              |
|-------------------------------------------------------------------|--------------------------|---|---------|--------|--------------|
| Urine Present; Red Blood Cell Count Decreased; Walking Disability | Teotard                  | S | Oral    |        | Not Reported |
|                                                                   | Tritace                  | S | Oral    |        | Not Reported |
|                                                                   | Cipralext                | S | Oral    |        | Not Reported |
|                                                                   | Controloc                | S | Oral    |        | Not Reported |
|                                                                   | Lamisil                  | C | Topical | Unspec | Not Reported |
|                                                                   | Twinlab Omega-3 Fish Oil | C | Oral    |        | Not Reported |
|                                                                   | Solgar Magnesium         | C | Oral    |        | Not Reported |
|                                                                   | Rizolip                  | C | Oral    | Unspec | Not Reported |
|                                                                   | Kal B-Complex            | C | Oral    |        | Not Reported |

| <u>FDA Received Date</u>                                                                                                     | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|-------------------------------------------|-----------------|--------------|----------------|
| 12-Oct-2012                                                                                                                  | 8839336        | DIRECT           | Y                  | DS, OT          |                      |                                           | 44 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                        | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                        | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Depression; Impaired Self-Care; Loss Of Personal Independence In Daily Activities; Pain; Product Substitution Issue | Escitalopram   |                  |                    | S               | Oral                 | Escitalopram 100mg T 1/2 Tablets P.O. Qam |                 | Not Reported |                |
|                                                                                                                              | Escitalopram   |                  |                    | S               | Oral                 | Escitalopram 10mg Tablet Po Qam           |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                                                           | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 12-Oct-2012                                                                                                                                                                        | 8839429        | DIRECT           |                    |                 |                      |                      | 69 YR           | Female     | USA            |
| <u>Preferred Term</u>                                                                                                                                                              | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Abdominal Pain Upper; Asthenia; Blood Pressure Increased; Fatigue; Formication; Gastrointestinal Pain; Hot Flush; Loss Of Consciousness; Product Substitution Issue; Skin Disorder | Escitalopram   |                  |                    | S               | Oral                 |                      |                 | Teva       |                |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                        | <u>Case #</u>                                                                     | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|------------------|--------------------|-----------------|----------------------|------------------------------|-----------------|--------------|----------------|
| 12-Oct-2012                                                                     | 9227139                                                                           | NON-EXPEDITED    | Y                  | RI, OT          | 1000029076           |                              | 53 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                           | <u>Product</u>                                                                    | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Angioedema; Rash                                                                | Lexapro (Escitalopram Oxalate) (10 Milligram, Tablets)                            |                  |                    | S               | Oral                 | 10 Mg (10mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                 | Amlodipine (Amlodipine) (Amlodipine)                                              |                  |                    | C               |                      |                              |                 | Not Reported |                |
|                                                                                 | Zolpidem (Zolpidem) (Zolpidem)                                                    |                  |                    | C               |                      |                              |                 | Not Reported |                |
|                                                                                 | Hyzaar (Hyzaar) (Hyzaar)                                                          |                  |                    | C               |                      |                              |                 | Not Reported |                |
|                                                                                 | Premarin (Estrogen Conjugated) (Estrogens Conjugated)                             |                  |                    | C               |                      |                              |                 | Not Reported |                |
|                                                                                 | Toprol (Metoprolol Succinate) (Metoprolol Succinate)                              |                  |                    | C               |                      |                              |                 | Not Reported |                |
|                                                                                 | Trazodone (Trazodone) (Trazodone)                                                 |                  |                    | C               |                      |                              |                 | Not Reported |                |
|                                                                                 | Maxalt (Rizatriptan) (Rizatriptan)                                                |                  |                    | C               |                      |                              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                        | <u>Case #</u>                                                                     | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Oct-2012                                                                     | 9227154                                                                           | NON-EXPEDITED    |                    | HO              | 1000029116           |                              | 21 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                           | <u>Product</u>                                                                    | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Anger; Crying; Social Avoidant Behaviour; Suicidal Behaviour; Suicidal Ideation | Lexapro (Escitalopram Oxalate)                                                    |                  |                    | S               | Oral                 |                              |                 | Not Reported |                |
|                                                                                 | Lexapro (Escitalopram Oxalate)                                                    |                  |                    | S               | Oral                 |                              |                 | Not Reported |                |
|                                                                                 | Loestrin Fe (Norethindrone, Ethinyl Estradiol) (Norethindrone, Ethinyl Estradiol) |                  |                    | C               |                      |                              |                 | Not Reported |                |
|                                                                                 |                                                                                   |                  |                    |                 |                      |                              |                 |              |                |
| <u>FDA Received Date</u>                                                        | <u>Case #</u>                                                                     | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Oct-2012                                                                     | 9227158                                                                           | NON-EXPEDITED    |                    | RI, OT          | 1000029147           |                              |                 | Female       | USA            |
| <u>Preferred Term</u>                                                           | <u>Product</u>                                                                    | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Suicide Attempt                                                     | Lexapro                                                                           |                  |                    | S               | Oral                 |                              |                 | Not Reported |                |

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

Oral

| <a href="#">FDA Received Date</a>                                                                                                      | <a href="#">Case #</a>                                                    | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>  | <a href="#">Age</a>      | <a href="#">Sex</a>                          | <a href="#">Country</a> |
|----------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|--------------------------------|--------------------------|----------------------------------------------|-------------------------|
| 12-Oct-2012                                                                                                                            | 9227160                                                                   | NON-EXPEDITED             |                             | RI, OT                   | 1000029221                    |                                | 30 YR                    | Female                                       | USA                     |
| <a href="#">Preferred Term</a>                                                                                                         | <a href="#">Product</a>                                                   | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>    | <a href="#">Duration</a> | <a href="#">Mfr</a>                          |                         |
| Depression; Fatigue; Suicidal Ideation                                                                                                 | Lexapro                                                                   |                           |                             | S                        | Oral                          | 20 Mg ( 20 Mg, 1 In 1 D), Oral |                          | Not Reported                                 |                         |
| <a href="#">FDA Received Date</a>                                                                                                      | <a href="#">Case #</a>                                                    | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>  | <a href="#">Age</a>      | <a href="#">Sex</a>                          | <a href="#">Country</a> |
| 12-Oct-2012                                                                                                                            | 9227164                                                                   | NON-EXPEDITED             |                             | RI, OT                   | 1000029263                    |                                | 40 YR                    | Male                                         | USA                     |
| <a href="#">Preferred Term</a>                                                                                                         | <a href="#">Product</a>                                                   | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>    | <a href="#">Duration</a> | <a href="#">Mfr</a>                          |                         |
| Blood Testosterone Decreased; Feeling Cold; Hyperhidrosis; Irritability; Libido Decreased; Suicidal Ideation; Tremor; Weight Increased | Lexapro<br>Wellburtin (Bupropion Hydrochloride) (Bupropion Hydrochloride) |                           |                             | S<br>C                   |                               |                                |                          | Not Reported<br>Not Reported                 |                         |
| <a href="#">FDA Received Date</a>                                                                                                      | <a href="#">Case #</a>                                                    | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>  | <a href="#">Age</a>      | <a href="#">Sex</a>                          | <a href="#">Country</a> |
| 12-Oct-2012                                                                                                                            | 9227177                                                                   | NON-EXPEDITED             | Y                           |                          | 1000029279                    |                                | 49 YR                    | Male                                         | USA                     |
| <a href="#">Preferred Term</a>                                                                                                         | <a href="#">Product</a>                                                   | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>    | <a href="#">Duration</a> | <a href="#">Mfr</a>                          |                         |
| Depression; Fatigue; Self-Injurious Ideation                                                                                           | Lexapro<br>Rebif<br>Marijuana                                             |                           |                             | S<br>S<br>C              | Oral<br>Subcutaneous          | 3 Doses In One Week.           |                          | Not Reported<br>Not Reported<br>Not Reported |                         |
| <a href="#">FDA Received Date</a>                                                                                                      | <a href="#">Case #</a>                                                    | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>  | <a href="#">Age</a>      | <a href="#">Sex</a>                          | <a href="#">Country</a> |
| 12-Oct-2012                                                                                                                            | 9227187                                                                   | NON-EXPEDITED             |                             | RI, OT                   | 1000029340                    |                                | 35 YR                    | Female                                       | USA                     |
| <a href="#">Preferred Term</a>                                                                                                         | <a href="#">Product</a>                                                   | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>    | <a href="#">Duration</a> | <a href="#">Mfr</a>                          |                         |

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

|                                                |                                                                    |        |      |  |  |  |  |              |              |
|------------------------------------------------|--------------------------------------------------------------------|--------|------|--|--|--|--|--------------|--------------|
| Agitation; Anger; Crying;<br>Suicidal Ideation | Lexapro (Escitalopram Oxalate)<br>(20 Milligram, Tablets)<br>Xanax | S<br>C | Oral |  |  |  |  | Not Reported | Not Reported |
|------------------------------------------------|--------------------------------------------------------------------|--------|------|--|--|--|--|--------------|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Oct-2012              | 9227201       | NON-EXPEDITED    |                    | RI, OT          | 1000029610           |                      | 37 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                                                           | <u>Product</u>                                                                                                                                              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>      | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                                                   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|------------|------------------|--------------|--------------------|-----------------|--------------------------------------------------------------|
| Anxiety; Blood Pressure<br>Increased; Chest<br>Discomfort; Dyskinesia;<br>Nervousness;<br>Restlessness; Skin<br>Burning Sensation;<br>Suicidal Ideation;<br>Withdrawal Syndrome | Escitalopram<br>Levothyroxine (Levothyroxine<br>Sodium) (Levothyroxine Sodium)<br>Omeprazole (Omeprazole)<br>(Omeprazole)<br>Fish Oil (Fish Oil) (Fish Oil) |              |            | S<br>C<br>C<br>C | Oral         |                    |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Oct-2012              | 9227209       | NON-EXPEDITED    |                    |                 | 1000029628           |                      | 78 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>                                                                                                                                                                                                                                                                                                                        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>                              | <u>Route</u>     | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                                                                                                   |
|-----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|------------|------------------------------------------|------------------|--------------------|-----------------|--------------------------------------------------------------------------------------------------------------|
| Hypertension          | Lexapro<br><br>Cymbalta<br>Spiriva<br>Hydrochlorothiazide<br>(Hydrochlorothiazide)(Hydrochlorothiazide)<br>Synthroid (Levothyroxine Sodium)(Levothyroxine Sodium)<br>Crestor (Rosuvastatin Calcium)(Rosuvastatin Calcium)<br>Boniva (Ibandronate Sodium)(Ibandronate Sodium)<br>Dexlansoprazole<br>(Dexlansoprazole)(Dexlansoprazole) |              |            | S<br><br>S<br>C<br>C<br>C<br>C<br>C<br>C | Oral<br><br>Oral |                    |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |

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

Albuterol (Albuterol)(Albuterol)  
Symbicort (Budesonide,  
Formoterol)(Budesonide,  
Formoterol)

C  
C

Not Reported  
Not Reported

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Oct-2012              | 9227213       | NON-EXPEDITED    | Y                  | RI, OT          | 1000029980           |                      | 56 YR      | Female     | USA            |

| <u>Preferred Term</u>  | <u>Product</u>                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------|--------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Ventricular Arrhythmia | Lexapro (Escitalopram Oxalate) |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Oct-2012              | 9227332       | NON-EXPEDITED    |                    | HO              | 1000025159           |                      | 50 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                      | <u>Product</u>                                               | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------|--------------|------------|-------------|--------------|--------------------------------|-----------------|--------------|
| Agitation; Crying;<br>Depression; Irritability;<br>Overdose; Overdose;<br>Paraesthesia; Suicide<br>Attempt | Lexapro (Escitalopram Oxalate)<br>(20 Milligram, Tablets)    |              |            | S           | Oral         | 20mg (20mg, 1 In 1 D),<br>Oral |                 | Not Reported |
|                                                                                                            | Lexapro (Escitalopram Oxalate)<br>(20 Milligram, Tablets)    |              |            | S           | Oral         | 30mg (30mg, 1 In 1 D),<br>Oral |                 | Not Reported |
|                                                                                                            | Depakote (Valproate<br>Semisodium)                           |              |            | C           |              |                                |                 | Not Reported |
|                                                                                                            | Klonopin (Clonazepam)<br>(Tablets)                           |              |            | C           |              |                                |                 | Not Reported |
|                                                                                                            | Ambien (Zolpidem Tartrate)                                   |              |            | S           |              |                                |                 | Not Reported |
|                                                                                                            | Sleeping Pills Nos (Sleeping<br>Pills Nos)                   |              |            | S           |              |                                |                 | Not Reported |
|                                                                                                            | Unspecified Medications Nos<br>(Unspecified Medications Nos) |              |            | S           |              |                                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Oct-2012              | 9227340       | NON-EXPEDITED    |                    | HO              | 1000025511           |                      | 61 YR      | Female     | USA            |

| <u>Preferred Term</u>                                        | <u>Product</u>                                            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------|-----------------------------------------------------------|--------------|------------|-------------|--------------|--------------------------------|-----------------|--------------|
| Ataxia; Hallucination;<br>Insomnia; Panic Attack;<br>Vertigo | Lexapro (Escitalopram Oxalate)<br>20 Milligram, Tableets) |              |            | S           | Oral         | 20mg (20mg, 1 In 1 D),<br>Oral |                 | Not Reported |

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| <u>FDA Received Date</u>                                                                             | <u>Case #</u>                               | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------|---------------------------------------------|------------------|--------------------|-----------------|----------------------|--------------------------------|-----------------|--------------|----------------|
| 12-Oct-2012                                                                                          | 9227359                                     | NON-EXPEDITED    |                    | HO              | 1000026846           |                                | 26 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                | <u>Product</u>                              | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Suicide Attempt                                                                                      | Lexapro                                     |                  |                    | S               | Oral                 | 10mg (10mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                                                                      | Keppra (Levetiracetam)                      |                  |                    | C               |                      |                                |                 | Not Reported |                |
|                                                                                                      | Zonegran (Zonisamide)                       |                  |                    | C               |                      |                                |                 | Not Reported |                |
|                                                                                                      | Vimpat (Lacosamide)                         |                  |                    | C               |                      |                                |                 | Not Reported |                |
|                                                                                                      | Lorazepam (Lorazepam)                       |                  |                    | C               |                      |                                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                             | <u>Case #</u>                               | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Oct-2012                                                                                          | 9227376                                     | NON-EXPEDITED    | Y                  | RI, OT          | 1000027216           |                                |                 | Male         | DNK            |
| <u>Preferred Term</u>                                                                                | <u>Product</u>                              | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Suicidal Ideation                                                                                    | Lexapro (Escitalopram Oxalate)              |                  |                    | S               | Oral                 |                                |                 | Not Reported |                |
|                                                                                                      | Sabril                                      |                  |                    | S               | Oral                 |                                |                 | Not Reported |                |
|                                                                                                      | Anti-Epileptic Drugs (Anti-Epileptic Drugs) |                  |                    | C               | Oral                 |                                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                             | <u>Case #</u>                               | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Oct-2012                                                                                          | 9227386                                     | NON-EXPEDITED    |                    | RI, OT          | 1000027292           |                                |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                | <u>Product</u>                              | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Pressure Increased;<br>Burning Sensation; Cold<br>Sweat; Feeling Abnormal;<br>Headache; Nausea | Lexapro (Escitalopram Oxalate)              |                  |                    | S               |                      | 5 Gm, 1 In 1 D                 |                 | Not Reported |                |
|                                                                                                      | Armour (Thyroid (Thyroid)                   |                  |                    | C               |                      |                                |                 | Armour       |                |
|                                                                                                      | Ativan (Lorazepam)<br>(Lorazepam)           |                  |                    | C               |                      |                                |                 | Not Reported |                |
|                                                                                                      | Xanax                                       |                  |                    | C               |                      |                                |                 | Not Reported |                |
|                                                                                                      | Catapres (Clonidine) (Clonidine)            |                  |                    | C               |                      |                                |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                          | <u>Case #</u>                                     | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
|-----------------------------------------------------------------------------------|---------------------------------------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------------------------|----------------|
| 12-Oct-2012                                                                       | 9227395                                           | NON-EXPEDITED    |                    | DE              | 1000027438           |                      | 49 YR           | Male                         | USA            |
| <u>Preferred Term</u>                                                             | <u>Product</u>                                    | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Completed Suicide                                                                 | Lexapro<br>Toprol XI (Metoprolol)<br>(Metoprolol) |                  |                    | S<br>C          |                      |                      |                 | Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                          | <u>Case #</u>                                     | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 12-Oct-2012                                                                       | 9227404                                           | NON-EXPEDITED    | Y                  | RI, OT          | 1000028429           |                      |                 | Female                       | USA            |
| <u>Preferred Term</u>                                                             | <u>Product</u>                                    | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Cardiac Flutter; Hair<br>Colour Changes; Tremor;<br>Vision Blurred                | Lexapro                                           |                  |                    | S               |                      |                      |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                                                          | <u>Case #</u>                                     | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 12-Oct-2012                                                                       | 9227413                                           | NON-EXPEDITED    |                    | RI, OT          | 1000028448           |                      | 84 YR           | Female                       | USA            |
| <u>Preferred Term</u>                                                             | <u>Product</u>                                    | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Crying; Diarrhoea; Feeling<br>Abnormal; Insomnia; Neck<br>Pain; Suicidal Ideation | Lexapro<br>Vitamin B 12                           |                  |                    | S<br>C          | Oral                 | (5 Mg, 1 In 1 D)     |                 | Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                          | <u>Case #</u>                                     | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 12-Oct-2012                                                                       | 9227420                                           | NON-EXPEDITED    |                    | RI, OT          | 1000028865           |                      |                 | Male                         | USA            |
| <u>Preferred Term</u>                                                             | <u>Product</u>                                    | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Depression; Mania                                                                 | Lexapro                                           |                  |                    | S               |                      | 1 In 1 D             |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                                                          | <u>Case #</u>                                     | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 12-Oct-2012                                                                       | 9227599                                           | NON-EXPEDITED    | Y                  | DE              | 1000030062           |                      |                 | Male                         | USA            |

# FDA Adverse Event Reporting System

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### Detailed Report

| <u>Preferred Term</u>                                                   | <u>Product</u>                                                                                | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>         | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>                                                   |                |
|-------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------|------------------|--------------------|------------------|----------------------|---------------------------------------------|-----------------|--------------------------------------------------------------|----------------|
| Completed Suicide;<br>Depression;<br>Tachyphrenia;<br>Unevaluable Event | Escitalopram                                                                                  |                  |                    | S                | Oral                 |                                             |                 | Not Reported                                                 |                |
| <u>FDA Received Date</u>                                                | <u>Case #</u>                                                                                 | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u> | <u>503B Facility</u>                        | <u>Age</u>      | <u>Sex</u>                                                   | <u>Country</u> |
| 12-Oct-2012                                                             | 9227611                                                                                       | NON-EXPEDITED    |                    | HO               | 1000030362           |                                             | 90 YR           | Female                                                       | USA            |
| <u>Preferred Term</u>                                                   | <u>Product</u>                                                                                | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>         | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>                                                   |                |
| Anaemia; Contusion;<br>Dizziness; Fall; Fatigue                         | Lexapro<br>Aspirin (Acetylsalicylic Acid)<br>Warfarin (Warfarin)<br>Diazepam (Diazepam)       |                  |                    | S<br>C<br>C<br>S |                      |                                             |                 | Forest<br>Not Reported<br>Not Reported<br>Not Reported       |                |
| <u>FDA Received Date</u>                                                | <u>Case #</u>                                                                                 | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u> | <u>503B Facility</u>                        | <u>Age</u>      | <u>Sex</u>                                                   | <u>Country</u> |
| 12-Oct-2012                                                             | 9227622                                                                                       | NON-EXPEDITED    | Y                  | RI, OT           | 1000030447           |                                             | 40 YR           | Female                                                       | USA            |
| <u>Preferred Term</u>                                                   | <u>Product</u>                                                                                | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>         | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>                                                   |                |
| Anxiety; Insomnia; Panic<br>Attack; Suicidal Ideation;<br>Tachyphrenia  | Escitalopram                                                                                  |                  |                    | S                | Oral                 |                                             |                 | Not Reported                                                 |                |
| <u>FDA Received Date</u>                                                | <u>Case #</u>                                                                                 | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u> | <u>503B Facility</u>                        | <u>Age</u>      | <u>Sex</u>                                                   | <u>Country</u> |
| 12-Oct-2012                                                             | 9227633                                                                                       | NON-EXPEDITED    |                    | RI, OT           | 1000030561           |                                             | 58 YR           | Female                                                       | USA            |
| <u>Preferred Term</u>                                                   | <u>Product</u>                                                                                | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>         | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>                                                   |                |
| Abdominal Discomfort;<br>Anxiety; Fatigue; Feeling<br>Abnormal; Malaise | Lexapro<br>Xanax Xr<br>Alprazolam<br>Lipitor (Atorvastatin Calcium)<br>(Atorvastatin Calcium) |                  |                    | S<br>S<br>S<br>C | <br>Oral<br>Oral     | 1 In 1 D<br>1mg, 3 In 1 D<br>1 Mg, 3 In 1 D |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |                |

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| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 12-Oct-2012              | 9227638        | NON-EXPEDITED    |                    | RI, OT          | 100030625            |                      | 51 YR           | Female     | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Platelet Count Decreased | Lexapro        |                  |                    | S               |                      |                      |                 |            | Not Reported   |

| <u>FDA Received Date</u>                     | <u>Case #</u>                     | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|----------------------------------------------|-----------------------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 12-Oct-2012                                  | 9227646                           | NON-EXPEDITED    |                    | RI, OT          | 1000030827           |                      | 48 YR           | Male       | USA            |
| <u>Preferred Term</u>                        | <u>Product</u>                    | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Hypersensitivity; Pyrexia; Unevaluable Event | Lexapro                           |                  |                    | S               |                      |                      |                 |            | Not Reported   |
|                                              | Escitalopram                      |                  |                    | S               |                      |                      |                 |            | Not Reported   |
|                                              | Lipitor (Atorvastatin Calcium)    |                  |                    | S               |                      | (80 Mg, 1 In 1 D)    |                 |            | Not Reported   |
|                                              | Alprazolam (Alprazolam)           |                  |                    | S               |                      |                      |                 |            | Not Reported   |
|                                              | Carvedilol                        |                  |                    | S               |                      |                      |                 |            | Not Reported   |
|                                              | Unspecified                       |                  |                    | S               |                      |                      |                 |            | Not Reported   |
|                                              | Nitrostat( Nitroglycerin)         |                  |                    | C               |                      |                      |                 |            | Not Reported   |
|                                              | (Nitroglycerin)                   |                  |                    |                 |                      |                      |                 |            |                |
|                                              | Aspirin (Acetylsalicylic Acid)    |                  |                    | C               |                      |                      |                 |            | Not Reported   |
|                                              | (Acetylsalicylic Acid)            |                  |                    |                 |                      |                      |                 |            |                |
|                                              | Quinapril (Quinapril) (Quinapril) |                  |                    | C               |                      |                      |                 |            | Not Reported   |
|                                              | Plavix (Clopidogrel Bisulfate)    |                  |                    | C               |                      |                      |                 |            | Not Reported   |
|                                              | (Clopidogrel Bisulfate)           |                  |                    |                 |                      |                      |                 |            |                |
|                                              | Xanax                             |                  |                    | C               |                      |                      |                 |            | Not Reported   |
|                                              | Coreg (Carvedilol) (Carvedilol)   |                  |                    | C               |                      |                      |                 |            | Not Reported   |

| <u>FDA Received Date</u>                    | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 12-Oct-2012                                 | 9227654        | NON-EXPEDITED    |                    | RI, OT          | 1000031506           |                      | 56 YR           | Female     | USA            |
| <u>Preferred Term</u>                       | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Fatigue; Heart Rate Increased; Palpitations | Lexapro        |                  |                    | S               | Oral                 | 10 Mg, 1 In 1 D      |                 |            | Not Reported   |



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| <u>FDA Received Date</u>                                                         | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 12-Oct-2012                                                                      | 9227663        | NON-EXPEDITED    | Y                  | RI, OT          | 1000037036           |                      |                 | Male         | USA            |
| <u>Preferred Term</u>                                                            | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hepatic Enzyme Increased                                                         | Lexapro        |                  |                    | S               |                      |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                         | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Oct-2012                                                                      | 9227666        | NON-EXPEDITED    |                    | DE              | 1000031572           |                      |                 | Male         | USA            |
| <u>Preferred Term</u>                                                            | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Drug Ineffective; Off Label Use                               | Escitalopram   |                  |                    | S               | Oral                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                         | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Oct-2012                                                                      | 9227672        | NON-EXPEDITED    |                    | RI, OT          | 1000037120           |                      | 31 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                            | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Hallucination; Hypoaesthesia; Nausea; Suicidal Ideation; Tachyphrenia | Lexapro        |                  |                    | S               | Oral                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                         | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Oct-2012                                                                      | 9227674        | NON-EXPEDITED    | Y                  | RI, OT          | 1000036640           |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                            | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Gastrointestinal Haemorrhage                                                     | Lexapro        |                  |                    | S               | Oral                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                         | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Oct-2012                                                                      | 9227680        | NON-EXPEDITED    |                    | RI, OT          | 1000036719           |                      | 32 YR           | Female       | USA            |

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| <u>Preferred Term</u>                               | <u>Product</u>                          | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|-----------------------------------------------------|-----------------------------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Depression; Suicidal Ideation                       | Lexapro                                 |                  |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                     | Clonazepam (Clonazepam)<br>(Clonazepam) |                  |                    | C               | Oral                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                            | <u>Case #</u>                           | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Oct-2012                                         | 9227693                                 | NON-EXPEDITED    |                    | RI, OT          | 100023627            |                      | 78 YR           | Male         | USA            |
| <u>Preferred Term</u>                               | <u>Product</u>                          | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective; Suicidal Ideation                 | Lexapro                                 |                  |                    | S               | Oral                 | 20 Mg, 1 In 1 D      |                 | Not Reported |                |
|                                                     | Advair                                  |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                     | Metformin                               |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                     | Glipizide                               |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                     | Levothyroxine                           |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                     | Zyprexa                                 |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                     | Lorazepam                               |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                     | Digoxin                                 |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                     | Taztia                                  |                  |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                            | <u>Case #</u>                           | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Oct-2012                                         | 9227707                                 | NON-EXPEDITED    | Y                  | RI, OT          | 1000023652           |                      | 42 YR           | Female       | USA            |
| <u>Preferred Term</u>                               | <u>Product</u>                          | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Depression; Mood Swings; Suicidal Ideation | Lexapro                                 |                  |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                     | Lexapro                                 |                  |                    | S               | Oral                 | Stopped              |                 | Not Reported |                |
|                                                     | Lexapro                                 |                  |                    | S               | Oral<br>Oral         |                      |                 | Not Reported |                |
|                                                     | Lexapro                                 |                  |                    | S               | Oral<br>Oral         |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                            | <u>Case #</u>                           | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Oct-2012                                         | 9227719                                 | NON-EXPEDITED    | Y                  | RI, OT          | 1000024125           |                      | 55 YR           | Female       | USA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Electrocardiogram Qt Prolonged | Lexapro        |              |            | S           | Oral         | 10 Mg 1 In 1 D     |                 | Not Reported |
|                                | Vytorin        |              |            | C           |              |                    |                 | Not Reported |
|                                | Synthroid      |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Oct-2012              | 9227726       | NON-EXPEDITED    | Y                  | RI, OT          | 1000024585           |                      | 29 YR      | Female     | USA            |

| <u>Preferred Term</u>                            | <u>Product</u>                                                    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------|-------------------------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hypertension; Maternal Exposure During Pregnancy | Lexapro                                                           |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Zofran (Ondansetron)                                              |              |            | C           |              |                    |                 | Not Reported |
|                                                  | (Ondansetron)                                                     |              |            |             |              |                    |                 |              |
|                                                  | Prenatal Vitamin (Prenatal Vitamin) (Prenatal Vitamin)            |              |            | C           |              |                    |                 | Not Reported |
|                                                  | Zinc (Zinc) (Zinc)                                                |              |            | C           |              |                    |                 | Not Reported |
|                                                  | Fish Oil (Fish Oil) (Fish Oil)                                    |              |            | C           |              |                    |                 | Not Reported |
|                                                  | Vitamin B-12 (Cyanocobalamin) (Cyanocobalamin)                    |              |            | C           |              |                    |                 | Not Reported |
|                                                  | Valtrex (Valaciclovir Hydrochloride) (Valaciclovir Hydrochloride) |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Oct-2012              | 9227735       | NON-EXPEDITED    |                    | RI, OT          | 1000024785           |                      | 63 YR      | Female     | USA            |

| <u>Preferred Term</u>                           | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Crying; Depression; Insomnia; Suicidal Ideation | Escitalopram Oxalate |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Oct-2012              | 9227747       | NON-EXPEDITED    | Y                  | RI, OT          | 1000024939           |                      | 43 YR      | Female     | USA            |

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

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

|                   |                                                                  |   |      |  |  |  |  |  |  |              |
|-------------------|------------------------------------------------------------------|---|------|--|--|--|--|--|--|--------------|
| Suicidal Ideation | Lexapro                                                          | S | Oral |  |  |  |  |  |  | Not Reported |
|                   | Lipofen (Fenofibrate)                                            | C |      |  |  |  |  |  |  | Not Reported |
|                   | (Fenofibrate)                                                    |   |      |  |  |  |  |  |  |              |
|                   | Vicodin (Hydrocodone, Acetaminophen) (Hydrocodone Acetaminophen) | C |      |  |  |  |  |  |  | Not Reported |
|                   | Valium (Diazepam) (Diazepam)                                     | C |      |  |  |  |  |  |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Oct-2012              | 9227757       | NON-EXPEDITED    |                    | HO              | 1000025082           |                      | 15 YR      | Male       | USA            |

| <u>Preferred Term</u>                                     | <u>Product</u>                                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------|-----------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Off Label Use; Self-Injurious Ideation; Suicidal Ideation | Lexapro                                       |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                           | Focalin Xr (Dexmethylphenidate Hydrochloride) |              |            | C           |              |                    |                 | Not Reported |
|                                                           | (Dexmethylphenidate Hydrochloride)            |              |            |             |              |                    |                 |              |
|                                                           | Klonopin (Clonazepam) (Clonazepam)            |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Oct-2012              | 9227928       | NON-EXPEDITED    |                    | RI, OT          | 1000037681           |                      |            | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Urinary Retention     | Lexapro        |              |            | S           |              |                    |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Oct-2012              | 9227940       | NON-EXPEDITED    | Y                  | RI, OT          | 1000037755           |                      |            | Female     | USA            |

| <u>Preferred Term</u>         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Depression; Suicidal Ideation | Escitalopram   |              |            | S           | Oral         | Stopped            |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Oct-2012              | 10393363      | NON-EXPEDITED    |                    | OT              | 1000029112           |                      |            | Female     | USA            |

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

| <u>Preferred Term</u>               | <u>Product</u>                                                            | <u>Comp.</u>   | <u>OTC</u>         | <u>Role</u>        | <u>Route</u>    | <u>Dosage Text</u>                              | <u>Duration</u>      | <u>Mfr</u>      |            |                |
|-------------------------------------|---------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|------------|----------------|
| Hypersensitivity; Suicidal Ideation | Lexapro (Escitalopram Oxalate)                                            |                |                    | S                  |                 |                                                 |                      | Not Reported    |            |                |
|                                     | Calan(Verapamil)(Verapamil)                                               |                |                    | C                  |                 |                                                 |                      | Not Reported    |            |                |
|                                     | Coumadin(Warfarin)(Warfarin)                                              |                |                    | C                  |                 |                                                 |                      | Not Reported    |            |                |
|                                     | Avapro(Irbesartan)(Irbesartan)                                            |                |                    | C                  |                 |                                                 |                      | Not Reported    |            |                |
|                                     | Bystolic(Nebivolol Hydrochloride)(Nebivolol Hydrochloride)                |                |                    | C                  |                 |                                                 |                      | Not Reported    |            |                |
|                                     | Allegra(Fexofenadine Hydrochloride)(Fexofenadine Hydrochloride)           |                |                    | C                  |                 |                                                 |                      | Not Reported    |            |                |
|                                     | Anusol(Hydrocortisone)(Hydrocortisone)                                    |                |                    | C                  |                 |                                                 |                      | Not Reported    |            |                |
|                                     | Calcium(Calcium)(Calcium)                                                 |                |                    | C                  |                 |                                                 |                      | Not Reported    |            |                |
|                                     | Vitamin D3(Colecalciferol)(Colecalciferol)                                |                |                    | C                  |                 |                                                 |                      | Not Reported    |            |                |
|                                     | Multivitamin(Multivitamin)(Moltivitamin)                                  |                |                    | C                  |                 |                                                 |                      | Not Reported    |            |                |
|                                     | Vitamin C(Vitamin C)(Vitamin C)                                           |                |                    | C                  |                 |                                                 |                      | Not Reported    |            |                |
|                                     | Super B Complex(Super B Complex)(Super B Complex)                         |                |                    | C                  |                 |                                                 |                      | Not Reported    |            |                |
|                                     | Xanax(Alprazolam)(0.25 Milligram)(Alprazolam)                             |                |                    | C                  |                 |                                                 |                      | Not Reported    |            |                |
|                                     | Lyrica(Pregabalin)(Pregabalin)                                            |                |                    | C                  |                 |                                                 |                      | Not Reported    |            |                |
|                                     | Maxzide(Triamterene, Hydrochlorothiazide)(Triamteren Hydrochlorothiazide) |                |                    | C                  |                 |                                                 |                      | Not Reported    |            |                |
|                                     | Plaquenil(Hydrochloroquine)(Hydrochloroquine)                             |                |                    | C                  |                 |                                                 |                      | Not Reported    |            |                |
|                                     | Antivert(Meclizine)(Meclizine)                                            |                |                    | C                  |                 |                                                 |                      | Not Reported    |            |                |
|                                     | Symal(Symal)(Symal)                                                       |                |                    | C                  |                 |                                                 |                      | Not Reported    |            |                |
|                                     | Macrobid(Nitrofurantoin)(Nitrofurantoin)                                  |                |                    | C                  |                 |                                                 |                      | Not Reported    |            |                |
|                                     | <u>FDA Received Date</u>                                                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|                                     | 15-Oct-2012                                                               | 8838933        | EXPEDITED (15-DAY) |                    | HO, OT          | US-PAR<br>PHARMACEUTICAL,<br>INC-2012SCPR004649 |                      |                 | Unknown    | USA            |
|                                     | <u>Preferred Term</u>                                                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

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

|                                                     |              |   |         |              |              |
|-----------------------------------------------------|--------------|---|---------|--------------|--------------|
| Product Administration<br>Error; Serotonin Syndrome | Clonazepam   | S | Nasal   | Unk, Unknown | Par          |
|                                                     | Clonazepam   | S |         |              | Par          |
|                                                     | Escitalopram | S | Nasal   | 20 Mg, / Day | Not Reported |
|                                                     | Escitalopram | S |         |              | Not Reported |
|                                                     | Quetiapine   | S | Nasal   | Unk, Unknown | Not Reported |
|                                                     | Quetiapine   | S |         |              | Not Reported |
|                                                     | Percocet     | S | Nasal   | Unk, Unknown | Not Reported |
|                                                     | Cocaine      | S | Unknown | Unk, Unknown | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 15-Oct-2012              | 8839352       | EXPEDITED (15-DAY) |                    | OT              | BR-JNJFOC-20121004089 |                      |            | Female     | BRA            |

| <u>Preferred Term</u>                                                                                             | <u>Product</u>  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>  | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------|-----------------|--------------|------------|-------------|---------------|--------------------|-----------------|--------------|
| Balance Disorder;<br>Bradyphrenia; Gait<br>Disturbance; Language<br>Disorder; Malaise; Muscle<br>Rigidity; Tremor | Invega Sustenna |              |            | S           | Intramuscular |                    |                 | Not Reported |
|                                                                                                                   | Invega Sustenna |              |            | S           | Intramuscular |                    |                 | Not Reported |
|                                                                                                                   | Invega Sustenna |              |            | S           | Intramuscular |                    |                 | Not Reported |
|                                                                                                                   | Invega Sustenna |              |            | S           | Intramuscular |                    |                 | Not Reported |
|                                                                                                                   | Lexapro         |              |            | S           | Unknown       |                    |                 | Not Reported |
|                                                                                                                   | Lexapro         |              |            | S           | Unknown       |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Oct-2012              | 8839893       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000039396    |                      | 52 YR      | Male       | FRA            |

| <u>Preferred Term</u>                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Balance Disorder;<br>Bradycardia; Dizziness | Escitalopram   |              |            | S           | Oral         | 20 Mg              |                 | Forest       |
|                                             | Isoptine       |              |            | S           | Oral         | 120 Mg             |                 | Not Reported |
|                                             | Temerit        |              |            | S           | Oral         | 2.5 Mg             |                 | Not Reported |
|                                             | Temerit        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                             | Kardegic       |              |            | S           | Oral         | 160 Mg             |                 | Not Reported |
|                                             | Kardegic       |              |            | S           | Oral         |                    |                 | Not Reported |

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

|  |                        |   |      |                   |              |
|--|------------------------|---|------|-------------------|--------------|
|  | Unspecified Ingredient | S | Oral | 50 Mg/20 Mg Daily | Not Reported |
|  | Cozaar                 | S | Oral | 100 Mg            | Not Reported |
|  | Metformine             | C |      |                   | Not Reported |
|  | Symbicort Turbuhaler   | C |      |                   | Not Reported |
|  | Allopurinol            | C |      |                   | Not Reported |
|  | Atarax                 | C |      |                   | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Oct-2012              | 8840677       | EXPEDITED (15-DAY) |                    | OT              | CA-FRI-1000039421    |                      |            | Male       | CAN            |

| <u>Preferred Term</u>                    | <u>Product</u>             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>             |
|------------------------------------------|----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------------------|
| Myocardial Infarction;<br>Vascular Graft | Escitalopram<br>Water Pill |              |            | S<br>C      |              |                    |                 | Forest<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|------------|------------|----------------|
| 15-Oct-2012              | 8841116       | EXPEDITED (15-DAY) |                    | OT              | NZ-MYLANLABS-<br>2012S1020537 |                      | 2 YR       | Male       | NZL            |

| <u>Preferred Term</u>             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Accidental Exposure To<br>Product | Escitalopram   |              |            | S           | Oral         |                    |                 | Mylan      |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u>       | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------------|----------------------|----------------------|------------|------------|----------------|
| 15-Oct-2012              | 8842415       | DIRECT           |                    | DS, HO, LT, RI,<br>OT |                      |                      | 23 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                       | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>             |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------------------|
| Anxiety; Depression;<br>Derealisation; Emotional<br>Disorder; Hypoacusis;<br>Insomnia; Loss Of Libido;<br>Restlessness; Sexual<br>Dysfunction; Suicidal<br>Ideation; Tinnitus; Visual<br>Impairment; Withdrawal<br>Syndrome | Lexapro<br>Lexapro |              |            | S<br>C      | Oral         |                    |                 | Forest<br>Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                  | <u>Case #</u>                                                                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------------------|-----------------|--------------|----------------|
| 15-Oct-2012                                                                                                                                                               | 8842433                                                                       | DIRECT             |                    |                 |                      |                                  | 58 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                     | <u>Product</u>                                                                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Depression;<br>Incorrect Dose<br>Administered; Product<br>Substitution Issue                                                                                     | Escitalopram                                                                  |                    |                    | S               | Oral                 |                                  |                 | Mylan        |                |
| <u>FDA Received Date</u>                                                                                                                                                  | <u>Case #</u>                                                                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Oct-2012                                                                                                                                                               | 8822499                                                                       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000039110    |                                  | 26 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                                                                                     | <u>Product</u>                                                                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Pulmonary Infarction                                                                                                                                                      | Escitalopram                                                                  |                    |                    | S               | Oral                 | 15 Mg                            |                 | Forest       |                |
|                                                                                                                                                                           | Statin                                                                        |                    |                    | C               |                      |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                  | <u>Case #</u>                                                                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Oct-2012                                                                                                                                                               | 8829211                                                                       | EXPEDITED (15-DAY) | Y                  | DS, HO, LT      | DSM-2012-01036       |                                  | 47 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                                                     | <u>Product</u>                                                                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Potassium<br>Decreased; Confusional<br>State; Disorientation;<br>Hyponatraemia; Metabolic<br>Disorder; Osmotic<br>Demyelination Syndrome;<br>Pulmonary Hypertension | Olmetec                                                                       |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                                                                                                                                           | Seroplex                                                                      |                    |                    | S               | Oral                 |                                  |                 | Not Reported |                |
|                                                                                                                                                                           | Climaston (Estradiol,<br>Dydrogesterone) (***) (Estradiol,<br>Dydrogesterone) |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                                           | Levothyrox (Levothyroxine<br>Sodium) (Levothyroxine Sodium)                   |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                                           | Previscan (Fluindione)                                                        |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                                           | Veratran (Clotiazepam)                                                        |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                                           | (Clotiazepam)                                                                 |                    |                    |                 |                      |                                  |                 |              |                |
|                                                                                                                                                                           | Calciparine (Heparin Calcium)                                                 |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                                           | (Heparin Calcium)                                                             |                    |                    |                 |                      |                                  |                 |              |                |
|                                                                                                                                                                           | Volibris (Ambrisentan)                                                        |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                                           | (Ambrisentan)                                                                 |                    |                    |                 |                      |                                  |                 |              |                |



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

|  |                              |   |  |              |
|--|------------------------------|---|--|--------------|
|  | Revatio (Sildenafil Citrate) | C |  | Not Reported |
|  | (Sildenafil Citrate)         | C |  | Not Reported |
|  | Rebif                        | C |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Oct-2012              | 8842899       | EXPEDITED (15-DAY) | HO                 |                 | US-WATSON-2012-17656 |                      | 20 YR      | Male       | USA            |

| <u>Preferred Term</u>                                             | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>             | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------------------|---------------------------------|-----------------|--------------|
| Intentional Overdose;<br>Product Use Issue;<br>Serotonin Syndrome | Clonazepam (Unknown) |              |            | S           | Respiratory (inhalation) | Snorted Crushed Tablets         |                 | Watson       |
|                                                                   | Clonazepam (Unknown) |              |            | S           |                          |                                 |                 | Watson       |
|                                                                   | Quetiapine           |              |            | S           | Respiratory (inhalation) | 100 Mg, Snorted Crushed Tablets |                 | Not Reported |
|                                                                   | Quetiapine           |              |            | S           |                          |                                 |                 | Not Reported |
|                                                                   | Percocet /00446701/  |              |            | S           | Respiratory (inhalation) | Snorted Crushed Tablets         |                 | Not Reported |
|                                                                   | Percocet /00446701/  |              |            | S           |                          |                                 |                 | Not Reported |
|                                                                   | Escitalopram         |              |            | S           | Respiratory (inhalation) | 20 Mg, Snorted Crushed Tablets  |                 | Not Reported |
|                                                                   | Escitalopram         |              |            | S           |                          |                                 |                 | Not Reported |
|                                                                   | Cocaine              |              |            | S           | Respiratory (inhalation) | Unk                             |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Oct-2012              | 8843314       | EXPEDITED (15-DAY) | OT                 |                 | FR-FRI-1000039457    |                      |            | Female     | FRA            |

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

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Oct-2012              | 8843319       | EXPEDITED (15-DAY) | OT                 |                 | HR-FRI-1000039429    |                      |            | Male       | HRV            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Blood Cholesterol     | Escitalopram   |              |            | S           | Oral         | 5 Mg               |                 | Forest     |

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

|                            |                          |   |         |        |              |
|----------------------------|--------------------------|---|---------|--------|--------------|
| Increased; Blood Uric Acid | Aggrenox                 | S | Oral    | 50 Mg  | Not Reported |
| Increased; Constipation;   | Norprexanil              | S | Oral    | 5/5 Mg | Not Reported |
| Diarrhoea; Flatulence;     | Teotard                  | S | Oral    | 200 Mg | Not Reported |
| Haematocrit Decreased;     | Tritace                  | S | Oral    | 2.5 Mg | Not Reported |
| Haemoglobin Decreased;     | Controloc                | S | Oral    | 20 Mg  | Not Reported |
| Muscle Atrophy; Muscle     | Crestor                  | S | Oral    | 20 Mg  | Not Reported |
| Spasms; Myalgia; Nail      | Kal B-Complex            | S | Oral    | 100 Mg | Not Reported |
| Discolouration; Nitrite    | Twinlab Omega-3 Fish Oil | C | Oral    |        | Not Reported |
| Urine; Red Blood Cell      | Lamisil                  | C | Topical |        | Not Reported |
| Count Decreased; Walking   | Solgar Magnezij          | C | Oral    | 300 Mg | Not Reported |
| Disability                 | Rizolip                  | C | Oral    |        | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 17-Oct-2012              | 8774784       | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-2012220803 |                      |            | Female     | USA            |

| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Asthenia; Drug          | Effexor        |              |            | S           |              | Unk                |                 | Pfizer       |
| Dependence; Fatigue;    | Lexapro        |              |            | S           |              | 20 Mg, Unk         |                 | Not Reported |
| Feeling Abnormal;       |                |              |            |             |              |                    |                 |              |
| Influenza Like Illness; |                |              |            |             |              |                    |                 |              |
| Insomnia; Malaise;      |                |              |            |             |              |                    |                 |              |
| Nausea; Product Dose    |                |              |            |             |              |                    |                 |              |
| Omission                |                |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Oct-2012              | 8821183       | EXPEDITED (15-DAY) |                    |                 | IE-FRI-1000039113    |                      | 34 YR      | Male       | IRL            |

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

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 17-Oct-2012              | 8845213       | EXPEDITED (15-DAY) |                    | HO              | FR-009507513-1210FRA005110 |                      | 52 YR      | Male       | FRA            |

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

| <u>Preferred Term</u>                     | <u>Product</u>                     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------|------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Balance Disorder;<br>Bradycardia; Vertigo | Cozaar 100mg, Comprim?             |              |            | S           | Oral         | 100 Mg, Qd         |                 | Merck        |
|                                           | Pellicul?                          |              |            | S           | Oral         | 120 Mg, Qd         |                 | Not Reported |
|                                           | Isoptine                           |              |            | S           | Oral         | 2.5 Mg, Qd         |                 | Not Reported |
|                                           | Temerit                            |              |            | S           | Oral         | 160 Mg, Qd         |                 | Not Reported |
|                                           | Kardegic                           |              |            | S           | Oral         | 1 Df, Qd           |                 | Not Reported |
|                                           | Aldalix                            |              |            | S           | Oral         | 20 Mg, Qd          |                 | Not Reported |
|                                           | Seroplex                           |              |            | C           | Oral         |                    |                 | Not Reported |
|                                           | Atarax (Hydroxyzine Hydrochloride) |              |            | C           |              |                    |                 | Not Reported |
|                                           | Metformin                          |              |            | C           |              |                    |                 | Not Reported |
|                                           | Symbicort Turbuhaler               |              |            | C           |              |                    |                 | Not Reported |
|                                           | Allopurinol                        |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 17-Oct-2012              | 8846544       | EXPEDITED (15-DAY) |                    | OT              | US-GLAXOSMITHKLINE-A0997673A |                      | 41 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                   | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|-------------------------------------------------------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Abortion Spontaneous;<br>Drug Ineffective; Exposure<br>During Pregnancy | Wellbutrin                |              |            | S           | Unknown      |                    |                 | Glaxosmithkline |
|                                                                         | Celexa                    |              |            | S           | Unknown      |                    |                 | Not Reported    |
|                                                                         | Prozac                    |              |            | S           | Unknown      |                    |                 | Not Reported    |
|                                                                         | Lexapro                   |              |            | S           | Unknown      |                    |                 | Not Reported    |
|                                                                         | No Concurrent Medications |              |            | C           |              |                    |                 | Not Reported    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Oct-2012              | 8707198       | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000037618    |                      | 43 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                                                                                  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Agitation; Fatigue;<br>Hallucination; Increased<br>Appetite; Initial Insomnia;<br>Myalgia; Skin<br>Haemorrhage; Tremor | Escitalopram   |              |            | S           |              | 20 Mg              |                 | Forest       |
|                                                                                                                        | Zolpidem       |              |            | C           |              | 10 Mg              |                 | Not Reported |
|                                                                                                                        | Parkinane      |              |            | C           |              | 5 Mg               |                 | Not Reported |

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

|            |   |        |              |
|------------|---|--------|--------------|
| Bromazepam | C | 6 Mg   | Not Reported |
| Efferalgan | C | 1 Gram | Not Reported |
| Abilify    | C |        | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 18-Oct-2012              | 8770792       | EXPEDITED (15-DAY) |                    | HO              | JP-ASTRAZENECA-2012SE64633 |                      | 29 YR      | Female     | JPN            |

| <u>Preferred Term</u> | <u>Product</u>                         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                          | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------------------------|--------------|------------|-------------|---------------------------------------|--------------------|-----------------|--------------|
| Hepatitis Acute       | Fk949e                                 |              |            | S           | Oral                                  |                    |                 | Not Reported |
|                       | Lexapro                                |              |            | S           | Oral                                  |                    |                 | Not Reported |
|                       | Gaslon N                               |              |            | C           |                                       |                    |                 | Not Reported |
|                       | Kakkontou                              |              |            | C           | Oral                                  |                    |                 | Not Reported |
|                       | Kakkontou                              |              |            | C           | Oral                                  |                    |                 | Not Reported |
|                       | Cefapicol                              |              |            | C           | Intravenous (not otherwise specified) | 1 G                |                 | Not Reported |
|                       | Adona (Carbazochrome Sodium Sulfonate) |              |            | C           | Intravenous (not otherwise specified) | 50 Mg              |                 | Not Reported |
|                       | Lactec G                               |              |            | C           |                                       | 500 MI             |                 | Not Reported |
|                       | EI-Solution No. 3                      |              |            | C           |                                       | 500 To 1000 MI     |                 | Not Reported |
|                       | Beaslimin                              |              |            | C           |                                       | 10 MI              |                 | Not Reported |
|                       | Gaster                                 |              |            | C           |                                       | 20 Mg              |                 | Not Reported |
|                       | Amigrand                               |              |            | C           |                                       | 500 MI             |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Oct-2012              | 8801415       | EXPEDITED (15-DAY) |                    | DS              | FR-FRI-1000038395    |                      | 71 YR      | Female     | FRA            |

| <u>Preferred Term</u>                        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------|----------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Drug Interaction;<br>Extrapyramidal Disorder | Escitalopram   |              |            | S           | Oral         | 20 Mg                            |                 | Forest       |
|                                              | Inexium        |              |            | S           | Oral         | 20 Mg                            |                 | Not Reported |
|                                              | Durogesic      |              |            | C           | Transdermal  | 0.3333 Mcg (1 Df, 1 In 72 Hours) |                 | Not Reported |

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

|                        |   |      |                     |              |
|------------------------|---|------|---------------------|--------------|
| Hydrocortisone Roussel | C | Oral | 10 Mg               | Not Reported |
| Levothyrox             | C | Oral | 75 Mcg              | Not Reported |
| Seresta                | C | Oral | 40 Mg               | Not Reported |
| Zolpidem               | C | Oral | 10 Mg               | Not Reported |
| Parkinane              | C | Oral | 5 Mg                | Not Reported |
| Movicol                | C |      | According To Stools | Not Reported |
| Lansoyl                | C |      | According To Stools | Not Reported |
| Paracetamol            | C |      | 3 Gram              | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 18-Oct-2012              | 8805778       | EXPEDITED (15-DAY) |                    | DS, HO, OT      | FR-ASTRAZENECA-2012SE72437 |                      | 71 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                                                                                        | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Folate; Crying; Depression; Drug Interaction; Extrapyrimaldal Disorder; Fall; General Physical Health Deterioration; Suicidal Ideation | Inexium                |              |            | S           | Oral         |                    |                 | Astrazeneca  |
|                                                                                                                                              | Inexium                |              |            | S           | Oral         |                    |                 | Astrazeneca  |
|                                                                                                                                              | Seroplex               |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                                              | Durogesic              |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                                                              | Hydrocortizone Roussel |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                                                              | Zolpidem               |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                                                              | Seresta                |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                                                              | Levothyrox             |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                                                              | Parkinane Lp           |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                                                              | Movicol                |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                              | Lansoyl                |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                              | Paracetamol            |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|------------|------------|----------------|
| 18-Oct-2012              | 8847662       | EXPEDITED (15-DAY) |                    | DE, HO          | FR-EISAI INC-E2020-11520-SPO-FR |                      | 80 YR      | Female     | FRA            |

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

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

|                       |                        |   |                                       |             |              |
|-----------------------|------------------------|---|---------------------------------------|-------------|--------------|
| Hepatitis Cholestatic | Aricept                | S | Oral                                  |             | Not Reported |
|                       | Xatral                 | S | Oral                                  | 10 Mg/Day   | Not Reported |
|                       | Fluconazole            | S | Oral                                  | 200 Mg/Day  | Not Reported |
|                       | Ilomedine              | S | Intravenous (not otherwise specified) | 0.05 Mg/Day | Not Reported |
|                       | Previscan (Fluindione) | S | Oral                                  | 10 Mg/Day   | Not Reported |
|                       | Seroplex               | S | Oral                                  | 10 Mg/Day   | Not Reported |
|                       | Furosemide             | C |                                       | Unknown     | Not Reported |
|                       | Vanocymcin             | C |                                       | Unknown     | Not Reported |
|                       | Driptane               | C |                                       | Unknown     | Not Reported |
|                       | Paracetamol            | C |                                       | Unknown     | Not Reported |
|                       | Inexium                | C |                                       | Unknown     | Not Reported |
|                       | Effizinc               | C |                                       | Unknown     | Not Reported |
|                       | Diffu K                | C |                                       | Unknown     | Not Reported |
|                       | Vitamin D Nos          | C |                                       | Unknown     | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Oct-2012              | 8847708       | EXPEDITED (15-DAY) |                    | HO              | CH-TEVA-364562ISR    |                      | 73 YR      | Male       | CHE            |

| <u>Preferred Term</u>                                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|-----------------------|-----------------|--------------|
| Hyponatraemia;<br>Inappropriate Antidiuretic<br>Hormone Secretion | Nifedipine     |              |            | S           | Oral         | 30 Milligram Daily;   |                 | Teva         |
|                                                                   | Cipralax       |              |            | S           | Oral         | 10 Milligram Daily;   |                 | Not Reported |
|                                                                   | Cipralax       |              |            | S           | Oral         | 20 Milligram Daily;   |                 | Not Reported |
|                                                                   | Approvel       |              |            | C           | Oral         | 150 Milligram Daily;  |                 | Not Reported |
|                                                                   | Movicol        |              |            | C           | Oral         | 1 Dosage Forms Daily; |                 | Not Reported |
|                                                                   | Pantoprazole   |              |            | C           | Oral         | 40 Milligram Daily;   |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 18-Oct-2012              | 8848801       | EXPEDITED (15-DAY) |                    | OT              | IT-MYLANLABS-2012S1020958 |                      | 25 YR      | Female     | ITA            |

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

| <u>Preferred Term</u>                                                                                                                                                                                     | <u>Product</u>          | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|------------------|--------------------|-----------------|----------------------|------------------------|-----------------|--------------|----------------|
| Agitation; Drug Interaction; Hyperhidrosis; Withdrawal Syndrome                                                                                                                                           | Alprazolam              |                  |                    | S               | Oral                 |                        |                 | Mylan        |                |
|                                                                                                                                                                                                           | Citalopram Hydrobromide |                  |                    | S               |                      |                        |                 | Not Reported |                |
|                                                                                                                                                                                                           | Lexapro                 |                  |                    | S               |                      |                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                  | <u>Case #</u>           | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Oct-2012                                                                                                                                                                                               | 8849593                 | DIRECT           | Y                  | HO              |                      |                        | 29 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                     | <u>Product</u>          | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Malaise; Product Substitution Issue                                                                                                                                                              | Escitalopram            |                  |                    | S               | Oral                 | 20mg One At Bedtime Po |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                  | <u>Case #</u>           | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Oct-2012                                                                                                                                                                                               | 8849634                 | DIRECT           |                    | OT              |                      |                        | 73 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                     | <u>Product</u>          | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Anger; Apathy; Confusional State; Crying; Depressed Mood; Depressed Mood; Disturbance In Attention; Extraocular Muscle Disorder; Fatigue; Product Quality Issue; Product Substitution Issue; Sluggishness | Escitalopram            |                  |                    | S               | Oral                 | 1 Tablet At Bedtime Po | 5 DAY           | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                  | <u>Case #</u>           | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Oct-2012                                                                                                                                                                                               | 8851676                 | DIRECT           |                    | DS              |                      |                        | 40 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                     | <u>Product</u>          | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Brain Injury; Drug Dependence; Paraesthesia                                                                                                                                                               | Lexapro                 |                  |                    | S               |                      |                        |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 19-Oct-2012              | 8221973                 | EXPEDITED (15-DAY) | Y                  | HO, OT          | DSA_47885_2011       |                      | 60 YR           | Male         | KOR            |
| <u>Preferred Term</u>    | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Blood           | Bupropion Hydrochloride |                    |                    | S               |                      | (Df)                 |                 | Not Reported |                |
| Aldosterone Increased;   |                         |                    |                    |                 |                      | (Df)                 |                 |              |                |
| Blood Chloride           | Escitalopram            |                    |                    | S               |                      | Df                   |                 | Not Reported |                |
| Decreased; Blood Urea    | Mirtazapine             |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Increased;               | Alprazolam              |                    |                    | S               |                      | Df                   |                 | Not Reported |                |
| Carcinoembryonic Antigen | Clonazepam              |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Increased; Ejection      | Clopidogrel             |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Fraction Decreased;      | Simvastatin             |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Hyponatraemia; Insomnia; | Telmisartan             |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Po2 Decreased;           | Aspirin                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Secondary Adrenocortical |                         |                    |                    |                 |                      |                      |                 |              |                |
| Insufficiency; Weight    |                         |                    |                    |                 |                      |                      |                 |              |                |
| Increased                |                         |                    |                    |                 |                      |                      |                 |              |                |
| <u>FDA Received Date</u> | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Oct-2012              | 8849732                 | EXPEDITED (15-DAY) |                    | OT              | GB-FRI-1000039605    |                      | 57 YR           | Female       | GBR            |
| <u>Preferred Term</u>    | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Face Oedema; Oedema      | Escitalopram            |                    |                    | S               | Oral                 |                      |                 | Forest       |                |
| Peripheral; Swelling;    | Venlalic XI             |                    |                    | C               | Oral                 | 150 Mg               |                 | Not Reported |                |
| Weight Increased         | Venlalic XI             |                    |                    | C               | Oral                 | 75 Mg                |                 | Not Reported |                |
|                          | Zapain                  |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Oct-2012              | 8850742                 | EXPEDITED (15-DAY) |                    | OT              | CA-FRI-1000039604    |                      | 15 YR           | Female       | CAN            |
| <u>Preferred Term</u>    | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Fatigue; Muscle          | Escitalopram            |                    |                    | S               | Oral                 | 5 Mg                 |                 | Forest       |                |
| Contracture; Off Label   |                         |                    |                    |                 |                      |                      |                 |              |                |
| Use; Seizure; Tremor     |                         |                    |                    |                 |                      |                      |                 |              |                |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                       | <u>Case #</u>                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>            | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------|--------------------------------------------|--------------------|--------------------|-----------------|----------------------|-----------------------------------|-----------------|-----------------------|----------------|
| 19-Oct-2012                                                                                                    | 8854082                                    | DIRECT             |                    |                 |                      |                                   |                 | Female                | USA            |
| <u>Preferred Term</u>                                                                                          | <u>Product</u>                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>            |                |
| Blood Thyroid Stimulating Hormone Decreased; Fatigue; Overdose; Product Substitution Issue; Serotonin Syndrome | Escitalopram<br>Synthroid                  |                    |                    | S<br>C          | Oral                 |                                   |                 | Mylan<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                                       | <u>Case #</u>                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>            | <u>Country</u> |
| 21-Oct-2012                                                                                                    | 9227912                                    | NON-EXPEDITED      | Y                  | RI, OT          | 1000037193           |                                   | 30 YR           | Male                  | USA            |
| <u>Preferred Term</u>                                                                                          | <u>Product</u>                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>            |                |
| Priapism                                                                                                       | Lexapro                                    |                    |                    | S               | Oral                 | 20 Mg ( 20 Mg, 1 In 1 D),<br>Oral |                 | Not Reported          |                |
|                                                                                                                | Abilify ( Aripiprazole) ( Aripiprazole)    |                    |                    | C               |                      |                                   |                 | Not Reported          |                |
|                                                                                                                | Tegretal ( Carbamazepine) ( Carbamazepine) |                    |                    | C               |                      |                                   |                 | Not Reported          |                |
| <u>FDA Received Date</u>                                                                                       | <u>Case #</u>                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>            | <u>Country</u> |
| 22-Oct-2012                                                                                                    | 8498406                                    | EXPEDITED (15-DAY) |                    |                 | JP-FRI-1000029489    |                                   | 39 YR           | Male                  | JPN            |
| <u>Preferred Term</u>                                                                                          | <u>Product</u>                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>            |                |
| Decreased Appetite; Diarrhoea; Nausea                                                                          | Lexapro                                    |                    |                    | S               | Oral                 | 10 Mg                             |                 | Forest                |                |
|                                                                                                                | Alprazolam                                 |                    |                    | C               | Oral                 | 1.2 Mg                            |                 | Not Reported          |                |
| <u>FDA Received Date</u>                                                                                       | <u>Case #</u>                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>            | <u>Country</u> |
| 22-Oct-2012                                                                                                    | 8573027                                    | EXPEDITED (15-DAY) |                    |                 | JP-FRI-1000030539    |                                   | 38 YR           | Male                  | JPN            |
| <u>Preferred Term</u>                                                                                          | <u>Product</u>                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>            |                |

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

|                                          |               |   |      |       |              |
|------------------------------------------|---------------|---|------|-------|--------------|
| Decreased Appetite;<br>Diarrhoea; Thirst | Escitalopram  | S | Oral | 10 Mg | Forest       |
|                                          | Flunitrazepam | C | Oral | 1 Mg  | Not Reported |
|                                          | Etizolam      | C | Oral | 2 Mg  | Not Reported |
|                                          | Zolpidem      | C | Oral | 5 Mg  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------|----------------------|------------|------------|----------------|
| 23-Oct-2012              | 8822089       | EXPEDITED (15-DAY) |                    | HO, OT          | HU-RANBAXY-2012RR-60519 |                      | 53 YR      | Female     | HUN            |

| <u>Preferred Term</u>                                                                                                                                               | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Atrial Fibrillation; Atrial Tachycardia; Drug Interaction; Fatigue; Palpitations; Sinoatrial Block; Sinus Arrest; Sinus Bradycardia; Sinus Node Dysfunction; Tremor | Tegretol Cr                 |              |            | S           | Unknown      | 200 Mg, Qd         |                 | Not Reported |
|                                                                                                                                                                     | Unspecified Immunomodulator |              |            | S           | Unknown      | 200 Mg, Qd         |                 | Not Reported |
|                                                                                                                                                                     | Ciprallex                   |              |            | S           | Unknown      | 10 Mg              |                 | Not Reported |
|                                                                                                                                                                     | Nizoral                     |              |            | S           | Unknown      | 200 Mg, Qd         |                 | Not Reported |
|                                                                                                                                                                     | Lithium                     |              |            | S           | Unknown      | 250 Mg, Bid        |                 | Not Reported |
|                                                                                                                                                                     | Lithium                     |              |            | S           | Unknown      | 500 Mg, Bid        |                 | Not Reported |
|                                                                                                                                                                     | Levothyroxine               |              |            | S           | Unknown      | 150 □G, Unk        |                 | Not Reported |
|                                                                                                                                                                     | Atorvastatin                |              |            | S           | Unknown      | 40 Mg              |                 | Ranbaxy      |
|                                                                                                                                                                     | Clonazepam                  |              |            | S           | Unknown      | 1-1-2 Mg           |                 | Not Reported |
|                                                                                                                                                                     | Cinolazepam                 |              |            | S           | Unknown      | 40 Mg, Unk         |                 | Not Reported |
|                                                                                                                                                                     | Amiloride                   |              |            | S           | Unknown      | 5 Mg, Unk          |                 | Not Reported |
|                                                                                                                                                                     | Hydrochlorothiazide         |              |            | S           | Unknown      | 50 Mg, Unk         |                 | Ipca         |
|                                                                                                                                                                     | Acetylsalicylic Acid        |              |            | S           | Unknown      | 100 Mg             |                 | Not Reported |
|                                                                                                                                                                     | Clonazepam                  |              |            | S           | Unknown      | 0.5-0.5-3 Mg       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 23-Oct-2012              | 8854606       | EXPEDITED (15-DAY) |                    | HO, LT          | FR-PFIZER INC-2012259993 |                      | 67 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Suicide Attempt       | Xanax          |              |            | S           | Oral         | 0.25 Mg, 3x/Day    |                 | Pfizer     |

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

|  |          |   |      |                 |              |
|--|----------|---|------|-----------------|--------------|
|  | Xanax    | S | Oral | 0.25 Mg, 4x/Day | Pfizer       |
|  | Seroplex | S | Oral | 5 Mg, 1x/Day    | Not Reported |
|  | Seroplex | S | Oral | 10 Mg, 1x/Day   | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Oct-2012              | 8856135       | DIRECT           |                    | OT              |                      |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Alcohol Use; Amnesia;<br>Anxiety; Condition<br>Aggravated; Depressed<br>Mood; Drug Intolerance;<br>Fatigue; Product<br>Substitution Issue;<br>Somnolence; Therapeutic<br>Product Effect Decreased | Escitalopram   |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Oct-2012              | 8859453       | EXPEDITED (15-DAY) |                    | OT              | DSA_60271_2012       |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                                         | <u>Product</u>                            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>      | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                                                   |
|-------------------------------------------------------------------------------|-------------------------------------------|--------------|------------|------------------|--------------|--------------------|-----------------|--------------------------------------------------------------|
| Abortion Spontaneous;<br>Drug Ineffective; Maternal<br>Drugs Affecting Foetus | Wellbutrin<br>Celexa<br>Prozac<br>Lexapro |              |            | S<br>S<br>S<br>S |              |                    |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 23-Oct-2012              | 8873920       | EXPEDITED (15-DAY) |                    | DE, HO, OT      | FR-PFIZER INC-<br>2012262387 |                      | 80 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                                           | <u>Product</u>                         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>         | <u>Dosage Text</u>                                          | <u>Duration</u> | <u>Mfr</u>                       |
|-------------------------------------------------------------------------------------------------|----------------------------------------|--------------|------------|-------------|----------------------|-------------------------------------------------------------|-----------------|----------------------------------|
| Cholelithiasis; Clostridium<br>Difficile Colitis; Hepatitis<br>Cholestatic; Necrosis;<br>Sepsis | Aricept<br>Fluconazole<br>Escitalopram |              |            | S<br>S<br>S | Oral<br>Oral<br>Oral | 10 Mg, 1x/Day<br>200 Mg/Day<br>10 Mg/Day (10<br>Mg,Unknown) |                 | Pfizer<br>Pfizer<br>Not Reported |

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

|                        |   |                                       |             |              |
|------------------------|---|---------------------------------------|-------------|--------------|
| Xatral                 | S | Oral                                  | 10 Mg Daily | Not Reported |
| Iloprost               | S | Intravenous (not otherwise specified) | 0.05 Mg/Day | Not Reported |
| Previscan (Fluindione) | S | Oral                                  | 10 Mg Daily | Not Reported |
| Furosemide             | C |                                       | Unk         | Not Reported |
| Vancomycin             | C |                                       | Unk         | Not Reported |
| Driptane               | C |                                       | Unk         | Not Reported |
| Paracetamol            | C |                                       | Unk         | Not Reported |
| Inexium                | C |                                       | Unk         | Not Reported |
| Zinc Gluconate         | C |                                       | Unk         | Not Reported |
| Diffu K                | C |                                       | Unk         | Not Reported |
| Vitamin D Nos          | C |                                       | Unk         | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------------------------------------|----------------------|------------|------------|----------------|
| 24-Oct-2012              | 8849943       | EXPEDITED (15-DAY) |                    | OT              | HR-B.I.<br>PHARMACEUTICALS,I<br>NC./RIDGEFIELD-2012-<br>AP-00 |                      | 81 YR      | Male       | HRV            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                  | <u>Product</u>  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|--------------|------------|-------------|--------------|-----------------------|-----------------|----------------------|
| Blood Cholesterol Increased; Blood Uric Acid Increased; Constipation; Diarrhoea; Flatulence; Haematocrit Decreased; Haemoglobin Decreased; Muscle Atrophy; Muscle Spasms; Myalgia; Nail Discolouration; Nail Discolouration; Nitrite Urine Present; Red Blood Cell Count Decreased; Walking Disability | Aggrenox        |              |            | S           | Oral         | 25mg/200mg, 2 Per Day |                 | Boehringer Ingelheim |
|                                                                                                                                                                                                                                                                                                        | Norprexanil     |              |            | S           |              | 5 Mg                  |                 | Not Reported         |
|                                                                                                                                                                                                                                                                                                        | Teotard         |              |            | S           |              | 400 Mg                |                 | Not Reported         |
|                                                                                                                                                                                                                                                                                                        | Tritace         |              |            | S           |              | 2.5 Mg                |                 | Not Reported         |
|                                                                                                                                                                                                                                                                                                        | Cipralext       |              |            | S           |              | 5 Mg                  |                 | Not Reported         |
|                                                                                                                                                                                                                                                                                                        | Controloc       |              |            | S           |              | 20 Mg                 |                 | Not Reported         |
|                                                                                                                                                                                                                                                                                                        | Crestor         |              |            | S           |              | 20 Mg                 |                 | Not Reported         |
|                                                                                                                                                                                                                                                                                                        | Lamisil         |              |            | C           | Topical      |                       |                 | Not Reported         |
|                                                                                                                                                                                                                                                                                                        | Twinlab Omega-3 |              |            | C           | Oral         |                       |                 | Not Reported         |
|                                                                                                                                                                                                                                                                                                        | Kal B-Complex   |              |            | C           | Oral         | 100 Mg                |                 | Not Reported         |
|                                                                                                                                                                                                                                                                                                        | Solgar Magnezij |              |            | C           | Oral         | 300 Mg                |                 | Not Reported         |
|                                                                                                                                                                                                                                                                                                        | Rizolip         |              |            | C           |              |                       |                 | Not Reported         |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                    | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------|------------------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 24-Oct-2012                                                                                 | 8857679                            | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2012263615 |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                                       | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Weight Increased                                                                            | Effexor                            |                    |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                                                                                             | Lexapro                            |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                    | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Oct-2012                                                                                 | 8877503                            | EXPEDITED (15-DAY) |                    | OT              | AU-PFIZER INC-2012228813 |                      |                 | Female       | AUS            |
| <u>Preferred Term</u>                                                                       | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alopecia; Pharyngeal Swelling                                                               | Efexor Xr                          |                    |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                                                                                             | Lexapro                            |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                                                                                             | Cipramil [Citalopram Hydrobromide] |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                    | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Oct-2012                                                                                 | 9228387                            | NON-EXPEDITED      |                    | OT              | DSA_56025_2012           |                      |                 | Male         | USA            |
| <u>Preferred Term</u>                                                                       | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective; Insomnia; Mood Swings; Paranoia; Product Quality Issue; Suicidal Ideation | Wellbutrin                         |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                                                                             | Seroquel                           |                    |                    | S               |                          |                      | 3 YR            | Not Reported |                |
|                                                                                             | Lexapro                            |                    |                    | S               | Oral                     | (Df Oral)            |                 | Not Reported |                |
|                                                                                             | Pristiq 50 Mg (Not Specified)      |                    |                    | S               |                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                    | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Oct-2012                                                                                 | 8861276                            | DIRECT             | Y                  | OT              |                          |                      | 25 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                       | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depressive Symptom; Product Substitution Issue                                              | Escitalopram                       |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                      | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 25-Oct-2012                                                   | 8870122        | DIRECT           | Y                  | OT              |                      |                      | 48 YR           | Male       | USA            |
| <u>Preferred Term</u>                                         | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Anxiety; Disturbance In Attention; Product Substitution Issue | Escitalopram   |                  |                    | S               | Oral                 | 1 Tab Daily Orally   |                 | Teva       |                |

| <u>FDA Received Date</u>                                                                                                                                            | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>        | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|--------------------|--------------------|-----------------|----------------------|------------------------|-----------------|-------------------|----------------|
| 25-Oct-2012                                                                                                                                                         | 9178207           | EXPEDITED (15-DAY) |                    | OT              | US-RB-045963-12      |                        | < 1 DAY         | Male              | USA            |
| <u>Preferred Term</u>                                                                                                                                               | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>        |                |
| Dacryostenosis                                                                                                                                                      | Subutex           |                    |                    | S               | Transplacental       |                        |                 | Reckitt Benckiser |                |
| Congenital; Foetal Exposure During Pregnancy;                                                                                                                       | Prenatal Vitamins |                    |                    | S               | Transplacental       | Dosing Details Unknown |                 | Not Reported      |                |
| Gastrooesophageal Reflux Disease; Infantile Vomiting; Low Birth Weight Baby; Premature Baby; Rash Neonatal; Restlessness; Tremor Neonatal; Weight Decrease Neonatal | Lexapro           |                    |                    | S               | Transplacental       | Before Bed Time        |                 | Not Reported      |                |
|                                                                                                                                                                     | Nicotine          |                    |                    | S               | Transplacental       | Dosing Details Unknown |                 | Not Reported      |                |

| <u>FDA Received Date</u> | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|------------------------|--------------------|--------------------|-----------------|---------------------------------------|----------------------|-----------------|--------------|----------------|
| 26-Oct-2012              | 8863072                | EXPEDITED (15-DAY) |                    | DE, HO          | FR-SANOFI-AVENTIS-2012SA075643        |                      | 80 YR           | Female       | FRA            |
| <u>Preferred Term</u>    | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hepatitis Cholestatic    | Xatral                 |                    |                    | S               | Oral                                  |                      |                 | Not Reported |                |
|                          | Ilomedine              |                    |                    | S               | Intravenous (not otherwise specified) |                      |                 | Not Reported |                |
|                          | Aricept                |                    |                    | S               | Oral                                  |                      |                 | Not Reported |                |
|                          | Previscan (Fluindione) |                    |                    | S               | Oral                                  |                      |                 | Not Reported |                |

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

|  |                |   |      |              |
|--|----------------|---|------|--------------|
|  | Seroplex       | S | Oral | Not Reported |
|  | Fluconazole    | S | Oral | Not Reported |
|  | Vancomycine    | C |      | Not Reported |
|  | Driptane       | C |      | Not Reported |
|  | Paracetamol    | C |      | Not Reported |
|  | Inexium        | C |      | Not Reported |
|  | Rubozinc       | C |      | Not Reported |
|  | Diffu K        | C |      | Not Reported |
|  | Ergocalciferol | C |      | Not Reported |

| <u>FDA Received Date</u>                                               | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 26-Oct-2012                                                            | 8870308        | DIRECT           | Y                  |                 |                      |                      | 42 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Product Substitution Issue;<br>Therapeutic Product Effect<br>Decreased | Lexapro        |                  |                    | S               | Oral                 |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                        | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|------------------------------------------|----------------------|-----------------|--------------|----------------|
| 26-Oct-2012                                                                                                                                     | 8878982                | EXPEDITED (15-DAY) |                    | DE, HO          | FR-FRI-1000039790                        |                      | 80 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                           | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Carotid Artery Stenosis;<br>Cholelithiasis; Clostridium<br>Difficile Colitis; Hepatitis<br>Cholestatic; Lipase<br>Increased; Melaena;<br>Sepsis | Escitalopram           |                    |                    | S               | Oral                                     | 10 Mg                |                 | Forest       |                |
|                                                                                                                                                 | Ilomedine              |                    |                    | S               | Intravenous (not<br>otherwise specified) | 0.5 Mg               |                 | Not Reported |                |
|                                                                                                                                                 | Aricept                |                    |                    | S               | Oral                                     | 10 Mg                |                 | Not Reported |                |
|                                                                                                                                                 | Previscan (Fluindione) |                    |                    | S               | Oral                                     | 10 Mg                |                 | Not Reported |                |
|                                                                                                                                                 | Xatral                 |                    |                    | S               | Oral                                     | 10 Mg                |                 | Not Reported |                |
|                                                                                                                                                 | Fluconazole            |                    |                    | S               | Oral                                     | 200 Mg               |                 | Not Reported |                |
|                                                                                                                                                 | Driptane               |                    |                    | C               |                                          |                      |                 | Not Reported |                |
|                                                                                                                                                 | Paracetamol            |                    |                    | C               |                                          |                      |                 | Not Reported |                |
|                                                                                                                                                 | Inexium                |                    |                    | C               |                                          |                      |                 | Not Reported |                |
|                                                                                                                                                 | Effizinc               |                    |                    | C               |                                          |                      |                 | Not Reported |                |
|                                                                                                                                                 | Diffu-K                |                    |                    | C               |                                          |                      |                 | Not Reported |                |
|                                                                                                                                                 | Vitamin D Nos          |                    |                    | C               |                                          |                      |                 | Not Reported |                |

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

| Furosemide                                  |                                                              |                    | C                  |                 |                                                     | Not Reported         |                 |              |                |
|---------------------------------------------|--------------------------------------------------------------|--------------------|--------------------|-----------------|-----------------------------------------------------|----------------------|-----------------|--------------|----------------|
| Vancomycin                                  |                                                              |                    | C                  |                 |                                                     | Not Reported         |                 |              |                |
| <u>FDA Received Date</u>                    | <u>Case #</u>                                                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Oct-2012                                 | 8845290                                                      | EXPEDITED (15-DAY) |                    | HO              | NO-FRI-1000039451                                   |                      | 22 YR           | Male         | NOR            |
| <u>Preferred Term</u>                       | <u>Product</u>                                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain;<br>Diarrhoea; Haematochezia | Escitalopram                                                 |                    |                    | S               | Oral                                                | 5 Mg                 |                 | Forest       |                |
| <u>FDA Received Date</u>                    | <u>Case #</u>                                                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Oct-2012                                 | 8872517                                                      | EXPEDITED (15-DAY) |                    | DE              | US-ROXANE<br>LABORATORIES, INC.-<br>2012-RO-02130RO |                      | 29 YR           | Unknown      | USA            |
| <u>Preferred Term</u>                       | <u>Product</u>                                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Death                                       | Methadone                                                    |                    |                    | S               | Oral                                                |                      |                 | Roxane       |                |
|                                             | Alprazolam Intensol [Oral<br>Solution (Concentrate)] 1 Mg/ML |                    |                    | S               | Oral                                                |                      |                 | Roxane       |                |
|                                             | Escitalopram                                                 |                    |                    | S               | Oral                                                |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                    | <u>Case #</u>                                                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Oct-2012                                 | 9179378                                                      | EXPEDITED (15-DAY) |                    | OT              | CH-FRI-1000039792                                   |                      |                 | Female       | CHE            |
| <u>Preferred Term</u>                       | <u>Product</u>                                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bladder Cancer                              | Escitalopram                                                 |                    |                    | S               | Oral                                                | 10 Mg                |                 | Forest       |                |
|                                             | Escitalopram                                                 |                    |                    | S               |                                                     |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                    | <u>Case #</u>                                                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Oct-2012                                 | 9179706                                                      | EXPEDITED (15-DAY) |                    | OT              | US-FRI-1000039700                                   |                      | 45 YR           | Female       | USA            |
| <u>Preferred Term</u>                       | <u>Product</u>                                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Nephrolithiasis                             | Lexapro                                                      |                    |                    | S               | Oral                                                | 20 Mg                |                 | Forest       |                |



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

| <a href="#">FDA Received Date</a>                | <a href="#">Case #</a>                                       | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>                       | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|--------------------------------------------------|--------------------------------------------------------------|---------------------------|-----------------------------|--------------------------|-----------------------------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 30-Oct-2012                                      | 8872605                                                      | EXPEDITED (15-DAY)        |                             | DE                       | US-ROXANE<br>LABORATORIES, INC.-<br>2012-RO-02205RO |                               | 39 YR                    | Unknown             | USA                     |
| <a href="#">Preferred Term</a>                   | <a href="#">Product</a>                                      | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                               | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Completed Suicide                                | Alprazolam Intensol [Oral<br>Solution (Concentrate)] 1 Mg/ML |                           |                             | S                        | Oral                                                |                               |                          | Roxane              |                         |
|                                                  | Escitalopram                                                 |                           |                             | S                        | Oral                                                |                               |                          | Not Reported        |                         |
|                                                  | Chlorpheniramine                                             |                           |                             | S                        | Oral                                                |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                | <a href="#">Case #</a>                                       | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>                       | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 30-Oct-2012                                      | 8873064                                                      | EXPEDITED (15-DAY)        |                             | DE                       | US-ROXANE<br>LABORATORIES, INC.-<br>2012-RO-02214RO |                               | 34 YR                    | Unknown             | USA                     |
| <a href="#">Preferred Term</a>                   | <a href="#">Product</a>                                      | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                               | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Completed Suicide                                | Alprazolam Intensol [Oral<br>Solution (Concentrate)] 1 Mg/ML |                           |                             | S                        | Oral                                                |                               |                          | Roxane              |                         |
|                                                  | Tricyclic Antidepressant                                     |                           |                             | S                        | Oral                                                |                               |                          | Not Reported        |                         |
|                                                  | Escitalopram                                                 |                           |                             | S                        | Oral                                                |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                | <a href="#">Case #</a>                                       | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>                       | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 30-Oct-2012                                      | 8877228                                                      | EXPEDITED (15-DAY)        |                             | HO                       | NL-FRI-1000039918                                   |                               |                          | Unknown             | NLD                     |
| <a href="#">Preferred Term</a>                   | <a href="#">Product</a>                                      | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                               | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Dyspnoea; Foetal<br>Exposure During<br>Pregnancy | Escitalopram                                                 |                           |                             | S                        | Transplacental                                      |                               |                          | Forest              |                         |
|                                                  | Escitalopram                                                 |                           |                             | S                        | Transplacental                                      |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                | <a href="#">Case #</a>                                       | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>                       | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 30-Oct-2012                                      | 9182726                                                      | EXPEDITED (15-DAY)        |                             | DE                       | US-ROXANE<br>LABORATORIES, INC.-<br>2012-RO-02190RO |                               | 35 YR                    | Unknown             | USA                     |
| <a href="#">Preferred Term</a>                   | <a href="#">Product</a>                                      | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                               | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |

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

|                   |                     |   |      |              |
|-------------------|---------------------|---|------|--------------|
| Completed Suicide | Quetiapine Fumarate | S | Oral | Roxane       |
|                   | Topiramate          | S | Oral | Not Reported |
|                   | Escitalopram        | S | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-Oct-2012              | 8879066       | DIRECT           | Y                  | OT              |                      |                      | 36 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                  | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Blood Pressure Increased;<br>Depression; Feeling<br>Jittery; Headache;<br>Insomnia; Nausea; Panic<br>Attack; Product Quality<br>Issue; Product Substitution<br>Issue; Pruritus<br>Generalised; Therapeutic<br>Product Effect Decreased | Escitalopram Oxalate |              |            | S           | Oral         |                    |                 | Teva       |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|------------|------------|----------------|
| 31-Oct-2012              | 8879510       | EXPEDITED (15-DAY) |                    | HO, LT          | SZ-ASTRAZENECA-<br>2012SE81659 |                      | 46 YR      | Male       | CHE            |

| <u>Preferred Term</u> | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|------------------------|--------------|------------|-------------|-----------------------------|--------------------|-----------------|--------------|
| Torsade De Pointes    | Seroquel               |              |            | S           | Oral                        |                    |                 | Zeneca       |
|                       | Ciprallex              |              |            | S           | Oral                        |                    |                 | Not Reported |
|                       | Methadone              |              |            | S           | Oral                        |                    |                 | Not Reported |
|                       | Seresta                |              |            | C           | Oral                        |                    |                 | Not Reported |
|                       | Nexium                 |              |            | C           | Oral                        |                    |                 | Not Reported |
|                       | Berodual               |              |            | C           | Respiratory<br>(inhalation) |                    |                 | Not Reported |
|                       | Seretide               |              |            | C           | Respiratory<br>(inhalation) |                    |                 | Not Reported |
|                       | Mst (Morphine Sulfate) |              |            | C           |                             |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                 | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|--------------------------|---------------------------------------------|-----------------|--------------|----------------|
| 31-Oct-2012                                                              | 8879769                   | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000039883        |                                             | < 1 DAY         | Female       | USA            |
| <u>Preferred Term</u>                                                    | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Congenital Aortic Anomaly                                                | Lexapro                   |                    |                    | S               | Transplacental           |                                             |                 | Forest       |                |
| <u>FDA Received Date</u>                                                 | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Nov-2012                                                              | 8853257                   | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-2012262394 |                                             | 56 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                    | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Glucose Increased; Depression; Drug Ineffective; Suicidal Ideation | Pristiq                   |                    |                    | S               | Oral                     | 50 Mg, 1x/Day                               |                 | Pfizer       |                |
|                                                                          | Pristiq                   |                    |                    | S               | Oral                     | 50 Mg, 1x/Day                               |                 | Pfizer       |                |
|                                                                          | Venlafaxine Hydrochloride |                    |                    | S               | Oral                     | 75 Mg, 1x/Day                               |                 | Pfizer       |                |
|                                                                          | Escitalopram              |                    |                    | S               |                          | Unk                                         |                 | Not Reported |                |
|                                                                          | Advair                    |                    |                    | C               | Respiratory (inhalation) | Unk                                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                 | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Nov-2012                                                              | 8880746                   | EXPEDITED (15-DAY) |                    | HO              | IT-FRI-1000039957        |                                             | 41 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                    | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Overdose; Sopor                                              | Escitalopram              |                    |                    | S               | Oral                     | Intentional Overdose: 40 Tablets Of 10 Mg   |                 | Forest       |                |
|                                                                          | Largactil                 |                    |                    | S               | Oral                     | Intentional Overdose: 19 Tablets Of 100 Mg  |                 | Not Reported |                |
|                                                                          | Lendormin                 |                    |                    | S               | Oral                     | Intentional Overdose: 19 Tablets Of 0.25 Mg |                 | Not Reported |                |
|                                                                          | Depakin Chrono            |                    |                    | S               | Oral                     | Intentional Overdose: 54 Tablets Of 500 Mg  |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <a href="#">FDA Received Date</a>                                     | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>                   | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 01-Nov-2012                                                           | 8887660                 | DIRECT                    |                             |                          |                                                 |                               | 52 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>                                        | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                           | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Eyelid Irritation;<br>Hyperaesthesia; Pain;<br>Skin Burning Sensation | Escitalopram            |                           |                             | S                        | Oral                                            | 1 Tablet Daily                |                          | Teva                |                         |
| <a href="#">FDA Received Date</a>                                     | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>                   | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 01-Nov-2012                                                           | 8889330                 | DIRECT                    | Y                           | LT                       |                                                 |                               | 34 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                        | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                           | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Bipolar I Disorder; Disease<br>Recurrence; Suicidal<br>Ideation       | Lexapro                 |                           |                             | S                        | Oral                                            | 20 Mg One Daily Oral          | 3 WK                     | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                     | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>                   | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 02-Nov-2012                                                           | 8693720                 | EXPEDITED (15-DAY)        |                             | HO, OT                   | AT-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>16807471 |                               | 26 YR                    | Female              | AUT                     |
| <a href="#">Preferred Term</a>                                        | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                           | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Pulmonary Embolism                                                    | Abilify                 |                           |                             | S                        | Oral                                            |                               |                          | Not Reported        |                         |
|                                                                       | Abilify                 |                           |                             | S                        | Oral                                            |                               |                          | Not Reported        |                         |
|                                                                       | Trittico                |                           |                             | S                        |                                                 | 150mg                         |                          | Apothecon           |                         |
|                                                                       | Cipralex                |                           |                             | S                        |                                                 | 10 Mg                         |                          | Not Reported        |                         |
|                                                                       | Temesta (Lorazepam)     |                           |                             | S                        |                                                 |                               |                          | Not Reported        |                         |
|                                                                       | Truxal                  |                           |                             | S                        |                                                 | 2 Tabs                        |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                     | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>                   | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 02-Nov-2012                                                           | 8840313                 | EXPEDITED (15-DAY)        |                             | OT                       | FR-FRI-1000039422                               |                               | 47 YR                    | Female              | FRA                     |
| <a href="#">Preferred Term</a>                                        | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                           | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |

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

|                                                                              |                |                    |                    |                 |                                          |                      |                 |              |                |
|------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|------------------------------------------|----------------------|-----------------|--------------|----------------|
| Hepatocellular Injury                                                        |                | Escitalopram       |                    | S               | Oral                                     |                      | Forest          |              |                |
| <u>FDA Received Date</u>                                                     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Nov-2012                                                                  | 8884833        | EXPEDITED (15-DAY) |                    | DE, HO          | FR-FRI-1000040014                        |                      | 61 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State;<br>Depressed Level Of<br>Consciousness;<br>Disorientation | Escitalopram   |                    |                    | S               | Oral                                     |                      |                 | Forest       |                |
|                                                                              | Avastin        |                    |                    | S               | Intravenous (not<br>otherwise specified) | 7.5 Mg/Kg            |                 | Not Reported |                |
|                                                                              | Skenan         |                    |                    | S               | Oral                                     | 120 Mg               |                 | Not Reported |                |
|                                                                              | Actiskenan     |                    |                    | S               | Oral                                     |                      |                 | Not Reported |                |
|                                                                              | Lexomil        |                    |                    | S               | Oral                                     |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Nov-2012                                                                  | 8891344        | DIRECT             | Y                  | HO              |                                          |                      | 41 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Extrapyramidal Disorder                                                      | Escitalopram   |                    |                    | S               | Oral                                     | 20 Mg Daily Po       | 15 DAY          | Aurobindo    |                |
| <u>FDA Received Date</u>                                                     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Nov-2012                                                                  | 8891356        | DIRECT             | Y                  |                 |                                          |                      | 42 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Product Substitution Issue;<br>Therapeutic Product Effect<br>Decreased       | Lexapro        |                    |                    | S               | Oral                                     | 20 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Nov-2012                                                                  | 8886175        | EXPEDITED (15-DAY) |                    | DE, HO          | FR-ROCHE-1148807                         |                      | 61 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

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

|                                                                              |            |   |                                          |              |
|------------------------------------------------------------------------------|------------|---|------------------------------------------|--------------|
| Confusional State;<br>Depressed Level Of<br>Consciousness;<br>Disorientation | Avastin    | S | Intravenous (not<br>otherwise specified) | Not Reported |
|                                                                              | Lexomil    | S | Oral                                     | Not Reported |
|                                                                              | Skenan     | S | Oral                                     | Not Reported |
|                                                                              | Actiskenan | S | Oral                                     | Not Reported |
|                                                                              | Seroplex   | S | Oral                                     | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>       | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------------|------------------|--------------------|-----------------|----------------------|----------------------|------------------|--------------|----------------|
| 05-Nov-2012              | 8891375              | DIRECT           | Y                  | OT              |                      |                      | 26 YR            | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u>  | <u>Mfr</u>   |                |
| Anxiety                  | Escitalopram Oxalate |                  |                    | S               |                      |                      | 2 WEEK<br>4 WEEK | Not Reported |                |

| <u>FDA Received Date</u>                                               | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|------------------------------------|-----------------|--------------|----------------|
| 06-Nov-2012                                                            | 8896244        | DIRECT           | Y                  |                 |                      |                                    | 18 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Product Substitution Issue;<br>Therapeutic Product Effect<br>Decreased | Escitalopram   |                  |                    | S               | Oral<br>Oral         | 5 Mg 1 Daily Po<br>10mg 1 Daily Po |                 | Not Reported |                |

| <u>FDA Received Date</u>                                             | <u>Case #</u>    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------|------------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|-----------------|--------------|----------------|
| 07-Nov-2012                                                          | 8889946          | EXPEDITED (15-DAY) |                    | HO              | ES-ASTRAZENECA-<br>2012SE82879 |                      | 52 YR           | Male         | ESP            |
| <u>Preferred Term</u>                                                | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;<br>Dyspnoea; Respiratory<br>Depression; Somnolence | Atenolol         |                    |                    | S               | Oral                           |                      |                 | Zeneca       |                |
|                                                                      | Seroquel Prolong |                    |                    | S               | Oral                           |                      |                 | Not Reported |                |
|                                                                      | Escitalopram     |                    |                    | S               | Oral                           |                      |                 | Not Reported |                |
|                                                                      | Noctamide        |                    |                    | S               | Oral                           |                      |                 | Not Reported |                |
|                                                                      | Artane           |                    |                    | S               | Oral                           |                      |                 | Not Reported |                |

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

|                                                                                                                                                                          |                |                    |                    |                 |                          |                      |                 |            |                |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|------------|----------------|
| Hidrosaluretil                                                                                                                                                           |                |                    | C                  | Oral            |                          |                      | Not Reported    |            |                |
| <u>FDA Received Date</u>                                                                                                                                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 07-Nov-2012                                                                                                                                                              | 8890428        | EXPEDITED (15-DAY) |                    | OT              | US-TEVA-368252USA        |                      |                 | Female     | USA            |
| <u>Preferred Term</u>                                                                                                                                                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Abdominal Pain Upper; Asthenia; Blood Pressure Increased; Fatigue; Formication; Gastrointestinal Pain; Hot Flush; Loss Of Consciousness; Paraesthesia; Thinking Abnormal | Escitalopram   |                    |                    | S               |                          |                      |                 | Ivax       |                |
| <u>FDA Received Date</u>                                                                                                                                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 07-Nov-2012                                                                                                                                                              | 8891827        | EXPEDITED (15-DAY) |                    | OT              | AUR-APL-2012-04592       |                      | 56 YR           | Female     | USA            |
| <u>Preferred Term</u>                                                                                                                                                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Blood Glucose Increased; Depression; Suicidal Ideation; Therapy Non-Responder                                                                                            | Venlafaxine    |                    |                    | S               | Oral                     |                      |                 |            | Not Reported   |
|                                                                                                                                                                          | Escitalopram   |                    |                    | S               |                          |                      |                 |            | Not Reported   |
|                                                                                                                                                                          | Pristiq        |                    |                    | S               | Oral                     |                      |                 |            | Not Reported   |
|                                                                                                                                                                          | Advair         |                    |                    | S               | Respiratory (inhalation) |                      |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                                                                                                                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 07-Nov-2012                                                                                                                                                              | 8896428        | DIRECT             | Y                  |                 |                          |                      | 25 YR           | Male       | USA            |
| <u>Preferred Term</u>                                                                                                                                                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Disturbance In Attention; Fatigue; Insomnia; Product Quality Issue; Product Substitution Issue; Restlessness                                                             | Escitalopram   |                    |                    | S               |                          |                      |                 |            | Not Reported   |

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

| <u>FDA Received Date</u>                                                                                            | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|-----------------|--------------|----------------|
| 07-Nov-2012                                                                                                         | 8896432                   | DIRECT             | Y                  | OT              |                                |                      | 56 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                               | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated;<br>Decreased Interest;<br>Depressed Mood; Product<br>Substitution Issue;<br>Suicidal Ideation | Escitalopram              |                    |                    | S               |                                |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                            | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Nov-2012                                                                                                         | 8896471                   | DIRECT             |                    | LT              |                                |                      | 9 YR            | Female       | USA            |
| <u>Preferred Term</u>                                                                                               | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Suicidal Ideation                                                                                                   | Escitalopram              |                    |                    | S               | Oral                           |                      |                 | Mylan        |                |
|                                                                                                                     | Amphetamine Salts         |                    |                    | C               |                                |                      |                 | Not Reported |                |
|                                                                                                                     | Focalin                   |                    |                    | C               |                                |                      |                 | Not Reported |                |
|                                                                                                                     | Colace                    |                    |                    | C               |                                |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                            | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Nov-2012                                                                                                         | 8909232                   | EXPEDITED (15-DAY) | Y                  | HO, RI, OT      | 2012MA012717                   |                      | 26 YR           | Male         | BEL            |
| <u>Preferred Term</u>                                                                                               | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Colitis Ulcerative;                                                                                                 | Lorazepam                 |                    |                    | S               |                                |                      |                 | Purepac      |                |
| Constipation; Necrotising                                                                                           | Trazodone                 |                    |                    | S               |                                |                      |                 | Not Reported |                |
| Colitis; Overdose; Toxicity                                                                                         | Clotiapine                |                    |                    | S               |                                |                      |                 | Not Reported |                |
| To Various Agents                                                                                                   | Lamotrigine (Lamotrigine) |                    |                    | S               |                                |                      |                 | Not Reported |                |
|                                                                                                                     | Escitalopram              |                    |                    | S               |                                |                      |                 | Not Reported |                |
|                                                                                                                     | Quetiapine                |                    |                    | S               |                                |                      |                 | Not Reported |                |
|                                                                                                                     | Zuclopenthixol            |                    |                    | S               |                                | Q2w                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                            | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Nov-2012                                                                                                         | 8824908                   | EXPEDITED (15-DAY) |                    | HO              | JP-009507513-<br>1208JPN006967 |                      | 49 YR           | Female       | JPN            |



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| <u>Preferred Term</u> | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                          | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|------------------------|--------------|------------|-------------|---------------------------------------|---------------------------------|-----------------|--------------|
| Asthenia; Dizziness   | Pegintron              |              |            | S           | Subcutaneous                          | 1.3 Microgram Per Kilogram, Qw  |                 | Merck        |
|                       | Pegintron              |              |            | S           | Subcutaneous                          | 1.5 Microgram Per Kilogram, Unk |                 | Merck        |
|                       | Pegintron              |              |            | S           | Subcutaneous                          | 1.5 Microgram Per Kilogram, Qw  |                 | Merck        |
|                       | Pegintron              |              |            | S           | Subcutaneous                          | 40 Microgram Per Kilogram, Qw   |                 | Merck        |
|                       | Pegintron              |              |            | S           | Subcutaneous                          | 60 Microgram Per Kilogram, Qw   |                 | Merck        |
|                       | Pegintron              |              |            | S           | Subcutaneous                          | 80 Microgram Per Kilogram, Qw   |                 | Merck        |
|                       | Rebetol                |              |            | S           | Oral                                  | 800 Mg, Qd                      |                 | Merck        |
|                       | Rebetol                |              |            | S           | Oral                                  | 400 Mg, Qd                      |                 | Merck        |
|                       | Rebetol                |              |            | S           | Oral                                  | 800 Mg, Qd                      |                 | Merck        |
|                       | Telavic                |              |            | S           | Oral                                  | 2250 Mg, Qd                     |                 | Not Reported |
|                       | Telavic                |              |            | S           | Oral                                  | 1500 Mg, Qd                     |                 | Not Reported |
|                       | Lexapro                |              |            | S           | Oral                                  | 10 Mg, Qd                       |                 | Not Reported |
|                       | Desyrel                |              |            | S           | Oral                                  | 50 Mg, Qd                       |                 | Not Reported |
|                       | Mucosta                |              |            | C           | Oral                                  | 300 Mg, Qd                      |                 | Not Reported |
|                       | Loxonin                |              |            | C           | Oral                                  | Unk Unk, Prn                    |                 | Not Reported |
|                       | Aphtasolon             |              |            | C           | Parenteral                            | Unk Unk, Prn                    |                 | Not Reported |
|                       | Hachiazule Gargle      |              |            | C           | Parenteral                            | Unk, Prn                        |                 | Not Reported |
|                       | Nauzelin               |              |            | C           | Oral                                  | 3 Df, Qd                        |                 | Not Reported |
|                       | Nauzelin               |              |            | C           |                                       |                                 |                 | Not Reported |
|                       | Lac-B                  |              |            | C           | Oral                                  | 3 G, Qd                         |                 | Not Reported |
|                       | Primperan              |              |            | C           | Intravenous (not otherwise specified) | 1 Mg, Qd                        |                 | Not Reported |
|                       | Vitamedin              |              |            | C           | Oral                                  | 3 Df, Qd                        |                 | Not Reported |
|                       | Pursennid (Sennosides) |              |            | C           | Oral                                  | Unk, Prn                        |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                      | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------|-------------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| 08-Nov-2012                                                   | 8895316           | EXPEDITED (15-DAY) |                    | HO              | CA-ASTRAZENECA-2012SE84094 |                      | 91 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                         | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Product Prescribing Error; Upper Gastrointestinal Haemorrhage | Nexium            |                    |                    | S               | Oral                       |                      |                 | Astrazeneca  |                |
|                                                               | Cipraxel          |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                               | Coumadin          |                    |                    | C               |                            |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Nov-2012                                                   | 8895479           | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000040197          |                      |                 | Male         | FRA            |
| <u>Preferred Term</u>                                         | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Homicidal Ideation                                | Escitalopram      |                    |                    | S               | Oral                       |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Nov-2012                                                   | 8895770           | EXPEDITED (15-DAY) |                    | CA, HO, OT      | US-JNJFOC-20121101479      |                      |                 | Male         | USA            |
| <u>Preferred Term</u>                                         | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cleft Lip And Palate; Ear Infection                           | Topamax           |                    |                    | S               | Transplacental             |                      |                 | Not Reported |                |
|                                                               | Lexapro           |                    |                    | S               | Transplacental             |                      |                 | Not Reported |                |
|                                                               | Tramadol          |                    |                    | S               | Transplacental             |                      |                 | Not Reported |                |
|                                                               | Valacyclovir      |                    |                    | S               | Transplacental             |                      |                 | Not Reported |                |
|                                                               | Prenatal Vitamins |                    |                    | C               | Transplacental             |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Nov-2012                                                   | 8901171           | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000040250          |                      |                 | Male         | FRA            |
| <u>Preferred Term</u>                                         | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Reaction With Eosinophilia And Systemic                  | Escitalopram      |                    |                    | S               |                            |                      |                 | Forest       |                |

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|                         |              |   |                                       |          |              |
|-------------------------|--------------|---|---------------------------------------|----------|--------------|
| Symptoms; Skin Toxicity | Bendamustine | S | Intravenous (not otherwise specified) | 204.4 Mg | Not Reported |
|                         | Bendamustine | S | Intravenous (not otherwise specified) | 80 Mg/M2 | Not Reported |
|                         | Rituximab    | S | Subcutaneous                          | 850 Mg   | Not Reported |
|                         | Rituximab    | S | Subcutaneous                          | 1400 Mg  | Not Reported |
|                         | Rituximab    | S | Subcutaneous                          | 1400 Mg  | Not Reported |
|                         | Furosemide   | S |                                       |          | Not Reported |
|                         | Acebutolol   | C |                                       | 200 Mg   | Not Reported |
|                         | Arixtra      | C |                                       |          | Not Reported |
|                         | Arixtra      | C |                                       |          | Not Reported |
|                         | Solu-Medrol  | C |                                       | 60 Mg    | Not Reported |
|                         | Coaprovel    | C |                                       |          | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|------------|------------|----------------|
| 09-Nov-2012              | 8317902       | EXPEDITED (15-DAY) |                    | OT              | CA-NAPPMUNDI-CAN-2011-0002462 |                      | 55 YR      | Female     | CAN            |

  

| <u>Preferred Term</u>       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abdominal Discomfort;       | Butrans        |              |            | S           | Transdermal  | 20 Mcg, Q1h        |                 | Purdue       |
| Anxiety; Asthenia; Balance  | Butrans        |              |            | S           | Transdermal  | 15 Mcg, Q1h        |                 | Purdue       |
| Disorder; Diarrhoea;        | Butrans        |              |            | S           | Transdermal  | 10 Mcg, Q1h        |                 | Purdue       |
| Disorientation;             | Butrans        |              |            | S           | Transdermal  | 5 Mcg, Q1h         |                 | Purdue       |
| Disturbance In Attention;   | Cesamet        |              |            | S           | Oral         | 0.25 Mg, Daily     |                 | Not Reported |
| Dizziness; Drug             | Clonazepam     |              |            | S           | Oral         | 1 Mg, Tid Prn      |                 | Not Reported |
| Interaction; Dyspnoea;      | Baclofen       |              |            | S           |              | 10-20 Mg, Tid Prn  |                 | Not Reported |
| Euphoric Mood; Gait         | Cipralelex     |              |            | S           | Oral         | 10 Mg, Daily       |                 | Not Reported |
| Disturbance; Hallucination; | Cipralelex     |              |            | S           | Oral         | 20 Mg, Daily       |                 | Not Reported |
| Headache; Hypopnoea;        | Cipro XI       |              |            | C           | Oral         | 1000 Mg, Unk       |                 | Not Reported |
| Muscle Spasms;              | Furosemide     |              |            | C           | Oral         | 20 Mg, Daily       |                 | Not Reported |
| Palpitations; Pulse         | Bisoprolol     |              |            | C           | Oral         | 5 Mg, Daily        |                 | Not Reported |
| Abnormal; Somnolence;       | Wellbutrin XI  |              |            | C           | Oral         | 300 Mg, Daily      |                 | Not Reported |
| Urinary Tract Infection;    |                |              |            |             |              |                    |                 |              |
| Vomiting                    |                |              |            |             |              |                    |                 |              |

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## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                           | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------|--------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| 09-Nov-2012                                                        | 8772506            | EXPEDITED (15-DAY) |                    | LT              | AU-FRI-1000038314            |                      |                 | Female       | AUS            |
| <u>Preferred Term</u>                                              | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Gestational Diabetes;<br>Hyperemesis Gravidarum;<br>Pregnancy      | Lexapro            |                    |                    | S               |                              |                      |                 | Forest       |                |
|                                                                    | Aripiprazole       |                    |                    | S               |                              | 10 Mg                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                           | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Nov-2012                                                        | 8819171            | NON-EXPEDITED      |                    |                 | US-PFIZER INC-<br>2012241891 |                      | 79 YR           | Female       | USA            |
| <u>Preferred Term</u>                                              | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Glucose Increased;<br>Drug Ineffective; Memory<br>Impairment | Xanax              |                    |                    | S               | Oral                         | 0.5 Mg, As Needed    |                 | Pfizer       |                |
|                                                                    | Benicar            |                    |                    | S               | Oral                         | 20 Mg, Daily         |                 | Not Reported |                |
|                                                                    | Lexapro            |                    |                    | S               | Oral                         | 5 Mg, Daily          |                 | Not Reported |                |
|                                                                    | Alprazolam         |                    |                    | S               | Oral                         | 0.5 Mg, Unk          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                           | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Nov-2012                                                        | 8843524            | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000026589            |                      | 66 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                              | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Haematoma Muscle;<br>Lymphoedema                                   | Escitalopram       |                    |                    | S               | Oral                         | 10 Mg                |                 | Forest       |                |
|                                                                    | Lexomil            |                    |                    | C               |                              |                      |                 | Not Reported |                |
|                                                                    | Plavix             |                    |                    | C               | Oral                         | 1 Df                 |                 | Not Reported |                |
|                                                                    | Pravastatin        |                    |                    | C               | Oral                         | 1df                  |                 | Not Reported |                |
|                                                                    | Triatec (Ramipril) |                    |                    | C               | Oral                         | 1 Df                 |                 | Not Reported |                |
|                                                                    | Amlor              |                    |                    | C               | Oral                         | 1 Df                 |                 | Not Reported |                |
|                                                                    | Inipomp            |                    |                    | C               | Oral                         | 1 Df                 |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

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| <a href="#">FDA Received Date</a>          | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|--------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 09-Nov-2012                                | 8906374                 | DIRECT                    | Y                           |                          |                               |                               | 32 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>             | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Anxiety; Product Substitution Issue        | Lexapro                 |                           |                             | S                        | Oral                          |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>          | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 12-Nov-2012                                | 8903932                 | NON-EXPEDITED             |                             |                          | US-ASTRAZENECA-2012SE82545    |                               | 45 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>             | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Adverse Reaction; Injury; Off Label Use    | Seroquel                |                           |                             | S                        | Oral                          |                               |                          | Zeneca              |                         |
|                                            | Lexapro                 |                           |                             | S                        | Unknown                       |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>          | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 12-Nov-2012                                | 8906182                 | DIRECT                    |                             | DS, OT                   |                               |                               | 43 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>             | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Dysphagia; Glossitis; Mastication Disorder | Escitalopram            |                           |                             | S                        |                               |                               |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>          | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 13-Nov-2012                                | 8905499                 | NON-EXPEDITED             |                             |                          | US-BAYER-2012-114386          |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>             | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Interaction; Unevaluable Event        | Beyaz                   |                           |                             | S                        |                               | Unk                           |                          | Bayer               |                         |
|                                            | Lexapro                 |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
|                                            | Unspecified Ingredient  |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>          | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 13-Nov-2012                                | 8905692                 | EXPEDITED (15-DAY)        |                             | HO                       | US-FRI-1000040353             |                               | 61 YR                    | Male                | USA                     |

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| <u>Preferred Term</u>                                                                                                                                                         | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
| Vith Nerve Paralysis                                                                                                                                                          | Lexapro           |                    |                    | S               | Oral                      | 10 Mg                |                 | Forest       |                |
|                                                                                                                                                                               | Luaf41156         |                    |                    | S               | Oral                      | 0.5 Mg               |                 | Not Reported |                |
|                                                                                                                                                                               | Claritin          |                    |                    | C               |                           |                      |                 | Not Reported |                |
|                                                                                                                                                                               | Flonase           |                    |                    | C               |                           |                      |                 | Not Reported |                |
|                                                                                                                                                                               | Lisinopril        |                    |                    | C               |                           |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                      | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Nov-2012                                                                                                                                                                   | 8906470           | DIRECT             | Y                  | OT              |                           |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                         | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Dizziness;<br>Drug Intolerance;<br>Headache; Impaired Work<br>Ability; Loss Of Personal<br>Independence In Daily<br>Activities; Nausea; Panic<br>Attack; Vomiting | Escitalopram      |                    |                    | S               | Oral                      | 20mg 1qd Oral        | 5 DAY           | Not Reported |                |
|                                                                                                                                                                               | Escitalopram      |                    |                    | S               | Oral                      | 20mg 1qd Oral        | 5 DAY           | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                      | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Nov-2012                                                                                                                                                                   | 8346249           | EXPEDITED (15-DAY) |                    | OT              | US-JNJFOC-<br>20120106642 |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                         | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abortion Spontaneous;<br>Exposure During<br>Pregnancy                                                                                                                         | Topamax           |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                                                                                                                                                                               | Clindamycin       |                    |                    | S               | Vaginal                   |                      |                 | Not Reported |                |
|                                                                                                                                                                               | Terbutaline       |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                                                                                                                                                                               | Prometrium        |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                                                                                                                                                                               | Lexapro           |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                                                                                                                                                                               | Lithium Carbonate |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                                                                                                                                                                               | Betamethasone     |                    |                    | S               | Unknown                   |                      |                 | Not Reported |                |
|                                                                                                                                                                               | Nifedipine        |                    |                    | S               | Unknown                   |                      |                 | Not Reported |                |
|                                                                                                                                                                               | Zithromax         |                    |                    | S               | Unknown                   |                      |                 | Not Reported |                |

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|                                        |   |         |              |
|----------------------------------------|---|---------|--------------|
| Ethinyl Estradiol\Ethynodiol Diacetate | S | Oral    | Not Reported |
| Sulfamethoxazole\Trimethoprim          | S | Oral    | Not Reported |
| Nitrofurantoin                         | S | Oral    | Not Reported |
| Cephalexin                             | S | Oral    | Not Reported |
| Buspirone                              | S | Oral    | Not Reported |
| Ampicillin                             | S | Unknown | Not Reported |
| Natelle                                | C | Oral    | Not Reported |

| <u>FDA Received Date</u>                                                                                                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| 15-Nov-2012                                                                                                                                    | 8910889        | EXPEDITED (15-DAY) |                    | OT              | CH-ABBOTT-12P-151-0995317-00 |                      |                 | Female       | CHE            |
| <u>Preferred Term</u>                                                                                                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Chest Discomfort; Hyperhidrosis; Muscular Weakness; Nausea; Palpitations; Panic Reaction; Sleep Disorder; Suicidal Ideation; Tremor | Cipralelex     |                    |                    | S               | Oral                         | 5 Mg                 |                 | Not Reported |                |
|                                                                                                                                                | Cipralelex     |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                                                                                                                | Trittico       |                    |                    | C               | Oral                         |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                                                                                                   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 15-Nov-2012                                                                                                                                                                                                                | 8913964        | DIRECT           |                    |                 |                      |                      | 38 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                      | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Anxiety; Blood Pressure Increased; Disturbance In Attention; Disturbance In Attention; Dizziness; Fatigue; Feeling Abnormal; Headache; Hot Flush; Nausea; Product Substitution Issue; Tremor; Visual Impairment | Escitalopram   |                  |                    | S               | Oral                 |                      | 4 WEEK          | Not Reported |                |

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

| <u>FDA Received Date</u>                                                                                                                                           | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|-----------------|----------------|
| 15-Nov-2012                                                                                                                                                        | 8913971        | DIRECT             |                    | OT              |                              |                      | 57 YR           | Male            | USA            |
| <u>Preferred Term</u>                                                                                                                                              | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Diarrhoea; Drug Ineffective; Mental Disorder; Product Quality Issue; Product Substitution Issue                                                                    | Escitalopram   |                    |                    | S               | Oral                         | 1 Table Daily Po     |                 | Teva            |                |
| <u>FDA Received Date</u>                                                                                                                                           | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 15-Nov-2012                                                                                                                                                        | 8914006        | DIRECT             |                    | HO, LT          |                              |                      | 71 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                                                                                                              | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Blood Pressure Increased; Chest Discomfort; Crying; Heart Rate Increased; Hyperhidrosis; Hypersensitivity; Insomnia; Nausea; Nightmare; Product Substitution Issue | Lexapro        |                    |                    | S               | Oral                         | 20mg 1 In Pm Po      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                                                           | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 16-Nov-2012                                                                                                                                                        | 8483536        | EXPEDITED (15-DAY) |                    | CA, OT          | SI-GLAXOSMITHKLINE-B0791546A |                      | 182 DAY         | Male            | SVN            |
| <u>Preferred Term</u>                                                                                                                                              | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Cleft Lip; Foetal Exposure During Pregnancy; Ultrasound Scan Abnormal                                                                                              | Lamictal       |                    |                    | S               | Transplacental               | 75mg Per Day         |                 | Glaxosmithkline |                |
|                                                                                                                                                                    | Cipralext      |                    |                    | S               | Transplacental               | 15mg Per Day         |                 | Glaxosmithkline |                |
| <u>FDA Received Date</u>                                                                                                                                           | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 16-Nov-2012                                                                                                                                                        | 8786336        | EXPEDITED (15-DAY) |                    | HO              | CH-FRI-1000038538            |                      |                 | Female          | CHE            |
| <u>Preferred Term</u>                                                                                                                                              | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |



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|                                                                   |                               |   |      |         |              |
|-------------------------------------------------------------------|-------------------------------|---|------|---------|--------------|
| Blood Loss Anaemia;<br>Colitis; Haematemesis;<br>Intestinal Ulcer | Escitalopram                  | S | Oral | 15 Mg   | Forest       |
|                                                                   | Tilur                         | S | Oral | 1 Df    | Not Reported |
|                                                                   | Quetiapine                    | S | Oral | 50 Mg   | Not Reported |
|                                                                   | Novalgine (Metamizole Sodium) | C | Oral | 1000 Mg | Not Reported |
|                                                                   | Calcimagon D3                 | C | Oral | 2 Df    | Not Reported |
|                                                                   | Omezol                        | C | Oral | 80 Mg   | Not Reported |
|                                                                   | Lithium Aspartate             | C | Oral | 1 Df    | Not Reported |
|                                                                   | Neurontin                     | C | Oral | 900 Mg  | Not Reported |
|                                                                   | Requip                        | C | Oral | 2 Mg    | Not Reported |
|                                                                   | Madopar                       | C | Oral | 750 Mg  | Not Reported |
|                                                                   | Detrusitol                    | C | Oral | 2 Mg    | Not Reported |
|                                                                   | Motilium                      | C | Oral | 3 Df    | Not Reported |
|                                                                   | Euthyrox                      | C | Oral | 25 Mg   | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Nov-2012              | 8828773       | EXPEDITED (15-DAY) | HO                 |                 | AU-FRI-1000039272    |                      | 86 YR      | Female     | AUS            |

  

| <u>Preferred Term</u>                                                                                                                                   | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                      | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|--------------|------------|-------------|--------------|-----------------------------------------|-----------------|--------------|
| Anxiety; Cognitive<br>Disorder; Confusional<br>State; Dyspnoea;<br>Hyponatraemia; Joint<br>Swelling; Nausea;<br>Overdose; Psychotic<br>Disorder; Tremor | Lexapro             |              |            | S           | Oral         | 5 Mg                                    |                 | Forest       |
|                                                                                                                                                         | Lexapro             |              |            | S           |              | 20 Mg                                   |                 | Forest       |
|                                                                                                                                                         | Lexapro             |              |            | S           | Oral         | Extra Tablets-Dose,<br>Quantity Unknown |                 | Not Reported |
|                                                                                                                                                         | Irbesarten          |              |            | C           |              | 300 Mg                                  |                 | Not Reported |
|                                                                                                                                                         | Irbesarten          |              |            | C           |              | 75 Mg                                   |                 | Not Reported |
|                                                                                                                                                         | Furosemide          |              |            | C           |              |                                         |                 | Not Reported |
|                                                                                                                                                         | Glucosamine         |              |            | C           |              |                                         |                 | Not Reported |
|                                                                                                                                                         | Spironolactone      |              |            | C           |              |                                         |                 | Not Reported |
|                                                                                                                                                         | Magnesium Carbonate |              |            | C           |              |                                         |                 | Not Reported |
|                                                                                                                                                         | Dabigatran          |              |            | C           |              |                                         |                 | Not Reported |

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

| <u>FDA Received Date</u>                                             | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|-----------------|--------------|----------------|
| 16-Nov-2012                                                          | 8910951                | EXPEDITED (15-DAY) |                    | DE              | ES-SANOFI-AVENTIS-2012SA082354 |                      | 83 YR           | Female       | ESP            |
| <u>Preferred Term</u>                                                | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;<br>Inappropriate Antidiuretic<br>Hormone Secretion | Seguril                |                    |                    | S               | Oral                           |                      |                 | Not Reported |                |
|                                                                      | Escitalopram Oxalate   |                    |                    | S               | Oral                           |                      |                 | Not Reported |                |
|                                                                      | Spiriva                |                    |                    | C               | Respiratory<br>(inhalation)    |                      |                 | Not Reported |                |
|                                                                      | Coversyl /Fra/         |                    |                    | C               | Oral                           |                      |                 | Not Reported |                |
|                                                                      | Atorvastatin           |                    |                    | C               | Oral                           |                      |                 | Not Reported |                |
|                                                                      | Omeprazole             |                    |                    | C               | Oral                           |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                             | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Nov-2012                                                          | 8912643                | EXPEDITED (15-DAY) |                    | OT              | ES-TEVA-359895ISR              |                      |                 | Unknown      | ESP            |
| <u>Preferred Term</u>                                                | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;<br>Serotonin Syndrome                              | Azilect                |                    |                    | S               |                                |                      |                 | Teva         |                |
|                                                                      | Escitalopram           |                    |                    | S               |                                |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                             | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Nov-2012                                                          | 8912660                | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000040410              |                      | 47 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Haematuria; International<br>Normalised Ratio<br>Increased           | Escitalopram           |                    |                    | S               | Oral                           |                      |                 | Forest       |                |
|                                                                      | Previscan (Fluindione) |                    |                    | S               | Oral                           | 10 Mg                |                 | Not Reported |                |
|                                                                      | Calciparine            |                    |                    | S               | Subcutaneous                   | 15 Kiu lu (1000s)    |                 | Not Reported |                |
|                                                                      | Olmotec                |                    |                    | C               |                                |                      |                 | Not Reported |                |
|                                                                      | Climaston              |                    |                    | C               |                                |                      |                 | Not Reported |                |
|                                                                      | Levothyrox             |                    |                    | C               |                                |                      |                 | Not Reported |                |
|                                                                      | Veratran               |                    |                    | C               |                                |                      |                 | Not Reported |                |
|                                                                      | Volibris               |                    |                    | C               |                                |                      |                 | Not Reported |                |
|                                                                      | Revatio                |                    |                    | C               |                                |                      |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                             | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------|---------------------|--------------------|--------------------|-----------------|------------------------|----------------------|-----------------|--------------|----------------|
| 16-Nov-2012                                                          | 8914535             | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000040391      |                      | 42 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Amnesia;<br>Physical Assault                             | Escitalopram        |                    |                    | S               | Oral                   | 1 Df                 |                 | Forest       |                |
| <u>FDA Received Date</u>                                             | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Nov-2012                                                          | 8915344             | EXPEDITED (15-DAY) |                    | HO              | ES-GILEAD-2012-0064764 |                      | 83 YR           | Male         | ESP            |
| <u>Preferred Term</u>                                                | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyperkalaemia;<br>Hyponatraemia; Nausea;<br>Vomiting                 | Ranolazine          |                    |                    | S               |                        | 500 Mg, Unk          |                 | Gilead       |                |
|                                                                      | Eplerenone          |                    |                    | C               |                        | Unk                  |                 | Not Reported |                |
|                                                                      | Ivabradine          |                    |                    | C               |                        | Unk                  |                 | Not Reported |                |
|                                                                      | Glyceryl Trinitrate |                    |                    | C               |                        |                      |                 | Not Reported |                |
|                                                                      | Ramipril            |                    |                    | C               |                        |                      |                 | Not Reported |                |
|                                                                      | Acenocoumarol       |                    |                    | C               |                        |                      |                 | Not Reported |                |
|                                                                      | Pantoprazole        |                    |                    | C               |                        |                      |                 | Not Reported |                |
|                                                                      | Clorazepate         |                    |                    | C               |                        |                      |                 | Not Reported |                |
|                                                                      | Carvedilol          |                    |                    | C               |                        |                      |                 | Not Reported |                |
|                                                                      | Torsemide           |                    |                    | C               |                        |                      |                 | Not Reported |                |
|                                                                      | Escitalopram        |                    |                    | S               |                        |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                             | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Nov-2012                                                          | 8914555             | EXPEDITED (15-DAY) |                    | DE              | DE-FRI-1000040389      |                      |                 | Female       | DEU            |
| <u>Preferred Term</u>                                                | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Asphyxia; Completed<br>Suicide; Depression;<br>Hypoxia; Pulse Absent | Escitalopram        |                    |                    | S               | Oral                   | 5 Mg                 |                 | Forest       |                |
|                                                                      | Citalopram          |                    |                    | S               |                        | 10 Mg                |                 | Forest       |                |
|                                                                      | Lyrica              |                    |                    | S               | Oral                   | 50 Mg                |                 | Not Reported |                |
|                                                                      | Oxazepam            |                    |                    | S               | Oral                   | 15 Mg                |                 | Not Reported |                |
|                                                                      | Oxazepam            |                    |                    | S               | Oral                   | 25 Mg                |                 | Not Reported |                |

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|                                                   |                        | Zolpidem           | S                  | Oral            | 5 Mg                       |                      |                 | Not Reported |                |
|---------------------------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
|                                                   |                        | Medazepam          | S                  |                 |                            |                      |                 | Not Reported |                |
|                                                   |                        | Zopiclone          | S                  |                 |                            |                      |                 | Not Reported |                |
|                                                   |                        | Otc Sedatives      | C                  |                 |                            |                      |                 | Not Reported |                |
|                                                   |                        | Carbamazepine      | C                  | Oral            | 400 Mg                     |                      |                 | Not Reported |                |
|                                                   |                        | Carbamazepine      | C                  | Oral            | 600 Mg                     |                      |                 | Not Reported |                |
|                                                   |                        | Carbamazepine      | C                  | Oral            | 800 Mg                     |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                          | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Nov-2012                                       | 8915807                | EXPEDITED (15-DAY) |                    | OT              | IE-FRI-1000040464          |                      |                 | Male         | IRL            |
| <u>Preferred Term</u>                             | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Sodium Increased                            | Lexapro                |                    |                    | S               | Oral                       |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                          | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Nov-2012                                       | 8916891                | EXPEDITED (15-DAY) |                    | LT              | FR-FRI-1000040522          |                      | 67 YR           | Female       | FRA            |
| <u>Preferred Term</u>                             | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Haemorrhagic Stroke                               | Escitalopram           |                    |                    | S               | Oral                       |                      |                 | Forest       |                |
|                                                   | Previscan (Fluindione) |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                   | Lorazepam              |                    |                    | C               |                            |                      |                 | Not Reported |                |
|                                                   | Akineton               |                    |                    | C               |                            |                      |                 | Not Reported |                |
|                                                   | Micardis               |                    |                    | C               |                            |                      |                 | Not Reported |                |
|                                                   | Xeroquel               |                    |                    | C               |                            |                      |                 | Not Reported |                |
|                                                   | Ascofer                |                    |                    | C               |                            |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                          | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Nov-2012                                       | 8918540                | NON-EXPEDITED      |                    |                 | US-ASTRAZENECA-2012SE18892 |                      | 59 YR           | Female       | USA            |
| <u>Preferred Term</u>                             | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Adverse Event; Drug Interaction; Feeling Abnormal | Nexium                 |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                   | Lexapro                |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |

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|             |   |      |              |
|-------------|---|------|--------------|
| Lexapro     | S | Oral | Not Reported |
| Lexapro     | S | Oral | Not Reported |
| Lexapro     | S | Oral | Not Reported |
| Lexapro     | S | Oral | Not Reported |
| Lexapro     | S | Oral | Not Reported |
| Valium      | C |      | Not Reported |
| Bentyl      | C |      | Not Reported |
| Corgard     | C |      | Not Reported |
| Zantac      | C |      | Not Reported |
| Carafate    | C |      | Not Reported |
| Lyrica      | C |      | Not Reported |
| Elavil      | C |      | Not Reported |
| Zofran      | C |      | Not Reported |
| Vitamin E   | C |      | Not Reported |
| Co Q 10     | C |      | Not Reported |
| Vitamin B12 | C |      | Not Reported |
| Restasis    | C |      | Not Reported |
| Calcium     | C |      | Not Reported |
| Glucosamine | C |      | Not Reported |
| Fish Oil    | C |      | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Nov-2012              | 8674250       | EXPEDITED (15-DAY) |                    | OT              | JP-FRI-1000037216    |                      | 64 YR      | Female     | JPN            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Liver Disorder        | Lexapro        |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                       | Lexapro        |              |            | S           | Oral         | 20 Mg              |                 | Forest       |
|                       | Lexapro        |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                       | Selenica-R     |              |            | S           | Oral         | 400 Mg             |                 | Not Reported |
|                       | Selenica       |              |            | S           | Oral         | 600 Mg             |                 | Not Reported |
|                       | Zyprexa        |              |            | S           | Oral         | 5 Mg               |                 | Not Reported |
|                       | Zyprexa        |              |            | S           | Oral         | 10 Mg              |                 | Not Reported |
|                       | Zyprexa        |              |            | S           | Oral         | 15 Mg              |                 | Not Reported |
|                       | Zyprexa        |              |            | S           | Oral         | 10 Mg              |                 | Not Reported |

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

|  |           |   |      |        |  |              |
|--|-----------|---|------|--------|--|--------------|
|  | Dogmatyl  | C | Oral | 450 Mg |  | Not Reported |
|  | Wintermin | C |      | 30 Mg  |  | Not Reported |
|  | Nelbon    | C | Oral | 10 Mg  |  | Not Reported |
|  | Celecox   | C | Oral | 200 Mg |  | Not Reported |
|  | Mucosta   | C | Oral | 200 Mg |  | Not Reported |
|  | Magmitt   | C | Oral |        |  | Not Reported |
|  | Forsenid  | C | Oral |        |  | Not Reported |

| <u>FDA Received Date</u>              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 21-Nov-2012                           | 8920235        | EXPEDITED (15-DAY) | CA                 |                 | US-FRI-1000040534    |                      | < 1 DAY         | Male       | USA            |
| <u>Preferred Term</u>                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Congenital Anomaly;<br>Ectopic Kidney | Lexapro        |                    |                    | S               | Transplacental       |                      |                 | Forest     |                |

| <u>FDA Received Date</u>                                                   | <u>Case #</u>     | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------|-------------------|------------------|--------------------|-----------------|----------------------|-------------------------|-----------------|--------------|----------------|
| 21-Nov-2012                                                                | 8924265           | DIRECT           | Y                  |                 |                      |                         |                 | Female       | USA            |
| <u>Preferred Term</u>                                                      | <u>Product</u>    | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Headache;<br>Lacrimation Increased;<br>Product Substitution Issue | Escitalopram 20mg |                  |                    | S               | Oral                 | Escitalopram 20mg Qd Po |                 | Not Reported |                |

| <u>FDA Received Date</u>                                          | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|------------------------------|-------------------------------|-----------------|--------------|----------------|
| 22-Nov-2012                                                       | 8902906        | NON-EXPEDITED    |                    |                 | US-PFIZER INC-<br>2012279631 |                               | 30 YR           | Female       | USA            |
| <u>Preferred Term</u>                                             | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Arthropathy; Depression;<br>Drug Ineffective; Weight<br>Increased | Vistaril       |                  |                    | S               | Oral                         | 50 Mg, 3x/Day As<br>Necessary |                 | Pfizer       |                |
|                                                                   | Lexapro        |                  |                    | S               | Oral                         | 10 Mg, Daily                  |                 | Not Reported |                |
|                                                                   | Lexapro        |                  |                    | S               | Oral                         | 20 Mg, 1x/Day                 |                 | Not Reported |                |
|                                                                   | Lexapro        |                  |                    | S               | Oral                         | 10 Mg, 1x/Day                 |                 | Not Reported |                |

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

|  |          |   |      |                |              |
|--|----------|---|------|----------------|--------------|
|  | Klonopin | S | Oral | 0.5 Mg, 2x/Day | Not Reported |
|  | Topamax  | S |      | 25 Mg, Daily   | Not Reported |
|  | Cymbalta | S | Oral | 20 Mg, Daily   | Not Reported |
|  | Cymbalta | S |      |                | Not Reported |
|  | Adipex   | C |      | Unk            | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Nov-2012              | 8923401       | EXPEDITED (15-DAY) |                    | OT              | PHHY2012BR105759     |                      |            | Female     | BRA            |

| <u>Preferred Term</u>                                                   | <u>Product</u>               | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------|------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Asthenia; Blood Growth Hormone Decreased; Hypertension; Malaise; Nausea | Ludiomil                     |              |            | S           | Oral         | 1 Df, Daily        |                 | Not Reported |
|                                                                         | Calcium D3                   |              |            | S           | Oral         | 1 Df, Daily        |                 | Not Reported |
|                                                                         | Alendronate                  |              |            | S           | Oral         | 1 Df, Weekly       |                 | Novartis     |
|                                                                         | Estradiol                    |              |            | S           | Oral         | 1 Df, Daily        |                 | Not Reported |
|                                                                         | Rivotril                     |              |            | S           | Oral         | 1 Df, Daily        |                 | Not Reported |
|                                                                         | Exodus//Escitalopram Oxalate |              |            | S           |              | 10 Mg, Unk         |                 | Not Reported |
|                                                                         | Evista                       |              |            | S           | Oral         | 1 Df, Daily        |                 | Not Reported |
|                                                                         | Melatonin                    |              |            | S           | Oral         | 1 Df, Daily        |                 | Not Reported |
|                                                                         | Selozok                      |              |            | C           | Oral         | 1 Df, Daily        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Nov-2012              | 8937140       | EXPEDITED (15-DAY) | Y                  | OT              | AUR-APL-2012-04879   |                      |            | Male       | GBR            |

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

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Nov-2012              | 8880010       | EXPEDITED (15-DAY) |                    | OT              | JP-FRI-1000039847    |                      | 26 YR      | Female     | JPN            |

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

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

|                           |              |   |      |       |              |
|---------------------------|--------------|---|------|-------|--------------|
| Overdose; Suicide Attempt | Escitalopram | S | Oral | 10 Mg | Forest       |
|                           | Escitalopram | S | Oral |       | Forest       |
|                           | Nitrazepam   | S | Oral |       | Not Reported |
|                           | Nitrazepam   | S | Oral |       | Not Reported |
|                           | Cercine      | S | Oral |       | Not Reported |
|                           | Cercine      | S | Oral |       | Not Reported |

| <u>FDA Received Date</u>                        | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------|----------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 26-Nov-2012                                     | 8922416        | EXPEDITED (15-DAY) |                    | DE              | CH-JNJFOC-20121109166 |                      | 84 YR           | Female       | CHE            |
| <u>Preferred Term</u>                           | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cerebrovascular Accident; Fall; Spinal Fracture | Tramal         |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                 | Anxiolit       |                    |                    | S               | Unknown               |                      |                 | Not Reported |                |
|                                                 | Cipralext      |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                 | Lexotanil      |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                 | Paracetamol    |                    |                    | C               | Oral                  |                      |                 | Not Reported |                |
|                                                 | Amlodipine     |                    |                    | C               | Oral                  |                      |                 | Not Reported |                |
|                                                 | Atacand Plus   |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |
|                                                 | Calcimagon D3  |                    |                    | C               | Oral                  |                      |                 | Not Reported |                |
|                                                 | Ibuprofen      |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------|----------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 26-Nov-2012                                             | 8925360                    | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000040580    |                      | 53 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                   | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Generalised Tonic-Clonic Seizure; Loss Of Consciousness | Escitalopram Oral Solution |                    |                    | S               | Oral                 | 7 Mg                 |                 | Forest       |                |
|                                                         | Urbanyl                    |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |
|                                                         | Lamictal                   |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |
|                                                         | Keppra                     |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                         | Gardenal                   |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |



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

|                                                                                                                                                  |                     |                    |                    |                 |                                                     |                      |                 |              |                |
|--------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|--------------------|--------------------|-----------------|-----------------------------------------------------|----------------------|-----------------|--------------|----------------|
| Dafalgan                                                                                                                                         |                     |                    | C                  |                 | Oral                                                |                      | Not Reported    |              |                |
| <u>FDA Received Date</u>                                                                                                                         | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Nov-2012                                                                                                                                      | 8925400             | DIRECT             |                    | OT              |                                                     |                      | 27 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                            | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Dreams;<br>Dizziness Postural; Drug<br>Withdrawal Syndrome; Dry<br>Mouth; Hypoaesthesia;<br>Insomnia; Paraesthesia;<br>Seizure; Vertigo | Escitalopram Normal |                    |                    | S               | Oral                                                |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                         | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Nov-2012                                                                                                                                      | 8925721             | EXPEDITED (15-DAY) |                    | LT, OT          | BE-ROXANE<br>LABORATORIES, INC.-<br>2012-RO-02431RO |                      | 26 YR           | Male         | BEL            |
| <u>Preferred Term</u>                                                                                                                            | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Necrotising Colitis;<br>Overdose                                                                                                                 | Lorazepam           |                    |                    | S               |                                                     | 5 Mg                 |                 | Roxane       |                |
|                                                                                                                                                  | Quetiapine Fumarate |                    |                    | S               |                                                     | 900 Mg               |                 | Roxane       |                |
|                                                                                                                                                  | Clotiapine          |                    |                    | S               |                                                     | 40 Mg                |                 | Not Reported |                |
|                                                                                                                                                  | Trazodone           |                    |                    | S               |                                                     | 200 Mg               |                 | Not Reported |                |
|                                                                                                                                                  | Lamotrigine         |                    |                    | S               |                                                     | 200 Mg               |                 | Not Reported |                |
|                                                                                                                                                  | Escitalopram        |                    |                    | S               |                                                     | 10 Mg                |                 | Not Reported |                |
|                                                                                                                                                  | Zuclopenthixol      |                    |                    | S               |                                                     |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                         | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Nov-2012                                                                                                                                      | 8927976             | DIRECT             | Y                  |                 |                                                     |                      | 57 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                            | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective                                                                                                                                 | Escitalopram        |                    |                    | S               | Oral                                                |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

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### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                     | <u>Case #</u>           | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 26-Nov-2012                                                                                                                                                                                  | 8927990                 | DIRECT           | Y                  | OT              |                      |                      | 68 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                        | <u>Product</u>          | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Irritability;<br>Product Substitution Issue;<br>Restlessness                                                                                                                     | Escitalopram            |                  |                    | S               | Oral                 |                      |                 | Teva         |                |
| <u>FDA Received Date</u>                                                                                                                                                                     | <u>Case #</u>           | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Nov-2012                                                                                                                                                                                  | 8932470                 | DIRECT           | Y                  |                 |                      |                      | 39 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                        | <u>Product</u>          | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Confusional<br>State; Dizziness                                                                                                                                                     | Escitalopram 20 Mg Teva |                  |                    | S               | Oral                 |                      |                 | Teva         |                |
| <u>FDA Received Date</u>                                                                                                                                                                     | <u>Case #</u>           | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Nov-2012                                                                                                                                                                                  | 8932478                 | DIRECT           |                    | DS              |                      |                      | 35 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                        | <u>Product</u>          | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Dreams;<br>Abnormal Dreams;<br>Depression; Impaired<br>Work Ability; Mental<br>Disorder; Paraesthesia;<br>Product Formulation<br>Issue; Product Quality<br>Issue; Suicidal Ideation | Lexapro                 |                  |                    | S               | Oral                 |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                                                                                     | <u>Case #</u>           | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Nov-2012                                                                                                                                                                                  | 8932548                 | DIRECT           | Y                  | OT              |                      |                      | 51 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                        | <u>Product</u>          | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Fatigue;<br>Nausea                                                                                                                                                                | Escitalopram            |                  |                    | S               | Oral                 | 10 Mg 1 Qd Oral      |                 | Not Reported |                |

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## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>            | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------|-------------------|--------------------|--------------------|-----------------|------------------------------------------|----------------------|-----------------|--------------|----------------|
| 27-Nov-2012                         | 8876490           | EXPEDITED (15-DAY) |                    | OT              | US-FRI-1000039482                        |                      | 83 YR           | Female       | USA            |
| <u>Preferred Term</u>               | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bladder Cancer; Fall                | Escitalopram      |                    |                    | S               |                                          | 20mg                 |                 | Forest       |                |
|                                     | Escitalopram      |                    |                    | S               |                                          |                      |                 | Forest       |                |
|                                     | Aspirin           |                    |                    | C               |                                          | 325mg                |                 | Not Reported |                |
|                                     | Clonazepam        |                    |                    | C               |                                          | 1mg                  |                 | Not Reported |                |
|                                     | Meclozine         |                    |                    | C               |                                          | 25mg As Needed       |                 | Not Reported |                |
| <u>FDA Received Date</u>            | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Nov-2012                         | 8923922           | EXPEDITED (15-DAY) |                    | DS              | FI-SANOFI-AVENTIS-2012SA086280           |                      |                 | Male         | FIN            |
| <u>Preferred Term</u>               | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Brain Injury                        | Amaryl            |                    |                    | S               | Oral                                     |                      |                 | Not Reported |                |
|                                     | Escitalopram      |                    |                    | S               | Oral                                     |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>            | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Nov-2012                         | 8927359           | EXPEDITED (15-DAY) |                    | OT              | US-BRISTOL-MYERS SQUIBB COMPANY-17142068 |                      |                 | Female       | USA            |
| <u>Preferred Term</u>               | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Mania                               | Abilify Tabs 5 Mg |                    |                    | S               |                                          | 5 Mg                 |                 | Not Reported |                |
|                                     | Lexapro           |                    |                    | S               |                                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>            | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Nov-2012                         | 8928958           | EXPEDITED (15-DAY) |                    | OT              | CN-FRI-1000040641                        |                      | 16 YR           | Male         | CHN            |
| <u>Preferred Term</u>               | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypersomnia; Hypokinesia; Off Label | Lexapro           |                    |                    | S               | Oral                                     | 5 Mg                 |                 | Forest       |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                             |         |   |      |       |        |
|---------------------------------------------|---------|---|------|-------|--------|
| Use; Suicidal Ideation;<br>Weight Increased | Lexapro | S | Oral | 10 Mg | Forest |
|---------------------------------------------|---------|---|------|-------|--------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Nov-2012              | 8928967       | EXPEDITED (15-DAY) |                    | DE              | ES-FRI-1000040637    |                      | 83 YR      | Female     | ESP            |

| <u>Preferred Term</u>                                                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction;<br>Inappropriate Antidiuretic<br>Hormone Secretion | Escitalopram   |              |            | S           | Oral         | 20 Mg              |                 | Forest       |
|                                                                      | Seguril        |              |            | S           | Oral         | 40 Mg              |                 | Not Reported |
|                                                                      | Omeprazole     |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                      | Atorvastatin   |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                      | Coversyl       |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                      | Spiriva        |              |            | C           | Nasal        |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Nov-2012              | 8935381       | DIRECT           |                    |                 |                      |                      | 43 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Accident; Anxiety;<br>Coordination Abnormal;<br>Crying; Dizziness; Eye<br>Contusion; Loss Of<br>Proprioception; Product<br>Quality Issue; Product<br>Substitution Issue | Escitalopram   |              |            | S           | Oral         |                    |                 | Aurobindo  |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Nov-2012              | 8930217       | EXPEDITED (15-DAY) |                    | OT              | CH-FRI-1000040625    |                      |            | Female     | CHE            |

| <u>Preferred Term</u>                                                  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Ecchymosis; Platelet<br>Adhesiveness Decreased;<br>Prescribed Overdose | Escitalopram   |              |            | S           | Oral         | 5 Mg               |                 | Forest       |
|                                                                        | Escitalopram   |              |            | S           | Oral         | 25 Mg              |                 | Forest       |
|                                                                        | Tramal         |              |            | C           | Oral         | 37.5 Mg            |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Nov-2012              | 8930399       | EXPEDITED (15-DAY) |                    | DE              | CH-FRI-1000040642    |                      |            | Female     | CHE            |

| <u>Preferred Term</u>                              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------|----------------|--------------|------------|-------------|--------------|-------------------------|-----------------|--------------|
| Cerebrovascular Accident;<br>Fall; Spinal Fracture | Escitalopram   |              |            | S           | Oral         | 10 Mg                   |                 | Forest       |
|                                                    | Tramal         |              |            | S           | Oral         | 50 Mg                   |                 | Not Reported |
|                                                    | Anxiolit       |              |            | S           |              | 15 Mg (Before Sleeping) |                 | Not Reported |
|                                                    | Lexotanil      |              |            | S           |              | 1.5 Mg                  |                 | Not Reported |
|                                                    | Paracetamol    |              |            | C           |              | 4000 Mg                 |                 | Not Reported |
|                                                    | Amlodipine     |              |            | C           |              | 5 Mg                    |                 | Not Reported |
|                                                    | Atacand Plus   |              |            | C           |              |                         |                 | Not Reported |
|                                                    | Calcimagon D3  |              |            | C           |              |                         |                 | Not Reported |
|                                                    | Ibuprofen      |              |            | C           |              | 800 Mg                  |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Nov-2012              | 8931768       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000040620    |                      | 83 YR      | Female     | FRA            |

| <u>Preferred Term</u>                         | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------|--------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hyponatraemia; Incorrect<br>Dose Administered | Escitalopram       |              |            | S           | Oral         |                    |                 | Forest       |
|                                               | Lasilix            |              |            | S           | Oral         | 125 Mg             |                 | Not Reported |
|                                               | Plavix             |              |            | C           | Oral         | 75 Mg              |                 | Not Reported |
|                                               | Levothyrox         |              |            | C           |              | 1 Df               |                 | Not Reported |
|                                               | Triatec (Ramipril) |              |            | C           | Oral         | 0.625              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Nov-2012              | 8937814       | DIRECT           | Y                  | OT              |                      |                      | 48 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|----------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Product Quality Issue;<br>Product Substitution Issue;<br>Treatment Failure | Escitalopram   |              |            | S           | Oral         | 1 Tablet Daily Po  |                 | Aurobindo  |

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

| <u>FDA Received Date</u>                                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 28-Nov-2012                                                              | 8937996        | DIRECT             | Y                  | OT              |                      |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Insomnia; Irritability; Mood Swings; Product Substitution Issue          | Lexapro        |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                          | Celexa         |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Nov-2012                                                              | 8938351        | DIRECT             | Y                  | OT              |                      |                      | 38 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Product Quality Issue; Product Substitution Issue; Treatment Failure     | Escitalopram   |                    |                    | S               | Oral                 |                      |                 | Aurobindo    |                |
| <u>FDA Received Date</u>                                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Nov-2012                                                              | 8938364        | DIRECT             | Y                  | OT              |                      |                      | 48 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Product Quality Issue; Product Substitution Issue; Therapy Non-Responder | Escitalopram   |                    |                    | S               | Oral                 | 1 Tablet Daily Po    |                 | Aurobindo    |                |
| <u>FDA Received Date</u>                                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Nov-2012                                                              | 8636995        | EXPEDITED (15-DAY) |                    | HO              | IE-FRI-1000036597    |                      | 41 YR           | Male         | IRL            |
| <u>Preferred Term</u>                                                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Generalised Tonic-Clonic Seizure; Hyponatraemia; Rhabdomyolysis          | Escitalopram   |                    |                    | S               | Oral                 | 15 Mg                |                 | Forest       |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Nov-2012              | 8933972       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000040633    |                      | 51 YR      | Male       | FRA            |

| <u>Preferred Term</u>               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Angle Closure Glaucoma;<br>Overdose | Escitalopram   |              |            | S           | Oral         | 40 Mg              |                 | Forest       |
|                                     | Clopixol       |              |            | S           | Oral         | 20 Mg              |                 | Not Reported |
|                                     | Loxapac        |              |            | S           | Oral         | 100 Mg             |                 | Not Reported |
|                                     | Risperdal      |              |            | S           | Oral         | 12 Mg              |                 | Not Reported |
|                                     | Parkinane      |              |            | S           | Oral         | 10 Mg              |                 | Not Reported |
|                                     | Abilify        |              |            | S           | Oral         | 15 Mg              |                 | Not Reported |
|                                     | Trivastal      |              |            | C           | Oral         |                    |                 | Not Reported |
|                                     | Valium         |              |            | C           | Oral         | 15 Mg              |                 | Not Reported |
|                                     | Levothyrox     |              |            | C           | Oral         | 50 Mcg             |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Nov-2012              | 8942228       | DIRECT           | Y                  | HO              |                      |                      | 64 YR      | Female     | USA            |

| <u>Preferred Term</u>                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hyperthermia; Sepsis;<br>Serotonin Syndrome | Wellbutrin Sr  |              |            | S           |              |                    |                 | Not Reported |
|                                             | Lexapro        |              |            | S           |              |                    |                 | Not Reported |
|                                             | Famotadine     |              |            | C           |              |                    |                 | Not Reported |
|                                             | Protonix       |              |            | C           |              |                    |                 | Not Reported |
|                                             | Plavix         |              |            | C           |              |                    |                 | Not Reported |
|                                             | Furosemide     |              |            | C           |              |                    |                 | Not Reported |
|                                             | Isosorbide     |              |            | C           |              |                    |                 | Not Reported |
|                                             | Pletal         |              |            | C           |              |                    |                 | Not Reported |
|                                             | Vytorin        |              |            | C           |              |                    |                 | Not Reported |
|                                             | Metoprolam     |              |            | C           |              |                    |                 | Not Reported |
|                                             | Singulair      |              |            | C           |              |                    |                 | Not Reported |
|                                             | Aspirin        |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Nov-2012              | 8942236       | DIRECT           | Y                  |                 |                      |                      | 52 YR      | Female     | USA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                        | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|------------------------------------------------------------------------------|-------------------|--------------------|--------------------|-----------------|------------------------------------------|----------------------|-----------------|--------------|----------------|
| Alopecia; Asthenia; Depression; Product Substitution Issue; Weight Increased | Escitalopram 20mg |                    |                    | S               | Oral                                     | 20 Mg Daily Oral     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                     | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Nov-2012                                                                  | 8879529           | EXPEDITED (15-DAY) |                    | HO              | IT-ABBOTT-12P-083-1001620-00             |                      | 41 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                        | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Overdose; Sopor                                                  | Depakin Chrono    |                    |                    | S               | Oral                                     |                      |                 | Not Reported |                |
|                                                                              | Ciprallex         |                    |                    | S               | Oral                                     | 40 Tablets Of 10mg   |                 | Not Reported |                |
|                                                                              | Largactil         |                    |                    | S               | Oral                                     | 19tablets Of 100mg   |                 | Not Reported |                |
|                                                                              | Lendormin         |                    |                    | S               | Oral                                     | 19tablets Of 0.25mg  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                     | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Nov-2012                                                                  | 8935816           | EXPEDITED (15-DAY) |                    | HO              | FR-BRISTOL-MYERS SQUIBB COMPANY-17152265 |                      | 51 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                        | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Angle Closure Glaucoma                                                       | Abilify           |                    |                    | S               | Oral                                     |                      |                 | Not Reported |                |
|                                                                              | Loxapac           |                    |                    | S               | Oral                                     |                      |                 | Not Reported |                |
|                                                                              | Risperdal         |                    |                    | S               | Oral                                     |                      |                 | Not Reported |                |
|                                                                              | Parkinane         |                    |                    | S               | Oral                                     |                      |                 | Not Reported |                |
|                                                                              | Clopixol          |                    |                    | S               | Oral                                     |                      |                 | Not Reported |                |
|                                                                              | Seroplex          |                    |                    | S               | Oral                                     |                      |                 | Not Reported |                |
|                                                                              | Trivastal         |                    |                    | C               |                                          |                      |                 | Not Reported |                |
|                                                                              | Valium            |                    |                    | C               |                                          |                      |                 | Not Reported |                |
| Levothyrox                                                                   |                   |                    | C                  |                 |                                          |                      | Not Reported    |              |                |
| <u>FDA Received Date</u>                                                     | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Nov-2012                                                                  | 8937585           | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000040712                        |                      | 80 YR           | Male         | FRA            |



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

| <u>Preferred Term</u>      | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|--------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction; Vomiting | Escitalopram       |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                            | Colchimax (France) |              |            | S           | Oral         |                    |                 | Not Reported |
|                            | Pyostacine         |              |            | S           | Oral         | 3 G                |                 | Not Reported |
|                            | Omeprazole         |              |            | S           | Oral         |                    |                 | Not Reported |
|                            | Xatral             |              |            | C           | Oral         | 10 Mg              |                 | Not Reported |
|                            | Kardegic           |              |            | C           | Oral         | 75 Mg              |                 | Not Reported |
|                            | Lasilix            |              |            | C           | Oral         | 40 Mg              |                 | Not Reported |
|                            | Plavix             |              |            | C           | Oral         |                    |                 | Not Reported |
|                            | Doliprane          |              |            | C           | Oral         | 4 G                |                 | Not Reported |
|                            | Crestor            |              |            | C           | Oral         | 10 Mg              |                 | Not Reported |
|                            | Ezetrol            |              |            | C           | Oral         | 10 Mg              |                 | Not Reported |
|                            | Procoralan         |              |            | C           | Oral         |                    |                 | Not Reported |
|                            | Inspra             |              |            | C           | Oral         |                    |                 | Not Reported |
|                            | Amiodarone         |              |            | C           | Oral         |                    |                 | Not Reported |
|                            | Losartan Potassium |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 03-Dec-2012              | 8194175       | EXPEDITED (15-DAY) |                    | DS, HO, OT      | CA-ASTRAZENECA-2011SE62178 |                      |            | Male       | CAN            |

| <u>Preferred Term</u>                                                                                                                                                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Diarrhoea Neonatal; Extrapyramidal Disorder; Foetal Exposure During Pregnancy; Hypertonia Neonatal; Neonatal Tachypnoea; Poor Quality Sleep; Selective Eating Disorder; Trismus | Seroquel       |              |            | S           | Transplacental |                    |                 | Not Reported |
|                                                                                                                                                                                 | Seroquel       |              |            | S           | Transplacental |                    |                 | Not Reported |
|                                                                                                                                                                                 | Cipralax       |              |            | S           | Transplacental |                    |                 | Not Reported |
|                                                                                                                                                                                 | Nortriptyline  |              |            | S           | Transplacental |                    |                 | Not Reported |
|                                                                                                                                                                                 | Gabapentin     |              |            | S           | Transplacental |                    |                 | Not Reported |
|                                                                                                                                                                                 | Benzotropine   |              |            | S           | Transplacental |                    |                 | Not Reported |
|                                                                                                                                                                                 | Zopiclone      |              |            | S           | Transplacental |                    |                 | Not Reported |
|                                                                                                                                                                                 | Rabeprazole    |              |            | S           | Transplacental |                    |                 | Not Reported |

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

|                                                                                        |                |                    |                    |                 |                                                 |                      |                 |              |                |
|----------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|--------------|----------------|
| Methadone                                                                              |                |                    | S                  |                 | Transplacental                                  |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Dec-2012                                                                            | 8467544        | EXPEDITED (15-DAY) |                    | DS              | FR-FRI-1000008839                               |                      |                 | Female       | FRA            |
| <u>Preferred Term</u>                                                                  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dyskinesia; Dyskinesia;<br>Dysphagia; Dystonia;<br>Speech Disorder                     | Escitalopram   |                    |                    | S               | Oral                                            | 10 Mg                |                 | Forest       |                |
|                                                                                        | Escitalopram   |                    |                    | S               |                                                 |                      |                 | Forest       |                |
|                                                                                        | Citalopram     |                    |                    | S               | Oral                                            | 20 Mg                |                 | Forest       |                |
|                                                                                        | Citalopram     |                    |                    | S               | Oral                                            | 30 Mg                |                 | Forest       |                |
|                                                                                        | Tamoxifen      |                    |                    | C               | Oral                                            | 1 Dosage Form        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Dec-2012                                                                            | 8880281        | EXPEDITED (15-DAY) |                    | HO              | AT-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>16776973 |                      | 71 YR           | Male         | AUT            |
| <u>Preferred Term</u>                                                                  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Creatine<br>Phosphokinase Increased;<br>Parkinson'S Disease                      | Abilify        |                    |                    | S               | Oral                                            |                      |                 | Not Reported |                |
|                                                                                        | Mirtazapine    |                    |                    | S               | Oral                                            |                      |                 | Not Reported |                |
|                                                                                        | Ciprallex      |                    |                    | S               | Oral                                            |                      |                 | Not Reported |                |
|                                                                                        | Praxiten       |                    |                    | S               | Oral                                            |                      |                 | Not Reported |                |
|                                                                                        | Simvastatin    |                    |                    | C               |                                                 |                      |                 | Not Reported |                |
|                                                                                        | Acemin         |                    |                    | C               |                                                 |                      |                 | Not Reported |                |
|                                                                                        | Laevolac       |                    |                    | C               |                                                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Dec-2012                                                                            | 8939078        | NON-EXPEDITED      |                    |                 | US-PFIZER INC-PRP-<br>00036                     |                      | 40 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Dizziness;<br>Dizziness; Fatigue;<br>Fatigue; Feeling<br>Abnormal; Feeling | Inderal        |                    |                    | S               | Oral                                            | 80 Mg, 1x/Day        |                 | Pfizer       |                |
|                                                                                        | Inderal        |                    |                    | S               |                                                 |                      |                 | Pfizer       |                |
|                                                                                        | Lexapro        |                    |                    | S               | Oral                                            | 10 Mg, 1x/Day,Week 1 |                 | Not Reported |                |

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|                                                                    |                |                    |                    |                 |             |                       |                      |                 |            |                |
|--------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|-------------|-----------------------|----------------------|-----------------|------------|----------------|
| Abnormal; Heart Rate                                               | Lexapro        |                    |                    | S               |             | 5 Mg, Unk,Week 2      |                      | Not Reported    |            |                |
| Abnormal; Malaise; Malaise                                         | Lexapro        |                    |                    | S               |             | 2.5 Mg, Unk,Week 3    |                      | Not Reported    |            |                |
| <u>FDA Received Date</u>                                           | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> |             | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 03-Dec-2012                                                        | 8941294        | NON-EXPEDITED      |                    |                 |             | US-BAYER-2012-117104  |                      | 50 YR           | Female     | USA            |
| <u>Preferred Term</u>                                              | <u>Product</u> |                    | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u> | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> |            | <u>Mfr</u>     |
| Fatigue; Sluggishness                                              | Betaseron      |                    |                    |                 | S           |                       | Unk                  |                 |            | Bayer          |
|                                                                    | Ampyra         |                    |                    |                 | S           | Oral                  | 10 Mg, Bid           |                 |            | Not Reported   |
|                                                                    | Lexapro        |                    |                    |                 | S           |                       | Unk                  |                 |            | Not Reported   |
|                                                                    | Prozac         |                    |                    |                 | S           |                       | Unk                  |                 |            | Not Reported   |
|                                                                    | Metoprolol     |                    |                    |                 | C           |                       | 50 Mg, Unk           |                 |            | Not Reported   |
|                                                                    | Aspirin        |                    |                    |                 | C           |                       | Unk                  |                 |            | Not Reported   |
|                                                                    | Fosamax        |                    |                    |                 | C           |                       | Unk                  |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                           | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> |             | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 04-Dec-2012                                                        | 8933714        | EXPEDITED (15-DAY) |                    | OT              |             | GB-FRI-1000040628     |                      | 33 YR           | Female     | GBR            |
| <u>Preferred Term</u>                                              | <u>Product</u> |                    | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u> | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> |            | <u>Mfr</u>     |
| Seizure                                                            | Escitalopram   |                    |                    |                 | S           |                       | 10 Mg                |                 |            | Forest         |
|                                                                    | Fluoxetine     |                    |                    |                 | C           |                       |                      |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                           | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> |             | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 04-Dec-2012                                                        | 8942473        | EXPEDITED (15-DAY) |                    | OT              |             | US-JNJFOC-20121111552 |                      | 17 YR           | Male       | USA            |
| <u>Preferred Term</u>                                              | <u>Product</u> |                    | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u> | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> |            | <u>Mfr</u>     |
| Adverse Drug Reaction; Imprisonment; Obsessive-Compulsive Disorder | Risperdal      |                    |                    |                 | S           | Oral                  |                      |                 |            | Not Reported   |
|                                                                    | Risperdal      |                    |                    |                 | S           | Oral                  |                      |                 |            | Not Reported   |
|                                                                    | Lexapro        |                    |                    |                 | S           | Oral                  |                      |                 |            | Not Reported   |
|                                                                    | Risperidone    |                    |                    |                 | S           | Oral                  |                      |                 |            | Not Reported   |

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| <u>FDA Received Date</u>                                                                                            | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 05-Dec-2012                                                                                                         | 8945257                | EXPEDITED (15-DAY) |                    | OT              | DE-FRI-1000040788    |                      |                 | Female       | DEU            |
| <u>Preferred Term</u>                                                                                               | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Pressure Increased;<br>Drug Interaction;<br>Hyperhidrosis; Malaise;<br>Pyrexia; Respiratory Rate<br>Increased | Escitalopram           |                    |                    | S               | Oral                 | 20 Mg                |                 | Forest       |                |
|                                                                                                                     | Escitalopram           |                    |                    | S               |                      |                      |                 | Forest       |                |
|                                                                                                                     | Pantoprazol            |                    |                    | S               | Oral                 | 40 Mg                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                            | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Dec-2012                                                                                                         | 8945260                | EXPEDITED (15-DAY) |                    | DS              | FI-FRI-1000040789    |                      |                 | Male         | FIN            |
| <u>Preferred Term</u>                                                                                               | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Brain Injury                                                                                                        | Escitalopram           |                    |                    | S               | Oral                 |                      |                 | Forest       |                |
|                                                                                                                     | Amaryl                 |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                            | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Dec-2012                                                                                                         | 8947449                | EXPEDITED (15-DAY) |                    | HO              | NZ-FRI-1000040816    |                      | 94 YR           | Female       | NZL            |
| <u>Preferred Term</u>                                                                                               | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;<br>Hyponatraemia                                                                                  | Escitalopram           |                    |                    | S               |                      | 5 Mg                 |                 | Forest       |                |
|                                                                                                                     | Escitalopram           |                    |                    | S               |                      | 10 Mg                |                 | Not Reported |                |
|                                                                                                                     | Omeprazole             |                    |                    | S               |                      | 20 Mg                |                 | Not Reported |                |
|                                                                                                                     | Tiotropium             |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                     | Metoprolol             |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                     | Isosorbide Mononitrate |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                     | Hydroxocobalamin       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                     | Salbutamol             |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                     | Aspirin                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                     | Zoledronic Acid        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                     | Cefaclor               |                    |                    | C               |                      |                      |                 | Not Reported |                |

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## Freedom of Information Act (FOIA)

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| <u>FDA Received Date</u>                                                                              | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 05-Dec-2012                                                                                           | 8952534                     | EXPEDITED (15-DAY) |                    | DS, LT, OT      | GB-FRI-1000040791    |                      | 29 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                                                 | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depersonalisation/Derealisation Disorder; Dissociation; Emotional Distress; Emotional Poverty; Nausea | Escitalopram                |                    |                    | S               | Oral                 | 5 Mg                 |                 | Forest       |                |
|                                                                                                       | Valium                      |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                              | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Dec-2012                                                                                           | 8952538                     | EXPEDITED (15-DAY) |                    | DE              | DK-FRI-1000040796    |                      | 34 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                 | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Electrocardiogram Qt Prolonged                                                                        | Escitalopram                |                    |                    | S               |                      | 20 Mg                |                 | Forest       |                |
|                                                                                                       | Sertindole                  |                    |                    | S               | Oral                 | 4 Mg                 |                 | Not Reported |                |
|                                                                                                       | Sertindole                  |                    |                    | S               | Oral                 | 8 Mg                 |                 | Not Reported |                |
|                                                                                                       | Sertindole                  |                    |                    | S               | Oral                 | 12 Mg                |                 | Not Reported |                |
|                                                                                                       | Sertindole                  |                    |                    | S               | Oral                 | 16 Mg                |                 | Not Reported |                |
|                                                                                                       | Sertindole                  |                    |                    | S               | Oral                 | 20 Mg                |                 | Not Reported |                |
|                                                                                                       | Sertindole                  |                    |                    | S               | Oral                 | 24 Mg                |                 | Not Reported |                |
|                                                                                                       | Zyprexa                     |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                       | Corodil (Enalapril Maleate) |                    |                    | C               | Oral                 | 15 Mg                |                 | Not Reported |                |
|                                                                                                       | Gestonette                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                              | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Dec-2012                                                                                           | 8958516                     | DIRECT             |                    | OT              |                      |                      | 44 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                 | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness                                                                                             | Lexapro 20mg - Generic      |                    |                    | S               |                      | 20 Mg 1 Qam          |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                  | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|----------------------------------|-----------------|--------------|----------------|
| 06-Dec-2012                                                               | 8875980                | EXPEDITED (15-DAY) |                    | DE, HO          | IT-FRI-1000014857    |                                  | 75 YR           | Male         | ITA            |
| <u>Preferred Term</u>                                                     | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Electrocardiogram Qt Prolonged; Pneumonia; Torsade De Pointes             | Escitalopram           |                    |                    | S               | Oral                 | 10 Mg                            |                 | Forest       |                |
|                                                                           | Rivastigmine           |                    |                    | S               | Oral                 | 3 Mg                             |                 | Not Reported |                |
|                                                                           | Lidocaine              |                    |                    | C               | Topical              |                                  |                 | Not Reported |                |
|                                                                           | Cortisone              |                    |                    | C               | Topical              |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                  | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Dec-2012                                                               | 8934443                | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000040676    |                                  | 86 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                     | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; International Normalised Ratio Increased; Off Label Use | Escitalopram           |                    |                    | S               | Oral                 |                                  |                 | Forest       |                |
|                                                                           | Previscan (Fluindione) |                    |                    | S               | Oral                 | 15 To 20 Mg Daily In The Evening |                 | Not Reported |                |
|                                                                           | Ixprim                 |                    |                    | S               | Oral                 |                                  |                 | Not Reported |                |
|                                                                           | Lipanthyl              |                    |                    | C               | Oral                 | 1 Df                             |                 | Not Reported |                |
|                                                                           | Acebutolol             |                    |                    | C               | Oral                 | 0.5 Df                           |                 | Not Reported |                |
|                                                                           | Vastarel               |                    |                    | C               | Oral                 | 1 Df                             |                 | Not Reported |                |
|                                                                           | Biperidys              |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                           | Niflugel               |                    |                    | C               |                      |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                  | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Dec-2012                                                               | 8948952                | EXPEDITED (15-DAY) |                    | DS              | FR-FRI-1000040841    |                                  | 60 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                     | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Pressure Increased; Chest Pain; Hypokalaemia; Nausea; Paraesthesia; | Escitalopram           |                    |                    | S               | Oral                 | 10 Mg                            |                 | Forest       |                |

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Presyncope; Syncope;  
Tremor

| <u>FDA Received Date</u> | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>             | <u>Country</u> |
|--------------------------|--------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------------------|----------------|
| 06-Dec-2012              | 8949855                  | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000040848    |                      | 33 YR           | Female                 | FRA            |
| <u>Preferred Term</u>    | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>             |                |
| Vaginal Haemorrhage      | Escitalopram<br>Lysanxia |                    |                    | S<br>C          |                      |                      |                 | Forest<br>Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                                                                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
| 06-Dec-2012                                                                                                                                                                               | 8953308        | EXPEDITED (15-DAY) |                    | OT              | US-JNJFOC-<br>20121112054 |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                                                                                                                                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Decreased Appetite;<br>Dizziness; Dyspepsia;<br>Extrapyramidal Disorder;<br>Hyperhidrosis; Increased<br>Appetite; Insomnia;<br>Nausea; Somnolence;<br>Vision Blurred; Weight<br>Decreased | Risperidone    |                    |                    | S               | Unknown                   |                      |                 | Not Reported |                |
|                                                                                                                                                                                           | Concerta       |                    |                    | S               |                           |                      |                 | Not Reported |                |
|                                                                                                                                                                                           | Adderall Xr    |                    |                    | S               | Unknown                   |                      |                 | Not Reported |                |
|                                                                                                                                                                                           | Daytrana       |                    |                    | S               | Unknown                   |                      |                 | Not Reported |                |
|                                                                                                                                                                                           | Vyvanse        |                    |                    | S               | Unknown                   |                      |                 | Not Reported |                |
|                                                                                                                                                                                           | Intuniv        |                    |                    | S               | Unknown                   |                      |                 | Not Reported |                |
|                                                                                                                                                                                           | Strattera      |                    |                    | S               | Unknown                   |                      |                 | Not Reported |                |
|                                                                                                                                                                                           | Abilify        |                    |                    | S               | Unknown                   |                      |                 | Not Reported |                |
|                                                                                                                                                                                           | Zyprexa        |                    |                    | S               | Unknown                   |                      |                 | Not Reported |                |
|                                                                                                                                                                                           | Zyprexa        |                    |                    | S               | Unknown                   |                      |                 | Not Reported |                |
|                                                                                                                                                                                           | Seroquel       |                    |                    | S               | Unknown                   |                      |                 | Not Reported |                |
|                                                                                                                                                                                           | Anafranil      |                    |                    | S               | Unknown                   |                      |                 | Not Reported |                |
|                                                                                                                                                                                           | Anafranil      |                    |                    | S               | Unknown                   |                      |                 | Not Reported |                |
|                                                                                                                                                                                           | Lexapro        |                    |                    | S               | Unknown                   |                      |                 | Not Reported |                |
|                                                                                                                                                                                           | Lexapro        |                    |                    | S               | Unknown                   |                      |                 | Not Reported |                |
|                                                                                                                                                                                           | Prozac         |                    |                    | S               | Unknown                   |                      |                 | Not Reported |                |
|                                                                                                                                                                                           | Prozac         |                    |                    | S               | Unknown                   |                      |                 | Not Reported |                |

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

|        |   |         |              |
|--------|---|---------|--------------|
| Luvox  | S | Unknown | Not Reported |
| Luvox  | S | Unknown | Not Reported |
| Zoloft | S | Unknown | Not Reported |
| Zoloft | S | Unknown | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u>                             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|-------------------------|--------------------------------------------------|-----------------|--------------|----------------|
| 07-Dec-2012              | 8950687        | EXPEDITED (15-DAY) |                    | OT              | TR-RANBAXY-2012RR-62394 |                                                  | 5 YR            | Female       | TUR            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>                               | <u>Duration</u> | <u>Mfr</u>   |                |
| Disinhibition            | Escitalopram   |                    |                    | S               | Unknown                 | 2-3 Mg/D;12 Wks                                  |                 | Not Reported |                |
|                          | Escitalopram   |                    |                    | S               |                         |                                                  |                 | Not Reported |                |
|                          | Risperidone    |                    |                    | S               | Unknown                 | 0.25-0.5 Mg/Day After Escitalopram Was Initiated |                 | Ranbaxy      |                |
|                          | Risperidone    |                    |                    | S               |                         |                                                  |                 | Ranbaxy      |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u>                                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|-------------------------|------------------------------------------------------|-----------------|--------------|----------------|
| 07-Dec-2012              | 8951091        | EXPEDITED (15-DAY) |                    | OT              | TR-RANBAXY-2012RR-62404 |                                                      | 4 YR            | Male         | TUR            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>                                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Disinhibition            | Escitalopram   |                    |                    | S               | Unknown                 | 2 Mg/D ; 2 Wks                                       |                 | Not Reported |                |
|                          | Risperidone    |                    |                    | S               | Unknown                 | 0.25-0.5 Mg Before And During Escitalopram Treatment |                 | Ranbaxy      |                |
|                          | Risperidone    |                    |                    | S               |                         |                                                      |                 | Ranbaxy      |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 10-Dec-2012              | 8777494        | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000038454    |                      | 56 YR           | Female       | FRA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Retinal Haemorrhage;     | Escitalopram   |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
| Vitreous Haemorrhage     | Mycoster       |                    |                    | C               | Oral                 | 3 Df                 |                 | Not Reported |                |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|-----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 10-Dec-2012              | 8955917         | EXPEDITED (15-DAY) |                    | HO              | US-FRI-1000040917    |                      | 47 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Back Pain; Sciatica      | Lexapro         |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                          | Luaf41156       |                    |                    | S               | Oral                 | 3 Mg                 |                 | Not Reported |                |
|                          | Lisinopril      |                    |                    | S               | Oral                 | 20 Mg                |                 | Not Reported |                |
|                          | Baby Aspirin    |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Lisinopril/Hctz |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Flexeril        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Oxycontin       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Oxycodone       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Neurontin       |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Dec-2012              | 8956803         | EXPEDITED (15-DAY) |                    | DE              | FR-FRI-1000040937    |                      | 55 YR           | Male         | FRA            |
| <u>Preferred Term</u>    | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cerebral Haematoma       | Escitalopram    |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                          | Plavix          |                    |                    | S               | Oral                 | 75 Mg                |                 | Not Reported |                |
|                          | Depakine Chrono |                    |                    | C               | Oral                 | 2250 Mg              |                 | Not Reported |                |
|                          | Lyrica          |                    |                    | C               | Oral                 | 200 Mg               |                 | Not Reported |                |
|                          | Urbanyl         |                    |                    | C               | Oral                 | 100 Mg               |                 | Not Reported |                |
|                          | Vimpat          |                    |                    | C               | Oral                 | 100 Mg               |                 | Not Reported |                |
|                          | Kredex          |                    |                    | C               | Oral                 | 12.5 Mg              |                 | Not Reported |                |
|                          | Tahor           |                    |                    | C               | Oral                 | 80 Mg                |                 | Not Reported |                |
|                          | Lercan          |                    |                    | C               | Oral                 | 20 Mg                |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Dec-2012              | 8915777         | EXPEDITED (15-DAY) |                    | OT              | JP-FRI-1000040465    |                      | 73 YR           | Male         | JPN            |

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

| <u>Preferred Term</u>                                                                                                                                                                                               | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| Haematuria; Urinary Retention                                                                                                                                                                                       | Lexapro                                 |                    |                    | S               | Oral                         | 10 Mg                |                 | Forest       |                |
|                                                                                                                                                                                                                     | Lendormin                               |                    |                    | C               | Oral                         | 0.25 Mg              |                 | Not Reported |                |
|                                                                                                                                                                                                                     | Magmitt                                 |                    |                    | C               | Oral                         | 330 Mg               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                            | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Dec-2012                                                                                                                                                                                                         | 8960906                                 | DIRECT             | Y                  | OT              |                              |                      | 24 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                               | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Intolerance; Unevaluable Event                                                                                                                                                                                 | Lexapro                                 |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                            | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Dec-2012                                                                                                                                                                                                         | 8960924                                 | DIRECT             | Y                  |                 |                              |                      | 22 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                               | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Drug Ineffective; Impaired Work Ability; Vision Blurred                                                                                                                                                  | Citalopram                              |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                     | Escitalopram                            |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                            | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Dec-2012                                                                                                                                                                                                         | 7376665                                 | EXPEDITED (15-DAY) |                    | CA, DE, OT      | US-ABBOTT-10P-163-0640912-00 |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                               | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anal Stenosis; Atrial Septal Defect; Cerebrospinal Fluid Leakage; Coarctation Of The Aorta; Congenital Heart Valve Disorder; Cryptorchism; Cytogenetic Abnormality; Foetal Exposure During Pregnancy; Hemivertebra; | Humira 40 Mg/ 0.8 MI Pre-Filled Syringe |                    |                    | S               | Transplacental               |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                     | Lexapro                                 |                    |                    | S               | Transplacental               |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                     | Trazodone                               |                    |                    | S               | Transplacental               |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                     | Enbrel                                  |                    |                    | S               | Transplacental               |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                     | Mucinex                                 |                    |                    | S               | Transplacental               |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                     | Tums                                    |                    |                    | S               | Transplacental               |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                     | Tylenol                                 |                    |                    | S               | Transplacental               |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Hydrocephalus; Kidney  
Enlargement;  
Macrocephaly;  
Neurodegenerative  
Disorder; Patent Ductus  
Arteriosus; Tachypnoea

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 12-Dec-2012              | 7523041       | EXPEDITED (15-DAY) |                    | HO              | US-ABBOTT-10P-163-0640911-00 |                      | 26 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                          | <u>Product</u>                          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Caesarean Section;<br>Dyspepsia; Exposure<br>During Pregnancy; Fall;<br>Fungal Infection;<br>Premature Delivery;<br>Respiratory Tract<br>Infection; Urinary Tract<br>Infection | Humira 40 Mg/ 0.8 MI Pre-Filled Syringe |              |            | S           | Other        |                                  |                 | Not Reported |
|                                                                                                                                                                                | Humira 40 Mg/ 0.8 MI Pre-Filled Syringe |              |            | S           |              |                                  |                 | Not Reported |
|                                                                                                                                                                                | Lexapro                                 |              |            | S           | Oral         |                                  |                 | Not Reported |
|                                                                                                                                                                                | Trazodone Hcl                           |              |            | C           | Oral         | 4 In One Day As Needed           |                 | Not Reported |
|                                                                                                                                                                                | Enbrel                                  |              |            | C           | Other        |                                  |                 | Not Reported |
|                                                                                                                                                                                | Mucinex                                 |              |            | C           | Oral         | 1-2 Pills Qd                     |                 | Not Reported |
|                                                                                                                                                                                | Prenatal Vitamins                       |              |            | C           |              | 1 Pill Qd                        |                 | Not Reported |
|                                                                                                                                                                                | Caffeine                                |              |            | C           | Oral         | 2.5 Servings Mountain Dew Daily  |                 | Not Reported |
|                                                                                                                                                                                | Caffeine                                |              |            | C           | Oral         | 5.67 Servings Mountain Dew Daily |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Dec-2012              | 8959298       | EXPEDITED (15-DAY) |                    | HO              | CH-ROCHE-1165319     |                      | 70 YR      | Female     | CHE            |

| <u>Preferred Term</u>                                                                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Electrocardiogram Qt<br>Prolonged; Fall;<br>Hypokalaemia;<br>Hyponatraemia; Muscular<br>Weakness | Rivotril       |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                  | Xanax          |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                  | Exforge Hct    |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                  | Cipraxel       |              |            | S           | Oral         |                    |                 | Not Reported |

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

|  |                       |   |                                       |              |
|--|-----------------------|---|---------------------------------------|--------------|
|  | Halcion               | S | Oral                                  | Not Reported |
|  | Temesta Expidet       | S | Oral                                  | Not Reported |
|  | Sirdalud              | S | Oral                                  | Not Reported |
|  | Seroquel              | S | Oral                                  | Not Reported |
|  | Movicol               | C |                                       | Not Reported |
|  | Aspirin Cardio        | C | Oral                                  | Not Reported |
|  | Magnesium Carbonate   | C | Oral                                  | Not Reported |
|  | Omeprazole            | C | Oral                                  | Not Reported |
|  | Ceftriaxone           | C | Intravenous (not otherwise specified) | Not Reported |
|  | Psychotropic Drug Nos | C |                                       | Not Reported |

| <u>FDA Received Date</u>                                     | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 12-Dec-2012                                                  | 8965568        | DIRECT           |                    |                 |                      |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                        | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Feeling Abnormal; Gait Disturbance; Seizure; Speech Disorder | Lexapro        |                  |                    | S               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                               | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 12-Dec-2012                                            | 8965575        | DIRECT           |                    | DS, HO, LT, OT  |                      |                      | 23 YR           | Female     | USA            |
| <u>Preferred Term</u>                                  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Abnormal Behaviour; Mania; Overdose; Unevaluable Event | Lexapro        |                  |                    | S               | Oral                 | 20mg Once Daily Po   |                 | Forest     |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|----------------------|-----------------------|-----------------|--------------|----------------|
| 12-Dec-2012              | 8965589        | DIRECT           |                    | OT              |                      |                       | 57 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Blepharospasm;           | Escitalopram   |                  |                    | S               | Oral                 | From The Time It Came |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Dizziness; Jaw Disorder;  
Muscle Spasms; Product  
Substitution Issue

Out Until Mid November

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Dec-2012              | 8965609       | DIRECT           |                    | DS, OT          |                      |                      | 42 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|----------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Affective Disorder;<br>Dizziness; Headache;<br>Irritability; Palpitations;<br>Product Substitution Issue | Escitalopram   |              |            | S           | Oral         |                    |                 | Mylan      |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 13-Dec-2012              | 8963070       | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-<br>2012313677 |                      | 49 YR      | Female     | USA            |

| <u>Preferred Term</u>                                               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Acne; Dermatitis;<br>Headache; Hypertension;<br>Hypoaesthesia; Rash | Pristiq        |              |            | S           |              | 50 Mg, Daily       |                 | Pfizer       |
|                                                                     | Pristiq        |              |            | S           |              | 100 Mg, Daily      |                 | Pfizer       |
|                                                                     | Prozac         |              |            | S           |              | Unk                |                 | Not Reported |
|                                                                     | Prozac         |              |            | S           |              |                    |                 | Not Reported |
|                                                                     | Paxil          |              |            | S           |              | Unk                |                 | Not Reported |
|                                                                     | Paxil          |              |            | S           |              |                    |                 | Not Reported |
|                                                                     | Celexa         |              |            | S           |              | Unk                |                 | Not Reported |
|                                                                     | Celexa         |              |            | S           |              |                    |                 | Not Reported |
|                                                                     | Lexapro        |              |            | S           |              | Unk                |                 | Not Reported |
|                                                                     | Lexapro        |              |            | S           |              |                    |                 | Not Reported |
|                                                                     | Wellbatrin     |              |            | C           |              | 300 Mg, Daily      |                 | Not Reported |
|                                                                     | Adderall       |              |            | C           |              | 30 Mg, Daily       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Dec-2012              | 8662915       | EXPEDITED (15-DAY) |                    | HO, LT          | CA-FRI-1000037012    |                      |            | Male       | CAN            |

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

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                                                                                                                  |              |   |      |  |  |  |  |        |
|--------------------------------------------------------------------------------------------------------------------------------------------------|--------------|---|------|--|--|--|--|--------|
| Blood Sodium Decreased;<br>Contusion; Delusional<br>Disorder, Unspecified<br>Type; Mental Disorder;<br>Paranoia; Pelvic Fracture;<br>Skin Injury | Escitalopram | S | Oral |  |  |  |  | Forest |
|--------------------------------------------------------------------------------------------------------------------------------------------------|--------------|---|------|--|--|--|--|--------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Dec-2012              | 8664746       | EXPEDITED (15-DAY) |                    | OT              | CA-FRI-1000037010    |                      | 21 YR      | Male       | CAN            |

| <u>Preferred Term</u>                                                                                                                                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Disturbance In Sexual<br>Arousal; Erectile<br>Dysfunction; Libido<br>Decreased; Orgasmic<br>Sensation Decreased;<br>Premature Ejaculation;<br>Suicidal Ideation | Escitalopram   |              |            | S           | Oral         | 20 Mg              |                 | Forest       |
|                                                                                                                                                                 | Escitalopram   |              |            | S           |              |                    |                 | Forest       |
|                                                                                                                                                                 | Quetiapine     |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 14-Dec-2012              | 8926068       | EXPEDITED (15-DAY) |                    | OT              | IT-JNJFOC-<br>20121110202 |                      | 34 YR      | Female     | ITA            |

| <u>Preferred Term</u>                                                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hypotension; Intentional<br>Overdose; Intentional Self-<br>Injury; Sluggishness | Haldol         |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                 | En             |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                 | Ciprallex      |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 14-Dec-2012              | 8962471       | EXPEDITED (15-DAY) |                    | HO              | FR-JNJFOC-<br>20121114425 |                      | 86 YR      | Male       | FRA            |

| <u>Preferred Term</u>                       | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction;                           | Ixprim                 |              |            | S           | Oral         |                    |                 | Not Reported |
| International Normalised<br>Ratio Increased | Previscan (Fluindione) |              |            | S           | Oral         | 0.25 Of A Tablet   |                 | Not Reported |
|                                             | Previscan (Fluindione) |              |            | S           | Oral         | 15-20mg            |                 | Not Reported |

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|                        |   |         |                  |              |
|------------------------|---|---------|------------------|--------------|
| Previscan (Fluindione) | S | Oral    | 0.25 Of A Tablet | Not Reported |
| Previscan (Fluindione) | S | Oral    | Half Tab         | Not Reported |
| Seroplex               | S | Unknown |                  | Not Reported |
| Biperidys              | C | Oral    |                  | Not Reported |
| Vastarel               | C | Oral    |                  | Not Reported |
| Niflugel               | C | Topical |                  | Not Reported |
| Lipanthyl              | C | Oral    |                  | Not Reported |
| Acebutolol             | C | Oral    |                  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 14-Dec-2012              | 8964168       | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2012300299 |                      | 44 YR      | Male       | USA            |

| <u>Preferred Term</u>                                        | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------------------------|-----------------|--------------|
| Blood Pressure Fluctuation; Heart Rate Irregular; Somnolence | Oxycodone Hydrochloride |              |            | S           | Oral         | 15 Mg, (Oral Every 4 Hrs As Needed ) |                 | Pfizer       |
|                                                              | Oxycodone Hydrochloride |              |            | S           | Oral         | 80 Mg, 2x/Day                        |                 | Pfizer       |
|                                                              | Ambien                  |              |            | S           | Oral         | 12.5 Mg, (At Bedtime)                |                 | Not Reported |
|                                                              | Lexapro                 |              |            | S           | Oral         | 20 Mg, Daily                         |                 | Not Reported |
|                                                              | Oxycontin               |              |            | S           | Oral         | 60 Mg, 2x/Day                        |                 | Not Reported |
|                                                              | Soma                    |              |            | S           | Oral         | 350 Mg, 2x/Day                       |                 | Not Reported |
|                                                              | Valium                  |              |            | S           | Oral         | 10 Mg, Daily                         |                 | Not Reported |
|                                                              | Xarelto                 |              |            | S           | Oral         | 10 Mg, Daily                         |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Dec-2012              | 8964185       | EXPEDITED (15-DAY) |                    | OT              | CA-FRI-1000036970    |                      | 23 YR      | Male       | CAN            |

| <u>Preferred Term</u>           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Headache; Malaise; Sensory Loss | Escitalopram   |              |            | S           |              | 10 Mg              |                 | Forest     |

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| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 14-Dec-2012                       | 8965133                | EXPEDITED (15-DAY)        |                             | CA                       | US-FRI-1000040942             |                               | < 1 DAY             | Male                | USA                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Congenital Anomaly; Talipes    | Lexapro                 |                       |                     | S                    | Transplacental        |                             |                          | Forest              |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 14-Dec-2012                       | 8965776                | EXPEDITED (15-DAY)        |                             | OT                       | IT-FRI-1000041047             |                               | 34 YR               | Female              | ITA                     |

| <a href="#">Preferred Term</a>                              | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|-------------------------------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Blood Pressure Decreased; Intentional Self-Injury; Overdose | Escitalopram            |                       |                     | S                    | Oral                  |                             |                          | Forest              |
|                                                             | Escitalopram            |                       |                     | S                    | Oral                  |                             |                          | Not Reported        |
|                                                             | Haldol                  |                       |                     | S                    | Oral                  |                             |                          | Not Reported        |
|                                                             | Haldol                  |                       |                     | S                    | Oral                  |                             |                          | Not Reported        |
|                                                             | En                      |                       |                     | S                    | Oral                  |                             |                          | Not Reported        |
|                                                             | En                      |                       |                     | S                    | Oral                  |                             |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 17-Dec-2012                       | 8786369                | EXPEDITED (15-DAY)        |                             | HO                       | FR-PFIZER INC-2012224870      |                               | 21 YR               | Female              | FRA                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Bone Marrow Failure            | Xanax                   |                       |                     | S                    | Oral                  | Unk                         |                          | Pfizer              |
|                                | Seroplex                |                       |                     | S                    | Oral                  | Unk                         |                          | Not Reported        |
|                                | Yaz                     |                       |                     | S                    | Oral                  | 1 Df, 1x/Day                |                          | Not Reported        |
|                                | Yaz                     |                       |                     | S                    |                       | Unk                         |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>  | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|--------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 17-Dec-2012                       | 8966757                | EXPEDITED (15-DAY)        |                             | HO                       | AU-SANOFI-AVENTIS-2012SA090914 |                               | 81 YR               | Female              | AUS                     |



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| <u>Preferred Term</u>                                                                      | <u>Product</u>                                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|--------------------------------------------------------------------------------------------|-----------------------------------------------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|-----------------|--------------|----------------|
| Abdominal Pain;<br>Hyponatraemia; Malaise;<br>Urinary Retention; Urine<br>Output Decreased | Lasix                                               |                    |                    | S               | Unknown                        |                      |                 | Not Reported |                |
|                                                                                            | Lasix                                               |                    |                    | S               | Unknown                        |                      |                 | Not Reported |                |
|                                                                                            | Lexapro                                             |                    |                    | S               | Oral                           |                      |                 | Not Reported |                |
|                                                                                            | Fish Oil                                            |                    |                    | C               |                                |                      |                 | Not Reported |                |
|                                                                                            | Coumadin                                            |                    |                    | C               |                                |                      |                 | Not Reported |                |
|                                                                                            | Chondroitin Sulfate<br>(Bovine)\Glucosamine Sulfate |                    |                    | C               |                                |                      |                 | Not Reported |                |
|                                                                                            | Lanoxin                                             |                    |                    | C               |                                |                      |                 | Not Reported |                |
|                                                                                            | Losec                                               |                    |                    | C               |                                |                      |                 | Not Reported |                |
|                                                                                            | Panadol                                             |                    |                    | C               |                                |                      |                 | Not Reported |                |
|                                                                                            | Folic Acid/Vitamin B12 Nos                          |                    |                    | C               |                                |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                   | <u>Case #</u>                                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Dec-2012                                                                                | 8918673                                             | EXPEDITED (15-DAY) |                    | HO              | JP-FRI-1000040463              |                      | 85 YR           | Female       | JPN            |
| <u>Preferred Term</u>                                                                      | <u>Product</u>                                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Fall; Femoral Neck<br>Fracture                                                             | Escitalopram                                        |                    |                    | S               | Oral                           | 10 Mg                |                 | Forest       |                |
|                                                                                            | Zopicool                                            |                    |                    | C               | Oral                           | 7.5 Mg               |                 | Not Reported |                |
|                                                                                            | Zestromin                                           |                    |                    | C               | Oral                           | 0.25 Mg              |                 | Not Reported |                |
|                                                                                            | Paruleon                                            |                    |                    | C               | Oral                           | 0.5 Mg               |                 | Not Reported |                |
|                                                                                            | Seniran                                             |                    |                    | C               | Oral                           | 2 Mg                 |                 | Not Reported |                |
|                                                                                            | Reflex                                              |                    |                    | C               | Oral                           | 15 Mg                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                   | <u>Case #</u>                                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Dec-2012                                                                                | 8946939                                             | EXPEDITED (15-DAY) |                    | OT              | FR-009507513-<br>1211FRA011526 |                      |                 | Female       | FRA            |
| <u>Preferred Term</u>                                                                      | <u>Product</u>                                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyperprolactinaemia                                                                        | Norset                                              |                    |                    | S               | Oral                           | Unk                  |                 | Merck        |                |
|                                                                                            | Seroplex                                            |                    |                    | S               | Oral                           | Unk                  |                 | Not Reported |                |

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| <u>FDA Received Date</u>                       | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                                                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|---------------------------------------------------------------------------|-----------------|--------------|----------------|
| 18-Dec-2012                                    | 8968142                   | EXPEDITED (15-DAY) |                    | HO, OT          | CH-JNJFOC-20121206158                           |                                                                           | 46 YR           | Female       | CHE            |
| <u>Preferred Term</u>                          | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                                        | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;<br>Serotonin Syndrome        | Darunavir                 |                    |                    | S               | Oral                                            |                                                                           |                 | Not Reported |                |
|                                                | Ritonavir                 |                    |                    | S               | Unknown                                         |                                                                           |                 | Not Reported |                |
|                                                | Emtricitabine W/Tenofovir |                    |                    | S               | Unknown                                         | Emtricitabine 200 Mg;<br>Tenofovir 245 Mg                                 |                 | Not Reported |                |
|                                                | Esomeprazole              |                    |                    | S               | Unknown                                         |                                                                           |                 | Not Reported |                |
|                                                | Escitalopram              |                    |                    | S               | Unknown                                         | Had Been Taking For 5<br>Years                                            |                 | Not Reported |                |
| <u>FDA Received Date</u>                       | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                                                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Dec-2012                                    | 8968383                   | NON-EXPEDITED      |                    |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>16766909 |                                                                           | 46 YR           | Male         | USA            |
| <u>Preferred Term</u>                          | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                                        | <u>Duration</u> | <u>Mfr</u>   |                |
| Behaviour Disorder; Mood<br>Altered; Nightmare | Abilify                   |                    |                    | S               |                                                 | Ablify 20mg Cuts Them In<br>Half For 10mg Daily Dose.<br>Started With 5mg |                 | Not Reported |                |
|                                                | Lexapro                   |                    |                    | S               |                                                 |                                                                           |                 | Not Reported |                |
|                                                | Keppra                    |                    |                    | S               |                                                 |                                                                           |                 | Not Reported |                |
|                                                | Synthroid                 |                    |                    | C               |                                                 |                                                                           |                 | Not Reported |                |
|                                                | Clonazepam                |                    |                    | C               |                                                 |                                                                           |                 | Not Reported |                |
|                                                | Paxil                     |                    |                    | C               |                                                 |                                                                           |                 | Not Reported |                |
| <u>FDA Received Date</u>                       | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                                                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Dec-2012                                    | 8968390                   | NON-EXPEDITED      |                    |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>16770547 |                                                                           | 42 YR           | Female       | USA            |
| <u>Preferred Term</u>                          | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                                        | <u>Duration</u> | <u>Mfr</u>   |                |
| Dyskinesia; Dystonia                           | Abilify                   |                    |                    | S               |                                                 |                                                                           |                 | Not Reported |                |
|                                                | Concerta                  |                    |                    | S               |                                                 |                                                                           |                 | Not Reported |                |
|                                                | Lexapro                   |                    |                    | S               |                                                 |                                                                           |                 | Not Reported |                |

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| <u>FDA Received Date</u>                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------|----------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 18-Dec-2012                               | 8968927        | EXPEDITED (15-DAY) |                    | DS, LT, OT      | GB-FRI-1000041096                               |                      | 26 YR           | Female       | GBR            |
| <u>Preferred Term</u>                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Iron Deficiency Anaemia                   | Escitalopram   |                    |                    | S               | Oral                                            | 10 Mg                |                 | Forest       |                |
|                                           | Escitalopram   |                    |                    | S               | Oral                                            |                      |                 | Forest       |                |
|                                           | Flupentixol    |                    |                    | C               | Oral                                            |                      |                 | Not Reported |                |
|                                           | Valproate      |                    |                    | C               | Oral                                            | 750 Mg               |                 | Not Reported |                |
| <u>FDA Received Date</u>                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Dec-2012                               | 8968935        | NON-EXPEDITED      |                    |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>16686867 |                      | 50 YR           | Female       | USA            |
| <u>Preferred Term</u>                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Cholesterol Increased               | Abilify        |                    |                    | S               |                                                 |                      |                 | Not Reported |                |
|                                           | Lexapro        |                    |                    | S               |                                                 |                      |                 | Not Reported |                |
|                                           | Lamictal       |                    |                    | S               |                                                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Dec-2012                               | 8968991        | NON-EXPEDITED      |                    |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>16341877 |                      | 17 YR           | Female       | USA            |
| <u>Preferred Term</u>                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hepatic Enzyme Increased; Malaise; Nausea | Abilify        |                    |                    | S               | Oral                                            |                      |                 | Not Reported |                |
|                                           | Lexapro        |                    |                    | S               | Oral                                            |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Dec-2012                               | 8969178        | NON-EXPEDITED      |                    |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>16299679 |                      | 56 YR           | Female       | USA            |
| <u>Preferred Term</u>                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Ammonia Increased; Swelling; Tremor       | Abilify        |                    |                    | S               |                                                 | 5mg:Feb2011,Dose     |                 | Not Reported |                |

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## Freedom of Information Act (FOIA)

### Detailed Report

|                          |                              |                   |                    |                 |             |                                                 |                                               |                                                |                              |                |                              |
|--------------------------|------------------------------|-------------------|--------------------|-----------------|-------------|-------------------------------------------------|-----------------------------------------------|------------------------------------------------|------------------------------|----------------|------------------------------|
|                          |                              | Lexapro<br>Keppra |                    |                 | S<br>C      |                                                 |                                               | Increased:10mg,Mar2011,<br>Decreased Later:2mg |                              |                | Not Reported<br>Not Reported |
| <u>FDA Received Date</u> | <u>Case #</u>                | <u>Case Type</u>  | <u>Health Prof</u> | <u>Outcomes</u> |             | <u>Mfr Control #</u>                            | <u>503B Facility</u>                          | <u>Age</u>                                     | <u>Sex</u>                   | <u>Country</u> |                              |
| 18-Dec-2012              | 8969374                      | NON-EXPEDITED     |                    |                 |             | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>16625220 |                                               |                                                | Unknown                      | USA            |                              |
| <u>Preferred Term</u>    | <u>Product</u>               |                   | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u> | <u>Route</u>                                    | <u>Dosage Text</u>                            | <u>Duration</u>                                | <u>Mfr</u>                   |                |                              |
| Tremor                   | Abilify<br>Lexapro           |                   |                    |                 | S<br>S      |                                                 |                                               |                                                | Not Reported<br>Not Reported |                |                              |
| <u>FDA Received Date</u> | <u>Case #</u>                | <u>Case Type</u>  | <u>Health Prof</u> | <u>Outcomes</u> |             | <u>Mfr Control #</u>                            | <u>503B Facility</u>                          | <u>Age</u>                                     | <u>Sex</u>                   | <u>Country</u> |                              |
| 18-Dec-2012              | 8969384                      | NON-EXPEDITED     |                    |                 |             | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>16626129 |                                               | 24 YR                                          | Female                       | USA            |                              |
| <u>Preferred Term</u>    | <u>Product</u>               |                   | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u> | <u>Route</u>                                    | <u>Dosage Text</u>                            | <u>Duration</u>                                | <u>Mfr</u>                   |                |                              |
| Akathisia                | Abilify Tabs 5 Mg<br>Lexapro |                   |                    |                 | S<br>S      |                                                 |                                               |                                                | Not Reported<br>Not Reported |                |                              |
| <u>FDA Received Date</u> | <u>Case #</u>                | <u>Case Type</u>  | <u>Health Prof</u> | <u>Outcomes</u> |             | <u>Mfr Control #</u>                            | <u>503B Facility</u>                          | <u>Age</u>                                     | <u>Sex</u>                   | <u>Country</u> |                              |
| 18-Dec-2012              | 8969590                      | NON-EXPEDITED     |                    |                 |             | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>16614141 |                                               | 45 YR                                          | Male                         | USA            |                              |
| <u>Preferred Term</u>    | <u>Product</u>               |                   | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u> | <u>Route</u>                                    | <u>Dosage Text</u>                            | <u>Duration</u>                                | <u>Mfr</u>                   |                |                              |
| Dysarthria               | Abilify                      |                   |                    |                 | S           |                                                 | Initially Given 5mg Then<br>Increased To 10mg |                                                | Not Reported                 |                |                              |
|                          | Lexapro<br>Klonopin          |                   |                    |                 | S<br>S      |                                                 | 1mg In Pm                                     |                                                | Not Reported<br>Sandoz       |                |                              |
| <u>FDA Received Date</u> | <u>Case #</u>                | <u>Case Type</u>  | <u>Health Prof</u> | <u>Outcomes</u> |             | <u>Mfr Control #</u>                            | <u>503B Facility</u>                          | <u>Age</u>                                     | <u>Sex</u>                   | <u>Country</u> |                              |
| 18-Dec-2012              | 8969838                      | NON-EXPEDITED     |                    |                 |             | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>16537342 |                                               | 6 YR                                           | Male                         | USA            |                              |
| <u>Preferred Term</u>    | <u>Product</u>               |                   | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u> | <u>Route</u>                                    | <u>Dosage Text</u>                            | <u>Duration</u>                                | <u>Mfr</u>                   |                |                              |

# FDA Adverse Event Reporting System

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|                          |                |                  |                    |                 |                                                 |                      |                 |            |                |
|--------------------------|----------------|------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|------------|----------------|
| Weight Increased         | Abilify        |                  |                    | S               |                                                 |                      |                 |            | Not Reported   |
|                          | Lexapro        |                  |                    | S               |                                                 |                      |                 |            | Not Reported   |
| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Dec-2012              | 8969864        | NON-EXPEDITED    |                    |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>16544926 |                      | 20 YR           | Female     | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Dyspnoea                 | Abilify        |                  |                    | S               |                                                 |                      |                 |            | Not Reported   |
|                          | Lexapro        |                  |                    | S               |                                                 |                      |                 |            | Not Reported   |
| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Dec-2012              | 8970001        | NON-EXPEDITED    |                    |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>16525016 |                      | 51 YR           | Female     | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Weight Increased         | Abilify Tabs   |                  |                    | S               |                                                 |                      |                 |            | Not Reported   |
|                          | Lexapro        |                  |                    | S               |                                                 |                      |                 |            | Not Reported   |
|                          | Klonopin       |                  |                    | C               |                                                 |                      |                 |            | Not Reported   |
| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Dec-2012              | 8970083        | NON-EXPEDITED    |                    | OT              | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>16217523 |                      | 15 YR           | Female     | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Clonic Convulsion        | Abilify        |                  |                    | S               |                                                 |                      |                 |            | Not Reported   |
|                          | Lexapro        |                  |                    | S               |                                                 |                      |                 |            | Not Reported   |
| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Dec-2012              | 8970231        | NON-EXPEDITED    |                    |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>16487878 |                      | 69 YR           | Female     | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Asthenia                 | Abilify        |                  |                    | S               |                                                 |                      |                 |            | Not Reported   |
|                          | Lexapro        |                  |                    | S               |                                                 |                      |                 |            | Not Reported   |

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| <u>FDA Received Date</u>                                | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------|-----------------|--------------------|--------------------|-----------------|-------------------------------------------------|-------------------------------|-----------------|--------------|----------------|
| 18-Dec-2012                                             | 8970392         | NON-EXPEDITED      |                    | OT              | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>17057035 |                               |                 | Female       | USA            |
| <u>Preferred Term</u>                                   | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Diabetes Mellitus                                       | Abilify         |                    |                    | S               |                                                 | 1df: Upto 15mg                |                 | Not Reported |                |
|                                                         | Lexapro         |                    |                    | S               |                                                 |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Dec-2012                                             | 8970506         | NON-EXPEDITED      |                    |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>16502742 |                               | 58 YR           | Female       | USA            |
| <u>Preferred Term</u>                                   | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| White Blood Cell Count<br>Decreased                     | Abilify         |                    |                    | S               |                                                 |                               |                 | Not Reported |                |
|                                                         | Wellbutrin      |                    |                    | S               |                                                 |                               |                 | Not Reported |                |
|                                                         | Lexapro         |                    |                    | S               |                                                 |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Dec-2012                                             | 8970779         | EXPEDITED (15-DAY) |                    | HO, OT          | CH-PFIZER INC-<br>2012305606                    |                               | 70 YR           | Female       | CHE            |
| <u>Preferred Term</u>                                   | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Back Pain; Balance<br>Disorder;                         | Xanax           |                    |                    | S               | Oral                                            | 1 Mg, 3x/Day                  |                 | Pfizer       |                |
| Electrocardiogram Qt<br>Prolonged; Fall;                | Temesta Expidet |                    |                    | S               | Oral                                            | 2.5 Mg, 4x/Day Maximal        |                 | Pfizer       |                |
| Hypokalaemia;                                           | Halcion         |                    |                    | S               | Oral                                            | 0.25 Mg, 1x/Day               |                 | Pfizer       |                |
| Hyponatraemia; Muscular<br>Weakness; Spinal<br>Fracture | Exforge Hct     |                    |                    | S               | Oral                                            | 5mg / 25mg / 160mg,<br>1x/Day |                 | Not Reported |                |
|                                                         | Cipralext       |                    |                    | S               | Oral                                            | 2x 10mg 1x/Day                |                 | Not Reported |                |
|                                                         | Sirdalud        |                    |                    | S               | Oral                                            | 4 Mg, 1x/Day                  |                 | Not Reported |                |
|                                                         | Rivotril        |                    |                    | S               | Oral                                            | 2x 2mg, 1x/Day                |                 | Not Reported |                |
|                                                         | Seroquel        |                    |                    | S               | Oral                                            | 1/2 300mg, 1x/Day             |                 | Not Reported |                |
|                                                         | Aspirin Cardio  |                    |                    | C               | Oral                                            | 100 Mg, Weekly (Monday)       |                 | Not Reported |                |
|                                                         | Mag 2 Forte     |                    |                    | C               | Oral                                            | Unk , 2x/Day                  |                 | Not Reported |                |

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|                                                                        |                        |                    |                    |                 |                                                 |                      |                 |              |                |
|------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|--------------|----------------|
| Omeprazole                                                             |                        |                    | C                  | Oral            | 40 Mg, 2x/Day                                   |                      |                 | Not Reported |                |
| Movicol                                                                |                        |                    | C                  |                 | Unk, 2x/Day                                     |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                               | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Dec-2012                                                            | 8971303                | EXPEDITED (15-DAY) | HO                 |                 | AU-FRI-1000041094                               |                      | 46 YR           | Male         | AUS            |
| <u>Preferred Term</u>                                                  | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Ataxia; Chills; Diplopia;<br>Dysarthria; Headache;<br>Pyrexia; Syncope | Escitalopram           |                    |                    | S               |                                                 | 20 Mg                |                 | Forest       |                |
|                                                                        | Diazepam               |                    |                    | S               |                                                 | 5 Mg                 |                 | Not Reported |                |
|                                                                        | Mirtazapine            |                    |                    | S               | Oral                                            | 60 Mg                |                 | Not Reported |                |
|                                                                        | Prazosin Hydrochloride |                    |                    | S               |                                                 | 1 Mg                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                               | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Dec-2012                                                            | 8972962                | NON-EXPEDITED      |                    |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>16458515 |                      | 83 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                  | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Vertigo                                                                | Abilify                |                    |                    | S               |                                                 |                      |                 | Not Reported |                |
|                                                                        | Lexapro                |                    |                    | S               |                                                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                               | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Dec-2012                                                            | 8972970                | NON-EXPEDITED      |                    |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>16461436 |                      | 49 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                  | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Weight Increased                                                       | Abilify                |                    |                    | S               |                                                 |                      |                 | Not Reported |                |
|                                                                        | Lexapro                |                    |                    | S               |                                                 |                      |                 | Not Reported |                |
|                                                                        | Klonopin               |                    |                    | S               |                                                 |                      |                 | Sandoz       |                |
| <u>FDA Received Date</u>                                               | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Dec-2012                                                            | 8973350                | NON-EXPEDITED      |                    |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>16940629 |                      | 32 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                  | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

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

|                                                                                           |             |   |      |                                               |              |
|-------------------------------------------------------------------------------------------|-------------|---|------|-----------------------------------------------|--------------|
| Confusional State;<br>Dysarthria; Dyskinesia;<br>Regurgitation; Swollen<br>Tongue; Tremor | Abilify     | S | Oral | From 06jun2012:5mg<br>Increased To 10mg/Daily | Not Reported |
|                                                                                           | Abilify     | S | Oral | From 06jun2012:5mg<br>Increased To 10mg/Daily | Not Reported |
|                                                                                           | Abilify     | S | Oral | From 06jun2012:5mg<br>Increased To 10mg/Daily | Not Reported |
|                                                                                           | Lexapro     | S |      | Reduced To 5 Mg                               | Not Reported |
|                                                                                           | Lexapro     | S |      | Reduced To 5 Mg                               | Not Reported |
|                                                                                           | Lexapro     | S |      | Reduced To 5 Mg                               | Not Reported |
|                                                                                           | Cogentin    | S |      | On 07jun2012 Dose<br>Decreased To 1 Mg/2/Day  | Sandoz       |
|                                                                                           | Depakote Er | C |      | 250mg Qam, 750<br>Mg/2/Day                    | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 18-Dec-2012              | 8973351       | NON-EXPEDITED    |                    |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>16940884 |                      | 44 YR      | Female     | USA            |

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

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 18-Dec-2012              | 8973366       | NON-EXPEDITED    |                    |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>16945958 |                      | 64 YR      | Female     | USA            |

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



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|                            |                |                  |                    |                 |                                                 |                                                                         |                 |              |                |
|----------------------------|----------------|------------------|--------------------|-----------------|-------------------------------------------------|-------------------------------------------------------------------------|-----------------|--------------|----------------|
| Viibryd                    |                |                  | S                  |                 |                                                 | Not Reported                                                            |                 |              |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                                                    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Dec-2012                | 8973439        | NON-EXPEDITED    |                    | OT              | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>16787723 |                                                                         | 52 YR           | Male         | USA            |
| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                                      | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Blood             | Abilify        |                  |                    | S               | Oral                                            | Increased To 15mg/Day                                                   |                 | Not Reported |                |
| Triglycerides Increased;   | Chantix        |                  |                    | S               |                                                 | Restarted On 2011.                                                      |                 | Not Reported |                |
| Constipation; Diarrhoea;   |                |                  |                    |                 |                                                 | Jul2012: 1mg                                                            |                 |              |                |
| Ejaculation Disorder;      | Geodon         |                  |                    | S               |                                                 |                                                                         |                 | Not Reported |                |
| Libido Decreased; Muscle   | Lexapro        |                  |                    | S               |                                                 |                                                                         |                 | Not Reported |                |
| Spasms; Sleep Disorder;    | Xanax          |                  |                    | C               |                                                 |                                                                         |                 | Not Reported |                |
| Suicidal Ideation; Thirst; | Lisinopril     |                  |                    | C               |                                                 | 1 Df = 20/25 Mg/Daily                                                   |                 | Not Reported |                |
| Urinary Retention          |                |                  |                    |                 |                                                 |                                                                         |                 |              |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                                                    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Dec-2012                | 8973471        | NON-EXPEDITED    |                    | DE, OT          | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>16819112 |                                                                         | 16 YR           | Female       | USA            |
| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                                      | <u>Duration</u> | <u>Mfr</u>   |                |
| Anger; Completed Suicide   | Abilify        |                  |                    | S               |                                                 | Adjunctive Therapy,Dose<br>Incd To 5mg Until 18apr12<br>Until 30apr2012 |                 | Not Reported |                |
|                            | Lexapro        |                  |                    | S               |                                                 | Incr To 10mg-5nov07<br>20mg-28oct10 Until<br>30apr2012                  |                 | Not Reported |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                                                    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Dec-2012                | 8973860        | NON-EXPEDITED    |                    |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>16895484 |                                                                         | 32 YR           | Female       | USA            |
| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                                      | <u>Duration</u> | <u>Mfr</u>   |                |
| Disorientation; Dysarthria | Abilify        |                  |                    | S               |                                                 |                                                                         |                 | Not Reported |                |
|                            | Lexapro        |                  |                    | S               |                                                 |                                                                         |                 | Not Reported |                |

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

| <u>FDA Received Date</u>                                                                                                             | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|------------------------------|----------------|
| 18-Dec-2012                                                                                                                          | 8973972                              | NON-EXPEDITED      |                    |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>16394827 |                      | 50 YR           | Female                       | USA            |
| <u>Preferred Term</u>                                                                                                                | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Tardive Dyskinesia                                                                                                                   | Abilify<br>Lexapro                   |                    |                    | S<br>S          |                                                 |                      |                 | Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                                                             | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 18-Dec-2012                                                                                                                          | 8978561                              | DIRECT             | Y                  | OT              |                                                 |                      | 40 YR           | Female                       | USA            |
| <u>Preferred Term</u>                                                                                                                | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Drug Withdrawal<br>Syndrome; Product<br>Substitution Issue                                                                           | Escalitalopram 10 Mg Teva<br>Lexapro |                    |                    | S<br>C          | Oral                                            | 10 Daily Po          | 5 MTH           | Teva<br>Not Reported         |                |
| <u>FDA Received Date</u>                                                                                                             | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 18-Dec-2012                                                                                                                          | 8983975                              | DIRECT             |                    | DS, HO, OT      |                                                 |                      |                 | Male                         | USA            |
| <u>Preferred Term</u>                                                                                                                | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Product Prescribing Error;<br>Seizure                                                                                                | Lexapro                              |                    |                    | S               |                                                 |                      |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                                                                                                             | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 19-Dec-2012                                                                                                                          | 8975034                              | EXPEDITED (15-DAY) |                    | OT              | US-FRI-1000041039                               |                      |                 | Female                       | USA            |
| <u>Preferred Term</u>                                                                                                                | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Abnormal Dreams;<br>Depression; Mental<br>Impairment; Paraesthesia;<br>Suicidal Ideation;<br>Therapeutic Product Effect<br>Decreased | Lexapro                              |                    |                    | S               |                                                 |                      |                 | Forest                       |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Dec-2012              | 8975814       | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000041152    |                      |            | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Seizure               | Escitalopram   |              |            | S           | Oral         | 10 Mg              |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Dec-2012              | 8976838       | EXPEDITED (15-DAY) |                    | HO              | JP-FRI-1000041102    |                      | 65 YR      | Male       | JPN            |

| <u>Preferred Term</u>                              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Benign Prostatic Hyperplasia; Condition Aggravated | Escitalopram   |              |            | S           | Oral         | 10mg               |                 | Forest       |
|                                                    | Meilax         |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                    | Halcion        |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                    | Hirnamin       |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                    | Mucosta        |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                    | Crestor        |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                    | Maintate       |              |            | C           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 19-Dec-2012              | 8977705       | EXPEDITED (15-DAY) |                    | HO              | FR-JNJFOC-20121208508 |                      | 41 YR      | Male       | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Oedema; Rash          | Prezista       |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Enfuvirtide    |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Tmc-125        |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Isentress      |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Kivexa         |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Seroplex       |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Norvir         |              |            | C           | Oral         |                    |                 | Not Reported |

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

|                          |                                |                    |                    |                 |                                       |                      |                 |              |                |
|--------------------------|--------------------------------|--------------------|--------------------|-----------------|---------------------------------------|----------------------|-----------------|--------------|----------------|
| Xanax                    |                                |                    | C                  |                 | Unknown                               |                      |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Dec-2012              | 8977734                        | EXPEDITED (15-DAY) |                    | OT              | CH-ASTRAZENECA-2012SE93758            |                      | < 1 DAY         | Female       | CHE            |
| <u>Preferred Term</u>    | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypernatraemia;          | Seroquel                       |                    |                    | S               | Transplacental                        |                      |                 | Zeneca       |                |
| Metabolic Acidosis;      | Ciprallex                      |                    |                    | S               | Transplacental                        |                      |                 | Not Reported |                |
| Premature Baby;          | Labetalol                      |                    |                    | C               |                                       |                      |                 | Not Reported |                |
| Respiratory Failure      |                                |                    |                    |                 |                                       |                      |                 |              |                |
| <u>FDA Received Date</u> | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Dec-2012              | 8977953                        | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000026955                     |                      | 64 YR           | Male         | FRA            |
| <u>Preferred Term</u>    | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Glomerulonephritis       | Escitalopram                   |                    |                    | S               | Oral                                  |                      |                 | Forest       |                |
| Membranous               | Escitalopram                   |                    |                    | S               | Oral                                  |                      |                 | Not Reported |                |
|                          | Lamaline                       |                    |                    | S               | Oral                                  |                      |                 | Not Reported |                |
|                          | (Acetaminophen\Caffeine\Opium) |                    |                    |                 |                                       |                      |                 |              |                |
|                          | Orencia                        |                    |                    | C               | Intravenous (not otherwise specified) |                      |                 | Not Reported |                |
|                          | Orencia                        |                    |                    | C               | Intravenous (not otherwise specified) |                      |                 | Not Reported |                |
|                          | Ezetrol                        |                    |                    | C               |                                       |                      |                 | Not Reported |                |
|                          | Ogast                          |                    |                    | C               | Oral                                  |                      |                 | Not Reported |                |
|                          | Atenolol                       |                    |                    | C               | Oral                                  |                      |                 | Not Reported |                |
|                          | Tanakan                        |                    |                    | C               |                                       |                      |                 | Not Reported |                |
|                          | Etioven                        |                    |                    | C               |                                       |                      |                 | Not Reported |                |
|                          | Biperidys                      |                    |                    | C               |                                       |                      |                 | Not Reported |                |
|                          | Legalon                        |                    |                    | C               |                                       |                      |                 | Not Reported |                |
|                          | Methotrexate                   |                    |                    | C               |                                       |                      |                 | Not Reported |                |
|                          | Speciafoldine                  |                    |                    | C               |                                       |                      |                 | Not Reported |                |
|                          | Alprazolam                     |                    |                    | C               |                                       |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 19-Dec-2012                                                                                                                                                | 8986325              | DIRECT             | Y                  | OT              |                      |                      | 30 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                      | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Nausea; Vomiting                                                                                                                               | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Mylan        |                |
|                                                                                                                                                            | Seroquel             |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                            | Vistaril             |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                            | Ativan               |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Dec-2012                                                                                                                                                | 8986775              | DIRECT             |                    | OT              |                      |                      | 32 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                      | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective; Emotional Disorder; Mental Status Changes; Mood Altered; Product Substitution Issue                                                      | Escitalopram         |                    |                    | S               | Oral                 |                      |                 | Mylan        |                |
| <u>FDA Received Date</u>                                                                                                                                   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Dec-2012                                                                                                                                                | 8662959              | EXPEDITED (15-DAY) |                    | HO, OT          | CA-FRI-1000037013    |                      | 67 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                                                                                                                      | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Electrocardiogram Qt Prolonged; Electrocardiogram Qt Prolonged; Electrolyte Imbalance; Hypokalaemia; Hypomagnesaemia; Torsade De Pointes | Escitalopram         |                    |                    | S               |                      |                      |                 | Forest       |                |
|                                                                                                                                                            | Furosemide           |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                            | Quetiapine           |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Dec-2012                                                                                                                                                | 8785989              | EXPEDITED (15-DAY) |                    | DE              | GB-FRI-1000038584    |                      | 31 YR           | Male         | GBR            |

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

| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u>   |                |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------------|-----------------------------------------------|-----------------|--------------|----------------|
| Overdose                 | Escitalopram   |                    |                    | S               | Oral                       | 10 Mg                                         |                 | Forest       |                |
|                          | Escitalopram   |                    |                    | S               | Oral                       |                                               |                 | Forest       |                |
|                          | Quetiapine     |                    |                    | S               | Oral                       | 450 Mg Daily In Divided Doses                 |                 | Not Reported |                |
|                          | Quetiapine     |                    |                    | S               | Oral                       |                                               |                 | Not Reported |                |
|                          | Mirtazapine    |                    |                    | S               | Oral                       | 45 Mg                                         |                 | Not Reported |                |
|                          | Mirtazapine    |                    |                    | S               | Oral                       |                                               |                 | Not Reported |                |
|                          | Diazepam       |                    |                    | C               | Oral                       | 5 Mg                                          |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Dec-2012              | 8796096        | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000038609          |                                               | 21 YR           | Female       | FRA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u>   |                |
| Bone Marrow Failure      | Escitalopram   |                    |                    | S               | Oral                       |                                               |                 | Forest       |                |
|                          | Xanax          |                    |                    | S               | Oral                       |                                               |                 | Not Reported |                |
|                          | Yaz            |                    |                    | S               | Oral                       | 0.02 Mg/3 Mg                                  |                 | Not Reported |                |
|                          | Yaz            |                    |                    | S               | Oral                       | 0.02 Mg/3 Mg                                  |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Dec-2012              | 8974685        | EXPEDITED (15-DAY) |                    | HO              | FR-ASTRAZENECA-2012SE92958 |                                               | 87 YR           | Male         | FRA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u>   |                |
| Dehydration; Hypotension | Symbicort      |                    |                    | S               | Respiratory (inhalation)   | 320/9 Ug Per Dose, One Inhalation Twice A Day |                 | Astrazeneca  |                |
|                          | Seroplex       |                    |                    | S               | Oral                       |                                               |                 | Not Reported |                |
|                          | Seroplex       |                    |                    | S               | Oral                       |                                               |                 | Not Reported |                |
|                          | Ixprim         |                    |                    | S               | Oral                       |                                               |                 | Not Reported |                |
|                          | Coaprovel      |                    |                    | S               | Oral                       |                                               |                 | Not Reported |                |
|                          | Coaprovel      |                    |                    | S               | Oral                       |                                               |                 | Not Reported |                |

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

|  |             |   |              |
|--|-------------|---|--------------|
|  | Xanax       | C | Not Reported |
|  | Imovane     | C | Not Reported |
|  | Abiraterone | C | Not Reported |
|  | Doliprane   | C | Not Reported |
|  | Travatan    | C | Not Reported |

| <u>FDA Received Date</u>                                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 20-Dec-2012                                               | 8976036        | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000041150    |                      | 84 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Arrhythmia; Atrial Fibrillation; Bradycardia; Tachycardia | Escitalopram   |                    |                    | S               | Oral                 | 20 Mg                |                 | Forest       |                |
|                                                           | Escitalopram   |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                                           | Spironolactone |                    |                    | C               |                      | 50 Mg                |                 | Not Reported |                |
|                                                           | Furosemide     |                    |                    | C               |                      | 20 Mg                |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| 20-Dec-2012                                                             | 8976057        | EXPEDITED (15-DAY) |                    | OT              | CH-ASTRAZENECA-2012SE93761 |                      | < 1 DAY         | Female       | CHE            |
| <u>Preferred Term</u>                                                   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypernatraemia; Metabolic Acidosis; Premature Baby; Respiratory Failure | Seroquel       |                    |                    | S               | Transplacental             |                      |                 | Zeneca       |                |
|                                                                         | Ciprallex      |                    |                    | S               | Transplacental             |                      |                 | Not Reported |                |
|                                                                         | Labetalol      |                    |                    | C               |                            |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 20-Dec-2012                                                                                                                                            | 8976214        | EXPEDITED (15-DAY) |                    | HO, OT          | PHHY2012BR116124     |                      | 70 YR           | Female       | BRA            |
| <u>Preferred Term</u>                                                                                                                                  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Pressure Inadequately Controlled; Blood Viscosity Increased; Burning Sensation; Coronary Artery Occlusion; Depression; Drug Ineffective; Feeling | Trileptal      |                    |                    | S               | Oral                 | 300 Mg, Unk          |                 | Not Reported |                |
|                                                                                                                                                        | Tofranil       |                    |                    | S               | Oral                 | 1 Df, Tid            |                 | Not Reported |                |
|                                                                                                                                                        | Tofranil       |                    |                    | S               | Oral                 | 1 Df, Tid            |                 | Not Reported |                |
|                                                                                                                                                        | Ludiomil       |                    |                    | S               | Oral                 | 25 Mg, Unk           |                 | Not Reported |                |
|                                                                                                                                                        | Valdoxan       |                    |                    | S               | Oral                 | 1 Df, Bid            |                 | Not Reported |                |

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

|                                                                                                                                 |                                  |   |      |                               |              |
|---------------------------------------------------------------------------------------------------------------------------------|----------------------------------|---|------|-------------------------------|--------------|
| Abnormal; Growth Retardation; Headache; Hyperhidrosis; Hypersensitivity; Hypertension; Tachycardia; Urticaria; Weight Increased | Glimepiride                      | S | Oral | 1 Df, Bid                     | Not Reported |
|                                                                                                                                 | Doxycycline                      | S | Oral | 1 Df At Night                 | Novartis     |
|                                                                                                                                 | Sertraline Hydrochloride         | S | Oral | 50 Mg, Unk                    | Not Reported |
|                                                                                                                                 | Amlodipine Besylate              | S | Oral |                               | Not Reported |
|                                                                                                                                 | Topiramate                       | S | Oral | 50 Mg, Unk                    | Not Reported |
|                                                                                                                                 | Rivotril                         | S | Oral | 4 Df At Night                 | Not Reported |
|                                                                                                                                 | Respiciil                        | S | Oral | 400 Mg, Unk                   | Not Reported |
|                                                                                                                                 | Socian                           | S | Oral | 50 Mg, Unk                    | Not Reported |
|                                                                                                                                 | Topamax                          | S | Oral | 1 Df, Bid                     | Not Reported |
|                                                                                                                                 | Duspatalin                       | S | Oral |                               | Not Reported |
|                                                                                                                                 | Prazol (Lansoprazole)            | S | Oral | 1 Df, Daily                   | Not Reported |
|                                                                                                                                 | Tolvon                           | S | Oral | 0.5 Df (Half Tablet At Night) | Not Reported |
|                                                                                                                                 | Exodus//Escitalopram Oxalate     | S | Oral |                               | Not Reported |
|                                                                                                                                 | Levoid                           | S | Oral |                               | Not Reported |
|                                                                                                                                 | Arflex                           | S | Oral |                               | Not Reported |
|                                                                                                                                 | Cebrin                           | S | Oral | 20 Mg, Unk                    | Not Reported |
|                                                                                                                                 | Remeron                          | S | Oral |                               | Not Reported |
|                                                                                                                                 | Tolrest                          | S | Oral |                               | Not Reported |
|                                                                                                                                 | Zetron (Bupropion Hydrochloride) | S | Oral | 105 Mg, Unk                   | Not Reported |
|                                                                                                                                 | Donaren                          | S | Oral | Unk                           | Not Reported |
|                                                                                                                                 | Neurotrypt                       | S | Oral | Unk                           | Not Reported |
|                                                                                                                                 | Buscopan                         | S |      | Unk                           | Not Reported |
|                                                                                                                                 | Citta                            | S | Oral | 1 Df, Daily                   | Not Reported |
|                                                                                                                                 | Norvasc                          | S | Oral | Unk                           | Not Reported |
|                                                                                                                                 | Cymbalta                         | S | Oral | 30 Mg, Unk                    | Not Reported |
|                                                                                                                                 | Selozok                          | S |      | Unk                           | Not Reported |
|                                                                                                                                 | Tryptanol                        | S | Oral | 1 Df, Bid                     | Not Reported |
|                                                                                                                                 | Tamiram                          | S | Oral | 1 Df, Bid                     | Not Reported |



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

| <u>FDA Received Date</u>                                             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 20-Dec-2012                                                          | 8976399        | EXPEDITED (15-DAY) |                    | OT              | DE-FRI-1000041156        |                      |                 | Female       | DEU            |
| <u>Preferred Term</u>                                                | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Drug Interaction; Muscle Spasms; Nausea; Tremor; Vomiting | Escitalopram   |                    |                    | S               |                          |                      |                 | Forest       |                |
|                                                                      | Candesartan    |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                                                      |                |                    |                    |                 |                          |                      |                 |              |                |
| <u>FDA Received Date</u>                                             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Dec-2012                                                          | 8977083        | EXPEDITED (15-DAY) |                    | HO, LT          | AU-FRI-1000041166        |                      |                 | Female       | AUS            |
| <u>Preferred Term</u>                                                | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Self-Injury; Obsessive-Compulsive Disorder               | Lexapro        |                    |                    | S               | Oral                     | 5 Mg                 |                 | Forest       |                |
|                                                                      | Lexapro        |                    |                    | S               | Oral                     | 10 Mg                |                 | Forest       |                |
|                                                                      | Lexapro        |                    |                    | S               | Oral                     | 5 Mg                 |                 | Forest       |                |
| <u>FDA Received Date</u>                                             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Dec-2012                                                          | 8977417        | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2012321662 |                      | 40 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity                                                | Gabapentin     |                    |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                                                                      | Lexapro        |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                                                                      | Hytrin         |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Dec-2012                                                          | 8977926        | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000041148        |                      | 87 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dehydration; Hypotension                                             | Escitalopram   |                    |                    | S               | Oral                     | 15 Mg                |                 | Forest       |                |

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

|                                                   | Coaprovel                  |                           | S                           | Oral                     | 150 Mg/12.5 Mg                |                               |                          | Not Reported        |                         |
|---------------------------------------------------|----------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
|                                                   | Symbicort                  |                           | S                           | Other                    | 800 Mg                        |                               |                          | Not Reported        |                         |
|                                                   | Ixprim                     |                           | S                           | Oral                     |                               |                               |                          | Not Reported        |                         |
|                                                   | Xanax                      |                           | C                           |                          |                               |                               |                          | Not Reported        |                         |
|                                                   | Imovane                    |                           | C                           |                          |                               |                               |                          | Not Reported        |                         |
|                                                   | Abiraterone Acetate        |                           | C                           |                          |                               |                               |                          | Not Reported        |                         |
|                                                   | Doliprane                  |                           | C                           |                          |                               |                               |                          | Not Reported        |                         |
|                                                   | Travatan                   |                           | C                           |                          |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                 | <a href="#">Case #</a>     | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 20-Dec-2012                                       | 8988340                    | DIRECT                    |                             | LT, OT                   |                               |                               | 41 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>                    | <a href="#">Product</a>    | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Aggression; Homicidal Ideation; Suicidal Ideation | Lexapro                    |                           |                             | S                        | Oral                          |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                 | <a href="#">Case #</a>     | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 21-Dec-2012                                       | 8979049                    | EXPEDITED (15-DAY)        |                             | HO, OT                   | CH-ASTRAZENECA-2011SE74604    |                               | 35 YR                    | Female              | CHE                     |
| <a href="#">Preferred Term</a>                    | <a href="#">Product</a>    | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Cardiac Failure; Exposure During Pregnancy        | Seroquel                   |                           |                             | S                        | Oral                          |                               |                          | Not Reported        |                         |
|                                                   | Cipralext                  |                           |                             | S                        | Oral                          |                               |                          | Not Reported        |                         |
|                                                   | Labetalol                  |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                 | <a href="#">Case #</a>     | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 21-Dec-2012                                       | 8979785                    | EXPEDITED (15-DAY)        |                             | OT                       | DE-FRI-1000041184             |                               |                          | Female              | DEU                     |
| <a href="#">Preferred Term</a>                    | <a href="#">Product</a>    | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug-Induced Liver Injury; Jaundice               | Escitalopram Oral Solution |                           |                             | S                        | Oral                          |                               |                          | Forest              |                         |
| <a href="#">FDA Received Date</a>                 | <a href="#">Case #</a>     | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 21-Dec-2012                                       | 8980179                    | EXPEDITED (15-DAY)        |                             | DE                       | PHHY2012GB117786              |                               | 31 YR                    | Male                | GBR                     |

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

| <u>Preferred Term</u>         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------|----------------|--------------|------------|-------------|--------------|-----------------------------|-----------------|--------------|
| Accidental Death;<br>Overdose | Quetiapine     |              |            | S           | Oral         | 450 Mg, Qd In Divided Doses |                 | Novartis     |
|                               | Quetiapine     |              |            | S           | Oral         | Overdose: Amount Unknown    |                 | Novartis     |
|                               | Mirtazapine    |              |            | S           | Oral         | 45 Mg, Qd                   |                 | Not Reported |
|                               | Mirtazapine    |              |            | S           | Oral         | Overdose: Amount Unknown    |                 | Not Reported |
|                               | Cipralex       |              |            | S           | Oral         | 10 Mg, Qd                   |                 | Not Reported |
|                               | Cipralex       |              |            | S           | Oral         | Overdose: Amount Unknown    |                 | Not Reported |
|                               | Diazepam       |              |            | C           | Oral         | 5 Mg,                       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Dec-2012              | 8980316       | EXPEDITED (15-DAY) |                    | HO              | PHHY2012CH114419     |                      | 70 YR      | Female     | CHE            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                    | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|--------------|------------|-------------|--------------|----------------------------------------|-----------------|--------------|
| Back Pain; Balance Disorder; C-Reactive Protein Increased; Electrocardiogram Qt Prolonged; Fall; Hypokalaemia; Hyponatraemia; Inflammation; Leukocytosis; Muscular Weakness; Nitrite Urine Present; Spinal Compression Fracture; Spinal Cord Compression | Sirdalud            |              |            | S           | Oral         | 4 Mg, Qd                               |                 | Not Reported |
|                                                                                                                                                                                                                                                          | Sirdalud            |              |            | S           |              | Unk Ukn, Unk                           |                 | Not Reported |
|                                                                                                                                                                                                                                                          | Exforge Hct         |              |            | S           | Oral         | 1 Df (160 Mg Val/ 5 Mg Aml/ 25 Mg Hct) |                 | Novartis     |
|                                                                                                                                                                                                                                                          | Rivotril            |              |            | S           | Oral         | 2 Mg Bid                               |                 | Not Reported |
|                                                                                                                                                                                                                                                          | Cipralex            |              |            | S           | Oral         | 10 Mg Bid                              |                 | Not Reported |
|                                                                                                                                                                                                                                                          | Cipralex            |              |            | S           |              | Unk Ukn, Unk                           |                 | Not Reported |
|                                                                                                                                                                                                                                                          | Halcion             |              |            | S           | Oral         | 0.25 Mg Qd                             |                 | Not Reported |
|                                                                                                                                                                                                                                                          | Halcion             |              |            | S           |              | Unk Ukn, Unk                           |                 | Not Reported |
|                                                                                                                                                                                                                                                          | Xanax               |              |            | S           | Oral         | 1 Mg Tid                               |                 | Not Reported |
|                                                                                                                                                                                                                                                          | Xanax               |              |            | S           |              | Unk Ukn, Unk                           |                 | Not Reported |
|                                                                                                                                                                                                                                                          | Temesta (Lorazepam) |              |            | S           | Oral         | 2.5 Mg Qid                             |                 | Not Reported |
|                                                                                                                                                                                                                                                          | Temesta (Lorazepam) |              |            | S           |              | Unk Ukn, Unk                           |                 | Not Reported |

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|  |                |   |      |              |              |
|--|----------------|---|------|--------------|--------------|
|  | Seroquel       | S | Oral | 150 Mg Qd    | Not Reported |
|  | Seroquel       | S |      | Unk Unk, Unk | Not Reported |
|  | Aspirin Cardio | C | Oral | 100 Mg, Qw   | Not Reported |
|  | Mag 2          | C | Oral |              | Not Reported |
|  | Omeprazole     | C | Oral | 40 Mg Bid    | Not Reported |
|  | Movicol        | C |      |              | Not Reported |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 21-Dec-2012                       | 8980710                | EXPEDITED (15-DAY)        |                             | OT                       | TR-FRI-1000041180             |                               | 30 YR               | Female              | TUR                     |

| <a href="#">Preferred Term</a>     | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Genital Haemorrhage;<br>Somnolence | Escitalopram            |                       |                     | S                    | Oral                  | 10 Mg                       |                          | Forest              |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 21-Dec-2012                       | 8997119                | EXPEDITED (15-DAY)        | Y                           | OT                       | AUR-APL-2012-05443            |                               | 58 YR               | Male                | CAN                     |

| <a href="#">Preferred Term</a>                                  | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|-----------------------------------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Abnormal Behaviour;<br>Aphasia; Atrophy; Disease<br>Progression | Citalopram (Citalopram) |                       |                     | S                    | Oral                  |                             |                          | Not Reported        |
|                                                                 | Paroxetine (Paroxetine) |                       |                     | S                    |                       | 5 And 10 Mg (1 D)           |                          | Not Reported        |
|                                                                 | Sertraline (Sertraline) |                       |                     | S                    |                       |                             |                          | Not Reported        |
|                                                                 | (Sertraline)            |                       |                     |                      |                       |                             |                          |                     |
|                                                                 | Olanzapine (Olanzapine) |                       |                     | S                    | Oral                  |                             |                          | Not Reported        |
|                                                                 | Quetiapine (Quetiapine) |                       |                     | S                    |                       |                             |                          | Not Reported        |
|                                                                 | (Quetiapine)            |                       |                     |                      |                       |                             |                          |                     |
|                                                                 | Escitalopram            |                       |                     | S                    |                       |                             |                          | Not Reported        |
|                                                                 | Haloperidol             |                       |                     | S                    |                       |                             |                          | Not Reported        |
|                                                                 | Clomipramine            |                       |                     | S                    | Oral                  |                             |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>                   | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 24-Dec-2012                       | 8983673                | EXPEDITED (15-DAY)        |                             | HO                       | FR-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>17217183 |                               | 87 YR               | Male                | FRA                     |

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

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

|                          |                             |   |                          |                      |
|--------------------------|-----------------------------|---|--------------------------|----------------------|
| Dehydration; Hypotension | Coaprovel Tabs 150mg/12.5mg | S | Oral                     | Bristol Myers Squibb |
|                          | Seroplex                    | S |                          | Not Reported         |
|                          | Symbicort                   | S | Respiratory (inhalation) | Not Reported         |
|                          | Ixprim                      | S | Oral                     | Not Reported         |
|                          | Xanax                       | C |                          | Not Reported         |
|                          | Imovane                     | C |                          | Not Reported         |
|                          | Doliprane                   | C |                          | Not Reported         |
|                          | Travatan                    | C |                          | Not Reported         |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 25-Dec-2012              | 8984769       | EXPEDITED (15-DAY) |                    | HO              | FR-JNJFOC-20121210374 |                      | 87 YR      | Male       | FRA            |

| <u>Preferred Term</u>             | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>             | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------|----------------------|--------------|------------|-------------|--------------------------|--------------------|-----------------|--------------|
| Dehydration; Hypotension; Malaise | Ixprim               |              |            | S           | Oral                     |                    |                 | Not Reported |
|                                   | Symbicort Turbohaler |              |            | S           | Respiratory (inhalation) |                    |                 | Not Reported |
|                                   | Coaprovel            |              |            | S           | Oral                     |                    |                 | Not Reported |
|                                   | Seroplex             |              |            | S           | Oral                     |                    |                 | Not Reported |
|                                   | Abiraterone Acetate  |              |            | C           | Oral                     |                    |                 | Not Reported |
|                                   | Doliprane            |              |            | C           | Oral                     |                    |                 | Not Reported |
|                                   | Travatan             |              |            | C           | Ophthalmic               |                    |                 | Not Reported |
|                                   | Xanax                |              |            | C           | Oral                     |                    |                 | Not Reported |
|                                   | Imovane              |              |            | C           | Oral                     |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Dec-2012              | 8905195       | EXPEDITED (15-DAY) |                    | DE, HO          | JP-FRI-1000040282    |                      | 93 YR      | Female     | JPN            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Hyponatraemia         | Lexapro        |              |            | S           | Oral         | 5 Mg               |                 | Forest     |
|                       | Lexapro        |              |            | S           | Oral         | 10 Mg              |                 | Forest     |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                              | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------------|--------------------------------|-----------------|--------------|----------------|
| 26-Dec-2012                                           | 8985342                | EXPEDITED (15-DAY) |                    | DE              | GB-009507513-1212GBR009641 |                                | 31 YR           | Male         | GBR            |
| <u>Preferred Term</u>                                 | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Overdose                                              | Mirtazapine            |                    |                    | S               | Oral                       | 45 Mg, Qd                      |                 | Merck        |                |
|                                                       | Mirtazapine            |                    |                    | S               | Oral                       | Unk                            |                 | Merck        |                |
|                                                       | Cipralelex             |                    |                    | S               | Oral                       | 10 Mg, Qd                      |                 | Not Reported |                |
|                                                       | Cipralelex             |                    |                    | S               |                            | Unk                            |                 | Not Reported |                |
|                                                       | Quetiapine Fumarate    |                    |                    | S               | Oral                       | 450 Mg, Qd                     |                 | Not Reported |                |
|                                                       | Quetiapine Fumarate    |                    |                    | S               | Oral                       | Unk                            |                 | Not Reported |                |
|                                                       | Diazepam               |                    |                    | C               | Oral                       | 5 Mg, Qd                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Dec-2012                                           | 8985502                | EXPEDITED (15-DAY) |                    | HO, OT          | FR-PFIZER INC-2012324789   |                                | 91 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                 | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Overdose; Retroperitoneal Haematoma | Cordarone              |                    |                    | S               | Oral                       | 200 Mg Daily                   |                 | Pfizer       |                |
|                                                       | Previscan (Fluindione) |                    |                    | S               | Oral                       | 20 Mg Daily                    |                 | Not Reported |                |
|                                                       | Previscan              |                    |                    | S               |                            |                                |                 | Not Reported |                |
|                                                       | Seroplex               |                    |                    | S               | Oral                       | 10 Mg Daily                    |                 | Not Reported |                |
|                                                       | Hyzaar                 |                    |                    | C               |                            | Unk                            |                 | Not Reported |                |
|                                                       | Imovane                |                    |                    | C               |                            | Unk                            |                 | Not Reported |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Dec-2012                                           | 8985817                | EXPEDITED (15-DAY) |                    | DE              | GB-ASTRAZENECA-2012SE95263 |                                | 31 YR           | Male         | GBR            |
| <u>Preferred Term</u>                                 | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Accidental Death; Overdose                            | Quetiapine             |                    |                    | S               | Oral                       | 450 Mg Daily, In Divided Doses |                 | Zeneca       |                |
|                                                       | Quetiapine             |                    |                    | S               | Oral                       |                                |                 | Zeneca       |                |

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|             |   |      |              |
|-------------|---|------|--------------|
| Quetiapine  | S | Oral | Zeneca       |
| Mirtazapine | S | Oral | Not Reported |
| Mirtazapine | S | Oral | Not Reported |
| Cipralex    | S | Oral | Not Reported |
| Cipralex    | S | Oral | Not Reported |
| Diazepam    | C |      | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Dec-2012              | 8986696       | EXPEDITED (15-DAY) | HO                 |                 | FR-ROCHE-1170221     |                      | 84 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                             | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------|----------------|--------------|------------|-------------|------------------------------------------|--------------------|-----------------|--------------|
| Hypertension;<br>Hypertensive Angiopathy;<br>Intracranial Haematoma | Mabthera       |              |            | S           | Intravenous (not<br>otherwise specified) |                    |                 | Not Reported |
|                                                                     | Apranax        |              |            | S           | Oral                                     |                    |                 | Not Reported |
|                                                                     | Seroplex       |              |            | S           | Oral                                     |                    |                 | Not Reported |
|                                                                     | Cortancyl      |              |            | S           | Oral                                     |                    |                 | Not Reported |
|                                                                     | Oroken         |              |            | C           | Oral                                     |                    |                 | Not Reported |
|                                                                     | Pantoprazole   |              |            | C           | Oral                                     |                    |                 | Not Reported |
|                                                                     | Doliprane      |              |            | C           | Oral                                     |                    |                 | Not Reported |
|                                                                     | Methotrexate   |              |            | C           |                                          |                    |                 | Not Reported |
|                                                                     | Salazopyrine   |              |            | C           |                                          |                    |                 | Not Reported |
|                                                                     | Plaquenil      |              |            | C           |                                          |                    |                 | Not Reported |
|                                                                     | Enbrel         |              |            | C           |                                          |                    |                 | Not Reported |
|                                                                     | Humira         |              |            | C           |                                          |                    |                 | Not Reported |
|                                                                     | Remicade       |              |            | C           |                                          |                    |                 | Not Reported |
|                                                                     | Naproxen       |              |            | C           |                                          |                    |                 | Not Reported |
|                                                                     | Cefixime       |              |            | C           |                                          |                    |                 | Not Reported |
|                                                                     | Pantoprazole   |              |            | C           |                                          |                    |                 | Not Reported |
|                                                                     | Prednisone     |              |            | C           |                                          |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Dec-2012              | 8494340       | EXPEDITED (15-DAY) |                    | OT              | JP-FRI-1000029490    |                      | 52 YR      | Male       | JPN            |

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

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

|                                           |                           |   |      |      |              |
|-------------------------------------------|---------------------------|---|------|------|--------------|
| Electrocardiogram Qt<br>Prolonged; Nausea | Lexapro                   | S | Oral | 10mg | Forest       |
|                                           | Lexapro                   | S | Oral | 10mg | Forest       |
|                                           | Mosapride Citrate Hydrate | C | Oral |      | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Dec-2012              | 8988114       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000041246    |                      | 84 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                             | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------|----------------|--------------|------------|-------------|------------------------------------------|--------------------|-----------------|--------------|
| Hypertension;<br>Hypertensive Angiopathy;<br>Intracranial Haematoma | Escitalopram   |              |            | S           | Oral                                     |                    |                 | Forest       |
|                                                                     | Mabthera       |              |            | S           | Intravenous (not<br>otherwise specified) |                    |                 | Not Reported |
|                                                                     | Mabthera       |              |            | S           | Intravenous (not<br>otherwise specified) |                    |                 | Not Reported |
|                                                                     | Apranax        |              |            | S           | Oral                                     |                    |                 | Not Reported |
|                                                                     | Cortancyl      |              |            | S           | Oral                                     | 20 Mg              |                 | Not Reported |
|                                                                     | Oroken         |              |            | C           | Oral                                     | 100 Mg Qod         |                 | Not Reported |
|                                                                     | Pantoprazole   |              |            | C           | Oral                                     | 20 Mg              |                 | Not Reported |
|                                                                     | Doliprane      |              |            | C           | Oral                                     | 4000 Mg            |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|------------|------------|----------------|
| 27-Dec-2012              | 8989258       | EXPEDITED (15-DAY) |                    | HO              | FR-009507513-<br>1212FRA008585 |                      | 41 YR      | Male       | FRA            |

| <u>Preferred Term</u> | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Oedema; Rash          | Isentress                |              |            | S           | Oral         | 400 Mg, Bid        |                 | Merck        |
|                       | Study Drug (Unspecified) |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                       | Tmc-114                  |              |            | S           | Oral         | 1200 Mg, Bid       |                 | Not Reported |
|                       | Tmc-125                  |              |            | S           | Unknown      | 400 Mg, Qd         |                 | Not Reported |
|                       | Kivexa                   |              |            | S           | Unknown      | 900 Mg, Qd         |                 | Not Reported |
|                       | Seroplex                 |              |            | S           | Oral         | 10 Mg, Qd          |                 | Not Reported |
|                       | Norvir                   |              |            | C           | Oral         | 200 Mg, Bid        |                 | Not Reported |



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

|                                                       |                      |                    |                    |                 |                      |                            |                 |              |                |
|-------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------------|-----------------|--------------|----------------|
| Xanax                                                 |                      |                    | C                  |                 | Oral                 | Unk                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Dec-2012                                           | 8990969              | DIRECT             | Y                  |                 |                      |                            |                 | Female       | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>   |                |
| Irritable Bowel Syndrome                              | Lexapro              |                    |                    | S               | Oral                 | 5 Mg Od Po Before 11/19/12 |                 | Not Reported |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Dec-2012                                           | 8990971              | DIRECT             |                    |                 |                      |                            | 62 YR           | Female       | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective; Product Substitution Issue          | Escitalopram Oxalate |                    |                    | S               | Oral                 | 5mg 1 Daily Oral           |                 | Not Reported |                |
|                                                       | Sertraline Hcl       |                    |                    | S               | Oral                 | 25mg 1 X Daily Oral        |                 | Not Reported |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Dec-2012                                           | 8991000              | DIRECT             | Y                  |                 |                      |                            |                 | Female       | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Tremor                                       | Escitalopram 20mg    |                    |                    | S               |                      |                            |                 | Not Reported |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Dec-2012                                           | 8991002              | DIRECT             |                    | OT              |                      |                            | 36 YR           | Female       | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Drug Ineffective; Product Substitution Issue | Escitalopram 20mg    |                    |                    | S               | Buccal               |                            |                 | Not Reported |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Dec-2012                                           | 8879988              | EXPEDITED (15-DAY) |                    | OT              | IE-FRI-1000039958    |                            | 46 YR           | Female       | IRL            |

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

| <u>Preferred Term</u>                                         | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| Arrhythmia;<br>Electrocardiogram Qt<br>Prolonged              | Lexapro        |                    |                    | S               | Oral                         | 10 Mg                |                 | Forest       |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Dec-2012                                                   | 8988598        | EXPEDITED (15-DAY) |                    | OT              | IT-PFIZER INC-<br>2012331106 |                      | 33 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                         | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Supraventricular<br>Tachycardia                               | Xanax          |                    |                    | S               | Oral                         | 3 Gtt, 1x/Day        |                 | Pfizer       |                |
|                                                               | Ciprallex      |                    |                    | S               | Oral                         | 10 Gtt, 1x/Day       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Dec-2012                                                   | 8990335        | EXPEDITED (15-DAY) |                    | OT              | CA-FRI-1000041283            |                      | 26 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                         | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dyspepsia; Seizure                                            | Escitalopram   |                    |                    | S               | Oral                         | 10 Mg                |                 | Forest       |                |
|                                                               | Lexapro        |                    |                    | C               | Oral                         |                      |                 | Not Reported |                |
|                                                               | Lexapro        |                    |                    | C               | Oral                         |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Dec-2012                                                   | 8990532        | EXPEDITED (15-DAY) |                    | HO              | JP-FRI-1000028239            |                      |                 | Female       | JPN            |
| <u>Preferred Term</u>                                         | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Inappropriate<br>Antidiuretic Hormone<br>Secretion | Lexapro        |                    |                    | S               | Oral                         | 10 Mg                |                 | Forest       |                |
|                                                               | Lexapro        |                    |                    | S               | Oral                         | 5 Mg                 |                 | Forest       |                |
|                                                               | Rheumatrex     |                    |                    | C               | Oral                         |                      |                 | Not Reported |                |
|                                                               | Remicade       |                    |                    | C               | Intravenous drip             |                      |                 | Not Reported |                |
|                                                               | Durotep        |                    |                    | C               | Topical                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

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### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Dec-2012              | 8990654       | EXPEDITED (15-DAY) |                    | LT              | JP-FRI-1000026517    |                      | 35 YR      | Male       | JPN            |

| <u>Preferred Term</u>                                                  | <u>Product</u>   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------|------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Asthenia; Bradycardia;<br>Headache; Loss Of<br>Consciousness; Parosmia | Lexapro          |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                                                        | Lexapro          |              |            | S           | Oral         | 20 Mg              |                 | Forest       |
|                                                                        | Dogmatyl         |              |            | C           | Oral         | 150 Mg             |                 | Not Reported |
|                                                                        | Wypax            |              |            | C           | Oral         | 1.5 Mg             |                 | Not Reported |
|                                                                        | Myslee           |              |            | C           | Oral         | 5 Mg               |                 | Not Reported |
|                                                                        | Depas (Etizolam) |              |            | C           | Oral         | 0.5 Mg             |                 | Not Reported |
|                                                                        | Lexotan          |              |            | C           | Oral         | 12 Mg              |                 | Not Reported |
|                                                                        | Asumeji          |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                        | Kipres           |              |            | C           | Oral         | 10 Mg              |                 | Not Reported |
|                                                                        | Takepron         |              |            | C           | Oral         | 30 Mg              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Dec-2012              | 8990659       | EXPEDITED (15-DAY) |                    | OT              | JP-FRI-1000025239    |                      | 38 YR      | Female     | JPN            |

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

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Dec-2012              | 8990782       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000041244    |                      | 91 YR      | Female     | FRA            |

| <u>Preferred Term</u>        | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Retroperitoneal<br>Haematoma | Escitalopram           |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                              | Previscan (Fluindione) |              |            | S           | Oral         | 20 Mg              |                 | Not Reported |
|                              | Cordarone              |              |            | S           | Oral         | 200 Mg             |                 | Not Reported |
|                              | Hyzaar                 |              |            | C           | Oral         | 50 Mg/12.5 Mg      |                 | Not Reported |

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

|                                                                                                                       |                           |                    |                    |                 |                       |                      |                 |              |                |
|-----------------------------------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| Imovane                                                                                                               |                           |                    | C                  | Oral            | 7.5 Mg                |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                              | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-Dec-2012                                                                                                           | 8992391                   | EXPEDITED (15-DAY) |                    | OT              | DE-JNJFOC-20121213294 |                      | 62 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                                                                                 | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Akathisia;<br>Choreoathetosis; Muscle<br>Rigidity; Myoclonus;<br>Nervousness; Reduced<br>Facial Expression | Paliperidone              |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                                       | Paliperidone              |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                                       | Escitalopram              |                    |                    | S               | Unknown               |                      |                 | Not Reported |                |
|                                                                                                                       | Escitalopram              |                    |                    | S               | Unknown               |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                              | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-Dec-2012                                                                                                           | 9013471                   | EXPEDITED (15-DAY) | Y                  | DE              | AUR-APL-2012-05538    |                      | 31 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                 | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Accidental Death;<br>Overdose; Toxicity To<br>Various Agents                                                          | Mirtazapine (Mirtazapine) |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                                       | Quetiapine                |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                                       | Cipralex                  |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                                       | Diazepam (Diazepam)       |                    |                    | C               |                       |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                              | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Jan-2013                                                                                                           | 8725431                   | EXPEDITED (15-DAY) |                    | HO              | JP-FRI-1000037747     |                      | 77 YR           | Female       | JPN            |
| <u>Preferred Term</u>                                                                                                 | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Glucose Increased;<br>Cholestasis; Drug Eruption                                                                | Lexapro                   |                    |                    | S               | Oral                  | 10 Mg                |                 | Forest       |                |
|                                                                                                                       | Paxil                     |                    |                    | S               | Oral                  | 10 Mg                |                 | Not Reported |                |
|                                                                                                                       | Paxil                     |                    |                    | S               | Oral                  | 20 Mg                |                 | Not Reported |                |
|                                                                                                                       | Paxil                     |                    |                    | S               | Oral                  | 10 Mg                |                 | Not Reported |                |
|                                                                                                                       | Tegretol                  |                    |                    | S               | Oral                  | 200 Mg               |                 | Not Reported |                |

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

|                  |   |       |        |              |
|------------------|---|-------|--------|--------------|
| Cephadol         | C | Oral  | 75 Mg  | Not Reported |
| Depas (Etizolam) | C | Oral  | 0.5 Mg | Not Reported |
| Bayaspirin       | C | Oral  | 100 Mg | Not Reported |
| Takepron         | C | Oral  | 15 Mg  | Not Reported |
| Pantosin         | C | Oral  | 3 G    | Not Reported |
| Magnesium Oxide  | C | Oral  | 1.5 G  | Not Reported |
| Aftach           | C | Other | 25 Mcg | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Jan-2013              | 8993214       | EXPEDITED (15-DAY) | HO, LT             |                 | CH-ROCHE-1175006     |                      | 90 YR      | Female     | CHE            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                    | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|-------------------------------------------------------|-----------------|--------------|
| Hepatocellular Injury | Rocephin       |              |            | S           | Unknown      |                                                       |                 | Not Reported |
|                       | Zaldiar        |              |            | S           | Oral         | 37.5 Mg Tramadol Hydrochloride And 325 Mg Paracetamol |                 | Not Reported |
|                       | Paracetamol    |              |            | S           | Oral         |                                                       |                 | Not Reported |
|                       | Xarelto        |              |            | S           | Unknown      |                                                       |                 | Not Reported |
|                       | Amlodipine     |              |            | S           | Unknown      |                                                       |                 | Not Reported |
|                       | Reminyl        |              |            | S           | Unknown      |                                                       |                 | Not Reported |
|                       | Zolpidem       |              |            | S           | Unknown      |                                                       |                 | Not Reported |
|                       | Inegy          |              |            | S           | Unknown      |                                                       |                 | Not Reported |
|                       | Cipralex       |              |            | S           | Unknown      |                                                       |                 | Not Reported |
|                       | Flagyl         |              |            | S           | Unknown      |                                                       |                 | Not Reported |
|                       | Esomeprazole   |              |            | S           | Unknown      |                                                       |                 | Not Reported |
|                       | Prednisone     |              |            | C           |              |                                                       |                 | Not Reported |
|                       | Omeprazole     |              |            | C           | Unknown      |                                                       |                 | Not Reported |
|                       | Ibuprofen      |              |            | C           | Unknown      |                                                       |                 | Not Reported |
|                       | Calciparin     |              |            | C           | Unknown      |                                                       |                 | Not Reported |
|                       | Calcimagon-D3  |              |            | C           | Unknown      |                                                       |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                                                                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|-----------------|--------------|----------------|
| 02-Jan-2013                                                                                                                                                                                                                                                    | 8993300              | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2012332632       |                      | 46 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agoraphobia; Anxiety; Appetite Disorder; Cough; Depression; Diarrhoea; Drug Ineffective; Fatigue; Fear; Feeling Abnormal; Headache; Lethargy; Loss Of Libido; Nasopharyngitis; Nausea; Obsessive Thoughts; Paraesthesia; Weight Increased; Withdrawal Syndrome | Pristiq              |                    |                    | S               |                                | 100 Mg, Unk          |                 | Pfizer       |                |
|                                                                                                                                                                                                                                                                | Effexor Xr           |                    |                    | S               |                                | Unk                  |                 | Pfizer       |                |
|                                                                                                                                                                                                                                                                | Wellbutrin           |                    |                    | S               |                                | Unk                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                | Paxil                |                    |                    | S               |                                | Unk                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                | Lexapro              |                    |                    | S               |                                | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Jan-2013                                                                                                                                                                                                                                                    | 8996998              | DIRECT             | Y                  | HO              |                                |                      | 60 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Blood Pressure Diastolic Increased; Confusional State; Heart Rate Abnormal; Nausea; Vision Blurred                                                                                                                                                    | Escitalopram Oxalate |                    |                    | S               | Oral                           | 10 Mg 1qd Po         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Jan-2013                                                                                                                                                                                                                                                    | 9000189              | EXPEDITED (15-DAY) |                    | HO, LT          | CH-SANOFI-AVENTIS-2012SA095627 |                      | 90 YR           | Female       | CHE            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hepatocellular Injury                                                                                                                                                                                                                                          | Zolpidem             |                    |                    | S               | Unknown                        |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                | Flagyl               |                    |                    | S               | Unknown                        |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                | Zaldiar              |                    |                    | S               | Oral                           |                      |                 | Not Reported |                |

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

|                          |   |         |              |
|--------------------------|---|---------|--------------|
| Paracetamol              | S | Oral    | Not Reported |
| Rocephin                 | S | Unknown | Not Reported |
| Xarelto                  | S | Unknown | Not Reported |
| Amlodipine               | S | Unknown | Not Reported |
| Esomeprazole             | S | Unknown | Not Reported |
| Galantamine Hydrobromide | S | Unknown | Not Reported |
| Inegy                    | S | Unknown | Not Reported |
| Escitalopram             | S | Unknown | Not Reported |
| Calciparin               | C |         | Not Reported |
| Omeprazole               | C |         | Not Reported |
| Ibuprofen                | C |         | Not Reported |
| Calcimagon-D3            | C |         | Not Reported |
| Prednisolone             | C |         | Not Reported |
| Asa                      | C |         | Not Reported |
| Heparin                  | C |         | Not Reported |
| Prednisone               | C |         | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Jan-2013              | 8930543       | EXPEDITED (15-DAY) |                    | OT              | SI-FRI-1000040624    |                      | 65 YR      | Male       | SVN            |

| <u>Preferred Term</u>                                           | <u>Product</u>  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------|-----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Arthralgia; Bursitis; Fall;<br>Off Label Use;<br>Osteoarthritis | Escitalopram    |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                                                 | Escitalopram    |              |            | S           | Oral         | 5 Mg               |                 | Forest       |
|                                                                 | Crestor         |              |            | C           | Oral         | 5 Mg               |                 | Not Reported |
|                                                                 | Aspirin Protect |              |            | C           | Oral         | 100 Mg             |                 | Not Reported |
|                                                                 | Micardis        |              |            | C           | Oral         | 40 Mg              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Jan-2013              | 8990312       | EXPEDITED (15-DAY) |                    | OT              | JP-FRI-1000041292    |                      |            | Female     | JPN            |

| <u>Preferred Term</u>                                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Asthenia; Initial Insomnia;<br>Loss Of Consciousness; | Lexapro        |              |            | S           | Oral         |                    |                 | Forest     |

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

|         |                  |   |      |              |
|---------|------------------|---|------|--------------|
| Malaise | Ganaton          | C | Oral | Not Reported |
|         | Lendormin        | C | Oral | Not Reported |
|         | Depas (Etizolam) | C | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------------------------------------|----------------------|------------|------------|----------------|
| 03-Jan-2013              | 8995305       | EXPEDITED (15-DAY) |                    | LT              | DE-B.I.<br>PHARMACEUTICALS,I<br>NC./RIDGEFIELD-2013-<br>DE-00 |                      | 56 YR      | Male       | DEU            |

| <u>Preferred Term</u>                                                                                                                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>           |
|--------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------|
| Cardiovascular<br>Insufficiency; Hypotension;<br>Incorrect Dose<br>Administered; Poor Quality<br>Sleep; Suicide Attempt;<br>Vomiting | Micardis Hct   |              |            | S           | Oral         | 105 Anz            |                 | Boehringer Ingelheim |
|                                                                                                                                      | Venlafaxin     |              |            | S           | Oral         | 50 Anz             |                 | Not Reported         |
|                                                                                                                                      | Amlodipin      |              |            | S           | Oral         | 150 Anz            |                 | Not Reported         |
|                                                                                                                                      | Cipralelex     |              |            | S           | Oral         | 14 Anz             |                 | Not Reported         |
|                                                                                                                                      | Zopiclone      |              |            | S           | Oral         | 10 Mg              |                 | Not Reported         |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|------------|------------|----------------|
| 03-Jan-2013              | 8998650       | EXPEDITED (15-DAY) |                    | HO, LT          | CH-009507513-<br>1212CHE010780 |                      | 90 YR      | Female     | CHE            |

| <u>Preferred Term</u> | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hepatocellular Injury | Inegy             |              |            | S           | Oral         | 10 Mg, Qd          |                 | Merck        |
|                       | Zaldiar           |              |            | S           | Oral         | 325 Mg, Qid        |                 | Not Reported |
|                       | Acetaminophen     |              |            | S           | Oral         | 1000 Mg, Qid       |                 | Not Reported |
|                       | Rocephin          |              |            | S           |              | 500 Mg, Tid        |                 | Not Reported |
|                       | Flagyl            |              |            | S           |              | 2000 Mg, Qd        |                 | Not Reported |
|                       | Xarelto           |              |            | S           |              | 10 Mg, Qd          |                 | Not Reported |
|                       | Amlodipine        |              |            | S           |              | 5 Mg, Qd           |                 | Not Reported |
|                       | Esomeprazole      |              |            | S           |              | 40 Mg, Qd          |                 | Not Reported |
|                       | Reminyl           |              |            | S           |              | 16 Mg, Qd          |                 | Not Reported |
|                       | Zolpidem Tartrate |              |            | S           |              | 5 Mg, Qd           |                 | Not Reported |
|                       | Cipralelex        |              |            | S           |              | 10 Mg, Qd          |                 | Not Reported |



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

|               |   |             |              |
|---------------|---|-------------|--------------|
| Calciparin    | C | Unk, Bid    | Not Reported |
| Omeprazole    | C | 20 Mg, Qd   | Not Reported |
| Ibuprofen     | C | 400 Mg, Prn | Not Reported |
| Calcimagon D3 | C | 500 Mg, Qd  | Not Reported |
| Prednisolone  | C | 10 Mg, Qd   | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------------|------------------|--------------------|-----------------|----------------------|-----------------------|-----------------|--------------|----------------|
| 03-Jan-2013              | 9000553              | DIRECT           | Y                  | OT              |                      |                       |                 | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Nausea; Vomiting         | Escitalopram Oxalate |                  |                    | S               | Oral                 | 10mg 1 Daily By Mouth |                 | Not Reported |                |

| <u>FDA Received Date</u>                                | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 04-Jan-2013                                             | 8916665        | EXPEDITED (15-DAY) |                    | CA              | BE-FRI-1000040473    |                      |                 | Unknown      | BEL            |
| <u>Preferred Term</u>                                   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Foetal Exposure During Pregnancy; Prader-Willi Syndrome | Escitalopram   |                    |                    | S               | Transplacental       | 10 Mg                |                 | Forest       |                |
|                                                         | Xanax Retard   |                    |                    | C               |                      | 0.5 Mg               |                 | Not Reported |                |
|                                                         | Rivotril       |                    |                    | C               |                      | 1 Mg                 |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 04-Jan-2013              | 8997385        | EXPEDITED (15-DAY) |                    | LT              | CH-FRI-1000041410    |                      |                 | Female       | CHE            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hepatocellular Injury    | Escitalopram   |                    |                    | S               |                      | 10 Mg                |                 | Forest       |                |
|                          | Zaldiar        |                    |                    | S               | Oral                 | 1300 Mg              |                 | Not Reported |                |
|                          | Paracetamol    |                    |                    | S               | Oral                 | 4000 Mg              |                 | Not Reported |                |
|                          | Rocephin       |                    |                    | S               |                      | 1500 Mg              |                 | Not Reported |                |
|                          | Flagyl         |                    |                    | S               |                      | 2000 Mg              |                 | Not Reported |                |
|                          | Xarelto        |                    |                    | S               |                      | 10 Mg                |                 | Not Reported |                |

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

|               |   |        |              |
|---------------|---|--------|--------------|
| Amlodipine    | S | 5 Mg   | Not Reported |
| Esomeprazole  | S | 40 Mg  | Not Reported |
| Reminyl       | S | 16 Mg  | Not Reported |
| Zolpidem      | S | 5 Mg   | Not Reported |
| Inegy         | S | 10 Mg  | Not Reported |
| Omeprazol     | C | 20 Mg  | Not Reported |
| Ibuprofen     | C |        | Not Reported |
| Calcimagon D3 | C | 500 Mg | Not Reported |
| Prednisolone  | C | 10 Mg  | Not Reported |
| Calciparin    | C |        | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 04-Jan-2013              | 8997592       | EXPEDITED (15-DAY) |                    | DE              | US-ASTRAZENECA-2013SE00362 |                      | 23 YR      | Female     | USA            |

| <u>Preferred Term</u>                            | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------|-----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide;<br>Toxicity To Various Agents | Quetiapine            |              |            | S           | Oral         |                    |                 | Zeneca       |
|                                                  | Escitalopram          |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Acetaminophen/Codeine |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Metaxalone            |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Jan-2013              | 9005158       | DIRECT           | Y                  | OT              |                      |                      | 61 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                    | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------|--------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Insomnia;<br>Lethargy; Mood Swings;<br>Product Substitution Issue;<br>Psychomotor Hyperactivity | Escitalopram 10 Mg |              |            | S           | Oral         | 1 Tab Qeve Po/047  |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Jan-2013              | 9005180       | DIRECT           |                    |                 |                      |                      | 33 YR      | Male       | USA            |

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

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                           | <u>Product</u>                           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                                   |                |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------|------------------|--------------------|------------------|----------------------|----------------------|-----------------|--------------------------------------------------------------|----------------|
| Blood Pressure Increased;<br>Condition Aggravated;<br>Drug Ineffective;<br>Dyspnoea; Malaise; Panic<br>Attack; Product<br>Substitution Issue                                                                                                                                                                                                                                                                                                                                    | Escitalopram                             |                  |                    | S                | Oral                 | 10 1 Po              |                 | Mylan                                                        |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <u>Case #</u>                            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                                   | <u>Country</u> |
| 07-Jan-2013                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 9005202                                  | DIRECT           | Y                  |                  |                      |                      | 58 YR           | Female                                                       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                           | <u>Product</u>                           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                                   |                |
| Anxiety; Tremor                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Escitalopram                             |                  |                    | S                |                      |                      |                 | Not Reported                                                 |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <u>Case #</u>                            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                                   | <u>Country</u> |
| 07-Jan-2013                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 9013252                                  | DIRECT           | Y                  | DS               |                      |                      | 16 YR           | Female                                                       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                           | <u>Product</u>                           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                                   |                |
| Akathisia; Anxiety;<br>Arthralgia; Back Pain;<br>Blood Pressure Increased;<br>Breast Disorder; Breast<br>Tenderness; Chills;<br>Decreased Appetite;<br>Diarrhoea; Disinhibition;<br>Disturbance In Attention;<br>Dizziness; Dyspepsia;<br>Eructation; Headache;<br>Hyperacusis;<br>Hyperaesthesia;<br>Hyperhidrosis;<br>Hypoaesthesia; Irritability;<br>Memory Impairment;<br>Mydriasis; Pain In<br>Extremity; Pain In<br>Extremity; Panic Attack;<br>Photophobia; Pollakiuria; | Lexapro<br>Medrol<br>Kenalog<br>Cymbalta |                  |                    | S<br>C<br>C<br>C | Oral                 |                      |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |                |

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

Tremor

| <a href="#">FDA Received Date</a>        | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>   | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|---------------------------------|--------------------------|---------------------|-------------------------|
| 07-Jan-2013                              | 9013403                 | DIRECT                    | Y                           |                          |                               |                                 | 62 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>           | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>     | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Agitation; Restlessness;<br>Tachyphrenia | Escitalopram            |                           |                             | S                        | Oral                          | Escitalopram 10mg Daily<br>(Po) |                          | Aurobindo           |                         |

| <a href="#">FDA Received Date</a>                                                                | <a href="#">Case #</a>                              | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a>                    | <a href="#">Country</a> |
|--------------------------------------------------------------------------------------------------|-----------------------------------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|----------------------------------------|-------------------------|
| 07-Jan-2013                                                                                      | 9132323                                             | EXPEDITED (15-DAY)        |                             | HO                       | ES-FRI-1000041409             |                               | 48 YR                    | Female                                 | ESP                     |
| <a href="#">Preferred Term</a>                                                                   | <a href="#">Product</a>                             | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a>                    |                         |
| Cardiac Arrest;<br>Cardiogenic Shock;<br>Hypokalaemia;<br>Hypomagnesaemia;<br>Torsade De Pointes | Escitalopram<br>Paracetamol<br>Lexatin (Bromazepam) |                           |                             | S<br>C<br>C              | Oral<br><br>Oral              | 20 Mg<br><br>9 Mg             |                          | Forest<br>Not Reported<br>Not Reported |                         |

| <a href="#">FDA Received Date</a>                   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a>          | <a href="#">Country</a> |
|-----------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|------------------------------|-------------------------|
| 07-Jan-2013                                         | 9500435                 | NON-EXPEDITED             | Y                           | OT                       | PHEH2012US017443              |                               | 47 YR                    | Female                       | USA                     |
| <a href="#">Preferred Term</a>                      | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a>          |                         |
| Lymphopenia; White<br>Blood Cell Count<br>Decreased | Gilenya<br>Lexapro      |                           |                             | S<br>S                   | Oral<br>Oral                  |                               |                          | Not Reported<br>Not Reported |                         |

| <a href="#">FDA Received Date</a>                                    | <a href="#">Case #</a>                                   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|----------------------------------------------------------------------|----------------------------------------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 08-Jan-2013                                                          | 8942866                                                  | EXPEDITED (15-DAY)        |                             | HO, OT                   | IT-FRI-1000040748             |                               | 51 YR                    | Female              | ITA                     |
| <a href="#">Preferred Term</a>                                       | <a href="#">Product</a>                                  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Depressed Level Of<br>Consciousness; Incorrect<br>Dose Administered; | Escitalopram Oral Solution<br>Escitalopram Oral Solution |                           |                             | S<br>S                   | Oral<br>Oral                  | 8 Gtt                         |                          | Forest<br>Forest    |                         |

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

|                 |                   |   |              |
|-----------------|-------------------|---|--------------|
| Overdose; Sopor | Tolep             | C | Not Reported |
|                 | Lyrica            | C | Not Reported |
|                 | Tavor (Lorazepam) | C | Not Reported |
|                 | Questran          | C | Not Reported |
|                 | Eutirox           | C | Not Reported |
|                 | Metformine        | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Jan-2013              | 9002831       | EXPEDITED (15-DAY) |                    | DE              | US-BAYER-2013-002223 |                      | 64 YR      | Female     | USA            |

| <u>Preferred Term</u>                            | <u>Product</u>               | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------|------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide;<br>Toxicity To Various Agents | Naproxen Sodium (<= 220 Mg)  |              |            | S           | Oral         |                    |                 | Bayer        |
|                                                  | Ciprofloxacin                |              |            | S           |              |                    |                 | Bayer        |
|                                                  | Desipramine                  |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Diltiazem Er                 |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Venlafaxine                  |              |            | S           |              |                    |                 | Not Reported |
|                                                  | Lamotrigine                  |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Hydrochlorothiazide          |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Armodafinil                  |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Potassium Chloride           |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Trifluoperazine              |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Escitalopram                 |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Thyroid Preparations         |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Pantoprazole                 |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Lansoprazole                 |              |            | S           |              |                    |                 | Not Reported |
|                                                  | Rosuvastatin                 |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Nitrofurantoin               |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Diclofenac                   |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Acetaminophen W/Hydrocodone  |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Acetaminophen W/Propoxyphene |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Solifenacin                  |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Progestine                   |              |            | S           | Oral         |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 08-Jan-2013              | 9003045       | EXPEDITED (15-DAY) |                    | DE              | US-ASTRAZENECA-2013SE00924 |                      | 64 YR      | Female     | USA            |

| <u>Preferred Term</u>                            | <u>Product</u>             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------|----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide;<br>Toxicity To Various Agents | Rosuvastatin               |              |            | S           | Oral         |                    |                 | Astrazeneca  |
|                                                  | Escitalopram               |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Venlafaxine                |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Potassium Chloride         |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Hydrochlorothiazide        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Acetaminophen Hydrocodone  |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Desipramine                |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Diltiazem                  |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Lamotrigine                |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Armodafinil                |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Trifluoperazine            |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Acetaminophen\Propoxyphene |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Thyroid Preparations       |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Pantoprazole               |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Lansoprazole               |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Naproxen                   |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Nitrofurantoin             |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Diclofenac                 |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Solifenacin                |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Ciprofloxacin              |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Progestin (Progesterone)   |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Jan-2013              | 9003454       | EXPEDITED (15-DAY) |                    | HO, OT          | PHEH2013US000499     |                      |            | Female     | USA            |

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

| <u>Preferred Term</u>                                                                                                                  | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
|----------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|-----------------|----------------|
| Anxiety; Cough; Depression; Dizziness; Fatigue; Feeling Abnormal; Heart Rate Decreased; Hyperhidrosis; Mental Impairment; Palpitations | Diovan                        |                    |                    | S               | Oral                         | 160 Mg, Qd           |                 | Novartis        |                |
|                                                                                                                                        | Losartan                      |                    |                    | S               | Oral                         | 100 Mg, Qd           |                 | Not Reported    |                |
|                                                                                                                                        | Escitalopram                  |                    |                    | S               |                              | 10 Mg, Qd            |                 | Not Reported    |                |
|                                                                                                                                        | Alprazolam Er                 |                    |                    | S               |                              | 1 Mg, Prn            |                 | Not Reported    |                |
|                                                                                                                                        | Accupril                      |                    |                    | S               | Oral                         | 20 Mg, Qd            |                 | Not Reported    |                |
|                                                                                                                                        | Metformin                     |                    |                    | C               | Oral                         | 1000 Mg, Qd          |                 | Not Reported    |                |
|                                                                                                                                        | Pravastatin                   |                    |                    | C               |                              | 20 Mg, Qd            |                 | Not Reported    |                |
|                                                                                                                                        | Zoloft                        |                    |                    | C               |                              | Unk Ukn, Unk         |                 | Not Reported    |                |
|                                                                                                                                        | Byetta                        |                    |                    | C               |                              | Unk Ukn, Unk         |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                               | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 08-Jan-2013                                                                                                                            | 9003663                       | NON-EXPEDITED      |                    |                 | US-GLAXOSMITHKLINE-A0957113A |                      | 76 YR           | Male            | USA            |
| <u>Preferred Term</u>                                                                                                                  | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Ageusia; Erectile Dysfunction; Taste Disorder                                                                                          | Lovaza                        |                    |                    | S               | Oral                         | 4cap Per Day         |                 | Glaxosmithkline |                |
|                                                                                                                                        | Lexapro                       |                    |                    | S               | Oral                         | 1tab Per Day         |                 | Not Reported    |                |
|                                                                                                                                        | Androgel                      |                    |                    | C               |                              |                      |                 | Not Reported    |                |
|                                                                                                                                        | Zocor                         |                    |                    | C               |                              |                      |                 | Glaxosmithkline |                |
|                                                                                                                                        | Hyzaar                        |                    |                    | C               |                              |                      |                 | Not Reported    |                |
|                                                                                                                                        | Niacin                        |                    |                    | C               |                              |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                               | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 08-Jan-2013                                                                                                                            | 9003947                       | EXPEDITED (15-DAY) |                    | DE              | US-BAYER-2013-001611         |                      | 57 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                                                                                  | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Toxicity To Various Agents                                                                                                             | Diphenhydramine Hydrochloride |                    | Y                  | S               |                              |                      |                 | Bayer           |                |
|                                                                                                                                        | Lamotrigine                   |                    |                    | S               |                              |                      |                 | Not Reported    |                |
|                                                                                                                                        | Escitalopram                  |                    |                    | S               |                              |                      |                 | Not Reported    |                |
|                                                                                                                                        | Aripiprazole                  |                    |                    | S               |                              |                      |                 | Not Reported    |                |

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

| <u>FDA Received Date</u>                                                          | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------|--------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 08-Jan-2013                                                                       | 9011495                        | EXPEDITED (15-DAY) |                    | DE              | 2013SP000020         |                      | 65 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                             | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                                                 | Eszopiclone                    |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                   | Metoprolol                     |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                   | All Other Therapeutic Products |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                   | Gabapentin                     |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                   | Quetiapine                     |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                   | Escitalopram                   |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                   | Acetaminophen W/Codeine        |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                   | Benzodiazepine                 |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                   | Simvastatin                    |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                          | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Jan-2013                                                                       | 9013766                        | DIRECT             | Y                  | OT              |                      |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                             | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Apathy; Condition Aggravated; Depression; Dizziness; Dizziness; Mental Impairment | Escitalopram                   |                    |                    | S               | Oral                 | 20 Mg Tab 1.5 Qd Po  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                          | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Jan-2013                                                                       | 9032414                        | EXPEDITED (15-DAY) | Y                  | HO, LT          | DSA_61675_2013       |                      | 90 YR           | Female       | CHE            |
| <u>Preferred Term</u>                                                             | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain; Acute                                                             | Flagyl                         |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Hepatic Failure;                                                                  | Zolpidem                       |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Diarrhoea; Diverticulitis;                                                        | Zaldiar                        |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
| Heparin-Induced Thrombocytopenia;                                                 | Paracetamol (Paracetamol)      |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
| Hepatocellular Injury;                                                            | Rocephin                       |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Pyrexia                                                                           | Xarelto                        |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                   | Amlodipine (Amlodipine)        |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                   | Esomeprazole (Esomeprazole)    |                    |                    | S               |                      |                      |                 | Not Reported |                |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|               |   |              |
|---------------|---|--------------|
| Reminyl       | S | Not Reported |
| Inegy         | S | Not Reported |
| Cipralex      | S | Not Reported |
| Calciparin    | C | Not Reported |
| Omeprazole    | C | Not Reported |
| Ibuprofen     | C | Not Reported |
| Calcimagon-D3 | C | Not Reported |
| Prednisolone  | C | Not Reported |
| Asa           | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Jan-2013              | 9157403       | DIRECT           | Y                  |                 |                      |                      | 23 YR      | Female     | USA            |

| <u>Preferred Term</u>                    | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------|-------------------|--------------|------------|-------------|--------------|---------------------|-----------------|--------------|
| Panic Attack; Product Substitution Issue | Escitalopram 20mg |              |            | S           | Oral         | 20mg Daily By Mouth |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Jan-2013              | 8993276       | EXPEDITED (15-DAY) |                    | HO              | IT-FRI-1000041325    |                      | 29 YR      | Female     | ITA            |

| <u>Preferred Term</u>                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Abuse; Intentional Self-Injury; Overdose | Escitalopram   |              |            | S           | Oral         |                    |                 | Forest       |
|                                               | Trittico       |              |            | S           | Oral         |                    |                 | Not Reported |
|                                               | Tegretol       |              |            | S           | Oral         |                    |                 | Not Reported |
|                                               | Rivotril       |              |            | S           | Oral         |                    |                 | Not Reported |
|                                               | Zyprexa        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                               | Dulcolax       |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 09-Jan-2013              | 9005570       | EXPEDITED (15-DAY) |                    | DE              | US-PFIZER INC-2013005790 |                      | 62 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Completed Suicide     | Verapamil Hcl  |              |            | S           |              | Unk                |                 | Pfizer     |

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

|                                                       |                           |                    |                    |                 |                            |                      |                 |              |                |
|-------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| Escitalopram                                          |                           |                    | S                  |                 |                            | Not Reported         |                 |              |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Jan-2013                                           | 9005955                   | EXPEDITED (15-DAY) |                    | DE              | US-PFIZER INC-2013006721   |                      | 54 YR           | Female       | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Completed Suicide; Respiratory Arrest | Gabapentin                |                    |                    | S               |                            |                      |                 | Pfizer       |                |
|                                                       | Quetiapine                |                    |                    | S               |                            |                      |                 | Not Reported |                |
|                                                       | Escitalopram              |                    |                    | S               |                            |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Jan-2013                                           | 9010483                   | EXPEDITED (15-DAY) |                    | DE              | US-ASTRAZENECA-2013SE01317 |                      | 63 YR           | Male         | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Toxicity To Various Agents         | Metoprolol                |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                       | Quetiapine                |                    |                    | S               | Oral                       |                      |                 | Zeneca       |                |
|                                                       | Escitalopram              |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                       | Unspecified Ingredient    |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                       | Acetaminophen And Codeine |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                       | Benzodiazepine            |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                       | Eszopiclone               |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                       | Simvastatin               |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                       | Gabapentin                |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Jan-2013                                           | 9010555                   | EXPEDITED (15-DAY) |                    | DE              | US-PFIZER INC-2013004575   |                      | 52 YR           | Female       | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                     | Oxycodone Hydrochloride   |                    |                    | S               |                            | Unk                  |                 | Pfizer       |                |
|                                                       | Acetaminophen             |                    |                    | S               |                            | Unk                  |                 | Not Reported |                |
|                                                       | Escitalopram              |                    |                    | S               |                            | Unk                  |                 | Not Reported |                |

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

| <u>FDA Received Date</u>            | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------|-------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 09-Jan-2013                         | 9011178                 | EXPEDITED (15-DAY) |                    | DE              | US-PFIZER INC-2013007454 |                      | 23 YR           | Female       | USA            |
| <u>Preferred Term</u>               | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                   | Metaxalone              |                    |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                                     | Escitalopram            |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                                     | Quetiapine              |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                                     | Acetaminophen W/Codeine |                    |                    | S               |                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>            | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Jan-2013                         | 9011197                 | EXPEDITED (15-DAY) |                    | DE              | US-PFIZER INC-2013006081 |                      | 65 YR           | Male         | USA            |
| <u>Preferred Term</u>               | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                   | Gabapentin              |                    |                    | S               |                          |                      |                 | Pfizer       |                |
|                                     | Metoprolol              |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                     | Quetiapine              |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                     | Escitalopram            |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                     | Acetaminophen W/Codeine |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                     | Eszopiclone             |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                     | Simvastatin             |                    |                    | S               |                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>            | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Jan-2013                         | 8984956                 | EXPEDITED (15-DAY) |                    | HO              | PHHY2012IT118492         |                      |                 | Female       | ITA            |
| <u>Preferred Term</u>               | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Abuse; Intentional Self-Injury | Tegretol                |                    |                    | S               | Oral                     | 10 Df, Unk           |                 | Novartis     |                |
|                                     | Trittico                |                    |                    | S               | Oral                     | 10 Df, Unk           |                 | Not Reported |                |
|                                     | Dulcolax                |                    |                    | S               | Oral                     | 5 Df, Unk            |                 | Not Reported |                |
|                                     | Rivotril                |                    |                    | S               | Oral                     | 10 Df, Unk           |                 | Not Reported |                |
|                                     | Zyprexa                 |                    |                    | S               | Oral                     | 2 Df, Unk            |                 | Not Reported |                |
|                                     | Ciprallex               |                    |                    | S               | Oral                     | 10 Df, Unk           |                 | Not Reported |                |

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

| <u>FDA Received Date</u>                         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| 10-Jan-2013                                      | 9006679        | EXPEDITED (15-DAY) |                    | DE              | US-PFIZER INC-2013005800   |                      | 46 YR           | Female       | USA            |
| <u>Preferred Term</u>                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                | Verapamil Hcl  |                    |                    | S               | Oral                       |                      |                 | Pfizer       |                |
|                                                  | Amitriptyline  |                    |                    | S               |                            | Unk                  |                 | Not Reported |                |
|                                                  | Escitalopram   |                    |                    | S               |                            |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Jan-2013                                      | 9006879        | EXPEDITED (15-DAY) |                    | DE              | US-ASTRAZENECA-2013SE01329 |                      | 18 YR           | Male         | USA            |
| <u>Preferred Term</u>                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Toxicity To Various Agents                       | Quetiapine     |                    |                    | S               | Oral                       |                      |                 | Zeneca       |                |
|                                                  | Escitalopram   |                    |                    | S               |                            |                      |                 | Not Reported |                |
|                                                  | Chlorpromazine |                    |                    | S               |                            |                      |                 | Not Reported |                |
|                                                  | Valproic Acid  |                    |                    | S               |                            |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Jan-2013                                      | 9006923        | EXPEDITED (15-DAY) |                    | DE              | US-ASTRAZENECA-2013SE01748 |                      | 55 YR           | Male         | USA            |
| <u>Preferred Term</u>                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Toxicity To Various Agents | Lisinopril     |                    |                    | S               | Oral                       |                      |                 | Zeneca       |                |
|                                                  | Quetiapine     |                    |                    | S               |                            |                      |                 | Not Reported |                |
|                                                  | Escitalopram   |                    |                    | S               |                            |                      |                 | Not Reported |                |
|                                                  | Trazodone      |                    |                    | S               |                            |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Jan-2013                                      | 9006924        | EXPEDITED (15-DAY) |                    | DE              | US-ASTRAZENECA-2013SE01709 |                      | 54 YR           | Female       | USA            |
| <u>Preferred Term</u>                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

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

|                            |              |   |      |              |
|----------------------------|--------------|---|------|--------------|
| Cardio-Respiratory Arrest; | Quetiapine   | S | Oral | Zeneca       |
| Completed Suicide;         | Escitalopram | S | Oral | Not Reported |
| Toxicity To Various Agents | Gabapentin   | S | Oral | Not Reported |

| <u>FDA Received Date</u>                         | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------|-----------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| 10-Jan-2013                                      | 9009591         | EXPEDITED (15-DAY) |                    | DE              | US-ASTRAZENECA-2013SE01642 |                      | 42 YR           | Female       | USA            |
| <u>Preferred Term</u>                            | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Toxicity To Various Agents | Quetiapine      |                    |                    | S               | Oral                       |                      |                 | Zeneca       |                |
|                                                  | Escitalopram    |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                  | Hydroxyzine     |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                  | Citalopram      |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                  | Buspirone       |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                  | Cyclobenzaprine |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                  | Levothyroxine   |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 10-Jan-2013              | 9009738        | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000041471    |                      |                 | Female     | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Cleft Lip And Palate     | Lexapro        |                    |                    | S               | Transplacental       |                      |                 | Forest     |                |

| <u>FDA Received Date</u>                                                                                | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 10-Jan-2013                                                                                             | 9009957        | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000028948    |                      | < 1 DAY         | Male       | USA            |
| <u>Preferred Term</u>                                                                                   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Bicuspid Aortic Valve;<br>Congenital Anomaly;<br>Patent Ductus Arteriosus;<br>Ventricular Septal Defect | Lexapro        |                    |                    | S               | Transplacental       |                      |                 | Forest     |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                              | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|------------------------------|--------------------------------------------------|-----------------|--------------|----------------|
| 10-Jan-2013                                                                                                                                                                                           | 9009973                 | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000041469            |                                                  | < 1 DAY         | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                 | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                               | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrial Septal Defect;<br>Congenital Anomaly; Limb<br>Reduction Defect; Patent<br>Ductus Arteriosus;<br>Ventricular Septal Defect                                                                      | Lexapro                 |                    |                    | S               | Transplacental               |                                                  |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                                                                                              | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Jan-2013                                                                                                                                                                                           | 8926768                 | EXPEDITED (15-DAY) |                    | OT              | BR-PFIZER INC-<br>2012294611 |                                                  | 48 YR           | Female       | BRA            |
| <u>Preferred Term</u>                                                                                                                                                                                 | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                               | <u>Duration</u> | <u>Mfr</u>   |                |
| Amnesia; Asphyxia; Chest<br>Pain; Confusional State;<br>Dyspnoea; Feeling<br>Abnormal; Feeling<br>Abnormal; Heart Rate<br>Increased; Mania; Panic<br>Disorder; Suicidal<br>Ideation; Uterine Disorder | Efexor Xr               |                    |                    | S               | Oral                         | 1 Capsule (75 Mg), 1x/Day                        |                 | Pfizer       |                |
|                                                                                                                                                                                                       | Efexor Xr               |                    |                    | S               |                              | 1 Capsule (75 Mg), 2x/Day                        |                 | Pfizer       |                |
|                                                                                                                                                                                                       | Efexor Xr               |                    |                    | S               |                              | 1 Capsule (75mg) And 1<br>Capsule (37.5mg) A Day |                 | Pfizer       |                |
|                                                                                                                                                                                                       | Efexor Xr               |                    |                    | S               | Oral                         | 37.5 Mg, Unk                                     |                 | Pfizer       |                |
|                                                                                                                                                                                                       | Citalopram              |                    |                    | S               |                              | Unk                                              |                 | Not Reported |                |
|                                                                                                                                                                                                       | Lexapro                 |                    |                    | S               |                              | Half Tablet Of 10mg<br>(5mg), 1x/Day             |                 | Not Reported |                |
|                                                                                                                                                                                                       | Stilnox                 |                    |                    | C               |                              | Unk                                              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                              | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Jan-2013                                                                                                                                                                                           | 9008345                 | NON-EXPEDITED      |                    |                 | US-PFIZER INC-<br>2013011779 |                                                  |                 | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                 | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                               | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety                                                                                                                                                                                               | Lyrica                  |                    |                    | S               |                              | 50 Mg, 2x/Day                                    |                 | Pfizer       |                |
|                                                                                                                                                                                                       | Lyrica                  |                    |                    | S               |                              | 100 Mg, 2x/Day                                   |                 | Pfizer       |                |
|                                                                                                                                                                                                       | Oxycodone Hydrochloride |                    |                    | S               |                              | Unk                                              |                 | Pfizer       |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| Lexapro                                                  |                               |                    | S                  |                 |                                                 | Unk                  |                 |              | Not Reported   |
|----------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|--------------|----------------|
| <u>FDA Received Date</u>                                 | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Jan-2013                                              | 9008360                       | EXPEDITED (15-DAY) |                    | DE              | US-PAR<br>PHARMACEUTICAL,<br>INC-2013SCPR004884 |                      | 46 YR           | Male         | USA            |
| <u>Preferred Term</u>                                    | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Death                                 | Ibuprofen                     |                    |                    | S               | Oral                                            | Unk, Unknown         |                 | Par          |                |
|                                                          | Valproic Acid                 |                    |                    | S               | Oral                                            | Unk, Unknown         |                 | Not Reported |                |
|                                                          | Hydroxyzine                   |                    |                    | S               | Oral                                            | Unk, Unknown         |                 | Not Reported |                |
|                                                          | Cyclobenzaprine               |                    |                    | S               | Oral                                            | Unk, Unknown         |                 | Not Reported |                |
|                                                          | Escitalopram                  |                    |                    | S               | Oral                                            | Unk, Unknown         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                 | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Jan-2013                                              | 9008557                       | EXPEDITED (15-DAY) |                    | DE              | US-PFIZER INC-<br>2013007075                    |                      | 66 YR           | Female       | USA            |
| <u>Preferred Term</u>                                    | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Completed<br>Suicide; Respiratory Arrest | Oxycodone Hydrochloride       |                    |                    | S               |                                                 |                      |                 | Pfizer       |                |
|                                                          | Triazolam                     |                    |                    | S               |                                                 |                      |                 | Pfizer       |                |
|                                                          | Lithium                       |                    |                    | S               |                                                 |                      |                 | Not Reported |                |
|                                                          | Escitalopram                  |                    |                    | S               |                                                 |                      |                 | Not Reported |                |
|                                                          | Methylphenidate Hydrochloride |                    |                    | S               |                                                 | Unk                  |                 | Not Reported |                |
|                                                          | Aripiprazole                  |                    |                    | S               |                                                 |                      |                 | Not Reported |                |
|                                                          | Simvastatin                   |                    |                    | S               |                                                 |                      |                 | Not Reported |                |
|                                                          | Valaciclovir                  |                    |                    | S               |                                                 | Unk                  |                 | Not Reported |                |
|                                                          | Propoxyphene                  |                    |                    | S               |                                                 |                      |                 | Not Reported |                |
|                                                          | Hydrocodone                   |                    |                    | S               |                                                 |                      |                 | Not Reported |                |
|                                                          | Acetaminophen                 |                    |                    | S               |                                                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                 | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Jan-2013                                              | 9009057                       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000041551                               |                      | 80 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                    | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

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

|                                                                  |                                   |   |      |        |              |
|------------------------------------------------------------------|-----------------------------------|---|------|--------|--------------|
| Confusional State; Drug Interaction; Hypokalaemia; Hyponatraemia | Escitalopram                      | S | Oral | 5 Mg   | Forest       |
|                                                                  | Omeprazole                        | S | Oral | 20 Mg  | Not Reported |
|                                                                  | Hytacand                          | S | Oral | 1 Df   | Not Reported |
|                                                                  | Loxen (Nicardipine Hydrochloride) | C |      | 100 Mg | Not Reported |
|                                                                  | Tenormine                         | C |      | 100 Mg | Not Reported |
|                                                                  | Simvastatin                       | C |      | 20 Mg  | Not Reported |
|                                                                  | Gliclazide                        | C |      | 1 Df   | Not Reported |
|                                                                  | Seresta                           | C |      |        | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Jan-2013              | 9018186       | DIRECT           |                    | OT              |                      |                      | 48 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                         | <u>Product</u>  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------|-----------------|--------------|------------|-------------|--------------|---------------------|-----------------|--------------|
| Anxiety; Depression; Dizziness; Product Substitution Issue; Suicidal Ideation | Ic-Escitalopram |              |            | S           | Oral         | 10 Mg Once Daily Po |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Jan-2013              | 9018208       | DIRECT           | Y                  | RI              |                      |                      | 69 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|------------------------|-----------------|--------------|
| Abdominal Discomfort; Depressed Mood; Disease Recurrence; Insomnia; Loss Of Personal Independence In Daily Activities; Palpitations; Panic Attack; Product Substitution Issue; Visual Impairment | Lexapro        |              |            | S           | Oral         | 20mg 1/2 Tab. A Day Po | 2 MTH           | Not Reported |
|                                                                                                                                                                                                  | Escitalopram   |              |            | C           |              |                        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Jan-2013              | 9034378       | EXPEDITED (15-DAY) | Y                  | DE, HO, OT      | 2013P1000002         |                      | 72 YR      | Female     | GRC            |



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

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                | <u>Product</u>                                                                                                                                                                                                                                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                                                        | <u>Route</u>                                                                                                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                                                                                                                                                                                                   |                |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|--------------------|--------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------|----------------------|-----------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|
| Acute Kidney Injury; Acute<br>Respiratory Distress<br>Syndrome; Cardio-<br>Respiratory Arrest;<br>Depressed Level Of<br>Consciousness; Drug<br>Interaction;<br>Haemodialysis;<br>Hyperpyrexia;<br>Leukocytosis; Muscle<br>Rigidity; Neurotoxicity;<br>Pyrexia; Rhabdomyolysis;<br>Stupor; Tachypnoea | Lithium<br>Amlodipine<br>Escitalopram<br>Buspirone<br>Irbesartan                                                                                                                                                                                    |                    |                    | S<br>S<br>S<br>S<br>S                                              |                                                                                                              |                      |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported                                                                                                                                                 |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                             | <u>Case #</u>                                                                                                                                                                                                                                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>                                                    | <u>Mfr Control #</u>                                                                                         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                                                                                                                                                                                                   | <u>Country</u> |
| 14-Jan-2013                                                                                                                                                                                                                                                                                          | 9011963                                                                                                                                                                                                                                             | EXPEDITED (15-DAY) |                    | DE, HO, OT                                                         | US-UCBSA-074782                                                                                              |                      | 64 YR           | Female                                                                                                                                                                                                                       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                | <u>Product</u>                                                                                                                                                                                                                                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                                                        | <u>Route</u>                                                                                                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                                                                                                                                                                                                   |                |
| Completed Suicide                                                                                                                                                                                                                                                                                    | Pantoprazole Sodium<br>Acetaminophen\Hydrocodone<br>Desipramine<br>Diltiazem<br>Venlafaxine<br>Lamotrigine<br>Hydrochlorothiazide<br>Armodafinil<br>Potassium Chloride<br>Trifluoperazine<br>Escitalopram<br>Lansoprazole<br>Rovustatin<br>Naproxen |                    |                    | S<br>S<br>S<br>S<br>S<br>S<br>S<br>S<br>S<br>S<br>S<br>S<br>S<br>S | Oral<br>Oral<br>Oral<br>Oral<br>Oral<br>Oral<br>Oral<br>Oral<br>Oral<br>Oral<br>Oral<br>Oral<br>Oral<br>Oral | Extended Release     |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |                |

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

|                            |   |      |              |
|----------------------------|---|------|--------------|
| Nitrofurantoin             | S | Oral | Not Reported |
| Diclofenac                 | S | Oral | Not Reported |
| Acetaminophen/Propoxyphene | S | Oral | Not Reported |
| Solifenacin                | S | Oral | Not Reported |
| Ciprofloxacin              | S | Oral | Not Reported |
| Progestine                 | S | Oral | Not Reported |

| <u>FDA Received Date</u>                                                      | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------|-----------------------------------|--------------------|--------------------|-----------------|----------------------------|-------------------------|-----------------|--------------|----------------|
| 14-Jan-2013                                                                   | 9012666                           | EXPEDITED (15-DAY) |                    | HO              | FR-ASTRAZENECA-2013SE00789 |                         | 80 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                         | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State;<br>Hypokalaemia;<br>Hyponatraemia;<br>Polydipsia; Vomiting | Hytacand                          |                    |                    | S               | Oral                       | 16/12.5 Mg/D, 1df Daily |                 | Astrazeneca  |                |
|                                                                               | Omeprazole                        |                    |                    | S               | Oral                       |                         |                 | Not Reported |                |
|                                                                               | Seroplex                          |                    |                    | S               | Oral                       |                         |                 | Not Reported |                |
|                                                                               | Loxen (Nicardipine Hydrochloride) |                    |                    | C               | Oral                       |                         |                 | Not Reported |                |
|                                                                               | Tenormine                         |                    |                    | C               | Oral                       |                         |                 | Not Reported |                |
|                                                                               | Simvastatine                      |                    |                    | C               | Oral                       |                         |                 | Not Reported |                |
|                                                                               | Gliclazide                        |                    |                    | C               | Oral                       |                         |                 | Not Reported |                |
|                                                                               | Seresta                           |                    |                    | C               | Oral                       |                         |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                          | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 14-Jan-2013                                                                                                                                       | 9012900        | EXPEDITED (15-DAY) |                    | OT              | US-FRI-1000041546    |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                             | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Atypical<br>Pneumonia; Crying;<br>Dizziness; Gait<br>Disturbance; Gastritis;<br>Headache; Paraesthesia;<br>Wrong Product<br>Administered | Escitalopram   |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                                                                                                                                   | Escitalopram   |                    |                    | S               | Oral                 | 10 Mg                |                 | Not Reported |                |
|                                                                                                                                                   | Evista         |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                   | Synthroid      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                   | Celebrex       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                   | Remicade       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                   | Sulfasalazine  |                    |                    | C               |                      |                      |                 | Not Reported |                |

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

|  |                     |   |  |              |
|--|---------------------|---|--|--------------|
|  | Simvastatin         | C |  | Not Reported |
|  | Diovan              | C |  | Not Reported |
|  | Toprol XL           | C |  | Not Reported |
|  | Hydrochlorothiazide | C |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 14-Jan-2013              | 9013046       | EXPEDITED (15-DAY) |                    | OT              | US-009507513-1301USA001994 |                      |            | Male       | USA            |

| <u>Preferred Term</u>                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Apraxia; Foetal Exposure During Pregnancy | Singulair      |              |            | S           |              |                    |                 | Merck        |
|                                           | Ibuprofen      |              |            | S           |              |                    |                 | Not Reported |
|                                           | Folsan         |              |            | S           |              |                    |                 | Not Reported |
|                                           | Presinol       |              |            | S           |              |                    |                 | Not Reported |
|                                           | Symbicort      |              |            | S           |              |                    |                 | Not Reported |
|                                           | Berotec        |              |            | S           |              |                    |                 | Not Reported |
|                                           | Thyronajod     |              |            | S           |              |                    |                 | Not Reported |
|                                           | Ciprallex      |              |            | S           |              |                    |                 | Not Reported |
|                                           | Topamax        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 14-Jan-2013              | 9013047       | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2013011896 |                      | 64 YR      | Male       | USA            |

| <u>Preferred Term</u>                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Burning Sensation; Insomnia | Lyrica         |              |            | S           | Oral         | 50 Mg, 2x/Day      |                 | Pfizer       |
|                                      | Lyrica         |              |            | S           | Oral         | 50 Mg, 2x/Day      |                 | Pfizer       |
|                                      | Lyrica         |              |            | S           | Oral         | 100 Mg, 2x/Day     |                 | Pfizer       |
|                                      | Lexapro        |              |            | S           |              | 10 Mg, Daily       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Jan-2013              | 9122062       | EXPEDITED (15-DAY) |                    | OT              | GB-FRI-1000041593    |                      | 24 YR      | Female     | GBR            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Infertility Female    | Escitalopram   |              |            | S           | Oral         | 20 Mg              |                 | Forest       |
|                       | Ramipril       |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Jan-2013              | 8949339       | EXPEDITED (15-DAY) |                    | DE              | PHHY2012DE112191     |                      | 87 YR      | Male       | DEU            |

| <u>Preferred Term</u>                                                                                                                                                | <u>Product</u>                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Loss Anaemia;<br>Chest Pain; Dyspnoea;<br>Faeces Discoloured;<br>Gastrointestinal<br>Haemorrhage; Myocardial<br>Infarction; Pallor;<br>Ventricular Hypokinesia | Acetylsalicylic Acid           |              |            | S           |              | 100 Mg, Per Day    |                 | Not Reported |
|                                                                                                                                                                      | Escitalopram                   |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                      | Citalopram                     |              |            | S           |              | 20 Mg, Per Day     |                 | Novartis     |
|                                                                                                                                                                      | Olanzapine                     |              |            | C           |              | 5 Mg, Unk          |                 | Not Reported |
|                                                                                                                                                                      | Zopiclone                      |              |            | C           |              | 7.5 Mg, Unk        |                 | Not Reported |
|                                                                                                                                                                      | Nitrendipine                   |              |            | C           |              | 20 Mg, Unk         |                 | Not Reported |
|                                                                                                                                                                      | Bisoprolol                     |              |            | C           |              | 5 Mg, Unk          |                 | Not Reported |
|                                                                                                                                                                      | Lisinopril/Hydrochlorothiazide |              |            | C           |              | 20/12.5 Mg Per Day |                 | Not Reported |
|                                                                                                                                                                      | Buprenorphine                  |              |            | C           |              | 20 Ug/Hr, Unk      |                 | Not Reported |
|                                                                                                                                                                      | Vitamin B12                    |              |            | C           |              | 1000 Ug, Weekly    |                 | Not Reported |
|                                                                                                                                                                      | Pregabalin                     |              |            | C           |              | 150 Mg, Unk        |                 | Not Reported |
|                                                                                                                                                                      | Lactulose                      |              |            | C           |              | 10 MI, Unk         |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 15-Jan-2013              | 9014427       | EXPEDITED (15-DAY) |                    | DE              | US-JNJFOC-20130104870 |                      | 48 YR      | Female     | USA            |

| <u>Preferred Term</u>                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide;<br>Toxicity To Various Agents | Risperidone    |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Propranolol    |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Oxycodone      |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Trazodone      |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Clonazepam     |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Hydroxyzine    |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Temazepam      |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Benztrapine    |              |            | S           | Oral         |                    |                 | Not Reported |

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

|                                                                                                                                                                                                                     |                                                                           | Escitalopram       |                    | S               | Oral                 |                      |                 | Not Reported      |                |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|-------------------|----------------|
|                                                                                                                                                                                                                     |                                                                           | Ondansetron        |                    | S               | Oral                 |                      |                 | Not Reported      |                |
| <u>FDA Received Date</u>                                                                                                                                                                                            | <u>Case #</u>                                                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>        | <u>Country</u> |
| 15-Jan-2013                                                                                                                                                                                                         | 9015716                                                                   | EXPEDITED (15-DAY) | Y                  | OT              | 20120779             |                      | 32 YR           | Female            | CHE            |
| <u>Preferred Term</u>                                                                                                                                                                                               | <u>Product</u>                                                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>        |                |
| Abortion Early; Exposure During Pregnancy                                                                                                                                                                           | Venofer                                                                   |                    |                    | S               | Intravenous drip     | 4 In 1 Total         |                 | Not Reported      |                |
|                                                                                                                                                                                                                     | Cipralext                                                                 |                    |                    | S               |                      |                      |                 | Not Reported      |                |
|                                                                                                                                                                                                                     | Unspecified Medication                                                    |                    |                    | S               |                      |                      |                 | Not Reported      |                |
| <u>FDA Received Date</u>                                                                                                                                                                                            | <u>Case #</u>                                                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>        | <u>Country</u> |
| 15-Jan-2013                                                                                                                                                                                                         | 9034961                                                                   | EXPEDITED (15-DAY) | Y                  | HO, LT          | 2013-00048           |                      | 25 YR           | Female            | CAN            |
| <u>Preferred Term</u>                                                                                                                                                                                               | <u>Product</u>                                                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>        |                |
| Cardiotoxicity; Coma; Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Hypocalcaemia; Hypokalaemia; Hypotension; Intentional Overdose; Overdose; Pulse Absent; Suicide Attempt; Tachycardia | Fluoxetine Hydrochloride (Unknown) (Fluoxetine Hydrochloride) Unk, Unkunk |                    |                    | S               |                      |                      |                 | Not Reported      |                |
|                                                                                                                                                                                                                     | Olanzapine                                                                |                    |                    | S               |                      |                      |                 | Not Reported      |                |
|                                                                                                                                                                                                                     | Quetiapine Fumarate                                                       |                    |                    | S               |                      |                      |                 | Not Reported      |                |
|                                                                                                                                                                                                                     | Gabapentin                                                                |                    |                    | S               |                      |                      |                 | Not Reported      |                |
|                                                                                                                                                                                                                     | Escitalopram (Escitalopram)                                               |                    |                    | S               |                      |                      |                 | Not Reported      |                |
|                                                                                                                                                                                                                     | Amitriptyline (Amitriptyline)                                             |                    |                    | S               |                      |                      |                 | Not Reported      |                |
|                                                                                                                                                                                                                     |                                                                           |                    |                    |                 |                      |                      |                 |                   |                |
| <u>FDA Received Date</u>                                                                                                                                                                                            | <u>Case #</u>                                                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>        | <u>Country</u> |
| 16-Jan-2013                                                                                                                                                                                                         | 7868619                                                                   | EXPEDITED (15-DAY) |                    | OT              | US-RB-024190-11      |                      | 38 YR           | Female            | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                               | <u>Product</u>                                                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>        |                |
| Abortion Spontaneous; Exposure During Pregnancy                                                                                                                                                                     | Suboxone Tablet                                                           |                    |                    | S               | Sublingual           |                      |                 | Reckitt Benckiser |                |
|                                                                                                                                                                                                                     | Subutex                                                                   |                    |                    | S               | Sublingual           |                      |                 | Reckitt Benckiser |                |
|                                                                                                                                                                                                                     | Lexapro                                                                   |                    |                    | S               | Unknown              | Dosage Information   |                 | Not Reported      |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Unknown- 20 Milligrams  
Daily

| <u>FDA Received Date</u>                                                                                                                              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 16-Jan-2013                                                                                                                                           | 7989798              | EXPEDITED (15-DAY) | Y                  | HO              | 2011AP000994                                    |                      | 33 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Drug Interaction;                                                                                                                         | Lithium Carbonate    |                    |                    | S               |                                                 |                      |                 | Not Reported |                |
| Electrocardiogram Qt Prolonged; Intentional Overdose; Lethargy; Mental Status Changes; Sinus Bradycardia; Suicide Attempt; Toxicity To Various Agents | Escitalopram Oxalate |                    |                    | S               |                                                 |                      |                 | Not Reported |                |
|                                                                                                                                                       | Alcohol              |                    |                    | S               |                                                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Jan-2013                                                                                                                                           | 9015132              | EXPEDITED (15-DAY) |                    | DE              | US-PAR<br>PHARMACEUTICAL,<br>INC-2013SCPR004966 |                      | 46 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Death                                                                                                                              | Verapamil            |                    |                    | S               | Oral                                            | Unk, Unknown         |                 | Par          |                |
|                                                                                                                                                       | Amitriptyline        |                    |                    | S               | Oral                                            | Unk, Unknown         |                 | Not Reported |                |
|                                                                                                                                                       | Escitalopram         |                    |                    | S               | Oral                                            | Unk, Unknown         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Jan-2013                                                                                                                                           | 9015706              | EXPEDITED (15-DAY) |                    | OT              | GB-FRI-1000041627                               |                      |                 | Female       | GBR            |
| <u>Preferred Term</u>                                                                                                                                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Glucose Fluctuation; Blood Pressure Fluctuation; Condition Aggravated; Hyperhidrosis; Migraine;                                                 | Escitalopram         |                    |                    | S               | Oral                                            | 10 Mg                |                 | Forest       |                |
|                                                                                                                                                       | Escitalopram         |                    |                    | S               | Oral                                            | 20 Mg                |                 | Forest       |                |
|                                                                                                                                                       | Duloxetine           |                    |                    | C               |                                                 | 60 Mg                |                 | Not Reported |                |

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

|                                                    |            |   |       |              |
|----------------------------------------------------|------------|---|-------|--------------|
| Sinusitis; Suicidal Ideation;<br>Tinnitus; Vertigo | Duloxetine | C | 30 Mg | Not Reported |
|----------------------------------------------------|------------|---|-------|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Jan-2013              | 9015979       | EXPEDITED (15-DAY) |                    | OT              | US-FRI-1000041583    |                      | 39 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                                                | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>             |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------------------|
| Contusion; Cough; Drug Interaction; Fall; Loss Of Consciousness; Oral Fungal Infection; Periorbital Haematoma; Skin Burning Sensation; Syncope; Urinary Incontinence | Lexapro<br>Cymbalta |              |            | S<br>S      |              |                    |                 | Forest<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 16-Jan-2013              | 9016533       | EXPEDITED (15-DAY) |                    | HO, OT          | US-009507513-1301USA003476 |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                                             | <u>Product</u>   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------|------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Balance Disorder; Dehydration; Fall; Infection; Migraine; Urinary Tract Infection | Singulair        |              |            | S           |              | 10 Mg, Unk                    |                 | Merck        |
|                                                                                   | Mirapex          |              |            | S           |              | 0.75 Mg, (0.25 Mg And 0.5 Mg) |                 | Not Reported |
|                                                                                   | Ambien           |              |            | S           |              | 5 Mg, Qd                      |                 | Not Reported |
|                                                                                   | Adderall Tablets |              |            | S           |              | 10 Mg, Bid                    |                 | Not Reported |
|                                                                                   | Lyrica           |              |            | S           |              | 100 Mg, Tid                   |                 | Not Reported |
|                                                                                   | Lexapro          |              |            | S           |              | 20 Mg, Qd                     |                 | Not Reported |
|                                                                                   | Nitrofurantoin   |              |            | S           |              | 100 Mg, Bid                   |                 | Not Reported |
|                                                                                   | Loratadine       |              |            | S           |              | 10 Mg, Unk                    |                 | Not Reported |
|                                                                                   | Gilenya          |              |            | S           | Oral         | 0.5 Mg, Qd                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 16-Jan-2013              | 9016765       | EXPEDITED (15-DAY) |                    | HO, OT          | CH-009507513-1301CHE004817 |                      | 22 YR      | Male       | CHE            |

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

| <u>Preferred Term</u>                                                                 | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------------------------------------------|-----------------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|--------------|----------------|
| Ataxia; Hypokalaemia;<br>Intentional Overdose;<br>Suicide Attempt;<br>Tachycardia     | Remeron                           |                    |                    | S               | Oral                                            | 90 Mg, Once          |                 | Merck        |                |
|                                                                                       | Escitalopram                      |                    |                    | S               | Oral                                            | 90 Mg, Once          |                 | Not Reported |                |
|                                                                                       | Quetiapine Fumarate               |                    |                    | S               | Oral                                            | 300 Mg, Once         |                 | Not Reported |                |
|                                                                                       | Topiramate                        |                    |                    | S               | Oral                                            | Unk, Once            |                 | Not Reported |                |
|                                                                                       | Methylenedioxymethamphetami<br>ne |                    |                    | S               |                                                 | 1 Df, Once           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                              | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Jan-2013                                                                           | 9034430                           | DIRECT             |                    | OT              |                                                 |                      | 33 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                 | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Diarrhoea; Dizziness;<br>Fatigue; Hyperhidrosis;<br>Nausea; Palpitations;<br>Vomiting | Escitalopram                      |                    |                    | S               | Oral                                            | 5 Mg 1 Pill/Day Oral |                 | Teva         |                |
| <u>FDA Received Date</u>                                                              | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Jan-2013                                                                           | 9123963                           | EXPEDITED (15-DAY) |                    | DE              | US-PAR<br>PHARMACEUTICAL,<br>INC-2013SCPR004955 |                      | 64 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                 | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Death                                                              | Venlafaxine Hydrochloride         |                    |                    | S               | Oral                                            | Unk, Unknown         |                 | Par          |                |
|                                                                                       | Ciprofloxacin Er                  |                    |                    | S               | Oral                                            | Unk, Unknown         |                 | Par          |                |
|                                                                                       | Desipramine                       |                    |                    | S               | Oral                                            | Unk, Unknown         |                 | Not Reported |                |
|                                                                                       | Diltiazem                         |                    |                    | S               | Oral                                            | Unk Unk, Unknown     |                 | Not Reported |                |
|                                                                                       | Lamotrigine                       |                    |                    | S               | Oral                                            | Unk, Unknown         |                 | Not Reported |                |
|                                                                                       | Hydrochlorothiazide               |                    |                    | S               | Oral                                            | Unk Unk, Unknown     |                 | Not Reported |                |
|                                                                                       | Armodafinil                       |                    |                    | S               | Oral                                            | Unk, Unknown         |                 | Not Reported |                |
|                                                                                       | Potassium Chloride                |                    |                    | S               | Oral                                            | Unk, Unknown         |                 | Not Reported |                |
|                                                                                       | Trifluoperazine                   |                    |                    | S               | Oral                                            | Unk, Unknown         |                 | Not Reported |                |
|                                                                                       | Escitalopram                      |                    |                    | S               | Oral                                            | Unk Unk, Unknown     |                 | Not Reported |                |



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

|                                 |   |      |                  |              |
|---------------------------------|---|------|------------------|--------------|
| Thyroid Preparations            | S | Oral | Unk, Unknown     | Not Reported |
| Pantoprazole                    | S | Oral | Unk, Unknown     | Not Reported |
| Lansoprazole                    | S | Oral | Unk, Unknown     | Not Reported |
| Rovustatin                      | S | Oral | Unk, Unknown     | Not Reported |
| Naproxen                        | S | Oral | Unk, Unknown     | Not Reported |
| Nitrofurantoin                  | S | Oral | Unk, Unknown     | Not Reported |
| Diclofenac                      | S | Oral | Unk, Unknown     | Not Reported |
| Acetaminophen W/Hydrocodone     | S | Oral | Unk Unk, Unknown | Not Reported |
| Acetaminophen<br>W/Propoxyphene | S | Oral | Unk, Unknown     | Not Reported |
| Solifenacin                     | S | Oral | Unk, Unknown     | Not Reported |
| Progestin                       | S | Oral | Unk, Unknown     | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Jan-2013              | 9124090       | EXPEDITED (15-DAY) |                    | DE              | FR-FRI-1000041667    |                      | 71 YR      | Male       | FRA            |

  

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Haematemesis          | Escitalopram   |              |            | S           | Oral         | 1 Df               |                 | Forest       |
|                       | Memantine      |              |            | S           | Oral         |                    |                 | Forest       |
|                       | Oxazepam       |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Risperidone    |              |            | S           | Oral         | 1 Mg               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 16-Jan-2013              | 9124308       | NON-EXPEDITED    |                    |                 | US-PFIZER INC-<br>2013016923 |                      |            | Female     | USA            |

  

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Ineffective      | Lyrica         |              |            | S           |              | Unk                |                 | Pfizer       |
|                       | Lexapro        |              |            | S           |              | 10 Mg, Unk         |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 16-Jan-2013                                                      | 9124437        | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000041626    |                      | 29 YR           | Female     | FRA            |
| <u>Preferred Term</u>                                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Cervix Oedema;<br>Dysphagia; Pharyngeal<br>Oedema; Tongue Oedema | Escitalopram   |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest     |                |

| <u>FDA Received Date</u>                        | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------|-----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 16-Jan-2013                                     | 9124456         | EXPEDITED (15-DAY) |                    | DE, HO, OT      | US-UCBSA-074690      |                      | 66 YR           | Female       | USA            |
| <u>Preferred Term</u>                           | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardio-Respiratory Arrest;<br>Completed Suicide | Methylphenidate |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                 | Lithium         |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                 | Escitalopram    |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                 | Aripiprazole    |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                 | Simvastatin     |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                 | Valacyclovir    |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                 | Propoxyphene    |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                 | Hydrocodone     |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                 | Oxycodone       |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                 | Triazolam       |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                 | Acetaminophen   |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|------------------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|-----------------|--------------|----------------|
| 17-Jan-2013              | 8679002                | EXPEDITED (15-DAY) |                    | DS              | FR-009507513-<br>1207FRA000929 |                      | 62 YR           | Female       | FRA            |
| <u>Preferred Term</u>    | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Extrapyramidal Disorder  | Aerius (Desloratadine) |                    |                    | S               | Oral                           | 5 Mg, Prn            |                 | Merck        |                |
|                          | Vidora                 |                    |                    | S               | Oral                           | 25 Mg, Unknown       |                 | Not Reported |                |

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

|  |                                                      |   |            |              |              |
|--|------------------------------------------------------|---|------------|--------------|--------------|
|  | Seroplex                                             | S | Oral       | 20 Mg, Qd    | Not Reported |
|  | Stagid                                               | C | Oral       | 700 Mg, Tid  | Not Reported |
|  | Atenolol                                             | C | Oral       | 50 Mg, Qd    | Not Reported |
|  | Tareg                                                | C | Oral       | 40 Mg, Qd    | Not Reported |
|  | Lysanxia                                             | C | Oral       | 1 Df, Tid    | Not Reported |
|  | Zolpidem Tartrate                                    | C | Oral       | 1 Df, Qd     | Not Reported |
|  | Ixprim (Acetaminophen (+)<br>Tramadol Hydrochloride) | C | Oral       | Unk          | Not Reported |
|  | Paracetamol                                          | C | Oral       | Unk          | Not Reported |
|  | Ster-Dex                                             | C | Ophthalmic | Unk, Unknown | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Jan-2013              | 9017340       | EXPEDITED (15-DAY) |                    | HO              | IT-FRI-1000041707    |                      | 45 YR      | Female     | ITA            |

| <u>Preferred Term</u>                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Flushing; Hypotension;<br>Intentional Self-Injury | Escitalopram   |              |            | S           | Oral         | 28 Df              |                 | Forest       |
|                                                   | Etilotx        |              |            | S           |              | 30 Df              |                 | Not Reported |
|                                                   | Cannabis       |              |            | S           |              |                    |                 | Not Reported |
|                                                   | Beer           |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>        | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------------|----------------------|------------|------------|----------------|
| 17-Jan-2013              | 9017400       | EXPEDITED (15-DAY) |                    | HO, LT          | CA-NICOBREVP-<br>2013-00048 |                      | 25 YR      | Female     | CAN            |

| <u>Preferred Term</u>                                                                                                                                                                                                     | <u>Product</u>                        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiotoxicity; Coma;<br>Electrocardiogram Qrs<br>Complex Prolonged;<br>Electrocardiogram Qt<br>Prolonged;<br>Hypocalcaemia;<br>Hypokalaemia;<br>Hypotension; Intentional<br>Overdose; Overdose;<br>Pulse Absent; Suicide | Fluoxetine Hydrochloride<br>(Unknown) |              |            | S           | Unknown      | Unk, Unknown       |                 | Watson       |
|                                                                                                                                                                                                                           | Olanzapine                            |              |            | S           | Unknown      | Unk, Unknown       |                 | Not Reported |
|                                                                                                                                                                                                                           | Quetiapine Fumarate                   |              |            | S           | Unknown      | Unk, Unknown       |                 | Not Reported |
|                                                                                                                                                                                                                           | Gabapentin (Unknown)                  |              |            | S           | Unknown      | Unk, Unknown       |                 | Watson       |
|                                                                                                                                                                                                                           | Escitalopram                          |              |            | S           | Unknown      | Unk, Unknown       |                 | Not Reported |
|                                                                                                                                                                                                                           | Amitriptyline                         |              |            | S           | Oral         | Unk, Unknown       |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Attempt; Tachycardia

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 17-Jan-2013              | 9125199        | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000041706    |                      | 74 YR           | Male         | FRA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Haemorrhage              | Escitalopram   |                    |                    | S               | Oral                 | 20 Mg                |                 | Forest       |                |
|                          | Pradaxa        |                    |                    | S               | Oral                 | 220 Mg               |                 | Not Reported |                |
|                          | Pradaxa        |                    |                    | S               | Oral                 | 220 Mg               |                 | Not Reported |                |
|                          | Kardegic       |                    |                    | S               | Oral                 | 75 Mg                |                 | Not Reported |                |
|                          | Kardegic       |                    |                    | S               | Oral                 | 75 Mg                |                 | Not Reported |                |
|                          | Amiodarone     |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Hemigoxine     |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Simvastatine   |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Tamsulosine    |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Burinex        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Nozinan        |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 18-Jan-2013                                                                                                | 8554650        | EXPEDITED (15-DAY) |                    |                 | JP-FRI-1000030371    |                      |                 | Female     | JPN            |
| <u>Preferred Term</u>                                                                                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Corneal Reflex Decreased; Excessive Eye Blinking; Headache; Muscle Rigidity; Paraesthesia; Seizure; Tremor | Lexapro        |                    |                    | S               | Oral                 |                      |                 | Forest     |                |

| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 18-Jan-2013               | 8949489        | EXPEDITED (15-DAY) |                    | HO              | GB-FRI-1000040847    |                      | 51 YR           | Male       | GBR            |
| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Depression; Irritability; | Escitalopram   |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest     |                |

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

|                           |              |   |      |       |              |
|---------------------------|--------------|---|------|-------|--------------|
| Psychotic Disorder; Sleep | Escitalopram | S | Oral | 10 Mg | Forest       |
| Disorder; Withdrawal      | Lyrica       | S | Oral | 50 Mg | Not Reported |
| Syndrome                  | Lyrica       | S | Oral | 50 Mg | Not Reported |
|                           | Lorazepam    | C | Oral |       | Not Reported |

| <u>FDA Received Date</u>      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------|----------------|--------------------|--------------------|-----------------|--------------------------|-------------------------------------|-----------------|--------------|----------------|
| 18-Jan-2013                   | 8972238        | EXPEDITED (15-DAY) |                    | HO              | GB-PFIZER INC-2012317903 |                                     | 51 YR           | Male         | GBR            |
| <u>Preferred Term</u>         | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Depression;          | Lyrica         |                    |                    | S               | Oral                     | 50 Mg, 1x/Day                       |                 | Pfizer       |                |
| Irritability; Paranoia; Sleep | Lyrica         |                    |                    | S               |                          |                                     |                 | Pfizer       |                |
| Disorder; Withdrawal          | Cipralext      |                    |                    | S               | Oral                     | 10 Mg, 1x/Day                       |                 | Not Reported |                |
| Syndrome                      | Cipralext      |                    |                    | S               |                          |                                     |                 | Not Reported |                |
|                               | Lorazepam      |                    |                    | C               | Oral                     | Nocturnal, As Needed. Rarely Taken. |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|-------------------------------------------|----------------------|-----------------|--------------|----------------|
| 18-Jan-2013              | 9017758        | EXPEDITED (15-DAY) |                    | DE              | US-PAR PHARMACEUTICAL, INC-2013SCPR004992 |                      | 62 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Death | Verapamil      |                    |                    | S               | Oral                                      | Unk, Unknown         |                 | Par          |                |
|                          | Escitalopram   |                    |                    | S               | Oral                                      | Unk, Unknown         |                 | Not Reported |                |

| <u>FDA Received Date</u>   | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------|-----------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 18-Jan-2013                | 9018010         | EXPEDITED (15-DAY) |                    | DE, HO          | US-JNJFOC-20130106571 |                      | 42 YR           | Female       | USA            |
| <u>Preferred Term</u>      | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Toxicity To Various Agents | Cyclobenzaprine |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                            | Quetiapine      |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                            | Hydroxyzine     |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |

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

|               |   |      |              |
|---------------|---|------|--------------|
| Citalopram    | S | Oral | Not Reported |
| Escitalopram  | S | Oral | Not Reported |
| Buspirone     | S | Oral | Not Reported |
| Levothyroxine | S | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|---------------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| 18-Jan-2013              | 9019242                   | EXPEDITED (15-DAY) |                    | DE              | US-ABBOTT-13P-163-1037392-00 |                      | 18 YR           | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Death                    | Valproic Acid             |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                          | Escitalopram              |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                          | Chlorpromazine            |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                          | Quetiapine                |                    |                    | S               |                              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Jan-2013              | 9019248                   | EXPEDITED (15-DAY) |                    | DE              | US-ABBOTT-13P-163-1037383-00 |                      | 46 YR           | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide        | Valproic Acid             |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                          | Ibuprofen                 |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                          | Escitalopram              |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                          | Hydroxyzine               |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                          | Cyclobenzaprine           |                    |                    | S               |                              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Jan-2013              | 9019292                   | EXPEDITED (15-DAY) |                    | DE              | US-ABBOTT-13P-163-1037188-00 |                      | 64 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide        | Acetaminophen\Hydrocodone |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                          | Potassium Chloride        |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                          | Diltiazem                 |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                          | Escitalopram              |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                          | Pantoprazole              |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                          | Lansoprazole              |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                          | Desipramine               |                    |                    | S               |                              |                      |                 | Not Reported |                |

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

|                            |   |              |
|----------------------------|---|--------------|
| Venlafaxine                | S | Not Reported |
| Lamotrigine                | S | Not Reported |
| Hydrochlorothiazide        | S | Not Reported |
| Armodafinil                | S | Not Reported |
| Trifluoperazine            | S | Not Reported |
| Thyroid Preparations       | S | Not Reported |
| Rovustatin                 | S | Not Reported |
| Naproxen                   | S | Not Reported |
| Nitrofurantoin             | S | Not Reported |
| Diclofenac                 | S | Not Reported |
| Acetaminophen/Propoxyphene | S | Not Reported |
| Solifenacin                | S | Not Reported |
| Ciprofloxacin              | S | Not Reported |
| Progesterin (Progesterone) | S | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>        | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------------|----------------------|------------|------------|----------------|
| 18-Jan-2013              | 9019592       | EXPEDITED (15-DAY) |                    | DE              | US-SHIONOGI, INC-2013000066 |                      | 64 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Nitrofurantoin       |              |            | S           |              | Unk                |                 | Shionogi     |
|                       | Naproxen             |              |            | S           |              | Unk                |                 | Shionogi     |
|                       | Desipramine Hcl      |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Diltiazem Xr         |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Venlafaxine          |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Lamotrigine          |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Hydrochlorothiazide  |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Armodafinil          |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Potassium Chloride   |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Trifluoperazine      |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Escitalopram         |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Thyroid Preparations |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Pantoprazole         |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Lansoprazole         |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Rosuvastatin         |              |            | S           |              | Unk                |                 | Not Reported |

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

|  |                                      |   |     |              |
|--|--------------------------------------|---|-----|--------------|
|  | Diclofenac Potassium                 | S | Unk | Not Reported |
|  | Acetaminophen\Hydrocodone Bitartrate | S | Unk | Not Reported |
|  | Propoxyphene Hcl And Acetaminophen   | S | Unk | Not Reported |
|  | Solifenacin                          | S | Unk | Not Reported |
|  | Ciprofloxacin                        | S | Unk | Not Reported |
|  | Progestine                           | S | Unk | Not Reported |

| <u>FDA Received Date</u>     | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------|----------------|------------------|--------------------|-----------------|------------------------------------------|----------------------|-----------------|--------------|----------------|
| 18-Jan-2013                  | 9019641        | NON-EXPEDITED    |                    |                 | US-BRISTOL-MYERS SQUIBB COMPANY-16680480 |                      | 6 YR            | Male         | USA            |
| <u>Preferred Term</u>        | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Decreased Appetite; Vomiting | Abilify        |                  |                    | S               | Oral                                     |                      |                 | Not Reported |                |
|                              | Lexapro        |                  |                    | S               |                                          |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 18-Jan-2013                                                                      | 9021909        | EXPEDITED (15-DAY) |                    | OT              | GB-FRI-1000041247    |                      | 37 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Disorientation; Dizziness; Impaired Driving Ability; Malaise; Migraine | Escitalopram   |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                                                                  | Ciprallex      |                    |                    | C               | Oral                 | 10 Mg                |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                          | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------|-----------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 18-Jan-2013                                                                       | 9022039         | EXPEDITED (15-DAY) |                    | DE, HO          | US-JNJFOC-20130106004 |                      | 66 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                             | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Completed Suicide; Respiratory Arrest; Toxicity To Various Agents | Methylphenidate |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                   | Acetaminophen   |                    | Y                  | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                   | Acetaminophen   |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |



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

|  |              |   |   |      |  |              |
|--|--------------|---|---|------|--|--------------|
|  | Simvastatin  | Y | S | Oral |  | Not Reported |
|  | Lithium      |   | S | Oral |  | Not Reported |
|  | Escitalopram |   | S | Oral |  | Not Reported |
|  | Aripiprazole |   | S | Oral |  | Not Reported |
|  | Valacyclovir |   | S | Oral |  | Not Reported |
|  | Propoxyphene |   | S | Oral |  | Not Reported |
|  | Hydrocodone  |   | S | Oral |  | Not Reported |
|  | Oxycodone    |   | S | Oral |  | Not Reported |
|  | Triazolam    |   | S | Oral |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|-----------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| 18-Jan-2013              | 9022237         | EXPEDITED (15-DAY) |                    | DE              | US-ABBOTT-13P-163-1037334-00 |                      | 42 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide        | Levothyroxine   |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                          | Quetiapine      |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                          | Hydroxyzine     |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                          | Citalopram      |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                          | Escitalopram    |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                          | Buspirone       |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                          | Cyclobenzaprine |                    |                    | S               |                              |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 18-Jan-2013                                | 9036764        | DIRECT           | Y                  | OT              |                      |                      | 11 YR           | Female       | USA            |
| <u>Preferred Term</u>                      | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depressed Mood; Product Substitution Issue | Lexapro        |                  |                    | S               | Oral                 |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 18-Jan-2013              | 9036800        | DIRECT           |                    |                 |                      |                      | 70 YR           | Female     | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

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

|                                                                                   |                         |                    |                    |                 |                      |                      |                 |              |                |
|-----------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Dizziness; Fall; Product Substitution Issue; Vertigo                              |                         | Lexapro            | S                  | Oral            | Aurobindo            |                      |                 |              |                |
| <u>FDA Received Date</u>                                                          | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Jan-2013                                                                       | 9059981                 | EXPEDITED (15-DAY) | Y                  | DE              | TIR-01708            |                      | 42 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                             | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                                                 | Levothyroxine           |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                   | Quetiapine              |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                   | Hydroxyzine             |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                   | Citalopram              |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                   | Escitalopram            |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                   | Buspirone               |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                   | Cyclobenzaprine         |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                          | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Jan-2013                                                                       | 9060078                 | EXPEDITED (15-DAY) | Y                  | DE              | AUR-APL-2013-00555   |                      | 65 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                             | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                                                 | Metoprolol              |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                   | Gabapentin (Gabapentin) |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                   | Simvastatin             |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                   | Quetiapine              |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                   | Escitalopram            |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                   | Acetaminophen/Codeine   |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                   | Eszopiclone             |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                          | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Jan-2013                                                                       | 9060216                 | EXPEDITED (15-DAY) | Y                  | DE              | AUR-APL-2013-00456   |                      | 48 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                             | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Completed Suicide; Respiratory Arrest; Toxicity To Various Agents | Risperidone             |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                   | Ondansetron             |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                   | Propranolol             |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                   | Oxycodone (Oxycodone)   |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                   | Trazodone               |                    |                    | S               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|              |   |              |
|--------------|---|--------------|
| Clonazepam   | S | Not Reported |
| Hydroxyzine  | S | Not Reported |
| Temazepam    | S | Not Reported |
| Benzotropine | S | Not Reported |
| Escitalopram | S | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Jan-2013              | 8942890       | EXPEDITED (15-DAY) |                    | OT              | CA-FRI-1000040753    |                      | 72 YR      | Female     | CAN            |

| <u>Preferred Term</u>                                                                           | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------------|-----------------|--------------|
| Agitation; Blood Sodium Decreased; Confusional State; Seizure; Skin Disorder; Urinary Retention | Escitalopram         |              |            | S           | Oral         | 20 Mg                    |                 | Forest       |
|                                                                                                 | Escitalopram         |              |            | S           | Oral         | 10 Mg                    |                 | Forest       |
|                                                                                                 | Alcohol              |              |            | S           |              |                          |                 | Not Reported |
|                                                                                                 | Acetylsalicylic Acid |              |            | C           | Oral         | Daily Dose Not Reported. |                 | Not Reported |
|                                                                                                 | Norvasc              |              |            | C           | Oral         |                          |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 21-Jan-2013              | 9023954       | EXPEDITED (15-DAY) |                    | DE              | US-JNJFOC-20130106624 |                      | 57 YR      | Female     | USA            |

| <u>Preferred Term</u>                         | <u>Product</u>  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------|-----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide; Toxicity To Various Agents | Diphenhydramine |              | Y          | S           | Oral         |                    |                 | Not Reported |
|                                               | Lamotrigine     |              |            | S           | Oral         |                    |                 | Not Reported |
|                                               | Escitalopram    |              |            | S           | Oral         |                    |                 | Not Reported |
|                                               | Aripiprazole    |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 21-Jan-2013              | 9024339       | EXPEDITED (15-DAY) |                    | DE              | US-JNJFOC-20130106461 |                      | 23 YR      | Female     | USA            |

| <u>Preferred Term</u>                         | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------|-----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide; Toxicity To Various Agents | Acetaminophen/Codeine |              |            | S           | Oral         |                    |                 | Not Reported |
|                                               | Metaxalone            |              |            | S           | Oral         |                    |                 | Not Reported |
|                                               | Escitalopram          |              |            | S           | Oral         |                    |                 | Not Reported |

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

|                                                                                                   |                       |                    |                    |                 |                       |                      |                 |              |                |
|---------------------------------------------------------------------------------------------------|-----------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| Quetiapine                                                                                        |                       |                    | S                  |                 | Oral                  |                      | Not Reported    |              |                |
| <u>FDA Received Date</u>                                                                          | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Jan-2013                                                                                       | 9024458               | EXPEDITED (15-DAY) |                    | DE, HO          | US-JNJFOC-20130106398 |                      | 52 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                             | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Incorrect Route Of Product<br>Administration; Toxicity To<br>Various Agents | Acetaminophen         |                    | Y                  | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                   | Acetaminophen         |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                   | Escitalopram          |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                   | Oxycodone             |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                   | Benzodiazepine Nos    |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                          | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Jan-2013                                                                                       | 9025090               | EXPEDITED (15-DAY) |                    | DE              | US-JNJFOC-20130106600 |                      | 65 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                             | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Toxicity To Various Agents                                                  | Acetaminophen/Codeine |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                   | Simvastatin           |                    | Y                  | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                   | Metoprolol            |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                   | Calcium Antagonists   |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                   | Gabapentin            |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                   | Quetiapine            |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                   | Escitalopram          |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                   | Benzodiazepine Nos    |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                   | Eszopiclone           |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                          | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Jan-2013                                                                                       | 8834171               | EXPEDITED (15-DAY) |                    | HO              | US-TEVA-363380USA     |                      |                 | Male         | USA            |
| <u>Preferred Term</u>                                                                             | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

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Anxiety; Blood Pressure Increased; Chest Discomfort; Confusional State; Dizziness      Escitalopram      S      Ivax

| <u>FDA Received Date</u> | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|---------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 22-Jan-2013              | 9001511             | EXPEDITED (15-DAY) |                    | DE              | US-PFIZER INC-2013004413 |                      | 46 YR           | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide        | Ibuprofen           |                    |                    | S               | Oral                     | Unk                  |                 | Pfizer       |                |
|                          | Hydroxyzine Pamoate |                    |                    | S               | Oral                     | Unk                  |                 | Not Reported |                |
|                          | Cyclobenzaprine     |                    |                    | S               | Oral                     | Unk                  |                 | Not Reported |                |
|                          | Escitalopram        |                    |                    | S               | Oral                     | Unk                  |                 | Not Reported |                |
|                          | Valproic Acid       |                    |                    | S               | Oral                     | Unk                  |                 | Not Reported |                |

| <u>FDA Received Date</u>                              | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 22-Jan-2013                                           | 9003258                 | EXPEDITED (15-DAY) |                    | DE              | US-PFIZER INC-2013007285 |                      | 48 YR           | Female       | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Completed Suicide; Respiratory Arrest | Propanolol Hcl          |                    |                    | S               | Oral                     | Unk                  |                 | Unknown      |                |
|                                                       | Oxycodone Hydrochloride |                    |                    | S               | Oral                     | Unk                  |                 | Pfizer       |                |
|                                                       | Ondansetron             |                    |                    | S               | Oral                     | Unk                  |                 | Pfizer       |                |
|                                                       | Hydroxyzine Pamoate     |                    |                    | S               | Oral                     | Unk                  |                 | Pfizer       |                |
|                                                       | Trazodone               |                    |                    | S               | Oral                     | Unk                  |                 | Not Reported |                |
|                                                       | Clonazepam              |                    |                    | S               | Oral                     | Unk                  |                 | Not Reported |                |
|                                                       | Risperidone             |                    |                    | S               | Oral                     | Unk                  |                 | Not Reported |                |
|                                                       | Temazepam               |                    |                    | S               | Oral                     | Unk                  |                 | Not Reported |                |
|                                                       | Benzotropine Mesylate   |                    |                    | S               | Oral                     | Unk                  |                 | Not Reported |                |
|                                                       | Escitalopram            |                    |                    | S               | Oral                     | Unk                  |                 | Not Reported |                |

# FDA Adverse Event Reporting System

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### Detailed Report

| <u>FDA Received Date</u>                                                          | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 22-Jan-2013                                                                       | 9006683                     | EXPEDITED (15-DAY) |                    | DE              | US-PFIZER INC-2013006530 |                      | 42 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                             | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                                                 | Levothyroxine Sodium        |                    |                    | S               | Oral                     | Unk                  |                 | Pfizer       |                |
|                                                                                   | Quetiapine                  |                    |                    | S               | Oral                     | Unk                  |                 | Not Reported |                |
|                                                                                   | Hydroxyzine                 |                    |                    | S               | Oral                     | Unk                  |                 | Not Reported |                |
|                                                                                   | Citalopram                  |                    |                    | S               | Oral                     | Unk                  |                 | Not Reported |                |
|                                                                                   | Escitalopram                |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                                                                                   | Buspirone                   |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                                                                                   | Cyclobenzaprine             |                    |                    | S               | Oral                     | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                          | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Jan-2013                                                                       | 9025252                     | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000041755        |                      | < 1 DAY         | Male         | USA            |
| <u>Preferred Term</u>                                                             | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Craniosynostosis                                                                  | Lexapro                     |                    |                    | S               | Transplacental           |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                          | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Jan-2013                                                                       | 9061547                     | EXPEDITED (15-DAY) | Y                  | DE, OT          | AUR-APL-2013-00565       |                      | 66 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                             | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Completed Suicide; Respiratory Arrest; Toxicity To Various Agents | Simvastatin                 |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                                                                   | Valacyclovir                |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                                                                   | Lithium (Lithium)           |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                                                                                   | Escitalopram                |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                                                                   | Methylphenidate             |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                                                                   | Aripiprazole (Aripiprazole) |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                                                                   | Propoxyphene                |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                                                                   | Hydrocodone (Hydrocodone)   |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                                                                   | Oxycodone (Oxycodone)       |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                                                                   | Triazolam                   |                    |                    | S               |                          |                      |                 | Not Reported |                |

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

|                             |                            |                    |                    |                 |                      |                      |                 |              |                |
|-----------------------------|----------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Acetaminophen (Paracetamol) |                            |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>    | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Jan-2013                 | 9061825                    | EXPEDITED (15-DAY) | Y                  | DE              | 2013POI058000041     |                      | 52 YR           | Female       | USA            |
| <u>Preferred Term</u>       | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide           | Oxycodone Hcl              |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                             | Acetaminophen              |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                             | Escitalopram               |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                             | Benzodiazepine             |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>    | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Jan-2013                 | 9093963                    | EXPEDITED (15-DAY) | Y                  | DE              | 2013POI077000003     |                      | 64 YR           | Female       | USA            |
| <u>Preferred Term</u>       | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide           | Zipsor                     |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                             | Desipramine                |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                             | Diltiazem                  |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                             | Venlafaxine                |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                             | Lamotrigine                |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                             | Hydrochlorothiazide        |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                             | Armodafinil                |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                             | Potassium Chloride         |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                             | Trifluoperazine            |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                             | Escitalopram               |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                             | Thyroid                    |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                             | Pantoprazole               |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                             | Lansoprazole               |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                             | Rovustatin                 |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                             | Naproxen                   |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                             | Nitrofurantoin             |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                             | Acetaminophen\Hydrocodone  |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                             | Acetaminophen/Propoxyphene |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |

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

|               |   |      |              |
|---------------|---|------|--------------|
| Solifenacin   | S | Oral | Not Reported |
| Ciprofloxacin | S |      | Not Reported |
| Progestin     | S | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Jan-2013              | 9094276       | EXPEDITED (15-DAY) | Y                  | DE              | 2013POI058000060     |                      | 66 YR      | Female     | USA            |

| <u>Preferred Term</u>                                 | <u>Product</u>  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------|-----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiac Arrest; Completed Suicide; Respiratory Arrest | Oxycodone       |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                       | Lithium         |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                       | Escitalopram    |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                       | Methylphenidate |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                       | Aripiprazole    |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                       | Simvastatin     |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                       | Valacyclovir    |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                       | Propoxyphene    |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                       | Hydrocodone     |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                       | Triazolam       |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                       | Acetaminophen   |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Jan-2013              | 9096389       | EXPEDITED (15-DAY) | Y                  | DE              | 2013POI058000062     |                      | 48 YR      | Female     | USA            |

| <u>Preferred Term</u>                                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiac Arrest; Completed Suicide; Respiratory Arrest | Oxycodone Hcl  |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                       | Propranolol    |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                       | Trazodone      |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                       | Clonazepam     |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                       | Hydroxyzine    |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                       | Risperidone    |              |            | S           | Oral         |                    |                 | Not Reported |



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

|              |   |      |              |
|--------------|---|------|--------------|
| Temazepam    | S | Oral | Not Reported |
| Benzotropine | S | Oral | Not Reported |
| Escitalopram | S | Oral | Not Reported |
| Ondansetron  | S | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Jan-2013              | 9027318       | EXPEDITED (15-DAY) |                    | OT              | DE-FRI-1000041935    |                      | 50 YR      | Male       | DEU            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Asthmatic Crisis      | Escitalopram   |              |            | S           |              | 20 Mg              |                 | Forest       |
|                       | Neuroleptics   |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Jan-2013              | 9027365       | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000041764    |                      | < 1 DAY    | Female     | USA            |

| <u>Preferred Term</u>                                                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|----------------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|------------|
| Arnold-Chiari Malformation; Cerebral Palsy; Congenital Hydrocephalus | Lexapro        |              |            | S           | Transplacental |                    |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Jan-2013              | 9038823       | DIRECT           |                    | DE              |                      |                      | 68 YR      | Male       | CAN            |

| <u>Preferred Term</u>                                                                              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                  | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|-----------------------------------------------------|-----------------|--------------|
| Asphyxia; Cold Sweat; Completed Suicide; Feeling Cold; Hyperhidrosis; Insomnia; Sexual Dysfunction | Ciprallex      |              |            | S           | Oral         | 20 Mg (For 2 Days) Am By 2 DAY Mouth Sept 5-19 / 12 |                 | Not Reported |
|                                                                                                    | Quetiapine     |              |            | S           | Oral         | 25 Mg Pm By Mouth Sept. 11 - 19 / 12                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Jan-2013              | 9031585       | EXPEDITED (15-DAY) |                    | HO              | AU-ROCHE-1182239     |                      | 46 YR      | Male       | AUS            |

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

| <u>Preferred Term</u>                                                  | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Ataxia; Chills; Diplopia;<br>Dysarthria; Headache;<br>Pyrexia; Syncope | Diazepam               |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                        | Escitalopram           |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                        | Mirtazapine            |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                        | Prazosin Hydrochloride |              |            | S           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Jan-2013              | 9096392       | EXPEDITED (15-DAY) | Y                  | DE              | 2013SP000332         |                      | 64 YR      | Female     | USA            |

| <u>Preferred Term</u>                            | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide;<br>Toxicity To Various Agents | Diltiazem Hydrochloride |              |            | S           |              |                    |                 | Not Reported |
|                                                  | Naproxen                |              |            | S           |              |                    |                 | Not Reported |
|                                                  | Diclofenac Sodium       |              |            | S           |              |                    |                 | Not Reported |
|                                                  | Ciprofloxacin           |              |            | S           |              |                    |                 | Not Reported |
|                                                  | Desipramine             |              |            | S           |              |                    |                 | Not Reported |
|                                                  | Venlafaxine             |              |            | S           |              |                    |                 | Not Reported |
|                                                  | Lamotrigine             |              |            | S           |              |                    |                 | Not Reported |
|                                                  | Hydrochlorothiazide     |              |            | S           |              |                    |                 | Not Reported |
|                                                  | Armodafinil             |              |            | S           |              |                    |                 | Not Reported |
|                                                  | Potassium Chloride      |              |            | S           |              |                    |                 | Not Reported |
|                                                  | Trifluoperazine         |              |            | S           |              |                    |                 | Not Reported |
|                                                  | Escitalopram            |              |            | S           |              |                    |                 | Not Reported |
|                                                  | Pantoprazole            |              |            | S           |              |                    |                 | Not Reported |
|                                                  | Lansoprazole            |              |            | S           |              |                    |                 | Not Reported |
|                                                  | Rosuvastatin            |              |            | S           |              |                    |                 | Not Reported |
|                                                  | Nitrofurantoin          |              |            | S           |              |                    |                 | Not Reported |
|                                                  | Acetaminophen           |              |            | S           |              |                    |                 | Not Reported |
|                                                  | Hydrocodone             |              |            | S           |              |                    |                 | Not Reported |
|                                                  | Propoxyphene            |              |            | S           |              |                    |                 | Not Reported |
|                                                  | Progesterone            |              |            | S           |              |                    |                 | Not Reported |
|                                                  | Solifenacin             |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Jan-2013              | 9096721       | EXPEDITED (15-DAY) | Y                  | OT              | AUR-APL-2013-00326   |                      | 46 YR      | Female     | IND            |

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

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

|                                 |                             |   |      |              |
|---------------------------------|-----------------------------|---|------|--------------|
| Cerebral Cyst;<br>Galactorrhoea | Escitalopram (Escitalopram) | S | Oral | Not Reported |
|                                 | Glibenclamide               | S |      | Not Reported |
|                                 | Imipramine                  | S |      | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Jan-2013              | 8961243       | EXPEDITED (15-DAY) |                    | LT, OT          | PHEH2012US024269     |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|------------------------------|-----------------|--------------|
| Drug Hypersensitivity;<br>Malaise; Malignant<br>Melanoma; Thyroid<br>Disorder | Vivelle Dot    |              |            | S           | Transdermal  | 0.025 Mg, Qw2 (Twice Weekly) |                 | Novartis     |
|                                                                               | Cafergot       |              |            | S           |              |                              |                 | Not Reported |
|                                                                               | Amoxapine      |              |            | S           |              |                              |                 | Not Reported |
|                                                                               | Lexapro        |              |            | S           |              |                              |                 | Not Reported |
|                                                                               | Codeine        |              |            | S           |              |                              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Jan-2013              | 9029454       | EXPEDITED (15-DAY) |                    | DE              | PHHY2013US006994     |                      | 64 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Diclofenac                |              |            | S           |              | Unk Ukn, Unk       |                 | Novartis     |
|                       | Pantoprazole              |              |            | S           |              | Unk Ukn, Unk       |                 | Not Reported |
|                       | Potassium Chloride        |              |            | S           |              | Unk Ukn, Unk       |                 | Not Reported |
|                       | Desipramine               |              |            | S           |              | Unk Ukn, Unk       |                 | Not Reported |
|                       | Diltiazem                 |              |            | S           |              | Unk Ukn, Unk       |                 | Not Reported |
|                       | Venlafaxine Hydrochloride |              |            | S           |              | Unk Ukn, Unk       |                 | Not Reported |
|                       | Lamotrigine               |              |            | S           |              | Unk Ukn, Unk       |                 | Not Reported |
|                       | Hydrochlorothiazide       |              |            | S           |              | Unk Ukn, Unk       |                 | Not Reported |
|                       | Trifluoperazine           |              |            | S           |              | Unk Ukn, Unk       |                 | Not Reported |
|                       | Escitalopram              |              |            | S           |              | Unk Ukn, Unk       |                 | Not Reported |
|                       | Lansoprazole              |              |            | S           |              | Unk Ukn, Unk       |                 | Not Reported |
|                       | Rosuvastatin              |              |            | S           |              | Unk Ukn, Unk       |                 | Not Reported |
|                       | Naproxen                  |              |            | S           |              | Unk Ukn, Unk       |                 | Not Reported |

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

|  |                                 |   |              |              |
|--|---------------------------------|---|--------------|--------------|
|  | Nitrofurantoin                  | S | Unk Ukn, Unk | Not Reported |
|  | Solifenacin                     | S | Unk Ukn, Unk | Not Reported |
|  | Ciprofloxacin                   | S | Unk Ukn, Unk | Not Reported |
|  | Progestin                       | S | Unk Ukn, Unk | Not Reported |
|  | Acetaminophen<br>W/Propoxyphene | S | Unk Ukn, Unk | Not Reported |
|  | Acetaminophen W/Hydrocodone     | S |              | Not Reported |
|  | Armodafinil                     | S | Unk Ukn, Unk | Not Reported |
|  | Thyroid Preparations            | S | Unk Ukn, Unk | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Jan-2013              | 9029669       | EXPEDITED (15-DAY) |                    | DE              | PHHY2013US007176     |                      | 66 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Methylphenidate            |              |            | S           |              |                    |                 | Novartis     |
|                       | Paracetamol                |              |            | S           |              |                    |                 | Not Reported |
|                       | Escitalopram               |              |            | S           |              |                    |                 | Not Reported |
|                       | Aripiprazole               |              |            | S           |              |                    |                 | Not Reported |
|                       | Simvastatin                |              |            | S           |              |                    |                 | Not Reported |
|                       | Propoxyphene Hydrochloride |              |            | S           |              |                    |                 | Not Reported |
|                       | Oxycodone Hydrochloride    |              |            | S           |              |                    |                 | Not Reported |
|                       | Triazolam                  |              |            | S           |              |                    |                 | Not Reported |
|                       | Lithium                    |              |            | S           |              |                    |                 | Not Reported |
|                       | Hydrocodone                |              |            | S           |              |                    |                 | Not Reported |
|                       | Valacyclovir               |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Jan-2013              | 9127089       | EXPEDITED (15-DAY) |                    | DE              | PHHY2013US006979     |                      | 18 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Death                 | Valproic Acid  |              |            | S           |              |                    |                 | Novartis     |
|                       | Chlorpromazine |              |            | S           |              |                    |                 | Not Reported |
|                       | Quetiapine     |              |            | S           |              |                    |                 | Not Reported |
|                       | Escitalopram   |              |            | S           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Jan-2013              | 9129121       | EXPEDITED (15-DAY) |                    | DE              | US-FRI-1000041991    |                      | 64 YR      | Female     | USA            |

| <u>Preferred Term</u>                                    | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiac Arrest; Completed<br>Suicide; Respiratory Arrest | Diltiazem                 |              |            | S           |              |                    |                 | Forest       |
|                                                          | Escitalopram              |              |            | S           |              |                    |                 | Forest       |
|                                                          | Desipramine               |              |            | S           |              |                    |                 | Not Reported |
|                                                          | Venlafaxine               |              |            | S           |              |                    |                 | Not Reported |
|                                                          | Lamotrigine               |              |            | S           |              |                    |                 | Not Reported |
|                                                          | Hydrochlorothiazide       |              |            | S           |              |                    |                 | Not Reported |
|                                                          | Armodafinil               |              |            | S           |              |                    |                 | Not Reported |
|                                                          | Potassium Chloride        |              |            | S           |              |                    |                 | Not Reported |
|                                                          | Trifluoperazine           |              |            | S           |              |                    |                 | Not Reported |
|                                                          | Thyroid Preparations      |              |            | S           |              |                    |                 | Not Reported |
|                                                          | Pantoprazole              |              |            | S           |              |                    |                 | Not Reported |
|                                                          | Lansoprazole              |              |            | S           |              |                    |                 | Not Reported |
|                                                          | Rovustatin                |              |            | S           |              |                    |                 | Not Reported |
|                                                          | Naproxen                  |              |            | S           |              |                    |                 | Not Reported |
|                                                          | Nitrofurantoin            |              |            | S           |              |                    |                 | Not Reported |
|                                                          | Diclofenac                |              |            | S           |              |                    |                 | Not Reported |
|                                                          | Acetaminophen\Hydrocodone |              |            | S           |              |                    |                 | Not Reported |
|                                                          | Acetaminophenpropoxyphene |              |            | S           |              |                    |                 | Not Reported |
|                                                          | Solifenacin               |              |            | S           |              |                    |                 | Not Reported |
|                                                          | Ciprofloxacin             |              |            | S           |              |                    |                 | Not Reported |
|                                                          | Progestin                 |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Jan-2013              | 9129402       | EXPEDITED (15-DAY) |                    | DE              | US-FRI-1000041988    |                      | 42 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Citalopram      |              |            | S           |              |                    |                 | Forest       |
|                       | Escitalopram    |              |            | S           |              |                    |                 | Forest       |
|                       | Levothroid      |              |            | S           |              |                    |                 | Forest       |
|                       | Quetiapine      |              |            | S           |              |                    |                 | Not Reported |
|                       | Hydroxyzine     |              |            | S           |              |                    |                 | Not Reported |
|                       | Buspirone       |              |            | S           |              |                    |                 | Not Reported |
|                       | Cyclobenzaprine |              |            | S           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>              | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------|-------------------------------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| 25-Jan-2013                           | 9129477                             | EXPEDITED (15-DAY) |                    | OT              | IT-ROCHE-1180915           |                      | 40 YR           | Female       | ITA            |
| <u>Preferred Term</u>                 | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Self-Injury               | Rivotril                            |                    |                    | S               | Oral                       | 2,5 Mg/ML Oral Drops |                 | Not Reported |                |
|                                       | Entact                              |                    |                    | S               | Oral                       | 10 Mg                |                 | Not Reported |                |
|                                       | Effexor                             |                    |                    | S               | Oral                       | 75 Mg                |                 | Not Reported |                |
| <u>FDA Received Date</u>              | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Jan-2013                           | 9129684                             | EXPEDITED (15-DAY) |                    | OT              | IN-PFIZER INC-2013018091   |                      | 46 YR           | Female       | IND            |
| <u>Preferred Term</u>                 | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cyst; Drug Interaction; Galactorrhoea | Escitalopram Oxalate                |                    |                    | S               | Unknown                    | 20 Mg, 1x/Day        |                 | Not Reported |                |
|                                       | Escitalopram Oxalate                |                    |                    | S               |                            |                      |                 | Not Reported |                |
|                                       | Glibenclamide                       |                    |                    | S               | Oral                       | 5 Mg, 1x/Day         |                 | Pfizer       |                |
|                                       | Imipramine                          |                    |                    | S               | Unknown                    | 75 Mg, 1x/Day        |                 | Not Reported |                |
|                                       | Imipramine                          |                    |                    | S               |                            |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>              | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Jan-2013                           | 9133584                             | EXPEDITED (15-DAY) |                    | DE              | US-009507513-1301USA009945 |                      | 65 YR           | Male         | USA            |
| <u>Preferred Term</u>                 | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Toxicity To Various Agents            | Simvastatin                         |                    |                    | S               | Oral                       |                      |                 | Merck        |                |
|                                       | Acetaminophen (+) Codeine Phosphate |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                       | Metoprolol                          |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                       | Gabapentin                          |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                       | Quetiapine Fumarate                 |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                       | Escitalopram                        |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                       | Eszopiclone                         |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                       |                                     |                    |                    |                 |                            |                      |                 |              |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                    | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 28-Jan-2013                                                                 | 9033553                   | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000042164                               |                      | 87 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                       | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Purpura;<br>Thrombocytopenia                                                | Escitalopram              |                    |                    | S               | Oral                                            |                      |                 | Forest       |                |
|                                                                             | Evista                    |                    |                    | C               | Oral                                            |                      |                 | Not Reported |                |
|                                                                             | Tanakan                   |                    |                    | C               | Oral                                            |                      |                 | Not Reported |                |
|                                                                             | Uvedose                   |                    |                    | C               | Oral                                            |                      |                 | Not Reported |                |
|                                                                             | Cacit [Calcium Carbonate] |                    |                    | C               | Oral                                            |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                    | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Jan-2013                                                                 | 9033571                   | EXPEDITED (15-DAY) |                    | DE              | PHHY2013US007397                                |                      | 46 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                       | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Drug<br>Level Increased                                  | Valproic Acid             |                    |                    | S               |                                                 |                      |                 | Novartis     |                |
|                                                                             | Hydroxyzine               |                    |                    | S               |                                                 |                      |                 | Not Reported |                |
|                                                                             | Cyclobenzaprine           |                    |                    | S               |                                                 |                      |                 | Not Reported |                |
|                                                                             | Escitalopram              |                    |                    | S               |                                                 |                      |                 | Not Reported |                |
|                                                                             | Ibuprofen                 |                    |                    | S               |                                                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                    | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Jan-2013                                                                 | 9046479                   | DIRECT             |                    | OT              |                                                 |                      | 48 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                       | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain Upper;<br>Anxiety; Depression;<br>Product Substitution Issue | Escitalopram              |                    |                    | S               | Oral                                            | One A Day Po         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                    | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Jan-2013                                                                 | 9062555                   | EXPEDITED (15-DAY) |                    | DE              | US-PAR<br>PHARMACEUTICAL,<br>INC-2013SCPR005495 |                      | 48 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                       | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

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

|                                                        |                 |   |      |              |              |
|--------------------------------------------------------|-----------------|---|------|--------------|--------------|
| Cardio-Respiratory Arrest;<br>Completed Suicide; Death | Propranolol Hcl | S | Oral | Unk, Unknown | Par          |
|                                                        | Clonazepam      | S | Oral | Unk, Unknown | Par          |
|                                                        | Risperidone     | S | Oral | Unk, Unknown | Par          |
|                                                        | Ondansetron     | S | Oral | Unk, Unknown | Par          |
|                                                        | Oxycodone       | S | Oral | Unk, Unknown | Not Reported |
|                                                        | Trazodone       | S | Oral | Unk, Unknown | Not Reported |
|                                                        | Hydroxyzine     | S | Oral | Unk, Unknown | Not Reported |
|                                                        | Temazepam       | S | Oral | Unk, Unknown | Not Reported |
|                                                        | Benzotropine    | S | Oral | Unk, Unknown | Not Reported |
|                                                        | Escitalopram    | S | Oral | Unk, Unknown | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 28-Jan-2013              | 9067282       | EXPEDITED (15-DAY) |                    | DE              | US-PAR<br>PHARMACEUTICAL,<br>INC-2013SCPR005077 |                      | 39 YR      | Female     | USA            |

| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide; Death | Clonazepam     |              |            | S           | Oral         | Unk, Unknown       |                 | Par          |
|                          | Escitalopram   |              |            | S           | Oral         | Unk, Unknown       |                 | Not Reported |
|                          | Lamotrigine    |              |            | S           | Oral         | Unk, Unknown       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Jan-2013              | 9068452       | EXPEDITED (15-DAY) |                    | DE              | PHHY2013US006687     |                      | 65 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u>                                    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|---------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Metoprolol                                        |              |            | S           |              | Unk Ukn, Unk       |                 | Novartis     |
|                       | Acetaminophen (Paracetamol),<br>Codeine Phosphate |              |            | S           |              | Unk Ukn, Unk       |                 | Not Reported |
|                       | Gabapentin                                        |              |            | S           |              | Unk Ukn, Unk       |                 | Not Reported |
|                       | Quetiapine                                        |              |            | S           |              | Unk Ukn, Unk       |                 | Not Reported |
|                       | Escitalopram                                      |              |            | S           |              | Unk Ukn, Unk       |                 | Not Reported |
|                       | Simvastatin                                       |              |            | S           |              | Unk Ukn, Unk       |                 | Not Reported |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                                                                                                                                                                                                                                                                                                         |                      |                    |                    |                 |                                                 |                      |                 |                  |                |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|------------------|----------------|
| Eszopiclone                                                                                                                                                                                                                                                                                                                             |                      |                    | S                  |                 | Unk Unkn, Unk                                   |                      |                 | Not Reported     |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 28-Jan-2013                                                                                                                                                                                                                                                                                                                             | 9068681              | EXPEDITED (15-DAY) |                    | OT              | US-TEVA-382594USA                               |                      |                 | Female           | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |
| Coeliac Disease                                                                                                                                                                                                                                                                                                                         | Escitalopram         |                    |                    | S               |                                                 |                      |                 | Ivax             |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 29-Jan-2013                                                                                                                                                                                                                                                                                                                             | 8891446              | EXPEDITED (15-DAY) |                    | OT              | 2012AP003451                                    |                      |                 | Female           | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |
| Arthralgia; Asthenia;<br>Decreased Appetite;<br>Depression; Diarrhoea;<br>Dizziness Postural; Drug<br>Ineffective; Fatigue; Head<br>Discomfort; Headache;<br>Hypertension;<br>Metamorphopsia; Myalgia;<br>Nausea; Palpitations;<br>Product Substitution Issue;<br>Suicidal Ideation; Throat<br>Irritation; Urticaria; Vision<br>Blurred | Escitalopram Oxalate |                    |                    | S               |                                                 |                      |                 | Not Reported     |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 29-Jan-2013                                                                                                                                                                                                                                                                                                                             | 8969971              | EXPEDITED (15-DAY) |                    | HO, OT          | US-<br>ELI_LILLY_AND_COMP<br>ANY-US201212003168 |                      |                 | Male             | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |
| Chronic Obstructive<br>Pulmonary Disease;                                                                                                                                                                                                                                                                                               | Cymbalta             |                    |                    | S               |                                                 | 60 Mg, Qd            |                 | Eli Lilly And Co |                |
| Contusion; Cough; Drug<br>Interaction; Eye                                                                                                                                                                                                                                                                                              | Lexapro              |                    |                    | S               |                                                 | Unk, Unknown         |                 | Not Reported     |                |
| Contusion; Fall; Loss Of<br>Consciousness; Seizure;                                                                                                                                                                                                                                                                                     | Hydrocodone          |                    |                    | C               |                                                 | Unk, Unknown         |                 | Not Reported     |                |
|                                                                                                                                                                                                                                                                                                                                         | Klonopin             |                    |                    | C               |                                                 | Unk, Unknown         |                 | Not Reported     |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                 |                 |   |              |              |
|-------------------------------------------------|-----------------|---|--------------|--------------|
| Skin Abrasion; Syncope;<br>Urinary Incontinence | Dexlansoprazole | C | Unk, Unknown | Not Reported |
|-------------------------------------------------|-----------------|---|--------------|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Jan-2013              | 9038093       | EXPEDITED (15-DAY) |                    | DE              | US-FRI-1000042145    |                      | 48 YR      | Female     | USA            |

| <u>Preferred Term</u>                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardio-Respiratory Arrest;<br>Completed Suicide | Escitalopram   |              |            | S           |              |                    |                 | Forest       |
|                                                 | Propranolol    |              |            | S           |              |                    |                 | Not Reported |
|                                                 | Oxycodone      |              |            | S           |              |                    |                 | Not Reported |
|                                                 | Trazodone      |              |            | S           |              |                    |                 | Not Reported |
|                                                 | Clonazepam     |              |            | S           |              |                    |                 | Not Reported |
|                                                 | Hydroxyzine    |              |            | S           |              |                    |                 | Not Reported |
|                                                 | Risperidone    |              |            | S           |              |                    |                 | Not Reported |
|                                                 | Temazepam      |              |            | S           |              |                    |                 | Not Reported |
|                                                 | Benzotropine   |              |            | S           |              |                    |                 | Not Reported |
| Ondansetron                                     |                |              | S          |             |              |                    | Not Reported    |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Jan-2013              | 9038116       | EXPEDITED (15-DAY) |                    | DE              | US-FRI-1000042148    |                      | 18 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Death                 | Escitalopram   |              |            | S           |              |                    |                 | Forest       |
|                       | Chlorpromazine |              |            | S           |              |                    |                 | Not Reported |
|                       | Quetiapine     |              |            | S           |              |                    |                 | Not Reported |
|                       | Valproic Acid  |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------------|----------------------|------------|------------|----------------|
| 29-Jan-2013              | 9038122       | EXPEDITED (15-DAY) |                    | HO, OT          | US-<br>GLAXOSMITHKLINE-<br>A0958320A |                      | 36 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u>      |
|--------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|---------------------|-----------------|-----------------|
| Atrial Fibrillation; III-<br>Defined Disorder;<br>Myocardial Infarction;<br>Nasopharyngitis; Panic<br>Attack; Stress; Suicidal | Wellbutrin     |              |            | S           |              | 300mg Twice Per Day |                 | Glaxosmithkline |
|                                                                                                                                | Effexor        |              |            | S           |              |                     |                 | Glaxosmithkline |
|                                                                                                                                | Ambien         |              |            | S           |              |                     |                 | Not Reported    |
|                                                                                                                                | Zyprexa        |              |            | S           |              |                     |                 | Glaxosmithkline |
|                                                                                                                                | Lexapro        |              |            | S           |              |                     |                 | Not Reported    |

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

|                           |           |   |         |  |  |  |  |                 |
|---------------------------|-----------|---|---------|--|--|--|--|-----------------|
| Ideation; Suicide Attempt | Adderall  | S |         |  |  |  |  | Not Reported    |
|                           | Concerta  | S |         |  |  |  |  | Glaxosmithkline |
|                           | Ativan    | S | Unknown |  |  |  |  | Not Reported    |
|                           | Depakote  | S | Unknown |  |  |  |  | Not Reported    |
|                           | Trileptal | S | Unknown |  |  |  |  | Not Reported    |
|                           | Lithium   | S | Unknown |  |  |  |  | Glaxosmithkline |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|--------------------------------------|----------------------|-----------------|-----------------|----------------|
| 29-Jan-2013              | 9038131        | NON-EXPEDITED    |                    |                 | US-<br>GLAXOSMITHKLINE-<br>A0960858A |                      |                 | Female          | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Adverse Event            | Wellbutrin     |                  |                    | S               | Unknown                              |                      |                 | Glaxosmithkline |                |
|                          | Lexapro        |                  |                    | S               | Unknown                              |                      |                 | Not Reported    |                |

| <u>FDA Received Date</u>                                      | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|---------------------------------------------------------------|----------------|------------------|--------------------|-----------------|--------------------------------------|----------------------|-----------------|-----------------|----------------|
| 29-Jan-2013                                                   | 9038176        | NON-EXPEDITED    |                    |                 | US-<br>GLAXOSMITHKLINE-<br>A0975005A |                      |                 | Female          | USA            |
| <u>Preferred Term</u>                                         | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Anger; Therapeutic<br>Response Decreased;<br>Weight Increased | Wellbutrin     |                  |                    | S               | Oral                                 |                      |                 | Glaxosmithkline |                |
|                                                               | Lexapro        |                  |                    | S               | Unknown                              |                      |                 | Not Reported    |                |
|                                                               | Crestor        |                  |                    | C               |                                      |                      |                 | Glaxosmithkline |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|--------------------------------------|----------------------|-----------------|-----------------|----------------|
| 29-Jan-2013              | 9038186        | NON-EXPEDITED    |                    |                 | US-<br>GLAXOSMITHKLINE-<br>A0977564A |                      |                 | Female          | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Alopecia                 | Wellbutrin     |                  |                    | S               | Oral                                 | 150mg Per Day        |                 | Glaxosmithkline |                |
|                          | Lexapro        |                  |                    | S               | Oral                                 | 10mg Per Day         |                 | Not Reported    |                |

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

| <u>FDA Received Date</u>                                              | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|------------------------------|-----------------------|-----------------|--------------|----------------|
| 29-Jan-2013                                                           | 9038280                 | EXPEDITED (15-DAY) |                    | DE              | US-FRI-1000042149            |                       | 54 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                 | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardio-Respiratory Arrest;<br>Completed Suicide                       | Escitalopram            |                    |                    | S               |                              |                       |                 | Forest       |                |
|                                                                       | Quetiapine              |                    |                    | S               |                              |                       |                 | Not Reported |                |
|                                                                       | Gabapentin              |                    |                    | S               |                              |                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                              | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Jan-2013                                                           | 9038286                 | EXPEDITED (15-DAY) |                    | HO, OT          | CH-009507513-1301CHE011765   |                       | 50 YR           | Female       | CHE            |
| <u>Preferred Term</u>                                                 | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Coma; Electrocardiogram<br>Qt Prolonged; Overdose;<br>Suicide Attempt | Remeron                 |                    |                    | S               | Oral                         | 30 Mg; 60 Units Once  |                 | Merck        |                |
|                                                                       | Trimipramine            |                    |                    | S               | Oral                         | 25 Mg; 50 Units, Once |                 | Not Reported |                |
|                                                                       | Escitalopram            |                    |                    | S               | Oral                         | 10 Df, Once           |                 | Not Reported |                |
|                                                                       | Alprazolam              |                    |                    | S               | Oral                         | Unk, Once             |                 | Not Reported |                |
|                                                                       | Trospium Chloride       |                    |                    | S               | Unknown                      | 40 Mg, Once           |                 | Not Reported |                |
|                                                                       | Tramadol Hydrochloride  |                    |                    | S               | Unknown                      | Unk, Once             |                 | Not Reported |                |
|                                                                       | Acetaminophen           |                    |                    | S               | Unknown                      | Unk, Once             |                 | Not Reported |                |
|                                                                       | Esomeprazole            |                    |                    | S               | Unknown                      | Unk, Once             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                              | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Jan-2013                                                           | 9041863                 | NON-EXPEDITED      |                    |                 | US-ABBOTT-12P-163-0893986-00 |                       | 52 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                 | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Nasopharyngitis; Rash;<br>Rash; Skin Irritation; Skin<br>Irritation   | Humira 40 Mg/0.8 MI Pen |                    |                    | S               |                              | 80 Mg Once            |                 | Not Reported |                |
|                                                                       | Humira 40 Mg/0.8 MI Pen |                    |                    | S               |                              |                       |                 | Not Reported |                |
|                                                                       | Humira 40 Mg/0.8 MI Pen |                    |                    | S               |                              |                       |                 | Not Reported |                |
|                                                                       | Lexapro                 |                    |                    | S               |                              |                       |                 | Not Reported |                |
|                                                                       | Xanax                   |                    |                    | C               |                              |                       |                 | Not Reported |                |
|                                                                       | Aspirin                 |                    |                    | C               |                              |                       |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                   | <u>Case #</u>                        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------|--------------------------------------|------------------|--------------------|-----------------|----------------------|----------------------------------|-----------------|--------------|----------------|
| 29-Jan-2013                                                                                                | 9049033                              | DIRECT           | Y                  | OT              |                      |                                  | 31 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                      | <u>Product</u>                       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Rash Pruritic                                                                                              | Escitalopram 10 Mg                   |                  |                    | S               | Oral                 | 10 Mg Orally Daily Aprox 3/20/12 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                   | <u>Case #</u>                        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Jan-2013                                                                                                | 9049037                              | DIRECT           | Y                  | OT              |                      |                                  | 61 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                      | <u>Product</u>                       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Depressed Mood; Dizziness; Irritability; Product Substitution Issue                                        | Escitalopram 5 Mg Daily              |                  |                    | S               | Oral                 |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                   | <u>Case #</u>                        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Jan-2013                                                                                                | 9049040                              | DIRECT           | Y                  |                 |                      |                                  | 25 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                      | <u>Product</u>                       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Crying; Depression; Fatigue; Headache; Product Substitution Issue                                          | Escitalopram                         |                  |                    | S               | Oral                 |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                   | <u>Case #</u>                        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Jan-2013                                                                                                | 9049044                              | DIRECT           | Y                  | OT              |                      |                                  | 40 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                      | <u>Product</u>                       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Disturbance In Attention; Feeling Of Despair; Malaise; Panic Attack; Product Substitution Issue | Lexapro - Generic Escitalopram 20 Mg |                  |                    | S               |                      |                                  | 8 YR            | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                      | <u>Case #</u> | <u>Case Type</u>         | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>                                     | <u>Sex</u>      | <u>Country</u> |
|-----------------------------------------------------------------------------------------------|---------------|--------------------------|--------------------|-----------------|----------------------|----------------------|------------------------------------------------|-----------------|----------------|
| 29-Jan-2013                                                                                   | 9049053       | DIRECT                   | Y                  | OT              |                      |                      |                                                | Female          | USA            |
| <u>Preferred Term</u>                                                                         |               | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>          | <u>Route</u>         | <u>Dosage Text</u>                             | <u>Duration</u> | <u>Mfr</u>     |
| Affective Disorder; Product Substitution Issue                                                |               | Escitalopram 15 Mg       |                    |                 | S                    | Oral                 | 15 Mg Po Qdy 3 Mos Of Brand 6 Weeks Of Generic | 3 MTH<br>6 WEEK | Not Reported   |
| <u>FDA Received Date</u>                                                                      | <u>Case #</u> | <u>Case Type</u>         | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>                                     | <u>Sex</u>      | <u>Country</u> |
| 29-Jan-2013                                                                                   | 9049055       | DIRECT                   | Y                  | OT              |                      |                      | 50 YR                                          | Female          | USA            |
| <u>Preferred Term</u>                                                                         |               | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>          | <u>Route</u>         | <u>Dosage Text</u>                             | <u>Duration</u> | <u>Mfr</u>     |
| Libido Decreased; Product Substitution Issue                                                  |               | Escitalopram             |                    |                 | S                    | Oral                 | 1 Tab Daily 1 Month By Mouth                   | 1 MTH           | Not Reported   |
| <u>FDA Received Date</u>                                                                      | <u>Case #</u> | <u>Case Type</u>         | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>                                     | <u>Sex</u>      | <u>Country</u> |
| 29-Jan-2013                                                                                   | 9049058       | DIRECT                   | Y                  |                 |                      |                      | 51 YR                                          | Female          | USA            |
| <u>Preferred Term</u>                                                                         |               | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>          | <u>Route</u>         | <u>Dosage Text</u>                             | <u>Duration</u> | <u>Mfr</u>     |
| Apathy; Depression; Feeling Abnormal; Middle Insomnia; Product Substitution Issue             |               | Escitalopram 20 Mg Mylan |                    |                 | S                    | Oral                 |                                                |                 | Mylan          |
| <u>FDA Received Date</u>                                                                      | <u>Case #</u> | <u>Case Type</u>         | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>                                     | <u>Sex</u>      | <u>Country</u> |
| 29-Jan-2013                                                                                   | 9049061       | DIRECT                   | Y                  |                 |                      |                      |                                                | Unknown         | USA            |
| <u>Preferred Term</u>                                                                         |               | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>          | <u>Route</u>         | <u>Dosage Text</u>                             | <u>Duration</u> | <u>Mfr</u>     |
| Anxiety; Drug Ineffective; Insomnia; Product Substitution Issue; Therapeutic Response Changed |               | Escitalopram             |                    |                 | S                    |                      |                                                |                 | Not Reported   |

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

| <u>FDA Received Date</u>                                                | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|------------------------------------|-----------------|--------------|----------------|
| 29-Jan-2013                                                             | 9049072        | DIRECT           | Y                  | OT              |                      |                                    | 59 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective; Product Substitution Issue                            | Escitalopram   |                  |                    | S               |                      | 1 Tab 2 Day Ongoing                |                 | Not Reported |                |
|                                                                         | Diltiazem      |                  |                    | C               |                      |                                    |                 | Not Reported |                |
|                                                                         | Amitriptyline  |                  |                    | C               |                      |                                    |                 | Not Reported |                |
|                                                                         | Lexose         |                  |                    | C               |                      |                                    |                 | Not Reported |                |
|                                                                         | Crestor        |                  |                    | C               |                      |                                    |                 | Not Reported |                |
|                                                                         | Flonase        |                  |                    | C               |                      |                                    |                 | Not Reported |                |
|                                                                         | Beber Asa      |                  |                    | C               |                      |                                    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Jan-2013                                                             | 9052001        | DIRECT           |                    |                 |                      |                                    | 27 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Condition Aggravated; Mood Altered; Product Substitution Issue | Lexapro        |                  |                    | S               |                      | Lexapro 5 Mg Daily 6/12 - Current  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Jan-2013                                                             | 9052006        | DIRECT           | Y                  | OT              |                      |                                    | 44 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Depression; Product Substitution Issue                         | Escitalopram   |                  |                    | S               | Oral                 | 20 Mg Po Daily 08-15-12 To Present |                 | Not Reported |                |
|                                                                         | Clonazepam     |                  |                    | C               |                      |                                    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Jan-2013                                                             | 9052007        | DIRECT           | Y                  | OT              |                      |                                    | 53 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Disease                                                     | Escitalopram   |                  |                    | S               | Oral                 |                                    |                 | Not Reported |                |

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Recurrence; Product  
Substitution Issue

| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 29-Jan-2013              | 9070248              | EXPEDITED (15-DAY) |                    | OT              | IT-WATSON-2013-01078 |                      | 53 YR           | Male         | ITA            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Depression      | Alprazolam (Unknown) |                    |                    | S               | Oral                 | 1 Mg, Total          |                 | Watson       |                |
|                          | Cipralext            |                    |                    | S               | Oral                 | 60 Mg, Total         |                 | Not Reported |                |
|                          | Laroxyl              |                    |                    | S               | Oral                 | 20 Mg, Total         |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|---------------------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| 29-Jan-2013              | 9074746                   | EXPEDITED (15-DAY) |                    | HO, OT          | US-009507513-1301USA012773 |                      |                 | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Suicide Attempt          | Singulair                 |                    |                    | S               |                            |                      |                 | Merck        |                |
|                          | Quetiapine Fumarate       |                    |                    | S               |                            |                      |                 | Not Reported |                |
|                          | Escitalopram              |                    |                    | S               |                            |                      |                 | Not Reported |                |
|                          | Tolterodine               |                    |                    | S               |                            |                      |                 | Not Reported |                |
|                          | Naproxen                  |                    |                    | S               |                            |                      |                 | Not Reported |                |
|                          | Pantoprazole              |                    |                    | S               |                            |                      |                 | Not Reported |                |
|                          | Dicyclomine Hydrochloride |                    |                    | S               |                            |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                     | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------|-----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 29-Jan-2013                                  | 9074899         | EXPEDITED (15-DAY) |                    | DE              | US-FRI-1000042143    |                      | 66 YR           | Female       | USA            |
| <u>Preferred Term</u>                        | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardio-Respiratory Arrest; Completed Suicide | Escitalopram    |                    |                    | S               |                      |                      |                 | Forest       |                |
|                                              | Lithium         |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                              | Methylphenidate |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                              | Aripiprazole    |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                              | Simvastatin     |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                              | Valacyclovir    |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                              | Propoxyphene    |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                              | Hydrocodone     |                    |                    | S               |                      |                      |                 | Not Reported |                |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                          |                         | Oxycodone        |                    | S               |                              |                         |                 |              | Not Reported   |
|--------------------------|-------------------------|------------------|--------------------|-----------------|------------------------------|-------------------------|-----------------|--------------|----------------|
|                          |                         | Triazolam        |                    | S               |                              |                         |                 |              | Not Reported   |
|                          |                         | Acetaminophen    |                    | S               |                              |                         |                 |              | Not Reported   |
| <u>FDA Received Date</u> | <u>Case #</u>           | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Jan-2013              | 9076209                 | NON-EXPEDITED    |                    |                 | US-ABBOTT-12P-163-0952017-00 |                         | 68 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>          | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Fall; Injection Site     | Humira 40 Mg/0.8 MI Pen |                  |                    | S               |                              |                         |                 | Not Reported |                |
| Erythema; Injection Site | Sinemet                 |                  |                    | S               |                              | 25/100mg Tid To         |                 | Not Reported |                |
| Erythema; Injection Site |                         |                  |                    |                 |                              | 25/100mg 2 Tab Tid To 1 |                 |              |                |
| Pruritus; Muscular       |                         |                  |                    |                 |                              | Tab Tid                 |                 |              |                |
| Weakness; Pain; Pain;    | Lexapro                 |                  |                    | S               |                              |                         |                 | Not Reported |                |
| Pain In Extremity;       | Proair                  |                  |                    | C               | Respiratory (inhalation)     |                         |                 | Not Reported |                |
| Parkinsonism; Rash       |                         |                  |                    |                 |                              |                         |                 |              |                |
| Papular; Rash Papular;   | Flovent Diskus          |                  |                    | C               |                              |                         |                 | Not Reported |                |
| Rash Papular;            | Tylenol Extra Strength  |                  |                    | C               |                              |                         |                 | Not Reported |                |
| Rheumatoid Arthritis     | Calcium Nasal Spray     |                  |                    | C               |                              | Daily                   |                 | Not Reported |                |
|                          | Lasix                   |                  |                    | C               |                              | Daily                   |                 | Not Reported |                |
|                          | Levothyroxin            |                  |                    | C               |                              | Daily                   |                 | Not Reported |                |
|                          | Metoprolol              |                  |                    | C               |                              |                         |                 | Not Reported |                |
|                          | Estropipate             |                  |                    | C               |                              | Daily                   |                 | Not Reported |                |
|                          | Klonopin                |                  |                    | C               |                              |                         |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>           | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Jan-2013              | 9077123                 | NON-EXPEDITED    |                    |                 | US-ABBOTT-12P-163-0938654-00 |                         | 34 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>          | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Injection Site  | Humira 40 Mg/0.8 MI Pen |                  |                    | S               |                              |                         |                 | Not Reported |                |
| Haemorrhage              | Lexapro                 |                  |                    | S               |                              |                         |                 | Not Reported |                |
|                          | Zyrtec                  |                  |                    | C               |                              | Daily                   |                 | Not Reported |                |
|                          | Benadryl                |                  |                    | C               |                              | Daily                   |                 | Not Reported |                |
|                          | Birth Control Pill      |                  |                    | C               |                              |                         |                 | Not Reported |                |
|                          | Lexapro                 |                  |                    | C               |                              | 10mg Daily              |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                  |                    |                    |                    |                 |                                                 |                                                                                                               |                 |              |                |
|--------------------------------------------------|--------------------|--------------------|--------------------|-----------------|-------------------------------------------------|---------------------------------------------------------------------------------------------------------------|-----------------|--------------|----------------|
| Lexapro                                          |                    |                    | C                  |                 |                                                 | Not Reported                                                                                                  |                 |              |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                                                                                          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Jan-2013                                      | 8459297            | EXPEDITED (15-DAY) |                    | OT              | JP-FRI-1000029057                               |                                                                                                               | 53 YR           | Female       | JPN            |
| <u>Preferred Term</u>                            | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                                                                            | <u>Duration</u> | <u>Mfr</u>   |                |
| Visual Acuity Reduced                            | Lexapro            |                    |                    | S               | Oral                                            | 10 Mg                                                                                                         |                 | Forest       |                |
|                                                  | Lexapro            |                    |                    | S               |                                                 | 20 Mg                                                                                                         |                 | Forest       |                |
|                                                  | Myslee             |                    |                    | C               | Oral                                            |                                                                                                               |                 | Not Reported |                |
|                                                  | Meilax             |                    |                    | C               | Oral                                            |                                                                                                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                                                                                          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Jan-2013                                      | 8986987            | EXPEDITED (15-DAY) |                    | HO, OT          | FR-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>17226309 |                                                                                                               | 57 YR           | Male         | FRA            |
| <u>Preferred Term</u>                            | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                                                                            | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;<br>Hyponatraemia               | Abilify Tabs 10 Mg |                    |                    | S               | Oral                                            |                                                                                                               |                 | Not Reported |                |
|                                                  | Atacand            |                    |                    | S               | Oral                                            | Scored Tabs                                                                                                   |                 | Not Reported |                |
|                                                  | Seroplex           |                    |                    | S               | Oral                                            | Film Coated Tabs                                                                                              |                 | Not Reported |                |
|                                                  | Depakote           |                    |                    | S               |                                                 | 250mg Gastro Resistant<br>Tabs 6sep12,Incre To 1gm<br>Daily, Decre To 500mg On<br>04oct12,250mg On<br>16oct12 |                 | Not Reported |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                                                                                          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Jan-2013                                      | 9014152            | EXPEDITED (15-DAY) |                    | DE              | US-JNJFOC-<br>20130104191                       |                                                                                                               | 46 YR           | Male         | USA            |
| <u>Preferred Term</u>                            | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                                                                            | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Toxicity To Various Agents | Ibuprofen          |                    |                    | S               | Oral                                            |                                                                                                               |                 | Not Reported |                |
|                                                  | Cyclobenzaprine    |                    |                    | S               | Oral                                            |                                                                                                               |                 | Not Reported |                |
|                                                  | Valproic Acid      |                    |                    | S               | Oral                                            |                                                                                                               |                 | Not Reported |                |

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

|              |   |      |              |
|--------------|---|------|--------------|
| Hydroxyzine  | S | Oral | Not Reported |
| Escitalopram | S | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Jan-2013              | 9023595       | EXPEDITED (15-DAY) | HO                 |                 | FR-FRI-1000041769    |                      | 56 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                  | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                 | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------|---------------------|--------------|------------|-------------|------------------------------|--------------------|-----------------|--------------|
| Enanthema; Eosinophilia; Pruritus; Rash Maculo-Papular | Escitalopram        |              |            | S           | Oral                         | 20 Mg              |                 | Forest       |
|                                                        | Valproate Sodium    |              |            | S           | Oral                         | 600 Mg             |                 | Not Reported |
|                                                        | Valdoxan            |              |            | S           | Oral                         | 25 Mg              |                 | Not Reported |
|                                                        | Rhinureflex         |              |            | S           | Oral                         | 1 Df               |                 | Not Reported |
|                                                        | Claradol            |              |            | S           | Occlusive dressing technique | 2 Df               |                 | Not Reported |
|                                                        | Spifen              |              |            | S           | Oral                         | 1200 Mg            |                 | Not Reported |
|                                                        | Megamag             |              |            | S           | Oral                         | 135 Mg             |                 | Not Reported |
|                                                        | Motilium            |              |            | S           | Oral                         |                    |                 | Not Reported |
|                                                        | Ideos               |              |            | C           | Oral                         |                    |                 | Not Reported |
|                                                        | Temesta (Lorazepam) |              |            | C           | Oral                         | 0.75 Mg            |                 | Not Reported |
|                                                        | Xyzall              |              |            | C           | Oral                         | 5 Mg               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Jan-2013              | 9051964       | DIRECT           |                    | OT              |                      |                      | 34 YR      | Male       | USA            |

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

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Jan-2013              | 9051970       | DIRECT           | Y                  | OT              |                      |                      | 51 YR      | Female     | USA            |

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

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

|                              |                          |                    |                    |                 |                      |                      |                 |              |                |
|------------------------------|--------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Palpitations; Skin Papilloma | Escitalopram             |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>     | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Jan-2013                  | 9051973                  | DIRECT             | Y                  | RI, OT          |                      |                      | 16 YR           | Male         | USA            |
| <u>Preferred Term</u>        | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Suicidal Ideation            | Escitalopram 20 Mg Mylan |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>     | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Jan-2013                  | 9078887                  | EXPEDITED (15-DAY) |                    | OT              | FR-TEVA-382409ISR    |                      | 44 YR           | Female       | FRA            |
| <u>Preferred Term</u>        | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hepatitis Acute              | Alprazolam               |                    |                    | S               | Unknown              |                      |                 |              | Teva           |
|                              | Etifoxine                |                    |                    | S               | Unknown              |                      |                 |              | Not Reported   |
|                              | Escitalopram             |                    |                    | S               | Unknown              |                      |                 |              | Not Reported   |
| <u>FDA Received Date</u>     | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Jan-2013                  | 9079033                  | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000042154    |                      | < 1 DAY         | Male         | USA            |
| <u>Preferred Term</u>        | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Coarctation Of The Aorta     | Lexapro                  |                    |                    | S               | Transplacental       |                      |                 | Forest       |                |
| <u>FDA Received Date</u>     | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Jan-2013                  | 9079055                  | EXPEDITED (15-DAY) |                    | DE              | US-FRI-1000042216    |                      | 26 YR           | Female       | USA            |
| <u>Preferred Term</u>        | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Death                        | Lexapro                  |                    |                    | S               |                      |                      |                 |              | Forest         |
|                              | Hydrocodone              |                    |                    | S               |                      |                      |                 |              | Not Reported   |
|                              | Alcohol                  |                    |                    | S               |                      |                      |                 |              | Not Reported   |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 30-Jan-2013                                                                                                                             | 9079181                   | EXPEDITED (15-DAY) |                    | OT              | BR-FRI-1000042213    |                      |                 | Female       | BRA            |
| <u>Preferred Term</u>                                                                                                                   | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Asphyxia; Chest Pain;<br>Confusional State;<br>Dyspnoea; Feeling<br>Abnormal; Mania; Panic<br>Attack; Suicidal Ideation;<br>Tachycardia | Lexapro                   |                    |                    | S               | Oral                 | 5 Mg                 |                 | Forest       |                |
|                                                                                                                                         | Lexapro                   |                    |                    | S               | Oral                 | 10 Mg                |                 | Not Reported |                |
|                                                                                                                                         | Efexor Xr                 |                    |                    | C               | Oral                 | 75 Mg                |                 | Not Reported |                |
|                                                                                                                                         | Stilnox                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                         | Rivotril                  |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Jan-2013                                                                                                                             | 9094042                   | EXPEDITED (15-DAY) | Y                  | DE              | DSA_61931_2013       |                      | 64 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                   | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Intentional Product<br>Misuse; Toxicity To<br>Various Agents                                                      | Diltiazem Hydrochloride   |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                                         | Venlafaxine Hydrochloride |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                                         | Lansoprazole              |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                                         | Pantoprazole              |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                                         | Ciprofloxacin             |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                                         | Desipramine Hydrochloride |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                                         | Lamotrigine               |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                                         | Hydrochlorothiazide       |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                                         | Potassium Chloride        |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                                         | Escitalopram Oxalate      |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                                         | Naproxen                  |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                                         | Solifenacin Succinate     |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                                         | Hydrocodone/Paracetamol   |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                                         | Di-Gesic                  |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                                         | Trifluoperazine           |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |

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

|                                |   |      |              |
|--------------------------------|---|------|--------------|
| Diclofenac                     | S | Oral | Not Reported |
| Progesterone                   | S | Oral | Not Reported |
| All Other Therapeutic Products | S | Oral | Not Reported |
| Nitrofurantoin                 | S | Oral | Not Reported |

| <u>FDA Received Date</u>                                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 31-Jan-2013                                                                         | 9045478        | EXPEDITED (15-DAY) |                    | HO              | CH-FRI-1000042320    |                      |                 | Female       | CHE            |
| <u>Preferred Term</u>                                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Altered State Of Consciousness; Drug Abuse; Intentional Overdose; Suicide Attempt   | Escitalopram   |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                                                                     | Tranxilium     |                    |                    | S               | Oral                 | 10 Mg                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-Jan-2013                                                                         | 9069545        | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000042322    |                      | 35 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anterograde Amnesia; Behaviour Disorder; Product Dispensing Error                   | Escitalopram   |                    |                    | S               | Oral                 | 15 Mg                |                 | Forest       |                |
|                                                                                     | Escitalopram   |                    |                    | S               | Oral                 | 15 Mg                |                 | Forest       |                |
|                                                                                     | Zolpidem       |                    |                    | S               | Oral                 | 1 Df                 |                 | Not Reported |                |
|                                                                                     | Alprazolam     |                    |                    | S               | Oral                 | 0.25 Mg Bid Or Tid   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-Jan-2013                                                                         | 9088943        | EXPEDITED (15-DAY) |                    | HO, LT          | PHHY2013ES008520     |                      | 59 YR           | Female       | ESP            |
| <u>Preferred Term</u>                                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Coma; Coma Scale Abnormal; Drug Interaction; Intentional Overdose; Long Qt Syndrome | Anafranil      |                    |                    | S               | Oral                 | 12 Df, Daily         |                 | Not Reported |                |
|                                                                                     | Clotiapine     |                    |                    | S               | Oral                 | Unk Ukn, Unk         |                 | Not Reported |                |
|                                                                                     | Escitalopram   |                    |                    | S               | Oral                 | Unk Ukn, Unk         |                 | Not Reported |                |
|                                                                                     | Quetiapine     |                    |                    | S               | Oral                 | Unk Ukn, Unk         |                 | Novartis     |                |

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

|                         |   |      |              |              |
|-------------------------|---|------|--------------|--------------|
| Flunitrazepam           | S | Oral | Unk Ukn, Unk | Not Reported |
| Levomepromazine Maleate | S | Oral | Unk Ukn, Unk | Not Reported |
| Diazepam                | C |      |              | Not Reported |
| Calodis                 | C |      |              | Not Reported |
| Loxifan                 | C |      |              | Not Reported |
| Benadon                 | C |      |              | Not Reported |

| <u>FDA Received Date</u>       | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------|-------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 31-Jan-2013                    | 9089118           | EXPEDITED (15-DAY) |                    | HO              | IT-PFIZER INC-2013034204 |                      | 78 YR           | Male         | ITA            |
| <u>Preferred Term</u>          | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Haematuria; Rectal Haemorrhage | Amiodarone Hcl    |                    |                    | S               | Oral                     | 200 Mg, Daily        |                 | Pfizer       |                |
|                                | Cipralext         |                    |                    | S               | Oral                     | 10 Drops, Daily      |                 | Not Reported |                |
|                                | Sintrom           |                    |                    | S               | Oral                     | 1 Mg, Daily          |                 | Not Reported |                |
|                                | Lanoxin           |                    |                    | C               |                          | Unk                  |                 | Not Reported |                |
|                                | Lansox            |                    |                    | C               |                          | Unk                  |                 | Not Reported |                |
|                                | Haldol            |                    |                    | C               |                          | Unk                  |                 | Not Reported |                |
|                                | Tavor (Lorazepam) |                    |                    | C               |                          | Unk                  |                 | Not Reported |                |
|                                | Calcium           |                    |                    | C               |                          | Unk                  |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                     | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------|-----------------|--------------------|--------------------|-----------------|----------------------------|------------------------|-----------------|--------------|----------------|
| 31-Jan-2013                                                                                                  | 9091254         | EXPEDITED (15-DAY) |                    | HO, LT, OT      | ES-ASTRAZENECA-2013SE06058 |                        | 59 YR           | Female       | ESP            |
| <u>Preferred Term</u>                                                                                        | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Pressure Decreased; Cerebral Ischaemia; Coma; Drug Interaction; Intentional Overdose; Long Qt Syndrome | Seroquel        |                    |                    | S               | Oral                       | 6 Tablets Single Dose  |                 | Zeneca       |                |
|                                                                                                              | Escitalopram    |                    |                    | S               | Oral                       |                        |                 | Not Reported |                |
|                                                                                                              | Anafranil       |                    |                    | S               | Oral                       | 50 Dragees Single Dose |                 | Not Reported |                |
|                                                                                                              | Etumina         |                    |                    | S               | Oral                       | 30 Tablets Single Dose |                 | Not Reported |                |
|                                                                                                              | Rohypnol        |                    |                    | S               | Oral                       | 20 Tablets Single Dose |                 | Not Reported |                |
|                                                                                                              | Levomepromazine |                    |                    | S               | Oral                       | 20 Tablets Single Dose |                 | Not Reported |                |
|                                                                                                              | Diazepam        |                    |                    | C               |                            |                        |                 | Not Reported |                |

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

|         |   |              |
|---------|---|--------------|
| Calodis | C | Not Reported |
| Loxifan | C | Not Reported |
| Benadon | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Feb-2013              | 8673159       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000037145    |                      | 89 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u>                                                                                                      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|---------------------------------------------------------------------------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Pancytopenia          | Escitalopram                                                                                                        |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                       | Lovenox                                                                                                             |              |            | C           | Subcutaneous | 4000 lu            |                 | Not Reported |
|                       | Pravastatin Sodium                                                                                                  |              |            | C           | Oral         | 20 Mg              |                 | Not Reported |
|                       | Levothyrox                                                                                                          |              |            | C           | Oral         | 125 Mcg            |                 | Not Reported |
|                       | Cardensiel                                                                                                          |              |            | C           | Oral         | 2.5 Mg             |                 | Not Reported |
|                       | Inexium                                                                                                             |              |            | C           | Oral         | 20 Mg              |                 | Not Reported |
|                       | Kardegic                                                                                                            |              |            | C           | Oral         | 75 Mg              |                 | Not Reported |
|                       | Transipeg (Polyethylene Glycol 3350\Potassium Chloride\Sodium Bicarbonate\Sodium Chloride\Sodium Sulfate Anhydrous) |              |            | C           | Oral         | 5.9 Mg             |                 | Not Reported |
|                       | Paracetamol                                                                                                         |              |            | C           | Oral         |                    |                 | Not Reported |
|                       | Lantus                                                                                                              |              |            | C           | Other        | 18 lu              |                 | Not Reported |
|                       | Lasilix                                                                                                             |              |            | C           | Oral         | 40 Mg              |                 | Not Reported |
|                       | Triatec (Ramipril)                                                                                                  |              |            | C           | Oral         | 2.5 Mg             |                 | Not Reported |
|                       | Rocephine                                                                                                           |              |            | C           | Other        | 1 G                |                 | Not Reported |
|                       | Adancor                                                                                                             |              |            | C           | Oral         | 20 Mg              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Feb-2013              | 9053939       | DIRECT           |                    | Y               |                      |                      | 37 YR      | Female     | USA            |

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



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

|                                                             |              |   |      |        |        |
|-------------------------------------------------------------|--------------|---|------|--------|--------|
| Anxiety; Decreased<br>Appetite; Depression;<br>Panic Attack | Escitalopram | S | Oral | 4 WEEK | Forest |
|-------------------------------------------------------------|--------------|---|------|--------|--------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Feb-2013              | 9087494       | EXPEDITED (15-DAY) | HO                 |                 | IT-FRI-1000042346    |                      | 78 YR      | Male       | ITA            |

| <u>Preferred Term</u>             | <u>Product</u>             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------|----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Haematuria; Rectal<br>Haemorrhage | Escitalopram Oral Solution |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                   | Sintrom                    |              |            | S           | Oral         | 1 Mg               |                 | Not Reported |
|                                   | Cordarone                  |              |            | S           | Oral         | 200 Mg             |                 | Not Reported |
|                                   | Lansox                     |              |            | C           | Oral         | 15 Mg              |                 | Not Reported |
|                                   | Lanoxin                    |              |            | C           | Oral         |                    |                 | Not Reported |
|                                   | Haldol                     |              |            | C           | Oral         | 16 Drops Daily     |                 | Not Reported |
|                                   | Tavor (Lorazepam)          |              |            | C           | Oral         |                    |                 | Not Reported |
|                                   | Calcium Sandoz             |              |            | C           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Feb-2013              | 8907373       | EXPEDITED (15-DAY) | HO                 |                 | AU-FRI-1000040355    |                      | 81 YR      | Female     | AUS            |

| <u>Preferred Term</u>                                                                      | <u>Product</u>               | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------|------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abdominal Pain;<br>Hyponatraemia; Malaise;<br>Urinary Retention; Urine<br>Output Decreased | Lexapro                      |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                                                                            | Lasix                        |              |            | S           |              |                    |                 | Not Reported |
|                                                                                            | Losec                        |              |            | C           |              |                    |                 | Not Reported |
|                                                                                            | Blackmores Fish Oil          |              |            | C           |              |                    |                 | Not Reported |
|                                                                                            | Coumadin                     |              |            | C           |              |                    |                 | Not Reported |
|                                                                                            | Chondroitin Sulfate          |              |            | C           |              |                    |                 | Not Reported |
|                                                                                            | (Bovine)\Glucosamine Sulfate |              |            |             |              |                    |                 |              |
|                                                                                            | Lanoxin                      |              |            | C           |              |                    |                 | Not Reported |
|                                                                                            | Panadol Osteo                |              |            | C           |              |                    |                 | Not Reported |
| Vitamin B12 Nos                                                                            |                              |              | C          |             |              |                    | Not Reported    |              |

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

| <u>FDA Received Date</u>                                                                                                  | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------|------------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|---------------------------|-----------------|------------------------------|----------------|
| 04-Feb-2013                                                                                                               | 9049059                      | EXPEDITED (15-DAY) |                    | OT              | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>17316720 |                           | 55 YR           | Male                         | USA            |
| <u>Preferred Term</u>                                                                                                     | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>                   |                |
| Arthralgia; Fatigue; Mania                                                                                                | Abilify Tabs 5 Mg<br>Lexapro |                    |                    | S<br>S          |                                                 |                           |                 | Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                                                  | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 04-Feb-2013                                                                                                               | 9057377                      | EXPEDITED (15-DAY) |                    | OT              | PHHY2013BR001460                                |                           | 54 YR           | Female                       | BRA            |
| <u>Preferred Term</u>                                                                                                     | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>                   |                |
| Asthenia; Depression;<br>Dizziness; Headache;<br>Hyperinsulinaemia;<br>Hyperthyroidism;<br>Hypothyroidism;<br>Tachycardia | Ludiomil                     |                    |                    | S               | Oral                                            | 2 Tablet (75 Mg) Daily    |                 | Not Reported                 |                |
|                                                                                                                           | Ludiomil                     |                    |                    | S               | Oral                                            | 1 Tablet (75 Mg) Daily    |                 | Not Reported                 |                |
|                                                                                                                           | Ludiomil                     |                    |                    | S               | Oral                                            | 1 Tablet (25 Mg) Daily    |                 | Not Reported                 |                |
|                                                                                                                           | Ludiomil                     |                    |                    | S               | Oral                                            | Half Tablet (25 Mg) Daily |                 | Not Reported                 |                |
|                                                                                                                           | Ludiomil                     |                    |                    | S               | Oral                                            | 1 Tablet (25 Mg) Daily    |                 | Not Reported                 |                |
|                                                                                                                           | Ludiomil                     |                    |                    | S               | Oral                                            | Half Tablet (25 Mg Daily  |                 | Not Reported                 |                |
|                                                                                                                           | Fluoxetine                   |                    |                    | S               | Oral                                            | 20 Mg, Daily              |                 | Novartis                     |                |
|                                                                                                                           | Maprotilina                  |                    |                    | S               | Oral                                            | 1 Df, Daily               |                 | Not Reported                 |                |
|                                                                                                                           | Espram                       |                    |                    | S               | Oral                                            | 10 Mg, Daily              |                 | Not Reported                 |                |
|                                                                                                                           | Frontal                      |                    |                    | C               | Oral                                            | 1 Tablet Daily (1mg)      |                 | Not Reported                 |                |
|                                                                                                                           | Aradois H                    |                    |                    | C               | Oral                                            | 0.5 Tablet (50/12.5mg)    |                 | Not Reported                 |                |
|                                                                                                                           | Somalgin                     |                    |                    | C               | Oral                                            | 1 Df, Qd                  |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                                                                                                  | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 04-Feb-2013                                                                                                               | 9057505                      | DIRECT             | Y                  |                 |                                                 |                           | 34 YR           | Male                         | USA            |
| <u>Preferred Term</u>                                                                                                     | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>                   |                |
| Abnormal Behaviour;<br>Aggression; Agitation;                                                                             | Escitalopram                 |                    |                    | S               | Oral                                            |                           |                 | Teva                         |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Feeling Jittery;  
Hallucination; Paranoia;  
Vocal Cord Disorder

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Feb-2013              | 9057942       | DIRECT           | Y                  | OT              |                      |                      | 53 YR      | Female     | USA            |

| <u>Preferred Term</u>                        | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|----------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Drug Ineffective; Product Substitution Issue | Escitalopram Oxalate |              |            | S           | Oral         |                    | 5 MTH           | Teva       |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Feb-2013              | 9057944       | DIRECT           |                    | OT              |                      |                      | 38 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Disorientation; Headache; Migraine; Product Complaint; Product Substitution Issue; Somnolence; Tremor; Vision Blurred | Escitalopram   |              |            | S           | Oral         |                    |                 | Apotex     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Feb-2013              | 9058160       | DIRECT           | Y                  | OT              |                      |                      | 48 YR      | Female     | USA            |

| <u>Preferred Term</u>                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Anxiety; Decreased Appetite; Panic Attack | Escitalopram   |              |            | S           | Oral         |                    | 4 WEEK          | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Feb-2013              | 9139494       | EXPEDITED (15-DAY) | Y                  | DE              | NSR_00832_2013       |                      | 46 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Hydroxyzine    |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |

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

|                 |   |      |           |              |
|-----------------|---|------|-----------|--------------|
| Valproic Acid   | S | Oral | (Df Oral) | Not Reported |
| Ibuprofen       | S | Oral | (Df Oral) | Not Reported |
| Cyclobenzaprine | S | Oral | (Df Oral) | Not Reported |
| Escitalopram    | S | Oral | (Df Oral) | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Feb-2013              | 9139955       | EXPEDITED (15-DAY) | Y                  | DE              | NSR_00843_2013       |                      | 42 YR      | Female     | USA            |

| <u>Preferred Term</u>           | <u>Product</u>  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------|-----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide;<br>Poisoning | Hydroxyzine     |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                 | Quetiapine      |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                 | Citalopram      |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                 | Escitalopram    |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                 | Buspirone       |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                 | Cyclobenzaprine |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                 | Levothyroxine   |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Feb-2013              | 9145551       | EXPEDITED (15-DAY) | Y                  | DE              | NSR_00906_2013       |                      | 48 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiac Arrest; Completed<br>Suicide; Poisoning<br>Deliberate; Respiratory<br>Arrest | Propranolol    |              |            | S           | Oral         | (Df)               |                 | Not Reported |
|                                                                                      | Hydroxyzine    |              |            | S           | Oral         | (Df)               |                 | Not Reported |
|                                                                                      | Oxycodone      |              |            | S           | Oral         | (Df)               |                 | Not Reported |
|                                                                                      | Trazodone      |              |            | S           | Oral         | (Df)               |                 | Not Reported |
|                                                                                      | Clonazepam     |              |            | S           | Oral         | (Df)               |                 | Not Reported |
|                                                                                      | Risperidone    |              |            | S           | Oral         | (Df)               |                 | Not Reported |
|                                                                                      | Temazepam      |              |            | S           | Oral         | (Df)               |                 | Not Reported |
|                                                                                      | Benzotropine   |              |            | S           | Oral         | (Df)               |                 | Not Reported |
|                                                                                      | Escitalopram   |              |            | S           | Oral         | (Df)               |                 | Not Reported |

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

|                                                                                    |                |                  |                    |                 |                      |                      |                 |            |                |  |
|------------------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|--|
| Ondansetron                                                                        |                |                  | S                  |                 | Oral                 |                      | (Df)            |            | Not Reported   |  |
| <u>FDA Received Date</u>                                                           | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |  |
| 05-Feb-2013                                                                        | 9058351        | DIRECT           |                    | LT              |                      |                      | 59 YR           | Female     | USA            |  |
| <u>Preferred Term</u>                                                              | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |  |
| Abdominal Pain Upper; Anxiety; Dizziness; Hypertension; Product Substitution Issue | Escitalopram   |                  |                    | S               | Oral                 |                      |                 | Teva       |                |  |

|                              |                            |                    |                    |                 |                      |                      |                 |              |                |
|------------------------------|----------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| <u>FDA Received Date</u>     | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Feb-2013                  | 9139038                    | EXPEDITED (15-DAY) | Y                  | DE              | DEP_00836_00836_2013 |                      | 65 YR           | Male         | USA            |
| <u>Preferred Term</u>        | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Poisoning | Gabapentin                 |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                              | Metoprolol                 |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                              | Calcium Channel Blockers   |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                              | Quetiapine                 |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                              | Escitalopram               |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                              | Acetaminophen W/Codeine    |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                              | Benzodiazepine Derivatives |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                              | Eszopiclone                |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                              | Simvastatin                |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |

|                          |                         |                    |                    |                 |                      |                      |                 |              |                |
|--------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| <u>FDA Received Date</u> | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Feb-2013              | 9139133                 | EXPEDITED (15-DAY) | Y                  | DE              | VAL_01340_2013       |                      | 65 YR           | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide        | Metoprolol              |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                          | Acetaminophen W/Codeine |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                          | Gabapentin              |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                          | Quetiapine              |                    |                    | S               |                      |                      |                 | Not Reported |                |

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

|                                                                        | Escitalopram         |                    |                    | S               |                      |                      |                 |              | Not Reported   |
|------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
|                                                                        | Simvastatin          |                    |                    | S               |                      |                      |                 |              | Not Reported   |
|                                                                        | Eszopiclone          |                    |                    | S               |                      |                      |                 |              | Not Reported   |
| <u>FDA Received Date</u>                                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Feb-2013                                                            | 9140566              | EXPEDITED (15-DAY) | Y                  | DE              | DEP_00841_2013       |                      | 54 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Completed<br>Suicide; Poisoning;<br>Respiratory Arrest | Gabapentin           |                    |                    | S               |                      | Df                   |                 | Not Reported |                |
|                                                                        | Quetiapine           |                    |                    | S               |                      | Df Oral              |                 | Not Reported |                |
|                                                                        | Escitalopram         |                    |                    | S               |                      | Df Oral              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Feb-2013                                                            | 9059632              | DIRECT             | Y                  |                 |                      |                      | 15 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dermatitis; Scratch                                                    | Escitalopram         |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                        | Pamelor              |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Feb-2013                                                            | 9060253              | DIRECT             |                    | DE              |                      |                      | 64 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Toxicity To Various Agents                       | Lansoprazole         |                    |                    | S               | Oral                 |                      |                 | Takeda       |                |
|                                                                        | Diltiazem Hcl        |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                        | Venlafaxine Hcl      |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                        | Pantoprazole         |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                        | Diclofenac Epolamine |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                        | Ciprofloxacin        |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                        | Desipramine          |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                        | Lamotrigine          |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |

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

|                            |   |      |              |
|----------------------------|---|------|--------------|
| Hydrochlorothiazide        | S | Oral | Not Reported |
| Armodafinil                | S | Oral | Not Reported |
| Potassium Chloride         | S | Oral | Not Reported |
| Trifluoperazine            | S | Oral | Not Reported |
| Escitalopram               | S | Oral | Not Reported |
| Naproxen                   | S | Oral | Not Reported |
| Nitrofurantoin             | S | Oral | Not Reported |
| Acetaminophen/Hydrocodone  | S | Oral | Not Reported |
| Acetaminophen/Propoxyphene | S | Oral | Not Reported |
| Solifenacin                | S | Oral | Not Reported |
| Progestin (Progesterone)   | S | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Feb-2013              | 9145921       | EXPEDITED (15-DAY) | Y                  | DE              | NSR_00894_2013       |                      | 64 YR      | Female     | USA            |

| <u>Preferred Term</u>           | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide;<br>Poisoning | Venlafaxine          |              |            | S           | Oral         |                    |                 | Not Reported |
|                                 | Desipramine          |              |            | S           | Oral         |                    |                 | Not Reported |
|                                 | Diltiazem            |              |            | S           | Oral         |                    |                 | Not Reported |
|                                 | Lamotrigine          |              |            | S           | Oral         |                    |                 | Not Reported |
|                                 | Hydrochlorothiazide  |              |            | S           | Oral         |                    |                 | Not Reported |
|                                 | Armodafinil          |              |            | S           | Oral         |                    |                 | Not Reported |
|                                 | Potassium Chloride   |              |            | S           | Oral         |                    |                 | Not Reported |
|                                 | Trifluoperazine      |              |            | S           | Oral         |                    |                 | Not Reported |
|                                 | Escitalopram         |              |            | S           | Oral         |                    |                 | Not Reported |
|                                 | Thyroid Preparations |              |            | S           | Oral         |                    |                 | Not Reported |
|                                 | Pantoprazole         |              |            | S           | Oral         |                    |                 | Not Reported |
|                                 | Lansoprazole         |              |            | S           | Oral         |                    |                 | Not Reported |
|                                 | Rosuvastatin         |              |            | S           | Oral         |                    |                 | Not Reported |

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

|  |                              |   |      |              |
|--|------------------------------|---|------|--------------|
|  | Naproxen                     | S | Oral | Not Reported |
|  | Nitrofurantoin               | S | Oral | Not Reported |
|  | Diclofenac                   | S | Oral | Not Reported |
|  | Acetaminophen W/Hydrocodone  | S | Oral | Not Reported |
|  | Acetaminophen W/Propoxyphene | S | Oral | Not Reported |
|  | Solifenacin                  | S | Oral | Not Reported |
|  | Ciprofloxacin                | S | Oral | Not Reported |
|  | Progestin                    | S | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Feb-2013              | 9146062       | EXPEDITED (15-DAY) | Y                  | DE              | NSR_00855_2013       |                      | 57 YR      | Female     | USA            |

| <u>Preferred Term</u>        | <u>Product</u>  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------|-----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide; Poisoning | Lamotrigine     |              |            | S           | Oral         |                    |                 | Not Reported |
|                              | Diphenhydramine |              |            | S           | Oral         |                    |                 | Not Reported |
|                              | Escitalopram    |              |            | S           |              |                    |                 | Not Reported |
|                              | Aripiprazole    |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Feb-2013              | 9146761       | EXPEDITED (15-DAY) | Y                  | DE              | NSR_00853_2013       |                      | 39 YR      | Female     | USA            |

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

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 07-Feb-2013              | 9005360       | EXPEDITED (15-DAY) |                    | DE              | US-PFIZER INC-2013007612 |                      | 64 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Completed Suicide     | Diltiazem Hcl             |              |            | S           | Oral         | Unk                |                 | Unknown    |
|                       | Venlafaxine Hydrochloride |              |            | S           | Oral         | Unk                |                 | Pfizer     |



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

|                            |   |      |     |              |
|----------------------------|---|------|-----|--------------|
| Pantoprazole               | S | Oral | Unk | Pfizer       |
| Lansoprazole               | S | Oral | Unk | Unknown      |
| Diclofenac Epolamine       | S | Oral | Unk | Unknown      |
| Ciprofloxacin              | S |      |     | Not Reported |
| Desipramine                | S | Oral | Unk | Not Reported |
| Lamotrigine                | S | Oral | Unk | Not Reported |
| Hydrochlorothiazide        | S | Oral | Unk | Not Reported |
| Armodafinil                | S | Oral | Unk | Not Reported |
| Potassium Chloride         | S | Oral | Unk | Not Reported |
| Trifluoperazine            | S | Oral | Unk | Not Reported |
| Escitalopram               | S | Oral | Unk | Not Reported |
| Naproxen                   | S | Oral | Unk | Not Reported |
| Nitrofurantoin             | S | Oral | Unk | Not Reported |
| Acetaminophen\Hydrocodone  | S | Oral | Unk | Not Reported |
| Acetaminophen/Propoxyphene | S | Oral | Unk | Not Reported |
| Solifenacin                | S | Oral | Unk | Not Reported |
| Progestin                  | S | Oral | Unk | Not Reported |

| <u>FDA Received Date</u>                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 07-Feb-2013                                | 9053250        | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000042490    |                      | 44 YR           | Male         | FRA            |
| <u>Preferred Term</u>                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain;<br>Hypertriglyceridaemia   | Escitalopram   |                    |                    | S               | Oral                 | 20 Mg                |                 | Forest       |                |
| <u>FDA Received Date</u>                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Feb-2013                                | 9060067        | DIRECT             | Y                  | OT              |                      |                      | 34 YR           | Female       | USA            |
| <u>Preferred Term</u>                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Product<br>Substitution Issue; | Escitalopram   |                    |                    | S               | Oral                 |                      |                 | Mylan        |                |
|                                            | Geodon         |                    |                    | C               |                      |                      |                 | Not Reported |                |

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

|                   |                         |   |              |
|-------------------|-------------------------|---|--------------|
| Suicidal Ideation | Wellbutrin Generic      | C | Not Reported |
|                   | Prozac Generic          | C | Not Reported |
|                   | Lamictal Generic        | C | Not Reported |
|                   | Spironolactone Genericm | C | Not Reported |
|                   | Lunesta                 | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Feb-2013              | 9096231       | EXPEDITED (15-DAY) |                    | LT              | FR-FRI-1000042451    |                      | 96 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Cardiac Failure;<br>Hyponatraemia;<br>Respiratory Distress | Escitalopram   |              |            | S           | Oral         | 15 Mg              |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 07-Feb-2013              | 9096307       | EXPEDITED (15-DAY) |                    | OT              | CA-JNJFOC-20130114957 |                      | 31 YR      | Female     | CAN            |

| <u>Preferred Term</u>                                                                                                                                                | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                             | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|------------------------------------------|--------------------|-----------------|--------------|
| Abortion Spontaneous;<br>Arthralgia; Blood Iron<br>Decreased; Exposure<br>During Pregnancy; Lung<br>Infection; Melanocytic<br>Naevus; Rheumatoid<br>Factor Increased | Remicade             |              |            | S           | Intravenous (not<br>otherwise specified) |                    |                 | Not Reported |
|                                                                                                                                                                      | Tylenol With Codeine |              |            | S           | Unknown                                  |                    |                 | Not Reported |
|                                                                                                                                                                      | Imodium              |              |            | S           | Unknown                                  |                    |                 | Not Reported |
|                                                                                                                                                                      | Ventolin             |              |            | S           | Unknown                                  |                    |                 | Not Reported |
|                                                                                                                                                                      | Tecta                |              |            | S           | Unknown                                  |                    |                 | Not Reported |
|                                                                                                                                                                      | Cipralex             |              |            | S           | Unknown                                  |                    |                 | Not Reported |
|                                                                                                                                                                      | Multivitamins        |              |            | C           | Unknown                                  |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Feb-2013              | 9120032       | EXPEDITED (15-DAY) |                    | HO, OT          | PHEH2013US002804     |                      |            | Female     | USA            |

| <u>Preferred Term</u>                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Arthralgia; Asthenia;<br>Breast Cancer; | Femara         |              |            | S           |              | 2.5 Mg, Qd         |                 | Novartis     |
|                                         | Zometa         |              |            | S           |              | Unk Unk, Unk       |                 | Not Reported |

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

|                        |               |   |              |              |
|------------------------|---------------|---|--------------|--------------|
| Depression; Fatigue;   | Arimidex      | S | Unk Ukn, Unk | Not Reported |
| Headache;              | Lexapro       | S | Unk Ukn, Unk | Not Reported |
| Lymphoedema; Malignant | Tamoxifen     | C | Unk Ukn, Unk | Not Reported |
| Neoplasm Progression;  | Toremifene    | C | Unk Ukn, Unk | Not Reported |
| Metastases To Bone;    | Wellbutrin Xr | C | Unk Ukn, Unk | Not Reported |
| Nausea; Pallor; Renal  | Taxol         | C | Unk Ukn, Unk | Not Reported |
| Impairment; Suicide    | Gemcitabine   | C | Unk Ukn, Unk | Not Reported |
| Attempt; Tardive       | Navelbine     | C | Unk Ukn, Unk | Not Reported |
| Dyskinesia; Tooth      | Vitamin D3    | C | Unk Ukn, Unk | Not Reported |
| Fracture               | Cozaar        | C | Unk Ukn, Unk | Not Reported |
|                        | Metformin     | C | Unk Ukn, Unk | Not Reported |
|                        | Omeprazole    | C | Unk Ukn, Unk | Not Reported |
|                        | Senna         | C | Unk Ukn, Unk | Not Reported |
|                        | Atenolol      | C | Unk Ukn, Unk | Not Reported |
|                        | Zofran        | C | Unk Ukn, Unk | Not Reported |
|                        | Naprosyn      | C | Unk Ukn, Unk | Not Reported |
|                        | Compazine     | C | Unk Ukn, Unk | Not Reported |
|                        | Trazodone     | C | Unk Ukn, Unk | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Feb-2013              | 8895875       | EXPEDITED (15-DAY) | HO                 |                 | JP-FRI-1000040172    |                      | 21 YR      | Female     | JPN            |

| <u>Preferred Term</u>                                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Agitation; Delirium;<br>Hyperthyroidism;<br>Overdose; Tachycardia | Lexapro        |              |            | S           | Oral         |                    |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Feb-2013              | 9010700       | EXPEDITED (15-DAY) | HO                 |                 | FR-FRI-1000041482    |                      | 76 YR      | Female     | FRA            |

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

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

|                                         |              |   |      |       |  |              |
|-----------------------------------------|--------------|---|------|-------|--|--------------|
| Drug Interaction; Rectal<br>Haemorrhage | Escitalopram | S | Oral |       |  | Forest       |
|                                         | Inexium      | S | Oral | 20 Mg |  | Not Reported |
|                                         | Lantus       | C |      |       |  | Not Reported |
|                                         | Atenolol     | C |      | 50 Mg |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Feb-2013              | 9045327       | EXPEDITED (15-DAY) |                    | DE              | FR-FRI-1000042328    |                      |            | Female     | FRA            |

| <u>Preferred Term</u>                                                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiac Failure; Diabetes<br>Mellitus; Hyponatraemia;<br>Nausea; Vomiting | Escitalopram   |              |            | S           | Oral         | 5 Mg               |                 | Forest       |
|                                                                           | Cordarone      |              |            | C           |              |                    |                 | Not Reported |
|                                                                           | Plavix         |              |            | C           |              |                    |                 | Not Reported |
|                                                                           | Burinex        |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Feb-2013              | 9054313       | EXPEDITED (15-DAY) |                    | DE              | CHPA2013US002546     |                      | 57 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Diphenhydramine |              | Y          | S           | Oral         | Unk, Unk           |                 | Novartis     |
|                       | Lamotrigine     |              |            | S           | Oral         | Unk, Unk           |                 | Not Reported |
|                       | Escitalopram    |              |            | S           | Oral         | Unk, Unk           |                 | Not Reported |
|                       | Aripiprazole    |              |            | S           | Oral         | Unk, Unk           |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------------------|----------------------|------------|------------|----------------|
| 08-Feb-2013              | 9054507       | NON-EXPEDITED    |                    |                 | US-<br>GLAXOSMITHKLINE-<br>A0998441A |                      | 57 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Anxiety               | Paxil          |              |            | S           |              | 5mg Alternate Days |                 | Glaxosmithkline |
|                       | Escitalopram   |              |            | S           |              | 5mg Per Day        |                 | Mylan           |
|                       | Xanax          |              |            | C           |              |                    |                 | Glaxosmithkline |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Feb-2013              | 9113640       | EXPEDITED (15-DAY) |                    | DE              | CHPA2013US002527     |                      | 64 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>               | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Lansoprazole                 |              |            | S           | Oral         | Unk, Unk           |                 | Novartis     |
|                       | Desipramine                  |              |            | S           | Oral         | Unk, Unk           |                 | Not Reported |
|                       | Diltiazem Er                 |              |            | S           | Oral         | Unk, Unk           |                 | Not Reported |
|                       | Venlafaxine                  |              |            | S           | Oral         | Unk, Unk           |                 | Not Reported |
|                       | Lamotrigine                  |              |            | S           | Oral         | Unk, Unk           |                 | Not Reported |
|                       | Hydrochlorothiazide          |              |            | S           | Oral         | Unk, Unk           |                 | Not Reported |
|                       | Armodafinil                  |              |            | S           | Oral         | Unk, Unk           |                 | Not Reported |
|                       | Potassium Chloride           |              |            | S           | Oral         | Unk, Unk           |                 | Not Reported |
|                       | Trifluoperazine              |              |            | S           | Oral         | Unk, Unk           |                 | Not Reported |
|                       | Escitalopram                 |              |            | S           | Oral         | Unk, Unk           |                 | Not Reported |
|                       | Thyroid Preparations         |              |            | S           | Oral         | Unk, Unk           |                 | Not Reported |
|                       | Pantoprazole                 |              |            | S           | Oral         | Unk, Unk           |                 | Not Reported |
|                       | Naproxen                     |              |            | S           | Oral         | Unk, Unk           |                 | Not Reported |
|                       | Nitrofurantoin               |              |            | S           | Oral         | Unk, Unk           |                 | Not Reported |
|                       | Diclofenac                   |              |            | S           | Oral         | Unk, Unk           |                 | Not Reported |
|                       | Acetaminophen W/Hydrocodone  |              |            | S           | Oral         | Unk, Unk           |                 | Not Reported |
|                       | Acetaminophen W/Propoxyphene |              |            | S           | Oral         | Unk, Unk           |                 | Not Reported |
|                       | Solifenacin                  |              |            | S           | Oral         | Unk, Unk           |                 | Not Reported |
|                       | Ciprofloxacin                |              |            | S           | Oral         | Unk, Unk           |                 | Not Reported |
|                       | Progestin                    |              |            | S           | Oral         | Unk, Unk           |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Feb-2013              | 9113938       | EXPEDITED (15-DAY) |                    | DE, OT          | CHPA2013US002528     |                      | 66 YR      | Female     | USA            |

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

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                 |                             |   |   |      |          |              |
|-------------------------------------------------|-----------------------------|---|---|------|----------|--------------|
| Cardio-Respiratory Arrest;<br>Completed Suicide | Acetaminophen (Paracetamol) | Y | S | Oral | Unk, Unk | Novartis     |
|                                                 | Lithium                     |   | S | Oral | Unk, Unk | Not Reported |
|                                                 | Escitalopram                |   | S | Oral | Unk, Unk | Not Reported |
|                                                 | Methylphenidate             |   | S | Oral | Unk, Unk | Not Reported |
|                                                 | Aripiprazole                |   | S | Oral | Unk, Unk | Not Reported |
|                                                 | Simvastatin                 |   | S | Oral | Unk, Unk | Not Reported |
|                                                 | Valaciclovir                |   | S | Oral | Unk, Unk | Not Reported |
|                                                 | Propoxyphene                |   | S | Oral | Unk, Unk | Not Reported |
|                                                 | Hydrocodone                 |   | S | Oral | Unk, Unk | Not Reported |
|                                                 | Oxycodone                   |   | S | Oral | Unk, Unk | Not Reported |
|                                                 | Triazolam                   |   | S | Oral | Unk, Unk | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Feb-2013              | 9113984       | EXPEDITED (15-DAY) |                    | DE              | CHPA2013US002435     |                      | 52 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Acetaminophen (Paracetamol) | Y            |            | S           |              | Unk, Unk           |                 | Novartis     |
|                       | Escitalopram                |              |            | S           |              | Unk, Unk           |                 | Not Reported |
|                       | Oxycodone                   |              |            | S           |              | Unk, Unk           |                 | Not Reported |
|                       | Benzodiazepines             |              |            | S           |              | Unk, Unk           |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Feb-2013              | 9117247       | EXPEDITED (15-DAY) |                    | OT              | US-FRI-1000042420    |                      | 52 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Retinal Detachment    | Lexapro        |              |            | S           |              |                    |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Feb-2013              | 8988918       | EXPEDITED (15-DAY) |                    | OT              | US-FRI-1000041249    |                      | 64 YR      | Female     | USA            |

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

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

|                                                           |               |   |      |           |              |
|-----------------------------------------------------------|---------------|---|------|-----------|--------------|
| Anal Haemorrhage;<br>Gastric Dilatation; Off<br>Label Use | Lexapro       | S | Oral | 10 Mg     | Forest       |
|                                                           | Lexapro       | S | Oral | 10 Mg Qod | Forest       |
|                                                           | Aspirin       | C |      |           | Not Reported |
|                                                           | Levothyroxine | C |      | 50 Mcg    | Not Reported |
|                                                           | Vitamin B12   | C |      |           | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 11-Feb-2013              | 9058949       | NON-EXPEDITED    |                    |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>16432361 |                      | 76 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>           |
|-----------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------|
| Drug Eruption         | Metformin Hcl        |              |            | S           |              |                    |                 | Bristol Myers Squibb |
|                       | Plavix               |              |            | S           |              |                    |                 | Sanofi Aventis       |
|                       | Plavix               |              |            | S           |              |                    |                 | Sanofi Aventis       |
|                       | Ramipril             |              |            | S           |              |                    |                 | Not Reported         |
|                       | Furosemide           |              |            | S           |              |                    |                 | Not Reported         |
|                       | Simvastatin          |              |            | S           |              |                    |                 | Not Reported         |
|                       | Lexapro              |              |            | S           |              |                    |                 | Not Reported         |
|                       | Folic Acid           |              |            | S           |              |                    |                 | Not Reported         |
|                       | Amlodipine           |              |            | S           |              |                    |                 | Not Reported         |
|                       | Metoprolol Succinate |              |            | S           |              |                    |                 | Not Reported         |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>        | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------------|----------------------|------------|------------|----------------|
| 11-Feb-2013              | 9077164       | EXPEDITED (15-DAY) |                    | DE              | US-RANBAXY-2013US-<br>64449 |                      | 64 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>                          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-----------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Ciprofloxacin                           |              |            | S           | Oral         |                    |                 | Ranbaxy      |
|                       | Pantoprazole                            |              |            | S           | Oral         |                    |                 | Ranbaxy      |
|                       | Pantoprazole                            |              |            | S           |              | Unk                |                 | Ranbaxy      |
|                       | Acetaminophen\Hydrocodone<br>Bitartrate |              |            | S           | Oral         |                    |                 | Ranbaxy      |
|                       | Venlafaxin                              |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Rosuvastatin                            |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                       | Escitalopram                            |              |            | S           | Oral         |                    |                 | Not Reported |

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

|                           |   |         |              |
|---------------------------|---|---------|--------------|
| Lamotrigina               | S | Oral    | Not Reported |
| Diclofenac                | S | Oral    | Not Reported |
| Lansoprazole              | S | Oral    | Not Reported |
| Naproxen                  | S | Oral    | Ranbaxy      |
| Nitrofurantoin            | S | Oral    | Ranbaxy      |
| Hydrochlorothiazide       | S | Oral    | Ipca         |
| Solifenacin               | S | Oral    | Not Reported |
| Potassium Chloride        | S | Oral    | Not Reported |
| Progesterone              | S | Oral    | Not Reported |
| Diltiazem                 | S | Unknown | Unk          |
| Desipramine               | S | Oral    | Not Reported |
| Armodafonil               | S | Oral    | Not Reported |
| Trifluoperazine           | S | Oral    | Not Reported |
| Acetaminophenpropoxyphene | S | Oral    | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 11-Feb-2013              | 9112803       | EXPEDITED (15-DAY) |                    | HO              | FR-ASTRAZENECA-2013SE00665 |                      | 76 YR      | Female     | FRA            |

| <u>Preferred Term</u>                              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Inhibitory Drug Interaction;<br>Rectal Haemorrhage | Inexium        |              |            | S           | Oral         |                    |                 | Astrazeneca  |
|                                                    | Seroplex       |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                    | Lantus         |              |            | C           |              |                    |                 | Not Reported |
|                                                    | Atenolol       |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|------------|------------|----------------|
| 11-Feb-2013              | 9113118       | EXPEDITED (15-DAY) |                    | HO              | DK-SANOFI-AVENTIS-2013SA010006 |                      |            | Male       | DNK            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Urinary Retention     | Xatral         |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Quetiapine     |              |            | S           | Oral         | Form: 245          |                 | Not Reported |



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

|                                                                                   |                           |                    |                    |                 |                      |                      |                 |              |                |
|-----------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Escitalopram                                                                      |                           |                    | S                  |                 | Unknown              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                          | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Feb-2013                                                                       | 9060413                   | EXPEDITED (15-DAY) |                    | DE              | US-BANPHARM-20130650 |                      | 46 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                             | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                                                 | Valproic Acid             |                    |                    | S               | Oral                 | Unk,                 |                 | Not Reported |                |
|                                                                                   | Hydroxyzine               |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                   | Ibuprofen Unknown Product |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                   | Cyclobenzaprine           |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                   | Escitalopram              |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                          | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Feb-2013                                                                       | 9060429                   | EXPEDITED (15-DAY) |                    | DE              | US-BANPHARM-20130666 |                      | 18 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                             | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Death                                                                             | Valproic Acid             |                    |                    | S               | Oral                 | Unk,                 |                 | Not Reported |                |
|                                                                                   | Chlorpromazine            |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                   | Quetiapine                |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                   | Escitalopram              |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                          | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Feb-2013                                                                       | 9068530                   | DIRECT             | Y                  |                 |                      |                      | 36 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                             | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Dizziness; Headache; Muscle Twitching; Paraesthesia; Withdrawal Syndrome | Escitalopram              |                    |                    | S               | Oral                 | 20 Mg Daily Po       |                 | Aurobindo    |                |
| <u>FDA Received Date</u>                                                          | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Feb-2013                                                                       | 9097244                   | EXPEDITED (15-DAY) |                    | DE, OT          | US-NOVEN-13US006165  |                      | 66 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                             | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

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

|                                                 |                            |   |      |     |              |
|-------------------------------------------------|----------------------------|---|------|-----|--------------|
| Cardio-Respiratory Arrest;<br>Completed Suicide | Lithium Carbonate          | S | Oral | Unk | Noven        |
|                                                 | Methylphenidate            | S | Oral | Unk | Noven        |
|                                                 | Escitalopram               | S | Oral | Unk | Not Reported |
|                                                 | Aripiprazole               | S | Oral | Unk | Not Reported |
|                                                 | Simvastatin                | S | Oral | Unk | Not Reported |
|                                                 | Valacyclovir Hydrochloride | S | Oral | Unk | Not Reported |
|                                                 | Propoxyphene               | S | Oral | Unk | Not Reported |
|                                                 | Hydrocodone                | S | Oral | Unk | Not Reported |
|                                                 | Oxycodone                  | S | Oral | Unk | Not Reported |
|                                                 | Triazolam                  | S | Oral | Unk | Not Reported |
|                                                 | Acetaminophen              | S | Oral | Unk | Not Reported |

| <u>FDA Received Date</u>                                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 12-Feb-2013                                                | 9097703        | EXPEDITED (15-DAY) |                    | OT              | US-FRI-1000042506    |                      | 52 YR           | Male         | USA            |
| <u>Preferred Term</u>                                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Coordination<br>Abnormal; Haemorrhagic<br>Stroke | Lexapro        |                    |                    | S               |                      |                      |                 | Forest       |                |
|                                                            | Lexapro        |                    |                    | S               |                      |                      |                 | Forest       |                |
|                                                            | Interferon Nos |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>     | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 13-Feb-2013                  | 9092584        | DIRECT           |                    | OT              |                      |                      | 38 YR           | Female       | USA            |
| <u>Preferred Term</u>        | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypersomnia;<br>Paraesthesia | Cymbalta       |                  |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                              | Lexapro        |                  |                    | S               | Oral                 |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 13-Feb-2013              | 9093135        | DIRECT           | Y                  | OT              |                      |                      | 47 YR           | Female     | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

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

|                             |              |   |      |       |              |
|-----------------------------|--------------|---|------|-------|--------------|
| Anxiety; Asthma;            | Escitalopram | S | Oral | 3 MTH | Not Reported |
| Headache; Heart Rate        | Escitalopram | C |      |       | Not Reported |
| Irregular; Irritability;    |              |   |      |       |              |
| Product Substitution Issue; |              |   |      |       |              |
| Weight Increased            |              |   |      |       |              |

| <u>FDA Received Date</u>                | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------|---------------------------|--------------------|--------------------|-----------------|----------------------|---------------------------------------------------------------------|-----------------|--------------|----------------|
| 13-Feb-2013                             | 9098491                   | EXPEDITED (15-DAY) |                    | OT              | US-WATSON-2013-01825 |                                                                     | 60 YR           | Male         | USA            |
| <u>Preferred Term</u>                   | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;<br>Serotonin Syndrome | Trazodone Hydrochloride   |                    |                    | S               | Unknown              | 100 Mg, Daily                                                       |                 | Watson       |                |
|                                         | Escitalopram              |                    |                    | S               | Oral                 | 20 Mg, Daily                                                        |                 | Not Reported |                |
|                                         | Methylthioninium Chloride |                    |                    | S               | Unknown              | 1 Mg/Kg Bolus, Followed<br>By 0.5 Mg/Kg/Hour<br>Continuous Infusion |                 | Not Reported |                |
|                                         | Phenylephrine             |                    |                    | C               | Unknown              | Unk, Unknown                                                        |                 | Not Reported |                |

| <u>FDA Received Date</u>                               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| 13-Feb-2013                                            | 9098675        | EXPEDITED (15-DAY) |                    | HO              | FR-ASTRAZENECA-2013SE09321 |                      | 83 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Fall;<br>Hyponatraemia; Nausea;<br>Vomiting | Hytacand       |                    |                    | S               | Oral                       | 16/12.5 Mg/D         |                 | Astrazeneca  |                |
|                                                        | Seroplex       |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                        | Seroplex       |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                        | Plavix         |                    |                    | C               |                            |                      |                 | Not Reported |                |
|                                                        | Foradil        |                    |                    | C               |                            |                      |                 | Not Reported |                |
|                                                        | Stilnox        |                    |                    | C               |                            |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 13-Feb-2013              | 9098726        | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000042538    |                      | < 1 DAY         | Male       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Multiple Cardiac Defects | Lexapro        |                    |                    | S               | Transplacental       |                      |                 | Forest     |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                        | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 13-Feb-2013                                                                                                                                                     | 9098727        | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000042516    |                      | < 1 DAY         | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                           | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Congenital Anomaly;<br>Developmental Delay;<br>Heterotaxia; Pulmonary<br>Artery Atresia;<br>Transposition Of The<br>Great Vessels; Ventricular<br>Septal Defect | Lexapro        |                    |                    | S               | Transplacental       |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                                                        | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Feb-2013                                                                                                                                                     | 9060762        | EXPEDITED (15-DAY) |                    | HO              | IT-FRI-1000042319    |                      | 76 YR           | Male         | ITA            |
| <u>Preferred Term</u>                                                                                                                                           | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Epilepsy; Hyponatraemia                                                                                                                                         | Escitalopram   |                    |                    | S               | Oral                 | 20 Mg                |                 | Forest       |                |
|                                                                                                                                                                 | Pantoprazolo   |                    |                    | C               |                      | 40 Mg                |                 | Not Reported |                |
|                                                                                                                                                                 | Halcion        |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                        | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Feb-2013                                                                                                                                                     | 9066464        | EXPEDITED (15-DAY) |                    | HO              | IE-FRI-1000042579    |                      |                 | Male         | IRL            |
| <u>Preferred Term</u>                                                                                                                                           | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Low Birth Weight Baby                                                                                                                                           | Lexapro        |                    |                    | S               | Transplacental       |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                                                        | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Feb-2013                                                                                                                                                     | 9085369        | EXPEDITED (15-DAY) |                    | HO              | FI-FRI-1000042315    |                      | 14 YR           | Female       | FIN            |
| <u>Preferred Term</u>                                                                                                                                           | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Epilepsy; Off Label Use                                                                                                                                         | Escitalopram   |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                                                                                                                                                 | Escitalopram   |                    |                    | S               |                      |                      |                 | Forest       |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|------------------------------------------------------------|-----------------|--------------|----------------|
| 14-Feb-2013                                                                                                                                                  | 9094909        | DIRECT             |                    | DE, LT, OT      |                      |                                                            | 66 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Chest Pain;<br>Confusional State;<br>Disorientation;<br>Unresponsive To Stimuli                                                                   | Lexapro        |                    |                    | S               | Oral                 | 10mg? Once Daily? Po                                       |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                                                     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Feb-2013                                                                                                                                                  | 9099714        | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000042629    |                                                            |                 | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                                        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Vision Blurred; Vitreous<br>Floaters                                                                                                                         | Escitalopram   |                    |                    | S               | Oral                 | 10 Mg                                                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                                                     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Feb-2013                                                                                                                                                  | 8164685        | EXPEDITED (15-DAY) |                    | HO, OT          | PHHY2011FR82671      |                                                            | 77 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                                                                        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Anxiety;<br>Confusional State;<br>Creatinine Renal<br>Clearance Decreased;<br>Renal Failure; Seizure;<br>Status Epilepticus;<br>Suicidal Ideation | Exelon Patch   |                    |                    | S               | Transdermal          | 9.5 Mg/24 Hr                                               |                 | Novartis     |                |
|                                                                                                                                                              | Exelon Patch   |                    |                    | S               | Transdermal          | 4.6 Mg Daily                                               |                 | Novartis     |                |
|                                                                                                                                                              | Seroplex       |                    |                    | S               |                      | 15 Mg (10 Mg In The<br>Morning And 5 Mg In The<br>Evening) |                 | Not Reported |                |
|                                                                                                                                                              | Aldactazine    |                    |                    | C               |                      | 0.5 Df, Qd                                                 |                 | Not Reported |                |
|                                                                                                                                                              | Neurontin      |                    |                    | C               |                      | 600 Mg Daily                                               |                 | Not Reported |                |
|                                                                                                                                                              | Neurontin      |                    |                    | C               |                      | 1200 Mg Daily                                              |                 | Not Reported |                |
|                                                                                                                                                              | Gardenal       |                    |                    | C               |                      | 10 Mg, Qd                                                  |                 | Not Reported |                |
|                                                                                                                                                              | Tiapridal      |                    |                    | C               |                      | 100 Mg, Tid                                                |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Feb-2013              | 8455433       | EXPEDITED (15-DAY) |                    | OT              | JP-FRI-1000028582    |                      | 33 YR      | Male       | JPN            |

| <u>Preferred Term</u>                                                                                                                                                              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Blood Cholesterol Increased; Hypertriglyceridaemia; Liver Disorder | Lexapro        |              |            | S           | Oral         | 20 Mg              |                 | Forest       |
|                                                                                                                                                                                    | Tapizol        |              |            | S           | Oral         | 10 Mg              |                 | Not Reported |
|                                                                                                                                                                                    | Abilify        |              |            | S           | Oral         | 3 Mg               |                 | Not Reported |
|                                                                                                                                                                                    | Dogmatyl       |              |            | S           | Oral         | 100 Mg             |                 | Not Reported |
|                                                                                                                                                                                    | Meilax         |              |            | C           | Oral         | 2 Mg               |                 | Not Reported |
|                                                                                                                                                                                    | Flunitrazepam  |              |            | C           | Oral         | 1 Mg               |                 | Not Reported |
|                                                                                                                                                                                    | Rize           |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                                                    | Podonin-S      |              |            | C           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 15-Feb-2013              | 9012698       | EXPEDITED (15-DAY) |                    | DE              | US-ABBOTT-13P-163-1035670-00 |                      | 64 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Potassium Chloride        |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Lansoprazole              |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Diltiazem                 |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Pantoprazole              |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Ciprofloxacin             |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Escitalopram              |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Naproxen                  |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Armodafinil               |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Trifluoperazine           |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Venlafaxine Hydrochloride |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Diclofenac Sodium         |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Desipramine               |              |            | S           | Oral         |                    |                 | Not Reported |

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

|                                        |   |      |              |
|----------------------------------------|---|------|--------------|
| Lamotrigine                            | S | Oral | Not Reported |
| Hydrochlorothiazide                    | S | Oral | Not Reported |
| Nitrofurantoin                         | S | Oral | Not Reported |
| Acetaminophen W/Hydrocodone Bitartrate | S | Oral | Not Reported |
| Solifenacin                            | S | Oral | Not Reported |
| Progestin                              | S | Oral | Not Reported |
| Procet                                 | S | Oral | Not Reported |
| [Hydrocodone,Paracetamol]              |   |      |              |
| Thyroid Preparations                   | S |      | Not Reported |
| Rosuvastatin Calcium                   | S |      | Not Reported |
| Dextropropoxyphene/Paracetamol         | S | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Feb-2013              | 9064228       | EXPEDITED (15-DAY) |                    | HO              | IT-FRI-1000042492    |                      | 33 YR      | Female     | ITA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Overdose; Sopor       | Escitalopram   |              |            | S           | Oral         | 40 Mg              |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Feb-2013              | 9068936       | EXPEDITED (15-DAY) |                    | DE              | US-BANPHARM-20130737 |                      | 64 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>                           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Naproxen                                 |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Desipramine                              |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Diltiazem Hydrochloride Extended Release |              |            | S           |              |                    |                 | Not Reported |
|                       | Venlafaxine                              |              |            | S           |              |                    |                 | Not Reported |
|                       | Lamotrigine                              |              |            | S           |              |                    |                 | Not Reported |
|                       | Hydrochlorothiazide                      |              |            | S           |              |                    |                 | Not Reported |
|                       | Armodafinil                              |              |            | S           |              |                    |                 | Not Reported |
|                       | Potassium Chloride                       |              |            | S           |              |                    |                 | Not Reported |
|                       | Trifluoperazine                          |              |            | S           |              |                    |                 | Not Reported |
|                       | Escitalopram                             |              |            | S           |              |                    |                 | Not Reported |

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

|                            |   |              |
|----------------------------|---|--------------|
| Unspecified Ingredient     | S | Not Reported |
| Pantoprazole               | S | Not Reported |
| Lansoprazole               | S | Not Reported |
| Rovustatin                 | S | Not Reported |
| Nitrofurantoin             | S | Not Reported |
| Diclofenac                 | S | Not Reported |
| Acetaminophen\Hydrocodone  | S | Not Reported |
| Acetaminophen/Propoxyphene | S | Not Reported |
| Solifenacin                | S | Not Reported |
| Ciprofloxacin              | S | Not Reported |
| Progestin                  | S | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Feb-2013              | 9069377       | EXPEDITED (15-DAY) |                    | DE              | US-BANPHARM-20130820 |                      | 57 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>                  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|---------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Diphenhydramine Unknown Product |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Lamotrigine                     |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Escitalopram                    |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Aripiprazole                    |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Feb-2013              | 9101320       | NON-EXPEDITED    |                    |                 | US-BAYER-2013-004977 |                      | 45 YR      | Female     | USA            |

| <u>Preferred Term</u>                             | <u>Product</u>                                         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------|--------------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Menorrhagia; Product Use In Unapproved Indication | Aleve                                                  |              |            | S           | Oral         | 5 Mg, Unk          |                 | Bayer        |
|                                                   | Bayer Genuine Aspirin Original Strength                |              |            | S           |              |                    |                 | Bayer        |
|                                                   | Ibuprofen                                              |              |            | S           |              | Unk                |                 | Bayer        |
|                                                   | Escitalopram                                           |              |            | S           | Oral         | 5 Mg, Unk          |                 | Not Reported |
|                                                   | Nyquil                                                 |              |            | S           |              |                    |                 | Not Reported |
|                                                   | Dayquil [Dextromet Hbr, Guaif, Paracet, Pseudoeph Hcl] |              |            | S           |              | Unk                |                 | Not Reported |



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

|        |   |     |              |
|--------|---|-----|--------------|
| Bc     | S | Unk | Not Reported |
| Zantac | C | Unk | Not Reported |
| Nexium | C |     | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 18-Feb-2013              | 9093309       | EXPEDITED (15-DAY) |                    | HO, OT          | CH-009507513-1302CHE006880 |                      | 53 YR      | Female     | CHE            |

| <u>Preferred Term</u>   | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------|-------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Confusional State;      | Remeron           |              |            | S           | Oral         | 10 Df, Once        |                 | Merck        |
| Contusion; Fall;        | Zolpidem Tartrate |              |            | S           | Oral         | 56 Df, Once        |                 | Not Reported |
| Hyperreflexia; Skin     | Escitalopram      |              |            | S           | Oral         | 28 Df, Once        |                 | Not Reported |
| Laceration; Somnolence; |                   |              |            |             |              |                    |                 |              |
| Suicide Attempt         |                   |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------------------------------------|----------------------|------------|------------|----------------|
| 18-Feb-2013              | 9101058       | EXPEDITED (15-DAY) |                    | DE              | US-COVIDIEN/TYCO HEALTHCARE/MALLIN CKRODT-T20130069 |                      | 48 YR      | Female     | USA            |

| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardio-Respiratory Arrest; | Roxicodone     |              |            | S           | Oral         | Unk                |                 | Tyco         |
| Completed Suicide          | Temazepam      |              |            | S           | Oral         |                    |                 | Tyco         |
|                            | Propranolol    |              |            | S           | Oral         |                    |                 | Not Reported |
|                            | Trazodone      |              |            | S           | Oral         |                    |                 | Not Reported |
|                            | Clonazepam     |              |            | S           | Oral         |                    |                 | Not Reported |
|                            | Hydroxyzine    |              |            | S           | Oral         |                    |                 | Not Reported |
|                            | Risperidone    |              |            | S           | Oral         |                    |                 | Not Reported |
|                            | Benzotropine   |              |            | S           | Oral         |                    |                 | Not Reported |
|                            | Escitalopram   |              |            | S           | Oral         |                    |                 | Not Reported |
|                            | Ondansetron    |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------------|----------------------|------------|------------|----------------|
| 18-Feb-2013              | 9101646       | EXPEDITED (15-DAY) |                    | DE              | US-COVIDIEN/TYCO HEALTHCARE/MALLIN |                      | 23 YR      | Female     | USA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

CKRODT-T20130042

| <u>Preferred Term</u> | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Acetaminophen/Codeine Tablets |              |            | S           | Oral         | Unk                |                 | Tyco         |
|                       | Metaxalone                    |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Escitalopram                  |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Quetiapine                    |              |            | S           |              | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------------------------------------------|----------------------|------------|------------|----------------|
| 18-Feb-2013              | 9101852       | EXPEDITED (15-DAY) |                    | DE              | US-COVIDIEN/TYCO<br>HEALTHCARE/MALLIN<br>CKRODT-T20130069 |                      | 65 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Acetaminophen/Codeine Tablets |              |            | S           | Oral         | Unk                |                 | Tyco         |
|                       | Metoprolol                    |              |            | S           |              |                    |                 | Not Reported |
|                       | Calcium Antagonist            |              |            | S           |              |                    |                 | Not Reported |
|                       | Gabapentin                    |              |            | S           |              |                    |                 | Not Reported |
|                       | Quetiapine                    |              |            | S           |              |                    |                 | Not Reported |
|                       | Escitalopram                  |              |            | S           |              |                    |                 | Not Reported |
|                       | Benzodiazepine Derivatives    |              |            | S           |              |                    |                 | Not Reported |
|                       | Eszopiclone                   |              |            | S           |              |                    |                 | Not Reported |
|                       | Simvastatin                   |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------------------------------------------|----------------------|------------|------------|----------------|
| 18-Feb-2013              | 9101903       | EXPEDITED (15-DAY) |                    | DE              | US-COVIDIEN/TYCO<br>HEALTHCARE/MALLIN<br>CKRODT-T20130058 |                      | 52 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Roxicodone                 |              |            | S           |              | Unk                |                 | Tyco         |
|                       | Acetaminophen              |              |            | S           |              |                    |                 | Not Reported |
|                       | Escitalopram               |              |            | S           |              |                    |                 | Not Reported |
|                       | Benzodiazepine Derivatives |              |            | S           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u>                                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|-----------------------------------------------------|--------------------|--------------------|-----------------|-----------------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 18-Feb-2013              | 9102395                                             | EXPEDITED (15-DAY) |                    | DE              | US-COVIDIEN/TYCO<br>HEALTHCARE/MALLIN<br>CKRODT-T20130067 |                      | 64 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>                                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide        | Acetaminophen\Hydrocodone<br>Bitartrate<br>Pennsaid |                    |                    | S               | Oral                                                      | Unk                  |                 | Tyco         |                |
|                          | Desipramine                                         |                    |                    | S               | Oral                                                      |                      |                 | Tyco         |                |
|                          | Diltiazem Er                                        |                    |                    | S               | Oral                                                      |                      |                 | Not Reported |                |
|                          | Venlafaxine                                         |                    |                    | S               | Oral                                                      |                      |                 | Not Reported |                |
|                          | Lamotrigine                                         |                    |                    | S               | Oral                                                      |                      |                 | Not Reported |                |
|                          | Hydrochlorothiazide                                 |                    |                    | S               | Oral                                                      |                      |                 | Not Reported |                |
|                          | Armodafinil                                         |                    |                    | S               | Oral                                                      |                      |                 | Not Reported |                |
|                          | Potassium Chloride                                  |                    |                    | S               | Oral                                                      |                      |                 | Not Reported |                |
|                          | Trifluoperazine                                     |                    |                    | S               | Oral                                                      |                      |                 | Not Reported |                |
|                          | Escitalopram                                        |                    |                    | S               | Oral                                                      |                      |                 | Not Reported |                |
|                          | Thyroid Preparations                                |                    |                    | S               | Oral                                                      |                      |                 | Not Reported |                |
|                          | Pantoprazole                                        |                    |                    | S               | Oral                                                      |                      |                 | Not Reported |                |
|                          | Lansoprazole                                        |                    |                    | S               | Oral                                                      |                      |                 | Not Reported |                |
|                          | Rosuvastatin                                        |                    |                    | S               | Oral                                                      |                      |                 | Not Reported |                |
|                          | Naproxen                                            |                    |                    | S               | Oral                                                      |                      |                 | Not Reported |                |
|                          | Nitrofurantoin                                      |                    |                    | S               | Oral                                                      |                      |                 | Not Reported |                |
|                          | Acetaminophen<br>W/Propoxyphene                     |                    |                    | S               | Oral                                                      |                      |                 | Not Reported |                |
|                          | Solifenacin                                         |                    |                    | S               | Oral                                                      |                      |                 | Not Reported |                |
|                          | Ciprofloxacin                                       |                    |                    | S               | Oral                                                      |                      |                 | Not Reported |                |
|                          | Progestin                                           |                    |                    | S               |                                                           |                      |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>                                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Feb-2013              | 9102421                                             | EXPEDITED (15-DAY) |                    | DE              | US-COVIDIEN/TYCO<br>HEALTHCARE/MALLIN                     |                      | 66 YR           | Female       | USA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

CKRODT-T20130067

| <u>Preferred Term</u>                           | <u>Product</u>             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------|----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardio-Respiratory Arrest;<br>Completed Suicide | Methylin                   |              |            | S           | Oral         | Unk                |                 | Tyco         |
|                                                 | Roxicodone                 |              |            | S           |              |                    |                 | Tyco         |
|                                                 | Lithium                    |              |            | S           |              |                    |                 | Not Reported |
|                                                 | Escitalopram               |              |            | S           |              |                    |                 | Not Reported |
|                                                 | Aripiprazole               |              |            | S           |              |                    |                 | Not Reported |
|                                                 | Simvastatin                |              |            | S           |              |                    |                 | Not Reported |
|                                                 | Valacyclovir Hydrochloride |              |            | S           |              |                    |                 | Not Reported |
|                                                 | Propoxyphene               |              |            | S           |              |                    |                 | Not Reported |
|                                                 | Hydrocodone                |              |            | S           |              |                    |                 | Not Reported |
|                                                 | Triazolam                  |              |            | S           |              |                    |                 | Not Reported |
|                                                 | Acetaminophen              |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 19-Feb-2013              | 8990027       | EXPEDITED (15-DAY) |                    | OT              | IT-ABBOTT-12P-083-1025461-00 |                      | 17 YR      | Female     | ITA            |

| <u>Preferred Term</u>                      | <u>Product</u>  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------|-----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Mental Disorder; Off Label<br>Use; Syncope | Akineton        |              |            | S           | Oral         | 8 Drop Daily       |                 | Not Reported |
|                                            | Depakine Chrono |              |            | S           | Oral         |                    |                 | Not Reported |
|                                            | Talofen         |              |            | S           | Oral         |                    |                 | Not Reported |
|                                            | Cipralelex      |              |            | S           | Oral         |                    |                 | Not Reported |
|                                            | Cipralelex      |              |            | S           |              |                    |                 | Not Reported |
|                                            | Abilify         |              |            | S           | Oral         | Every Other Day    |                 | Not Reported |
|                                            | Abilify         |              |            | S           |              |                    |                 | Not Reported |
|                                            | Evra            |              |            | S           | Transdermal  |                    |                 | Not Reported |
|                                            | Diazepam        |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 19-Feb-2013              | 9051016       | EXPEDITED (15-DAY) |                    | HO, OT          | ES-PFIZER INC-2013044367 |                      | 71 YR      | Male       | ESP            |

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

| <u>Preferred Term</u>                       | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------|-----------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Drug Interaction; Urinary Retention         | Morphine Sulfate                        |                    |                    | S               | Oral                 | 30 Mg, Daily         |                 | Pfizer       |                |
|                                             | Pregabalin                              |                    |                    | S               | Oropharingeal        | 25 Mg, Unk           |                 | Pfizer       |                |
|                                             | Esertia                                 |                    |                    | S               | Oral                 | 20 Mg, 2x/Day        |                 | Not Reported |                |
|                                             | Zomorph                                 |                    |                    | S               | Oral                 | 60 Mg, Daily         |                 | Not Reported |                |
|                                             | Humalog Mix Pen                         |                    |                    | C               | Subcutaneous         | Unk                  |                 | Not Reported |                |
|                                             | Lantus                                  |                    |                    | C               | Subcutaneous         | 32 lu, 1x/Day        |                 | Not Reported |                |
| <u>FDA Received Date</u>                    | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Feb-2013                                 | 9136945                                 | EXPEDITED (15-DAY) |                    | DS              | FR-FRI-1000042711    |                      | 40 YR           | Female       | FRA            |
| <u>Preferred Term</u>                       | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Disturbance In Attention; Memory Impairment | Escitalopram                            |                    |                    | S               |                      | 15 Mg                |                 | Forest       |                |
| <u>FDA Received Date</u>                    | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Feb-2013                                 | 9146396                                 | EXPEDITED (15-DAY) | Y                  | DE              | 2013-00284           |                      | 55 YR           | Male         | USA            |
| <u>Preferred Term</u>                       | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                           | Lisinopril (Lisinopril)                 |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                             | Quetiapine                              |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                             | Escitalopram                            |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                             | Trazodone                               |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                    | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Feb-2013                                 | 9312072                                 | EXPEDITED (15-DAY) | Y                  | DE              | THQ2013A00261        |                      | 64 YR           | Female       | USA            |
| <u>Preferred Term</u>                       | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                           | Lansoprazole (Lansoprazole)             |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                             | Diltiazem Hcl (Diltiazem Hydrochloride) |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                             | Venlafaxine Hcl (Venlafaxine            |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                             |                                         |                    |                    |                 |                      |                      |                 |              |                |

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

|                                                                    |   |      |  |  |  |  |  |  |              |
|--------------------------------------------------------------------|---|------|--|--|--|--|--|--|--------------|
| Hydrochloride)                                                     |   |      |  |  |  |  |  |  |              |
| Pantoprazole                                                       | S | Oral |  |  |  |  |  |  | Not Reported |
| Diclofenac Epolamine                                               | S | Oral |  |  |  |  |  |  | Not Reported |
| Ciprofloxacin                                                      | S |      |  |  |  |  |  |  | Not Reported |
| Desipramine                                                        | S | Oral |  |  |  |  |  |  | Not Reported |
| Lamotrigine                                                        | S | Oral |  |  |  |  |  |  | Not Reported |
| Hydrochlorothiazide                                                | S | Oral |  |  |  |  |  |  | Not Reported |
| Armodafinil                                                        | S | Oral |  |  |  |  |  |  | Not Reported |
| Potassium Chloride                                                 | S | Oral |  |  |  |  |  |  | Not Reported |
| Trifluoperazine                                                    | S | Oral |  |  |  |  |  |  | Not Reported |
| Escitalopram                                                       | S | Oral |  |  |  |  |  |  | Not Reported |
| Naproxen                                                           | S | Oral |  |  |  |  |  |  | Not Reported |
| Nitrofurantoin                                                     | S | Oral |  |  |  |  |  |  | Not Reported |
| Acetaminophen/Hydrocodone<br>(Paracetamol, Hydrocodone)            | S | Oral |  |  |  |  |  |  | Not Reported |
| Acetaminophen/Propoxyphene<br>(Paracetamol,<br>Dextropropoxyphene) | S | Oral |  |  |  |  |  |  | Not Reported |
| Solifenacin                                                        | S | Oral |  |  |  |  |  |  | Not Reported |
| Progesterin (Progesterone)                                         | S | Oral |  |  |  |  |  |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Feb-2013              | 8611165       | EXPEDITED (15-DAY) |                    | HO, OT          | DE-FRI-1000031251    |                      | 24 YR      | Female     | DEU            |

| <u>Preferred Term</u>            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|----------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Generalised Tonic-Clonic Seizure | Escitalopram   |              |            | S           | Oral         | 20 Mg              |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Feb-2013              | 9061703       | EXPEDITED (15-DAY) | Y                  | DE              | AUR-APL-2013-00516   |                      | 64 YR      | Female     | USA            |

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

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

|                                                  |                                              |   |      |         |              |
|--------------------------------------------------|----------------------------------------------|---|------|---------|--------------|
| Completed Suicide;<br>Toxicity To Various Agents | Venlafaxine                                  | S |      | Unknown | Not Reported |
|                                                  | Nitrofurantoin                               | S |      | Unknown | Not Reported |
|                                                  | Diclofenac (Diclofenac)                      | S |      | Unknown | Not Reported |
|                                                  | Acetaminophen/ Hydrocodone                   | S |      | Unknown | Not Reported |
|                                                  | Acetaminophen/Propoxyphene                   | S |      | Unknown | Not Reported |
|                                                  | Solifenacin                                  | S | Oral | Oral    | Not Reported |
|                                                  | Lamotrigine (Lamotrigine)                    | S |      | Unknown | Not Reported |
|                                                  | Hydrochlorothiazide<br>(Hydrochlorothiazide) | S |      | Unknown | Not Reported |
|                                                  | Ciprofloxacin (Ciprofloxacin)                | S |      | Unknown | Not Reported |
|                                                  | Naproxen (Naproxen)                          | S |      | Unknown | Not Reported |
|                                                  | Escitalopram                                 | S |      | Unknown | Not Reported |
|                                                  | Desipramine (Desipramine)<br>(Desipramine)   | S | Oral | Unknown | Not Reported |
|                                                  | Rosuvastatin (Rosuvastatin)                  | S |      | Unknown | Not Reported |
|                                                  | Diltiazem                                    | S |      | Unknown | Not Reported |
|                                                  | Lansoprazole (Lansoprazole)                  | S |      | Unknown | Not Reported |
|                                                  | Armodafinil                                  | S |      | Unknown | Not Reported |
|                                                  | Pantoprazole (Pantoprazole)                  | S |      | Unknown | Not Reported |
|                                                  | Unspecified Ingredient                       | S |      | Unknown | Not Reported |
|                                                  | Escitalopram (Escitalopram)                  | S |      | Unknown | Not Reported |
|                                                  | Trifluoperazine                              | S |      | Unknown | Not Reported |
|                                                  | Potassium Chloride (Potassium<br>Chloride)   | S |      | Unknown | Not Reported |
|                                                  | Progesterin (Progesterone)                   | S |      |         | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Feb-2013              | 9101164       | DIRECT           | Y                  |                 |                      |                      |            | Female     | USA            |

  

| <u>Preferred Term</u>                                | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Dispensed To Wrong<br>Patient; Medication Error | Escitalopram Oxalate |              |            | S           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                                     | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>               | <u>Age</u>       | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|--------------------|--------------------|-----------------|----------------------|------------------------------------|------------------|--------------|----------------|
| 20-Feb-2013                                                                                                                                                                                                                  | 9105954                    | EXPEDITED (15-DAY) |                    | HO, LT          | AU-FRI-1000042748    |                                    | 25 YR            | Female       | AUS            |
| <u>Preferred Term</u>                                                                                                                                                                                                        | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                 | <u>Duration</u>  | <u>Mfr</u>   |                |
| Intentional Self-Injury;<br>Obsessive-Compulsive<br>Disorder                                                                                                                                                                 | Lexapro                    |                    |                    | S               | Oral                 | 5 Mg                               |                  | Forest       |                |
|                                                                                                                                                                                                                              | Lexapro                    |                    |                    | S               | Oral                 | 10 Mg                              |                  | Forest       |                |
|                                                                                                                                                                                                                              | Lexapro                    |                    |                    | S               | Oral                 | 5 Mg                               |                  | Forest       |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                     | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>               | <u>Age</u>       | <u>Sex</u>   | <u>Country</u> |
| 20-Feb-2013                                                                                                                                                                                                                  | 9106012                    | EXPEDITED (15-DAY) |                    | HO              | IT-FRI-1000042749    |                                    | 36 YR            | Male         | ITA            |
| <u>Preferred Term</u>                                                                                                                                                                                                        | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                 | <u>Duration</u>  | <u>Mfr</u>   |                |
| Overdose; Pain; Vomiting                                                                                                                                                                                                     | Escitalopram Oral Solution |                    |                    | S               | Oral                 | Overdose: Cipralext 20 MI<br>Total |                  | Forest       |                |
|                                                                                                                                                                                                                              | Alcohol                    |                    |                    | S               |                      |                                    |                  | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                     | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>               | <u>Age</u>       | <u>Sex</u>   | <u>Country</u> |
| 20-Feb-2013                                                                                                                                                                                                                  | 9114892                    | DIRECT             |                    | OT              |                      |                                    | 33 YR            | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                        | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                 | <u>Duration</u>  | <u>Mfr</u>   |                |
| Anxiety; Decreased<br>Appetite; Depression;<br>Nausea; Panic Attack;<br>Performance Status<br>Decreased; Product<br>Substitution Issue; Quality<br>Of Life Decreased;<br>Suicidal Ideation;<br>Vomiting; Weight<br>Decreased | Escitalopram               |                    |                    | S               | Oral                 |                                    | 2 WEEK<br>2 WEEK | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                     | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>               | <u>Age</u>       | <u>Sex</u>   | <u>Country</u> |
| 20-Feb-2013                                                                                                                                                                                                                  | 9145310                    | EXPEDITED (15-DAY) | Y                  | DE              | 2013-00382           |                                    | 65 YR            | Male         | USA            |



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

| <u>Preferred Term</u> | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Simvastatin           |              |            | S           |              |                    |                 | Not Reported |
|                       | Quetiapine            |              |            | S           |              |                    |                 | Not Reported |
|                       | Escitalopram          |              |            | S           |              |                    |                 | Not Reported |
|                       | Metoprolol            |              |            | S           |              |                    |                 | Not Reported |
|                       | Gabapentin            |              |            | S           |              |                    |                 | Not Reported |
|                       | Acetaminophen/Codeine |              |            | S           |              |                    |                 | Not Reported |
|                       | Eszopiclone           |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Feb-2013              | 9075985       | EXPEDITED (15-DAY) |                    | CA, DE, OT      | US-FRI-1000041995    |                      | < 1 DAY    | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                 | <u>Product</u>   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Atrial Septal Defect; Cleft Lip; Cleft Palate; Congenital Anomaly; Cytogenetic Abnormality; Deafness; Double Outlet Right Ventricle; Exomphalos; Lung Disorder; Multiple Cardiac Defects; Neural Tube Defect; Newborn Persistent Pulmonary Hypertension; Pulmonary Artery Stenosis Congenital; Talipes; Transposition Of The Great Vessels; Ventricular Septal Defect | Lexapro          |              |            | S           | Transplacental |                    |                 | Forest       |
|                                                                                                                                                                                                                                                                                                                                                                       | Zoloft           |              |            | S           | Transplacental |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                       | Prenatal Vitamin |              |            | S           | Transplacental |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Feb-2013              | 9115380       | DIRECT           | Y                  | OT              |                      |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Depression            | Escitalopram 20mg Generic |              |            | S           | Oral         |                    | 30 DAY          | Unknown    |

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

| <u>FDA Received Date</u>          | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------|-----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 21-Feb-2013                       | 9118815               | DIRECT             |                    |                 |                      |                      |                 | Female       | USA            |
| <u>Preferred Term</u>             | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective;<br>Palpitations | Citalopram 20 Mg      |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                   | Escitalopram          |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>          | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Feb-2013                       | 9148345               | EXPEDITED (15-DAY) | Y                  | DE              | 2013-00500           |                      | 66 YR           | Female       | USA            |
| <u>Preferred Term</u>             | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                 | Simvastatin (Unknown) |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                   | Escitalopram          |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                   | Lithium               |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                   | Methylphenidate       |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                   | Aripiprazole          |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                   | Valacyclovir          |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                   | Propoxyphene          |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                   | Hydrocodone           |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                   | Oxycodone             |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                   | Triazolam             |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                   | Acetaminophen         |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>          | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Feb-2013                       | 9101173               | EXPEDITED (15-DAY) |                    | OT              | US-FRI-1000042670    |                      |                 | Female       | USA            |
| <u>Preferred Term</u>             | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Obesity                           | Escitalopram          |                    |                    | S               |                      |                      |                 | Forest       |                |
|                                   | Escitalopram          |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                   | Clozaril              |                    |                    | S               | Oral                 | 300 Mg               |                 | Not Reported |                |
|                                   | Clozaril              |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                   | Clozaril              |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                   | Clozaril              |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                   | Eskalith Cr           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                   | Eskalith Cr           |                    |                    | C               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| 22-Feb-2013                                                                                                                                                                         | 9108605        | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000042856            |                      | < 1 DAY         | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Congenital Anomaly;<br>Gastroesophageal Reflux<br>Disease; Patent Ductus<br>Arteriosus; Talipes                                                                                     | Lexapro        |                    |                    | S               | Transplacental               |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                                                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Feb-2013                                                                                                                                                                         | 9119388        | DIRECT             | Y                  | OT              |                              |                      | 29 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Behaviour;<br>Cognitive Disorder                                                                                                                                           | Escitalopram   |                    |                    | S               |                              | Lexapro 20 Mg Qd     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Feb-2013                                                                                                                                                                         | 9119453        | DIRECT             | Y                  | OT              |                              |                      | 52 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Irritability; Tension                                                                                                                                                               | Lexapro        |                    |                    | S               | Oral                         | 10 Mg. Daily Po      |                 | Teva         |                |
| <u>FDA Received Date</u>                                                                                                                                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Feb-2013                                                                                                                                                                         | 8012810        | EXPEDITED (15-DAY) |                    | CA, DE, HO, OT  | US-PFIZER INC-<br>2011139942 |                      | 2 DAY           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aortic Stenosis; Aortic<br>Valve Disease Mixed;<br>Bicuspid Aortic Valve;<br>Endocarditis; Foetal<br>Exposure During<br>Pregnancy; Intracranial<br>Venous Sinus<br>Thrombosis; Left | Zoloft         |                    |                    | S               | Transplacental               | 50 Mg, 1x/Day        |                 | Pfizer       |                |
|                                                                                                                                                                                     | Lexapro        |                    |                    | S               | Transplacental               | Unk                  |                 | Not Reported |                |
|                                                                                                                                                                                     | Hydroxyzine    |                    |                    | C               | Transplacental               | Unk                  |                 | Not Reported |                |
|                                                                                                                                                                                     | Amoxil         |                    |                    | C               | Transplacental               | Unk                  |                 | Not Reported |                |
|                                                                                                                                                                                     | Chromagen Ob   |                    |                    | C               | Transplacental               | Unk                  |                 | Not Reported |                |

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

|                                                                                                                                                                                                                  |                                                                                                                                                |                                           |                                                                                                                                                                |                                                                       |                                                                                                                                              |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------|
| Ventricular Dysfunction;<br>Left Ventricular Failure;<br>Lung Assist Device<br>Therapy; Mediastinal<br>Haemorrhage; Patent<br>Ductus Arteriosus;<br>Pulmonary Valve<br>Incompetence; Pulmonary<br>Valve Stenosis | Naproxen Sodium S<br>Nistatin<br>Dulcolax<br>Serax<br>Promethazine<br>Acetaminophen\Hydrocodone<br>Bitartrate<br>Ortho Tri Cyclen<br>Palgic Ds | C<br>C<br>C<br>C<br>C<br>C<br>C<br>C<br>C | Transplacental<br>Transplacental<br>Transplacental<br>Transplacental<br>Transplacental<br>Transplacental<br>Transplacental<br>Transplacental<br>Transplacental | Unk<br>Unk<br>Unk<br>15 Mg, 1x/Day<br>Unk<br>Unk<br>Unk<br>Unk<br>Unk | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Feb-2013              | 8468684       | EXPEDITED (15-DAY) |                    |                 | JP-FRI-1000029186    |                      | 33 YR      | Male       | JPN            |

| <u>Preferred Term</u>                     | <u>Product</u>                       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>      | <u>Route</u>                 | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>                                             |
|-------------------------------------------|--------------------------------------|--------------|------------|------------------|------------------------------|------------------------------------|-----------------|--------------------------------------------------------|
| Blood Creatine<br>Phosphokinase Increased | Lexapro<br>Myslee<br>Rize<br>Goodmin |              |            | S<br>C<br>C<br>C | Oral<br>Oral<br>Oral<br>Oral | 20 Mg<br>10 Mg<br>10 Mg<br>0.25 Mg |                 | Forest<br>Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 25-Feb-2013              | 9121472       | NON-EXPEDITED    |                    |                 | US-PFIZER INC-<br>2013065355 |                      | 42 YR      | Female     | USA            |

| <u>Preferred Term</u>                | <u>Product</u>                                               | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>           | <u>Route</u> | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>                                                             |
|--------------------------------------|--------------------------------------------------------------|--------------|------------|-----------------------|--------------|---------------------------------|-----------------|------------------------------------------------------------------------|
| Paraesthesia Oral; Taste<br>Disorder | Protonix<br>Benadryl<br>Lexapro<br>Klonopin<br>Vitamin D Nos |              |            | S<br>S<br>S<br>S<br>S |              | Unk<br>Unk<br>Unk<br>Unk<br>Unk |                 | Pfizer<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                             | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| 26-Feb-2013                                                          | 8934442                | EXPEDITED (15-DAY) |                    | OT              | DE-FRI-1000040677          |                      | 26 YR           | Male         | DEU            |
| <u>Preferred Term</u>                                                | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Solar Dermatitis                                                     | Escitalopram           |                    |                    | S               | Oral                       | 20 Mg                |                 | Forest       |                |
| <u>FDA Received Date</u>                                             | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Feb-2013                                                          | 9119626                | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000042915          |                      | 92 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;<br>International Normalised<br>Ratio Increased     | Escitalopram           |                    |                    | S               | Oral                       | 5 Mg                 |                 | Forest       |                |
|                                                                      | Previscan (Fluindione) |                    |                    | S               | Oral                       | 1 Df                 |                 | Not Reported |                |
|                                                                      | Paracetamol            |                    |                    | C               | Oral                       |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                             | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Feb-2013                                                          | 9119862                | EXPEDITED (15-DAY) |                    | DS, OT          | BR-ASTRAZENECA-2013SE11396 |                      |                 | Female       | BRA            |
| <u>Preferred Term</u>                                                | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Foot Fracture; Pulmonary<br>Embolism                                 | Seroquel               |                    |                    | S               | Oral                       |                      |                 | Zeneca       |                |
|                                                                      | Lexapro                |                    |                    | S               | Unknown                    |                      |                 | Not Reported |                |
|                                                                      | Unspecified Ingredient |                    |                    | S               | Unknown                    |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                             | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Feb-2013                                                          | 9120583                | EXPEDITED (15-DAY) |                    | DE              | US-ROCHE-1194082           |                      | 48 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest;<br>Respiratory Arrest;<br>Toxicity To Various Agents | Clonazepam             |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                                      | Clonazepam             |                    |                    | S               | Oral                       | Overdose             |                 | Not Reported |                |
|                                                                      | Propranolol            |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |

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

|              |   |      |          |              |
|--------------|---|------|----------|--------------|
| Propranolol  | S | Oral | Overdose | Not Reported |
| Oxycodone    | S | Oral |          | Not Reported |
| Oxycodone    | S | Oral | Overdose | Not Reported |
| Trazodone    | S | Oral |          | Not Reported |
| Trazodone    | S | Oral | Overdose | Not Reported |
| Hydroxyzine  | S | Oral |          | Not Reported |
| Hydroxyzine  | S | Oral | Overdose | Not Reported |
| Risperidone  | S | Oral |          | Not Reported |
| Risperidone  | S | Oral | Overdose | Not Reported |
| Temazepam    | S | Oral |          | Not Reported |
| Temazepam    | S | Oral | Overdose | Not Reported |
| Benztropine  | S | Oral |          | Not Reported |
| Benztropine  | S | Oral | Overdose | Not Reported |
| Escitalopram | S | Oral |          | Not Reported |
| Escitalopram | S | Oral | Overdose | Not Reported |
| Ondansetron  | S | Oral |          | Not Reported |
| Ondansetron  | S | Oral | Overdose | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Feb-2013              | 9123227       | DIRECT           |                    | OT              |                      |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                            | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------|--------------------|--------------|------------|-------------|--------------|----------------------|-----------------|--------------|
| Product Substitution Issue;<br>Supraventricular<br>Extrasystoles | Escitalopram 10 Mg |              |            | S           | Oral         | I Dose, Once/Day, Po | 5 WEEK          | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Feb-2013              | 9145510       | DIRECT           | Y                  | OT              |                      |                      | 22 YR      | Female     | USA            |

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

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

|                                                            |                                                             |   |      |              |
|------------------------------------------------------------|-------------------------------------------------------------|---|------|--------------|
| Drug Ineffective; Mood Altered; Product Substitution Issue | Escitalopram                                                | S | Oral | Not Reported |
|                                                            | Loestrin 24 Fe Tabs (Norethin Ace-Eth Estrad-Fe Tabs)       | C |      | Not Reported |
|                                                            | Lexapro 20 Mg Tabs (Escitalopram Oxalate)                   | C |      | Not Reported |
|                                                            | Trazodone Hcl 50 Mg Tabs (Trazodone Hcl)                    | C |      | Not Reported |
|                                                            | Adderall Xr 30 Mg Xr24h-Cap (Amphetamine-Dextroamphetamine) | C |      | Not Reported |
|                                                            | Anusol-Hc 25mg Supp (Hydrocortisone Acetate)                | C |      | Not Reported |
|                                                            | Flexeril 10mg Tabs (Cyclobenzaprine Hcl)                    | C |      | Not Reported |
|                                                            | Naprosyn 375 Mg Tabs (Naproxen)                             | C |      | Not Reported |
|                                                            |                                                             |   |      |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Feb-2013              | 9123771       | EXPEDITED (15-DAY) |                    | DE              | US-ROCHE-1194074     |                      | 64 YR      | Female     | USA            |

| <u>Preferred Term</u>      | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Toxicity To Various Agents | Naproxen            |              |            | S           | Oral         |                    |                 | Not Reported |
|                            | Naproxen            |              |            | S           | Oral         | Overdose           |                 | Not Reported |
|                            | Desipramine         |              |            | S           | Oral         |                    |                 | Not Reported |
|                            | Desipramine         |              |            | S           | Oral         | Overdose           |                 | Not Reported |
|                            | Diltiazem           |              |            | S           | Oral         |                    |                 | Not Reported |
|                            | Diltiazem           |              |            | S           | Oral         | Overdose           |                 | Not Reported |
|                            | Venlafaxine         |              |            | S           | Oral         |                    |                 | Not Reported |
|                            | Venlafaxine         |              |            | S           | Oral         | Overdose           |                 | Not Reported |
|                            | Lamotrigine         |              |            | S           | Oral         |                    |                 | Not Reported |
|                            | Lamotrigine         |              |            | S           | Oral         | Overdose           |                 | Not Reported |
|                            | Hydrochlorothiazide |              |            | S           | Oral         |                    |                 | Not Reported |
|                            | Hydrochlorothiazide |              |            | S           | Oral         | Overdose           |                 | Not Reported |
|                            | Armodafinil         |              |            | S           | Oral         |                    |                 | Not Reported |

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

|                            |   |      |          |              |
|----------------------------|---|------|----------|--------------|
| Armodafinil                | S | Oral | Overdose | Not Reported |
| Potassium Chloride         | S | Oral |          | Not Reported |
| Potassium Chloride         | S | Oral | Overdose | Not Reported |
| Trifluoperazine            | S | Oral |          | Not Reported |
| Trifluoperazine            | S | Oral | Overdose | Not Reported |
| Escitalopram               | S | Oral |          | Not Reported |
| Escitalopram               | S | Oral | Overdose | Not Reported |
| Pantoprazole               | S | Oral |          | Not Reported |
| Pantoprazole               | S | Oral | Overdose | Not Reported |
| Lansoprazole               | S | Oral |          | Not Reported |
| Lansoprazole               | S | Oral | Overdose | Not Reported |
| Rosuvastatin               | S | Oral |          | Not Reported |
| Rosuvastatin               | S | Oral | Overdose | Not Reported |
| Nitrofurantoin             | S | Oral |          | Not Reported |
| Nitrofurantoin             | S | Oral | Overdose | Not Reported |
| Diclofenac                 | S | Oral |          | Not Reported |
| Diclofenac                 | S | Oral | Overdose | Not Reported |
| Acetaminophen\Hydrocodone  | S | Oral |          | Not Reported |
| Acetaminophen\Hydrocodone  | S | Oral | Overdose | Not Reported |
| Acetaminophen/Propoxyphene | S | Oral |          | Not Reported |
| Acetaminophen/Propoxyphene | S | Oral | Overdose | Not Reported |
| Solifenacin                | S | Oral |          | Not Reported |
| Solifenacin                | S | Oral | Overdose | Not Reported |
| Ciprofloxacin              | S | Oral |          | Not Reported |
| Ciprofloxacin              | S | Oral | Overdose | Not Reported |
| Progestin                  | S | Oral |          | Not Reported |
| Progestin                  | S | Oral | Overdose | Not Reported |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Feb-2013              | 9124371       | EXPEDITED (15-DAY) |                    | DE, HO, OT      | PHHY2013GR019098     |                      | 72 YR      | Female     | GRC            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                            | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Acute Kidney Injury; Acute Respiratory Distress Syndrome; Cardio-Respiratory Arrest; Depressed Level Of Consciousness; Drug Interaction; Hyperpyrexia; Leukocytosis; Muscle Rigidity; Myoglobinuria; Neuroleptic Malignant Syndrome; Pyrexia; Rhabdomyolysis; Stupor; Tachypnoea | Escitalopram            |              |            | S           |              | 20 Mg, Qd          |                 | Not Reported |
|                                                                                                                                                                                                                                                                                  | Buspirone Hydrochloride |              |            | S           |              | 10 Mg, Qd          |                 | Novartis     |
|                                                                                                                                                                                                                                                                                  | Amlodipine Besylate     |              |            | S           |              | 5 Mg, Qd           |                 | Not Reported |
|                                                                                                                                                                                                                                                                                  | Irbesartan              |              |            | S           |              | 150 Mg, Qd         |                 | Not Reported |
|                                                                                                                                                                                                                                                                                  | Lithium Carbonate       |              |            | S           |              | 300 Mg, Tid        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Feb-2013              | 9124950       | EXPEDITED (15-DAY) |                    | DE              | US-ROCHE-1194060     |                      | 39 YR      | Female     | USA            |

| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Toxicity To Various Agents | Clonazepam     |              |            | S           | Oral         |                    |                 | Not Reported |
|                            | Clonazepam     |              |            | S           | Oral         | Overdose           |                 | Not Reported |
|                            | Escitalopram   |              |            | S           | Oral         |                    |                 | Not Reported |
|                            | Escitalopram   |              |            | S           | Oral         | Overdose           |                 | Not Reported |
|                            | Lamotrigine    |              |            | S           | Oral         |                    |                 | Not Reported |
|                            | Lamotrigine    |              |            | S           | Oral         | Overdose           |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Feb-2013              | 9135981       | EXPEDITED (15-DAY) | Y                  | DE              | AUR-APL-2013-00617   |                      | 55 YR      | Male       | USA            |

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

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

|                                                  |                         |   |  |  |  |  |  |  |              |
|--------------------------------------------------|-------------------------|---|--|--|--|--|--|--|--------------|
| Completed Suicide;<br>Toxicity To Various Agents | Lisinopril (Lisinopril) | S |  |  |  |  |  |  | Not Reported |
|                                                  | Quetiapine (Quetiapine) | S |  |  |  |  |  |  | Not Reported |
|                                                  | Escitalopram            | S |  |  |  |  |  |  | Not Reported |
|                                                  | Trazodone (Trazodone)   | S |  |  |  |  |  |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Feb-2013              | 9136026       | EXPEDITED (15-DAY) | Y                  | DE              | AUR-APL-2013-00461   |                      | 39 YR      | Female     | USA            |

| <u>Preferred Term</u>                            | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------|-----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide;<br>Toxicity To Various Agents | Lamotrigine (Lamotrigine)   |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Escitalopram (Escitalopram) |              |            | S           |              |                    |                 | Not Reported |
|                                                  | Clonazepam (Clonazepam)     |              |            | S           |              |                    |                 | Not Reported |
|                                                  | (Clonazepam)                |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Feb-2013              | 9138986       | EXPEDITED (15-DAY) | Y                  | OT              | AUR-APL-2013-00656   |                      | 42 YR      | Female     | USA            |

| <u>Preferred Term</u>                            | <u>Product</u>  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------|-----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide;<br>Toxicity To Various Agents | Citalopram      |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Cyclobenzaprine |              |            | S           |              |                    |                 | Not Reported |
|                                                  | Quetiapine      |              |            | S           |              |                    |                 | Not Reported |
|                                                  | Hydroxyzine     |              |            | S           |              |                    |                 | Not Reported |
|                                                  | Escitalopram    |              |            | S           |              |                    |                 | Not Reported |
|                                                  | Buspirone       |              |            | S           |              |                    |                 | Not Reported |
|                                                  | Levothyroxine   |              |            | S           |              |                    |                 | Not Reported |
|                                                  |                 |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Feb-2013              | 9145365       | EXPEDITED (15-DAY) | Y                  | DE              | AUR-APL-2013-00321   |                      | 57 YR      | Female     | USA            |

| <u>Preferred Term</u>                            | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide;<br>Toxicity To Various Agents | Lamotrigine (Lamotrigine) |              |            | S           | Oral         | Unknown            |                 | Not Reported |
|                                                  | Diphenhydramine           |              |            | S           |              | Oral               |                 | Not Reported |
|                                                  | (Diphenhydramine)         |              |            |             |              |                    |                 |              |
|                                                  | Escitalopram              |              |            | S           |              | Unknown            |                 | Not Reported |

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

|                                                                                   |                         |                    |                    |                 |                      |                      |                 |              |                |
|-----------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Aripiprazole (Aripiprazole)                                                       |                         |                    | S                  |                 | Unknown              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                          | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Feb-2013                                                                       | 9145625                 | DIRECT             |                    | OT              |                      |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                             | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective; Product Substitution Issue                                      | Lexapro                 |                    |                    | S               | Oral                 |                      |                 |              | Not Reported   |
| <u>FDA Received Date</u>                                                          | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Feb-2013                                                                       | 9145981                 | DIRECT             | Y                  | OT              |                      |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                             | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective; Hallucination; Nausea; Panic Attack; Vomiting                   | Celexa                  |                    |                    | S               |                      |                      |                 |              | Not Reported   |
|                                                                                   | Paxil                   |                    |                    | S               |                      |                      |                 |              | Not Reported   |
|                                                                                   | Lexapro                 |                    |                    | S               |                      |                      |                 |              | Not Reported   |
|                                                                                   | Citalopram              |                    |                    | S               |                      |                      |                 |              | Not Reported   |
|                                                                                   | Sertraline              |                    |                    | S               |                      |                      |                 |              | Not Reported   |
|                                                                                   | Zoloft                  |                    |                    | C               |                      |                      |                 |              | Not Reported   |
| <u>FDA Received Date</u>                                                          | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Feb-2013                                                                       | 9148785                 | EXPEDITED (15-DAY) | Y                  | DE              | AUR-APL-2013-00600   |                      | 54 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                             | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Completed Suicide; Respiratory Arrest; Toxicity To Various Agents | Gabapentin (Gabapentin) |                    |                    | S               |                      |                      |                 |              | Not Reported   |
|                                                                                   | Escitalopram            |                    |                    | S               |                      |                      |                 |              | Not Reported   |
|                                                                                   | Quetiapine (Quetiapine) |                    |                    | S               | Oral                 |                      |                 |              | Not Reported   |
| <u>FDA Received Date</u>                                                          | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Feb-2013                                                                       | 8174938                 | EXPEDITED (15-DAY) | Y                  | HO, OT          | JPI-P-017046         |                      | 37 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                             | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Chronic Fatigue                                                                   | Xyrem                   |                    |                    | S               | Oral                 | Nightly              |                 |              | Not Reported   |

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

|                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                               |                                      |      |                                                                  |                                                                                                                              |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|------|------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------|
| Syndrome; Diarrhoea;<br>Fibromyalgia; Hiatus<br>Hernia; Intervertebral Disc<br>Degeneration;<br>Intervertebral Disc<br>Protrusion; Oesophageal<br>Disorder; Oral Herpes;<br>Osteoarthritis; Pancreatic<br>Enzyme Abnormality;<br>Rectal Haemorrhage;<br>Road Traffic Accident;<br>Spinal Meningeal Cyst;<br>Transient Ischaemic<br>Attack; Weight Decreased | Alosetron<br>Armodafinil<br>Cyclobenzaprine<br>Naproxen<br>Hydrocodone<br>Escitalopram<br>Pantoprazole Sodium<br>Valacyclovir | S<br>C<br>C<br>C<br>C<br>S<br>S<br>S | Oral | 4.5 Gm (2.25 Gm, 2 In 1<br>D)<br><br><br><br><br><br>As Required | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|------|------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Feb-2013              | 9050662       | EXPEDITED (15-DAY) |                    | HO, OT          | JP-FRI-1000042409    |                      | 55 YR      | Female     | JPN            |

| <u>Preferred Term</u>     | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|-------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug-Induced Liver Injury | Lexapro           |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                           | Lithium Carbonate |              |            | S           | Oral         | 800 Mg             |                 | Not Reported |
|                           | Amoxan            |              |            | C           | Oral         | 100 Mg             |                 | Not Reported |
|                           | Crestor           |              |            | C           | Oral         | 2.5 Mg             |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------------------|----------------------|------------|------------|----------------|
| 28-Feb-2013              | 9127846       | NON-EXPEDITED    |                    |                 | US-<br>GLAXOSMITHKLINE-<br>A1004740A |                      |            | Male       | USA            |

| <u>Preferred Term</u>                                              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|--------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Asthenia; Disturbance In<br>Attention; Drug Ineffective;<br>Tremor | Lamictal       |              |            | S           |              |                    |                 | Glaxosmithkline |
|                                                                    | Escitalopram   |              |            | S           |              |                    |                 | Glaxosmithkline |
|                                                                    | Vyvanse        |              |            | S           |              |                    |                 | Not Reported    |
|                                                                    | Abilify        |              |            | S           |              |                    |                 | Not Reported    |
|                                                                    | Flaxseed Oil   |              |            | S           |              |                    |                 | Not Reported    |

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| <a href="#">FDA Received Date</a>                                                                                                    | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>  | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|--------------------------------------------------------------------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|--------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 28-Feb-2013                                                                                                                          | 9127973                 | EXPEDITED (15-DAY)        |                             | CA                       | US-FRI-1000042932              |                               | < 1 DAY                  | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                                                                       | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>          | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Atrial Septal Defect;<br>Multiple Congenital<br>Abnormalities; Patent<br>Ductus Arteriosus;<br>Transposition Of The<br>Great Vessels | Lexapro                 |                           |                             | S                        | Transplacental                 |                               |                          | Forest              |                         |
| <a href="#">FDA Received Date</a>                                                                                                    | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>  | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 28-Feb-2013                                                                                                                          | 9128874                 | EXPEDITED (15-DAY)        |                             | HO                       | CH-ASTRAZENECA-<br>2013SE11778 |                               | 84 YR                    | Female              | CHE                     |
| <a href="#">Preferred Term</a>                                                                                                       | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>          | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Fall; Neck Pain;<br>Pancytopenia; Pyrexia;<br>Therapeutic Product Effect<br>Incomplete; Viral Infection                              | Nexium                  |                           |                             | S                        | Oral                           |                               |                          | Astrazeneca         |                         |
|                                                                                                                                      | Ciprallex               |                           |                             | S                        | Unknown                        |                               |                          | Not Reported        |                         |
|                                                                                                                                      | Remeron                 |                           |                             | S                        | Oral                           |                               |                          | Not Reported        |                         |
|                                                                                                                                      | De-Ursil                |                           |                             | C                        | Oral                           |                               |                          | Not Reported        |                         |
|                                                                                                                                      | Aspirin Cardio          |                           |                             | C                        | Oral                           |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                                    | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>  | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 28-Feb-2013                                                                                                                          | 9146768                 | DIRECT                    | Y                           | OT                       |                                |                               | 61 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                                                                       | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>          | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Dizziness; Nausea                                                                                                                    | Escitalopram 20mg       |                           |                             | S                        | Oral                           |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                                    | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>  | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 28-Feb-2013                                                                                                                          | 9148269                 | DIRECT                    | Y                           |                          |                                |                               | 37 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                                                                       | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>          | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |

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

|                                                  |                    |   |                                |      |              |
|--------------------------------------------------|--------------------|---|--------------------------------|------|--------------|
| Product Substitution Issue;<br>Unevaluable Event | Escitalopram 10 Mg | S | 10mg 1/D / Pill For 2<br>Years | 2 YR | Not Reported |
|                                                  | Prozac             | S | 20 Mg 1/ D/Pill                |      | Not Reported |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 01-Mar-2013                       | 9131279                | EXPEDITED (15-DAY)        | DE                          |                          | CA-FRI-1000043005             |                               | 62 YR               | Male                | CAN                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Death                          | Escitalopram            |                       |                     | S                    | Oral                  | 10 Mg                       |                          | Forest              |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 01-Mar-2013                       | 9149923                | DIRECT                    |                             | OT                       |                               |                               | 62 YR               | Female              | USA                     |

| <a href="#">Preferred Term</a>                                                       | <a href="#">Product</a>               | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------------------------------------------------------------|---------------------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Depression; Drug<br>Ineffective; Product<br>Substitution Issue;<br>Suicidal Ideation | Escalipram -Lexapro Generic-<br>20 Mf |                       |                     | S                    | Oral                  | 20 Mg 1 Per Day Po          |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 01-Mar-2013                       | 9153024                | DIRECT                    |                             | OT                       |                               |                               | 80 YR               | Female              | USA                     |

| <a href="#">Preferred Term</a>                                                       | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------------------------------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Burning Sensation; Chest<br>Discomfort; Confusional<br>State; Nausea;<br>Nervousness | Escitalopram            |                       |                     | S                    | Oral                  |                             |                          | Teva                |
|                                                                                      | Escitalopram            |                       |                     | S                    | Oral                  |                             |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 01-Mar-2013                       | 9506225                | NON-EXPEDITED             | DE                          |                          | RB-36229-2012                 |                               | 48 YR               | Male                | USA                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Toxicity To Various Agents     | Suboxone                |                       |                     | S                    |                       |                             |                          | Not Reported        |

# FDA Adverse Event Reporting System

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Escitalopram  
Acetaminophen W/  
Hydrocodone

S  
S

Not Reported  
Not Reported

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 04-Mar-2013              | 8562690       | EXPEDITED (15-DAY) |                    | HO, LT          | CH-ASTRAZENECA-2012SE30117 |                      | 46 YR      | Female     | CHE            |

| <u>Preferred Term</u>                                                                                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>             | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------------------|--------------------|-----------------|--------------|
| Confusional State; Drug Interaction; Hyperhidrosis; Mydriasis; Myoclonus; Serotonin Syndrome; Tremor | Nexium         |              |            | S           | Oral                     |                    |                 | Not Reported |
|                                                                                                      | Cipralext      |              |            | S           | Oral                     |                    |                 | Not Reported |
|                                                                                                      | Prezista       |              |            | S           | Oral                     |                    |                 | Not Reported |
|                                                                                                      | Norvir         |              |            | S           | Oral                     |                    |                 | Not Reported |
|                                                                                                      | Truvada        |              |            | C           | Oral                     | 200/245 Mg Daily   |                 | Not Reported |
|                                                                                                      | Kapanol        |              |            | C           | Oral                     |                    |                 | Not Reported |
|                                                                                                      | Wellvone       |              |            | C           | Oral                     |                    |                 | Not Reported |
|                                                                                                      | Noroxin        |              |            | C           | Oral                     |                    |                 | Not Reported |
|                                                                                                      | Anxiolit       |              |            | C           | Oral                     |                    |                 | Not Reported |
|                                                                                                      | Torasemid      |              |            | C           | Oral                     |                    |                 | Not Reported |
|                                                                                                      | Importal       |              |            | C           | Oral                     |                    |                 | Not Reported |
|                                                                                                      | Seretide       |              |            | C           | Respiratory (inhalation) |                    |                 | Not Reported |
|                                                                                                      | Nasonex        |              |            | C           | Nasal                    |                    |                 | Not Reported |
|                                                                                                      | Rohypnol       |              |            | C           | Oral                     |                    |                 | Not Reported |
|                                                                                                      | Intelence      |              |            | C           |                          |                    |                 | Not Reported |
|                                                                                                      | Isentress      |              |            | C           |                          |                    |                 | Not Reported |
| 3 Tc                                                                                                 |                |              | C          |             |                          |                    | Not Reported    |              |
| Aldactone                                                                                            |                |              | C          |             |                          |                    | Not Reported    |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Mar-2013              | 9058845       | EXPEDITED (15-DAY) |                    | OT              | US-FRI-1000042337    |                      | 37 YR      | Female     | USA            |

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

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|                                                                                               |                        |        |              |                |                        |
|-----------------------------------------------------------------------------------------------|------------------------|--------|--------------|----------------|------------------------|
| Disturbance In Attention;<br>Dyspepsia; Dysphemia;<br>Headache; Hemiparesis;<br>Hypoaesthesia | Escitalopram<br>Zyrtec | S<br>C | Oral<br>Oral | 10 Mg<br>Daily | Forest<br>Not Reported |
|-----------------------------------------------------------------------------------------------|------------------------|--------|--------------|----------------|------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 04-Mar-2013              | 9095660       | EXPEDITED (15-DAY) |                    | HO, LT          | AT-PFIZER INC-<br>2013054234 |                      | 65 YR      | Female     | AUT            |

| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Ventricular Extrasystoles | Edronax        |              |            | S           |              | 4 Mg, Unk          |                 | Pfizer       |
|                           | Tritace        |              |            | S           | Oral         | 2.5 Mg, Daily      |                 | Pfizer       |
|                           | Quilonorm      |              |            | S           | Unknown      | 225 Mg, Daily      |                 | Not Reported |
|                           | Quilonorm      |              |            | S           | Unknown      | 675 Mg, Daily      |                 | Not Reported |
|                           | Quilonorm      |              |            | S           | Unknown      | 450 Mg, Daily      |                 | Not Reported |
|                           | Cipralext      |              |            | S           |              | 10 Mg, Unk         |                 | Not Reported |
|                           | Lamictal       |              |            | S           |              | 50 Mg, Unk         |                 | Not Reported |
|                           | Risperdal      |              |            | S           | Unknown      | 3 Mg, Daily        |                 | Not Reported |
|                           | Risperdal      |              |            | S           | Unknown      | 2 Mg, Daily        |                 | Not Reported |
|                           | Euthyrox       |              |            | S           |              | 75 Ug, Unk         |                 | Not Reported |
|                           | Pantoloc       |              |            | S           |              | 40 Mg, Unk         |                 | Not Reported |
|                           | Seroquel       |              |            | S           | Oral         | 100 Mg, 1x/Day     |                 | Not Reported |
|                           | Venlafab       |              |            | S           | Oral         | 150 Mg, Daily      |                 | Not Reported |
|                           | Venlafab       |              |            | S           | Oral         | 300 Mg, Daily      |                 | Not Reported |
|                           | Escitalopram   |              |            | C           |              | Unk                |                 | Not Reported |
|                           | Lamotrigine    |              |            | C           |              | Unk                |                 | Not Reported |
|                           | Pantoprazole   |              |            | C           |              | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|------------|------------|----------------|
| 04-Mar-2013              | 9135655       | EXPEDITED (15-DAY) |                    | OT              | CH-MYLANLABS-<br>2013S1004115 |                      | 46 YR      | Female     | CHE            |

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



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

|                                         |              |   |         |                                                                   |              |
|-----------------------------------------|--------------|---|---------|-------------------------------------------------------------------|--------------|
| Drug Interaction;<br>Serotonin Syndrome | Darunavir    | S | Unknown |                                                                   | Not Reported |
|                                         | Ritonavir    | S | Unknown |                                                                   | Not Reported |
|                                         | Esomeprazole | S | Unknown | 40mg Daily                                                        | Not Reported |
|                                         | Escitalopram | S | Unknown |                                                                   | Mylan        |
|                                         | Truvada      | C | Unknown | Emtricitabine<br>200/Tenofovir Disoproxil<br>Fumarate 245mg Daily | Not Reported |

| <u>FDA Received Date</u>          | <u>Case #</u>     | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------|-------------------|------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 04-Mar-2013                       | 9137753           | NON-EXPEDITED    |                    |                 | US-ENDO<br>PHARMACEUTICALS<br>INC.-PERC20110027 |                      | 37 YR           | Male         | USA            |
| <u>Preferred Term</u>             | <u>Product</u>    | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Panic<br>Attack | Percocet          |                  |                    | S               | Oral                                            | 10/625 Mg            |                 | Not Reported |                |
|                                   | Lexapro           |                  |                    | S               | Oral                                            |                      |                 | Not Reported |                |
|                                   | Lortab            |                  |                    | C               | Oral                                            | Unk                  |                 | Not Reported |                |
|                                   | Dextroamphetamine |                  |                    | C               |                                                 | Unk                  |                 | Not Reported |                |
|                                   | Clonazepam        |                  |                    | C               |                                                 | Unk                  |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                                            | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 04-Mar-2013                                                                                                                                                         | 9150052        | DIRECT           |                    |                 |                      |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>                                                                                                                                               | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Agitation; Anxiety;<br>Economic Problem;<br>Memory Impairment;<br>Product Substitution Issue;<br>Therapeutic Product Effect<br>Decreased; Therapy Non-<br>Responder | Escitalopram   |                  |                    | S               |                      |                      |                 | Teva       |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Mar-2013              | 9153345       | DIRECT           |                    |                 |                      |                      | 40 YR      | Male       | USA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                                         | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|-----------------------------------------------------------------------------------------------|----------------------|------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|--------------|----------------|
| Anxiety; Condition Aggravated; Insomnia; Irritable Bowel Syndrome; Product Substitution Issue | Escitalopram         |                  |                    | S               | Oral                                            |                      |                 | Teva         |                |
| <u>FDA Received Date</u>                                                                      | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Mar-2013                                                                                   | 9153399              | DIRECT           | Y                  | OT              |                                                 |                      | 66 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                         | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Eructation; Food Intolerance; Nausea; Product Substitution Issue; Retching                    | Escitalopram Oxalate |                  |                    | S               | Oral                                            |                      |                 | Teva         |                |
| <u>FDA Received Date</u>                                                                      | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Mar-2013                                                                                   | 9138775              | NON-EXPEDITED    |                    | DE              | US-ENDO<br>PHARMACEUTICALS<br>INC.-PERC20110001 |                      | 49 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                         | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cerebrovascular Accident; Chest Pain; Drug Abuse                                              | Percocet-5           |                  |                    | S               | Oral                                            | 5/325 Mg             |                 | Not Reported |                |
|                                                                                               | Percocet-5           |                  |                    | S               |                                                 |                      |                 | Not Reported |                |
|                                                                                               | Lexapro              |                  |                    | S               | Oral                                            |                      |                 | Not Reported |                |
|                                                                                               | Soma                 |                  |                    | S               | Oral                                            |                      |                 | Not Reported |                |
|                                                                                               | Soma                 |                  |                    | S               |                                                 |                      |                 | Not Reported |                |
|                                                                                               | Valium               |                  |                    | S               |                                                 | Unk                  |                 | Not Reported |                |
|                                                                                               | Fentora              |                  |                    | S               | Buccal                                          |                      |                 | Not Reported |                |
|                                                                                               | Fentora              |                  |                    | S               |                                                 |                      |                 | Not Reported |                |
|                                                                                               | Fentanyl             |                  |                    | S               | Transdermal                                     | Unk                  |                 | Not Reported |                |
|                                                                                               | Fentanyl             |                  |                    | S               |                                                 |                      |                 | Not Reported |                |
| Zipsor                                                                                        |                      |                  | S                  | Oral            | 25 Mg                                           |                      | Not Reported    |              |                |
| Zipsor                                                                                        |                      |                  | S                  |                 |                                                 |                      | Not Reported    |              |                |

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

| <u>FDA Received Date</u>                                                                                    | <u>Case #</u>                         | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                                                                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------|---------------------------------------|------------------|--------------------|-----------------|------------------------------|---------------------------------------------------------------------------------------|-----------------|--------------|----------------|
| 05-Mar-2013                                                                                                 | 9139672                               | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2013073565     |                                                                                       | 57 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                       | <u>Product</u>                        | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                                                                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Memory Impairment;<br>Psychiatric Symptom                                                                   | Zoloft                                |                  |                    | S               |                              | Unk                                                                                   |                 | Pfizer       |                |
|                                                                                                             | Celexa                                |                  |                    | S               |                              | Unk                                                                                   |                 | Not Reported |                |
|                                                                                                             | Prozac                                |                  |                    | S               |                              | Unk                                                                                   |                 | Not Reported |                |
|                                                                                                             | Lexapro                               |                  |                    | S               |                              | Unk                                                                                   |                 | Not Reported |                |
|                                                                                                             | Paxil                                 |                  |                    | S               |                              | Unk                                                                                   |                 | Not Reported |                |
|                                                                                                             | Trazodone                             |                  |                    | S               |                              | Unk                                                                                   |                 | Not Reported |                |
|                                                                                                             | Wellbutrin                            |                  |                    | S               |                              | Unk                                                                                   |                 | Not Reported |                |
|                                                                                                             | Cymbalta                              |                  |                    | S               |                              | Unk                                                                                   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                    | <u>Case #</u>                         | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                                                                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Mar-2013                                                                                                 | 9150639                               | DIRECT           |                    | OT              |                              |                                                                                       | 60 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                       | <u>Product</u>                        | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                                                                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Depression;<br>Headache; Hot Flush;<br>Muscular Weakness;<br>Nausea; Product<br>Substitution Issue | Escitalopram 10mg Aurobiudo<br>Pharma |                  |                    | S               |                              | Expiration 08-Feb-2014                                                                |                 | Aurobindo    |                |
| <u>FDA Received Date</u>                                                                                    | <u>Case #</u>                         | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                                                                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Mar-2013                                                                                                 | 9252320                               | NON-EXPEDITED    | Y                  | DS              | 163-21880-12083000           |                                                                                       | 56 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                       | <u>Product</u>                        | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                                                                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Fatigue; Oedema<br>Peripheral                                                                               | Revlimid                              |                  |                    | S               | Oral<br>Oral<br>Oral<br>Oral | 5 Mg, 1 In 1 D, Po<br>10 Mg, 1 In 1 D, Po<br>5 Mg, 1 In 1 D, Po<br>5 Mg, 1 In 2 D, Po |                 | Not Reported |                |
|                                                                                                             | Dexamethasone                         |                  |                    | S               |                              |                                                                                       |                 | Not Reported |                |

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

|                                 |   |              |
|---------------------------------|---|--------------|
| (Dexamethasone)                 |   |              |
| Aspirin (Acetylsalicylic Acid)  | S | Not Reported |
| Lipitor (Atorvastatin) (40      | S | Not Reported |
| Milligram, Tablets)             |   |              |
| Calcium (Calcium)               | S | Not Reported |
| Coreg (Carvedilol)              | S | Not Reported |
| Centrum (Centrum) (Tablets)     | S | Not Reported |
| Fragmin (Heparin-Fraction,      | S | Not Reported |
| Sodium Salt)                    |   |              |
| Allopurinol                     | S | Not Reported |
| Ergocalciferol (Ergocalciferol) | S | Not Reported |
| Lexapro (Escitalopram Oxalate)  | S | Not Reported |
| Gemfibrozil (Gemfibrozil)       | S | Not Reported |
| Acetaminophen\Hydrocodone       | S | Not Reported |
| Bitartrate                      |   |              |
| Hydroxyzine (Hydroxyzine)       | S | Not Reported |
| Keppra (Levetiracetam)          | S | Not Reported |
| Magnesium Oxide (Magnesium      | S | Not Reported |
| Oxide) (500 Milligram, Tablets) |   |              |
| Ritalin                         | S | Not Reported |
| Nortriptyline (Nortriptyline)   | S | Not Reported |
| Protonix                        | S | Not Reported |
| Phenergan (Promethazine)        | S | Not Reported |
| Maxalt (Rizatriptan Benzoate)   | S | Not Reported |
| Valtrex (Valciclovir            | S | Not Reported |
| Hydrochloride)                  |   |              |
| Vitamin D (Ergocalciferol)      | S | Not Reported |
| (Capsules)                      |   |              |
| Platelets (Platelets)           | S | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Mar-2013              | 9252440       | NON-EXPEDITED    | Y                  | HO, OT          | 163-21880-12083020   |                      | 46 YR      | Female     | USA            |

| <u>Preferred Term</u>        | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------|----------------------|--------------|------------|-------------|--------------|---------------------|-----------------|--------------|
| Herpes Zoster;<br>Thrombosis | Revlimid             |              |            | S           | Oral         | 25 Mg, 1 In 1 D, Po |                 | Not Reported |
|                              |                      |              |            |             | Oral         | 10 Mg, 1 In 1 D, Po |                 |              |
|                              | Valacyclovir         |              |            | S           |              |                     |                 | Not Reported |
|                              | Prochlorperazine     |              |            | S           |              |                     |                 | Not Reported |
|                              | Oxycontin (Oxycodone |              |            | S           |              |                     |                 | Not Reported |
|                              | Hydrochloride)       |              |            |             |              |                     |                 |              |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                         |   |              |
|-------------------------|---|--------------|
| Enoxaparin (Enoxaparin) | S | Not Reported |
| Oxycodone (Oxycodone)   | S | Not Reported |
| Lexapro                 | S | Not Reported |
| Protonix                | S | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Mar-2013              | 8442926       | EXPEDITED (15-DAY) |                    | DE, OT          | JP-FRI-1000028810    |                      | 79 YR      | Male       | JPN            |

| <u>Preferred Term</u>                                               | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Interstitial Lung Disease;<br>Pneumonia Aspiration;<br>Pneumothorax | Lexapro                |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                                                     | Keishi-Ka-Shakuyaku-To |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                     | Ganaton                |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                     | Myslee                 |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                     | Yodel-S                |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                     | Celecox                |              |            | C           | Oral         | 200 Mg             |                 | Not Reported |
|                                                                     | Takepron               |              |            | C           | Oral         | 30 Mg              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Mar-2013              | 8554479       | EXPEDITED (15-DAY) |                    | HO, LT          | FR-FRI-1000030395    |                      | 52 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                                          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Asterixis; Encephalopathy;<br>Hepatic Failure; Hepatitis<br>Acute; Jaundice; Liver<br>Disorder | Escitalopram   |              |            | S           |              |                    |                 | Forest       |
|                                                                                                | Esperal        |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                | Utrogestan     |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                | Seresta        |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                | Levothyroxine  |              |            | C           |              | 75 Mg              |                 | Not Reported |
|                                                                                                | Estreva        |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                | Milnacipran    |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 06-Mar-2013              | 9030466       | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-<br>2013024458 |                      | 43 YR      | Female     | USA            |

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

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

|                                                                                         |                   |   |      |                                               |              |
|-----------------------------------------------------------------------------------------|-------------------|---|------|-----------------------------------------------|--------------|
| Crying; Depression; Drug Ineffective; Product Use In Unapproved Indication; Social Fear | Pristiq           | S | Oral | Unk                                           | Pfizer       |
|                                                                                         | Pristiq           | S | Oral | 50 Mg, 2x/Day                                 | Pfizer       |
|                                                                                         | Pristiq           | S | Oral | 50 Mg, 3x/Day                                 | Pfizer       |
|                                                                                         | Pristiq           | S | Oral | 100 Mg, 2x/Day                                | Pfizer       |
|                                                                                         | Pristiq           | S | Oral | 100mg Morning, 50mg Afternoon And 100mg Night | Pfizer       |
|                                                                                         | Pristiq           | S | Oral | 50 Mg, Five Times Daily                       | Pfizer       |
|                                                                                         | Zoloft            | S |      | Unk                                           | Pfizer       |
|                                                                                         | Lithium Carbonate | S |      | 300 Mg, 3x/Day                                | Pfizer       |
|                                                                                         | Prozac            | S |      | Unk                                           | Not Reported |
|                                                                                         | Lamictal          | S |      | Unk                                           | Not Reported |
|                                                                                         | Wellbutrin        | S |      | Unk                                           | Not Reported |
|                                                                                         | Lexapro           | S |      | Unk                                           | Not Reported |
|                                                                                         | Abilify           | S |      | 10 Mg,Daily                                   | Not Reported |
|                                                                                         | Topamax           | S |      | Unk                                           | Not Reported |
|                                                                                         | Klonopin          | S |      | Unk                                           | Not Reported |
|                                                                                         | Valium            | S |      | Unk                                           | Not Reported |
|                                                                                         | Paxil             | S |      | Unk                                           | Not Reported |
|                                                                                         | Celexa            | S |      | Unk                                           | Not Reported |
|                                                                                         | Cymbalta          | S |      | Unk                                           | Not Reported |
|                                                                                         | Anafranil         | S |      | Unk                                           | Not Reported |
|                                                                                         | Imipramine        | S |      | Unk                                           | Not Reported |
|                                                                                         | Tegretol          | S |      | Unk                                           | Not Reported |
|                                                                                         | Luvox             | S |      | Unk                                           | Not Reported |
|                                                                                         | Seroquel          | S |      | Unk                                           | Not Reported |
|                                                                                         | Depakote          | S |      | Unk                                           | Not Reported |
|                                                                                         | Seroquel Xr       | C |      | 250 Mg, Daily                                 | Not Reported |
|                                                                                         | Xanax             | C |      | 0.5 Mg, As Needed                             | Not Reported |
|                                                                                         | Adderall          | C |      | 5 Mg, 2x/Day                                  | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 06-Mar-2013              | 9143244       | EXPEDITED (15-DAY) |                    | DE              | US-ASTELLAS-2013JP003245 |                      | 64 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>               | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Solifenacin                  |              |            | S           | Oral         |                    |                 | Astellas     |
|                       | Desipramine                  |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                       | Diltiazem                    |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Venlafaxine                  |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                       | Lamotrigine                  |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                       | Hydrochlorothiazide          |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                       | Armodafinil                  |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                       | Potassium Chloride           |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                       | Trifluoperazine              |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Escitalopram                 |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                       | Thyroid Preparations         |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                       | Pantoprazole                 |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                       | Lansoprazole                 |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                       | Rovustatin                   |              |            | C           | Oral         |                    |                 | Not Reported |
|                       | Naproxen                     |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Nitrofurantoin               |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                       | Diclofenac                   |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                       | Acetaminophen W/Hydrocodone  |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                       | Acetaminophen W/Propoxyphene |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                       | Ciprofloxacin                |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                       | Progestin                    |              |            | S           | Oral         | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Mar-2013              | 9143824       | EXPEDITED (15-DAY) |                    | HO              | IT-ROCHE-1197897     |                      | 20 YR      | Male       | ITA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Drug Abuse; Suicide Attempt; Toxicity To Various Agents | Valium               |                    |                    | S               | Unknown              |                      |                 | Not Reported |                |
|                                                         | Escitalopram Oxalate |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                         | Minias               |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                         | Alcohol              |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Mar-2013                                             | 9144330              | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000043174    |                      |                 | Female       | FRA            |
| <u>Preferred Term</u>                                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Gingival Bleeding; Puncture Site Haemorrhage            | Escitalopram         |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                                         | Triatec (Ramipril)   |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Mar-2013                                             | 9144370              | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000043173    |                      | 84 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hepatitis Cholestatic                                   | Escitalopram         |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                                         | Micardiplus          |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                         | Modopar              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                         | Spiriva              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                         | Gliclazide           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                         | Detrusitol           |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Mar-2013                                             | 9144656              | EXPEDITED (15-DAY) |                    | HO              | DE-FRI-1000043083    |                      |                 | Female       | DEU            |
| <u>Preferred Term</u>                                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Potentiating Drug Interaction; Urinary Retention        | Escitalopram         |                    |                    | S               | Oral                 | 5 Mg                 |                 | Forest       |                |
|                                                         | Mirtazapin           |                    |                    | S               | Oral                 | 15 Mg                |                 | Not Reported |                |
|                                                         | Metoprolol           |                    |                    | S               | Oral                 | 95 Mg                |                 | Not Reported |                |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|           |   |      |         |              |
|-----------|---|------|---------|--------------|
| Tafil     | C | Oral | 1.5 Mg  | Not Reported |
| Tafil     | C | Oral | 2.5 Mg  | Not Reported |
| Hct Hexal | C | Oral | 12.5 Mg | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 07-Mar-2013              | 6679655       | EXPEDITED (15-DAY) |                    | CA, DE, HO, OT  | US-PFIZER INC-2008049876 |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                         | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Aortic Valve Stenosis;<br>Atrioventricular Septal<br>Defect; Foetal Exposure<br>During Pregnancy;<br>Hepatic Congestion;<br>Hypoplastic Left Heart<br>Syndrome; Lung Disorder;<br>Mitral Valve Hypoplasia;<br>Multiple Congenital<br>Abnormalities; Newborn<br>Persistent Pulmonary<br>Hypertension; Patent<br>Ductus Arteriosus; Renal<br>Tubular Necrosis; Right<br>Ventricular Hypertrophy | Zoloft              |              |            | S           | Transplacental | 50 Mg, 1x/Day      |                 | Pfizer       |
|                                                                                                                                                                                                                                                                                                                                                                                               | Zoloft              |              |            | S           |                |                    |                 | Pfizer       |
|                                                                                                                                                                                                                                                                                                                                                                                               | Lexapro             |              |            | S           | Transplacental | 10 Mg, 1x/Day      |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                               | Prenatal Vitamins   |              |            | C           | Transplacental | Unk                |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                               | Reglan              |              |            | C           | Transplacental | 10 Mg, Unk         |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                               | Zyrtec              |              |            | C           | Transplacental | 10 Mg, Unk         |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                               | Benadryl            |              |            | C           | Transplacental | Unk                |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                               | Tylenol             |              |            | C           | Transplacental | Unk                |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                               | Robitussin "Robins" |              |            | C           | Transplacental | Unk                |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                               | Z-Pack              |              |            | C           | Transplacental | Unk                |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                               | Kaopectate          |              |            | C           | Transplacental | Unk                |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                               | Darvocet            |              |            | C           | Transplacental | Unk                |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                               | Cephalexin          |              |            | C           | Transplacental | 500 Mg, Unk        |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                               | Zithromax           |              |            | C           | Transplacental | 250 Mg, Unk        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 07-Mar-2013              | 9146841       | EXPEDITED (15-DAY) |                    | HO, LT          | CH-PFIZER INC-2013077482 |                      | 53 YR      | Female     | CHE            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|----------------------|-----------------|--------------|
| Hepatic Failure       | Lyrica         |              |            | S           | Oral         | 150 Mg, 2x/Day       |                 | Pfizer       |
|                       | Irfen          |              |            | S           | Oral         | 600 Mg, Up To 7x/Day |                 | Not Reported |
|                       | Surmontil      |              |            | S           | Oral         | 75 Mg, 1x/Day        |                 | Not Reported |

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

|  |                        |   |      |                  |              |
|--|------------------------|---|------|------------------|--------------|
|  | Cipralext              | S | Oral | 10 Mg, 1x/Day    | Not Reported |
|  | Methadone              | S | Oral | 40 Mg, 2x/Day    | Not Reported |
|  | Aspirin Cardio         | C | Oral | 100 Mg, 1x/Day   | Not Reported |
|  | Triatec Comp           | C | Oral | 25mg/5mg, 1x/Day | Not Reported |
|  | Pantozol (Switzerland) | C | Oral | 40 Mg, 1x/Day    | Not Reported |
|  | Paracetamol            | C |      | Unk              | Not Reported |
|  | Ibuprofen              | C |      | 200 Mg, Unk      | Not Reported |

| <u>FDA Received Date</u>              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 07-Mar-2013                           | 9147502        | EXPEDITED (15-DAY) |                    | OT              | US-TEVA-389639USA    |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypertension; Obesity;<br>Tachycardia | Escitalopram   |                    |                    | S               |                      |                      |                 | Ivax         |                |
|                                       | Escitalopram   |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                       | Clozaril       |                    |                    | S               | Oral                 | 300 Milligram Daily; |                 | Not Reported |                |
|                                       | Eskalith       |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|--------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|---------------------------------------------------------------|----------------------|-----------------|----------------------|----------------|
| 07-Mar-2013                                                                                | 9147771        | EXPEDITED (15-DAY) |                    | HO, LT          | ES-B.I.<br>PHARMACEUTICALS,I<br>NC./RIDGEFIELD-2013-<br>ES-00 |                      | 89 YR           | Female               | ESP            |
| <u>Preferred Term</u>                                                                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Confusional State; Drug<br>Interaction; Inappropriate<br>Antidiuretic Hormone<br>Secretion | Micardisplus   |                    |                    | S               | Oral                                                          | 1 Anz                |                 | Boehringer Ingelheim |                |
|                                                                                            | Escitalopram   |                    |                    | S               | Oral                                                          | 15 Mg                |                 | Not Reported         |                |
|                                                                                            | Captopril      |                    |                    | C               | Oral                                                          | 50 Mg                |                 | Not Reported         |                |
|                                                                                            | Orfidal Wyeth  |                    |                    | C               | Oral                                                          | 2 Mg                 |                 | Not Reported         |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 07-Mar-2013              | 9154998        | DIRECT           | Y                  |                 |                      |                      | 35 YR           | Male       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

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

|                                                                               |                |                                       |                    |                 |                               |                        |                 |              |                |
|-------------------------------------------------------------------------------|----------------|---------------------------------------|--------------------|-----------------|-------------------------------|------------------------|-----------------|--------------|----------------|
| Anxiety; Depressed Mood;<br>Disease Recurrence;<br>Product Substitution Issue |                | Escitalopram 10mg Aurobiudo<br>Pharma |                    | S               | Oral                          |                        | Not Reported    |              |                |
| <u>FDA Received Date</u>                                                      | <u>Case #</u>  | <u>Case Type</u>                      | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Mar-2013                                                                   | 9155005        | DIRECT                                | Y                  |                 |                               |                        |                 | Female       | USA            |
| <u>Preferred Term</u>                                                         | <u>Product</u> | <u>Comp.</u>                          | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective                                                              | Escitalopram   |                                       |                    | S               | Oral                          | 10 Mg Daily Oral (047) |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                      | <u>Case #</u>  | <u>Case Type</u>                      | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Mar-2013                                                                   | 9148817        | EXPEDITED (15-DAY)                    |                    | OT              | US-JNJFOC-<br>20130216891     |                        |                 | Female       | USA            |
| <u>Preferred Term</u>                                                         | <u>Product</u> | <u>Comp.</u>                          | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Loss Of Weight;                                                      | Topamax        |                                       |                    | S               | Oral                          |                        |                 | Not Reported |                |
| Alopecia; Depression; Hair                                                    | Topamax        |                                       |                    | S               | Oral                          |                        |                 | Not Reported |                |
| Texture Abnormal;                                                             | Topamax        |                                       |                    | S               | Oral                          |                        |                 | Not Reported |                |
| Influenza Like Illness;                                                       | Topamax        |                                       |                    | S               | Oral                          |                        |                 | Not Reported |                |
| Memory Impairment;                                                            | Topamax        |                                       |                    | S               | Oral                          |                        |                 | Not Reported |                |
| Migraine; Musculoskeletal                                                     | Gabapentin     |                                       |                    | S               | Unknown                       |                        |                 | Not Reported |                |
| Pain; Nausea; Neoplasm;                                                       | Lyrica         |                                       |                    | S               | Unknown                       |                        |                 | Not Reported |                |
| Nephrolithiasis; Vomiting                                                     | Lexapro        |                                       |                    | S               | Unknown                       |                        |                 | Not Reported |                |
|                                                                               | Synthroid      |                                       |                    | C               | Oral                          |                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                      | <u>Case #</u>  | <u>Case Type</u>                      | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Mar-2013                                                                   | 9148819        | EXPEDITED (15-DAY)                    |                    | DE, HO          | GR-MYLANLABS-<br>2013S1004397 |                        | 72 YR           | Female       | GRC            |
| <u>Preferred Term</u>                                                         | <u>Product</u> | <u>Comp.</u>                          | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Acute Kidney Injury; Acute                                                    | Lithium        |                                       |                    | S               | Unknown                       |                        |                 | Not Reported |                |
| Respiratory Distress                                                          | Escitalopram   |                                       |                    | S               | Unknown                       |                        |                 | Not Reported |                |
| Syndrome; Cardio-                                                             | Buspirone      |                                       |                    | S               | Unknown                       |                        |                 | Not Reported |                |
| Respiratory Arrest; Drug                                                      | Amlodipine     |                                       |                    | S               | Unknown                       |                        |                 | Not Reported |                |
| Interaction; Neuroleptic                                                      |                |                                       |                    |                 |                               |                        |                 |              |                |
| Malignant Syndrome;                                                           |                |                                       |                    |                 |                               |                        |                 |              |                |

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

|                                                                                                                        |                         |                           |                             |                          |                                                               |                               |                          |                     |                         |
|------------------------------------------------------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|---------------------------------------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Rhabdomyolysis                                                                                                         |                         | Irbesartan                |                             | S                        |                                                               | Unknown                       |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>                                                                                      | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>                                 | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 08-Mar-2013                                                                                                            | 9152543                 | EXPEDITED (15-DAY)        |                             | HO                       | JP-B.I.<br>PHARMACEUTICALS,I<br>NC./RIDGEFIELD-2013-<br>BI-05 |                               | 82 YR                    | Female              | JPN                     |
| <a href="#">Preferred Term</a>                                                                                         | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                                         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Hyponatraemia                                                                                                          | Micardis                |                           |                             | S                        | Oral                                                          |                               |                          |                     | Boehringer Ingelheim    |
|                                                                                                                        | Lexapro                 |                           |                             | S                        | Oral                                                          |                               |                          |                     | Not Reported            |
|                                                                                                                        | Flutran                 |                           |                             | S                        | Oral                                                          |                               |                          |                     | Not Reported            |
| <a href="#">FDA Received Date</a>                                                                                      | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>                                 | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 08-Mar-2013                                                                                                            | 9153963                 | DIRECT                    |                             | HO                       |                                                               |                               | 31 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>                                                                                         | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                                         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Anxiety; Condition Aggravated; Feeling Abnormal; Headache; Palpitations; Product Substitution Issue; Suicidal Ideation | Escitalopram 20mg       |                           |                             | S                        | Oral                                                          | 15 Mg To 20 Mg                |                          |                     | Mylan                   |
|                                                                                                                        | Lexapro                 |                           |                             | C                        |                                                               |                               |                          |                     | Not Reported            |
| <a href="#">FDA Received Date</a>                                                                                      | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>                                 | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 08-Mar-2013                                                                                                            | 9154175                 | DIRECT                    | Y                           | OT                       |                                                               |                               |                          | Male                | USA                     |
| <a href="#">Preferred Term</a>                                                                                         | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                                         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Ineffective; Product Substitution Issue                                                                           | Escitalopram            |                           |                             | S                        | Oral                                                          | 20mg Am Po Jan - March 2012   |                          |                     | Not Reported            |
| <a href="#">FDA Received Date</a>                                                                                      | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>                                 | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 08-Mar-2013                                                                                                            | 9157279                 | DIRECT                    |                             | OT                       |                                                               |                               | 22 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                                                         | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                                         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |

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

|                                                                            |         |   |              |
|----------------------------------------------------------------------------|---------|---|--------------|
| Disturbance In Attention;<br>Dizziness; Feeling<br>Abnormal; Hallucination | Lexapro | S | Not Reported |
|----------------------------------------------------------------------------|---------|---|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Mar-2013              | 9157424       | DIRECT           |                    | OT              |                      |                      | 71 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                        | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|--------------|------------|-------------|--------------|---------------------------|-----------------|------------|
| Anxiety; Asthenia; Blood Pressure Fluctuation;<br>Blood Pressure Increased;<br>Dizziness; Feeling Hot;<br>Headache; Heart Rate Abnormal;<br>Musculoskeletal Stiffness;<br>Musculoskeletal Stiffness;<br>Nausea; Paraesthesia | Lexapro / Forest Pharmace |              |            | S           |              | Took 1/2 Tab 20 Mg 1x Day |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Mar-2013              | 8301396       | EXPEDITED (15-DAY) |                    | CA, OT          | US-RB-035466-11      |                      |            | Male       | USA            |

| <u>Preferred Term</u>                          | <u>Product</u>  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>        |
|------------------------------------------------|-----------------|--------------|------------|-------------|----------------|------------------------|-----------------|-------------------|
| Cleft Palate; Foetal Exposure During Pregnancy | Suboxone Film   |              |            | S           | Transplacental | Suboxone Film          |                 | Reckitt Benckiser |
|                                                | Lexapro         |              |            | S           | Transplacental |                        |                 | Not Reported      |
|                                                | Marijuana       |              |            | S           | Transplacental | Dosing Details Unknown |                 | Not Reported      |
|                                                | Benzodiazepines |              |            | S           | Transplacental | Dosing Details Unknown |                 | Not Reported      |
|                                                | Opiates         |              |            | S           | Transplacental | Dosing Details Unknown |                 | Not Reported      |
|                                                | Nicotine        |              |            | S           | Transplacental | Dosing Details Unknown |                 | Not Reported      |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 11-Mar-2013              | 9153466       | EXPEDITED (15-DAY) |                    | OT              | GR-MYLANLABS-2013S1004298 |                      | 84 YR      | Female     | GRC            |

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

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

|                |              |   |      |              |
|----------------|--------------|---|------|--------------|
| Pseudodementia | Escitalopram | S | Oral | Mylan        |
|                | Ramipril     | C | Oral | Not Reported |
|                | Lexotanil    | C |      | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Mar-2013              | 9154780       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000043239    |                      | 83 YR      | Male       | FRA            |

| <u>Preferred Term</u>      | <u>Product</u>                    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|-----------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Aphasia; Urinary Retention | Escitalopram                      |              |            | S           | Oral         | 5 Mg               |                 | Forest       |
|                            | Aspegic [Acetylsalicylate Lysine] |              |            | C           |              | 100 Mg             |                 | Not Reported |
|                            | Triatec (Ramipril)                |              |            | C           |              | 1.25 Mg            |                 | Not Reported |
|                            | Triatec (Ramipril)                |              |            | C           |              |                    |                 | Not Reported |
|                            | Bisocel                           |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Mar-2013              | 9154801       | EXPEDITED (15-DAY) |                    | DE, OT          | GB-FRI-1000042718    |                      | 20 YR      | Male       | GBR            |

| <u>Preferred Term</u>                                                                                                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|----------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Completed Suicide; Dissociation; Dizziness; Feeling Abnormal; Feeling Abnormal; Insomnia; Suicidal Ideation; Withdrawal Syndrome | Escitalopram   |              |            | S           | Oral         | 10 Mg              |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 11-Mar-2013              | 9154925       | NON-EXPEDITED    |                    |                 | US-ABBOTT-12P-163-0967412-00 |                      | 42 YR      | Female     | USA            |

| <u>Preferred Term</u>                        | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>  | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------|-----------------------|--------------|------------|-------------|---------------|--------------------|-----------------|--------------|
| Abnormal Dreams; Mood Altered; Off Label Use | Lupron Depot 11.25 Mg |              |            | S           | Intramuscular |                    |                 | Not Reported |
|                                              | Lexapro               |              |            | S           |               |                    |                 | Not Reported |
|                                              | Depakote              |              |            | C           |               |                    |                 | Not Reported |
|                                              | Toprol XL             |              |            | C           |               |                    |                 | Not Reported |
|                                              | Zonisamide            |              |            | C           |               |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                              | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------|------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 11-Mar-2013                                                                           | 9155731                            | EXPEDITED (15-DAY) |                    | HO              | PHHY2013IT022172     |                      |                 | Male         | ITA            |
| <u>Preferred Term</u>                                                                 | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Suicide Attempt; Toxicity To Various Agents                                           | Diazepam                           |                    |                    | S               |                      |                      |                 | Novartis     |                |
|                                                                                       | Lormetazepam                       |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                       | Escitalopram                       |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                              | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Mar-2013                                                                           | 9155742                            | EXPEDITED (15-DAY) |                    | HO              | IT-FRI-1000043247    |                      | 20 YR           | Male         | ITA            |
| <u>Preferred Term</u>                                                                 | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Suicide Attempt; Toxicity To Various Agents                                           | Escitalopram Oral Solution         |                    |                    | S               | Oral                 | 10 Df                |                 | Forest       |                |
|                                                                                       | Minias                             |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                       | Valium                             |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                              | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Mar-2013                                                                           | 9157806                            | DIRECT             |                    | OT              |                      |                      | 48 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                 | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agoraphobia; Drug Ineffective; Hypertension; Panic Attack; Product Substitution Issue | Escitalopram 10mg Aurobiudo Pharma |                    |                    | S               | Oral                 |                      |                 | Teva         |                |
| <u>FDA Received Date</u>                                                              | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Mar-2013                                                                           | 9157351                            | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000043245    |                      | 58 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                 | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hepatitis                                                                             | Escitalopram                       |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                                                                       | Escitalopram                       |                    |                    | S               |                      |                      |                 | Forest       |                |
|                                                                                       | Pegasys                            |                    |                    | S               | Intravenous (not     | 180 Mcg Weekly       |                 | Not Reported |                |

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

|                                                                                                                                                       |                         |                    |                    |                 |                      |                      |                 |              |                |
|-------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Copegus                                                                                                                                               |                         | S                  |                    | Oral            |                      | 1000 Mg              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                              | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Mar-2013                                                                                                                                           | 9158371                 | EXPEDITED (15-DAY) | DE                 |                 | GR-TEVA-390030ISR    |                      | 72 YR           | Female       | GRC            |
| <u>Preferred Term</u>                                                                                                                                 | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Acute Kidney Injury; Acute Respiratory Distress Syndrome; Cardio-Respiratory Arrest; Drug Interaction; Neuroleptic Malignant Syndrome; Rhabdomyolysis | Amlodipine              |                    |                    | S               | Unknown              | 5 Milligram Daily;   |                 | Teva         |                |
|                                                                                                                                                       | Lithium                 |                    |                    | S               | Unknown              | 900 Milligram Daily; |                 | Not Reported |                |
|                                                                                                                                                       | Escitalopram            |                    |                    | S               | Unknown              | 20 Milligram Daily;  |                 | Not Reported |                |
|                                                                                                                                                       | Buspirone               |                    |                    | S               | Unknown              | 10 Milligram Daily;  |                 | Not Reported |                |
|                                                                                                                                                       | Irbesartan              |                    |                    | S               | Unknown              | 150 Milligram Daily; |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                              | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Mar-2013                                                                                                                                           | 9159273                 | DIRECT             | Y                  |                 |                      |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                                                                                                 | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective; Drug Intolerance; Fatigue; Myalgia                                                                                                  | Escitalopram            |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                              | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Mar-2013                                                                                                                                           | 9162721                 | EXPEDITED (15-DAY) | Y                  | DE              | AMLO20130006         |                      | 72 YR           | Female       | GRC            |
| <u>Preferred Term</u>                                                                                                                                 | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Acute Kidney Injury; Acute Respiratory Distress Syndrome; Antipsychotic Drug Level Increased;                                                         | Amlodipine Besylate     |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
| Blood Sodium Increased;                                                                                                                               | Irbesartan              |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
| Blood Uric Acid Increased;                                                                                                                            | Lithium Carbonate       |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
| Cardio-Respiratory Arrest;                                                                                                                            | Escitalopram Oxalate    |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Haemodialysis;                                                                                                                                        | Buspirone Hydrochloride |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Neuroleptic Malignant  
Syndrome;  
Rhabdomyolysis

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 13-Mar-2013              | 7853856       | NON-EXPEDITED    |                    |                 | US-ABBOTT-10P-163-0640781-00 |                      | 52 YR      | Male       | USA            |

| <u>Preferred Term</u>           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Somnolence; Trismus;<br>Trismus | Depakote       |              |            | S           | Oral         |                    |                 | Not Reported |
|                                 | Depakote       |              |            | S           | Oral         |                    |                 | Not Reported |
|                                 | Depakote       |              |            | S           |              |                    |                 | Not Reported |
|                                 | Lexapro        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                 | Lexapro        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                 | Lexapro        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                 | Lexapro        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                 | Lexapro        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                 | Seroquel       |              |            | S           | Oral         |                    |                 | Not Reported |
|                                 | Seroquel       |              |            | S           | Oral         |                    |                 | Not Reported |
|                                 | Seroquel       |              |            | S           | Oral         |                    |                 | Not Reported |
|                                 | Synthroid      |              |            | C           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Mar-2013              | 9002329       | EXPEDITED (15-DAY) |                    | OT              | JP-FRI-1000040680    |                      | 82 YR      | Female     | JPN            |

| <u>Preferred Term</u>                          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Long Qt Syndrome;<br>Ventricular Extrasystoles | Lexapro        |              |            | S           | Oral         | 20 Mg              |                 | Forest       |
|                                                | Betamac        |              |            | S           | Oral         | 150 Mg             |                 | Not Reported |
|                                                | Solanax        |              |            | C           | Oral         | 1.2 Mg             |                 | Not Reported |
|                                                | Myslee         |              |            | C           | Oral         | 10 Mg              |                 | Not Reported |
|                                                | Mexitil        |              |            | C           | Oral         | 150 Mg             |                 | Not Reported |
|                                                | Diovan         |              |            | C           | Oral         | 40 Mg              |                 | Not Reported |

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

|         |   |      |        |              |
|---------|---|------|--------|--------------|
| Actonel | C | Oral | 2.5 Mg | Not Reported |
| Magmitt | C | Oral | 990 Mg | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Mar-2013              | 9109801       | EXPEDITED (15-DAY) | HO                 |                 | AT-FRI-1000042800    |                      |            | Female     | AUT            |

| <u>Preferred Term</u>        | <u>Product</u>                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------|--------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Dermatitis Atopic; Urticaria | Escitalopram                   |              |            | S           | Oral         | 5 Mg               |                 | Forest       |
|                              | Escitalopram                   |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                              | Stablon                        |              |            | S           | Oral         | 37.5               |                 | Not Reported |
|                              | Cymbalta                       |              |            | S           |              | 60                 |                 | Not Reported |
|                              | Trittico                       |              |            | C           |              | 200                |                 | Not Reported |
|                              | Dominal (Acetylsalicylic Acid) |              |            | C           |              | 80                 |                 | Not Reported |
|                              | Valdoxan                       |              |            | C           |              | 25                 |                 | Not Reported |
|                              | Valdoxan                       |              |            | C           |              | 50                 |                 | Not Reported |
|                              | Valdoxan                       |              |            | C           |              | 50                 |                 | Not Reported |
|                              | Cetirizin                      |              |            | C           |              | 20                 |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 13-Mar-2013              | 9160372       | EXPEDITED (15-DAY) |                    | OT              | FR-JNJFOC-20130216988 |                      | 52 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Pemphigoid            | Risperdal      |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Seroplex       |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Tercian        |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Depakote       |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Solian         |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Imovane        |              |            | S           | Unknown      |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                      | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------------|----------------|
| 13-Mar-2013                                                                                                                                                                                   | 9161503                     | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000043263    |                      | < 1 DAY         | Male             | USA            |
| <u>Preferred Term</u>                                                                                                                                                                         | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |
| Spina Bifida                                                                                                                                                                                  | Lexapro<br>Celexa           |                    |                    | S<br>S          |                      |                      |                 | Forest<br>Forest |                |
| <u>FDA Received Date</u>                                                                                                                                                                      | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 13-Mar-2013                                                                                                                                                                                   | 9163059                     | DIRECT             |                    | OT              |                      |                      | 51 YR           | Female           | USA            |
| <u>Preferred Term</u>                                                                                                                                                                         | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |
| Anxiety; Chemical Poisoning; Dizziness; Feeling Abnormal; Impaired Driving Ability; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Product Quality Issue; Tremor; Tremor | Escitalopram                |                    |                    | S               | Oral                 |                      |                 | Camber           |                |
| <u>FDA Received Date</u>                                                                                                                                                                      | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 13-Mar-2013                                                                                                                                                                                   | 9173436                     | EXPEDITED (15-DAY) | Y                  | OT              | AUR-APL-2013-02172   |                      | 56 YR           | Female           | IND            |
| <u>Preferred Term</u>                                                                                                                                                                         | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |
| Condition Aggravated; Depression; Gastritis; Tardive Dyskinesia                                                                                                                               | Amisulpride                 |                    |                    | S               |                      |                      | 1 DAY<br>1 DAY  | Not Reported     |                |
|                                                                                                                                                                                               | Escitalopram (Escitalopram) |                    |                    | S               |                      |                      | 1 WEEK          | Not Reported     |                |
|                                                                                                                                                                                               | Fluvoxamine                 |                    |                    | S               |                      |                      |                 | Not Reported     |                |
| <u>FDA Received Date</u>                                                                                                                                                                      | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 14-Mar-2013                                                                                                                                                                                   | 8916971                     | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000040524    |                      | 92 YR           | Male             | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                         | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |

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

|                                |              |   |      |         |              |
|--------------------------------|--------------|---|------|---------|--------------|
| Cyanosis; Respiratory Distress | Escitalopram | S | Oral | 10 Mg   | Forest       |
|                                | Tiapridal    | S | Oral | 75 Mg   | Not Reported |
|                                | Imovane      | S | Oral | 3.75 Mg | Not Reported |
|                                | Seresta      | S | Oral | 10 Mg   | Not Reported |
|                                | Coversyl     | C |      |         | Not Reported |
|                                | Lasilix      | C |      |         | Not Reported |
|                                | Inexium      | C |      |         | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Mar-2013              | 9162307       | EXPEDITED (15-DAY) |                    | HO              | PHHY2013ES023194     |                      | 69 YR      | Female     | ESP            |

| <u>Preferred Term</u>           | <u>Product</u>  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                    | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------|-----------------|--------------|------------|-------------|--------------|-------------------------------------------------------|-----------------|--------------|
| Drug Interaction; Hyponatraemia | Dafiro Hct      |              |            | S           | Oral         | 1 Df, Qd (160 Mg Vals, 10 Mg Amlol And 12.5 Mg Hydro) |                 | Novartis     |
|                                 | Escitalopram    |              |            | S           | Oral         | 1 Df, Qd                                              |                 | Not Reported |
|                                 | Lorazepam Cinfa |              |            | C           |              | 1 Mg, Unk                                             |                 | Not Reported |
|                                 | Dianben         |              |            | C           |              | 850 Mg, Unk                                           |                 | Not Reported |
|                                 | Simvastatin     |              |            | C           |              | Unk Ukn, Unk                                          |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Mar-2013              | 9162933       | EXPEDITED (15-DAY) |                    | OT              | ZA-FRI-1000043364    |                      | 28 YR      | Female     | ZAF            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cushing'S Syndrome    | Escitalopram   |              |            | S           | Oral         | 20 Mg              |                 | Forest       |
|                       | Yasmin         |              |            | C           | Oral         |                    |                 | Not Reported |
|                       | Trepiline      |              |            | C           | Oral         | 20 Mg              |                 | Not Reported |
|                       | Stilpane       |              |            | C           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 14-Mar-2013              | 9163501       | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-2013084207 |                      | 38 YR      | Male       | USA            |

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

| <u>Preferred Term</u>                                                                                                | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
|----------------------------------------------------------------------------------------------------------------------|-------------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|----------------------|----------------|
| Atrial Fibrillation;<br>Imprisonment; Myocardial<br>Infarction;<br>Nasopharyngitis; Panic<br>Attack; Suicide Attempt | Effexor           |                    |                    | S               |                                                 | Unk                  |                 | Pfizer               |                |
|                                                                                                                      | Ativan            |                    |                    | S               |                                                 | Unk                  |                 | Pfizer               |                |
|                                                                                                                      | Lithium Carbonate |                    |                    | S               |                                                 | Unk                  |                 | Pfizer               |                |
|                                                                                                                      | Wellbutrin        |                    |                    | S               |                                                 | Unk                  |                 | Not Reported         |                |
|                                                                                                                      | Concerta          |                    |                    | S               |                                                 | Unk                  |                 | Not Reported         |                |
|                                                                                                                      | Depakote          |                    |                    | S               |                                                 | Unk                  |                 | Not Reported         |                |
|                                                                                                                      | Trileptal         |                    |                    | S               |                                                 | Unk                  |                 | Not Reported         |                |
|                                                                                                                      | Lexapro           |                    |                    | S               |                                                 | Unk                  |                 | Not Reported         |                |
|                                                                                                                      | Ambien            |                    |                    | S               |                                                 | Unk                  |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                                                             | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 14-Mar-2013                                                                                                          | 9163649           | EXPEDITED (15-DAY) |                    | DE              | GR-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>17442690 |                      | 72 YR           | Female               | GRC            |
| <u>Preferred Term</u>                                                                                                | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Drug Interaction;<br>Neuroleptic Malignant<br>Syndrome                                                               | Irbesartan        |                    |                    | S               |                                                 |                      |                 | Bristol Myers Squibb |                |
|                                                                                                                      | Buspirone         |                    |                    | S               |                                                 |                      |                 | Not Reported         |                |
|                                                                                                                      | Lithium           |                    |                    | S               |                                                 |                      |                 | Not Reported         |                |
|                                                                                                                      | Amlodipine        |                    |                    | S               |                                                 |                      |                 | Not Reported         |                |
|                                                                                                                      | Escitalopram      |                    |                    | S               |                                                 |                      |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                                                             | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 14-Mar-2013                                                                                                          | 9163674           | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000043278                               |                      | < 1 DAY         | Male                 | USA            |
| <u>Preferred Term</u>                                                                                                | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Coarctation Of The Aorta                                                                                             | Lexapro           |                    |                    | S               | Transplacental                                  |                      |                 | Forest               |                |
| <u>FDA Received Date</u>                                                                                             | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 14-Mar-2013                                                                                                          | 9163692           | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000043270                               |                      | < 1 DAY         | Male                 | USA            |
| <u>Preferred Term</u>                                                                                                | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |

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

|                                   |                         |                           |                             |                          |                               |                               |                             |                          |                         |
|-----------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|-----------------------------|--------------------------|-------------------------|
| Talipes                           | Lexapro                 |                           | S                           | Transplacental           |                               |                               |                             | Forest                   |                         |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>         | <a href="#">Sex</a>      | <a href="#">Country</a> |
| 14-Mar-2013                       | 9163802                 | EXPEDITED (15-DAY)        |                             | CA                       | US-FRI-1000043280             |                               | < 1 DAY                     | Female                   | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> |                           | <a href="#">Comp.</a>       | <a href="#">OTC</a>      | <a href="#">Role</a>          | <a href="#">Route</a>         | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a>     |
| Atrial Septal Defect              | Lexapro                 |                           |                             | S                        |                               | Transplacental                |                             |                          | Forest                  |
|                                   | Celexa                  |                           |                             | S                        |                               |                               |                             |                          | Forest                  |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>         | <a href="#">Sex</a>      | <a href="#">Country</a> |
| 14-Mar-2013                       | 9163969                 | EXPEDITED (15-DAY)        |                             | CA                       | US-FRI-1000043291             |                               | < 1 DAY                     | Female                   | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> |                           | <a href="#">Comp.</a>       | <a href="#">OTC</a>      | <a href="#">Role</a>          | <a href="#">Route</a>         | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a>     |
| Cleft Lip; Cleft Palate           | Lexapro                 |                           |                             | S                        |                               |                               |                             |                          | Forest                  |
|                                   | Celexa                  |                           |                             | S                        |                               |                               |                             |                          | Forest                  |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>         | <a href="#">Sex</a>      | <a href="#">Country</a> |
| 14-Mar-2013                       | 9167300                 | DIRECT                    | Y                           | LT                       |                               |                               | 50 YR                       | Male                     | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> |                           | <a href="#">Comp.</a>       | <a href="#">OTC</a>      | <a href="#">Role</a>          | <a href="#">Route</a>         | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a>     |
| Suicidal Ideation                 | Escitalopram Oxalate    |                           |                             | S                        |                               | 1 Tab Daily                   | 3 MTH                       |                          | Not Reported            |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>         | <a href="#">Sex</a>      | <a href="#">Country</a> |
| 15-Mar-2013                       | 8697780                 | EXPEDITED (15-DAY)        |                             | OT                       | US-ASTRAZENECA-2012SE47720    |                               | 56 YR                       | Female                   | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> |                           | <a href="#">Comp.</a>       | <a href="#">OTC</a>      | <a href="#">Role</a>          | <a href="#">Route</a>         | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a>     |
| Abdominal Pain Upper;             | Nexium                  |                           |                             | S                        |                               | Oral                          |                             |                          | Not Reported            |
| Anxiety; Feeding Disorder;        | Lexapro                 |                           |                             | S                        |                               | Oral                          |                             |                          | Not Reported            |
| Gait Inability; Intentional       | Protonix                |                           |                             | S                        |                               | Unknown                       |                             |                          | Not Reported            |
| Product Misuse;                   |                         |                           |                             |                          |                               |                               |                             |                          |                         |
| Neurological Procedural           |                         |                           |                             |                          |                               |                               |                             |                          |                         |
| Complication; Product             |                         |                           |                             |                          |                               |                               |                             |                          |                         |
| Dose Omission; Vomiting           |                         |                           |                             |                          |                               |                               |                             |                          |                         |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                         | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------|-----------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 15-Mar-2013                                                                                                      | 8957565         | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000040914        |                      | 29 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                            | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Homicide; Road Traffic Accident; Suicide Attempt                                                                 | Escitalopram    |                    |                    | S               | Oral                     | 5 Mg                 |                 | Forest       |                |
|                                                                                                                  | Methadone       |                    |                    | C               |                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                         | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Mar-2013                                                                                                      | 9138280         | EXPEDITED (15-DAY) |                    | DE, HO, OT      | GR-RANBAXY-2013RR-65730  |                      | 72 YR           | Female       | GRC            |
| <u>Preferred Term</u>                                                                                            | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Acute Respiratory Distress Syndrome; Cardio-Respiratory Arrest; Drug Interaction; Neuroleptic Malignant Syndrome | Escitalopram    |                    |                    | S               | Unknown                  | 20 Mg, Qd            |                 | Not Reported |                |
|                                                                                                                  | Lithium         |                    |                    | S               | Unknown                  | 300 Mg, Tid          |                 | Not Reported |                |
|                                                                                                                  | Buspirone       |                    |                    | S               | Unknown                  | 10 Mg, Qd            |                 | Not Reported |                |
|                                                                                                                  | Amlodipine      |                    |                    | S               | Unknown                  | 5 Mg, Qd             |                 | Ranbaxy      |                |
|                                                                                                                  | Irbesartan      |                    |                    | S               | Unknown                  | 150 Mg, Qd           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                         | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Mar-2013                                                                                                      | 9161098         | EXPEDITED (15-DAY) |                    | OT              | TR-FRI-1000043298        |                      | 43 YR           | Female       | TUR            |
| <u>Preferred Term</u>                                                                                            | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Serotonin Syndrome                                                                             | Escitalopram    |                    |                    | S               |                          | 20 Mg                |                 | Forest       |                |
|                                                                                                                  | Isoniazid       |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                                                                                                  | Corticosteroids |                    |                    | C               |                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                         | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Mar-2013                                                                                                      | 9164792         | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-2013085507 |                      | 42 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                            | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Loss Of Weight; Alopecia; Depression; Hair                                                              | Lyrica          |                    |                    | S               |                          | Unk                  |                 | Pfizer       |                |

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

|                           |            |   |      |                         |              |
|---------------------------|------------|---|------|-------------------------|--------------|
| Texture Abnormal;         | Gabapentin | S |      | Unk                     | Pfizer       |
| Influenza Like Illness;   | Topamax    | S | Oral | 100 Mg, 1x/Day (50mg, 2 | Not Reported |
| Memory Impairment;        |            |   |      | In 1 Day)               |              |
| Migraine; Musculoskeletal | Topamax    | S |      |                         | Not Reported |
| Pain; Nausea; Neoplasm;   | Lexapro    | S |      | Unk                     | Not Reported |
| Nephrolithiasis; Vomiting | Synthroid  | C |      | 175 Ug, In 1 Day        | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------------------------------------|----------------------|------------|------------|----------------|
| 15-Mar-2013              | 9166001       | EXPEDITED (15-DAY) |                    | DE              | GR-ROXANE<br>LABORATORIES, INC.-<br>2013-RO-00374RO |                      | 72 YR      | Female     | GRC            |

| <u>Preferred Term</u>      | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Acute Respiratory Distress | Lithium Carbonate       |              |            | S           |              | 900 Mg             |                 | Roxane       |
| Syndrom; Cardio-           | Amlodipine              |              |            | S           |              | 5 Mg               |                 | Roxane       |
| Respiratory Arrest;        | Irbesartan              |              |            | S           |              | 150 Mg             |                 | Roxane       |
| Neuroleptic Malignant      | Escitalopram Oxalate    |              |            | S           |              | 20 Mg              |                 | Not Reported |
| Syndrom                    | Buspirone Hydrochloride |              |            | S           |              | 10 Mg              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Mar-2013              | 9166997       | EXPEDITED (15-DAY) |                    | HO              | FR-TEVA-390507ISR    |                      | 67 YR      | Male       | FRA            |

| <u>Preferred Term</u>       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------|----------------|--------------|------------|-------------|--------------|---------------------------|-----------------|--------------|
| Abdominal Pain; Acute       | Metformine     |              |            | S           | Oral         | 2550 Milligram Daily;     |                 | Goldline     |
| Kidney Injury;              | Atenolol       |              |            | S           | Oral         | 100 Milligram Daily;      |                 | Not Reported |
| Bradycardia; Diarrhoea;     | Atenolol       |              |            | S           | Oral         | 100 Milligram Daily;      |                 | Not Reported |
| Disorientation;             | Verapamil      |              |            | S           | Oral         | 240 Milligram Daily;      |                 | Not Reported |
| Hyperkalaemia;              | Cokenzen       |              |            | S           | Oral         | 1 Dosage Forms Daily;     |                 | Not Reported |
| Hypotension; Lactic         |                |              |            |             |              | Candesartan Cilexetil     |                 |              |
| Acidosis; Malaise; Pyrexia; |                |              |            |             |              | 16mg/ Hydrochlorothiazide |                 |              |
| Septic Shock;               |                |              |            |             |              | 12.5mg                    |                 |              |
| Staphylococcal              | Glucor         |              |            | S           | Oral         | 150 Milligram Daily;      |                 | Not Reported |
| Bacteraemia; Vomiting       | Mediatsensyl   |              |            | S           | Oral         | 180 Milligram Daily;      |                 | Not Reported |



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|              |   |      |                       |              |
|--------------|---|------|-----------------------|--------------|
| Ciprofibrate | S | Oral | 1 Dosage Forms Daily; | Not Reported |
| Seroplex     | S | Oral | 10 Milligram Daily;   | Not Reported |
| Seroplex     | S | Oral | 10 Milligram Daily;   | Not Reported |
| Norset       | S | Oral | 15 Milligram Daily;   | Not Reported |
| Xanax        | S | Oral | 3 Dosage Forms Daily; | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Mar-2013              | 9167451       | EXPEDITED (15-DAY) | OT                 |                 | GR-ACCORD-016890     |                      | 63 YR      | Female     | GRC            |

| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Bruxism; Off Label Use | Escitalopram   |              |            | S           |              |                    |                 | Accord     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Mar-2013              | 9168352       | EXPEDITED (15-DAY) | HO                 |                 | FR-FRI-1000043429    |                      | 64 YR      | Male       | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Mouth Haemorrhage     | Escitalopram   |              |            | S           | Oral         | 20 Mg              |                 | Forest       |
|                       | Clopidogrel    |              |            | S           |              | 1 Df               |                 | Not Reported |
|                       | Perindopril    |              |            | C           |              |                    |                 | Not Reported |
|                       | Verapamil      |              |            | C           |              |                    |                 | Not Reported |
|                       | Simvastatin    |              |            | C           |              |                    |                 | Not Reported |
|                       | Prednisone     |              |            | C           |              |                    |                 | Not Reported |
|                       | Esomeprazole   |              |            | C           |              |                    |                 | Not Reported |
|                       | Symbicort      |              |            | C           |              |                    |                 | Not Reported |
|                       | Alprazolam     |              |            | C           |              |                    |                 | Not Reported |
|                       | Doliprane      |              |            | C           |              |                    |                 | Not Reported |
|                       | Forlax         |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 18-Mar-2013              | 9168770       | EXPEDITED (15-DAY) | HO                 |                 | FR-PFIZER INC-2013085553 |                      | 68 YR      | Male       | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Neutropenia;          | Inspra         |              |            | S           | Oral         | 25 Mg, Daily       |                 | Pfizer     |

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

|                  |                        |   |                                       |                |              |
|------------------|------------------------|---|---------------------------------------|----------------|--------------|
| Thrombocytopenia | Calciparin             | S | Subcutaneous                          | 0.2 MI, 2x/Day | Not Reported |
|                  | Clamoxyl (Amoxicillin) | S | Oral                                  | 1 G, 2x/Day    | Not Reported |
|                  | Zeclar                 | S | Oral                                  | 500 Mg, 2x/Day | Not Reported |
|                  | Seroplex               | S | Oral                                  | 10 Mg, Daily   | Not Reported |
|                  | Paracetamol            | S | Intravenous (not otherwise specified) | 1 G, 4x/Day    | Not Reported |
|                  | Crestor                | S | Oral                                  | 5 Mg, Daily    | Not Reported |
|                  | Plavix                 | S | Oral                                  | 75 Mg, Daily   | Not Reported |
|                  | Kardegic               | S | Oral                                  | 75 Mg, Daily   | Not Reported |
|                  | Inexium                | S | Oral                                  | 40 Mg, Daily   | Not Reported |

|                          |               |                    |                    |                 |                      |                      |            |            |                |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
| 18-Mar-2013              | 9169409       | EXPEDITED (15-DAY) |                    | HO, LT          | CH-TEVA-390523ISR    |                      | 53 YR      | Female     | CHE            |

| <u>Preferred Term</u>     | <u>Product</u>   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                             | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|------------------|--------------|------------|-------------|--------------|--------------------------------------------------------------------------------|-----------------|--------------|
| Hepatic Failure; Overdose | Irfen            |              |            | S           | Oral         | 1800 Milligram Daily;                                                          |                 | Ivax         |
|                           | Irfen            |              |            | S           | Oral         | Dosing Scheme Unclear, Up To 7 Tablets Per Day, Start Date Unknown             |                 | Ivax         |
|                           | Surmontil        |              |            | S           | Oral         | 75 Milligram Daily; Start Date Unknown                                         |                 | Not Reported |
|                           | Cipralext        |              |            | S           | Oral         | 10 Milligram Daily; Start Date Unknown                                         |                 | Not Reported |
|                           | Methadon Streuli |              |            | S           | Oral         | 80 Milligram Daily; Start Date Unknown                                         |                 | Not Reported |
|                           | Lyrice           |              |            | S           | Oral         | 300 Milligram Daily; Start Date Unknown                                        |                 | Not Reported |
|                           | Aspirin Cardio   |              |            | C           | Oral         | 100 Milligram Daily;                                                           |                 | Not Reported |
|                           | Triatec Comp     |              |            | C           | Oral         | 1 Dosage Forms Daily; 1 Dosage Form = 25 Mg Hydrochlorothiazide/ 5 Mg Ramipril |                 | Not Reported |

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

Pantozol (Switzerland) C Oral 40 Milligram Daily; Long-Term Therapy Not Reported

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 18-Mar-2013                       | 9169636                | EXPEDITED (15-DAY)        |                             | OT                       | AU-FRI-1000043491             |                               |                     | Male                | AUS                     |

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

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 18-Mar-2013                       | 9171271                | DIRECT                    | Y                           | OT                       |                               |                               |                     | Male                | USA                     |

| <a href="#">Preferred Term</a>               | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|----------------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Drug Ineffective; Product Substitution Issue | Escitalopram            |                       |                     | S                    | Oral                  |                             |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 18-Mar-2013                       | 9173481                | DIRECT                    | Y                           |                          |                               |                               | 42 YR               | Female              | USA                     |

| <a href="#">Preferred Term</a>                        | <a href="#">Product</a>   | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|-------------------------------------------------------|---------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Feeling Abnormal; Feeling Abnormal; Thinking Abnormal | Escitalopram, 10 Mg, Teva |                       |                     | S                    |                       |                             |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 19-Mar-2013                       | 8990870                | EXPEDITED (15-DAY)        |                             | HO                       | JP-009507513-1212JPN011109    |                               | 27 YR               | Female              | JPN                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Fall; Fracture                 | Remeron                 |                       |                     | S                    | Oral                  | 0.5 Df, Qd                  |                          | Merck               |
|                                | Remeron                 |                       |                     | S                    | Oral                  | 1 Df, Qd                    |                          | Merck               |
|                                | Lexapro                 |                       |                     | S                    | Oral                  | 10 Mg, Qd                   |                          | Not Reported        |
|                                | Solanax                 |                       |                     | S                    | Oral                  | 1.2 Mg, Qd                  |                          | Not Reported        |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|         |   |      |            |              |
|---------|---|------|------------|--------------|
| Loxonin | S | Oral | 60 Mg, Qd  | Not Reported |
| Mucosta | S | Oral | 300 Mg, Qd | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 19-Mar-2013              | 9024924       | EXPEDITED (15-DAY) |                    | HO, OT          | US-MERCK-1001USA00361 |                      | 15 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                    | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>  | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------|-----------------------|--------------|------------|-------------|---------------|----------------------------------|-----------------|--------------|
| Abdominal Pain;<br>Abdominal Pain;<br>Depression; Gastritis;<br>Suicidal Behaviour;<br>Suicidal Ideation | Raltegravir Potassium |              |            | S           | Oral          | 400 Mg, Bid                      |                 | Merck        |
|                                                                                                          | Raltegravir Potassium |              |            | S           | Oral          | 400 Mg, Bid                      |                 | Merck        |
|                                                                                                          | Raltegravir Potassium |              |            | S           | Oral          | 400 Mg, Bid                      |                 | Merck        |
|                                                                                                          | Darunavir             |              |            | C           | Oral          | 600 Mg, Bid                      |                 | Not Reported |
|                                                                                                          | Darunavir             |              |            | C           | Oral          | Unk Unk, Bid                     |                 | Not Reported |
|                                                                                                          | Ritonavir             |              |            | C           | Oral          | 100 Mg, Bid                      |                 | Not Reported |
|                                                                                                          | Ritonavir             |              |            | C           | Oral          | Unk Unk, Bid                     |                 | Not Reported |
|                                                                                                          | Etravirine            |              |            | C           | Oral          | 200 Mg, Bid                      |                 | Not Reported |
|                                                                                                          | Bactrim Ds            |              |            | C           | Oral          | On Monday, Tuesday And Wednesday |                 | Not Reported |
|                                                                                                          | Melatonin             |              |            | C           | Oral          |                                  |                 | Not Reported |
|                                                                                                          | Lexapro               |              |            | S           | Oral          | 5 Mg, Qd                         |                 | Not Reported |
|                                                                                                          | Lexapro               |              |            | S           | Oral          | 10 Mg, Qd                        |                 | Not Reported |
|                                                                                                          | Epzicom               |              |            | S           | Oral          | 600/300                          |                 | Not Reported |
|                                                                                                          | Epzicom               |              |            | S           | Oral          | 600/300                          |                 | Not Reported |
|                                                                                                          | Depo-Provera          |              |            | C           | Intramuscular | Unk Unk, Qm3                     |                 | Not Reported |
|                                                                                                          | Zoloft                |              |            | C           | Oral          | Unk Unk, Qd                      |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Mar-2013              | 9171973       | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000043480    |                      | < 1 DAY    | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|------------|
| Congenital Anomaly;   | Lexapro        |              |            | S           | Transplacental |                    |                 | Forest     |

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

Craniosynostosis

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Mar-2013              | 9171984       | EXPEDITED (15-DAY) |                    | CA              | NO-FRI-1000043500    |                      |            | Male       | NOR            |

| <u>Preferred Term</u>                                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|------------|
| Foetal Exposure During Pregnancy; Ventricular Septal Defect | Escitalopram   |              |            | S           | Transplacental | 10 Mg              |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Mar-2013              | 9172134       | EXPEDITED (15-DAY) |                    | HO              | IT-FRI-1000043368    |                      | 41 YR      | Female     | ITA            |

| <u>Preferred Term</u>                                                                               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Electrocardiogram Qt Prolonged; Hypotension; Intentional Overdose; Intentional Self-Injury; Syncope | Escitalopram   |              |            | S           | Oral         | 20 Mg              |                 | Forest       |
|                                                                                                     | Escitalopram   |              |            | S           |              | 70 Unit Dose       |                 | Forest       |
|                                                                                                     | Depakin Chrono |              |            | S           | Oral         | 500 Mg             |                 | Not Reported |
|                                                                                                     | Depakin Chrono |              |            | S           |              | 40 Unit Dose       |                 | Not Reported |
|                                                                                                     | Torvast        |              |            | S           | Oral         | 20 Mg              |                 | Not Reported |
|                                                                                                     | Torvast        |              |            | S           |              | 35 Unit Dose       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Mar-2013              | 9172223       | EXPEDITED (15-DAY) |                    | HO, OT          | RS-FRI-1000043541    |                      | 65 YR      | Male       | SRB            |

| <u>Preferred Term</u>                                                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Diarrhoea; Gastritis; Hepatitis Toxic; Nausea; Transaminases Increased; Vomiting | Escitalopram   |              |            | S           | Oral         | 5 Mg               |                 | Forest       |
|                                                                                  | Escitalopram   |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                                                                  | Bromazepam     |              |            | C           | Oral         | 1.5 Mg             |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Mar-2013              | 9173184       | DIRECT           | Y                  | HO              |                      |                      | 50 YR      | Female     | USA            |

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

| <u>Preferred Term</u>                                                                                                                                                                                                                                       | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| Chest Pain; Dizziness; Dyspnoea                                                                                                                                                                                                                             | Escitalopram Oxalate              |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                    | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Mar-2013                                                                                                                                                                                                                                                 | 9173351                           | DIRECT             |                    | OT              |                          |                      | 37 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                       | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Headache; Muscle Spasms; Pain In Extremity                                                                                                                                                                                                      | Escitalopram Oxalate              |                    |                    | S               |                          |                      | 4 DAY           | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                    | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Mar-2013                                                                                                                                                                                                                                                 | 6128914                           | EXPEDITED (15-DAY) |                    | DE              | US-JNJFOC-20060902622    |                      | 18 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                       | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Apnoea; Blood Creatine Phosphokinase Increased; Completed Suicide; Hepatic Function Abnormal; Hypotension; Intentional Overdose; Myoglobin Blood Increased; Renal Impairment; Respiratory Failure; Subarachnoid Haemorrhage; Tachycardia; Urinary Retention | Cyclobenzaprine                   |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                             | Ibuprofen                         |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                             | Pseudoephedrine Hydrochloride     |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                             | Aspirin                           |                    | Y                  | S               | Oral                     |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                             | Acetaminophen & Codeine Phosphate |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                             | Naproxen                          |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                             | Escitalopram                      |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                    | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Mar-2013                                                                                                                                                                                                                                                 | 7924667                           | EXPEDITED (15-DAY) |                    | DS, OT          | US-PFIZER INC-2008067170 |                      | 60 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                       | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depressed Mood; Dissociation; Disturbance                                                                                                                                                                                                                   | Sertraline Hcl                    |                    |                    | S               |                          | Unk                  |                 | Pfizer       |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                                               |                           |   |     |              |
|-------------------------------------------------------------------------------|---------------------------|---|-----|--------------|
| In Sexual Arousal;<br>Disturbance In Sexual<br>Arousal; Emotional<br>Disorder | Paroxetine                | S | Unk | Unknown      |
|                                                                               | Venlafaxine Hydrochloride | S | Unk | Pfizer       |
|                                                                               | Fluoxetine Hcl            | S | Unk | Pfizer       |
|                                                                               | Escitalopram Oxalate      | S | Unk | Not Reported |

| <u>FDA Received Date</u>            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 20-Mar-2013                         | 9016040        | EXPEDITED (15-DAY) |                    | OT              | CH-FRI-1000041665    |                      |                 | Female       | CHE            |
| <u>Preferred Term</u>               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Generalised Tonic-Clonic<br>Seizure | Escitalopram   |                    |                    | S               |                      |                      |                 | Forest       |                |
|                                     | Levaxin        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                     | Augmentin      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                     | Depakin        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                     | Rivotril       |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                              | <u>Case #</u>                 | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|------------------|--------------------|-----------------|----------------------|--------------------------|-----------------|--------------|----------------|
| 20-Mar-2013                                                                                                                                           | 9174230                       | NON-EXPEDITED    |                    | DE              | US-JNJFOC-2006111647 |                          | 18 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                 | <u>Product</u>                | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Hepatic Function<br>Abnormal; Intentional<br>Overdose; Renal<br>Impairment; Respiratory<br>Failure; Subarachnoid<br>Haemorrhage | Pseudoephedrine Hydrochloride |                  | Y                  | S               | Oral                 |                          |                 | Not Reported |                |
|                                                                                                                                                       | Pseudoephedrine Hydrochloride |                  |                    | S               | Oral                 | Daily Dose Text: Unknown |                 | Not Reported |                |
|                                                                                                                                                       | Ibuprofen                     |                  |                    | S               | Oral                 | Daily Dose Text: Unknown |                 | Not Reported |                |
|                                                                                                                                                       | Ibuprofen                     |                  |                    | S               | Oral                 | Daily Dose Text: Unknown |                 | Not Reported |                |
|                                                                                                                                                       | Acetylsalicylic Acid          |                  | Y                  | S               | Oral                 | Daily Dose Text: Unknown |                 | Not Reported |                |
|                                                                                                                                                       | Paracetamol+Codeine           |                  |                    | S               | Oral                 | Daily Dose Text: Unknown |                 | Not Reported |                |
|                                                                                                                                                       | Naproxen                      |                  |                    | S               | Oral                 | Daily Dose Text: Unknown |                 | Not Reported |                |
|                                                                                                                                                       | Escitalopram                  |                  |                    | S               | Oral                 | Daily Dose Text: Unknown |                 | Not Reported |                |
|                                                                                                                                                       | Cyclobenzaprine Hydrochloride |                  |                    | S               | Oral                 | Daily Dose Text: Unknown |                 | Not Reported |                |
|                                                                                                                                                       |                               |                  |                    |                 |                      |                          |                 |              |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Mar-2013              | 9175273       | EXPEDITED (15-DAY) |                    | OT              | SE-FRI-1000043509    |                      | 55 YR      | Female     | SWE            |

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

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Eye Haemorrhage       | Escitalopram   |              |            | S           | Oral         | 5 Mg               |                 | Forest       |
|                       | Escitalopram   |              |            | S           | Oral         | 10 Mg              |                 | Not Reported |
|                       | Almogran       |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 21-Mar-2013              | 9178020       | EXPEDITED (15-DAY) |                    | HO              | FR-ASTRAZENECA-2013SE16980 |                      | 69 YR      | Male       | FRA            |

| <u>Preferred Term</u>                  | <u>Product</u>                          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                          | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------|-----------------------------------------|--------------|------------|-------------|---------------------------------------|--------------------|-----------------|--------------|
| Anaemia; Neutropenia; Thrombocytopenia | Inexium                                 |              |            | S           | Oral                                  |                    |                 | Not Reported |
|                                        | Crestor                                 |              |            | S           | Oral                                  |                    |                 | Not Reported |
|                                        | Seroplex                                |              |            | S           | Oral                                  |                    |                 | Not Reported |
|                                        | Plavix                                  |              |            | S           | Oral                                  |                    |                 | Not Reported |
|                                        | Paracetamol Macopharma (Non Az Product) |              |            | S           | Intravenous (not otherwise specified) |                    |                 | Not Reported |
|                                        | Calciparine                             |              |            | S           | Subcutaneous                          |                    |                 | Not Reported |
|                                        | Clamoxyl (Amoxicillin)                  |              |            | S           | Oral                                  |                    |                 | Not Reported |
|                                        | Zeclar                                  |              |            | S           | Oral                                  |                    |                 | Not Reported |
|                                        | Inspira                                 |              |            | S           | Oral                                  |                    |                 | Not Reported |
|                                        | Kardegic                                |              |            | S           | Oral                                  |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Mar-2013              | 9182112       | DIRECT           |                    | DS, OT          |                      |                      | 59 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Anxiety; Anxiety; Drug Ineffective; Feeding Disorder; Impaired Work Ability; Insomnia; Irritability; Loss Of Employment; Obsessive-Compulsive Disorder; | Lexapro        |              |            | S           | Oral         |                    |                 | Teva       |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Product Substitution Issue;  
Tachyphrenia; Weight  
Decreased

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 21-Mar-2013                       | 9182286                 | DIRECT                    | Y                           | LT                       |                               |                               | 50 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Suicidal Ideation                 | Escitalopram Oxalate    |                           |                             | S                        |                               | 1 Tab Daily                   | 3 MTH                    | Not Reported        |                         |

| <a href="#">FDA Received Date</a>                                                                                                               | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 21-Mar-2013                                                                                                                                     | 9189243                 | DIRECT                    |                             | OT                       |                               |                               | 44 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>                                                                                                                  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Disease Recurrence; Drug Ineffective; Drug Withdrawal Syndrome; Post Concussion Syndrome; Product Formulation Issue; Product Substitution Issue | Escitalopram            |                           |                             | S                        | Oral                          | 10 Mg 1x Day Po               | 1 WEEK<br>1 DAY          | Not Reported        |                         |

| <a href="#">FDA Received Date</a>     | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a>    | <a href="#">Country</a> |
|---------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|------------------------|-------------------------|
| 22-Mar-2013                           | 9182787                 | EXPEDITED (15-DAY)        |                             | OT                       | US-FRI-1000043618             |                               |                          | Female                 | USA                     |
| <a href="#">Preferred Term</a>        | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a>    |                         |
| Anger; Drug Hypersensitivity; Seizure | Lexapro<br>Cymbalta     |                           |                             | S<br>S                   |                               |                               |                          | Forest<br>Not Reported |                         |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>      | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|-----------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 22-Mar-2013                       | 9190001                     | EXPEDITED (15-DAY)        | Y                           | OT                       | GR-MACLEODS<br>PHARMA-000074  |                               | 63 YR                    | Female              | GRC                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a>     | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Bruxism; Headache;                | Escitalopram (Escitalopram) |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |

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Toothache

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Mar-2013              | 9190610       | EXPEDITED (15-DAY) | Y                  | OT              | 2013P1003357         |                      | 43 YR      | Female     | TUR            |

| <u>Preferred Term</u>                                                                                                                                        | <u>Product</u>  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Clonus; Confusional State;<br>Extensor Plantar<br>Response; Hyperexplexia;<br>Muscle Rigidity; Pyrexia;<br>Serotonin Syndrome;<br>Toxicity To Various Agents | Isoniazid       |              |            | S           |              |                    | 3 MTH           | Not Reported |
|                                                                                                                                                              | Escitalopram    |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                              | Corticosteroids |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                              |                 |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 25-Mar-2013              | 9152330       | EXPEDITED (15-DAY) |                    | HO, LT, OT      | AU-JNJFOC-20130215510 |                      | 29 YR      | Female     | AUS            |

| <u>Preferred Term</u>                                                                               | <u>Product</u>   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>  | <u>Dosage Text</u>                                                                     | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------|------------------|--------------|------------|-------------|---------------|----------------------------------------------------------------------------------------|-----------------|--------------|
| Exposure During<br>Pregnancy; Gestational<br>Diabetes; Premature<br>Labour; Respiratory<br>Distress | Risperdal Consta |              |            | S           | Intramuscular | The Start Date Was Pre-Pregnancy And Expsoure Time In Gestational Week Was 34/40 Weeks |                 | Not Reported |
|                                                                                                     | Quetiapine       |              |            | S           | Oral          |                                                                                        |                 | Not Reported |
|                                                                                                     | Escitalopram     |              |            | S           | Oral          |                                                                                        |                 | Not Reported |
|                                                                                                     | Novorapid        |              |            | S           | Subcutaneous  |                                                                                        |                 | Not Reported |
|                                                                                                     | Protaphane       |              |            | S           | Subcutaneous  |                                                                                        |                 | Not Reported |
|                                                                                                     | Oxycontin        |              |            | S           | Oral          | 20-30 Mg                                                                               |                 | Not Reported |
|                                                                                                     | Oxynorm          |              |            | S           | Oral          | 5-10 Mg                                                                                |                 | Not Reported |
|                                                                                                     | Elevit           |              |            | C           | Oral          | X1                                                                                     |                 | Not Reported |
|                                                                                                     | Vitamin D Nos    |              |            | C           | Oral          | X1                                                                                     |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 25-Mar-2013              | 9184843       | EXPEDITED (15-DAY) |                    | DE              | US-PFIZER INC-2006111647 |                      | 18 YR      | Male       | USA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                                                                                                                          | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|--------------------------------------|----------------------|-----------------|-----------------|----------------|
| Completed Suicide;<br>Hepatic Function<br>Abnormal; Intentional<br>Overdose; Intentional<br>Overdose; Renal<br>Impairment; Respiratory<br>Failure; Subarachnoid<br>Haemorrhage | Ibuprofen                     |                    |                    | S               | Oral                                 |                      |                 | Pfizer          |                |
|                                                                                                                                                                                | Naproxen Sodium               |                    |                    | S               | Oral                                 |                      |                 | Pfizer          |                |
|                                                                                                                                                                                | Escitalopram Oxalate          |                    |                    | S               | Oral                                 | Unk                  |                 | Not Reported    |                |
|                                                                                                                                                                                | Acetaminophen W/Codeine       |                    |                    | S               | Oral                                 | Unk                  |                 | Not Reported    |                |
|                                                                                                                                                                                | Aspirin                       |                    |                    | S               | Oral                                 |                      |                 | Not Reported    |                |
|                                                                                                                                                                                | Cyclobenzaprine Hcl           |                    |                    | S               | Oral                                 | Unk                  |                 | Not Reported    |                |
|                                                                                                                                                                                | Pseudoephedrine Hydrochloride |                    |                    | S               | Oral                                 | Unk                  |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                                                                       | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 25-Mar-2013                                                                                                                                                                    | 9186197                       | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000043633                    |                      | 38 YR           | Female          | FRA            |
| <u>Preferred Term</u>                                                                                                                                                          | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Pruritus; Urticaria                                                                                                                                                            | Escitalopram                  |                    |                    | S               | Oral                                 | 10 Mg                |                 | Forest          |                |
|                                                                                                                                                                                | Escitalopram                  |                    |                    | S               | Oral                                 | 10 Mg                |                 | Forest          |                |
|                                                                                                                                                                                | Propanolol                    |                    |                    | C               |                                      | 0.25 Dosage Forms    |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                                                                       | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 25-Mar-2013                                                                                                                                                                    | 9186288                       | EXPEDITED (15-DAY) |                    | HO              | SE-<br>GLAXOSMITHKLINE-<br>B0876936A |                      | 23 YR           | Female          | SWE            |
| <u>Preferred Term</u>                                                                                                                                                          | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Fatigue; Muscle<br>Contractions Involuntary;<br>Suicide Attempt                                                                                                                | Alvedon                       |                    | Y                  | S               | Unknown                              |                      |                 | Glaxosmithkline |                |
|                                                                                                                                                                                | Voxra                         |                    |                    | S               | Unknown                              |                      |                 | Glaxosmithkline |                |
|                                                                                                                                                                                | Lamotrigine                   |                    |                    | S               | Unknown                              |                      |                 | Glaxosmithkline |                |
|                                                                                                                                                                                | Zopiklon                      |                    |                    | S               | Unknown                              |                      |                 | Glaxosmithkline |                |
|                                                                                                                                                                                | Cipralext                     |                    |                    | S               | Unknown                              |                      |                 | Glaxosmithkline |                |
| <u>FDA Received Date</u>                                                                                                                                                       | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 25-Mar-2013                                                                                                                                                                    | 9187882                       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000043687                    |                      | 15 YR           | Female          | FRA            |

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

| <u>Preferred Term</u>                                                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Bicytopenia; Labelled Drug-Drug Interaction Medication Error; Product Use Issue | Escitalopram   |              |            | S           | Oral         | 5 Mg               |                 | Forest       |
|                                                                                 | Depakine       |              |            | S           | Oral         | 600 Mg             |                 | Not Reported |
|                                                                                 | Theralene      |              |            | S           | Oral         | 5 Mg               |                 | Not Reported |
|                                                                                 | Tercian        |              |            | S           | Oral         | 25 Mg              |                 | Not Reported |
|                                                                                 | Atarax         |              |            | C           | Oral         | 25 Mg              |                 | Not Reported |
|                                                                                 | Xanax          |              |            | C           | Oral         | 0.25 Mg            |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Mar-2013              | 9188155       | EXPEDITED (15-DAY) |                    | HO              | CH-FRI-1000043627    |                      |            | Female     | CHE            |

| <u>Preferred Term</u>                                                                               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------------|-----------------|--------------|
| Apathy; Bradycardia; Electrocardiogram Qt Interval Abnormal; Hypotension; Overdose; Suicide Attempt | Escitalopram   |              |            | S           | Oral         | 20 Mg                    |                 | Forest       |
|                                                                                                     | Inderal La     |              |            | S           | Oral         | 800 Mg                   |                 | Not Reported |
|                                                                                                     | Zolpidem       |              |            | S           | Oral         | 40 Mg                    |                 | Not Reported |
|                                                                                                     | Cymbalta       |              |            | S           | Oral         | Between 150 Mg To 300 Mg |                 | Not Reported |
|                                                                                                     | Laxoberon      |              |            | C           |              |                          |                 | Not Reported |
|                                                                                                     | Isoptin        |              |            | C           | Oral         | 240 Mg                   |                 | Not Reported |
|                                                                                                     | Demetrin       |              |            | C           | Oral         | 10 Mg                    |                 | Not Reported |
|                                                                                                     | Calcimagon D3  |              |            | C           | Oral         | 1 Df                     |                 | Not Reported |
|                                                                                                     | Trittico       |              |            | C           | Oral         | 50 Mg                    |                 | Not Reported |
|                                                                                                     | Duphalac       |              |            | C           |              |                          |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Mar-2013              | 9193612       | DIRECT           |                    | OT              |                      |                      | 42 YR      | Female     | USA            |

| <u>Preferred Term</u>                                          | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|----------------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Anxiety; Apathy; Depression; Headache; Insomnia; Mood Altered; | Escitalopram 5 Mg Teva |              |            | S           | Oral         | 5 Mg 1x Daily Po   |                 | Teva       |
|                                                                |                        |              |            |             | Oral         | 2.5 Mg 1x Daily Po |                 |            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Night Sweats; Palpitations;  
Product Substitution Issue

| <u>FDA Received Date</u>                                                                 | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|------------------------------------------------------------------------------------------|----------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 25-Mar-2013                                                                              | 9195715              | DIRECT           | Y                  | OT              |                      |                      | 66 YR           | Female     | USA            |
| <u>Preferred Term</u>                                                                    | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Eructation; Nausea;<br>Product Quality Issue;<br>Product Substitution Issue;<br>Retching | Escitalopram Oxalate |                  |                    | S               | Oral                 |                      |                 | Teva       |                |

| <u>FDA Received Date</u>                                                                                                  | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 25-Mar-2013                                                                                                               | 9195730        | DIRECT           | Y                  | OT              |                      |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>                                                                                                     | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Depression; Lethargy;<br>Product Quality Issue;<br>Product Substitution Issue;<br>Product Substitution Issue;<br>Sedation | Escitalopram   |                  |                    | S               | Oral                 |                      |                 | Teva       |                |

| <u>FDA Received Date</u>                    | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 26-Mar-2013                                 | 9188914        | EXPEDITED (15-DAY) |                    | OT              | PHHY2013US027927     |                      | 60 YR           | Male         | USA            |
| <u>Preferred Term</u>                       | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Body Temperature Increased; Chills; Clonus; | Methylene Blue |                    |                    | S               |                      | 1 Mg/Kg Per Hour     |                 | Not Reported |                |
| Hypertonia; Hypotension;                    | Methylene Blue |                    |                    | S               |                      | 0.5 Mg/Kg Per Hour   |                 | Not Reported |                |
| Hypoxia; Mydriasis;                         | Escitalopram   |                    |                    | S               | Oral                 | 20 Mg, Daily         |                 | Not Reported |                |
| Myoclonus; Nystagmus;<br>Serotonin Syndrome | Trazodone      |                    |                    | S               | Oral                 | 100 Mg Daily         |                 | Novartis     |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Mar-2013              | 9191296       | EXPEDITED (15-DAY) |                    | OT              | PHHY2013BR028434     |                      |            | Male       | BRA            |

# FDA Adverse Event Reporting System

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| <u>Preferred Term</u>                                                                                                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abnormal Behaviour;<br>Decreased Interest;<br>Depression; Panic<br>Disorder; Post-Traumatic<br>Stress Disorder; Sedation | Pamelor        |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                          | Clonazepam     |              |            | S           |              |                    |                 | Novartis     |
|                                                                                                                          | Diazepam       |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                          | Rivotril       |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                          | Bromazepam     |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                          | Paroxetine     |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                          | Amitriptyline  |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                          | Pristiq        |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                          | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Mar-2013              | 7711469       | EXPEDITED (15-DAY) | Y                  | DE, HO          | AUR-APL-2010-02726   |                      | 58 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                          | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Apnoea; Cardiac Arrest;<br>Coma; Electrocardiogram<br>Qt Prolonged; Fall;<br>Malaise; Neurological<br>Decompensation; Sinus<br>Tachycardia; Torsade De<br>Pointes; Ventricular<br>Fibrillation | Fluoxetine              |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                | Escitalopram Oxalate    |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                | Trazodone Hydrochloride |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                | Buspirone               |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                | Temazepam               |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                |                         |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Mar-2013              | 8445397       | EXPEDITED (15-DAY) |                    | HO              | JP-FRI-1000028406    |                      | 59 YR      | Female     | JPN            |

| <u>Preferred Term</u>                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Condition Aggravated;<br>Liver Disorder | Lexapro        |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                         | Lexapro        |              |            | S           | Oral         | 20 Mg              |                 | Forest       |
|                                         | Lexapro        |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                         | Risperdal      |              |            | S           | Oral         | 1 MI               |                 | Not Reported |
|                                         | Risperdal      |              |            | S           | Oral         | 0.5 MI             |                 | Not Reported |
|                                         | Risperdal      |              |            | S           | Oral         | 1.5 MI             |                 | Not Reported |

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|  |           |   |      |         |  |              |
|--|-----------|---|------|---------|--|--------------|
|  | Risperdal | S | Oral | 2 MI    |  | Not Reported |
|  | Jzoloft   | C |      |         |  | Not Reported |
|  | Magmitt   | C | Oral | 1980 Mg |  | Not Reported |
|  | Sennoside | C | Oral | 24 Mg   |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Mar-2013              | 9194353       | EXPEDITED (15-DAY) |                    | OT              | US-RB-051453-13      |                      | < 1 DAY    | Male       | USA            |

| <u>Preferred Term</u>                            | <u>Product</u>  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u>                              | <u>Duration</u> | <u>Mfr</u>        |
|--------------------------------------------------|-----------------|--------------|------------|-------------|----------------|-------------------------------------------------|-----------------|-------------------|
| Foetal Exposure During Pregnancy; Premature Baby | Suboxone Tablet |              |            | S           | Transplacental |                                                 |                 | Reckitt Benckiser |
|                                                  | Clonazepam      |              |            | S           | Transplacental | Dosing Details Unknown, Dosing Frequency: Daily |                 | Not Reported      |
|                                                  | Lexapro         |              |            | S           | Transplacental | Dosing Details Unknown, Dosing Frequency: Daily |                 | Not Reported      |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Mar-2013              | 9198703       | DIRECT           | Y                  | DS, RI          |                      |                      | 57 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Depression            | Lexapro 20mg - Generic  |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Wellbutrin XL (Generic) |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Zoloft                  |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Mar-2013              | 9198758       | DIRECT           |                    | OT              |                      |                      | 41 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                       | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------|--------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Ageusia; Erectile Dysfunction; Product Substitution Issue; Weight Decreased | Escitalopram 10 Mg |              |            | S           | Oral         |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

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| <u>FDA Received Date</u>                                                    | <u>Case #</u>           | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------|-------------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 27-Mar-2013                                                                 | 9198792                 | DIRECT           |                    | OT              |                      |                      | 41 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                       | <u>Product</u>          | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Ageusia; Erectile Dysfunction; Product Substitution Issue; Weight Decreased | Escitalopram 10 Mg      |                  |                    | S               | Oral                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                    | <u>Case #</u>           | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Mar-2013                                                                 | 9199691                 | DIRECT           | Y                  | DS, RI          |                      |                      | 52 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                       | <u>Product</u>          | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Irritability; Social Avoidant Behaviour                            | Lexapro                 |                  |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                             | Wellbutrin XL (Generic) |                  |                    | S               | Oral                 | 450mg Po Qam         |                 | Not Reported |                |
|                                                                             | Zoloft                  |                  |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                    | <u>Case #</u>           | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Mar-2013                                                                 | 9199695                 | DIRECT           | Y                  |                 |                      |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                       | <u>Product</u>          | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Product Substitution Issue; Tremor                                 | Lexapro                 |                  |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                    | <u>Case #</u>           | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Mar-2013                                                                 | 9203359                 | NON-EXPEDITED    | Y                  | DE              | 2013-00634           |                      | 64 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                       | <u>Product</u>          | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Suicidal Ideation                                                           | Lamotrigine             |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                             | Venlafaxine             |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                             | Escitalopram (Unknown)  |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                             | Pantoprazole            |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                             | Ciprofloxacin           |                  |                    | S               |                      |                      |                 | Not Reported |                |



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|                            |   |              |
|----------------------------|---|--------------|
| Hydrochlorothizide         | S | Not Reported |
| Desipramine                | S | Not Reported |
| Diltiazem Extended Release | S | Not Reported |
| Armodafinil                | S | Not Reported |
| Potassium Chloride         | S | Not Reported |
| Trifluoperazine            | S | Not Reported |
| Lansoprazole (Unknown)     | S | Not Reported |
| Rosuvastatin (Unknown)     | S | Not Reported |
| Naproxen (Unknown)         | S | Not Reported |
| Nitrofurantoin             | S | Not Reported |
| Diclofenac (Unknown)       | S | Not Reported |
| Acetaminophen/Hydrocodone  | S | Not Reported |
| Acetaminophen/Propoxyphene | S | Not Reported |
| Solifenacin                | S | Not Reported |
| Progestin                  | S | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Mar-2013              | 9203376       | NON-EXPEDITED    | Y                  | DE              | 2013-00635           |                      | 57 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Suicidal Ideation     | Lamotrigine (Lamotrigine) |              |            | S           |              |                    |                 | Not Reported |
|                       | Escitalopram              |              |            | S           |              |                    |                 | Not Reported |
|                       | Diphenhydramine           |              |            | S           |              |                    |                 | Not Reported |
|                       | Aripiprazole              |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Mar-2013              | 9055019       | EXPEDITED (15-DAY) |                    | OT              | IE-FRI-1000042406    |                      | 25 YR      | Female     | IRL            |

| <u>Preferred Term</u>                                                                                                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Bruxism; Confusional State; Fatigue; Hyperhidrosis; Lethargy; Memory Impairment; Myalgia; Seizure Like Phenomena; Sleep Disorder | Lexapro        |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                                                                                                                  | Lexapro        |              |            | S           | Oral         | 5 Mg               |                 | Forest       |
|                                                                                                                                  | Cilest         |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                                                  | Xanax          |              |            | C           |              |                    |                 | Not Reported |

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| <u>FDA Received Date</u>                                        | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 28-Mar-2013                                                     | 9152332              | EXPEDITED (15-DAY) |                    | HO, LT, OT      | AU-JNJFOC-20130215511 |                      | < 1 DAY         | Female       | AUS            |
| <u>Preferred Term</u>                                           | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Premature Baby;<br>Respiratory Distress;<br>Withdrawal Syndrome | Risperdal Consta     |                    |                    | S               | Transplacental        |                      |                 | Not Reported |                |
|                                                                 | Quetiapine           |                    |                    | S               | Transplacental        |                      |                 | Not Reported |                |
|                                                                 | Escitalopram         |                    |                    | S               | Transplacental        |                      |                 | Not Reported |                |
|                                                                 | Novorapid            |                    |                    | S               | Transplacental        |                      |                 | Not Reported |                |
|                                                                 | Protaphane           |                    |                    | S               | Transplacental        |                      |                 | Not Reported |                |
|                                                                 | Oxycontin            |                    |                    | S               | Transplacental        |                      |                 | Not Reported |                |
|                                                                 | Oxynorm              |                    |                    | S               | Transplacental        |                      |                 | Not Reported |                |
|                                                                 | Elevit               |                    |                    | S               | Transplacental        |                      |                 | Not Reported |                |
|                                                                 | Vitamin D Nos        |                    |                    | S               | Transplacental        |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                        | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Mar-2013                                                     | 9196528              | EXPEDITED (15-DAY) |                    | DE              | FR-FRI-1000043767     |                      | 84 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                           | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Haemorrhagic Stroke                                             | Escitalopram         |                    |                    | S               |                       | 15 Mg                |                 | Forest       |                |
|                                                                 | Kardegic             |                    |                    | S               | Oral                  | 75 Mg                |                 | Not Reported |                |
|                                                                 | Memantine            |                    |                    | C               | Oral                  | 20 Mg                |                 | Not Reported |                |
|                                                                 | Cardensiel           |                    |                    | C               | Oral                  | 1.5 Mg               |                 | Not Reported |                |
|                                                                 | Hemigoxine Nativelle |                    |                    | C               | Oral                  | 0.125 Mg             |                 | Not Reported |                |
|                                                                 | Crestor              |                    |                    | C               | Oral                  | 5 Mg                 |                 | Not Reported |                |
|                                                                 | Chondrosulf          |                    |                    | C               | Oral                  | 1200 Mg              |                 | Not Reported |                |
|                                                                 | Cacit Vitamine D3    |                    |                    | C               | Oral                  |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                        | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Mar-2013                                                     | 9196594              | EXPEDITED (15-DAY) |                    | DS              | FR-FRI-1000043784     |                      | 48 YR           | Female       | FRA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                                                                                                                                                                                                        | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                       | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|------------------------------------|----------------------|-----------------|--------------|----------------|
| Withdrawal Syndrome                                                                                                                                                                                                                                          | Escitalopram                  |                    |                    | S               | Oral                               | 15 Mg                |                 | Forest       |                |
|                                                                                                                                                                                                                                                              | Escitalopram                  |                    |                    | S               | Oral                               | 5 Mg                 |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                     | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Mar-2013                                                                                                                                                                                                                                                  | 9197346                       | EXPEDITED (15-DAY) |                    | DE              | US-PFIZER INC-<br>HQWYE305803NOV06 |                      | 18 YR           | Unknown      | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                        | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                       | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Overdose                                                                                                                                                                                                                                         | Ibuprofen                     |                    |                    | S               | Oral                               |                      |                 | Pfizer       |                |
|                                                                                                                                                                                                                                                              | Escitalopram Oxalate          |                    |                    | S               | Oral                               | Unknown              |                 | Not Reported |                |
|                                                                                                                                                                                                                                                              | Pseudoephedrine Hydrochloride |                    |                    | S               | Oral                               | Unknown              |                 | Not Reported |                |
|                                                                                                                                                                                                                                                              | Acetaminophen W/Codeine       |                    |                    | S               | Oral                               | Unknown              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                     | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Mar-2013                                                                                                                                                                                                                                                  | 9197859                       | EXPEDITED (15-DAY) |                    | DS, LT          | NO-FRI-1000043809                  |                      | 58 YR           | Female       | NOR            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                        | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                       | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blister; Fatigue; General<br>Physical Health<br>Deterioration; Gingival<br>Bleeding; Headache;<br>Oropharyngeal Plaque;<br>Pyrexia; Rash; Rash<br>Vesicular; Serotonin<br>Syndrome; Skin<br>Haemorrhage; Swelling;<br>Visual Impairment; Weight<br>Increased | Escitalopram                  |                    |                    | S               |                                    | 10 Mg                |                 | Forest       |                |
|                                                                                                                                                                                                                                                              | Escitalopram                  |                    |                    | S               |                                    | 20 Mg                |                 | Forest       |                |
|                                                                                                                                                                                                                                                              | Escitalopram                  |                    |                    | S               |                                    | 10 Mg                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                     | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Mar-2013                                                                                                                                                                                                                                                  | 9197865                       | EXPEDITED (15-DAY) |                    | DE              | US-FRI-1000043842                  |                      | 50 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                        | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                       | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

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

|                                                                                               |                           |                    |                    |                 |                      |                      |                 |              |                |
|-----------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Death                                                                                         | Lexapro                   |                    |                    | S               |                      |                      |                 |              | Forest         |
| <u>FDA Received Date</u>                                                                      | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Mar-2013                                                                                   | 9199752                   | DIRECT             | Y                  | OT              |                      |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                         | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Fatigue; Irritability; Product Substitution Issue; Therapeutic Response Decreased | Lexapro                   |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                      | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Mar-2013                                                                                   | 9199756                   | DIRECT             | Y                  | OT              |                      |                      | 14 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                         | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated; Depression; Nausea; Product Substitution Issue                          | Escitalopram Oxalate      |                    |                    | S               | Oral                 | 20 Mg 1/2 Qam Po     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                      | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Mar-2013                                                                                   | 9202061                   | EXPEDITED (15-DAY) | Y                  | HO, RI          | 2013AP003859         |                      | 60 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                         | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Serotonin Syndrome                                                                            | Trazodone Hydrochloride   |                    |                    | S               |                      | Hs                   |                 | Not Reported |                |
|                                                                                               | Escitalopram Oxalate      |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                               | Methylthioninium Chloride |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                      | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Mar-2013                                                                                   | 9203487                   | EXPEDITED (15-DAY) | Y                  | DS, OT          | 08-AUR-04980         |                      | 60 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                                         | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Emotional Distress; Female Sexual Arousal                                                     | Fluoxetine (Fluoxetine)   |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                               | Paroxetine (Paroxetine)   |                    |                    | S               |                      |                      |                 | Not Reported |                |

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|          |                             |   |              |
|----------|-----------------------------|---|--------------|
| Disorder | Sertraline (Sertraline)     | S | Not Reported |
|          | (Sertraline)                |   |              |
|          | Escitalopram (Escitalopram) | S | Not Reported |
|          | Venlafaxine                 | S | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Mar-2013              | 8070524       | EXPEDITED (15-DAY) | Y                  | OT              | AUR-APL-2011-04016   |                      | 42 YR      | Female     | IND            |

| <u>Preferred Term</u>       | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anhedonia; Asthenia;        | Mirtazapine (Mirtazapine) |              |            | S           |              |                    | 1 DAY           | Not Reported |
| Depressed Mood;             | Fluoxetine                |              |            | S           |              |                    |                 | Not Reported |
| Depression; Irritability;   | Escitalopram Oxalate      |              |            | S           |              |                    | 1 DAY           | Not Reported |
| Logorrhoea; Mania; Pain;    |                           |              |            |             |              |                    |                 |              |
| Pressure Of Speech;         |                           |              |            |             |              |                    |                 |              |
| Psychomotor                 |                           |              |            |             |              |                    |                 |              |
| Hyperactivity; Speech       |                           |              |            |             |              |                    |                 |              |
| Disorder; Suicidal Ideation |                           |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Mar-2013              | 9171554       | EXPEDITED (15-DAY) |                    | OT              | JP-FRI-1000025967    |                      | 60 YR      | Female     | JPN            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Neurogenic Bladder;   | Lexapro        |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
| Neuroleptic Malignant | Seroquel       |              |            | C           | Oral         | 150                |                 | Not Reported |
| Syndrome              | Blopress       |              |            | C           | Oral         | 8 Mg               |                 | Not Reported |
|                       | Thyradin       |              |            | C           | Oral         |                    |                 | Not Reported |
|                       | Heberna        |              |            | C           | Oral         | 75 Mg              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Mar-2013              | 9202332       | DIRECT           |                    | OT              |                      |                      | 84 YR      | Female     | USA            |

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

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                     | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|-------------------------|----------------------|-----------------|--------------|----------------|
| 29-Mar-2013                                                                                                                                                                                                  | 9203769                   | EXPEDITED (15-DAY) | Y                  | HO              | SYM-2013-02122          |                      | 23 YR           | Female       | SWE            |
| <u>Preferred Term</u>                                                                                                                                                                                        | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Fatigue; Incorrect Dose Administered; Muscle Contractions Involuntary; Suicide Attempt                                                                                                                       | Voxra                     |                    |                    | S               | Oral                    |                      |                 | Not Reported |                |
|                                                                                                                                                                                                              | Ciprallex                 |                    |                    | S               |                         |                      |                 | Not Reported |                |
|                                                                                                                                                                                                              | Paracetamol               |                    |                    | S               |                         |                      |                 | Not Reported |                |
|                                                                                                                                                                                                              | Lamotrigine (Lamotrigine) |                    |                    | S               |                         |                      |                 | Not Reported |                |
|                                                                                                                                                                                                              | Zopiclone                 |                    |                    | S               |                         |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                     | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Mar-2013                                                                                                                                                                                                  | 9203778                   | DIRECT             | Y                  | OT              |                         |                      | 21 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                        | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Condition Aggravated; Drug Ineffective; Hypotension; Product Substitution Issue                                                                                                                     | Escitalopram 10 Mg        |                    |                    | S               | Oral                    |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                     | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Apr-2013                                                                                                                                                                                                  | 9203418                   | EXPEDITED (15-DAY) |                    | HO, OT          | US-RANBAXY-2010US-40576 |                      | 70 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                        | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Acute Hepatic Failure; Cholestasis; Coagulopathy; Drug Interaction; Encephalopathy; Hepatic Necrosis; Hepatitis; Hepatotoxicity; Liver Transplant; Portal Tract Inflammation; Therapeutic Response Decreased | Enalapril Maleate         |                    |                    | S               | Unknown                 | Unk                  |                 | Ranbaxy      |                |
|                                                                                                                                                                                                              | Escitalopram              |                    |                    | S               | Unknown                 | Unk                  |                 | Not Reported |                |
|                                                                                                                                                                                                              | Simvastatin/ Ezetimibe    |                    |                    | S               | Unknown                 | 10 Mg/40 Mg/Day      |                 | Not Reported |                |
|                                                                                                                                                                                                              | Simvastatin/ Ezetimibe    |                    |                    | S               |                         |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                     | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|--------------------------|-------------------------------------------------------------|-----------------|--------------|----------------|
| 02-Apr-2013                                                                                                                                                                  | 9204387                 | EXPEDITED (15-DAY) |                    | HO, LT, OT      | CH-PFIZER INC-2013083426 |                                                             | 31 YR           | Male         | CHE            |
| <u>Preferred Term</u>                                                                                                                                                        | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain; Cardiac Arrest; Drug Interaction; Generalised Tonic-Clonic Seizure; Hypokalaemia; Hypomagnesaemia; Long Qt Syndrome; Torsade De Pointes; Withdrawal Syndrome | Escitalopram Oxalate    |                    |                    | S               |                          | Unk                                                         |                 | Not Reported |                |
|                                                                                                                                                                              | Ondansetron Hcl         |                    |                    | S               |                          | Unk                                                         |                 | Pfizer       |                |
|                                                                                                                                                                              | Methadone               |                    |                    | S               | Oral                     | 50-60 Mg Per Day                                            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                     | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Apr-2013                                                                                                                                                                  | 9529849                 | NON-EXPEDITED      |                    | HO, OT          | RB-48589-2013            |                                                             |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                        | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy                                                                                                          | Suboxone                |                    |                    | S               | Transplacental           | (16 Mg Suboxone Film Transplacental)                        |                 | Not Reported |                |
|                                                                                                                                                                              |                         |                    |                    |                 | Transplacental           | (6 Mg, Suboxone Film Transplacental)                        |                 |              |                |
|                                                                                                                                                                              | Lexapro (Not Specified) |                    |                    | S               | Transplacental           | (10 Mg Transplacental) (6 Mg, Suboxone Film Transplacental) |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                     | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Apr-2013                                                                                                                                                                  | 8942431                 | EXPEDITED (15-DAY) |                    | OT              | GB-FRI-1000040757        |                                                             | 58 YR           | Male         | GBR            |
| <u>Preferred Term</u>                                                                                                                                                        | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Affect Lability; Asthenopia; Confusional State; Disturbance In Attention; Drug Interaction; Furuncle; Irritability; Malaise; Mental Fatigue; Metal Poisoning;                | Escitalopram            |                    |                    | S               | Oral                     | 20 Mg                                                       |                 | Forest       |                |
|                                                                                                                                                                              | Escitalopram            |                    |                    | S               |                          |                                                             |                 | Forest       |                |
|                                                                                                                                                                              | Aspirin                 |                    |                    | C               |                          | 75 Mg                                                       |                 | Not Reported |                |
|                                                                                                                                                                              | Allopurinol             |                    |                    | C               |                          | 100 Mg                                                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| Tinnitus                                                                                               | Valaciclovir                                               |                    |                    |                 |                      | 500 Mg               |                 |              | Not Reported   |
|--------------------------------------------------------------------------------------------------------|------------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
|                                                                                                        | Diazepam                                                   |                    |                    |                 |                      |                      |                 |              | Not Reported   |
| <u>FDA Received Date</u>                                                                               | <u>Case #</u>                                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Apr-2013                                                                                            | 8957416                                                    | EXPEDITED (15-DAY) |                    | OT              | DE-FRI-1000040974    |                      | 24 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                                                                  | <u>Product</u>                                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Generalised Tonic-Clonic Seizure                                                                       | Escitalopram Oral Solution                                 |                    |                    | S               | Oral                 | 20 Mg                |                 | Forest       |                |
|                                                                                                        | Olanzapine                                                 |                    |                    | C               | Oral                 | 10 Mg                |                 | Not Reported |                |
|                                                                                                        | Lyrica                                                     |                    |                    | C               | Oral                 | 150 Mg               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                               | <u>Case #</u>                                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Apr-2013                                                                                            | 9206846                                                    | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000043956    |                      | 89 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                  | <u>Product</u>                                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyperthermia; Loss Of Consciousness; Urinary Retention; Vomiting                                       | Escitalopram                                               |                    |                    | S               | Oral                 | 1 Df                 |                 | Forest       |                |
|                                                                                                        | Lercapress (Enalapril Maleate\Lercanidipine Hydrochloride) |                    |                    | S               | Oral                 | 20 Mg/10 Mg          |                 | Not Reported |                |
|                                                                                                        | Lexomil                                                    |                    |                    | S               | Oral                 | 0.75 Df              |                 | Not Reported |                |
|                                                                                                        | Loxapac                                                    |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                               | <u>Case #</u>                                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Apr-2013                                                                                            | 9207066                                                    | EXPEDITED (15-DAY) |                    | OT              | PHEH2013US007262     |                      |                 | Male         | USA            |
| <u>Preferred Term</u>                                                                                  | <u>Product</u>                                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrial Fibrillation; Disability; Myocardial Infarction; Nasopharyngitis; Panic Attack; Suicide Attempt | Trileptal                                                  |                    |                    | S               |                      | Unk Ukn, Unk         |                 | Novartis     |                |
|                                                                                                        | Concerta                                                   |                    |                    | S               |                      | Unk Ukn, Unk         |                 | Not Reported |                |
|                                                                                                        | Effexor                                                    |                    |                    | S               |                      | Unk Ukn, Unk         |                 | Not Reported |                |
|                                                                                                        | Lexapro                                                    |                    |                    | S               |                      | Unk Ukn, Unk         |                 | Not Reported |                |
|                                                                                                        | Ambien                                                     |                    |                    | S               |                      | Unk Ukn, Unk         |                 | Not Reported |                |



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

|            |   |              |              |
|------------|---|--------------|--------------|
| Lithium    | S | Unk Ukn, Unk | Not Reported |
| Ativan     | S | Unk Ukn, Unk | Not Reported |
| Depakote   | S | Unk Ukn, Unk | Not Reported |
| Wellbutrin | S | Unk Ukn, Unk | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 03-Apr-2013              | 9207722        | EXPEDITED (15-DAY) |                    | LT              | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>18713701 |                      | 60 YR           | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Serotonin Syndrome       | Trazodone Hcl  |                    |                    | S               |                                                 | At Bedtime           |                 | Apothecon    |                |
|                          | Methylene Blue |                    |                    | S               |                                                 | 0.5mg/Kg/Hrs         |                 | Not Reported |                |
|                          | Escitalopram   |                    |                    | S               | Oral                                            |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 03-Apr-2013              | 9208266        | EXPEDITED (15-DAY) |                    | CA, OT          | US-FRI-1000043878    |                      |                 | Female     | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Talipes                  | Lexapro        |                    |                    | S               | Transplacental       |                      |                 | Forest     |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 03-Apr-2013              | 9208293        | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000043880    |                      | < 1 DAY         | Unknown    | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Diaphragmatic Hernia     | Lexapro        |                    |                    | S               | Transplacental       |                      |                 | Forest     |                |

| <u>FDA Received Date</u> | <u>Case #</u>      | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|--------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 03-Apr-2013              | 9209155            | DIRECT           | Y                  | DS              |                      |                      | 21 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>     | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Product Complaint;       | Escitalopram 10 Mg |                  |                    | S               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Therapeutic Response  
Changed

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Apr-2013              | 9209564       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000043957    |                      | 99 YR      | Female     | FRA            |

| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Coma; Respiratory Distress | Escitalopram   |              |            | S           |              | 5 Mg               |                 | Forest       |
|                            | Seresta        |              |            | S           | Oral         | 25 Mg              |                 | Not Reported |
|                            | Furosemide     |              |            | C           |              |                    |                 | Not Reported |
|                            | Aldactone      |              |            | C           |              |                    |                 | Not Reported |
|                            | Bisoprolol     |              |            | C           |              |                    |                 | Not Reported |
|                            | Effexor        |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Apr-2013              | 9210854       | EXPEDITED (15-DAY) |                    | DS, OT          | US-FRI-1000043890    |                      |            | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                                                          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Atrial Fibrillation; Intentional Self-Injury; Myocardial Infarction; Nasopharyngitis; Panic Attack; Unevaluable Event; Unevaluable Event; Unevaluable Event; Unevaluable Event | Lexapro        |              |            | S           |              |                    |                 | Forest       |
|                                                                                                                                                                                | Effexor        |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                | Wellbutrin     |              |            | S           |              | 600 Mg             |                 | Not Reported |
|                                                                                                                                                                                | Concerta       |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                | Ativan         |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                | Depakote       |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                | Trileptal      |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                | Ambien         |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                | Lithium        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 05-Apr-2013              | 8495002       | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2012084147 |                      | 76 YR      | Female     | USA            |

| <u>Preferred Term</u>                                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Anxiety; Anxiety; Decreased Appetite; Drug Ineffective; Insomnia; | Xanax Xr       |              |            | S           |              | 2 Mg, 1x/Day       |                 | Pfizer     |
|                                                                   | Zoloft         |              |            | S           |              | Unk                |                 | Pfizer     |

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

|                                      |           |   |                |              |
|--------------------------------------|-----------|---|----------------|--------------|
| Nausea; Nervousness;<br>Panic Attack | Lexapro   | S | Unk            | Not Reported |
|                                      | Prozac    | S | Unk            | Not Reported |
|                                      | Tenormin  | C | 25 Mg, Daily   | Not Reported |
|                                      | Captopril | C | 25 Mg, 2x/Day  | Not Reported |
|                                      | Glyburide | C | 1.25 Mg, Daily | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Apr-2013              | 9178396       | EXPEDITED (15-DAY) |                    | HO, OT          | SE-FRI-1000043576    |                      |            | Female     | SWE            |

| <u>Preferred Term</u>                                                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Fatigue; Muscle<br>Contractions Involuntary;<br>Overdose; Suicide Attempt | Escitalopram   |              |            | S           |              | 5-6 Daily Doses    |                 | Forest       |
|                                                                           | Alvedon        |              |            | S           |              | Some Tablets       |                 | Not Reported |
|                                                                           | Lamotrigine    |              |            | S           |              | 5-6 Daily Doses    |                 | Not Reported |
|                                                                           | Zopiklon       |              |            | S           |              | 5-6 Daily Doses    |                 | Not Reported |
|                                                                           | Voxra          |              |            | S           |              | 5-6 Daily Doses    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Apr-2013              | 9196554       | EXPEDITED (15-DAY) |                    | OT              | GB-FRI-1000043781    |                      | 21 YR      | Female     | GBR            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Neutropenia           | Escitalopram   |              |            | S           | Oral         | 10 Mg              |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Apr-2013              | 9214237       | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000044051    |                      | 361 DAY    | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|------------|
| Arnold-Chiari<br>Malformation; Conus<br>Medullaris Syndrome;<br>Lipoma; Spina Bifida<br>Occulta; Spinal Disorder;<br>Spine Malformation; | Lexapro        |              |            | S           | Transplacental |                    |                 | Forest     |

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

Syringomyelia; Tethered  
Cord Syndrome

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 05-Apr-2013                       | 9215105                | EXPEDITED (15-DAY)        |                             | OT                       | PL-FRI-1000044038             |                               | 67 YR               | Female              | POL                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Genital Haemorrhage            | Escitalopram            |                       |                     | S                    | Oral                  | 10 Mg                       |                          | Forest              |
|                                | Betaloc Zok             |                       |                     | C                    | Oral                  | 50 Mg                       |                          | Not Reported        |
|                                | Prestarium              |                       |                     | C                    | Oral                  | 5 Mg                        |                          | Not Reported        |
|                                | Olicard                 |                       |                     | C                    | Oral                  | 40 Mg                       |                          | Not Reported        |
|                                | Torasemide              |                       |                     | C                    | Oral                  | 5 Mg                        |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 05-Apr-2013                       | 9215276                | EXPEDITED (15-DAY)        |                             | HO                       | US-PFIZER INC-<br>2013104582  |                               | 67 YR               | Female              | USA                     |

| <a href="#">Preferred Term</a>                                            | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|---------------------------------------------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Depression; Drug<br>Ineffective; Intentional<br>Overdose; Suicide Attempt | Sonata                  |                       |                     | S                    |                       | 10 Mg, As Needed            |                          | Pfizer              |
|                                                                           | Valium                  |                       |                     | S                    |                       | 5 Mg, As Needed             |                          | Not Reported        |
|                                                                           | Escitalopram            |                       |                     | S                    | Oral                  | 10 Mg, 1 In 1 Day (Daily)   |                          | Not Reported        |
|                                                                           | Escitalopram            |                       |                     | S                    | Oral                  | 20 Mg, 1 In 1 Day (Daily)   |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 05-Apr-2013                       | 9218963                | DIRECT                    | Y                           | OT                       |                               |                               | 16 YR               | Male                | USA                     |

| <a href="#">Preferred Term</a>          | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|-----------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Headache; Product<br>Substitution Issue | Escitalopram            |                       |                     | S                    | Oral                  |                             |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 05-Apr-2013                       | 9219368                | EXPEDITED (15-DAY)        | Y                           | HO, LT                   | TRAZ20130001                  |                               | 60 YR               | Male                | USA                     |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                           | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|-----------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Encephalopathy;<br>Serotonin Syndrome                           | Trazodone Hydrochloride |                    |                    | S               | Oral                 | 1 In 1 D             |                 | Not Reported |                |
|                                                                 | Escitalopram            |                    |                    | S               | Oral                 | 1 In 1 D             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                        | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Apr-2013                                                     | 9131252                 | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000043004    |                      | 24 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                           | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Ecchymosis; Inflammation;<br>Influenza Like Illness;<br>Pyrexia | Escitalopram            |                    |                    | S               | Oral                 | 5 Mg                 |                 | Forest       |                |
|                                                                 | Escitalopram            |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                                                 | Escitalopram            |                    |                    | S               | Oral                 | 5 Mg                 |                 | Not Reported |                |
|                                                                 | Escitalopram            |                    |                    | S               | Oral                 | 10 Mg                |                 | Not Reported |                |
|                                                                 | Escitalopram            |                    |                    | S               | Oral                 | 5 Mg                 |                 | Not Reported |                |
|                                                                 | Oral Contraceptive Nos  |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                        | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Apr-2013                                                     | 9216857                 | EXPEDITED (15-DAY) |                    | DE, OT          | ZA-FRI-1000044037    |                      | 29 YR           | Female       | ZAF            |
| <u>Preferred Term</u>                                           | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Arrhythmia; Sudden Death                                        | Escitalopram            |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                                                 | Femodene                |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                        | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Apr-2013                                                     | 9217079                 | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000044070    |                      | 61 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                           | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hepatocellular Injury                                           | Escitalopram            |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
| <u>FDA Received Date</u>                                        | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Apr-2013                                                     | 9217086                 | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000044067    |                      | 91 YR           | Female       | FRA            |

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

| <u>Preferred Term</u>                                                       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|-----------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
| Drug Interaction;<br>Duodenal Ulcer; Iron<br>Deficiency Anaemia;<br>Melaena | Escitalopram         |                    |                    | S               | Oral                      | 5 Mg                 |                 | Forest       |                |
|                                                                             | Kardegic             |                    |                    | S               | Oral                      | 75 Mg                |                 | Not Reported |                |
|                                                                             | Temesta (Lorazepam)  |                    |                    | C               | Oral                      | 5 Mg                 |                 | Not Reported |                |
|                                                                             | Hemigoxine Nativelle |                    |                    | C               | Oral                      | 0.0625 Mg            |                 | Not Reported |                |
|                                                                             | Selokeen             |                    |                    | C               | Oral                      | 200 Mg               |                 | Not Reported |                |
|                                                                             | Lasilix              |                    |                    | C               | Oral                      | 40 Mg                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Apr-2013                                                                 | 9219322              | DIRECT             |                    | DE              |                           |                      | 33 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Intentional Overdose                                  | Klonopin             |                    |                    | S               |                           |                      |                 | Roche        |                |
|                                                                             | Lexapro              |                    |                    | S               |                           |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Apr-2013                                                                 | 9219476              | DIRECT             | Y                  | OT              |                           |                      | 22 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Nausea;<br>Product Substitution Issue;<br>Vomiting               | Escitalopram Oxalate |                    |                    | S               | Oral                      |                      |                 | Teva         |                |
| <u>FDA Received Date</u>                                                    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Apr-2013                                                                 | 9220585              | EXPEDITED (15-DAY) |                    | LT              | FR-JNJFOC-<br>20130401408 |                      | 84 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrioventricular Block<br>Complete                                          | Haldol               |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                                                                             | Seroplex             |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |

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

| <u>FDA Received Date</u>                                                                                                                   | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>        | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------|-------------------|--------------------|--------------------|-----------------|--------------------------------|-----------------------------|-----------------|-------------------|----------------|
| 10-Apr-2013                                                                                                                                | 9058312           | EXPEDITED (15-DAY) |                    | OT              | US-RB-044862-12                |                             | 3 DAY           | Male              | USA            |
| <u>Preferred Term</u>                                                                                                                      | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>        |                |
| Drug Withdrawal Syndrome Neonatal; Exposure Via Breast Milk; Foetal Exposure During Pregnancy; Upper Limb Fracture                         | Suboxone Tablet   |                    |                    | S               | Transplacental                 |                             |                 | Reckitt Benckiser |                |
|                                                                                                                                            | Suboxone Tablet   |                    |                    | S               | Transplacental                 |                             |                 | Reckitt Benckiser |                |
|                                                                                                                                            | Suboxone Tablet   |                    |                    | S               | Transmammary                   |                             |                 | Reckitt Benckiser |                |
|                                                                                                                                            | Seroquel          |                    |                    | S               | Transplacental                 |                             |                 | Not Reported      |                |
|                                                                                                                                            | Lexapril          |                    |                    | S               | Transplacental                 |                             |                 | Not Reported      |                |
|                                                                                                                                            | Nicotine          |                    |                    | S               | Transplacental                 | 3 Packs Of Cigarettes Daily |                 | Not Reported      |                |
|                                                                                                                                            | Nicotine          |                    |                    | S               | Transplacental                 | 17 Cigarettes Daily         |                 | Not Reported      |                |
|                                                                                                                                            | Prenatal Vitamins |                    |                    | S               | Transplacental                 | Dosing Details Unknown      |                 | Not Reported      |                |
|                                                                                                                                            | Pain Medication   |                    |                    | S               | Unknown                        | Dosing Details Unknown      |                 | Not Reported      |                |
| <u>FDA Received Date</u>                                                                                                                   | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>        | <u>Country</u> |
| 10-Apr-2013                                                                                                                                | 9222505           | EXPEDITED (15-DAY) |                    | DS, HO, OT      | US-SANOFI-AVENTIS-2013SA035501 |                             | 38 YR           | Male              | USA            |
| <u>Preferred Term</u>                                                                                                                      | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>        |                |
| Adverse Event; Atrial Fibrillation; Economic Problem; Legal Problem; Myocardial Infarction; Nasopharyngitis; Panic Attack; Suicide Attempt | Ambien            |                    |                    | S               |                                |                             |                 | Not Reported      |                |
|                                                                                                                                            | Effexor           |                    |                    | S               |                                |                             |                 | Not Reported      |                |
|                                                                                                                                            | Wellbutrin        |                    |                    | S               |                                |                             |                 | Not Reported      |                |
|                                                                                                                                            | Concerta          |                    |                    | S               |                                |                             |                 | Not Reported      |                |
|                                                                                                                                            | Ativan            |                    |                    | S               |                                |                             |                 | Not Reported      |                |
|                                                                                                                                            | Depakote          |                    |                    | S               |                                |                             |                 | Not Reported      |                |
|                                                                                                                                            | Trileptal         |                    |                    | S               |                                |                             |                 | Not Reported      |                |
|                                                                                                                                            | Lexapro           |                    |                    | S               |                                |                             |                 | Not Reported      |                |
| <u>FDA Received Date</u>                                                                                                                   | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>        | <u>Country</u> |
| 10-Apr-2013                                                                                                                                | 9222691           | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000044141              |                             | 15 YR           | Female            | FRA            |
| <u>Preferred Term</u>                                                                                                                      | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>        |                |

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

|                                       |              |   |      |         |              |
|---------------------------------------|--------------|---|------|---------|--------------|
| Off Label Use; Overdose;<br>Poisoning | Escitalopram | S | Oral | 1 Df    | Forest       |
|                                       | Advil        | S | Oral | 3200 Mg | Not Reported |
|                                       | Rhinadvil    | S | Oral | 1200 Mg | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 10-Apr-2013              | 9222701        | EXPEDITED (15-DAY) |                    | HO              | FR-PFIZER INC-2013104926 |                      | 15 YR           | Female       | FRA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Poisoning                | Advil          |                    |                    | S               | Oral                     | 16 Df, Single        |                 | Pfizer       |                |
|                          | Rhinadvil      |                    |                    | S               | Oral                     | 6 Df, Single         |                 | Pfizer       |                |
|                          | Seroplex       |                    |                    | S               | Oral                     | 1 Df, Single         |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 10-Apr-2013                                                                                      | 9222749              | EXPEDITED (15-DAY) |                    | HO              | IT-PFIZER INC-2013112801 |                      | 32 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Abuse; Headache;<br>Intentional Self-Injury;<br>Pain In Extremity;<br>Tachycardia; Vomiting | Misofenac            |                    |                    | S               | Oral                     | 9 Df, Daily          |                 | Pfizer       |                |
|                                                                                                  | Tachipirina          |                    |                    | S               | Oral                     | 2000 Mg, Daily       |                 | Not Reported |                |
|                                                                                                  | Escitalopram Oxalate |                    |                    | S               | Oral                     | 360 Mg, Unk          |                 | Not Reported |                |

| <u>FDA Received Date</u>                                            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 10-Apr-2013                                                         | 9222813              | EXPEDITED (15-DAY) |                    | OT              | US-SHIRE-ALL1-2013-02055 |                      | 15 YR           | Female       | USA            |
| <u>Preferred Term</u>                                               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Irritability;<br>Suicidal Ideation; Weight<br>Decreased | Vyvanse              |                    |                    | S               | Oral                     | Unk, Unknown         |                 | Shire        |                |
|                                                                     | Escitalopram Oxalate |                    |                    | S               | Oral                     | 5 Mg, 1x/Day:Qd      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Apr-2013              | 9223112       | EXPEDITED (15-DAY) |                    | OT              | PHHY2013BR032414     |                      | 28 YR      | Female     | BRA            |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                  | <u>Product</u>  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------|-----------------|--------------|------------|-------------|--------------|-----------------------|-----------------|--------------|
| Anxiety; Drug Interaction;<br>Norepinephrine Increased | Ritalina        |              |            | S           | Oral         | 1.5 Df (10 Mg), Daily |                 | Novartis     |
|                                                        | Ritalina        |              |            | S           | Oral         | 1 Df, Daily           |                 | Novartis     |
|                                                        | Escitalopram    |              |            | S           | Oral         | 1 Df, Daily           |                 | Not Reported |
|                                                        | Antidepressants |              |            | S           |              |                       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Apr-2013              | 9120802       | EXPEDITED (15-DAY) |                    | HO              | IT-FRI-1000042946    |                      | 23 YR      | Male       | ITA            |

| <u>Preferred Term</u>                | <u>Product</u>             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------|----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Off Label Use; Serotonin<br>Syndrome | Escitalopram Oral Solution |              |            | S           | Oral         | 15 Drops           |                 | Forest       |
|                                      | Valium                     |              |            | C           | Oral         | 30 Drops           |                 | Not Reported |
|                                      | Growth Hormone             |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 11-Apr-2013              | 9135109       | NON-EXPEDITED    |                    |                 | US-PFIZER INC-<br>2013075067 |                      | 34 YR      | Female     | USA            |

| <u>Preferred Term</u>                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------|----------------|--------------|------------|-------------|--------------|-----------------------|-----------------|--------------|
| Drug Ineffective;<br>Headache; Somnolence | Lyrica         |              |            | S           | Oral         | 50 Mg, 2x/Day         |                 | Pfizer       |
|                                           | Lyrica         |              |            | S           |              |                       |                 | Pfizer       |
|                                           | Caffeine       |              |            | S           |              | Unk                   |                 | Not Reported |
|                                           | Lexapro        |              |            | S           |              | Unk                   |                 | Not Reported |
|                                           | Lantus         |              |            | C           |              | 35 Iu, Daily At Night |                 | Not Reported |
|                                           | Novolog        |              |            | C           |              | 9 Iu, After Each Meal |                 | Not Reported |
|                                           | Depakote       |              |            | C           |              | Unk                   |                 | Not Reported |
|                                           | Hydroxyzine    |              |            | C           |              | Unk                   |                 | Not Reported |
|                                           | Hydroxyzine    |              |            | C           |              |                       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Apr-2013              | 9178217       | EXPEDITED (15-DAY) |                    | OT              | US-RB-022557-11      |                      |            | Female     | USA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                                                                                 | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>        |                |
|---------------------------------------------------------------------------------------------------------------------------------------|-------------------|--------------------|--------------------|-----------------|--------------------------|------------------------------|-----------------|-------------------|----------------|
| Dehydration; Exposure During Pregnancy; Fatigue; Hot Flush; Labour Pain; Panic Attack; Premature Delivery; Thirst                     | Subutex           |                    |                    | S               | Unknown                  |                              |                 | Reckitt Benckiser |                |
|                                                                                                                                       | Lexapro           |                    |                    | S               | Unknown                  | Before Bed Time              |                 | Not Reported      |                |
|                                                                                                                                       | Nicotine          |                    |                    | S               | Respiratory (inhalation) | Smoking Throughout Pregnancy |                 | Not Reported      |                |
|                                                                                                                                       | Prenatal Vitamins |                    |                    | C               | Unknown                  | Dosing Details Unknown       |                 | Not Reported      |                |
| <u>FDA Received Date</u>                                                                                                              | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>        | <u>Country</u> |
| 11-Apr-2013                                                                                                                           | 9224559           | EXPEDITED (15-DAY) |                    | DS, HO, OT      | US-JNJFOC-20130401623    |                              |                 | Male              | USA            |
| <u>Preferred Term</u>                                                                                                                 | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>        |                |
| Atrial Fibrillation; Disability; Hospitalisation; Imprisonment; Myocardial Infarction; Nasopharyngitis; Panic Attack; Suicide Attempt | Concerta          |                    |                    | S               | Oral                     |                              |                 | Not Reported      |                |
|                                                                                                                                       | Wellbutrin        |                    |                    | S               | Unknown                  |                              |                 | Not Reported      |                |
|                                                                                                                                       | Effexor           |                    |                    | S               | Unknown                  |                              |                 | Not Reported      |                |
|                                                                                                                                       | Lexapro           |                    |                    | S               | Unknown                  |                              |                 | Not Reported      |                |
|                                                                                                                                       | Lithium           |                    |                    | S               | Unknown                  |                              |                 | Not Reported      |                |
|                                                                                                                                       | Ativan            |                    |                    | S               | Unknown                  |                              |                 | Not Reported      |                |
|                                                                                                                                       | Ambien            |                    |                    | S               | Unknown                  |                              |                 | Not Reported      |                |
|                                                                                                                                       | Depakote          |                    |                    | S               | Unknown                  |                              |                 | Not Reported      |                |
| Trileptal                                                                                                                             |                   |                    | S                  | Unknown         |                          |                              | Not Reported    |                   |                |
| <u>FDA Received Date</u>                                                                                                              | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>        | <u>Country</u> |
| 11-Apr-2013                                                                                                                           | 9225524           | EXPEDITED (15-DAY) |                    | HO              | DE-FRI-1000044165        |                              | 72 YR           | Female            | DEU            |
| <u>Preferred Term</u>                                                                                                                 | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>        |                |
| Delirium; Drug Interaction; Prescribed Overdose; Toxicity To Various Agents                                                           | Escitalopram      |                    |                    | S               | Oral                     | 40 Mg                        |                 | Forest            |                |
|                                                                                                                                       | Tramal            |                    |                    | S               |                          | 100 Mg                       |                 | Not Reported      |                |
|                                                                                                                                       | Tramal            |                    |                    | S               |                          | 150 Mg                       |                 | Not Reported      |                |
|                                                                                                                                       | Tavor (Lorazepam) |                    |                    | C               |                          | 0.5 Mg                       |                 | Not Reported      |                |
|                                                                                                                                       | Ascotop           |                    |                    | C               |                          |                              |                 | Not Reported      |                |

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|             |   |        |              |
|-------------|---|--------|--------------|
| Ass         | C | 100 Mg | Not Reported |
| Bisoprolol  | C | 10 Mg  | Not Reported |
| Diclo Kd    | C | 75 Mg  | Not Reported |
| Pantoprazol | C | 40 Mg  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Apr-2013              | 9226334       | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000044218    |                      | 37 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Burning Sensation     | Escitalopram   |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                       | Ibuprofene     |              |            | C           | Oral         | 1200 Mg            |                 | Not Reported |
|                       | Biocaliptol    |              |            | C           | Oral         | 4 Df               |                 | Not Reported |
|                       | Qlaira         |              |            | C           | Oral         | 1 Df               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Apr-2013              | 9226377       | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000044105    |                      | < 1 DAY    | Female     | USA            |

| <u>Preferred Term</u>                                                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-------------------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|------------|
| Congenital Anomaly;<br>Fallot'S Tetralogy;<br>Ventricular Septal Defect | Lexapro        |              |            | S           | Transplacental |                    |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Apr-2013              | 9226379       | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000044107    |                      | < 1 DAY    | Male       | USA            |

| <u>Preferred Term</u>                                                                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|------------|
| Congenital Anomaly;<br>Patent Ductus Arteriosus;<br>Talipes; Ventricular Septal<br>Defect | Lexapro        |              |            | S           | Transplacental |                    |                 | Forest     |

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

| <u>FDA Received Date</u>                                                       | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                                                | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
|--------------------------------------------------------------------------------|--------------------|--------------------|--------------------|-----------------|-------------------------------------------------|---------------------------------------------------------------------|-----------------|------------------------------|----------------|
| 12-Apr-2013                                                                    | 9227653            | EXPEDITED (15-DAY) |                    | OT              | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>18753988 |                                                                     |                 | Male                         | USA            |
| <u>Preferred Term</u>                                                          | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                                  | <u>Duration</u> | <u>Mfr</u>                   |                |
| Mania                                                                          | Abilify<br>Lexapro |                    |                    | S<br>S          |                                                 |                                                                     |                 | Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                       | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                                                | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 12-Apr-2013                                                                    | 9229864            | DIRECT             | Y                  |                 |                                                 |                                                                     | 57 YR           | Female                       | USA            |
| <u>Preferred Term</u>                                                          | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                                  | <u>Duration</u> | <u>Mfr</u>                   |                |
| Drug Ineffective                                                               | Lexapro            |                    |                    | S               | Oral                                            |                                                                     |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                                                       | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                                                | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 15-Apr-2013                                                                    | 9119639            | EXPEDITED (15-DAY) |                    | HO, LT, OT      | AU-ASTRAZENECA-<br>2013SE12519                  |                                                                     | 29 YR           | Female                       | AUS            |
| <u>Preferred Term</u>                                                          | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                                  | <u>Duration</u> | <u>Mfr</u>                   |                |
| Exposure During<br>Pregnancy; Gestational<br>Diabetes; Respiratory<br>Distress | Seroquel Xr        |                    |                    | S               | Oral                                            | 50 Mg/Day At 34/40 Wks<br>P/N 10wks                                 |                 | Not Reported                 |                |
|                                                                                | Risperdal Consta   |                    |                    | S               | Intramuscular                                   | 37.5 Mg, 2/52 Fortnightly<br>Initiated Pre-Pregnancy<br>And Ongoing |                 | Not Reported                 |                |
|                                                                                | Escitalopram       |                    |                    | S               | Oral                                            | 40 Mg/Day Pre-Pregnancy<br>And Ongoing                              |                 | Not Reported                 |                |
|                                                                                | Oxycontin          |                    |                    | S               | Oral                                            | 20-30 Mg/Day Initiated At<br>27/40 Weeks And Stopped<br>At Birth    |                 | Not Reported                 |                |
|                                                                                | Oxynorm            |                    |                    | S               | Oral                                            | 5-10 Mg/Day Initiated At<br>27/40 Weeks And Stopped<br>At Birth     |                 | Not Reported                 |                |
|                                                                                | Elevit             |                    |                    | C               | Oral                                            | 1 Tablet/Day From First<br>Trimester And Stopped At                 |                 | Not Reported                 |                |

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

|            |   |              |                                                        |              |
|------------|---|--------------|--------------------------------------------------------|--------------|
| Vit D      | C | Oral         | Birth<br>1 Tablet/Day From First Trimester And Ongoing | Not Reported |
| Novorapid  | C | Subcutaneous | From 32/40 Weeks Until Birth, Three Times A Day        | Not Reported |
| Protophane | C | Subcutaneous | From 32/40 Weeks Until Birth, At Night                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 15-Apr-2013              | 9119674       | EXPEDITED (15-DAY) |                    | DS, HO, LT, OT  | AU-ASTRAZENECA-2013SE12513 |                      | < 1 DAY    | Female     | AUS            |

| <u>Preferred Term</u>                                                   | <u>Product</u>   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u>                                                   | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------|------------------|--------------|------------|-------------|----------------|----------------------------------------------------------------------|-----------------|--------------|
| Drug Withdrawal Syndrome Neonatal; Premature Baby; Respiratory Distress | Seroquel Xr      |              |            | S           | Transplacental | 50 Mg/Day Initiated At 34/40 Weeks And Stopped At Delivery           |                 | Not Reported |
|                                                                         | Risperdal Consta |              |            | S           | Transplacental | 37.5 Mg, 2/52 Fortnightly Initiated Pre-Pregnancy And Ongoing        |                 | Not Reported |
|                                                                         | Escitalopram     |              |            | S           | Transplacental | 40 Mg/Day Initiated Pre-Pregnancy And Is Ongoing                     |                 | Not Reported |
|                                                                         | Oxynorm          |              |            | S           | Transplacental | 20-30 Mg/Day, Fortnightly, Initiated At 27/40 Weeks Stopped At Birth |                 | Not Reported |
|                                                                         | Oxycontin        |              |            | S           | Transplacental | 5-10 Mg/Day Initiated At 27/40 Weeks Stopped At Birth                |                 | Not Reported |
|                                                                         | Elevit           |              |            | C           | Transplacental | 1 Tablet/Day, Initiated Since 1 Trimester                            |                 | Not Reported |
|                                                                         | Vitamin D Nos    |              |            | C           | Transplacental | 1 Tablet/Day, Initiated Since 1 Trimester                            |                 | Not Reported |
|                                                                         | Novorapid        |              |            | C           | Transplacental | 1 Tablet/Day, Initiated Since 1 Trimester                            |                 | Not Reported |
|                                                                         | Protophane       |              |            | C           | Transplacental | 1 Tablet/Day, Initiated Since 1 Trimester                            |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                             | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 15-Apr-2013                                                                                                          | 9158600                     | EXPEDITED (15-DAY) |                    | OT              | US-FRI-1000043193    |                      | 68 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Breast Cancer; Crying;<br>Depressed Mood;<br>Impatience                                                              | Lexapro                     |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                                                                                                      | Lexapro                     |                    |                    | S               | Oral                 | 7.5 Mg               |                 | Forest       |                |
|                                                                                                                      | Lexapro                     |                    |                    | S               | Oral                 | 5 Mg                 |                 | Forest       |                |
|                                                                                                                      | Lexapro                     |                    |                    | S               | Oral                 | 2.5 Mg               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                             | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Apr-2013                                                                                                          | 9224839                     | EXPEDITED (15-DAY) | Y                  | HO              | AUR-APL-2013-02849   |                      | 60 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Encephalopathy;<br>Hypotension; Hypoxia;<br>Metabolic Disorder;<br>Serotonin Syndrome;<br>Toxicity To Various Agents | Escitalopram (Escitalopram) |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                      | Trazodone (Trazodone)       |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                      | Methylthioninium Chloride   |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                      | Phenylephrine               |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                      | Methylthioninium Chloride   |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                             | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Apr-2013                                                                                                          | 9230954                     | EXPEDITED (15-DAY) |                    | LT              | FR-FRI-1000044251    |                      | 84 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrioventricular Block<br>Complete                                                                                   | Escitalopram                |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                                                                                                      | Haldol                      |                    |                    | S               | Oral                 | 14 Df                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                             | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Apr-2013                                                                                                          | 9231020                     | EXPEDITED (15-DAY) |                    | HO, OT          | US-ROCHE-1211783     |                      | 67 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

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

|                                                                     |              |   |         |              |
|---------------------------------------------------------------------|--------------|---|---------|--------------|
| Depression; Drug Ineffective; Intentional Overdose; Suicide Attempt | Valium       | S | Unknown | Not Reported |
|                                                                     | Valium       | S | Unknown | Not Reported |
|                                                                     | Escitalopram | S | Oral    | Not Reported |
|                                                                     | Escitalopram | S | Oral    | Not Reported |
|                                                                     | Sonata       | S | Unknown | Not Reported |
|                                                                     | Sonata       | S | Unknown | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Apr-2013              | 9231185       | EXPEDITED (15-DAY) |                    | OT              | PHHY2013TR034975     |                      | 43 YR      | Female     | TUR            |

| <u>Preferred Term</u>                                                                                                                                      | <u>Product</u>  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Clonus; Confusional State; Drug Interaction; Hoffmann'S Sign; Hyperreflexia; Muscle Contractions Involuntary; Muscle Rigidity; Pyrexia; Serotonin Syndrome | Escitalopram    |              |            | S           |              | 20 Mg, Daily       |                 | Not Reported |
|                                                                                                                                                            | Isoniazid       |              |            | S           |              |                    |                 | Novartis     |
|                                                                                                                                                            | Corticosteroids |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Apr-2013              | 9232889       | DIRECT           |                    | HO              |                      |                      | 70 YR      | Female     | USA            |

| <u>Preferred Term</u>                                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Drug Interaction; Food Interaction; Visual Impairment | Diovan         |              |            | S           | Oral         | 160mg Daily Po     | 5 YR            | Novartis   |
|                                                       | Lamotrigine    |              |            | S           | Oral         | 100mg Daily Po     | 5 YR            | Cadila     |
|                                                       | Escitalopram   |              |            | S           | Oral         | 7.5mg Daily Po     | 6 MTH           | Forest     |
|                                                       | Bupropion      |              |            | S           | Oral         | 50mg Daily Po      |                 | Sandoz     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Apr-2013              | 9233343       | DIRECT           |                    | OT              |                      |                      | 23 YR      | Female     | USA            |

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

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

|                                                                                                                      |              |   |      |      |           |
|----------------------------------------------------------------------------------------------------------------------|--------------|---|------|------|-----------|
| Anxiety; Depressed Mood;<br>Drug Withdrawal<br>Syndrome; Fatigue;<br>Headache; Nausea;<br>Product Substitution Issue | Escitalopram | S | Oral | 2 YR | Aurobindo |
|----------------------------------------------------------------------------------------------------------------------|--------------|---|------|------|-----------|

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 16-Apr-2013                       | 9049613                | EXPEDITED (15-DAY)        | LT                          |                          | JP-FRI-1000042415             |                               | 69 YR               | Female              | JPN                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Ventricular Fibrillation       | Lexapro                 |                       |                     | S                    | Oral                  | 10 Mg                       |                          | Forest              |
|                                | Eticalm                 |                       |                     | C                    | Oral                  | 0.5 Mg                      |                          | Not Reported        |
|                                | Flunitrazepam           |                       |                     | C                    | Oral                  | 1 Mg                        |                          | Not Reported        |
|                                | Sediel                  |                       |                     | C                    | Oral                  | 10 Mg                       |                          | Not Reported        |
|                                | Irbetan                 |                       |                     | C                    | Oral                  |                             |                          | Not Reported        |
|                                | Allermist               |                       |                     | C                    | Nasal                 |                             |                          | Not Reported        |
|                                | Halcion                 |                       |                     | C                    | Oral                  |                             |                          | Not Reported        |
|                                | Goodmin                 |                       |                     | C                    | Oral                  |                             |                          | Not Reported        |
|                                | Tsumura                 |                       |                     | C                    | Oral                  |                             |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 16-Apr-2013                       | 9071271                | EXPEDITED (15-DAY)        | HO                          |                          | FR-FRI-1000042203             |                               | 42 YR               | Male                | FRA                     |

| <a href="#">Preferred Term</a>           | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|------------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Poisoning Deliberate;<br>Suicide Attempt | Escitalopram            |                       |                     | S                    | Oral                  |                             |                          | Forest              |
|                                          | Noctran                 |                       |                     | S                    |                       |                             |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 16-Apr-2013                       | 9236026                | DIRECT                    | Y                           | OT                       |                               |                               | 63 YR               | Female              | USA                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Arthralgia; Myalgia            | Escitalopram            |                       |                     | S                    | Oral                  |                             |                          | Teva                |



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

| <u>FDA Received Date</u>                                                                                                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|---------------------------|-------------------------|-----------------|--------------|----------------|
| 17-Apr-2013                                                                                                                                         | 9147444        | EXPEDITED (15-DAY) |                    | HO              | IT-PFIZER INC-2013078839  |                         | 41 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                                                                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Electrocardiogram Qt Prolonged; Hypotension; Intentional Overdose; Intentional Self-Injury; Syncope                                                 | Torvast        |                    |                    | S               | Oral                      | 35 Df, Unit Doses Total |                 | Pfizer       |                |
|                                                                                                                                                     | Depakin Chrono |                    |                    | S               | Oral                      | 40 Df, Unit Doses Total |                 | Not Reported |                |
|                                                                                                                                                     | Cipraxel       |                    |                    | S               | Oral                      | 70 Df, Unit Doses Total |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Apr-2013                                                                                                                                         | 9236098        | EXPEDITED (15-DAY) |                    | OT              | PHHY2013IE036211          |                         | 52 YR           | Female       | IRL            |
| <u>Preferred Term</u>                                                                                                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Compulsive Shopping; Depression; Hypersexuality; Impulse-Control Disorder; Libido Increased; Poisoning Deliberate; Sexually Inappropriate Behaviour | Stalevo        |                    |                    | S               |                           | 100 Mg, 6 Times Daily   |                 | Not Reported |                |
|                                                                                                                                                     | Amantadine     |                    |                    | S               |                           | 100 Mg, Tid             |                 | Not Reported |                |
|                                                                                                                                                     | Selegiline     |                    |                    | S               |                           | 5 Mg, Daily             |                 | Not Reported |                |
|                                                                                                                                                     | Pramipexole    |                    |                    | S               |                           | 0.18 Mg, Daily          |                 | Not Reported |                |
|                                                                                                                                                     | Alprazolam     |                    |                    | S               |                           | 0.5 Mg, Daily           |                 | Novartis     |                |
|                                                                                                                                                     | Escitalopram   |                    |                    | S               |                           | 10 Mg, Daily            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Apr-2013                                                                                                                                         | 9236657        | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000044385         |                         | < 1 DAY         | Unknown      | USA            |
| <u>Preferred Term</u>                                                                                                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Talipes                                                                                                                                             | Lexapro        |                    |                    | S               | Transplacental            |                         |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Apr-2013                                                                                                                                         | 9237313        | EXPEDITED (15-DAY) |                    | OT              | TR-MYLANLABS-2013S1007783 |                         | 43 YR           | Female       | TUR            |
| <u>Preferred Term</u>                                                                                                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |

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

|                                                                        |              |   |         |           |              |
|------------------------------------------------------------------------|--------------|---|---------|-----------|--------------|
| Drug Interaction;<br>Electromyogram<br>Abnormal; Serotonin<br>Syndrome | Escitalopram | S | Unknown | 20 Mg/Day | Mylan        |
|                                                                        | Isoniazid    | S | Unknown |           | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Apr-2013              | 9240301       | EXPEDITED (15-DAY) | Y                  | HO              | 2013HINLIT0078       |                      | 60 YR      | Male       | USA            |

  

| <u>Preferred Term</u> | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>      | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-----------------------------|--------------|------------|-------------|-------------------|------------------------------|-----------------|--------------|
| Serotonin Syndrome    | Escitalopram (Escitalopram) |              |            | S           | Oral              | 20 Mg/Day                    |                 | Not Reported |
|                       | Methylthioninium Chloride   |              |            | S           | Intravenous bolus |                              |                 | Not Reported |
|                       | Trazodone (Trazodone)       |              |            | S           | Intravenous bolus | 0.5 Mg/Kg/Hour<br>(Bed Time) |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> |             | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>   | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-------------|-----------------|-----------------------|----------------------|--------------|------------|----------------|
| 18-Apr-2013              | 9000246        | EXPEDITED (15-DAY) |                    |             | HO, LT          | CH-JNJFOC-20130101511 |                      | 90 YR        | Female     | CHE            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u> | <u>Route</u>    | <u>Dosage Text</u>    | <u>Duration</u>      | <u>Mfr</u>   |            |                |
| Hepatocellular Injury    | Zaldiar        |                    |                    | S           | Oral            |                       |                      | Not Reported |            |                |
|                          | Zaldiar        |                    |                    | S           | Oral            | 325 Mg 4 Times A Day  |                      | Not Reported |            |                |
|                          | Xarelto        |                    |                    | S           | Oral            | 10 Mg Cumulative Dose |                      | Not Reported |            |                |
|                          | Paracetamol    |                    | Y                  | S           | Oral            |                       |                      | Not Reported |            |                |
|                          | Paracetamol    |                    |                    | S           | Oral            | 4 Doses A Day         |                      | Not Reported |            |                |
|                          | Reminyl        |                    |                    | S           | Oral            |                       |                      | Not Reported |            |                |
|                          | Esomeprazole   |                    |                    | S           | Oral            |                       |                      | Not Reported |            |                |
|                          | Flagyl         |                    |                    | S           | Oral            | 2000 Mg Once A Day    |                      | Not Reported |            |                |
|                          | Cipralex       |                    |                    | S           | Oral            |                       |                      | Not Reported |            |                |
|                          | Inegy          |                    |                    | S           | Oral            |                       |                      | Not Reported |            |                |
|                          | Zolpidem       |                    |                    | S           | Oral            |                       |                      | Not Reported |            |                |
|                          | Rocephin       |                    |                    | S           | Oral            | 500 Mg 3 Times A Day  |                      | Not Reported |            |                |
|                          | Amlodipine     |                    |                    | S           | Oral            |                       |                      | Not Reported |            |                |

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

|               |   |         |              |
|---------------|---|---------|--------------|
| Ibuprofen     | C | Oral    | Not Reported |
| Omeprazole    | C | Oral    | Not Reported |
| Calciparin    | C | Unknown | Not Reported |
| Calcimagon D3 | C | Oral    | Not Reported |
| Prednisolone  | C | Oral    | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Apr-2013              | 9225536       | EXPEDITED (15-DAY) | HO                 |                 | IT-FRI-1000044164    |                      | 16 YR      | Female     | ITA            |

| <u>Preferred Term</u>                                          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|----------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Hypokinesia; Long Qt Syndrome; Off Label Use; Overdose; Tremor | Escitalopram   |              |            | S           | Oral         | 200 Mg             |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 18-Apr-2013              | 9238615       | EXPEDITED (15-DAY) |                    | DS              | FR-ABBOTT-13P-056-1076954-00 |                      | 48 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                                  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Creatine Phosphokinase Increased; Myalgia; Neuropathy Peripheral | Norvir         |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                        | Intelence      |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                        | Seroplex       |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                        | Isentress      |              |            | C           |              |                    |                 | Not Reported |
|                                                                        | Prezista       |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Apr-2013              | 9239278       | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000044387    |                      | < 1 DAY    | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|------------|
| Talipes               | Lexapro        |              |            | S           | Transplacental |                    |                 | Forest     |

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

| <u>FDA Received Date</u>                                  | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|-----------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|----------------------|----------------|
| 18-Apr-2013                                               | 9240581                | EXPEDITED (15-DAY) |                    | OT              | SE-NICOBREDEVP-2013-06702 |                      | 23 YR           | Female               | SWE            |
| <u>Preferred Term</u>                                     | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Fatigue; Muscle Contractions Involuntary; Suicide Attempt | Lamotrigine (Unknown)  |                    |                    | S               | Unknown                   | Unk                  |                 | Watson               |                |
|                                                           | Escitalopram (Unknown) |                    |                    | S               | Unknown                   | Unk                  |                 | Not Reported         |                |
|                                                           | Paracetamol (Unknown)  |                    |                    | S               | Unknown                   | Unk                  |                 | Actavis Mid Atlantic |                |
|                                                           | Zopiklon               |                    |                    | S               | Unknown                   | Unk                  |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                  | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 18-Apr-2013                                               | 9240681                | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000044389         |                      |                 | Unknown              | USA            |
| <u>Preferred Term</u>                                     | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Congenital Anomaly; Oesophageal Atresia                   | Lexapro                |                    |                    | S               | Transplacental            |                      |                 | Forest               |                |
| <u>FDA Received Date</u>                                  | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 18-Apr-2013                                               | 9240943                | DIRECT             | Y                  |                 |                           |                      | 11 YR           | Female               | USA            |
| <u>Preferred Term</u>                                     | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Product Substitution Issue                                | Lexapro                |                    |                    | S               |                           |                      |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                  | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 19-Apr-2013                                               | 9100326                | EXPEDITED (15-DAY) |                    | OT              | AT-PFIZER INC-2013058634  |                      | 61 YR           | Female               | AUT            |
| <u>Preferred Term</u>                                     | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Amnesia; Hyponatraemia                                    | Halcion                |                    |                    | S               |                           | 0.25 Mg, 1x/Day      |                 | Pfizer               |                |
|                                                           | Ciprallex              |                    |                    | S               |                           | 5 Mg, 1x/Day         |                 | Not Reported         |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                         | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>                               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|--------------------|--------------------|-----------------|-----------------------|----------------------------------------------------|-----------------|--------------|----------------|
| 19-Apr-2013                                                                                                                                                                                      | 9104870           | EXPEDITED (15-DAY) |                    | DE, HO, OT      | US-JNJFOC-20130206776 |                                                    | 61 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                            | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>                                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State;<br>Constipation; Death;<br>Depression; Drug<br>Ineffective; Drug<br>Interaction; Failure To<br>Thrive; Hallucination;<br>Malignant Neoplasm<br>Progression; Overdose;<br>Pain | Nucynta Er        |                    |                    | S               | Oral                  | 100 Mg- 3 Tablets -Twice<br>A Day                  |                 | Not Reported |                |
|                                                                                                                                                                                                  | Nucynta Er        |                    |                    | S               | Oral                  | Twice Daily                                        |                 | Not Reported |                |
|                                                                                                                                                                                                  | Nucynta           |                    |                    | S               | Oral                  | 50 Mg, 3 Tablets Every 4-<br>6 Hours As Needed     |                 | Not Reported |                |
|                                                                                                                                                                                                  | Lexapro           |                    |                    | S               | Unknown               | Once Daily                                         |                 | Not Reported |                |
|                                                                                                                                                                                                  | Omeprazole        |                    |                    | C               | Unknown               | Once A Day                                         |                 | Not Reported |                |
|                                                                                                                                                                                                  | Oxazepam          |                    |                    | C               | Unknown               | Once A Day                                         |                 | Not Reported |                |
|                                                                                                                                                                                                  | Magic Mouthwash   |                    |                    | C               | Unknown               | Unspecified -Tea Spoon-<br>Every 4 Hours As Needed |                 | Not Reported |                |
|                                                                                                                                                                                                  | Magnesium Lactate |                    |                    | C               | Unknown               | Unspecified -Tea Spoon-<br>Every 4 Hours As Needed |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                         | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>                               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Apr-2013                                                                                                                                                                                      | 9243070           | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000044432     |                                                    | < 1 DAY         | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                            | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>                                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Pulmonary Valve Stenosis<br>Congenital                                                                                                                                                           | Lexapro           |                    |                    | S               | Transplacental        |                                                    |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                                                                                         | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>                               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Apr-2013                                                                                                                                                                                      | 9247772           | DIRECT             |                    |                 |                       |                                                    |                 | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                            | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>                                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain;<br>Abdominal Pain;<br>Diarrhoea; Discomfort;<br>Loss Of Personal                                                                                                                 | Lexapro           |                    |                    | S               | Oral                  | 10 Mg 1/2 8 Day Po                                 |                 | Forest       |                |

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

Independence In Daily  
Activities

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Apr-2013              | 8987631       | EXPEDITED (15-DAY) |                    | OT              | CH-FRI-1000026462    |                      |            | Female     | CHE            |

| <u>Preferred Term</u>                                                                               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Caesarean Section;<br>Generalised Oedema;<br>Pregnancy; Uterine<br>Contractions During<br>Pregnancy | Escitalopram   |              |            | S           |              | 20 Mg              |                 | Forest       |
|                                                                                                     | Seroquel       |              |            | S           |              | 600 Mg             |                 | Not Reported |
|                                                                                                     | Labetalol      |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Apr-2013              | 8988022       | EXPEDITED (15-DAY) |                    | HO, OT          | CH-FRI-1000041216    |                      | 1 DAY      | Unknown    | CHE            |

| <u>Preferred Term</u>                                                                                                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Foetal Exposure During<br>Pregnancy;<br>Hypernatraemia;<br>Metabolic Acidosis;<br>Premature Baby;<br>Respiratory Failure | Escitalopram   |              |            | S           | Transplacental |                    |                 | Forest       |
|                                                                                                                          | Seroquel       |              |            | S           |                |                    |                 | Not Reported |
|                                                                                                                          | Labetalol      |              |            | C           |                |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Apr-2013              | 8988137       | EXPEDITED (15-DAY) |                    | HO, OT          | CH-FRI-1000041217    |                      | 1 DAY      | Unknown    | CHE            |

| <u>Preferred Term</u>                                                                                                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Foetal Exposure During<br>Pregnancy;<br>Hypernatraemia;<br>Metabolic Acidosis;<br>Premature Baby;<br>Respiratory Failure | Escitalopram   |              |            | S           | Transplacental |                    |                 | Forest       |
|                                                                                                                          | Seroquel       |              |            | S           |                |                    |                 | Not Reported |
|                                                                                                                          | Labetalol      |              |            | C           |                |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>           | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|------------------------------------|----------------|--------------------|--------------------|-----------------|--------------------------------------|-------------------------------------|-----------------|-----------------|----------------|
| 22-Apr-2013                        | 9244474        | EXPEDITED (15-DAY) |                    | HO              | PHHY2013FR037331                     |                                     | 61 YR           | Female          | FRA            |
| <u>Preferred Term</u>              | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>      |                |
| Balance Disorder;<br>Hyponatraemia | Nisisco        |                    |                    | S               | Oral                                 | 1 Df (160mg Vals/12.5mg Hctz) Daily |                 | Novartis        |                |
|                                    | Deroxat        |                    |                    | S               |                                      | 0.5 Df, Daily                       |                 | Not Reported    |                |
|                                    | Seroplex       |                    |                    | S               |                                      | Unk Ukn, Unk                        |                 | Not Reported    |                |
|                                    | Seresta        |                    |                    | C               |                                      | 50 Mg, Unk                          |                 | Not Reported    |                |
|                                    | Seresta        |                    |                    | C               |                                      | Increased Dose                      |                 | Not Reported    |                |
|                                    | Zocor          |                    |                    | C               |                                      | 1 Df, Daily                         |                 | Not Reported    |                |
|                                    | Stilnox        |                    |                    | C               |                                      | 1 Df (10mg), Daily                  |                 | Not Reported    |                |
| <u>FDA Received Date</u>           | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 22-Apr-2013                        | 9246896        | EXPEDITED (15-DAY) |                    | HO              | FR-<br>GLAXOSMITHKLINE-<br>B0883792A |                                     | 61 YR           | Female          | FRA            |
| <u>Preferred Term</u>              | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>      |                |
| Balance Disorder;<br>Hyponatraemia | Deroxat        |                    |                    | S               | Oral                                 | .5unit Per Day                      |                 | Glaxosmithkline |                |
|                                    | Seroplex       |                    |                    | S               | Oral                                 |                                     |                 | Unknown         |                |
|                                    | Nisisco        |                    |                    | S               | Oral                                 | 1unit Per Day                       |                 | Unknown         |                |
|                                    | Seresta        |                    |                    | C               | Oral                                 |                                     |                 | Unknown         |                |
|                                    | Zocor          |                    |                    | C               | Oral                                 | 20mg Per Day                        |                 | Unknown         |                |
|                                    | Stilnox        |                    |                    | C               | Oral                                 | 10mg Per Day                        |                 | Unknown         |                |
| <u>FDA Received Date</u>           | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 22-Apr-2013                        | 9253944        | DIRECT             |                    | DS              |                                      |                                     | 56 YR           | Male            | USA            |
| <u>Preferred Term</u>              | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>      |                |
| Parkinsonism                       | Lexapro        |                    |                    | S               | Oral                                 | 20 Mg. Once Daily Po                |                 | Not Reported    |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                        | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
| 22-Apr-2013                                                                                                                                                                     | 9254454           | DIRECT             |                    | OT              |                           |                      | 31 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                           | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anger; Anxiety; Crying;<br>Depression; Fatigue;<br>Feeling Abnormal;<br>Headache; Nausea; Sleep<br>Disorder; Suicidal<br>Ideation; Therapeutic<br>Response Changed;<br>Vomiting | Escitalopram      |                    |                    | S               | Oral                      |                      |                 | Aurobindo    |                |
| <u>FDA Received Date</u>                                                                                                                                                        | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Apr-2013                                                                                                                                                                     | 8261077           | EXPEDITED (15-DAY) |                    | CA              | US-JNJFOC-<br>20111107543 |                      |                 | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                           | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Growth Retardation;<br>Hypospadias                                                                                                                                              | Topamax           |                    |                    | S               | Transplacental            |                      |                 | Not Reported |                |
|                                                                                                                                                                                 | Topamax           |                    |                    | S               | Transplacental            |                      |                 | Not Reported |                |
|                                                                                                                                                                                 | Lexapro           |                    |                    | S               | Transplacental            |                      |                 | Not Reported |                |
|                                                                                                                                                                                 | Zofran            |                    |                    | S               | Transplacental            |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                        | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Apr-2013                                                                                                                                                                     | 9144600           | EXPEDITED (15-DAY) |                    | OT              | GB-FRI-1000043176         |                      | 65 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                                                                                                                           | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Clavicle Fracture; Forearm<br>Fracture                                                                                                                                          | Escitalopram      |                    |                    | S               | Oral                      | 20 Mg                |                 | Forest       |                |
|                                                                                                                                                                                 | Escitalopram      |                    |                    | S               | Oral                      | 10 Mg Daily          |                 | Forest       |                |
|                                                                                                                                                                                 | Calcihew D3 Forte |                    |                    | C               | Oral                      | Two Tablets Daily    |                 | Not Reported |                |
|                                                                                                                                                                                 | Alendronic Acid   |                    |                    | C               | Oral                      | 70 Mg Weekly         |                 | Not Reported |                |



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

| <u>FDA Received Date</u>                              | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u>                                                                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|--------------------------------|---------------------------------------------------------------------------------------|-----------------|--------------|----------------|
| 23-Apr-2013                                           | 9248822                | EXPEDITED (15-DAY) |                    | HO              | FR-SANOFI-AVENTIS-2013SA038240 |                                                                                       | 99 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                 | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>                                                                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State;<br>Hyponatraemia                   | Stilnox                |                    |                    | S               | Oral                           |                                                                                       |                 | Not Reported |                |
|                                                       | Seroplex               |                    |                    | S               | Oral                           |                                                                                       |                 | Not Reported |                |
|                                                       | Furosemide             |                    |                    | C               | Oral                           |                                                                                       |                 | Not Reported |                |
|                                                       | Digoxine               |                    |                    | C               | Oral                           | 0.125 Mg 1tablet 5 Days /7days                                                        |                 | Not Reported |                |
|                                                       | Previscan (Fluindione) |                    |                    | C               | Oral                           | 1/2 Tablet = 10 Mg Every Day Except Three Fourth Tablet = 15 Mg On Tuesday And Friday |                 | Not Reported |                |
|                                                       | Calcium/Colecalciferol |                    |                    | C               |                                | 1 Bag On Tuesday And On Friday                                                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u>                                                                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Apr-2013                                           | 9249551                | EXPEDITED (15-DAY) |                    | HO              | AU-FRI-1000044541              |                                                                                       | 44 YR           | Male         | AUS            |
| <u>Preferred Term</u>                                 | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>                                                                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Pleural Effusion                                      | Lexapro                |                    |                    | S               | Oral                           | 20 Mg                                                                                 |                 | Forest       |                |
|                                                       | Somac                  |                    |                    | S               |                                | 20 Mg                                                                                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u>                                                                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Apr-2013                                           | 9249632                | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000044547              |                                                                                       | 77 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                 | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>                                                                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Reaction With Eosinophilia And Systemic Symptoms | Escitalopram           |                    |                    | S               | Oral                           | 1 Df                                                                                  |                 | Forest       |                |
|                                                       | Cotriatec              |                    |                    | C               |                                |                                                                                       |                 | Not Reported |                |
|                                                       | Bisoprolol             |                    |                    | C               |                                |                                                                                       |                 | Not Reported |                |
|                                                       | Triatec (Ramipril)     |                    |                    | C               |                                |                                                                                       |                 | Not Reported |                |
|                                                       | Amarel                 |                    |                    | C               |                                |                                                                                       |                 | Not Reported |                |

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

| <u>FDA Received Date</u>                                                                                                                                                                                                                                                        | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|-----------------|----------------|
| 23-Apr-2013                                                                                                                                                                                                                                                                     | 9255096                | DIRECT             | Y                  |                 |                              |                      |                 | Female          | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                           | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Product Substitution Issue                                                                                                                                                                                                                                                      | Lexapro 20mg - Generic |                    |                    | S               | Oral                         | 1 Dose Po Daily      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                        | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 24-Apr-2013                                                                                                                                                                                                                                                                     | 8330966                | EXPEDITED (15-DAY) |                    | OT              | US-GLAXOSMITHKLINE-A0960414A |                      | 34 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                           | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Abortion Spontaneous; Bedridden; Depressed Mood; Depression; Disability; Disturbance In Attention; Drug Interaction; Drug Level Decreased; Exposure During Pregnancy; Hypersomnia; Loss Of Personal Independence In Daily Activities; Mood Altered; Prescribed Overdose; Stress | Lamictal               |                    |                    | S               | Oral                         | 300mg Unknown        |                 | Glaxosmithkline |                |
|                                                                                                                                                                                                                                                                                 | Lamotrigine            |                    |                    | S               | Oral                         | 300mg Unknown        |                 | Teva            |                |
|                                                                                                                                                                                                                                                                                 | Microgestin            |                    |                    | S               | Unknown                      |                      |                 | Not Reported    |                |
|                                                                                                                                                                                                                                                                                 | Geodon                 |                    |                    | S               | Unknown                      |                      |                 | Not Reported    |                |
|                                                                                                                                                                                                                                                                                 | Wellbutrin             |                    |                    | S               | Oral                         |                      |                 | Glaxosmithkline |                |
|                                                                                                                                                                                                                                                                                 | Effexor                |                    |                    | S               | Unknown                      |                      |                 | Glaxosmithkline |                |
|                                                                                                                                                                                                                                                                                 | Lexapro                |                    |                    | S               | Unknown                      |                      |                 | Not Reported    |                |
|                                                                                                                                                                                                                                                                                 | Contraceptive          |                    |                    | S               |                              |                      |                 | Not Reported    |                |
|                                                                                                                                                                                                                                                                                 | Lipitor                |                    |                    | C               | Oral                         |                      |                 | Glaxosmithkline |                |
|                                                                                                                                                                                                                                                                                 | Trileptal              |                    |                    | C               |                              |                      |                 | Not Reported    |                |
|                                                                                                                                                                                                                                                                                 | Nortriptyline          |                    |                    | C               |                              |                      |                 | Not Reported    |                |
|                                                                                                                                                                                                                                                                                 | Folplex                |                    |                    | C               |                              |                      |                 | Not Reported    |                |
|                                                                                                                                                                                                                                                                                 | Prenatal Vitamins      |                    |                    | C               |                              |                      |                 | Not Reported    |                |
|                                                                                                                                                                                                                                                                                 | Fish Oil               |                    |                    | C               |                              |                      |                 | Glaxosmithkline |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                        | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 24-Apr-2013                                                                                                                                                                                                                                                                     | 9252933                | EXPEDITED (15-DAY) |                    | OT              | US-FRI-S04-USA-08048-01      |                      | 42 YR           | Male            | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                           | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Agitation; Anxiety; Feeling Abnormal; Hallucination,                                                                                                                                                                                                                            | Lexapro                |                    |                    | S               | Oral                         |                      |                 | Forest          |                |
|                                                                                                                                                                                                                                                                                 | Lexapro                |                    |                    | S               |                              |                      |                 | Forest          |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Auditory; Homicide;  
Irritability; Nervousness;  
Withdrawal Syndrome

| <a href="#">FDA Received Date</a>                                         | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|---------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 24-Apr-2013                                                               | 9257764                 | DIRECT                    | Y                           |                          |                               |                               | 33 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>                                            | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Ineffective; Fatigue;<br>Irritability; Product<br>Substitution Issue | Escitalopram Oxalate    |                           |                             | S                        |                               |                               |                          | Torrent             |                         |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>            | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|--------------------------|---------------------------|-----------------------------|--------------------------|------------------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 25-Apr-2013                       | 7685386                  | EXPEDITED (15-DAY)        |                             | HO                       | US-BAXTER-<br>2010BH024940               |                               | 72 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                    | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Haemoglobin Decreased             | Lexapro                  |                           |                             | S                        | Oral                                     |                               |                          | Not Reported        |                         |
|                                   | Namenda                  |                           |                             | C                        | Oral                                     |                               |                          | Not Reported        |                         |
|                                   | Alendronate Sodium       |                           |                             | C                        | Oral                                     |                               |                          | Not Reported        |                         |
|                                   | Aspirine                 |                           |                             | C                        | Oral                                     |                               |                          | Not Reported        |                         |
|                                   | Folic Acid W/Vitamin B12 |                           |                             | C                        | Oral                                     |                               |                          | Not Reported        |                         |
|                                   | Loperamide Hydrochloride |                           |                             | C                        | Oral                                     |                               |                          | Not Reported        |                         |
|                                   | Calcium W/Vitamin D Nos  |                           |                             | C                        | Oral                                     |                               |                          | Not Reported        |                         |
|                                   | Exelon                   |                           |                             | C                        | Transdermal                              |                               |                          | Not Reported        |                         |
|                                   | Gammagard Liquid         |                           |                             | S                        | Intravenous (not<br>otherwise specified) | 200 Mg/ML Body Weight         |                          | Not Reported        |                         |
|                                   | Gammagard Liquid         |                           |                             | S                        | Intravenous (not<br>otherwise specified) | 200 Mg/ML Body Weight         |                          | Not Reported        |                         |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 25-Apr-2013                       | 9176089                 | EXPEDITED (15-DAY)        |                             | OT                       | CA-RB-046898-12               |                               | 32 YR                    | Female              | CAN                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |

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

|                   |                 |   |            |                   |
|-------------------|-----------------|---|------------|-------------------|
| Acute Hepatitis C | Suboxone Tablet | S | Sublingual | Reckitt Benckiser |
|                   | Suboxone Tablet | S | Sublingual | Reckitt Benckiser |
|                   | Oxazepam        | S | Oral       | Not Reported      |
|                   | Cipralelex      | S | Oral       | Not Reported      |
|                   | Valium          | S | Oral       | Not Reported      |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Apr-2013              | 9197745       | EXPEDITED (15-DAY) |                    | HO, OT          | SI-FRI-1000043815    |                      |            | Male       | SVN            |

| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Ischaemic Stroke; Seizure | Escitalopram   |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                           | Amlessa        |              |            | C           | Oral         | 4 Mg               |                 | Not Reported |
|                           | Concor Cor     |              |            | C           | Oral         | 2.5 Mg             |                 | Not Reported |
|                           | Atorvastatin   |              |            | C           | Oral         | 20 Mg              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 25-Apr-2013              | 9233819       | EXPEDITED (15-DAY) |                    | OT              | FI-PFIZER INC-2013112600 |                      | 81 YR      | Female     | FIN            |

| <u>Preferred Term</u>                                                                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiac Fibrillation; Contusion; Malaise; Mouth Swelling; Nausea; Swollen Tongue; Tremor | Xanor Depot    |              |            | S           |              | 0.5 Mg, Unk        |                 | Pfizer       |
|                                                                                          | Xanor Depot    |              |            | S           |              | 1 Mg, Unk          |                 | Pfizer       |
|                                                                                          | Xanor          |              |            | S           |              | Unk                |                 | Pfizer       |
|                                                                                          | Xanor          |              |            | S           |              | 0.5 Mg, 3x/Day     |                 | Pfizer       |
|                                                                                          | Cipralelex     |              |            | S           |              | Unk                |                 | Not Reported |
|                                                                                          | Norvasc        |              |            | C           |              |                    |                 | Not Reported |
|                                                                                          | Spirix         |              |            | C           |              |                    |                 | Not Reported |
|                                                                                          | Emconcor       |              |            | C           |              | 2.5 Mg, Unk        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Apr-2013              | 9253746       | EXPEDITED (15-DAY) |                    | DS, HO, LT      | CA-BAYER-2013-048886 |                      |            | Female     | CAN            |

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

| <u>Preferred Term</u>                                                | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
|----------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|--------------------------------|--------------------------------|-----------------|--------------|----------------|
| Pulmonary Embolism                                                   | Mirena         |                    |                    | S               | Intra-uterine                  | 20 Mcg/24hr, Cont              |                 | Bayer        |                |
|                                                                      | Cipralex       |                    |                    | S               | Oral                           | 20mg 1 Tablet, Qd              |                 | Not Reported |                |
|                                                                      | Pariet         |                    |                    | C               |                                |                                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Apr-2013                                                          | 9254079        | EXPEDITED (15-DAY) |                    | HO              | FR-SANOFI-AVENTIS-2013SA041573 |                                | 93 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State;<br>Hyponatraemia                                  | Lasilix        |                    |                    | S               | Oral                           | Strength:40mg Dose:1 Unit(S)   |                 | Not Reported |                |
|                                                                      | Perindopril    |                    |                    | S               | Oral                           | Strength:4mg Dose:1 Unit(S)    |                 | Not Reported |                |
|                                                                      | Omeprazole     |                    |                    | S               | Oral                           | Strength:20mg Dose:1 Unit(S)   |                 | Not Reported |                |
|                                                                      | Seroplex       |                    |                    | S               | Oral                           | Strength:5mg Dose:1 Unit(S)    |                 | Not Reported |                |
|                                                                      | Crestor        |                    |                    | S               | Oral                           | Strength: 10mg Dose:1 Unit(S)  |                 | Not Reported |                |
|                                                                      | Bisoce         |                    |                    | C               | Oral                           | Strength: 2.5mg Dose:2 Unit(S) |                 | Not Reported |                |
|                                                                      | Kardegic       |                    |                    | C               | Oral                           | Strength: 75mg Dose:1 Unit(S)  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Apr-2013                                                          | 9254691        | EXPEDITED (15-DAY) |                    | OT              | DE-FRI-1000044591              |                                |                 | Female       | DEU            |
| <u>Preferred Term</u>                                                | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Symmetrical Drug-Related<br>Intertriginous And Flexural<br>Exanthema | Escitalopram   |                    |                    | S               | Oral                           | 5 Mg                           |                 | Forest       |                |
|                                                                      | Quetiapin      |                    |                    | C               | Oral                           | 50 Mg                          |                 | Not Reported |                |
|                                                                      | Quetiapin      |                    |                    | C               | Oral                           | 100 Mg                         |                 | Not Reported |                |
|                                                                      | Quetiapin      |                    |                    | C               | Oral                           | 150 Mg                         |                 | Not Reported |                |

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

|           |   |               |           |              |
|-----------|---|---------------|-----------|--------------|
| Quetiapin | C | Oral          | 300 Mg    | Not Reported |
| Quetiapin | C | Oral          | 100 Mg    | Not Reported |
| Xeplion   | C | Intramuscular | 0.8929 Mg | Not Reported |
| Xeplion   | C | Intramuscular | 1.7857 Mg | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Apr-2013              | 9255075       | EXPEDITED (15-DAY) |                    | HO, LT          | FR-FRI-1000044672    |                      | 88 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u>                    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-----------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Bicytopenia           | Escitalopram                      |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                       | Oflocet                           |              |            | S           | Oral         | 400 Mg             |                 | Not Reported |
|                       | Loxen (Nicardipine Hydrochloride) |              |            | S           | Oral         | 100 Mg             |                 | Not Reported |
|                       | Haldol                            |              |            | S           | Oral         | 6 Df               |                 | Not Reported |
|                       | Xanax                             |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Apr-2013              | 9255105       | EXPEDITED (15-DAY) |                    | HO              | AU-FRI-1000044673    |                      | 77 YR      | Female     | AUS            |

| <u>Preferred Term</u>                                         | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Headache; Hyperhidrosis; Polyuria; Serotonin Syndrome; Tremor | Escitalopram           |              |            | S           | Oral         | 20 Mg              |                 | Forest       |
|                                                               | Escitalopram           |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                                               | Tramadol Hydrochloride |              |            | S           | Oral         | 200 Mg             |                 | Not Reported |
|                                                               | Paracetamol            |              |            | C           |              | 1995 Mg            |                 | Not Reported |
|                                                               | Vitamin B12 Nos        |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Apr-2013              | 9255126       | EXPEDITED (15-DAY) |                    | HO              | AU-FRI-1000044696    |                      | 17 YR      | Female     | AUS            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Contusion             | Escitalopram   |              |            | S           |              | 20 Mg              |                 | Forest     |

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| Ethinyloestradiol-Levonorgestrol<br>Ibuprofen         |                         |                           | C<br>C                      |                          | Not Reported<br>Not Reported  |                               |                          |                     |                         |
|-------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| <a href="#">FDA Received Date</a>                     | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 25-Apr-2013                                           | 9255169                 | EXPEDITED (15-DAY)        |                             | HO                       | FR-FRI-1000044675             |                               | 61 YR                    | Female              | FRA                     |
| <a href="#">Preferred Term</a>                        | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Balance Disorder;<br>Hyponatraemia                    | Escitalopram            |                           |                             | S                        | Oral                          |                               |                          | Forest              |                         |
|                                                       | Deroxat                 |                           |                             | S                        | Oral                          | 0.5 Df                        |                          | Not Reported        |                         |
|                                                       | Nisisco                 |                           |                             | S                        | Oral                          | 160 Mg/12.5 Mg                |                          | Not Reported        |                         |
|                                                       | Seresta                 |                           |                             | C                        | Oral                          | Dose Increased                |                          | Not Reported        |                         |
|                                                       | Zocor                   |                           |                             | C                        | Oral                          | 1 Df                          |                          | Not Reported        |                         |
|                                                       | Stilnox                 |                           |                             | C                        | Oral                          |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                     | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 25-Apr-2013                                           | 9255193                 | EXPEDITED (15-DAY)        |                             | HO                       | CA-FRI-1000044697             |                               | 14 YR                    | Female              | CAN                     |
| <a href="#">Preferred Term</a>                        | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Agitation; Cold Sweat; Off<br>Label Use; Palpitations | Escitalopram            |                           |                             | S                        | Oral                          |                               |                          | Forest              |                         |
| <a href="#">FDA Received Date</a>                     | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 25-Apr-2013                                           | 9255997                 | EXPEDITED (15-DAY)        |                             | OT                       | FR-FRI-1000044681             |                               | 89 YR                    | Female              | FRA                     |
| <a href="#">Preferred Term</a>                        | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Spontaneous Haematoma                                 | Escitalopram            |                           |                             | S                        | Oral                          | 5 Mg                          |                          | Forest              |                         |
|                                                       | Oxycontin               |                           |                             | C                        |                               | 5 Mg                          |                          | Not Reported        |                         |
|                                                       | Doliprane               |                           |                             | C                        |                               | 3 Gram                        |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                     | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 25-Apr-2013                                           | 9262431                 | DIRECT                    | Y                           | OT                       |                               |                               | 30 YR                    | Male                | USA                     |

# FDA Adverse Event Reporting System

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| <u>Preferred Term</u>                                                                                                              | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
|------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------------|-----------------------------|-----------------|--------------|----------------|
| Feeling Abnormal;<br>Impaired Work Ability;<br>Product Substitution Issue                                                          | Escitalopram           |                    |                    | S               | Oral                       | 1                           |                 | Mylan        |                |
| <u>FDA Received Date</u>                                                                                                           | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Apr-2013                                                                                                                        | 9256745                | EXPEDITED (15-DAY) |                    | HO, OT          | IT-009507513-1304ITA015121 |                             | 53 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                                                                              | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Coma; Hyperthermia<br>Malignant; Hypertonia;<br>Musculoskeletal Stiffness;<br>Neuroleptic Malignant<br>Syndrome;<br>Rhabdomyolysis | Remeron                |                    |                    | S               | Oral                       | 30 Mg, Qd                   |                 | Merck        |                |
|                                                                                                                                    | Remeron                |                    |                    | S               |                            |                             |                 | Merck        |                |
|                                                                                                                                    | Tolep                  |                    |                    | S               | Oral                       | 300 Mg, Qd                  |                 | Not Reported |                |
|                                                                                                                                    | Tolep                  |                    |                    | S               |                            |                             |                 | Not Reported |                |
|                                                                                                                                    | Largactil              |                    |                    | S               | Intramuscular              | 50 Mg, Total                |                 | Not Reported |                |
|                                                                                                                                    | Largactil              |                    |                    | S               |                            |                             |                 | Not Reported |                |
|                                                                                                                                    | Cipralelex             |                    |                    | S               | Oral                       | 10 Mg, Qd                   |                 | Not Reported |                |
|                                                                                                                                    | Cipralelex             |                    |                    | S               |                            |                             |                 | Not Reported |                |
|                                                                                                                                    | Xeristar               |                    |                    | S               | Oral                       | 60 Mg, Qd                   |                 | Not Reported |                |
|                                                                                                                                    | Xeristar               |                    |                    | S               |                            |                             |                 | Not Reported |                |
|                                                                                                                                    | Serenase (Haloperidol) |                    |                    | S               | Intramuscular              | 5 Mg Taken As A Single Dose |                 | Not Reported |                |
|                                                                                                                                    | Serenase               |                    |                    | S               |                            |                             |                 | Not Reported |                |
|                                                                                                                                    | Dominans               |                    |                    | S               | Oral                       | 10.5 Mg, Qd                 |                 | Not Reported |                |
| Dominans                                                                                                                           |                        |                    | S                  |                 |                            |                             | Not Reported    |              |                |
| Lithium Carbonate                                                                                                                  |                        |                    | S                  | Oral            | 300 Mg, Qd                 |                             | Not Reported    |              |                |
| Lithium Carbonate                                                                                                                  |                        |                    | S                  |                 |                            |                             | Not Reported    |              |                |
| Lamotrigine                                                                                                                        |                        |                    | S                  | Oral            | 100 Mg, Qd                 |                             | Not Reported    |              |                |
| <u>FDA Received Date</u>                                                                                                           | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Apr-2013                                                                                                                        | 9262741                | EXPEDITED (15-DAY) |                    | HO              | SYM-2013-03023             |                             | 38 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                              | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrial Fibrillation;                                                                                                               | Wellbutrin             |                    |                    | S               | Oral                       |                             |                 | Not Reported |                |



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|                           |                               |   |              |
|---------------------------|-------------------------------|---|--------------|
| Imprisonment;             | Ativan                        | S | Not Reported |
| Investigation; Myocardial | Effexor                       | S | Not Reported |
| Infarction;               | Ambien                        | S | Not Reported |
| Nasopharyngitis; Panic    | Adderall (Obetrol /01345401/) | S | Not Reported |
| Attack; Stress; Suicidal  | Concerta                      | S | Not Reported |
| Ideation; Suicide Attempt | Trileptal                     | S | Not Reported |
|                           | Lithium Salt                  | S | Not Reported |
|                           | Depakote                      | S | Not Reported |
|                           | Zyprexa                       | S | Not Reported |
|                           | Lexapro                       | S | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>                              | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|--------------------------------------------|------------------|--------------------|-----------------|----------------------|----------------------------------------------|-----------------|--------------|----------------|
| 26-Apr-2013              | 9531103                                    | NON-EXPEDITED    | Y                  | DE              | 2013-00615           |                                              | 54 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>                             | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                           | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide        | Quetiapine (Quetiapine Fumarate) (Unknown) |                  |                    | S               |                      | Unknown (Unknown, Unknown, Unknown), Unknown |                 | Not Reported |                |
|                          | Escitalopram (Unknown)                     |                  |                    | S               |                      |                                              |                 | Not Reported |                |
|                          | Gabapentin (Unknown)                       |                  |                    | S               |                      | Unknown (Unknown, Unknown, Unknown), Unknown |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>                   | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|---------------------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 26-Apr-2013              | 9531215                         | NON-EXPEDITED    | Y                  | DE              | 2013-00321           |                      | 23 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>                  | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide        | Quetiapine (Unknown)            |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                          | Escitalopram (Unknown)          |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                          | Acetaminophen/Codeine (Unknown) |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                          | Metaxalone                      |                  |                    | S               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Apr-2013              | 9531395       | NON-EXPEDITED    | Y                  | DE              | 2013-00598           |                      | 18 YR      | Male       | USA            |

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| <u>Preferred Term</u>                                                                                                                                                                | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
| Death                                                                                                                                                                                | Quetiapine (Unknown)      |                    |                    | S               |                           |                      |                 | Not Reported |                |
|                                                                                                                                                                                      | Escitalopram (Unknown)    |                    |                    | S               |                           |                      |                 | Not Reported |                |
|                                                                                                                                                                                      | Valproic Acid             |                    |                    | C               |                           |                      |                 | Not Reported |                |
|                                                                                                                                                                                      | Chlorpromazine            |                    |                    | S               |                           |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                             | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Apr-2013                                                                                                                                                                          | 9531443                   | NON-EXPEDITED      | Y                  | DE              | 2013-00609                |                      | 42 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                                                                                                                                                    | Quetiapine (Unknown)      |                    |                    | S               |                           |                      |                 | Not Reported |                |
|                                                                                                                                                                                      | Escitalopram (Unknown)    |                    |                    | S               |                           |                      |                 | Not Reported |                |
|                                                                                                                                                                                      | Citalopram (Unknown)      |                    |                    | S               |                           |                      |                 | Not Reported |                |
|                                                                                                                                                                                      | (Citalopram)              |                    |                    |                 |                           |                      |                 |              |                |
|                                                                                                                                                                                      | Hydroxyzine (Unknown)     |                    |                    | S               |                           |                      |                 | Not Reported |                |
|                                                                                                                                                                                      | Buspirone                 |                    |                    | S               |                           |                      |                 | Not Reported |                |
|                                                                                                                                                                                      | Cyclobenzaprine (Unknown) |                    |                    | S               |                           |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                             | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Apr-2013                                                                                                                                                                          | 8808036                   | EXPEDITED (15-DAY) |                    | OT              | GB-MYLANLABS-2012S1019037 |                      | 66 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                                                                                                                                | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Balance Disorder;<br>Circulatory Collapse;<br>Condition Aggravated;<br>Dizziness; Drug<br>Interaction; Gait<br>Disturbance; Headache;<br>Malaise; Nausea; Speech<br>Disorder; Tremor | Buspirone                 |                    |                    | S               | Oral                      |                      |                 | Mylan        |                |
|                                                                                                                                                                                      | Valium                    |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                      | Escitalopram              |                    |                    | S               |                           |                      |                 | Not Reported |                |
|                                                                                                                                                                                      | Lithium Carbonate         |                    |                    | C               | Oral                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                      | Lofepramine               |                    |                    | C               | Oral                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                      | Atorvastatin              |                    |                    | C               | Oral                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                      |                           |                    |                    |                 |                           |                      |                 |              |                |
| <u>FDA Received Date</u>                                                                                                                                                             | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Apr-2013                                                                                                                                                                          | 9261841                   | EXPEDITED (15-DAY) |                    | OT              | NZ-MYLANLABS-2013S1008327 |                      |                 | Female       | NZL            |
| <u>Preferred Term</u>                                                                                                                                                                | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

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|                                                                                                                                                                                    |                |                    |                    |                 |                      |                      |                 |              |                |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Hallucination, Auditory;<br>Mood Altered; Personality<br>Disorder; Somnolence                                                                                                      | Loxalate       | S                  | Oral               |                 | Mylan                |                      |                 |              |                |
|                                                                                                                                                                                    | Epilim         | C                  |                    |                 | Not Reported         |                      |                 |              |                |
| <u>FDA Received Date</u>                                                                                                                                                           | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Apr-2013                                                                                                                                                                        | 9261943        | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000044723    |                      | < 1 DAY         | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                              | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Attention<br>Deficit/Hyperactivity<br>Disorder; Autism<br>Spectrum Disorder;<br>Craniosynostosis;<br>Depression; Headache;<br>Language Disorder;<br>Nausea; Schizophrenia | Lexapro        |                    |                    | S               | Transplacental       |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                                                                           | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Apr-2013                                                                                                                                                                        | 9263883        | DIRECT             |                    |                 |                      |                      | 62 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                              | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective; Product<br>Quality Issue; Product<br>Substitution Issue                                                                                                          | Escitalopram   |                    |                    | S               | Oral                 |                      |                 | Teva         |                |
| <u>FDA Received Date</u>                                                                                                                                                           | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Apr-2013                                                                                                                                                                        | 9248813        | EXPEDITED (15-DAY) |                    | OT              | US-FRI-1000044644    |                      | 50 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                              | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bronchitis; Chest Pain;<br>Hypertension                                                                                                                                            | Lexapro        |                    |                    | S               | Oral                 | 20 Mg                |                 | Forest       |                |
|                                                                                                                                                                                    | Opc-34712      |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                                                                                    | Opc-34712      |                    |                    | S               | Oral                 | 1 Mg                 |                 | Not Reported |                |
|                                                                                                                                                                                    | Lisinopril     |                    |                    | C               | Oral                 | 20 Mg                |                 | Not Reported |                |
|                                                                                                                                                                                    | Coreg          |                    |                    | C               | Oral                 | 6.25 Mg              |                 | Not Reported |                |

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|                                  |                   |                    |                    |                 |                            |                      |                 |              |                |
|----------------------------------|-------------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| Acetaminophen                    |                   |                    | C                  |                 | 500 Mg                     |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>         | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Apr-2013                      | 9264295           | EXPEDITED (15-DAY) | CA                 |                 | US-FRI-1000044725          |                      | < 1 DAY         | Female       | USA            |
| <u>Preferred Term</u>            | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cleft Palate                     | Lexapro           |                    |                    | S               | Transplacental             |                      |                 | Forest       |                |
| <u>FDA Received Date</u>         | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-May-2013                      | 9163993           | EXPEDITED (15-DAY) | LT                 |                 | JP-FRI-1000043367          |                      | 47 YR           | Female       | JPN            |
| <u>Preferred Term</u>            | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Altered State Of Consciousness   | Lexapro           |                    |                    | S               | Oral                       | 10 Mg                |                 | Forest       |                |
|                                  | Amoxan            |                    |                    | C               | Oral                       | 100 Mg               |                 | Not Reported |                |
|                                  | Tofranil          |                    |                    | C               | Oral                       | 25 Mg                |                 | Not Reported |                |
|                                  | Tofranil          |                    |                    | C               | Oral                       | 150 Mg               |                 | Not Reported |                |
|                                  | Tetramide         |                    |                    | C               | Oral                       | 20 Mg                |                 | Not Reported |                |
|                                  | Tryptanol         |                    |                    | C               | Oral                       | 10 Mg                |                 | Not Reported |                |
|                                  | Lithium Carbonate |                    |                    | C               | Oral                       | 100 Mg               |                 | Not Reported |                |
|                                  | Dogmatyl          |                    |                    | C               | Oral                       |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>         | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-May-2013                      | 9265440           | EXPEDITED (15-DAY) | HO                 |                 | FR-ASTRAZENECA-2013SE28443 |                      | 93 YR           | Female       | FRA            |
| <u>Preferred Term</u>            | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State; Hyponatraemia | Omeprazole        |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                  | Crestor           |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                  | Seroplex          |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                  | Perindopril       |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                  | Perindopril       |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |

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|                                                                                           | Lasilix               |                    | S                  | Oral            |                      |                      |                 | Not Reported |                |
|-------------------------------------------------------------------------------------------|-----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
|                                                                                           | Bisoce                |                    | C                  | Oral            |                      |                      |                 | Not Reported |                |
|                                                                                           | Kardegic              |                    | C                  | Oral            |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                  | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-May-2013                                                                               | 9274767               | DIRECT             |                    | OT              |                      |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                     | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Irritability; Product Substitution Issue                                                  | Escitalopram          |                    |                    | S               |                      |                      |                 | Teva         |                |
| <u>FDA Received Date</u>                                                                  | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-May-2013                                                                               | 9274819               | DIRECT             |                    |                 |                      |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                                     | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Depressed Mood; Disease Recurrence; Drug Ineffective; Product Substitution Issue | Lexapro               |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                  | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-May-2013                                                                               | 9275390               | DIRECT             |                    | HO, LT          |                      |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                     | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Chest Pain; Headache; Insomnia; Withdrawal Syndrome                              | Lexapro               |                    |                    | S               |                      |                      | 1.5 YR          | Not Reported |                |
|                                                                                           | Prempro               |                    |                    | S               |                      |                      | 1 YR            | Not Reported |                |
| <u>FDA Received Date</u>                                                                  | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-May-2013                                                                               | 9276695               | EXPEDITED (15-DAY) |                    | OT              | SYM-2013-03220       |                      | 34 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                     | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abortion Spontaneous;                                                                     | Wellbutrin (Bupropion |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |



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| <u>FDA Received Date</u>                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 02-May-2013                                | 8940841        | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000040755    |                      | 46 YR           | Female       | FRA            |
| <u>Preferred Term</u>                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Loss Of Consciousness;<br>Weight Decreased | Escitalopram   |                    |                    | S               | Oral                 | 5 Mg                 |                 | Forest       |                |
|                                            | Escitalopram   |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                            | Escitalopram   |                    |                    | S               | Oral                 | 15 Mg                |                 | Forest       |                |
|                                            | Lexomil        |                    |                    | C               | Oral                 | 0.25 Mg              |                 | Not Reported |                |

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

| <u>FDA Received Date</u>                                                                                                                                                                        | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|----------------------|-----------------------------|-----------------|--------------|----------------|
| 02-May-2013                                                                                                                                                                                     | 9267334                   | EXPEDITED (15-DAY) |                    | HO              | DE-BANPHARM-20131221 |                             | 39 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                                                                                                                                                           | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Initial Insomnia; Middle Insomnia; Oedema Peripheral; Peripheral Swelling                                                                                                                       | Ibuprofen Unknown Product |                    |                    | S               | Oral                 | 1600 Mg Qd, Several Months, |                 | Not Reported |                |
|                                                                                                                                                                                                 | Remergil                  |                    |                    | S               |                      | 15 Mg, Qd,                  |                 | Not Reported |                |
|                                                                                                                                                                                                 | Remergil                  |                    |                    | S               |                      | 30 Mg,Qd                    |                 | Not Reported |                |
|                                                                                                                                                                                                 | Remergil                  |                    |                    | S               | Oral                 | 15 Mg, Qd,                  |                 | Not Reported |                |
|                                                                                                                                                                                                 | Cipralext                 |                    |                    | S               | Oral                 | 20 Mg Qd, Quite Some Time   |                 | Not Reported |                |
|                                                                                                                                                                                                 | Pantozol                  |                    |                    | C               | Oral                 | 40 Mg, Qd,                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                        | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-May-2013                                                                                                                                                                                     | 9268603                   | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000044727    |                             |                 | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                           | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Talipes                                                                                                                                                                                         | Lexapro                   |                    |                    | S               | Transplacental       |                             |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                                                                                        | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-May-2013                                                                                                                                                                                     | 9275636                   | DIRECT             |                    | DS              |                      |                             | 53 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                           | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Adrenocortical Insufficiency Acute; Anxiety; Decreased Appetite; Dry Mouth; Fear; Flat Affect; Headache; Insomnia; Major Depression; Mood Altered; Muscle Twitching; Palpitations; Panic Attack | Lexapro                   |                    |                    | S               | Oral                 | 5 Milligrams Once Daily Po  |                 | Not Reported |                |

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

| <u>FDA Received Date</u>                                                                                                                                                                         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 03-May-2013                                                                                                                                                                                      | 9173341        | EXPEDITED (15-DAY) |                    | CA, HO, OT      | US-JNJFOC-20130310413 |                      |                 | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrial Septal Defect;<br>Audiogram Abnormal;<br>Choanal Atresia;<br>Deformity; Emotional<br>Distress; Heart Valve<br>Incompetence; Nasal<br>Septum Deviation; Pain;<br>Social Avoidant Behaviour | Topamax        |                    |                    | S               | Transplacental        |                      |                 | Not Reported |                |
|                                                                                                                                                                                                  | Focalin Xr     |                    |                    | S               | Transplacental        |                      |                 | Not Reported |                |
|                                                                                                                                                                                                  | Metoclopramide |                    |                    | S               | Transplacental        |                      |                 | Not Reported |                |
|                                                                                                                                                                                                  | Clonazepam     |                    |                    | S               | Transplacental        |                      |                 | Not Reported |                |
|                                                                                                                                                                                                  | Lexapro        |                    |                    | S               | Transplacental        |                      |                 | Not Reported |                |
|                                                                                                                                                                                                  | Klonopin       |                    |                    | S               | Transplacental        |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-May-2013                                                                                                                                                                                      | 9247366        | EXPEDITED (15-DAY) |                    | OT              | US-JNJFOC-20130310412 |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Emotional Disorder;<br>Exposure During<br>Pregnancy                                                                                                                                              | Topamax        |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                                                                                                                  | Focalin Xr     |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                                                                                                                  | Focalin Xr     |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                                                                                                                  | Metoclopramide |                    |                    | S               | Unknown               |                      |                 | Not Reported |                |
|                                                                                                                                                                                                  | Clonazepam     |                    |                    | S               | Unknown               |                      |                 | Not Reported |                |
|                                                                                                                                                                                                  | Lexapro        |                    |                    | S               | Unknown               |                      |                 | Not Reported |                |
|                                                                                                                                                                                                  | Klonopin       |                    |                    | S               | Unknown               |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-May-2013                                                                                                                                                                                      | 9269743        | EXPEDITED (15-DAY) |                    | OT              | GB-FRI-1000044890     |                      | 66 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                                                                                                                                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Balance Disorder;<br>Circulatory Collapse;<br>Condition Aggravated;                                                                                                                              | Escitalopram   |                    |                    | S               | Oral                  |                      |                 | Forest       |                |
|                                                                                                                                                                                                  | Buspirone      |                    |                    | S               | Oral                  | 15 Mg                |                 | Not Reported |                |



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|                                                                                                   |                   |   |      |        |              |
|---------------------------------------------------------------------------------------------------|-------------------|---|------|--------|--------------|
| Dizziness; Drug Interaction; Gait Disturbance; Headache; Malaise; Nausea; Speech Disorder; Tremor | Valium            | S | Oral | 10 Mg  | Not Reported |
|                                                                                                   | Atorvastatin      | C | Oral |        | Not Reported |
|                                                                                                   | Lithium Carbonate | C | Oral | 400 Mg | Not Reported |
|                                                                                                   | Lofepamine        | C | Oral | 70 Mg  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 03-May-2013              | 9269892       | EXPEDITED (15-DAY) |                    | OT              | SE-JNJFOC-20130411076 |                      | 25 YR      | Male       | SWE            |

| <u>Preferred Term</u>                                                                                                                             | <u>Product</u>   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>  | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------|------------------|--------------|------------|-------------|---------------|--------------------|-----------------|--------------|
| Blunted Affect; General Physical Condition Abnormal; Hypersomnia; Increased Appetite; Laziness; Sluggishness; Suicidal Ideation; Weight Increased | Xeplion          |              |            | S           | Intramuscular |                    |                 | Not Reported |
|                                                                                                                                                   | Xeplion          |              |            | S           | Intramuscular |                    |                 | Not Reported |
|                                                                                                                                                   | Xeplion          |              |            | S           | Intramuscular |                    |                 | Not Reported |
|                                                                                                                                                   | Haldol           |              |            | S           | Oral          |                    |                 | Not Reported |
|                                                                                                                                                   | Haldol           |              |            | S           | Oral          |                    |                 | Not Reported |
|                                                                                                                                                   | Haldol           |              |            | S           | Oral          |                    |                 | Not Reported |
|                                                                                                                                                   | Haldol           |              |            | S           | Intramuscular |                    |                 | Not Reported |
|                                                                                                                                                   | Haldol           |              |            | S           | Intramuscular |                    |                 | Not Reported |
|                                                                                                                                                   | Haldol           |              |            | S           | Intramuscular |                    |                 | Not Reported |
|                                                                                                                                                   | Risperdal        |              |            | S           | Oral          |                    |                 | Not Reported |
|                                                                                                                                                   | Risperdal        |              |            | S           | Oral          |                    |                 | Not Reported |
|                                                                                                                                                   | Risperdal        |              |            | S           | Oral          |                    |                 | Not Reported |
|                                                                                                                                                   | Risperdal Consta |              |            | S           | Intramuscular |                    |                 | Not Reported |
|                                                                                                                                                   | Risperdal Consta |              |            | S           | Intramuscular |                    |                 | Not Reported |
|                                                                                                                                                   | Risperdal Consta |              |            | S           | Intramuscular |                    |                 | Not Reported |
|                                                                                                                                                   | Abilify          |              |            | S           | Unknown       |                    |                 | Not Reported |
|                                                                                                                                                   | Abilify          |              |            | S           | Unknown       |                    |                 | Not Reported |
|                                                                                                                                                   | Abilify          |              |            | S           | Unknown       |                    |                 | Not Reported |
|                                                                                                                                                   | Cisordinol       |              |            | S           | Unknown       |                    |                 | Not Reported |
|                                                                                                                                                   | Cisordinol       |              |            | S           | Unknown       |                    |                 | Not Reported |

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

|            |   |         |              |
|------------|---|---------|--------------|
| Cisordinol | S | Unknown | Not Reported |
| Trilafon   | S | Unknown | Not Reported |
| Trilafon   | S | Unknown | Not Reported |
| Trilafon   | S | Unknown | Not Reported |
| Cipralelex | S | Unknown | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-May-2013              | 9270561       | EXPEDITED (15-DAY) | HO                 |                 | PHHY2013IT041560     |                      |            | Female     | ITA            |

| <u>Preferred Term</u>                                                                                                                   | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>  | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------|------------|-------------|---------------|--------------------|-----------------|--------------|
| Coma; Confusional State; Hyperpyrexia; Musculoskeletal Stiffness; Myoclonus; Psychomotor Hyperactivity; Rhabdomyolysis; Tremor; Vertigo | Tolep                  |              |            | S           | Oral          | 300 Mg, Daily      |                 | Novartis     |
|                                                                                                                                         | Lamotrigine            |              |            | S           | Oral          | 100 Mg, Daily      |                 | Not Reported |
|                                                                                                                                         | Carbolithium           |              |            | S           | Oral          | 300 Mg, Daily      |                 | Not Reported |
|                                                                                                                                         | Dominans               |              |            | S           | Oral          | 10.5 Mg, Daily     |                 | Not Reported |
|                                                                                                                                         | Serenase (Haloperidol) |              |            | S           | Intramuscular | 5 Mg, Total        |                 | Not Reported |
|                                                                                                                                         | Xeristar               |              |            | S           | Oral          | 60 Mg, Daily       |                 | Not Reported |
|                                                                                                                                         | Cipralelex             |              |            | S           | Oral          | 10 Mg, Daily       |                 | Not Reported |
|                                                                                                                                         | Largactil              |              |            | S           | Intramuscular | 50 Mg, Total       |                 | Not Reported |
|                                                                                                                                         | Remeron                |              |            | S           | Oral          | 30 Mg, Daily       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-May-2013              | 9270850       | EXPEDITED (15-DAY) | HO                 |                 | IT-WATSON-2013-07481 |                      | 53 YR      | Female     | ITA            |

| <u>Preferred Term</u>                                                                                                                                                       | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Coma; Confusional State; Hyperthermia Malignant; Hypertonia; Muscle Rigidity; Myoclonus; Neuroleptic Malignant Syndrome; Psychomotor Hyperactivity; Rhabdomyolysis; Tremor; | Lamotrigine (Unknown) |              |            | S           | Oral         | 100 Mg, Daily      |                 | Watson       |
|                                                                                                                                                                             | Tolep                 |              |            | S           | Oral         | 300 Mg, Daily      |                 | Not Reported |
|                                                                                                                                                                             | Carbolithium          |              |            | S           | Oral         | 300 Mg, Daily      |                 | Not Reported |
|                                                                                                                                                                             | Dominans              |              |            | S           | Oral         | 10.5 Mg, Daily     |                 | Not Reported |
|                                                                                                                                                                             | Remeron               |              |            | S           | Oral         | 30 Mg, Daily       |                 | Not Reported |
|                                                                                                                                                                             | Cipralelex            |              |            | S           | Oral         | 10 Mg, Daily       |                 | Not Reported |

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

|         |                      |   |               |                       |              |
|---------|----------------------|---|---------------|-----------------------|--------------|
| Vertigo | Largactil /00011901/ | S | Intramuscular | 50 Mg, Unknown, Total | Not Reported |
|         | Serenase /00015301/  | S | Intramuscular | 5 Mg Total            | Not Reported |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 03-May-2013                       | 9277348                | DIRECT                    | Y                           |                          |                               |                               |                     | Female              | USA                     |

| <a href="#">Preferred Term</a>                                                                                     | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------------------------------------------------------------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Anxiety; Condition Aggravated; Product Substitution Issue; Therapeutic Product Effect Decreased; Unevaluable Event | Escitalopram 10 Mg      |                       |                     | S                    | Oral                  |                             | 1 MTH                    | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 03-May-2013                       | 9277410                | DIRECT                    |                             | OT                       |                               |                               | 22 YR               | Male                | USA                     |

| <a href="#">Preferred Term</a>                                                  | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|---------------------------------------------------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Drug Withdrawal Syndrome; Product Formulation Issue; Product Substitution Issue | Lexapro                 |                       |                     | S                    |                       |                             |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 06-May-2013                       | 9271912                | EXPEDITED (15-DAY)        |                             | HO                       | IT-TEVA-400688ISR             |                               | 53 YR               | Female              | ITA                     |

| <a href="#">Preferred Term</a>                                                       | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------------------------------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Coma; Confusional State;                                                             | Carbolithium            |                       |                     | S                    | Oral                  | 300 Milligram Daily;        |                          | Barr                |
| Hyperpyrexia; Muscle Rigidity; Psychomotor Hyperactivity; Reduced Facial Expression; | Lamotrigina             |                       |                     | S                    | Oral                  | 100 Milligram Daily;        |                          | Not Reported        |
| Rhabdomyolysis; Tremor; Vertigo                                                      | Dominans                |                       |                     | S                    | Oral                  | 10.5 Milligram Daily;       |                          | Not Reported        |
|                                                                                      | Serenase (Haloperidol)  |                       |                     | S                    | Intramuscular         | 5 Milligram Daily;          |                          | Not Reported        |
|                                                                                      | Xeristar                |                       |                     | S                    | Oral                  | 60 Milligram Daily;         |                          | Not Reported        |
|                                                                                      | Cipralelex              |                       |                     | S                    | Oral                  | 10 Milligram Daily;         |                          | Not Reported        |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|           |   |               |                      |              |
|-----------|---|---------------|----------------------|--------------|
| Largactil | S | Intramuscular | 50 Milligram Daily;  | Not Reported |
| Tolep     | S | Oral          | 300 Milligram Daily; | Not Reported |
| Remeron   | S | Oral          | 30 Milligram Daily;  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-May-2013              | 9272084       | EXPEDITED (15-DAY) | HO                 |                 | IT-FRI-1000044935    |                      | 53 YR      | Female     | ITA            |

| <u>Preferred Term</u>                                                                                                    | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>  | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------|------------------------|--------------|------------|-------------|---------------|--------------------|-----------------|--------------|
| Coma; Hyperthermia<br>Malignant; Hypertonia;<br>Muscle Rigidity;<br>Neuroleptic Malignant<br>Syndrome;<br>Rhabdomyolysis | Escitalopram           |              |            | S           | Oral          | 10 Mg              |                 | Forest       |
|                                                                                                                          | Dominans               |              |            | S           | Oral          | 10.5 Mg            |                 | Not Reported |
|                                                                                                                          | Carbolithium           |              |            | S           | Oral          | 300 Mg             |                 | Not Reported |
|                                                                                                                          | Lamotrigina            |              |            | S           | Oral          | 100 Mg             |                 | Not Reported |
|                                                                                                                          | Serenase (Haloperidol) |              |            | S           | Intramuscular | 5 Mg               |                 | Not Reported |
|                                                                                                                          | Xeristar               |              |            | S           | Oral          | 60 Mg              |                 | Not Reported |
|                                                                                                                          | Largactil              |              |            | S           | Intramuscular | 50 Mg              |                 | Not Reported |
|                                                                                                                          | Tolep                  |              |            | S           | Oral          | 300 Mg             |                 | Not Reported |
|                                                                                                                          | Remeron                |              |            | S           | Oral          | 30 Mg              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------------|----------------------|------------|------------|----------------|
| 06-May-2013              | 9272582       | EXPEDITED (15-DAY) | HO                 |                 | IT-GLAXOSMITHKLINE-<br>B0889138A |                      | 53 YR      | Female     | ITA            |

| <u>Preferred Term</u>                                                                                                                          | <u>Product</u>               | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>  | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|--------------|------------|-------------|---------------|--------------------|-----------------|-----------------|
| Coma; Confusional State;<br>Dizziness; Hyperpyrexia;<br>Muscle Rigidity;<br>Myoclonus; Psychomotor<br>Hyperactivity;<br>Rhabdomyolysis; Tremor | Lamotrigine                  |              |            | S           | Oral          | 100mg Per Day      |                 | Glaxosmithkline |
|                                                                                                                                                | Carbolithium                 |              |            | S           | Oral          | 300mg Per Day      |                 | Glaxosmithkline |
|                                                                                                                                                | Escitalopram Oxalate         |              |            | S           | Oral          | 10mg Per Day       |                 | Glaxosmithkline |
|                                                                                                                                                | Duloxetine Hydrochloride     |              |            | S           | Oral          | 60mg Per Day       |                 | Glaxosmithkline |
|                                                                                                                                                | Fluphenazine + Nortriptyline |              |            | S           | Oral          | 10.5mg Per Day     |                 | Glaxosmithkline |
|                                                                                                                                                | Chlorpromazine Hydrochloride |              |            | S           | Oral          | 10mg Per Day       |                 | Glaxosmithkline |
|                                                                                                                                                | Mirtazapine                  |              |            | S           | Oral          | 30mg Per Day       |                 | Not Reported    |
|                                                                                                                                                | Haloperidol                  |              |            | S           | Intramuscular | 5mg Per Day        |                 | Not Reported    |

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

|                                                                                                                                                                                                                                                                                  |                |                    |                    |                 |                                       |                      |                 |              |                |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|---------------------------------------|----------------------|-----------------|--------------|----------------|
| Oxcarbazepine                                                                                                                                                                                                                                                                    |                |                    | S                  | Oral            | 300mg Per Day                         |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-May-2013                                                                                                                                                                                                                                                                      | 9287973        | EXPEDITED (15-DAY) | Y                  | HO, LT, OT      | 2013P1005232                          |                      | 31 YR           | Male         | CHE            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain Upper; C-Reactive Protein Increased; Choking; Electrocardiogram T Wave Inversion; Faecaloma; Generalised Tonic-Clonic Seizure; Hypokalaemia; Hypomagnesaemia; Nausea; Stress Cardiomyopathy; Torsade De Pointes; Unresponsive To Stimuli; Ventricular Hypokinesia | Escitalopram   |                    |                    | S               | Intravenous (not otherwise specified) |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                  | Ondansetron    |                    |                    | S               |                                       |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                  | Methadone      |                    |                    | S               | Oral                                  |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-May-2013                                                                                                                                                                                                                                                                      | 9194232        | EXPEDITED (15-DAY) |                    | LT              | JP-FRI-1000043785                     |                      | 17 YR           | Female       | JPN            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Activation Syndrome; Off Label Use                                                                                                                                                                                                                                               | Lexapro        |                    |                    | S               | Oral                                  | 10 Mg                |                 | Forest       |                |
|                                                                                                                                                                                                                                                                                  | Lexapro        |                    |                    | S               | Oral                                  | 20 Mg                |                 | Forest       |                |
|                                                                                                                                                                                                                                                                                  | Lexapro        |                    |                    | S               | Oral                                  | 10 Mg                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-May-2013                                                                                                                                                                                                                                                                      | 9249737        | EXPEDITED (15-DAY) |                    | OT              | JP-FRI-1000044538                     |                      | 71 YR           | Female       | JPN            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Seizure                                                                                                                                                                                                                                                                          | Lexapro        |                    |                    | S               | Oral                                  | 10 Mg                |                 | Forest       |                |
|                                                                                                                                                                                                                                                                                  | Selenica-R     |                    |                    | C               | Oral                                  | 400 Mg               |                 | Not Reported |                |

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

|            |   |      |        |              |
|------------|---|------|--------|--------------|
| Lipitor    | C | Oral | 10 Mg  | Not Reported |
| Thyradin S | C | Oral | 50 Mg  | Not Reported |
| Symbicort  | C |      |        | Not Reported |
| Mosapride  | C | Oral | 15 Mg  | Not Reported |
| Lac-B      | C | Oral | 30 Mg  | Not Reported |
| Maglax     | C | Oral | 990 Mg | Not Reported |

| <u>FDA Received Date</u>                                                                                                       | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|--------------------------|----------------------------------------|-----------------|--------------|----------------|
| 07-May-2013                                                                                                                    | 9276034        | NON-EXPEDITED    |                    | OT              | US-PFIZER INC-2013139078 |                                        |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                          | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Gait Disturbance; Glucose Tolerance Impaired; Increased Appetite; Muscle Spasms; Oedema Peripheral; Weight Increased | Zoloft         |                  |                    | S               | Oral                     | 100 Mg, 1 In 1 D                       |                 | Pfizer       |                |
|                                                                                                                                | Lexapro        |                  |                    | S               | Oral                     | 10 Mg, 1 In 1 D                        |                 | Not Reported |                |
|                                                                                                                                | Amitriptyline  |                  |                    | S               | Oral                     | 25 Mg, 1 In 1 D                        |                 | Not Reported |                |
|                                                                                                                                | Warfarin       |                  |                    | C               | Oral                     | 8 Mg, Tu, Wed, Fri, Sat, Sun, 1 In 1 D |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                     | <u>Case #</u>      | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------|--------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 07-May-2013                                                                  | 9280125            | DIRECT           |                    | DS, RI, OT      |                      |                      | 59 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                        | <u>Product</u>     | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Female Sexual Arousal Disorder; Product Substitution Issue; Vaginal Disorder | Escitalopram 10 Mg |                  |                    | S               | Oral                 | 1                    |                 | Not Reported |                |

| <u>FDA Received Date</u>                      | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 07-May-2013                                   | 9298120        | NON-EXPEDITED    |                    |                 | PHEH2012US006354     |                      | 17 YR           | Female       | USA            |
| <u>Preferred Term</u>                         | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Behaviour; Acne; Blood Triglycerides | Afinitor (Rad) |                  |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                               | Carbatrol      |                  |                    | S               |                      |                      |                 | Not Reported |                |

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

|                                                         |                                       |   |              |
|---------------------------------------------------------|---------------------------------------|---|--------------|
| Increased; Emotional Disorder; Mood Altered; Stomatitis | Vitamin C                             | S | Not Reported |
|                                                         | Lexapro                               | S | Not Reported |
|                                                         | Stress B (Minerals Nos, Vitamins Nos) | S | Not Reported |
|                                                         | Metformin                             | S | Not Reported |
|                                                         | Risperdal                             | S | Not Reported |
|                                                         | Seroquel                              | S | Not Reported |
|                                                         | Nasonex                               | S | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-May-2013              | 9277906       | EXPEDITED (15-DAY) |                    | HO              | PHEH2013US010017     |                      | 17 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Adverse Reaction; Crying; Drug Ineffective; Fatigue; Feeling Abnormal | Trileptal      |              |            | S           |              |                    |                 | Novartis     |
|                                                                       | Concerta       |              |            | S           |              | Unk Ukn, Unk       |                 | Not Reported |
|                                                                       | Abilify        |              |            | S           |              | Unk Ukn, Unk       |                 | Not Reported |
|                                                                       | Abilify        |              |            | S           |              | Unk Ukn, Unk       |                 | Not Reported |
|                                                                       | Lexapro        |              |            | S           |              | Unk Ukn, Unk       |                 | Not Reported |
|                                                                       | Saphris        |              |            | S           |              | Unk Ukn, Unk       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 08-May-2013              | 9277967       | EXPEDITED (15-DAY) |                    | HO              | IT-JNJFOC-20130415555 |                      | 53 YR      | Female     | ITA            |

| <u>Preferred Term</u>                                                                                     | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>  | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------|------------------------|--------------|------------|-------------|---------------|--------------------|-----------------|--------------|
| Coma; Hyperthermia Malignant; Hypertonia; Muscle Rigidity; Neuroleptic Malignant Syndrome; Rhabdomyolysis | Serenase (Haloperidol) |              |            | S           | Intramuscular |                    |                 | Not Reported |
|                                                                                                           | Lamotrigina            |              |            | S           | Oral          |                    |                 | Not Reported |
|                                                                                                           | Carbolitium            |              |            | S           | Oral          |                    |                 | Not Reported |
|                                                                                                           | Dominans               |              |            | S           | Oral          |                    |                 | Not Reported |
|                                                                                                           | Xeristar               |              |            | S           | Oral          |                    |                 | Not Reported |
|                                                                                                           | Cipralex               |              |            | S           | Oral          |                    |                 | Not Reported |
|                                                                                                           | Largactil              |              |            | S           | Intramuscular |                    |                 | Not Reported |
|                                                                                                           | Tolep                  |              |            | S           | Oral          |                    |                 | Not Reported |

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

|                                                                            |                |                    |                    |                 |                                          |                      |                 |              |                |
|----------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|------------------------------------------|----------------------|-----------------|--------------|----------------|
| Remeron                                                                    |                |                    | S                  |                 | Oral                                     |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-May-2013                                                                | 9278582        | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000044966                        |                      | 27 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Incorrect Dose Administered; Malaise; Medication Error; Overdose; Vomiting | Escitalopram   |                    |                    | S               | Oral                                     | Overdose: 60 Mg      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-May-2013                                                                | 9278875        | EXPEDITED (15-DAY) |                    | OT              | PHHY2013IT043781                         |                      |                 | Female       | ITA            |
| <u>Preferred Term</u>                                                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Abuse; Dysarthria; Facial Bones Fracture; Mydriasis; Sopor            | Delorazepam    |                    |                    | S               | Oral                                     | 40 MI, Unk           |                 | Not Reported |                |
|                                                                            | Venlafaxine    |                    |                    | S               |                                          | 2100 Mg, Unk         |                 | Novartis     |                |
|                                                                            | Lexotan        |                    |                    | S               | Oral                                     | 27 Mg, Unk           |                 | Not Reported |                |
|                                                                            | Zoloft         |                    |                    | S               | Oral                                     | 750 Mg, Unk          |                 | Not Reported |                |
|                                                                            | Xanax          |                    |                    | S               | Oral                                     | 2.5 Mg, Unk          |                 | Not Reported |                |
|                                                                            | Entact         |                    |                    | S               | Oral                                     | 15 MI, Unk           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-May-2013                                                                | 9282197        | DIRECT             |                    | OT              |                                          |                      | 15 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Suicidal Ideation                                                          | Lexapro        |                    |                    | S               | Oral                                     |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-May-2013                                                                | 9281323        | EXPEDITED (15-DAY) |                    | OT              | US-BRISTOL-MYERS SQUIBB COMPANY-18862946 |                      | 40 YR           | Female       | USA            |



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

| <u>Preferred Term</u>                                                                                      | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
|------------------------------------------------------------------------------------------------------------|---------------------|--------------------|--------------------|-----------------|--------------------------|----------------------------------|-----------------|--------------|----------------|
| Insomnia; Mania; Pressure Of Speech                                                                        | Abilify             |                    |                    | S               |                          | Started On 2 Mg                  |                 | Not Reported |                |
|                                                                                                            | Lexapro             |                    |                    | S               |                          |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                   | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-May-2013                                                                                                | 9285628             | DIRECT             | Y                  | OT              |                          |                                  | 33 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                      | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Feeling Abnormal; Product Substitution Issue                                                               | Lexapro             |                    |                    | S               | Oral                     |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                   | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-May-2013                                                                                                | 9269483             | EXPEDITED (15-DAY) |                    | HO, OT          | FR-PFIZER INC-2013136238 |                                  | 88 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                      | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Hyponatraemia; Urinary Retention | Cordarone           |                    |                    | S               | Oral                     | 5 Times Weekly (Dose: 0.7143 Df) |                 | Pfizer       |                |
|                                                                                                            | Zofenil Duo         |                    |                    | S               | Oral                     | 1 Df, 1x/Day                     |                 | Not Reported |                |
|                                                                                                            | Seroplex            |                    |                    | S               | Oral                     | 10 Mg, Daily                     |                 | Not Reported |                |
|                                                                                                            | Mopral              |                    |                    | S               | Oral                     | 20 Mg, Daily                     |                 | Not Reported |                |
|                                                                                                            | Kardegic            |                    |                    | C               |                          | Unk                              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                   | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-May-2013                                                                                                | 9285687             | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-2013143980 |                                  |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                      | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Breath Odour; Drug Interaction; Malaise; Skin Odour Abnormal; Urinary Tract Infection                      | Amlodipine Besilate |                    |                    | S               |                          | Unk                              |                 | Pfizer       |                |
|                                                                                                            | Levothyroxine       |                    |                    | S               |                          | 50 Ug, Five Days A Week          |                 | Not Reported |                |
|                                                                                                            | Levothyroxine       |                    |                    | S               |                          | 75 Ug, Two Days In Weekend       |                 | Not Reported |                |
|                                                                                                            | Lexapro             |                    |                    | S               |                          | Unk                              |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| Synthroid                                |                                   |                    | S                  |                 | Unk                        |                       |                 | Not Reported |                |
|------------------------------------------|-----------------------------------|--------------------|--------------------|-----------------|----------------------------|-----------------------|-----------------|--------------|----------------|
| <u>FDA Received Date</u>                 | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-May-2013                              | 9286004                           | EXPEDITED (15-DAY) |                    | DE              | CH-ASTRAZENECA-2013SE32263 |                       | 40 YR           | Male         | CHE            |
| <u>Preferred Term</u>                    | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Death                                    | Seroquel                          |                    |                    | S               | Oral                       |                       |                 | Not Reported |                |
|                                          | Cipralext                         |                    |                    | S               | Oral                       |                       |                 | Not Reported |                |
|                                          | Ritaline                          |                    |                    | C               | Oral                       |                       |                 | Not Reported |                |
|                                          | Zyprexa                           |                    |                    | C               | Oral                       |                       |                 | Not Reported |                |
|                                          | Temesta (Lorazepam)               |                    |                    | C               |                            |                       |                 | Not Reported |                |
|                                          | Nicotinell                        |                    |                    | C               |                            | 14 Mg, 1 Per 24 Hours |                 | Not Reported |                |
|                                          | Irphen                            |                    |                    | C               |                            |                       |                 | Not Reported |                |
|                                          | Prazine (Promazine Hydrochloride) |                    |                    | C               |                            |                       |                 | Not Reported |                |
|                                          | Dafalgan                          |                    |                    | C               |                            |                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                 | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-May-2013                              | 9286427                           | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000045016          |                       | < 1 DAY         | Male         | USA            |
| <u>Preferred Term</u>                    | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrial Septal Defect; Congenital Anomaly | Lexapro                           |                    |                    | S               | Transplacental             |                       |                 | Forest       |                |
| <u>FDA Received Date</u>                 | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-May-2013                              | 9288129                           | EXPEDITED (15-DAY) |                    | OT              | CH-JNJFOC-20130500704      |                       | 21 YR           | Female       | CHE            |
| <u>Preferred Term</u>                    | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Exposure During Pregnancy                | Risperdal                         |                    |                    | S               | Unknown                    |                       |                 | Not Reported |                |
|                                          | Topamax                           |                    |                    | S               | Unknown                    |                       |                 | Not Reported |                |
|                                          | Atarax                            |                    |                    | S               | Unknown                    |                       |                 | Not Reported |                |
|                                          | Cipralext                         |                    |                    | S               | Unknown                    |                       |                 | Not Reported |                |

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

|                                                                                     |                |                    |                    |                 |                              |                      |                 |            |                |
|-------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|------------|----------------|
| Subutex                                                                             |                |                    | S                  | Unknown         |                              |                      |                 |            | Not Reported   |
| Trittico                                                                            |                |                    | S                  | Unknown         |                              |                      |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 14-May-2013                                                                         | 9290095        | DIRECT             | Y                  | OT              |                              |                      | 46 YR           | Female     | USA            |
| <u>Preferred Term</u>                                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Condition Aggravated;<br>Depression                                                 | Escitalopram   |                    |                    | S               |                              |                      |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 14-May-2013                                                                         | 9290676        | DIRECT             | Y                  |                 |                              |                      | 27 YR           | Male       | USA            |
| <u>Preferred Term</u>                                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Product Substitution Issue;<br>Tremor; Tremor                                       | Escitalopram   |                    |                    | S               | Oral                         | (1-4 Weeks)          |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 15-May-2013                                                                         | 8032500        | EXPEDITED (15-DAY) |                    | HO, LT, OT      | FR-PFIZER INC-<br>2011150703 |                      | 38 YR           | Male       | FRA            |
| <u>Preferred Term</u>                                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Hepatitis Acute;<br>Inflammation; Reye'S<br>Syndrome; Toxicity To<br>Various Agents | Xanax          |                    |                    | S               | Oral                         | 0.5 Mg, Unk          |                 |            | Pfizer         |
|                                                                                     | Avlocardyl     |                    |                    | S               | Oral                         | 40 Mg, Unk           |                 |            | Not Reported   |
|                                                                                     | Seroplex       |                    |                    | S               | Oral                         | 20 Mg, Unk           |                 |            | Not Reported   |
|                                                                                     | Norset         |                    |                    | S               | Oral                         | 15 Mg, Unk           |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 15-May-2013                                                                         | 9248875        | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000044495            |                      | 29 YR           | Male       | FRA            |
| <u>Preferred Term</u>                                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Epistaxis; Incorrect Dose<br>Administered; Incorrect                                | Escitalopram   |                    |                    | S               | Oral                         | Overdose: 90 Mg      |                 |            | Forest         |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Drug Administration Rate;  
Medication Error;  
Mydriasis; Off Label Use;  
Tachycardia; Vomiting

| <u>FDA Received Date</u>           | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                          | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|---------------------------------------------------------------|-----------------|------------|----------------|
| 15-May-2013                        | 9289994        | EXPEDITED (15-DAY) |                    | OT              | US-ACCORD-017588     |                                                               | 25 YR           | Male       | USA            |
| <u>Preferred Term</u>              | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                            | <u>Duration</u> | <u>Mfr</u> |                |
| Apathy; Off Label Use;<br>Sedation | Topiramate     |                    |                    | S               |                      | Drug Started With 50<br>Mg/Day And Increased To<br>100 Mg/Day |                 | Accord     |                |
|                                    | Escitalopram   |                    |                    | S               |                      |                                                               |                 | Accord     |                |

| <u>FDA Received Date</u>         | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 15-May-2013                      | 9290753                | EXPEDITED (15-DAY) |                    | OT              | JP-FRI-1000044717    |                      | 88 YR           | Female       | JPN            |
| <u>Preferred Term</u>            | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;<br>Hypotension | Lexapro                |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                  | Clotiazepam            |                    |                    | S               | Oral                 | 5 Mg                 |                 | Not Reported |                |
|                                  | Bayaspirin             |                    |                    | C               | Oral                 | 100 Mg               |                 | Not Reported |                |
|                                  | Irbetan                |                    |                    | C               | Oral                 | 50 Mg                |                 | Not Reported |                |
|                                  | Artist                 |                    |                    | C               | Oral                 | 2.5 Mg               |                 | Not Reported |                |
|                                  | Towarat-Cr             |                    |                    | C               | Oral                 | 20 Mg                |                 | Not Reported |                |
|                                  | Mequitolide            |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |
|                                  | Vasolator              |                    |                    | C               | Other                | 27 Mg                |                 | Not Reported |                |
|                                  | Crestor                |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |
|                                  | Glactiv                |                    |                    | C               | Oral                 | 50 Mg                |                 | Not Reported |                |
|                                  | Celecox                |                    |                    | C               | Oral                 | 200 Mg               |                 | Not Reported |                |
|                                  | Itopride Hydrochloride |                    |                    | C               | Oral                 | 150 Mg               |                 | Not Reported |                |
|                                  | Pocevin                |                    |                    | C               | Intramuscular        |                      |                 | Not Reported |                |
|                                  | Nitroglycerin          |                    |                    | C               | Sublingual           |                      |                 | Not Reported |                |

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

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 15-May-2013              | 9291118       | EXPEDITED (15-DAY) |                    | OT              | US-NICOBREDEVP-2013-08103 |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                    | <u>Product</u>                      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abortion Spontaneous; Bedridden; Decreased Activity; Depressed Mood; Depression; Disability; Disturbance In Attention; Drug Interaction; Drug Level Decreased; Hypersomnia; Impaired Work Ability; Loss Of Personal Independence In Daily Activities; Maternal Exposure During Pregnancy; Mood Altered; Overdose; Stress | Microgestin                         |              |            | S           | Oral         | Unk                |                 | Watson       |
|                                                                                                                                                                                                                                                                                                                          | Lamotrigine (Watson Laboratories)   |              |            | S           | Oral         | 300 Mg, Unk        |                 | Watson       |
|                                                                                                                                                                                                                                                                                                                          | Venlafaxine Hydrochloride (Unknown) |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                          | Lamictal                            |              |            | S           | Oral         | 300 Mg, Unk        |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                          | Ziprasidone                         |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                          | Wellbutrin                          |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                          | Lexapro                             |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                          | Atorvastatin Calcium                |              |            | C           | Unknown      | Unk                |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                          | Oxcarbazepine                       |              |            | C           | Unknown      | Unk                |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                          | Nortriptyline                       |              |            | C           | Unknown      | Unk                |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                          | Folplex                             |              |            | C           | Unknown      | Unk                |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                          | Prenatal Vitamins /01549301/        |              |            | C           | Unknown      | Unk                |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                          | Fish Oil                            |              |            | C           | Unknown      | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-May-2013              | 9292639       | DIRECT           |                    |                 |                      |                      | 63 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------------|-----------------|--------------|
| Urticaria             | Escitalopram   |              |            | S           |              | 10 Mg 1 Tab Daily 1g/250 |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-May-2013              | 9292703       | DIRECT           |                    |                 |                      |                      | 65 YR      | Male       | USA            |

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

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

|                                                                                                                                                                                                        |                  |                    |                    |                 |                          |                      |                 |              |                |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| Nightmare; Product Substitution Issue; Sleep Disorder                                                                                                                                                  |                  | Escitalopram       | S                  | Oral            | 10 Mg 1 Daily Oral       | 10 DAY               | Mylan           |              |                |
| <u>FDA Received Date</u>                                                                                                                                                                               | <u>Case #</u>    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-May-2013                                                                                                                                                                                            | 9197683          | EXPEDITED (15-DAY) |                    | OT              | IE-FRI-1000043807        |                      | 92 YR           | Female       | IRL            |
| <u>Preferred Term</u>                                                                                                                                                                                  | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dyskinesia; Head Titubation; Tremor                                                                                                                                                                    | Lexapro          |                    |                    | S               | Oral                     | 5 Mg                 |                 | Forest       |                |
|                                                                                                                                                                                                        | Amlodipine       |                    |                    | C               |                          |                      |                 | Not Reported |                |
|                                                                                                                                                                                                        | Statin           |                    |                    | C               |                          |                      |                 | Not Reported |                |
|                                                                                                                                                                                                        | Persantin Retard |                    |                    | C               |                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                               | <u>Case #</u>    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-May-2013                                                                                                                                                                                            | 9235077          | EXPEDITED (15-DAY) |                    | OT              | DE-FRI-1000044249        |                      | 19 YR           | Male         | DEU            |
| <u>Preferred Term</u>                                                                                                                                                                                  | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Bilirubin Increased; Condition Aggravated; Electrocardiogram St Segment Depression; Electrocardiogram T Wave Inversion | Escitalopram     |                    |                    | S               | Oral                     | 10 Mg                |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                                                                                               | <u>Case #</u>    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-May-2013                                                                                                                                                                                            | 9292023          | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2013150301 |                      | 36 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                  | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Malaise; Middle Insomnia; Nausea; Somnolence                                                                                                                                                           | Lyrica           |                    |                    | S               |                          | 75 Mg, Unk           |                 | Pfizer       |                |
|                                                                                                                                                                                                        | Lexapro          |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                                                                                                                                                                                                        | Xanax            |                    |                    | C               |                          | Unk                  |                 | Not Reported |                |

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

|             |   |                    |              |
|-------------|---|--------------------|--------------|
| Elavil      | C | Unk                | Not Reported |
| Vicodin     | C | 7.5mg/750mg        | Not Reported |
| Skelaxin    | C | Unk                | Not Reported |
| Tramadol    | C | Unk                | Not Reported |
| Tramadol    | C |                    | Not Reported |
| Mobic       | C | Unk                | Not Reported |
| Vitamin B12 | C | 1000mg Once A Week | Not Reported |

| <u>FDA Received Date</u>                                                                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 16-May-2013                                                                                                    | 9293718        | EXPEDITED (15-DAY) |                    | HO              | ES-FRI-1000045182    |                      | 64 YR           | Male         | ESP            |
| <u>Preferred Term</u>                                                                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| General Physical Health Deterioration;<br>Hyperprolactinaemia;<br>Inappropriate Antidiuretic Hormone Secretion | Escitalopram   |                    |                    | S               | Oral                 | 20 Mg                |                 | Forest       |                |
|                                                                                                                | Enalapril      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                | Tesavel        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                | Tranxilium     |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>  | <u>Case #</u>    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------|------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 17-May-2013               | 9241120          | EXPEDITED (15-DAY) |                    | LT, OT          | JP-FRI-1000044481    |                      | 80 YR           | Male         | JPN            |
| <u>Preferred Term</u>     | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Homicide; Suicide Attempt | Lexapro          |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                           | Mevan            |                    |                    | C               | Oral                 | 10 Mg                |                 | Not Reported |                |
|                           | Amlodipine Od    |                    |                    | C               | Oral                 | 5 Mg                 |                 | Not Reported |                |
|                           | Depas (Etizolam) |                    |                    | C               | Oral                 | 0.5 Mg               |                 | Not Reported |                |
|                           | Rebamipide       |                    |                    | C               | Oral                 | 300 Mg               |                 | Not Reported |                |
|                           | Neurotropin      |                    |                    | C               | Oral                 | 12 Ut                |                 | Not Reported |                |
|                           | Ringereaze       |                    |                    | C               | Oral                 | 60 Mg                |                 | Not Reported |                |
|                           | Pa               |                    |                    | C               | Oral                 | 2 Df                 |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 17-May-2013                         | 9269673        | EXPEDITED (15-DAY) |                    | HO              | JP-FRI-1000044889    |                      | 63 YR           | Female       | JPN            |
| <u>Preferred Term</u>               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anaphylactic Reaction               | Lexapro        |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                     | Limas          |                    |                    | S               | Oral                 | 200 Mg               |                 | Not Reported |                |
|                                     | Amoxan         |                    |                    | S               | Oral                 | 150 Mg               |                 | Not Reported |                |
|                                     | Diovan         |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |
|                                     | Solanax        |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |
|                                     | Lendem         |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-May-2013                         | 9279030        | EXPEDITED (15-DAY) |                    | OT              | US-FRI-1000044954    |                      | 63 YR           | Male         | USA            |
| <u>Preferred Term</u>               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Coma; Impulsive Behaviour; Overdose | Daliresp       |                    |                    | S               | Oral                 | 500 Mcg              |                 | Forest       |                |
|                                     | Prednisone     |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                     | Lexapro        |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                     | Xanax          |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                     | Morphine       |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                     | Oxycodone      |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-May-2013                         | 9295966        | EXPEDITED (15-DAY) |                    | OT              | CA-FRI-1000045206    |                      |                 | Female       | CAN            |
| <u>Preferred Term</u>               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Seizure           | Escitalopram   |                    |                    | S               | Oral                 |                      |                 | Forest       |                |
|                                     | Topamax        |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-May-2013                         | 9296708        | NON-EXPEDITED      |                    | HO              | JP-FRI-1000045247    |                      | 61 YR           | Female       | JPN            |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                                                    | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|----------------------------------------------------------------------------------------------------------|-----------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Dizziness; Seizure                                                                                       | Lexapro                           |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                 | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-May-2013                                                                                              | 9296781                           | EXPEDITED (15-DAY) |                    | DE              |                      | CH-FRI-1000045207    |                 | Male         | CHE            |
| <u>Preferred Term</u>                                                                                    | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Sudden Death                                                                                             | Escitalopram                      |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                                                                                          | Seroquel                          |                    |                    | S               | Oral                 | 400 Mg               |                 | Not Reported |                |
|                                                                                                          | Ritaline                          |                    |                    | C               | Oral                 | 20 Mg                |                 | Not Reported |                |
|                                                                                                          | Zyprexa                           |                    |                    | C               | Oral                 | 10 Mg                |                 | Not Reported |                |
|                                                                                                          | Temesta (Lorazepam)               |                    |                    | C               | Oral                 | 3 Mg                 |                 | Not Reported |                |
|                                                                                                          | Nicotinell                        |                    |                    | C               | Other                | 14 Mg                |                 | Not Reported |                |
|                                                                                                          | Irfen                             |                    |                    | C               | Oral                 | 120 Mg               |                 | Not Reported |                |
|                                                                                                          | Prazine (Promazine Hydrochloride) |                    |                    | C               |                      | 200 Mg               |                 | Not Reported |                |
|                                                                                                          | Dafalgan                          |                    |                    | C               | Oral                 | 4000 Mg              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                 | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-May-2013                                                                                              | 9297658                           | DIRECT             | Y                  | OT              |                      |                      | 37 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                    | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dyspnoea; Fear; Feeling Abnormal; Imprisonment; Incorrect Dose Administered; Separation Anxiety Disorder | Risperidone                       |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                          | Lexapro                           |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                 | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-May-2013                                                                                              | 9536631                           | NON-EXPEDITED      | Y                  |                 |                      | 1000042957           | 65 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                    | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

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

|                      |                                                                |   |      |                                  |              |
|----------------------|----------------------------------------------------------------|---|------|----------------------------------|--------------|
| Diarrhoea; Dizziness | Viibryd                                                        | S | Oral | 10 Mg (10 Mg, 1 In 1 D),<br>Oral | Not Reported |
|                      | Escitalopram (Escitalopram<br>Oxalate) (10 Milligram, Tablets) | S | Oral | 10 Mg (10 Mg, 1 In 1 D),<br>Oral | Not Reported |
|                      | Levothyroxine (Levothyroxine<br>Sodium) (Levothyroxine Sodium) | C | Oral | 5 Mg (5 Mg, 1 In 1 D), Oral      | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 20-May-2013              | 8664611       | EXPEDITED (15-DAY) |                    | OT              | IT-JNJFOC-<br>20120703801 |                      | 77 YR      | Female     | ITA            |

| <u>Preferred Term</u>                                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Medication Error; Sopor;<br>Wrong Product<br>Administered | Reminyl        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                           | Ciprallex      |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-May-2013              | 9155245       | EXPEDITED (15-DAY) |                    | DE              | JP-FRI-1000043171    |                      | 79 YR      | Male       | JPN            |

| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Delirium; Sudden Death | Escitalopram   |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                        | Escitalopram   |              |            | S           | Oral         | 20 Mg              |                 | Forest       |
|                        | Escitalopram   |              |            | S           | Oral         | 10 Mg              |                 | Not Reported |
|                        | Seniran        |              |            | S           | Oral         | 6 Mg               |                 | Not Reported |
|                        | Reflex         |              |            | S           | Oral         | 15mg               |                 | Not Reported |
|                        | Reflex         |              |            | S           | Oral         | 30mg               |                 | Not Reported |
|                        | Reflex         |              |            | S           | Oral         | 45mg               |                 | Not Reported |
|                        | Reflex         |              |            | S           | Oral         | 15mg               |                 | Not Reported |
|                        | Amaryl         |              |            | S           | Oral         | 1mg                |                 | Not Reported |
|                        | Rozerem        |              |            | C           | Oral         | 8mg                |                 | Not Reported |

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

| <u>FDA Received Date</u>                                         | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------|----------------------------|--------------------|--------------------|-----------------|----------------------------|------------------------------|-----------------|--------------|----------------|
| 20-May-2013                                                      | 9256012                    | EXPEDITED (15-DAY) |                    | LT              | IT-FRI-1000044676          |                              | 49 YR           | Male         | ITA            |
| <u>Preferred Term</u>                                            | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Abuse; Overdose;<br>Sopor                                   | Escitalopram Oral Solution |                    |                    | S               | Oral                       | Overdose: 15 MI (300 Mg)     |                 | Forest       |                |
|                                                                  | Xanax                      |                    |                    | S               | Oral                       | Overdose: 20 Tablets (60 Mg) |                 | Not Reported |                |
|                                                                  | Methadone Hydrochloride    |                    |                    | S               | Oral                       | 90 Mg                        |                 | Not Reported |                |
|                                                                  | Depakin                    |                    |                    | S               |                            | Overdose: 6 Sachet           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                         | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-May-2013                                                      | 9298579                    | EXPEDITED (15-DAY) |                    | LT, OT          | CA-ASTRAZENECA-2013SE34580 |                              | 67 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                            | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Electrocardiogram Qt<br>Prolonged; Torsade De<br>Pointes         | Quetiapine                 |                    |                    | S               | Oral                       |                              |                 | Zeneca       |                |
|                                                                  | Escitalopram               |                    |                    | S               |                            |                              |                 | Not Reported |                |
|                                                                  | Furosemide                 |                    |                    | S               |                            |                              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                         | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-May-2013                                                      | 9301632                    | DIRECT             | Y                  | OT              |                            |                              | 33 YR           | Female       | USA            |
| <u>Preferred Term</u>                                            | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Fear; Feeling Abnormal;<br>Product Substitution Issue            | Lexapro                    |                    |                    | S               | Oral                       |                              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                         | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-May-2013                                                      | 9413172                    | EXPEDITED (15-DAY) | Y                  | HO, OT          | AUR-APL-2013-03549         |                              | 53 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                            | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Coma; Hyperthermia<br>Malignant; Hypertonia;<br>Muscle Rigidity; | Lamotrigine (Lamotrigine)  |                    |                    | S               |                            |                              |                 | Not Reported |                |
|                                                                  | Remeron                    |                    |                    | S               |                            |                              |                 | Not Reported |                |
|                                                                  | Tolep                      |                    |                    | S               |                            |                              |                 | Not Reported |                |

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

|                                                   |                                                                                          |                            |                                                                                              |
|---------------------------------------------------|------------------------------------------------------------------------------------------|----------------------------|----------------------------------------------------------------------------------------------|
| Neuroleptic Malignant Syndrome;<br>Rhabdomyolysis | Carbolithium<br>Dominans<br>Xeristar<br>Cipralext<br>Largactil<br>Serenase (Haloperidol) | S<br>S<br>S<br>S<br>S<br>S | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |
|---------------------------------------------------|------------------------------------------------------------------------------------------|----------------------------|----------------------------------------------------------------------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-May-2013              | 8666895       | EXPEDITED (15-DAY) |                    | OT              | DE-FRI-1000037083    |                      | 47 YR      | Female     | DEU            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Uveitis               | Escitalopram   |              |            | S           | Oral         | 10 - 15 Mg         |                 | Forest       |
|                       | Cymbalta       |              |            | C           | Oral         | 60 Mg              |                 | Not Reported |
|                       | Metoprolol     |              |            | C           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-May-2013              | 9302950       | EXPEDITED (15-DAY) |                    | OT              | DE-FRI-1000045262    |                      |            | Male       | DEU            |

| <u>Preferred Term</u>                                                 | <u>Product</u>             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------------------------------------------------------|----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Prostatic Specific Antigen Increased; Restlessness; Urinary Retention | Escitalopram Oral Solution |              |            | S           | Oral         | 5 - 6 Mg           |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-May-2013              | 9302988       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000045263    |                      | 41 YR      | Male       | FRA            |

| <u>Preferred Term</u>                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------|----------------|--------------|------------|-------------|--------------|----------------------|-----------------|--------------|
| Coma; Overdose; Oxygen Saturation Decreased | Escitalopram   |              |            | S           | Oral         | Overdose: 60 Tablets |                 | Forest       |
|                                             | Zopiclone      |              |            | S           | Oral         |                      |                 | Not Reported |
|                                             | Tercian        |              |            | S           | Oral         |                      |                 | Not Reported |
|                                             | Depamide       |              |            | C           |              |                      |                 | Not Reported |
|                                             | Deroxat        |              |            | C           |              |                      |                 | Not Reported |
|                                             | Inexium        |              |            | C           |              |                      |                 | Not Reported |
|                                             | Valium         |              |            | C           |              |                      |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|           |   |              |
|-----------|---|--------------|
| Sulfarlem | C | Not Reported |
| Noctamide | C | Not Reported |
| Risperdal | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-May-2013              | 9303161       | EXPEDITED (15-DAY) |                    | HO              | IT-FRI-1000045264    |                      | 87 YR      | Male       | ITA            |

| <u>Preferred Term</u>  | <u>Product</u>             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------|----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abdominal Pain;        | Escitalopram Oral Solution |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
| Abdominal Pain Upper;  | Oxygen                     |              |            | S           |              |                    |                 | Not Reported |
| Agitation; Confusional | Lansoprazole               |              |            | S           |              | 15 Mg              |                 | Not Reported |
| State; Dehydration;    | Methylprednisolone         |              |            | S           |              | 8 Mg               |                 | Not Reported |
| Erythema; Faecaloma;   | Paracetamol                |              |            | S           |              | 1500 Mg            |                 | Not Reported |
| Haemorrhoids           | Acetylcysteine             |              |            | S           |              | 2 Df               |                 | Not Reported |
|                        | Fluticasone Aerosol        |              |            | S           |              |                    |                 | Not Reported |
|                        | Allopurinol                |              |            | S           |              | 300 Mg             |                 | Not Reported |
|                        | Furosemide                 |              |            | S           |              | 50 Mg              |                 | Not Reported |
|                        | Pregabalin                 |              |            | S           |              | 50 Mg              |                 | Not Reported |
|                        | Acetylsalicylic Acid       |              |            | S           |              | 1 Df               |                 | Not Reported |
|                        | Calcium Levofolate         |              |            | S           |              | 7.5 Mg             |                 | Not Reported |
|                        | Pentahydrate               |              |            |             |              |                    |                 |              |
|                        | Cyanocobalamin             |              |            | S           |              |                    |                 | Not Reported |
|                        | Calcitriol                 |              |            | S           |              | 0.25 Mg            |                 | Not Reported |
|                        | Promazine Hydrochloride    |              |            | S           |              | 5-10 Drops         |                 | Not Reported |
|                        | Delorazepam                |              |            | S           |              | 13 Drops           |                 | Not Reported |
|                        | Valerian                   |              |            | S           |              |                    |                 | Not Reported |
|                        | Liquorice                  |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-May-2013              | 9303355       | EXPEDITED (15-DAY) |                    | DE              | FR-FRI-1000045294    |                      | 92 YR      | Male       | FRA            |

| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|----------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Drug Interaction; Subdural | Escitalopram   |              |            | S           | Oral         | 1 Df               |                 | Forest     |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                               |                                          |   |      |      |              |
|-----------------------------------------------|------------------------------------------|---|------|------|--------------|
| Haematoma; Traumatic Intracranial Haemorrhage | Kardegic                                 | S | Oral | 1 Df | Not Reported |
|                                               | Inexium                                  | C | Oral | 1 Df | Not Reported |
|                                               | Lamaline (Acetaminophen\Caffeine\Opium ) | C | Oral | 2 Df | Not Reported |
|                                               | Lasilix Faible                           | C | Oral | 1 Df | Not Reported |
|                                               | Seresta                                  | C | Oral | 2 Df | Not Reported |
|                                               | Stilnox                                  | C | Oral | 1 Df | Not Reported |
|                                               | Triatec (Ramipril)                       | C | Oral | 1 Df | Not Reported |
|                                               | Forlax                                   | C | Oral | 1 Df | Not Reported |

| <u>FDA Received Date</u>                                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 22-May-2013                                                | 9304397        | EXPEDITED (15-DAY) |                    | OT              | PHHY2013GB050180     |                      | 30 YR           | Male         | GBR            |
| <u>Preferred Term</u>                                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alcohol Abuse; Drug Abuse; Hyperhidrosis; Libido Decreased | Citalopram     |                    |                    | S               | Oral                 | 20 Mg                |                 | Novartis     |                |
|                                                            | Escitalopram   |                    |                    | S               | Oral                 | 40 Mg                |                 | Not Reported |                |
|                                                            | Ventolin       |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 23-May-2013                                                         | 9033324        | EXPEDITED (15-DAY) |                    | HO, OT          | CA-FRI-1000042165    |                      | 1 DAY           | Male       | CAN            |
| <u>Preferred Term</u>                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Foetal Exposure During Pregnancy; Hypotonia; Respiratory Depression | Escitalopram   |                    |                    | S               | Transplacental       |                      |                 | Forest     |                |

| <u>FDA Received Date</u>                           | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 23-May-2013                                        | 9044105        | EXPEDITED (15-DAY) |                    | HO, OT          | CA-FRI-1000042207    |                      | 25 YR           | Female       | CAN            |
| <u>Preferred Term</u>                              | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Pressure Systolic Decreased; Cardiotoxicity; | Escitalopram   |                    |                    | S               |                      |                      |                 | Forest       |                |
|                                                    | Amitriptyline  |                    |                    | S               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                           |            |   |              |
|---------------------------|------------|---|--------------|
| Coma; Electrocardiogram   | Fluoxetine | S | Not Reported |
| Qrs Complex Prolonged;    | Gabapentin | S | Not Reported |
| Electrocardiogram Qt      | Olanzapine | S | Not Reported |
| Prolonged;                | Quetiapine | S | Not Reported |
| Haemodynamic Instability; |            |   |              |
| Hypocalcaemia;            |            |   |              |
| Hypokalaemia;             |            |   |              |
| Hypotension; Intentional  |            |   |              |
| Overdose; Pulse Absent;   |            |   |              |
| Suicide Attempt;          |            |   |              |
| Tachycardia               |            |   |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-May-2013              | 9306271       | EXPEDITED (15-DAY) | CA                 |                 | US-FRI-1000045236    |                      | < 1 DAY    | Male       | USA            |

| <u>Preferred Term</u>                                                                                        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|------------|
| Pulmonary Artery Stenosis<br>Congenital; Transposition<br>Of The Great Vessels;<br>Ventricular Septal Defect | Lexapro        |              |            | S           | Transplacental |                    |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-May-2013              | 9033194       | EXPEDITED (15-DAY) | LT                 |                 | CA-FRI-1000042163    |                      | 42 YR      | Male       | CAN            |

| <u>Preferred Term</u>                                                                    | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>             |
|------------------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------------------|
| Fall; Fatigue; Heart Rate<br>Increased; Hyperhidrosis;<br>Pallor; Somnolence;<br>Yawning | Escitalopram<br>Centrum |              |            | S<br>C      |              |                    |                 | Forest<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-May-2013              | 9033204       | EXPEDITED (15-DAY) | OT                 |                 | CA-FRI-1000042168    |                      | 27 YR      | Female     | CAN            |

| <u>Preferred Term</u>                                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|----------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Blood Disorder; Epistaxis;<br>Haematoma; Impaired<br>Healing; Menorrhagia; | Escitalopram   |              |            | S           | Oral         | 20 Mg              |                 | Forest     |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Nasal Disorder; Petechiae

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-May-2013              | 9033313       | EXPEDITED (15-DAY) |                    | LT              | CA-FRI-1000042167    |                      | 39 YR      | Female     | CAN            |

| <u>Preferred Term</u>                                                                                                                              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Asthenia; Confusional State; Dizziness; Hypersomnia; Hypoaesthesia; Loss Of Personal Independence In Daily Activities; Mental Impairment; Migraine | Escitalopram   |              |            | S           | Oral         | 5 Mg               |                 | Forest       |
|                                                                                                                                                    | Concerta       |              |            | S           | Oral         | 54 Mg              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 24-May-2013              | 9223204       | EXPEDITED (15-DAY) |                    | HO, OT          | JP-009507513-1304JPN002734 |                      | 65 YR      | Female     | JPN            |

| <u>Preferred Term</u>                                                                                                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Delirium; Extradural Haematoma; Fall; Pancytopenia; Pneumocephalus; Skull Fracture; White Blood Cell Count Decreased | Remeron        |              |            | S           | Oral         | 15 Mg, Qd          |                 | Merck        |
|                                                                                                                      | Undepre        |              |            | S           | Oral         | 25 Mg, Tid         |                 | Not Reported |
|                                                                                                                      | Cymbalta       |              |            | S           | Oral         | 20 Mg, Bid         |                 | Not Reported |
|                                                                                                                      | Lexapro        |              |            | S           | Oral         | 10 Mg, Qd          |                 | Not Reported |
|                                                                                                                      | Sulpiride      |              |            | C           | Oral         | 50 Mg, Tid         |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 24-May-2013              | 9307576       | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2013154469 |                      | 69 YR      | Male       | USA            |

| <u>Preferred Term</u>              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Ineffective; Drug Interaction | Viagra         |              |            | S           |              | 50 Mg, As Needed   |                 | Pfizer       |
|                                    | Lexapro        |              |            | S           |              | 20 Mg Daily        |                 | Not Reported |
|                                    | Wellbutrin     |              |            | S           |              | 150 Mg, 2x/Day     |                 | Not Reported |



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

| <u>FDA Received Date</u>                                                                             | <u>Case #</u>                                                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------|--------------------|--------------------|-----------------|--------------------------|------------------------------------------------------------|-----------------|--------------|----------------|
| 24-May-2013                                                                                          | 9308189                                                                | EXPEDITED (15-DAY) |                    | OT              | US-TEVA-406772USA        |                                                            |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                | <u>Product</u>                                                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Breath Odour; Drug Interaction; Malaise; Parosmia; Urinary Tract Infection                           | Levothyroxine Sodium For Injection,200 Mcg/6 MI Vial & 500 Mcg/6 MI Vi |                    |                    | S               |                          | 50 Mcg, Five Days A Week And 75mcg For Two Days In Weekend |                 | Teva         |                |
|                                                                                                      | Levoxyl                                                                |                    |                    | S               |                          |                                                            |                 | Not Reported |                |
|                                                                                                      | Lexapro                                                                |                    |                    | S               |                          |                                                            |                 | Not Reported |                |
|                                                                                                      | Amlodipine                                                             |                    |                    | S               |                          |                                                            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                             | <u>Case #</u>                                                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-May-2013                                                                                          | 9311586                                                                | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2013158678 |                                                            | 79 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                | <u>Product</u>                                                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity                                                                                | Lipitor                                                                |                    |                    | S               |                          | Unk                                                        |                 | Pfizer       |                |
|                                                                                                      | Lexapro                                                                |                    |                    | S               |                          | Unk                                                        |                 | Not Reported |                |
|                                                                                                      | Penicillin                                                             |                    |                    | S               |                          |                                                            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                             | <u>Case #</u>                                                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-May-2013                                                                                          | 9316489                                                                | DIRECT             |                    | HO              |                          |                                                            | 13 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                | <u>Product</u>                                                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Hallucination, Visual; Psychotic Disorder; Refusal Of Treatment By Relative; Self-Injurious Ideation | Escitalopram Oxalate                                                   |                    |                    | S               | Oral                     |                                                            |                 | Not Reported |                |
|                                                                                                      | Escitalopram Oxalate                                                   |                    |                    | C               |                          |                                                            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                             | <u>Case #</u>                                                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-May-2013                                                                                          | 9314807                                                                | EXPEDITED (15-DAY) |                    | OT              | GB-TEVA-407932ISR        |                                                            | 30 YR           | Male         | GBR            |
| <u>Preferred Term</u>                                                                                | <u>Product</u>                                                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                                         | <u>Duration</u> | <u>Mfr</u>   |                |

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

|                                                            |              |   |      |              |
|------------------------------------------------------------|--------------|---|------|--------------|
| Alcohol Abuse; Drug Abuse; Hyperhidrosis; Libido Decreased | Citalopram   | S | Oral | Ivax         |
|                                                            | Escitalopram | S | Oral | Not Reported |
|                                                            | Ventolin     | C |      | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 29-May-2013              | 9315338        | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2013163389 |                      | 45 YR           | Unknown      | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity    | Zoloft         |                  |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                          | Abilify        |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                          | Lexapro        |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                          | Lunesta        |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |

| <u>FDA Received Date</u>                          | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 29-May-2013                                       | 9315660        | EXPEDITED (15-DAY) |                    | OT              | CH-FRI-1000045444    |                      |                 | Female       | CHE            |
| <u>Preferred Term</u>                             | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dry Mouth; Restless Legs Syndrome; Sleep Disorder | Escitalopram   |                    |                    | S               | Oral                 |                      |                 | Forest       |                |
|                                                   | Cymbalta       |                    |                    | S               | Oral                 | 60 Mg                |                 | Not Reported |                |
|                                                   | Cymbalta       |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                   | Tramal         |                    |                    | S               | Oral                 | 75 Mg                |                 | Not Reported |                |
|                                                   | Salazopyrin    |                    |                    | C               | Oral                 | 1500 Mg              |                 | Not Reported |                |
|                                                   | Dafalgan       |                    |                    | C               | Oral                 | 4000 Mg              |                 | Not Reported |                |
|                                                   | Tilur          |                    |                    | C               | Oral                 | 180 Mg               |                 | Not Reported |                |
|                                                   | Esomeprazole   |                    |                    | C               | Oral                 | 20 Mg                |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 30-May-2013              | 9144365        | EXPEDITED (15-DAY) |                    | HO, LT          | SE-FRI-1000043130    |                      | 21 YR           | Male       | SWE            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

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

|                                                              |              |   |      |        |
|--------------------------------------------------------------|--------------|---|------|--------|
| Personality Change;<br>Suicidal Ideation; Suicide<br>Attempt | Escitalopram | S | Oral | Forest |
|--------------------------------------------------------------|--------------|---|------|--------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------|----------------------|------------|------------|----------------|
| 30-May-2013              | 9173945       | EXPEDITED (15-DAY) |                    | DE, HO, OT      | ES-CELGENEUS-144-<br>21880-13031817 |                      | 75 YR      | Male       | ESP            |

| <u>Preferred Term</u>     | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|--------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardio-Respiratory Arrest | Revlimid           |              |            | S           | Oral         | 10 Milligram       |                 | Celgene      |
|                           | Dexamethasone      |              |            | S           | Oral         | 40 Milligram       |                 | Not Reported |
|                           | Metamizole         |              |            | S           | Unknown      |                    |                 | Not Reported |
|                           | Paracetamol        |              |            | S           | Unknown      |                    |                 | Not Reported |
|                           | Durogesic          |              |            | S           | Unknown      |                    |                 | Not Reported |
|                           | Lactitol           |              |            | S           | Unknown      |                    |                 | Not Reported |
|                           | Lactitol           |              |            | S           | Unknown      |                    |                 | Not Reported |
|                           | Omeprazole         |              |            | S           | Unknown      |                    |                 | Not Reported |
|                           | Zoledronic Acid    |              |            | S           | Unknown      |                    |                 | Not Reported |
|                           | Zoledronic Acid    |              |            | S           | Unknown      |                    |                 | Not Reported |
|                           | Aas                |              |            | S           | Unknown      |                    |                 | Not Reported |
|                           | Salicylic Acid     |              |            | S           | Unknown      |                    |                 | Not Reported |
|                           | Levofloxacin       |              |            | S           | Unknown      |                    |                 | Not Reported |
|                           | Megestrol          |              |            | S           | Unknown      |                    |                 | Not Reported |
|                           | Potassium          |              |            | S           | Unknown      |                    |                 | Not Reported |
|                           | Calcium            |              |            | S           | Unknown      |                    |                 | Not Reported |
|                           | Methylprednisolone |              |            | S           | Unknown      |                    |                 | Not Reported |
|                           | Escitalopram       |              |            | S           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 30-May-2013              | 9192603       | NON-EXPEDITED    |                    |                 | US-PFIZER INC-<br>2013095165 |                      | 33 YR      | Female     | USA            |

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

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

|                           |                            |   |                |              |
|---------------------------|----------------------------|---|----------------|--------------|
| Abnormal Sensation In     | Effexor Xr                 | S | 150 Mg, Daily  | Pfizer       |
| Eye; Drug Ineffective;    | Effexor Xr                 | S | 75 Mg, Daily   | Pfizer       |
| Feeling Abnormal; Product | Effexor Xr                 | S | 37.5 Mg, Daily | Pfizer       |
| Dose Omission; Sensory    | Effexor Xr                 | S | Unk            | Pfizer       |
| Disturbance; Tinnitus     | Lexapro                    | S | Unk            | Not Reported |
|                           | Trazodone                  | C | Unk            | Not Reported |
|                           | Valaciclovir Hydrochloride | C | 500 Mg, Daily  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 30-May-2013              | 9280791       | EXPEDITED (15-DAY) |                    | HO, OT          | US-PFIZER INC-2013143519 |                      |            | Female     | USA            |

| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Apparent Death;            | Gabapentin     |              |            | S           |              | Unk                |                 | Pfizer       |
| Bedridden; Brain Injury;   | Lyrica         |              |            | S           |              | Unk                |                 | Pfizer       |
| Cognitive Disorder;        | Cymbalta       |              |            | S           |              | Unk                |                 | Not Reported |
| Complex Regional Pain      | Lexapro        |              |            | S           |              | Unk                |                 | Not Reported |
| Syndrome; Concussion;      |                |              |            |             |              |                    |                 |              |
| Contusion; Diarrhoea;      |                |              |            |             |              |                    |                 |              |
| Dyskinesia; Dyspnoea;      |                |              |            |             |              |                    |                 |              |
| Eye Contusion; Feeding     |                |              |            |             |              |                    |                 |              |
| Disorder; Feeling          |                |              |            |             |              |                    |                 |              |
| Abnormal; Injury;          |                |              |            |             |              |                    |                 |              |
| Irritability; Loss Of      |                |              |            |             |              |                    |                 |              |
| Personal Independence In   |                |              |            |             |              |                    |                 |              |
| Daily Activities; Malaise; |                |              |            |             |              |                    |                 |              |
| Memory Impairment; Pain;   |                |              |            |             |              |                    |                 |              |
| Pain; Swelling; Upper      |                |              |            |             |              |                    |                 |              |
| Limb Fracture; Vomiting;   |                |              |            |             |              |                    |                 |              |
| Weight Decreased;          |                |              |            |             |              |                    |                 |              |
| Withdrawal Syndrome        |                |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-May-2013              | 9316477       | EXPEDITED (15-DAY) |                    | OT              | GB-ACCORD-017761     |                      | 30 YR      | Male       | GBR            |

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

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

|                                                            |              |   |      |              |
|------------------------------------------------------------|--------------|---|------|--------------|
| Alcohol Abuse; Drug Abuse; Hyperhidrosis; Libido Decreased | Escitalopram | S | Oral | Accord       |
|                                                            | Citalopram   | S | Oral | Accord       |
|                                                            | Ventolin     | C |      | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-May-2013              | 9320352       | EXPEDITED (15-DAY) |                    | OT              | GB-FRI-1000045511    |                      | 30 YR      | Male       | GBR            |

| <u>Preferred Term</u>                                                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|-----------------------|-----------------|--------------|
| Alcohol Abuse; Drug Abuse; Hyperhidrosis; Libido Decreased; Overdose | Escitalopram   |              |            | S           | Oral         | Overdose: 40 Mg Daily |                 | Forest       |
|                                                                      | Citalopram     |              |            | C           | Oral         | 20 Mg                 |                 | Not Reported |
|                                                                      | Ventolin       |              |            | C           |              |                       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-May-2013              | 9321085       | DIRECT           |                    |                 |                      |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------|----------------|--------------|------------|-------------|--------------|---------------------|-----------------|--------------|
| Irritable Bowel Syndrome; Product Substitution Issue | Lexapro        |              |            | S           | Oral         | 20mg Daily By Mouth |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-May-2013              | 9213902       | EXPEDITED (15-DAY) |                    | OT              | IE-FRI-1000044030    |                      | 30 YR      | Female     | IRL            |

| <u>Preferred Term</u>                                                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Abdominal Discomfort; Dizziness; Visual Field Defect; Withdrawal Syndrome | Lexapro        |              |            | S           | Oral         | 20 Mg              |                 | Forest     |
|                                                                           | Lexapro        |              |            | S           | Oral         | 15 Mg              |                 | Forest     |
|                                                                           | Lexapro        |              |            | S           | Oral         | 10 Mg              |                 | Forest     |
|                                                                           | Lexapro        |              |            | S           | Oral         | 5 Mg               |                 | Forest     |
|                                                                           | Lexapro        |              |            | S           | Oral         | 10 Mg              |                 | Forest     |
|                                                                           | Lexapro        |              |            | S           |              |                    |                 | Forest     |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                               | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 31-May-2013                                                                                                                                                                            | 9213906                          | EXPEDITED (15-DAY) |                    | OT              | IE-FRI-1000044029    |                      |                 | Female       | IRL            |
| <u>Preferred Term</u>                                                                                                                                                                  | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Discomfort;<br>Withdrawal Syndrome                                                                                                                                           | Lexapro                          |                    |                    | S               | Oral                 |                      |                 | Forest       |                |
|                                                                                                                                                                                        | Lexapro                          |                    |                    | S               |                      | 10 Mg                |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                                                                               | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-May-2013                                                                                                                                                                            | 9321389                          | EXPEDITED (15-DAY) |                    | OT              | US-FRI-1000045429    |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                  | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Crohn'S Disease; Drug<br>Ineffective;<br>Haematochezia; Panic<br>Attack                                                                                                                | Celexa                           |                    |                    | S               |                      |                      |                 | Forest       |                |
|                                                                                                                                                                                        | Lexapro                          |                    |                    | S               |                      | 10 Mg                |                 | Forest       |                |
|                                                                                                                                                                                        | Humira                           |                    |                    | S               |                      | 40 Mg                |                 | Not Reported |                |
|                                                                                                                                                                                        | Lisinopril                       |                    |                    | C               |                      | 10/12.5mg            |                 | Not Reported |                |
|                                                                                                                                                                                        | Lisinopril                       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                        | Cartia (Diltiazem Hydrochloride) |                    |                    | C               |                      | 180 Mg               |                 | Forest       |                |
|                                                                                                                                                                                        | Asacol                           |                    |                    | C               |                      | 6 Dosage Forms       |                 | Not Reported |                |
|                                                                                                                                                                                        | Diphenhydramine                  |                    |                    | C               |                      | 25 Mg                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                               | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-May-2013                                                                                                                                                                            | 9321544                          | EXPEDITED (15-DAY) |                    | HO, OT          | US-FRI-1000045450    |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                  | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Apparent Death;<br>Bedridden; Complex<br>Regional Pain Syndrome;<br>Concussion; Contusion;<br>Decreased Appetite;<br>Diarrhoea; Drug<br>Withdrawal Syndrome;<br>Dyskinesia; Dysphagia; | Lexapro                          |                    |                    | S               |                      |                      |                 | Forest       |                |
|                                                                                                                                                                                        | Lyrica                           |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                        | Cymbalta                         |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                        | Gabapentin                       |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                        |                                  |                    |                    |                 |                      |                      |                 |              |                |

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

Dyspnoea; Eye Contusion;  
Fear Of Death; Irritability;  
Malaise; Memory  
Impairment; Mental  
Impairment; Movement  
Disorder; Negative  
Thoughts; Pain; Post-  
Traumatic Pain; Swelling;  
Unevaluable Event; Upper  
Limb Fracture; Vomiting;  
Weight Decreased

| <u>FDA Received Date</u>                                                                                                         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
| 31-May-2013                                                                                                                      | 9322479        | EXPEDITED (15-DAY) |                    | OT              | GB-MYLANLABS-2013S1011055 |                      | 30 YR           | Male         | GBR            |
| <u>Preferred Term</u>                                                                                                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alcohol Abuse; Drug Abuse; Hyperhidrosis; Libido Decreased                                                                       | Citalopram     |                    |                    | S               | Oral                      |                      |                 | Mylan        |                |
|                                                                                                                                  | Escitalopram   |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                                                                                                                                  | Ventolin       |                    |                    | C               |                           |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-May-2013                                                                                                                      | 9325656        | DIRECT             |                    |                 |                           |                      | 65 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Depression; Disturbance In Attention; Irritability; Product Substitution Issue; Quality Of Life Decreased; Tachypnea | Escitalopram   |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Jun-2013                                                                                                                      | 9194289        | EXPEDITED (15-DAY) |                    | HO              | US-FRI-1000043679         |                      | 67 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

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

|                           |              |   |      |                |              |
|---------------------------|--------------|---|------|----------------|--------------|
| Depression; Drug          | Escitalopram | S | Oral | 10mg           | Forest       |
| Ineffective; Intentional  | Escitalopram | S | Oral | 20mg           | Forest       |
| Overdose; Suicide Attempt | Sonata       | S |      | 10mg As Needed | Not Reported |
|                           | Valium       | S |      | 5mg As Needed  | Not Reported |

| <u>FDA Received Date</u>                                   | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------|-----------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 03-Jun-2013                                                | 9324904                           | EXPEDITED (15-DAY) |                    | OT              | GB-WATSON-2013-09631 |                      | 30 YR           | Male         | GBR            |
| <u>Preferred Term</u>                                      | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alcohol Abuse; Drug Abuse; Hyperhidrosis; Libido Decreased | Citalopram Hydrobromide (Unknown) |                    |                    | S               | Oral                 | 20mg Daily           |                 | Watson       |                |
|                                                            | Escitalopram                      |                    |                    | S               | Oral                 | 40 Mg, Daily         |                 | Not Reported |                |
|                                                            | Ventolin /00139502/               |                    |                    | C               | Unknown              | Unknown              |                 | Not Reported |                |

| <u>FDA Received Date</u>                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 03-Jun-2013                                                    | 9324921        | EXPEDITED (15-DAY) |                    | HO              | ES-TEVA-409397ISR    |                      | 78 YR           | Female       | ESP            |
| <u>Preferred Term</u>                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State; Drug Interaction; Dysarthria; Hallucination | Azilect        |                    |                    | S               | Oral                 | 1 Milligram Daily;   |                 | Teva         |                |
|                                                                | Ciprallex      |                    |                    | S               | Oral                 | 10 Milligram Daily;  |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                       | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 03-Jun-2013                                                                                                                    | 9325837        | DIRECT           |                    | OT              |                      |                      | 33 YR           | Male       | USA            |
| <u>Preferred Term</u>                                                                                                          | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Abnormal Behaviour; Product Quality Issue; Product Substitution Issue; Therapeutic Product Effect Decreased; Thinking Abnormal | Escitalopram   |                  |                    | S               |                      |                      |                 | Invagen    |                |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                          | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------|----------------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| 03-Jun-2013                                                                       | 9326557                    | DIRECT             | Y                  | HO              |                              |                      | 30 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                             | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Pruritus; Rash; Swelling<br>Face                                                  | Lexapro                    |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                                                                                   | Escitalopram               |                    |                    | S               |                              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                          | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Jun-2013                                                                       | 9278863                    | EXPEDITED (15-DAY) |                    | OT              | IT-FRI-1000044996            |                      | 31 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                             | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Abuse; Lethargy;<br>Mydriasis; Nasal Injury;<br>Overdose; Speech<br>Disorder | Escitalopram Oral Solution |                    |                    | S               | Oral                         |                      |                 | Forest       |                |
|                                                                                   | Delorazepam                |                    |                    | S               | Oral                         | 40 MI                |                 | Not Reported |                |
|                                                                                   | Venlafaxine Hydrochloride  |                    |                    | S               | Oral                         | 2100 Mg              |                 | Not Reported |                |
|                                                                                   | Lexotan                    |                    |                    | S               | Oral                         | 27 Mg                |                 | Not Reported |                |
|                                                                                   | Xanax                      |                    |                    | S               | Oral                         | 2.5 Mg               |                 | Not Reported |                |
|                                                                                   | Zoloft                     |                    |                    | S               | Oral                         | 750 Mg               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                          | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Jun-2013                                                                       | 9326190                    | EXPEDITED (15-DAY) |                    | CA, DE          | US-FRI-1000045583            |                      | < 1 DAY         | Male         | USA            |
| <u>Preferred Term</u>                                                             | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Newborn Persistent<br>Pulmonary Hypertension                                      | Lexapro                    |                    |                    | S               | Transplacental               |                      |                 | Forest       |                |
|                                                                                   | Lexapro                    |                    |                    | S               |                              |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                          | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Jun-2013                                                                       | 9327654                    | NON-EXPEDITED      |                    |                 | US-PFIZER INC-<br>2013167706 |                      | 37 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                             | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity                                                             | Pristiq                    |                    |                    | S               |                              | Unk                  |                 | Pfizer       |                |

# FDA Adverse Event Reporting System

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|             |   |     |              |
|-------------|---|-----|--------------|
| Flector     | S | Unk | Pfizer       |
| Mirtazapine | S | Unk | Not Reported |
| Ambien      | S | Unk | Not Reported |
| Cymbalta    | S | Unk | Not Reported |
| Lexapro     | S | Unk | Not Reported |
| Wellbutrin  | S | Unk | Not Reported |

| <u>FDA Received Date</u>                   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 04-Jun-2013                                | 9330734        | DIRECT           | Y                  | DS, OT          |                      |                      | 40 YR           | Male         | USA            |
| <u>Preferred Term</u>                      | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Panic Disorder; Product Substitution Issue | Escitalopram   |                  |                    | S               | Oral                 |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 05-Jun-2013              | 8541791        | EXPEDITED (15-DAY) |                    | LT              | JP-FRI-1000030140    |                      | 41 YR           | Male         | JPN            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypertriglyceridaemia    | Lexapro        |                    |                    | S               | Oral                 | 20 Mg                |                 | Forest       |                |
|                          | Reflex         |                    |                    | C               | Oral                 | 15 Mg                |                 | Not Reported |                |
|                          | Reflex         |                    |                    | C               |                      | 45 Mg                |                 | Not Reported |                |
|                          | Gasmotin       |                    |                    | C               | Oral                 | 5 Mg                 |                 | Not Reported |                |
|                          | Rohypnol       |                    |                    | C               | Oral                 | 2 Mg                 |                 | Not Reported |                |
|                          | Reslin         |                    |                    | C               | Oral                 | 200 Mg               |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| 05-Jun-2013              | 9246597        | EXPEDITED (15-DAY) |                    | LT              | IT-ABBOTT-13X-083-1079456-00 |                      | 49 YR           | Male         | ITA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Abuse; Somnolence   | Depakin        |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |

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|                         |   |      |                                             |              |
|-------------------------|---|------|---------------------------------------------|--------------|
| Xanax                   | S | Oral | Tablet, Extended Release,<br>20 Dosage Form | Not Reported |
| Methadone Hydrochloride | S | Oral |                                             | Not Reported |
| Entact                  | S | Oral |                                             | Not Reported |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 05-Jun-2013                       | 9338257                | DIRECT                    |                             |                          |                               |                               | 67 YR               | Female              | USA                     |

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

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 05-Jun-2013                       | 9338584                | DIRECT                    |                             | OT                       |                               |                               |                     | Unknown             | USA                     |

| <a href="#">Preferred Term</a>               | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|----------------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Drug Ineffective; Product Substitution Issue | Escitalopram            |                       |                     | S                    | Oral                  |                             | 3 DAY                    | Mylan               |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 05-Jun-2013                       | 9340490                | EXPEDITED (15-DAY)        | Y                           | OT                       | AUR-APL-2013-04602            |                               | 53 YR               | Male                | IND                     |

| <a href="#">Preferred Term</a>                                                                                                                                                                                                                                                     | <a href="#">Product</a>       | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Central Nervous System Infection; Cerebral Atrophy; Cerebral Ventricle Dilatation; Cognitive Disorder; Diabetic Retinopathy; Gait Disturbance; Lethargy; Memory Impairment; Neurological Decompensation; Normal Pressure Hydrocephalus; Peripheral Sensorimotor Neuropathy; Speech | Escitalopram (Escitalopram)   |                       |                     | S                    |                       |                             |                          | Not Reported        |
|                                                                                                                                                                                                                                                                                    | Pregabalin (Pregabalin)       |                       |                     | S                    |                       |                             |                          | Not Reported        |
|                                                                                                                                                                                                                                                                                    | Carbamazepine (Carbamazepine) |                       |                     | S                    |                       |                             |                          | Not Reported        |
|                                                                                                                                                                                                                                                                                    | Amitriptyline (Amitriptyline) |                       |                     | S                    |                       |                             |                          | Not Reported        |

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Disorder; Urinary  
Incontinence

| <u>FDA Received Date</u>                | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 06-Jun-2013                             | 9335118        | EXPEDITED (15-DAY) |                    | OT              | IN-FRI-1000045734    |                      | 53 YR           | Male         | IND            |
| <u>Preferred Term</u>                   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dementia; Gait<br>Disturbance; Lethargy | Escitalopram   |                    |                    | S               |                      |                      |                 | Forest       |                |
|                                         | Amitriptyline  |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                         | Carbamazepine  |                    |                    | S               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                  | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 06-Jun-2013                                                                               | 9339008        | DIRECT           | Y                  |                 |                      |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                     | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depressive Symptom;<br>Disease Recurrence;<br>Irritability; Product<br>Substitution Issue | Escitalopram   |                  |                    | S               | Oral                 | 1 Tab Daily          |                 | Not Reported |                |

| <u>FDA Received Date</u>                                       | <u>Case #</u>                                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------|--------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 06-Jun-2013                                                    | 9342046                                                | EXPEDITED (15-DAY) | Y                  | LT              | 2013AP005538         |                      | 51 YR           | Female       | AUS            |
| <u>Preferred Term</u>                                          | <u>Product</u>                                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Overdose;<br>Suicidal Ideation; Suicide<br>Attempt | Escitalopram (Escitalopram)                            |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                | Fluoxetine Hydrochloride<br>(Fluoxetine Hydrochloride) |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                | Esomeprazole Magnesium<br>(Esomeprazole Magnesium)     |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------------------|----------------------|-----------------|------------|----------------|
| 07-Jun-2013              | 9184552        | EXPEDITED (15-DAY) |                    | HO              | FR-ABBOTT-13X-056-<br>1065853-00 |                      | 68 YR           | Male       | FRA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                     | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

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|                                             |                        |   |              |              |              |
|---------------------------------------------|------------------------|---|--------------|--------------|--------------|
| Epistaxis; Neutropenia;<br>Thrombocytopenia | Zeclar                 | S | Oral         | 500 Mg Twice | Not Reported |
|                                             | Calciparine            | S | Subcutaneous |              | Not Reported |
|                                             | Clamoxyl (Amoxicillin) | S | Oral         |              | Not Reported |
|                                             | Seroplex               | S | Oral         |              | Not Reported |
|                                             | Paracetamol            | S | Oral         |              | Not Reported |
|                                             | Inspirale              | S | Oral         |              | Not Reported |
|                                             | Crestor                | S | Oral         |              | Not Reported |
|                                             | Plavix                 | S | Oral         |              | Not Reported |
|                                             | Kardegic               | S | Oral         |              | Not Reported |
|                                             | Inexium                | S | Oral         |              | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Jun-2013              | 9187149       | EXPEDITED (15-DAY) | HO                 |                 | FR-FRI-1000043685    |                      | 68 YR      | Male       | FRA            |

| <u>Preferred Term</u>            | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Neutropenia;<br>Thrombocytopenia | Escitalopram           |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                  | Clamoxyl (Amoxicillin) |              |            | S           | Oral         | 2 Gram             |                 | Not Reported |
|                                  | Zeclar                 |              |            | S           | Oral         | 1000 Mg            |                 | Not Reported |
|                                  | Calciparine            |              |            | C           | Other        | 0.4 MI             |                 | Not Reported |
|                                  | Paracetamol Macopharma |              |            | C           | Other        | 0.25 Gram          |                 | Not Reported |
|                                  | Inspira                |              |            | C           | Oral         | 25 Mg              |                 | Not Reported |
|                                  | Crestor                |              |            | C           | Oral         | 5 Mg               |                 | Not Reported |
|                                  | Plavix                 |              |            | C           | Oral         | 75 Mg              |                 | Not Reported |
|                                  | Kardegic               |              |            | C           | Oral         | 75 Mg              |                 | Not Reported |
|                                  | Inexium                |              |            | C           | Oral         | 40 Mg              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 07-Jun-2013              | 9200249       | EXPEDITED (15-DAY) | HO                 |                 | US-PFIZER INC-<br>2013094901 |                      | 60 YR      | Male       | USA            |

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

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|                   |                 |   |      |               |              |
|-------------------|-----------------|---|------|---------------|--------------|
| Suicidal Ideation | Ziprasidone Hcl | S | Oral | 60 Mg, 2x/Day | Pfizer       |
|                   | Lexapro         | S |      | Unk           | Not Reported |
|                   | Trazodone       | C | Oral | 150 Mg, Unk   | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 07-Jun-2013              | 9247309       | EXPEDITED (15-DAY) |                    | HO, LT          | FR-JNJFOC-20130408914 |                      | 88 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u>                     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Pancytopenia; Pyrexia | Haldol                             |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Oflocet                            |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Loxen (Niacardipine Hydrochloride) |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Seroplex                           |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Xanax                              |              |            | C           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Jun-2013              | 9336724       | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000045740    |                      | 56 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Loose Tooth           | Escitalopram        |              |            | S           | Oral         |                    |                 | Forest       |
|                       | Lexomil             |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Temesta (Lorazepam) |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Lysanxia            |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Jun-2013              | 9336735       | EXPEDITED (15-DAY) |                    | LT              | FR-FRI-1000045735    |                      | 25 YR      | Male       | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|-----------------------------|-----------------|------------|
| Coma; Overdose        | Escitalopram   |              |            | S           | Oral         |                             |                 | Forest     |
|                       | Escitalopram   |              |            | S           | Oral         | Overdose Of An Unknown Dose |                 | Forest     |

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|                                                                | Imovane        |                    | S                  | Oral            |                      |                             |                 | Not Reported |                |
|----------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|-----------------------------|-----------------|--------------|----------------|
|                                                                | Imovane        |                    | S                  | Oral            |                      | Overdose Of An Unknown Dose |                 | Not Reported |                |
|                                                                | Tercian        |                    | C                  |                 |                      |                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Jun-2013                                                    | 9336755        | EXPEDITED (15-DAY) |                    | HO              | ES-FRI-1000045738    |                             | 78 YR           | Female       | ESP            |
| <u>Preferred Term</u>                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State; Drug Interaction; Dysarthria; Hallucination | Escitalopram   |                    |                    | S               | Oral                 | 10 Mg                       |                 | Forest       |                |
|                                                                | Rasagiline     |                    |                    | S               | Oral                 | 1 Mg                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Jun-2013                                                    | 9340447        | EXPEDITED (15-DAY) |                    | CA              | DE-FRI-1000045758    |                             |                 | Male         | DEU            |
| <u>Preferred Term</u>                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Cleft Lip; Foetal Exposure During Pregnancy                    | Escitalopram   |                    |                    | S               | Transplacental       |                             |                 | Forest       |                |
|                                                                | Opipramol Dura |                    |                    | S               | Transplacental       | 300 Mg                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Jun-2013                                                    | 9340541        | DIRECT             |                    | HO              |                      |                             | 23 YR           | Male         | USA            |
| <u>Preferred Term</u>                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Panic Attack; Seizure                                          | Escitalopram   |                    |                    | S               | Oral                 |                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Jun-2013                                                    | 9341291        | DIRECT             |                    |                 |                      |                             |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Adverse Event; Feeling Abnormal; Insomnia;                     | Escitalopram   |                    |                    | S               |                      |                             |                 | Not Reported |                |
|                                                                | Lexapro        |                    |                    | S               | Oral                 | Strength: 10/20 1 Per Day   |                 | Forest       |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Product Quality Issue;  
Product Substitution Issue

Mouth

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Jun-2013              | 9236762       | EXPEDITED (15-DAY) |                    | HO, OT          | US-TEVA-398025USA    |                      | 51 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Aspiration; Cough;<br>Dehydration; Dysphagia;<br>Meningioma; Weight<br>Decreased | Escitalopram   |              |            | S           |              | 1/2 Tablet         |                 | Ivax         |
|                                                                                  | Metformin      |              |            | C           |              |                    |                 | Not Reported |
|                                                                                  | Estropipate    |              |            | C           |              |                    |                 | Not Reported |
|                                                                                  | Robinal        |              |            | C           |              |                    |                 | Not Reported |
|                                                                                  | Lipitor        |              |            | C           |              |                    |                 | Not Reported |
|                                                                                  | Lamictal       |              |            | C           |              |                    |                 | Not Reported |
|                                                                                  | Effexor        |              |            | C           |              |                    |                 | Not Reported |
|                                                                                  | Neurontin      |              |            | C           |              |                    |                 | Not Reported |
|                                                                                  | Hyzaar         |              |            | C           |              |                    |                 | Not Reported |
|                                                                                  | Tramadol       |              |            | C           |              |                    |                 | Not Reported |
|                                                                                  | Deplin         |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Jun-2013              | 9260765       | EXPEDITED (15-DAY) |                    | OT              | DK-FRI-1000044730    |                      | 40 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                                                                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Anxiety; Fatigue; Illusion;<br>Mania; Muscle Spasms;<br>Palpitations;<br>Restlessness; Sleep<br>Disorder; Suicidal<br>Ideation; Weight Increased | Escitalopram   |              |            | S           | Oral         | 20 Mg              |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Jun-2013              | 9343158       | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000045853    |                      | 42 YR      | Female     | FRA            |

| <u>Preferred Term</u>                          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Haemorrhage; Labelled<br>Drug-Drug Interaction | Escitalopram   |              |            | S           |              | 10 Mg              |                 | Forest       |
|                                                | Zyprexa        |              |            | S           |              |                    |                 | Not Reported |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                                                                                   |                             |                    |                    |                 |                      |                      |                 |              |                |
|-------------------------------------------------------------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Medication Error                                                                                                  | Xanax                       |                    |                    | C               | Oral                 | 2 Df                 |                 |              | Not Reported   |
| <u>FDA Received Date</u>                                                                                          | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Jun-2013                                                                                                       | 9291364                     | EXPEDITED (15-DAY) |                    | OT              | US-FRI-1000045024    |                      | 60 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                             | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anger; Angina Pectoris;<br>Depression;<br>Hypothyroidism                                                          | Lexapro                     |                    |                    | S               | Oral                 | 20 Mg                |                 | Forest       |                |
|                                                                                                                   | Lexapro                     |                    |                    | S               | Oral                 | 20 Mg                |                 | Forest       |                |
|                                                                                                                   | Viibryd                     |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                                                                                                   | Viibryd                     |                    |                    | S               | Oral                 | 20 Mg                |                 | Forest       |                |
|                                                                                                                   | Coumadin                    |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                   | Ibuprofen                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                   | Lasix                       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                   | Synthroid                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                          | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Jun-2013                                                                                                       | 9332718                     | EXPEDITED (15-DAY) |                    | OT              | AUR-APL-2013-04269   |                      | 30 YR           | Male         | GBR            |
| <u>Preferred Term</u>                                                                                             | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alcohol Abuse;<br>Confusional State; Drug<br>Abuse; Hyperhidrosis;<br>Loss Of Libido; Partner<br>Stress           | Citalopram (Citalopram)     |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                   | Escitalopram (Escitalopram) |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                   | Ventolin (Salbutamol)       |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                          | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Jun-2013                                                                                                       | 9345662                     | EXPEDITED (15-DAY) |                    | OT              | PHHY2013IN058944     |                      | 53 YR           | Male         | IND            |
| <u>Preferred Term</u>                                                                                             | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Apathy; Dementia; Gait<br>Disturbance; Lack Of<br>Spontaneous Speech;<br>Lethargy; Memory<br>Impairment; Movement | Amitriptyline               |                    |                    | S               |                      |                      |                 | Novartis     |                |
|                                                                                                                   | Carbamazepine               |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                   | Pregabalin                  |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                   | Escitalopram                |                    |                    | S               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Disorder; Normal Pressure  
Hydrocephalus; Peripheral  
Sensorimotor Neuropathy;  
Urinary Incontinence

| <u>FDA Received Date</u>                                                                                         | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------|-------------------------------------------|--------------------|--------------------|-----------------|--------------------------|------------------------------------------------|-----------------|--------------|----------------|
| 14-Jun-2013                                                                                                      | 9300530                                   | EXPEDITED (15-DAY) |                    | HO              | JP-FRI-1000045210        |                                                | 41 YR           | Male         | JPN            |
| <u>Preferred Term</u>                                                                                            | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                             | <u>Duration</u> | <u>Mfr</u>   |                |
| Depressed Level Of Consciousness;<br>Dysarthria; Overdose;<br>Peripheral Coldness;<br>Toxicity To Various Agents | Lexapro                                   |                    |                    | S               | Oral                     | Overdose: 5 Tablets                            |                 | Forest       |                |
|                                                                                                                  | Depakene                                  |                    |                    | S               | Oral                     | Overdose: 13 Tablet Of Sodium Valproate 200 Mg |                 | Not Reported |                |
|                                                                                                                  | Flunitrazepam                             |                    |                    | S               | Oral                     | 3 Mg                                           |                 | Not Reported |                |
|                                                                                                                  | Biofermin                                 |                    |                    | C               | Oral                     | 4 Df                                           |                 | Not Reported |                |
|                                                                                                                  | Primperan                                 |                    |                    | C               | Oral                     | 10 Mg                                          |                 | Not Reported |                |
|                                                                                                                  | Stomachics And Digestives                 |                    |                    | C               | Other                    |                                                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                         | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Jun-2013                                                                                                      | 9323706                                   | EXPEDITED (15-DAY) |                    | OT              | US-SHIRE-ALL1-2013-03472 |                                                | 49 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                            | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                             | <u>Duration</u> | <u>Mfr</u>   |                |
| Face Oedema; Oedema Peripheral                                                                                   | Blinded 489 (Lisdexamfetamine Dimesylate) |                    |                    | S               | Oral                     | Unk Unk, 1x/Day:Qd                             |                 | Shire        |                |
|                                                                                                                  | Blinded Duloxetine Hydrochloride          |                    |                    | S               | Oral                     | Unk Unk, 1x/Day:Qd                             |                 | Shire        |                |
|                                                                                                                  | Blinded Escitalopram Oxalate              |                    |                    | S               | Oral                     | Unk Unk, 1x/Day:Qd                             |                 | Shire        |                |
|                                                                                                                  | Blinded Placebo                           |                    |                    | S               | Oral                     | Unk Unk, 1x/Day:Qd                             |                 | Shire        |                |
|                                                                                                                  | Blinded Sertraline Hydrochloride          |                    |                    | S               | Oral                     | Unk Unk, 1x/Day:Qd                             |                 | Shire        |                |
|                                                                                                                  | Blinded Venlafaxine Hydrochloride         |                    |                    | S               | Oral                     | Unk Unk, 1x/Day:Qd                             |                 | Shire        |                |
|                                                                                                                  | Duloxetine Hydrochloride                  |                    |                    | S               | Unknown                  | 30 Mg, Unknown                                 |                 | Unknown      |                |
|                                                                                                                  | Duloxetine Hydrochloride                  |                    |                    | S               | Unknown                  | 60 Mg, Unknown                                 |                 | Unknown      |                |
|                                                                                                                  | Multivitamin /07504101/                   |                    |                    | C               | Unknown                  | Unk Unk, Unknown                               |                 | Not Reported |                |

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

|                      |   |         |                  |              |
|----------------------|---|---------|------------------|--------------|
| Fish Oil             | C | Unknown | Unk Unk, Unknown | Not Reported |
| Biotin               | C | Unknown | Unk Unk, Unknown | Not Reported |
| B-12                 | C | Unknown | Unk Unk, Unknown | Not Reported |
| Lutein /01638501/    | C | Unknown | Unk Unk, Unknown | Not Reported |
| Potassium            | C | Unknown | Unk Unk, Unknown | Not Reported |
| Probiotic /06395501/ | C | Unknown | Unk Unk, Unknown | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 14-Jun-2013              | 9347988       | EXPEDITED (15-DAY) |                    | DS, HO, OT      | FR-ASTRAZENECA-2013SE41168 |                      | 87 YR      | Male       | FRA            |

| <u>Preferred Term</u>    | <u>Product</u>                             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|--------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Metabolic Encephalopathy | Inexium                                    |              |            | S           | Oral         |                    |                 | Astrazeneca  |
|                          | Seroplex                                   |              |            | S           | Oral         |                    |                 | Not Reported |
|                          | Keal                                       |              |            | S           | Oral         |                    |                 | Not Reported |
|                          | Seretide Diskus                            |              |            | C           |              |                    |                 | Not Reported |
|                          | Spiriva                                    |              |            | C           |              |                    |                 | Not Reported |
|                          | Procoralan                                 |              |            | C           |              |                    |                 | Not Reported |
|                          | Amlor                                      |              |            | C           |              |                    |                 | Not Reported |
|                          | Gaviscon                                   |              |            | C           |              |                    |                 | Not Reported |
|                          | Tahor                                      |              |            | C           |              |                    |                 | Not Reported |
|                          | Kardegic                                   |              |            | C           |              |                    |                 | Not Reported |
|                          | Tardyferon B9 [Ferrous Sulfate;Folic Acid] |              |            | C           |              |                    |                 | Not Reported |
|                          | Motilium                                   |              |            | C           |              |                    |                 | Not Reported |
|                          | Kaleorid                                   |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Jun-2013              | 9348935       | EXPEDITED (15-DAY) |                    | OT              | PL-FRI-1000045925    |                      |            | Male       | POL            |

| <u>Preferred Term</u>                                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Immunosuppression; Myalgia; Nasal Inflammation; Tendon Pain | Lexapro        |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                                             | Lexapro        |              |            | S           | Oral         |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 14-Jun-2013                                              | 9348943        | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000045926    |                      | 91 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Toxic Skin Eruption                                      | Escitalopram   |                    |                    | S               | Oral                 |                      |                 | Forest       |                |
|                                                          | Coversyl       |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                          | Selokeen       |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                          | Paracetamol    |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                          | Lasilix        |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                          | Ogast          |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                          | Seresta        |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                          | Victan         |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Jun-2013                                              | 9348953        | EXPEDITED (15-DAY) |                    | DE              | CH-FRI-1000045928    |                      | 85 YR           | Male         | CHE            |
| <u>Preferred Term</u>                                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cerebral Haemorrhage                                     | Escitalopram   |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                                          | Xarelto        |                    |                    | S               | Oral                 | 20 Mg                |                 | Not Reported |                |
|                                                          | Xarelto        |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                          | Eltroxin       |                    |                    | C               | Oral                 | 0.1 Mg               |                 | Not Reported |                |
|                                                          | Pantoprazol    |                    |                    | C               | Oral                 | 40 Mg                |                 | Not Reported |                |
|                                                          | Symbicort      |                    |                    | C               | Other                | 200/6                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Jun-2013                                              | 9352984        | DIRECT             | Y                  |                 |                      |                      | 33 YR           | Male         | USA            |
| <u>Preferred Term</u>                                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anger; Anxiety; Diarrhoea;<br>Product Substitution Issue | Escitalopram   |                    |                    | S               |                      |                      |                 | Aurobindo    |                |

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

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 17-Jun-2013              | 8586962       | NON-EXPEDITED    |                    |                 | US-ASTRAZENECA-2012SE31459 |                      | 52 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Fatigue; Hypertension;<br>Hypothyroidism; Renal<br>Impairment; Somnolence;<br>Trismus | Seroquel       |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                       | Seroquel       |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                       | Seroquel       |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                       | Seroquel       |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                       | Seroquel       |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                       | Seroquel       |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                       | Metoprolol     |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                       | Lexapro        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                       | Lexapro        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                       | Lexapro        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                       | Lexapro        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                       | Lexapro        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                       | Lexapro        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                       | Lexapro        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                       | Lexapro        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                       | Lexapro        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                       | Lexapro        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                       | Lexapro        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                       | Depakote       |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                       | Depakote       |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                       | Depakote       |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                       | Depakote       |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                       | Depakote       |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                       | Synthroid      |              |            | C           | Oral         |                    |                 | Not Reported |

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| Clomipramine                          |                      |                    | C                  |                 |                      | Not Reported           |                 |              |                |
|---------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|------------------------|-----------------|--------------|----------------|
| <u>FDA Received Date</u>              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Jun-2013                           | 9350591              | EXPEDITED (15-DAY) |                    | OT              | US-ACCORD-018035     |                        | 64 YR           | Female       | USA            |
| <u>Preferred Term</u>                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Bursitis; Musculoskeletal Discomfort; | Escitalopram         |                    |                    | S               | Oral                 | Duration - 4-5 Months. |                 | Accord       |                |
| Musculoskeletal Discomfort;           | Trazodone            |                    |                    | C               | Oral                 |                        |                 | Not Reported |                |
| Musculoskeletal Stiffness;            | Adderall             |                    |                    | C               | Oral                 |                        |                 | Not Reported |                |
| Musculoskeletal Stiffness;            | Wellbutrin           |                    |                    | C               | Oral                 |                        |                 | Not Reported |                |
| Tendonitis; Weight Increased          | Concerta             |                    |                    | C               | Oral                 |                        |                 | Not Reported |                |
| <u>FDA Received Date</u>              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Jun-2013                           | 9350663              | EXPEDITED (15-DAY) |                    | HO              | PHHY2013NO059339     |                        | 38 YR           | Female       | NOR            |
| <u>Preferred Term</u>                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Epistaxis                             | Voltarol             |                    |                    | S               | Oral                 | 25 Mg, 3-4 Times Daily |                 | Novartis     |                |
|                                       | Escitalopram Actavis |                    |                    | S               | Oral                 | 15 Mg, Qd              |                 | Not Reported |                |
|                                       | Imovane              |                    |                    | C               | Oral                 | 7.5 Mg, Qd             |                 | Not Reported |                |
|                                       | Paracet              |                    |                    | C               | Oral                 | 500 Mg, (3-4 Times)    |                 | Not Reported |                |
| <u>FDA Received Date</u>              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Jun-2013                           | 9351102              | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000045842    |                        | < 1 DAY         | Male         | USA            |
| <u>Preferred Term</u>                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Congenital Anomaly; Talipes           | Lexapro              |                    |                    | S               | Transplacental       |                        |                 | Forest       |                |
| <u>FDA Received Date</u>              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Jun-2013                           | 9353649              | DIRECT             | Y                  |                 |                      |                        | 60 YR           | Female       | USA            |

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| <u>Preferred Term</u>                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|----------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|------------------------------------------|----------------------|-----------------|--------------|----------------|
| Product Substitution Issue;<br>Treatment Failure               | Escitalopram   |                    |                    | S               | Oral                                     |                      |                 | Camber       |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Jun-2013                                                    | 9359154        | EXPEDITED (15-DAY) | Y                  | HO              | 7215926                                  |                      | 43 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aplasia; Musculoskeletal<br>Pain; Pyrexia                      | Levothyrox     |                    |                    | S               | Oral                                     | From Long Term       |                 | Not Reported |                |
|                                                                | Taxotere       |                    |                    | S               | Intravenous (not<br>otherwise specified) | 180mg Per Cycle      |                 | Not Reported |                |
|                                                                | Seroplex       |                    |                    | S               | Oral                                     | From Long Term       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Jun-2013                                                    | 8584812        | EXPEDITED (15-DAY) |                    | DE              | JP-FRI-1000030817                        |                      | 21 YR           | Female       | JPN            |
| <u>Preferred Term</u>                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Death; Depression                                              | Lexapro        |                    |                    | S               | Oral                                     | 10 Mg                |                 | Forest       |                |
|                                                                | Medipeace      |                    |                    | S               | Oral                                     | 1 Mg                 |                 | Not Reported |                |
|                                                                | Amoban         |                    |                    | S               | Oral                                     | 7.5 Mg               |                 | Not Reported |                |
|                                                                | Mucosta        |                    |                    | C               | Oral                                     | 200 Mg               |                 | Not Reported |                |
|                                                                | Goodmin        |                    |                    | C               | Oral                                     | 0.25 Mg              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Jun-2013                                                    | 9353660        | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000045957                        |                      |                 | Male         | FRA            |
| <u>Preferred Term</u>                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Loss Of Consciousness;<br>Malaise; Product<br>Dispensing Error | Escitalopram   |                    |                    | S               |                                          |                      |                 | Forest       |                |
|                                                                | Modopar        |                    |                    | C               |                                          |                      |                 | Not Reported |                |
|                                                                | Cozaar         |                    |                    | C               |                                          |                      |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                                                                                                                                                                                                                          | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| 18-Jun-2013                                                                                                                                                                                                                                                                       | 9353856        | EXPEDITED (15-DAY) |                    | OT              | US-TEVA-412705USA            |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                             | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Coeliac Disease                                                                                                                                                                                                                                                                   | Escitalopram   |                    |                    | S               |                              |                      |                 | Ivax         |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                          | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Jun-2013                                                                                                                                                                                                                                                                       | 9354900        | DIRECT             |                    | DS, HO, LT      |                              |                      | 34 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                             | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Anger;<br>Asthenia; Decreased<br>Appetite; Depression;<br>Diarrhoea; Diplopia;<br>Dizziness; Dry Mouth;<br>Dyspepsia; Feeling<br>Abnormal; Hallucination;<br>Insomnia; Pollakiuria;<br>Sinus Disorder;<br>Sluggishness;<br>Somnolence; Suicidal<br>Ideation; Tinnitus | Escitalopram   |                    |                    | S               | Oral                         | 1 And A Half Pills   |                 | Unknown      |                |
|                                                                                                                                                                                                                                                                                   | Multi          |                    |                    | C               |                              |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                   | Calcium        |                    | Y                  | C               |                              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                          | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Jun-2013                                                                                                                                                                                                                                                                       | 9355246        | DIRECT             |                    |                 |                              |                      | 54 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                             | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Folliculitis; Scar; Skin<br>Disorder                                                                                                                                                                                                                                              | Escitalopram   |                    |                    | S               |                              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                          | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Jun-2013                                                                                                                                                                                                                                                                       | 9272873        | EXPEDITED (15-DAY) |                    | OT              | IT-PFIZER INC-<br>2013138192 |                      | 31 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                             | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |



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|                            |                 |   |      |                     |              |
|----------------------------|-----------------|---|------|---------------------|--------------|
| Blood Pressure Increased;  | Xanax           | S | Oral | 2.5 Mg, Total Dose  | Pfizer       |
| Coma Scale; Drug Abuse;    | Zoloft          | S | Oral | 750 Mg, Total Dose  | Pfizer       |
| Fall; Lethargy; Mydriasis; | Venlafaxine Hcl | S | Oral | 2100 Mg, Total Dose | Pfizer       |
| Nasal Injury; Somnolence;  | Lexotan         | S | Oral | 27 Mg, Total Dose   | Not Reported |
| Speech Disorder            | Entact          | S | Oral | 15 MI, Total Dose   | Not Reported |
|                            | Delorazepam     | S | Oral | 40 MI, Total Dose   | Not Reported |

| <u>FDA Received Date</u>                    | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------|----------------|--------------------|--------------------|-----------------|------------------------------|-------------------------|-----------------|--------------|----------------|
| 19-Jun-2013                                 | 9354829        | EXPEDITED (15-DAY) |                    | HO              | FR-ABBOTT-13X-056-1106176-00 |                         | 73 YR           | Male         | FRA            |
| <u>Preferred Term</u>                       | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrioventricular Block;                     | Depakine       |                    |                    | S               | Oral                         | 500 Milligram(S); Daily |                 | Not Reported |                |
| Bradycardia; Loss Of Consciousness; Malaise | Seroplex       |                    |                    | S               | Oral                         | 5 Milligram(S); Daily   |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 19-Jun-2013              | 9355289        | EXPEDITED (15-DAY) |                    | OT              | PL-ACCORD-018146     |                      | 63 YR           | Female       | POL            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Discomfort               | Escitalopram   |                    |                    | S               |                      |                      |                 | Accord       |                |
|                          | Amlodipine     |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Venlafaxine    |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                          | Bisoprolol     |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|--------------------------|--------------------------|-----------------|--------------|----------------|
| 19-Jun-2013              | 9355564        | EXPEDITED (15-DAY) |                    | HO, OT          | FR-PFIZER INC-2013182669 |                          | 88 YR           | Female       | FRA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyponatraemia;           | Cordarone      |                    |                    | S               | Oral                     | 200 Mg Five Times A Week |                 | Pfizer       |                |
| Transaminases Increased; | Zofenil Duo    |                    |                    | S               | Oral                     | 1 Df, Daily              |                 | Not Reported |                |
| Urinary Retention        | Mopral         |                    |                    | S               | Oral                     | 20 Mg, Daily             |                 | Not Reported |                |

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|                                                                                  | Seroplex                                               |                    | S                  | Oral            | 10 Mg, Daily              |                      | Not Reported    |              |                |
|----------------------------------------------------------------------------------|--------------------------------------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
|                                                                                  | Kardegic                                               |                    | C                  |                 | Unk                       |                      | Not Reported    |              |                |
| <u>FDA Received Date</u>                                                         | <u>Case #</u>                                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Jun-2013                                                                      | 9355904                                                | EXPEDITED (15-DAY) |                    | OT              | IN-MYLANLABS-2013S1012450 |                      | 53 YR           | Male         | IND            |
| <u>Preferred Term</u>                                                            | <u>Product</u>                                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dementia; Gait Disturbance; Multiple Drug Therapy; Normal Pressure Hydrocephalus | Escitalopram                                           |                    |                    | S               | Unknown                   |                      |                 | Mylan        |                |
|                                                                                  | Pregabalin                                             |                    |                    | S               | Unknown                   |                      |                 | Not Reported |                |
|                                                                                  | Amitriptyline                                          |                    |                    | S               | Unknown                   |                      |                 | Not Reported |                |
|                                                                                  | Carbamazepine                                          |                    |                    | S               | Unknown                   |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                         | <u>Case #</u>                                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Jun-2013                                                                      | 9356543                                                | EXPEDITED (15-DAY) |                    | OT              | NZ-MYLANLABS-2013S1012453 |                      | 47 YR           | Male         | NZL            |
| <u>Preferred Term</u>                                                            | <u>Product</u>                                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Pruritus; Swelling Face                                                          | Escitalopram                                           |                    |                    | S               | Oral                      |                      |                 | Mylan        |                |
|                                                                                  | Cipramil [Citalopram Hydrobromide]                     |                    |                    | C               | Oral                      |                      |                 | Not Reported |                |
|                                                                                  | Lorazepam                                              |                    |                    | C               | Oral                      |                      |                 | Not Reported |                |
|                                                                                  | Zopiclone                                              |                    |                    | C               | Oral                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                         | <u>Case #</u>                                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Jun-2013                                                                      | 9548455                                                | NON-EXPEDITED      | Y                  | OT              | HYCA20100001              |                      | 57 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                            | <u>Product</u>                                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cough; Dizziness                                                                 | Hycodan [Hydrocodone Bitartrate]                       |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                                                                                  | Lexapro (Escitalopram Oxalate) (10 Milligram, Tablets) |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                                                                                  | Inderal (Propranolol Hydrochloride)                    |                    |                    | C               | Oral                      |                      |                 | Not Reported |                |

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| <u>FDA Received Date</u>                     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------|----------------|--------------------|--------------------|-----------------|---------------------------------------|----------------------|-----------------|--------------|----------------|
| 20-Jun-2013                                  | 8610171        | EXPEDITED (15-DAY) |                    | DE, LT          | JP-FRI-1000031190                     |                      | 86 YR           | Male         | JPN            |
| <u>Preferred Term</u>                        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Inappropriate Antidiuretic Hormone Secretion | Lexapro        |                    |                    | S               | Oral                                  | 10 Mg                |                 | Forest       |                |
|                                              | Jzoloft        |                    |                    | S               | Oral                                  | 50 Mg                |                 | Not Reported |                |
|                                              | Gascon         |                    |                    | C               | Oral                                  | 120 Mg               |                 | Not Reported |                |
|                                              | Dogmatyl       |                    |                    | C               | Oral                                  | 100 Mg               |                 | Not Reported |                |
|                                              | Takepron       |                    |                    | C               | Oral                                  | 15 Mg                |                 | Not Reported |                |
|                                              | Predonine      |                    |                    | C               | Intravenous (not otherwise specified) | 10 Mg                |                 | Not Reported |                |
| <u>FDA Received Date</u>                     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Jun-2013                                  | 9308346        | EXPEDITED (15-DAY) |                    | OT              | US-FRI-1000045324                     |                      |                 | Male         | USA            |
| <u>Preferred Term</u>                        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Gynaecomastia                                | Lexapro        |                    |                    | S               | Oral                                  | 10 Mg                |                 | Forest       |                |
| <u>FDA Received Date</u>                     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Jun-2013                                  | 9321663        | EXPEDITED (15-DAY) |                    | HO              | JP-FRI-1000045486                     |                      | 57 YR           | Male         | JPN            |
| <u>Preferred Term</u>                        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Rhabdomyolysis                               | Lexapro        |                    |                    | S               | Oral                                  | 10 Mg                |                 | Forest       |                |
|                                              | Theodur        |                    |                    | S               | Oral                                  |                      |                 | Not Reported |                |
|                                              | Sekinarin      |                    |                    | S               | Oral                                  |                      |                 | Not Reported |                |
|                                              | Zyprexa        |                    |                    | C               | Oral                                  | 5 Mg                 |                 | Not Reported |                |
|                                              | Cymbalta       |                    |                    | C               | Oral                                  | 20 Mg                |                 | Not Reported |                |
|                                              | Reflex         |                    |                    | C               | Oral                                  | 15 Mg                |                 | Not Reported |                |
|                                              | Limas          |                    |                    | C               | Oral                                  | 400 Mg               |                 | Not Reported |                |

# FDA Adverse Event Reporting System

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### Detailed Report

|  |                         |   |      |        |  |              |
|--|-------------------------|---|------|--------|--|--------------|
|  | Depakene-R              | C | Oral | 400 Mg |  | Not Reported |
|  | Horizon                 | C | Oral | 10 Mg  |  | Not Reported |
|  | Wypax                   | C | Oral | 1 Mg   |  | Not Reported |
|  | Amlodipine              | C | Oral | 10 Mg  |  | Not Reported |
|  | Lipitor                 | C | Oral | 5 Mg   |  | Not Reported |
|  | Fluitran                | C | Oral | 2 Mg   |  | Not Reported |
|  | Lamisil                 | C | Oral | 125 Mg |  | Not Reported |
|  | Imidapril Hydrochloride | C | Oral | 5 Mg   |  | Not Reported |
|  | Cernilton               | C | Oral | 6 Df   |  | Not Reported |
|  | Lansoprazole            | C | Oral | 15 Mg  |  | Not Reported |
|  | Adetphos                | C | Oral | 300 Mg |  | Not Reported |
|  | Betahistine Mesilate    | C | Oral | 36 Mg  |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Jun-2013              | 9357809       | EXPEDITED (15-DAY) |                    | OT              | CH-FRI-1000046051    |                      |            | Female     | CHE            |

| <u>Preferred Term</u>            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Arthralgia; Condition Aggravated | Escitalopram   |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                  | Escitalopram   |              |            | S           |              |                    |                 | Forest       |
|                                  | Lexotanil      |              |            | C           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Jun-2013              | 9360923       | DIRECT           | Y                  |                 |                      |                      |            | Female     | USA            |

| <u>Preferred Term</u>           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------|----------------|--------------|------------|-------------|--------------|--------------------------|-----------------|--------------|
| Headache; Product Quality Issue | Lexapro        |              |            | S           | Oral         | Lexapro 10 Mg Daily Oral | 1 MTH           | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 21-Jun-2013              | 9272130       | EXPEDITED (15-DAY) |                    | HO, OT          | FR-ASTRAZENECA-2013SE29259 |                      | 88 YR      | Female     | FRA            |

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| <u>Preferred Term</u>                                                                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|------------------------|-----------------|--------------|
| Confusional State;<br>Hyponatraemia;<br>Transaminases Increased;<br>Urinary Retention | Mopral         |              |            | S           | Oral         |                        |                 | Not Reported |
|                                                                                       | Seroplex       |              |            | S           | Oral         |                        |                 | Not Reported |
|                                                                                       | Cordarone      |              |            | S           | Oral         |                        |                 | Not Reported |
|                                                                                       | Zofenil Duo    |              |            | S           | Oral         |                        |                 | Not Reported |
|                                                                                       | Kardegic       |              |            | C           |              | Long Lasting Treatment |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Jun-2013              | 9350659       | EXPEDITED (15-DAY) |                    | HO              | PHHY2013FR059946     |                      | 83 YR      | Female     | FRA            |

| <u>Preferred Term</u>        | <u>Product</u>                    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------|-----------------------------------|--------------|------------|-------------|--------------|----------------------|-----------------|--------------|
| Gastric Ulcer<br>Haemorrhage | Sandostatin                       |              |            | S           |              |                      |                 | Novartis     |
|                              | Lovenox                           |              |            | S           | Subcutaneous | 0.4 Mg /12 Hours Bid |                 | Not Reported |
|                              | Seroplex                          |              |            | S           | Oral         | 20 Mg, Bid           |                 | Not Reported |
|                              | Aspegic [Acetylsalicylate Lysine] |              |            | S           |              |                      |                 | Not Reported |
|                              | Tahor                             |              |            | C           | Oral         | 10 Mg, Qd            |                 | Not Reported |
|                              | Domperidone                       |              |            | C           |              | Unk Unk, Unk         |                 | Not Reported |
|                              | Perindopril Arrow                 |              |            | C           |              | 4 Mg, Bid            |                 | Not Reported |
|                              | Pyostacine                        |              |            | C           | Oral         | 1000 Mg, Tid         |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Jun-2013              | 9368937       | EXPEDITED (15-DAY) | Y                  | HO              | 2013000131           |                      | 91 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u>                         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Toxic Skin Eruption   | Aceon (Perindopril Erbumine)<br>Tablet |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Selokeen                               |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Seroplex                               |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Paracetamol (Paracetamol)              |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Lasilix (Furosemide)                   |              |            | S           |              |                    |                 | Not Reported |
|                       | Ogast                                  |              |            | S           |              |                    |                 | Not Reported |

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|                                                                                                           | Seresta (Oxazepam)       |                    | S                  | Oral            |                      |                             |                 | Not Reported |                |
|-----------------------------------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|----------------------|-----------------------------|-----------------|--------------|----------------|
|                                                                                                           | Victan                   |                    | S                  |                 |                      |                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Jun-2013                                                                                               | 9364603                  | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000046091    |                             | 61 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                     | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Alcohol Abuse; Altered State Of Consciousness; Cardiac Arrest; Coma; Overdose; Respiratory Distress       | Escitalopram             |                    |                    | S               | Oral                 |                             |                 | Forest       |                |
|                                                                                                           | Escitalopram             |                    |                    | S               |                      | Overdose Of Unknown Dose    |                 | Not Reported |                |
|                                                                                                           | Baclofene                |                    |                    | S               | Oral                 |                             |                 | Not Reported |                |
|                                                                                                           | Baclofene                |                    |                    | S               | Oral                 | Overdose Of An Unknown Dose |                 | Not Reported |                |
|                                                                                                           | Seresta                  |                    |                    | S               |                      | Overdose Of An Unknown Dose |                 | Not Reported |                |
|                                                                                                           | Lexomil                  |                    |                    | S               | Oral                 | Overdose Of Unknown Dose    |                 | Not Reported |                |
|                                                                                                           | Tramadol                 |                    |                    | S               | Oral                 | Overdose Of Unknown Dose    |                 | Not Reported |                |
|                                                                                                           | Zolpidem                 |                    |                    | S               | Oral                 | Overdose Of Unknown Dose    |                 | Not Reported |                |
|                                                                                                           | Risperidone              |                    |                    | S               | Oral                 | Overdose Of Unknown Dose    |                 | Not Reported |                |
|                                                                                                           | Anti-Vitamin K Nos       |                    |                    | C               |                      | Dose According To Inr       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Jun-2013                                                                                               | 9365470                  | DIRECT             |                    | OT              |                      |                             | 40 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                     | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Diarrhoea; Drug Withdrawal Syndrome; Feeling Abnormal; Headache; Irritability; Product Substitution Issue | Escitalopram             |                    |                    | S               | Oral                 |                             |                 | Camber       |                |
|                                                                                                           | Escitalopram 20 Mg Mylan |                    |                    | S               | Oral                 |                             |                 | Mylan        |                |

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

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|--------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 25-Jun-2013                       | 9194189                  | EXPEDITED (15-DAY)        |                             | OT                       | NO-FRI-1000043775             |                               | 47 YR                    | Female              | NOR                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Loss Of Consciousness             | Escitalopram             |                           |                             | S                        | Oral                          | 10 Mg                         |                          | Forest              |                         |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 25-Jun-2013                       | 9365915                  | EXPEDITED (15-DAY)        |                             | HO                       | TR-FRI-1000046089             |                               | 32 YR                    | Female              | TUR                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Bipolar Disorder                  | Escitalopram             |                           |                             | S                        |                               | 20 Mg                         |                          | Forest              |                         |
|                                   | Carbamazepine            |                           |                             | C                        |                               | 100 Mg                        |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 25-Jun-2013                       | 9366604                  | EXPEDITED (15-DAY)        |                             | OT                       | DK-FRI-1000046128             |                               | 40 YR                    | Female              | DNK                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Anaphylactic Shock                | Escitalopram             |                           |                             | S                        |                               |                               |                          | Forest              |                         |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 25-Jun-2013                       | 9366673                  | EXPEDITED (15-DAY)        |                             | OT                       | US-TEVA-405553USA             |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Anxiety; Chest Discomfort;        | Escitalopram             |                           |                             | S                        | Oral                          | 10 Milligram Daily;           |                          | Ivax                |                         |
| Diarrhoea; Dizziness;             | Levothyroxine Sodium     |                           |                             | C                        | Oral                          | .1 Milligram Daily;           |                          | Not Reported        |                         |
| Dyspnoea; Headache; Hip           | Lansoprazole             |                           |                             | C                        | Oral                          | 30 Milligram Daily;           |                          | Not Reported        |                         |
| Arthroplasty;                     |                          |                           |                             |                          |                               | Delayed Release               |                          |                     |                         |
| Hypothyroidism; Muscle            | Multivitamins And Iron   |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
| Twitching; Myocardial             | Pyridoxine Hydrochloride |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
| Infarction; Osteoarthritis;       |                          |                           |                             |                          |                               |                               |                          |                     |                         |
| Type V Hyperlipidaemia            |                          |                           |                             |                          |                               |                               |                          |                     |                         |

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| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Jun-2013              | 9367352       | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000046132    |                      | 84 YR      | Female     | FRA            |

| <u>Preferred Term</u>          | <u>Product</u>                                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------|------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Malaise; Petit Mal<br>Epilepsy | Citalopram                                     |              |            | S           |              | 10 Mg              |                 | Forest       |
|                                | Citalopram                                     |              |            | S           |              |                    |                 | Forest       |
|                                | Escitalopram                                   |              |            | S           |              | 5 Mg               |                 | Forest       |
|                                | Escitalopram                                   |              |            | S           |              |                    |                 | Forest       |
|                                | Zyprexa                                        |              |            | C           |              | 15 Mg              |                 | Not Reported |
|                                | Metformine                                     |              |            | C           |              |                    |                 | Not Reported |
|                                | Seresta                                        |              |            | C           |              |                    |                 | Not Reported |
|                                | Xelevia                                        |              |            | C           | Oral         |                    |                 | Not Reported |
|                                | Novonorm                                       |              |            | C           | Oral         |                    |                 | Not Reported |
|                                | Coversyl                                       |              |            | C           | Oral         |                    |                 | Not Reported |
|                                | Fenofibrate                                    |              |            | C           |              |                    |                 | Not Reported |
|                                | Kardegic                                       |              |            | C           | Oral         |                    |                 | Not Reported |
|                                | Havlane                                        |              |            | C           |              |                    |                 | Not Reported |
|                                | Cromedil                                       |              |            | C           |              |                    |                 | Not Reported |
|                                | Modopar                                        |              |            | C           | Oral         |                    |                 | Not Reported |
|                                | Lamaline<br>(Acetaminophen\Caffeine\Opium<br>) |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Jun-2013              | 9369394       | DIRECT           |                    |                 |                      |                      | 67 YR      | Female     | USA            |

| <u>Preferred Term</u>                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Ineffective; Product<br>Substitution Issue | Escitalopram   |              |            | S           | Oral         | 1/Day              | 3 MTH           | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Jun-2013              | 9378089       | EXPEDITED (15-DAY) | Y                  | OT              | 2013P1008592         |                      | 53 YR      | Male       | IND            |



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| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| Apathy; Central Nervous System Infection; Cerebral Ventricle Dilatation; Cognitive Disorder; Dementia; Diabetic Retinopathy; Gait Disturbance; Gait Disturbance; Lack Of Spontaneous Speech; Lethargy; Memory Impairment; Mini Mental Status Examination Abnormal; Neurological Decompensation; Normal Pressure Hydrocephalus; Peripheral Sensorimotor Neuropathy; Urinary Incontinence | Escitalopram         |                    |                    | S               |                          |                      | 3 MTH           | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                         | Pregabalin           |                    |                    | S               |                          |                      | 3 MTH           | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                         | Amitryptiline        |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                         | Carbamazipine        |                    |                    | S               |                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                                                                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Jun-2013                                                                                                                                                                                                                                                                                                                                                                             | 9291041              | EXPEDITED (15-DAY) |                    | OT              | CH-FRI-1000045147        |                      |                 | Male         | CHE            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Neutropenia                                                                                                                                                                                                                                                                                                                                                                             | Escitalopram         |                    |                    | S               | Oral                     | 10 Mg                |                 | Forest       |                |
|                                                                                                                                                                                                                                                                                                                                                                                         | Escitalopram         |                    |                    | S               |                          |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                                                                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Jun-2013                                                                                                                                                                                                                                                                                                                                                                             | 9315749              | EXPEDITED (15-DAY) |                    | OT              | IN-PFIZER INC-2013159634 |                      | 53 YR           | Male         | IND            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dementia; Gait Disturbance; Lethargy                                                                                                                                                                                                                                                                                                                                                    | Escitalopram Oxalate |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                         | Pregabalin           |                    |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                                                                                                                                                                                                                                                                                                                                                                                         | Carbamazepine        |                    |                    | S               | Unknown                  | Unk                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                         | Amitriptyline        |                    |                    | S               | Unknown                  | Unk                  |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|---------------------------------------------------------------------------|-----------------|--------------|----------------|
| 26-Jun-2013                                                              | 9369522        | EXPEDITED (15-DAY) |                    | HO              | DE-FRI-1000046084    |                                                                           |                 | Male         | DEU            |
| <u>Preferred Term</u>                                                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                        | <u>Duration</u> | <u>Mfr</u>   |                |
| C-Reactive Protein Increased; Dizziness; Nausea; Orthostatic Hypotension | Escitalopram   |                    |                    | S               | Oral                 | 10 Mg                                                                     |                 | Forest       |                |
|                                                                          | Escitalopram   |                    |                    | S               | Oral                 | 20 Mg                                                                     |                 | Not Reported |                |
|                                                                          | Clozapine      |                    |                    | S               | Oral                 | 25 Mg                                                                     |                 | Not Reported |                |
|                                                                          | Clozapine      |                    |                    | S               | Oral                 | 62.5 Mg                                                                   |                 | Not Reported |                |
|                                                                          | Clozapine      |                    |                    | S               |                      | Temporarily Dose Reduction; Thereafter Slow Dosage Increase To 150 Mg/Day |                 | Not Reported |                |
|                                                                          | Zeldox         |                    |                    | S               | Oral                 | 160 Mg                                                                    |                 | Not Reported |                |
|                                                                          | Enahexal       |                    |                    | S               | Oral                 | 5 Mg                                                                      |                 | Not Reported |                |
|                                                                          | Lamotrigin     |                    |                    | C               | Oral                 | 100 Mg                                                                    |                 | Not Reported |                |
|                                                                          | Ass            |                    |                    | C               | Oral                 | 300 Mg                                                                    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Jun-2013                                                              | 9369884        | EXPEDITED (15-DAY) |                    | HO              | JP-FRI-1000046217    |                                                                           | 31 YR           | Female       | JPN            |
| <u>Preferred Term</u>                                                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                        | <u>Duration</u> | <u>Mfr</u>   |                |
| Altered State Of Consciousness; Overdose                                 | Lexapro        |                    |                    | S               |                      | Overdose: 29 Tablets                                                      |                 | Forest       |                |
|                                                                          | Triazolam      |                    |                    | S               |                      | Overdose: 40 Tablets                                                      |                 | Not Reported |                |
|                                                                          | Clonazepam     |                    |                    | S               |                      | Overdose: 7 Tablets                                                       |                 | Not Reported |                |
|                                                                          | Flunitrazepam  |                    |                    | S               |                      | Overdose: 61 Tablets                                                      |                 | Not Reported |                |
|                                                                          | Blonanserlin   |                    |                    | S               |                      | Overdose: Unknown Dose                                                    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Jun-2013                                                              | 9370007        | EXPEDITED (15-DAY) |                    | CA, DS          | BE-FRI-1000046207    |                                                                           |                 | Unknown      | BEL            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                                                                                                                                                  | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| Foetal Exposure During Pregnancy;<br>Microphthalmos; Visual Impairment                                                                                                                                 | Escitalopram           |                    |                    | S               | Transplacental           |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                                                                                               | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Jun-2013                                                                                                                                                                                            | 9370048                | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-2013188156 |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                  | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Decreased Appetite;<br>Depression; Dry Mouth;<br>Fatigue; Nausea; Night Sweats; Urine Output Decreased                                                                                                 | Premarin               |                    |                    | S               |                          | Unk, (0.45)          |                 | Pfizer       |                |
|                                                                                                                                                                                                        | Zoloft                 |                    |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                                                                                                                                                                                                        | Lexapro                |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                               | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Jun-2013                                                                                                                                                                                            | 9370427                | EXPEDITED (15-DAY) |                    | LT, OT          | FR-PFIZER INC-2013188318 |                      | 63 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                                  | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Behaviour Disorder; Blood Alcohol Increased; Coma; Disorientation; Extrapyramidal Disorder; Hallucination; Hypertension; Hypothermia; Muscle Spasticity; Sinus Bradycardia; Toxicity To Various Agents | Lyrica                 |                    |                    | S               | Oral                     |                      |                 | Pfizer       |                |
|                                                                                                                                                                                                        | Lioresal               |                    |                    | S               | Oral                     | 10 Mg, Unk           |                 | Not Reported |                |
|                                                                                                                                                                                                        | Tranxene               |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                                                                                                                                                                                                        | Seroplex               |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                                                                                                                                                                                                        | Tramadol Hydrochloride |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                                                                                                                                                                                                        | Haldol                 |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                               | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Jun-2013                                                                                                                                                                                            | 9378664                | EXPEDITED (15-DAY) | Y                  | HO              | DSM-2013-00583           |                      | 79 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                  | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

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

|                    |             |   |      |                   |              |
|--------------------|-------------|---|------|-------------------|--------------|
| Confusional State; | Axeler      | S | Oral | 40/5 Mg           | Not Reported |
| Depression;        | Seroplex    | S | Oral | (10 Mg, 1 In 1 D) | Not Reported |
| Hyponatraemia      | Fenofibrate | S | Oral | (67 Mg, 1 In 1 D) | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Jun-2013              | 9548341       | NON-EXPEDITED    | Y                  | HO              | 299499               |                      | 47 YR      | Female     | USA            |

| <u>Preferred Term</u>              | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Feeling Abnormal;<br>Hypoaesthesia | Bupivacaine Hydrochloride |              |            | S           |              |                    |                 | Not Reported |
|                                    | Isovue                    |              |            | S           |              | 2 MI, Epidural     |                 | Not Reported |
|                                    | Lidocaine                 |              |            | C           |              |                    |                 | Not Reported |
|                                    | Kenalog-40                |              |            | S           |              | 2 MI, Epidural     |                 | Not Reported |
|                                    | Aspirin                   |              |            | C           |              |                    |                 | Not Reported |
|                                    | Actos                     |              |            | C           |              |                    |                 | Not Reported |
|                                    | Lithium                   |              |            | C           |              |                    |                 | Not Reported |
|                                    | Metoprol                  |              |            | C           |              |                    |                 | Not Reported |
|                                    | Lyrica                    |              |            | C           |              |                    |                 | Not Reported |
|                                    | Namenda                   |              |            | C           |              |                    |                 | Not Reported |
|                                    | Lexapro                   |              |            | S           |              |                    |                 | Not Reported |
|                                    | Singulair                 |              |            | C           |              |                    |                 | Not Reported |
|                                    | Mag-Ox                    |              |            | C           |              |                    |                 | Not Reported |
|                                    | Kcl                       |              |            | C           |              |                    |                 | Not Reported |
|                                    | Ativan                    |              |            | C           |              |                    |                 | Not Reported |
|                                    | Lisinopril                |              |            | C           |              |                    |                 | Not Reported |
|                                    | Simvastatin               |              |            | C           |              |                    |                 | Not Reported |
|                                    | Lasix                     |              |            | C           |              |                    |                 | Not Reported |
|                                    | Isosorbide                |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 27-Jun-2013              | 8830516       | EXPEDITED (15-DAY) |                    | DE, OT          | JP-PFIZER INC-<br>2012216483 |                      | 52 YR      | Female     | JPN            |

| <u>Preferred Term</u>                                                                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Affect Lability; Breast<br>Cancer; Device Occlusion;<br>Dizziness; Myoclonus;<br>Renal Failure; | Lyrica         |              |            | S           | Oral         | 75 Mg, 2x/Day      |                 | Pfizer     |
|                                                                                                 | Lyrica         |              |            | S           |              | 75 Mg, 1x/Day      |                 | Pfizer     |
|                                                                                                 | Lyrica         |              |            | S           |              | 25 Mg, 1x/Day      |                 | Pfizer     |

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

|            |             |   |             |               |              |
|------------|-------------|---|-------------|---------------|--------------|
| Somnolence | Lexapro     | S | Oral        | 10 Mg, 1x/Day | Not Reported |
|            | Lexapro     | S | Oral        | 10 Mg, 1x/Day | Not Reported |
|            | Fentos Tape | S | Transdermal | 6 Mg, 1x/Day  | Not Reported |
|            | Takepron Od | C | Oral        | 15 Mg, 1x/Day | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Jun-2013              | 9366802       | EXPEDITED (15-DAY) | LT                 |                 | FR-FRI-1000046092    |                      | 73 YR      | Male       | FRA            |

| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Atrioventricular Block; | Escitalopram   |              |            | S           | Oral         | 1 Df               |                 | Forest       |
| Bradycardia; Malaise;   | Escitalopram   |              |            | S           |              | 10 Mg              |                 | Forest       |
| Product Use In          | Depakine       |              |            | C           | Oral         | 1 Df               |                 | Not Reported |
| Unapproved Indication;  |                |              |            |             |              |                    |                 |              |
| Torsade De Pointes      |                |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------------------------|----------------------|------------|------------|----------------|
| 27-Jun-2013              | 9371064       | EXPEDITED (15-DAY) |                    | HO              | US-LUPIN<br>PHARMACEUTICALS<br>INC.-E2B_00000989 |                      | 49 DAY     | Male       | USA            |

| <u>Preferred Term</u>                                                                                                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Diarrhoea; Eye Movement<br>Disorder; Faeces<br>Discoloured; Irritability;<br>Neonatal Respiratory<br>Distress; Somnolence | Escitalopram   |              |            | S           | Transmammary |                    |                 | Lupin      |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Jun-2013              | 9371836       | EXPEDITED (15-DAY) |                    | OT              | GB-FRI-1000046212    |                      | 65 YR      | Female     | GBR            |

| <u>Preferred Term</u>                                                                                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Depressed Mood;<br>Depression; Diarrhoea;<br>Drug Ineffective; Malaise;<br>Product Substitution Issue | Escitalopram   |              |            | S           | Oral         | 10 Mg              |                 | Forest     |

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

| <a href="#">FDA Received Date</a>                                                                                                    | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|--------------------------------------------------------------------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 27-Jun-2013                                                                                                                          | 9371973                 | EXPEDITED (15-DAY)        |                             | HO                       | FR-FRI-1000046214             |                               | 40 YR                    | Female              | FRA                     |
| <a href="#">Preferred Term</a>                                                                                                       | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Vaginal Haemorrhage                                                                                                                  | Escitalopram            |                           |                             | S                        |                               | 15 Mg                         |                          | Forest              |                         |
|                                                                                                                                      | Antihypertensives       |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                                    | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 27-Jun-2013                                                                                                                          | 9372509                 | EXPEDITED (15-DAY)        |                             | OT                       | JP-FRI-1000046209             |                               | 78 YR                    | Female              | JPN                     |
| <a href="#">Preferred Term</a>                                                                                                       | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Granulocyte Count Decreased                                                                                                          | Lexapro                 |                           |                             | S                        | Oral                          | 10 Mg                         |                          | Forest              |                         |
| <a href="#">FDA Received Date</a>                                                                                                    | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 27-Jun-2013                                                                                                                          | 9372760                 | EXPEDITED (15-DAY)        |                             | CA, DE                   | US-FRI-1000046153             |                               | < 1 DAY                  | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                                                                       | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Anomalous Pulmonary Venous Connection; Atrial Septal Defect; Coarctation Of The Aorta; Congenital Anomaly; Ventricular Septal Defect | Lexapro                 |                           |                             | S                        | Transplacental                |                               |                          | Forest              |                         |
| <a href="#">FDA Received Date</a>                                                                                                    | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 27-Jun-2013                                                                                                                          | 9372983                 | EXPEDITED (15-DAY)        |                             | HO                       | KR-FRI-1000046210             |                               | 47 YR                    | Male                | KOR                     |
| <a href="#">Preferred Term</a>                                                                                                       | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Altered State Of Consciousness; Coma; Hyponatraemia; Respiration Abnormal; Seizure                                                   | Escitalopram            |                           |                             | S                        |                               | 5 Mg                          |                          | Forest              |                         |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

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| <u>FDA Received Date</u>                                                                                    | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>        | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------|-----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|-------------------|----------------|
| 27-Jun-2013                                                                                                 | 9373561         | EXPEDITED (15-DAY) |                    | DS              | CN-FRI-1000046278    |                      | 71 YR           | Female            | CHN            |
| <u>Preferred Term</u>                                                                                       | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>        |                |
| Renal Impairment                                                                                            | Escitalopram    |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest            |                |
|                                                                                                             | Mirtazapine     |                    |                    | S               |                      |                      |                 | Not Reported      |                |
| <u>FDA Received Date</u>                                                                                    | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>        | <u>Country</u> |
| 28-Jun-2013                                                                                                 | 9321695         | EXPEDITED (15-DAY) |                    | OT              | US-FRI-1000045527    |                      | 54 YR           | Male              | USA            |
| <u>Preferred Term</u>                                                                                       | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>        |                |
| Haematochezia                                                                                               | Escitalopram    |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest            |                |
|                                                                                                             | Escitalopram    |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest            |                |
|                                                                                                             | Escitalopram    |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest            |                |
|                                                                                                             | Asacol          |                    |                    | C               |                      | 4800 Mg              |                 | Not Reported      |                |
| <u>FDA Received Date</u>                                                                                    | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>        | <u>Country</u> |
| 28-Jun-2013                                                                                                 | 9375941         | EXPEDITED (15-DAY) |                    | OT              | CA-RB-055443-13      |                      | 3 DAY           | Male              | CAN            |
| <u>Preferred Term</u>                                                                                       | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>        |                |
| Drug Withdrawal Syndrome Neonatal; Exposure Via Breast Milk; Foetal Exposure During Pregnancy; Hyperthermia | Suboxone Tablet |                    |                    | S               | Transplacental       |                      |                 | Reckitt Benckiser |                |
|                                                                                                             | Subutex         |                    |                    | S               | Transplacental       |                      |                 | Reckitt Benckiser |                |
|                                                                                                             | Subutex         |                    |                    | S               | Transmammary         |                      |                 | Reckitt Benckiser |                |
|                                                                                                             | Cipralex        |                    |                    | S               | Transplacental       |                      |                 | Not Reported      |                |
|                                                                                                             | Steroids        |                    |                    | S               | Transplacental       | 2 Doses              |                 | Not Reported      |                |
|                                                                                                             | Nicotine        |                    |                    | S               | Transplacental       | <10 Daily            |                 | Not Reported      |                |
| <u>FDA Received Date</u>                                                                                    | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>        | <u>Country</u> |
| 28-Jun-2013                                                                                                 | 9380169         | EXPEDITED (15-DAY) | Y                  | OT              | AUR-APL-2013-05270   |                      | 31 YR           | Female            | DEU            |

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| <u>Preferred Term</u>                                                     | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>                                | <u>Duration</u> | <u>Mfr</u>           |                |
|---------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|------------------------------------------|---------------------------------------------------|-----------------|----------------------|----------------|
| Inappropriate Antidiuretic Hormone Secretion; Nocturia; Pollakiuria       | Paroxetine (Paroxetine) |                    |                    | S               | Oral                                     |                                                   |                 | Not Reported         |                |
|                                                                           | Ciprallex               |                    |                    | S               | Oral                                     |                                                   |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                  | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>                              | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 01-Jul-2013                                                               | 8844296                 | EXPEDITED (15-DAY) |                    | HO, LT          | AT-JNJFOC-20121002370                    |                                                   | 21 YR           | Male                 | AUT            |
| <u>Preferred Term</u>                                                     | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>                                | <u>Duration</u> | <u>Mfr</u>           |                |
| Drug Interaction; Panic Attack; Paranoia; Suicidal Ideation               | Concerta                |                    |                    | S               | Oral                                     |                                                   |                 | Not Reported         |                |
|                                                                           | Risperdal Consta        |                    |                    | S               | Intramuscular                            |                                                   |                 | Not Reported         |                |
|                                                                           | Nozinan                 |                    |                    | S               | Unknown                                  |                                                   |                 | Not Reported         |                |
|                                                                           | Ciprallex               |                    |                    | S               | Unknown                                  |                                                   |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                  | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>                              | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 01-Jul-2013                                                               | 9286407                 | EXPEDITED (15-DAY) |                    | OT              | US-FRI-1000044974                        |                                                   | < 1 DAY         | Male                 | USA            |
| <u>Preferred Term</u>                                                     | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>                                | <u>Duration</u> | <u>Mfr</u>           |                |
| Anxiety; Attention Deficit/Hyperactivity Disorder; Premature Baby         | Lexapro                 |                    |                    | S               | Transplacental                           |                                                   |                 | Forest               |                |
| <u>FDA Received Date</u>                                                  | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>                              | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 01-Jul-2013                                                               | 9376350                 | EXPEDITED (15-DAY) |                    | DE              | FR-BRISTOL-MYERS SQUIBB COMPANY-19043017 |                                                   | 75 YR           | Male                 | FRA            |
| <u>Preferred Term</u>                                                     | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>                                | <u>Duration</u> | <u>Mfr</u>           |                |
| Acute Coronary Syndrome; Intra-Abdominal Haematoma; Staphylococcal Sepsis | Coumadin Tabs 2 Mg      |                    |                    | S               | Oral                                     | Took 4x1/D For 5 Days From 27feb2013 To 03mar2013 |                 | Bristol Myers Squibb |                |
|                                                                           | Dafalgan                |                    |                    | S               |                                          | Capsules                                          |                 | Cadence              |                |
|                                                                           | Lovenox                 |                    |                    | S               | Subcutaneous                             | 1df-10000 Anti-Xa/1ml Soln For Inj In Prefilled   |                 | Not Reported         |                |



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|                   |   |                                                         |              |
|-------------------|---|---------------------------------------------------------|--------------|
| Seroplex          | S | Syringe                                                 | Not Reported |
| Topalgic (France) | S | Tablets                                                 | Not Reported |
| Lasilix Retard    | C | Capsule                                                 | Not Reported |
| Inegy             | C | Oral                                                    | Not Reported |
| Janumet           | C | 1 Df - 10mg/20mg Tablet                                 | Not Reported |
| Pariet            | C | 1 Df - 50mg/1000mg Tablet                               | Not Reported |
| Spiriva           | C | Tablets                                                 | Not Reported |
|                   |   | 1df - 18 Micro G, Powder For Inhalation In Hard Capsule | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Jul-2013              | 9376979       | EXPEDITED (15-DAY) |                    | HO              | JP-FRI-1000046317    |                      | 39 YR      | Male       | JPN            |

| <u>Preferred Term</u>                                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Depressed Level Of Consciousness; Mouth Breathing; Overdose | Lexapro        |              |            | S           | Oral         | Overdose 350 Mg    |                 | Forest       |
|                                                             | Solanax        |              |            | S           | Oral         | Overdose 210 Mg    |                 | Not Reported |
|                                                             | Dogmatyl       |              |            | S           | Oral         | Overdose 190 Mg    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 01-Jul-2013              | 9377040       | EXPEDITED (15-DAY) |                    | HO, OT          | IT-PFIZER INC-2013191013 |                      | 19 YR      | Female     | ITA            |

| <u>Preferred Term</u>                                                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|-----------------------------|-----------------|--------------|
| Agitation; Depression; Dysphoria; Intentional Overdose; Intentional Self-Injury | Xanax          |              |            | S           | Oral         | 1mg (4 Df Of 0.25 Mg) Total |                 | Pfizer       |
|                                                                                 | Entact         |              |            | S           | Oral         | 20 Mg, 1x/Day (1df)         |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 02-Jul-2013              | 9095657       | EXPEDITED (15-DAY) |                    | HO, OT          | FR-009507513-1302FRA006536 |                      | 45 YR      | Female     | FRA            |

# FDA Adverse Event Reporting System

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### Detailed Report

| <u>Preferred Term</u>             | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|-----------------------------------|-------------------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|-----------------|--------------|----------------|
| Pancreatitis                      | Victrelis               |                    |                    | S               | Oral                           | 2400 Mg, Qd          |                 | Merck        |                |
|                                   | Pegasys                 |                    |                    | S               | Subcutaneous                   | 1 Df, Qw             |                 | Not Reported |                |
|                                   | Copegus                 |                    |                    | S               |                                | 4 Df, Qd             |                 | Not Reported |                |
|                                   | Zyprexa                 |                    |                    | S               |                                | Unk                  |                 | Not Reported |                |
|                                   | Methadone Hydrochloride |                    |                    | S               |                                | Unk                  |                 | Not Reported |                |
|                                   | Seroplex                |                    |                    | S               |                                | 1 Df, Qd             |                 | Not Reported |                |
|                                   | Epoetin                 |                    |                    | C               |                                |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>          | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Jul-2013                       | 9379508                 | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000046300              |                      | 74 DAY          | Female       | USA            |
| <u>Preferred Term</u>             | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Craniosynostosis                  | Lexapro                 |                    |                    | S               | Transplacental                 |                      |                 | Forest       |                |
| <u>FDA Received Date</u>          | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Jul-2013                       | 9379530                 | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000046312              |                      | < 1 DAY         | Male         | USA            |
| <u>Preferred Term</u>             | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Limb Reduction Defect;<br>Talipes | Lexapro                 |                    |                    | S               | Transplacental                 |                      |                 | Forest       |                |
| <u>FDA Received Date</u>          | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Jul-2013                       | 9379538                 | EXPEDITED (15-DAY) |                    | HO, OT          | FR-009507513-<br>1306FRA013521 |                      |                 | Male         | FRA            |
| <u>Preferred Term</u>             | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Pancreatitis Acute                | Victrelis               |                    |                    | S               | Oral                           | Unk                  |                 | Merck        |                |
|                                   | Copegus                 |                    |                    | S               | Oral                           | Unk                  |                 | Not Reported |                |
|                                   | Pegasys                 |                    |                    | S               | Subcutaneous                   | Unk                  |                 | Not Reported |                |
|                                   | Seroplex                |                    |                    | S               | Oral                           | Unk                  |                 | Not Reported |                |

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| <u>FDA Received Date</u>                             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------|----------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 02-Jul-2013                                          | 9379573        | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000046308     |                      | 77 DAY          | Male         | USA            |
| <u>Preferred Term</u>                                | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Craniosynostosis                                     | Lexapro        |                    |                    | S               | Transplacental        |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Jul-2013                                          | 9380447        | EXPEDITED (15-DAY) |                    | OT              | HU-FRI-1000045778     |                      | 66 YR           | Female       | HUN            |
| <u>Preferred Term</u>                                | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hunger; Oedema; Weight Increased                     | Escitalopram   |                    |                    | S               | Oral                  | 10 Mg                |                 | Forest       |                |
|                                                      | Truxal Drazse  |                    |                    | S               | Oral                  | 15 Mg                |                 | Not Reported |                |
|                                                      | Truxal Drazse  |                    |                    | S               |                       |                      |                 | Not Reported |                |
|                                                      | Rivotril       |                    |                    | C               | Oral                  | 1 Mg                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Jul-2013                                          | 9380680        | EXPEDITED (15-DAY) |                    | OT              | IT-JNJFOC-20130616471 |                      | 44 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Self-Injury                              | Invega         |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                      | Lamictal       |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                      | Entact         |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Jul-2013                                          | 9384169        | DIRECT             |                    | OT              |                       |                      | 64 YR           | Female       | USA            |
| <u>Preferred Term</u>                                | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Hypertension; Nausea; Presyncope; Vertigo | Lexapro        |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                      | Victoza        |                    |                    | C               |                       |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

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| <u>FDA Received Date</u>                                                                                                                                                                    | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|--------------------|--------------------|-----------------|------------------------------------------|----------------------|-----------------|--------------|----------------|
| 03-Jul-2013                                                                                                                                                                                 | 9247008             | EXPEDITED (15-DAY) |                    | HO              | US-AMGEN-<br>USASP2013024370             |                      | 63 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                       | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Arthralgia; Drug<br>Interaction; Generalised<br>Tonic-Clonic Seizure;<br>Injection Site Erythema;<br>Injection Site Pain;<br>Injection Site Swelling;<br>Injection Site Warmth;<br>Migraine | Enbrel              |                    |                    | S               |                                          | 50 Mg, Qwk           |                 | Amgen        |                |
|                                                                                                                                                                                             | Enbrel              |                    |                    | S               |                                          |                      |                 | Amgen        |                |
|                                                                                                                                                                                             | Enbrel              |                    |                    | S               |                                          |                      |                 | Amgen        |                |
|                                                                                                                                                                                             | Tramadol /00599202/ |                    |                    | S               |                                          | Unk                  |                 | Not Reported |                |
|                                                                                                                                                                                             | Lexapro             |                    |                    | S               |                                          | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                    | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Jul-2013                                                                                                                                                                                 | 9357832             | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000046030                        |                      | 83 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                       | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Gastric Ulcer<br>Haemorrhage; Prescribed<br>Overdose                                                                                                                                        | Escitalopram        |                    |                    | S               | Oral                                     | 2 Df                 |                 | Forest       |                |
|                                                                                                                                                                                             | Lovenox             |                    |                    | S               | Other                                    | 2 Df                 |                 | Not Reported |                |
|                                                                                                                                                                                             | Aspegic Enfant      |                    |                    | S               |                                          | 1 Df                 |                 | Not Reported |                |
|                                                                                                                                                                                             | Sandostatine        |                    |                    | C               | Oral                                     |                      |                 | Not Reported |                |
|                                                                                                                                                                                             | Perindopril         |                    |                    | C               | Oral                                     | 2 Df                 |                 | Not Reported |                |
|                                                                                                                                                                                             | Pyostacine          |                    |                    | C               | Oral                                     | 6 Df                 |                 | Not Reported |                |
|                                                                                                                                                                                             | Tahor               |                    |                    | C               | Oral                                     | 1 Df                 |                 | Not Reported |                |
|                                                                                                                                                                                             | Domperidone         |                    |                    | C               |                                          | 3 Df                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                    | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Jul-2013                                                                                                                                                                                 | 9381605             | EXPEDITED (15-DAY) |                    | OT              | DE-JNJFOC-<br>20130612059                |                      | 61 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                                                                                                                                                       | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Diarrhoea;<br>Nervousness;                                                                                                                                                      | Remicade            |                    |                    | S               | Intravenous (not<br>otherwise specified) |                      |                 | Not Reported |                |

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

|                               |            |   |         |              |
|-------------------------------|------------|---|---------|--------------|
| Tachycardia; Weight Increased | Ciprallex  | S | Unknown | Not Reported |
|                               | Cymbalta   | S | Unknown | Not Reported |
|                               | Amineurin  | S | Unknown | Not Reported |
|                               | Mirtazapin | S | Unknown | Not Reported |
|                               | Cortison   | C | Unknown | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Jul-2013              | 9382018       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000046395    |                      | 40 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Mixed Liver Injury    | Escitalopram   |              |            | S           | Oral         |                    |                 | Forest       |
|                       | Tercian        |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Benzodiazepine |              |            | C           |              |                    |                 | Not Reported |
|                       | Xeroquel       |              |            | C           | Oral         |                    |                 | Not Reported |
|                       | Xeroquel       |              |            | C           | Oral         | 50 Mg              |                 | Not Reported |
|                       | Xeroquel       |              |            | C           | Oral         | 100 Mg             |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Jul-2013              | 9382036       | EXPEDITED (15-DAY) |                    | DE              | FR-FRI-1000046394    |                      | 75 YR      | Male       | FRA            |

| <u>Preferred Term</u>     | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|-------------------|--------------|------------|-------------|--------------|------------------------|-----------------|--------------|
| Intra-Abdominal Haematoma | Escitalopram      |              |            | S           | Oral         | 2 Df                   |                 | Forest       |
|                           | Lovenox           |              |            | S           | Subcutaneous | 20,000 Ui Anti-Xa/2 MI |                 | Not Reported |
|                           | Coumadine         |              |            | S           | Oral         | 4 Df                   |                 | Not Reported |
|                           | Coumadine         |              |            | S           | Oral         | 4.5 Df                 |                 | Not Reported |
|                           | Dafalgan          |              |            | S           | Oral         | 6 Df                   |                 | Not Reported |
|                           | Topalgic (France) |              |            | S           | Oral         | 2 Df                   |                 | Not Reported |
|                           | Lasilix Retard    |              |            | C           | Oral         | 1 Df                   |                 | Not Reported |
|                           | Inegy             |              |            | C           | Oral         | 10 Mg/ 20 Mg           |                 | Not Reported |
|                           | Janumet           |              |            | C           | Oral         | 50 Mg/1000 Mg Daily    |                 | Not Reported |

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

|         |   |                          |        |              |
|---------|---|--------------------------|--------|--------------|
| Spiriva | C | Respiratory (inhalation) | 18 Mcg | Not Reported |
| Pariet  | C | Oral                     | 1 Df   | Not Reported |

| <u>FDA Received Date</u>    | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------|-----------------------|--------------------|--------------------|-----------------|---------------------------------------|----------------------|-----------------|--------------|----------------|
| 03-Jul-2013                 | 9382082               | EXPEDITED (15-DAY) |                    | DE              | FR-GILEAD-2013-0078257                |                      | 69 YR           | Male         | FRA            |
| <u>Preferred Term</u>       | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Prothrombin Level Decreased | Viread                |                    |                    | S               | Oral                                  | 245 Mg, Unk          |                 | Gilead       |                |
|                             | Seroplex              |                    |                    | S               | Oral                                  | 10 Mg, Unk           |                 | Not Reported |                |
|                             | Aldactone /00006201/  |                    |                    | S               | Oral                                  | 25 Mg, Unk           |                 | Not Reported |                |
|                             | Noroxine              |                    |                    | S               | Oral                                  | 400 Mg, Unk          |                 | Not Reported |                |
|                             | Eupantol              |                    |                    | S               | Intravenous (not otherwise specified) | 40 Mg, Bid           |                 | Not Reported |                |
|                             | Ceftriaxone Panpharma |                    |                    | S               | Intravenous (not otherwise specified) | Unk                  |                 | Not Reported |                |
|                             | Avlocardyl /00030001/ |                    |                    | C               | Oral                                  | 80 Mg, Qd            |                 | Not Reported |                |
|                             | Vitamin B1            |                    |                    | C               | Oral                                  | 60 Mg, Unk           |                 | Not Reported |                |
|                             | Vitamin B6            |                    |                    | C               | Oral                                  | 500 Mg, Unk          |                 | Not Reported |                |
|                             | Phosphoneuros         |                    |                    | C               | Oral                                  | 50 Df, Tid           |                 | Not Reported |                |
|                             | Lovenox               |                    |                    | C               | Subcutaneous                          | 4000 Iu, Unk         |                 | Not Reported |                |
|                             | Mag 2 /00454301/      |                    |                    | C               | Oral                                  | 2 Df, Qd             |                 | Not Reported |                |

| <u>FDA Received Date</u>                           | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 03-Jul-2013                                        | 9382439        | EXPEDITED (15-DAY) |                    | CA, HO          | DE-FRI-1000046432    |                      |                 | Male         | DEU            |
| <u>Preferred Term</u>                              | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Foetal Exposure During Pregnancy; Pyloric Stenosis | Escitalopram   |                    |                    | S               | Transplacental       | 5 Mg                 |                 | Forest       |                |
|                                                    | Neovin         |                    |                    | C               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                        | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|-------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 04-Jul-2013                                     | 9350572        | EXPEDITED (15-DAY) |                    | HO              | IE-ACCORD-018082     |                      | 41 YR           | Male       | IRL            |
| <u>Preferred Term</u>                           | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Hyponatraemia;<br>Polydipsia;<br>Rhabdomyolysis | Escitalopram   |                    |                    | S               |                      |                      |                 | Accord     |                |

| <u>FDA Received Date</u>            | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------|--------------------------|--------------------|--------------------|-----------------|------------------------------------------|----------------------|-----------------|--------------|----------------|
| 04-Jul-2013                         | 9375238                  | EXPEDITED (15-DAY) |                    | DE              | FR-PFIZER INC-<br>2013190760             |                      | 69 YR           | Male         | FRA            |
| <u>Preferred Term</u>               | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Prothrombin Time Ratio<br>Decreased | Aldactone                |                    |                    | S               | Oral                                     | 25 Mg, 1x/Day        |                 | Pfizer       |                |
|                                     | Eupantol                 |                    |                    | S               | Intravenous (not<br>otherwise specified) | 40 Mg Daily          |                 | Pfizer       |                |
|                                     | Seroplex                 |                    |                    | S               | Oral                                     | 10 Mg, Unk           |                 | Not Reported |                |
|                                     | Viread                   |                    |                    | S               | Oral                                     | 245 Mg, Daily        |                 | Not Reported |                |
|                                     | Noroxin                  |                    |                    | S               | Oral                                     | 400 Mg, Daily        |                 | Not Reported |                |
|                                     | Ceftriaxone              |                    |                    | S               | Intravenous (not<br>otherwise specified) | Unk                  |                 | Not Reported |                |
|                                     | Avlocardyl               |                    |                    | C               | Oral                                     | 40 Mg, 2x/Day        |                 | Not Reported |                |
|                                     | Thiamine Hydrochloride   |                    |                    | C               | Oral                                     | 60 Mg, Unk           |                 | Not Reported |                |
|                                     | Pyridoxine Hydrochloride |                    |                    | C               | Oral                                     | 500 Mg, Unk          |                 | Not Reported |                |
|                                     | Phosphoneuros            |                    |                    | C               | Oral                                     | 50 Gtt, 3x/Day       |                 | Not Reported |                |
|                                     | Lovenox                  |                    |                    | C               | Subcutaneous                             | 4000 Iu, Unk         |                 | Not Reported |                |
|                                     | Mag 2                    |                    |                    | C               | Oral                                     | 2 Df, 2x/Day         |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|-----------------|------------|----------------|
| 04-Jul-2013              | 9383438        | EXPEDITED (15-DAY) |                    | DE              | FR-009507513-<br>1306FRA013640 |                      | 69 YR           | Male       | FRA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

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

|                             |                    |   |                                       |            |              |
|-----------------------------|--------------------|---|---------------------------------------|------------|--------------|
| Prothrombin Level Decreased | Noroxine           | S | Oral                                  | 400 Mg, Qd | Merck        |
|                             | Seroplex           | S | Oral                                  | 10 Mg, Qd  | Not Reported |
|                             | Viread             | S | Oral                                  | 245 Mg, Qd | Not Reported |
|                             | Aldactone Tablets  | S | Oral                                  | 25 Mg, Qd  | Not Reported |
|                             | Eupantol           | S | Intravenous (not otherwise specified) | 40 Mg, Bid | Not Reported |
|                             | Ceftriaxone Sodium | S | Intravenous (not otherwise specified) | Unk        | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 04-Jul-2013              | 9383784       | EXPEDITED (15-DAY) |                    | OT              | CH-009507513-1306CHE004503 |                      | 56 YR      | Male       | CHE            |

| <u>Preferred Term</u>                                                                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Depression; Muscle Spasms; Myoclonus; Therapeutic Response Unexpected; Unevaluable Event | Remeron        |              |            | S           | Oral         | Unk, Qd            |                 | Merck        |
|                                                                                          | Ciprallex      |              |            | S           | Oral         | 20 Mg, Qd          |                 | Not Reported |
|                                                                                          | Ritalin        |              |            | S           | Oral         | Unk, Qd            |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Jul-2013              | 7250828       | EXPEDITED (15-DAY) | Y                  | DE, OT          | AUR-APL-2009-01465   |                      | 18 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                       | <u>Product</u>                      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Alanine Aminotransferase Decreased; Apnoeic Attack; Aspartate Aminotransferase Increased; Blood Creatine Phosphokinase Increased; Blood Creatinine Increased; Blood Ph Decreased; Blood Potassium Increased; Hepatic Function Abnormal; Hypotension; Hypotonia; Intentional | Cyclobenzaprine                     |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                             | Ibuprofen                           |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                             | Naproxen                            |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                             | Escitalopram (Escitalopram)         |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                             | Pseudoephedrine Hydrochloride       |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                             | Aspirin                             |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                             | Acetaminophen 325 Mg//Codeine 30 Mg |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                             |                                     |              |            |             |              |                    |                 |              |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Overdose; International  
Normalised Ratio  
Decreased; Myoglobin  
Blood Increased; Pupillary  
Disorder; Renal  
Impairment; Respiratory  
Failure; Subarachnoid  
Haemorrhage; Suicide  
Attempt; Tachycardia;  
Thermometry Abnormal;  
Toxicologic Test  
Abnormal; Unresponsive  
To Stimuli; Urinary  
Retention

| <u>FDA Received Date</u>                               | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------|-----------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 08-Jul-2013                                            | 9388791                                 | EXPEDITED (15-DAY) |                    | DS, OT          | GB-FRI-1000046467    |                      |                 | Female       | GBR            |
| <u>Preferred Term</u>                                  | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Migraine;<br>Nausea; Withdrawal<br>Syndrome | Escitalopram                            |                    |                    | S               | Oral                 | 15 Mg                |                 | Forest       |                |
|                                                        | Escitalopram                            |                    |                    | S               | Oral                 | 12.5 Mg              |                 | Not Reported |                |
| <u>FDA Received Date</u>                               | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Jul-2013                                            | 9322157                                 | EXPEDITED (15-DAY) |                    | HO              | JP-FRI-1000045084    |                      | 49 YR           | Male         | JPN            |
| <u>Preferred Term</u>                                  | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;<br>Serotonin Syndrome                | Lexapro                                 |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                                        | Methista                                |                    |                    | S               | Oral                 | 1500 Mg              |                 | Not Reported |                |
|                                                        | Huscode                                 |                    |                    | S               | Oral                 | 6 Df                 |                 | Not Reported |                |
|                                                        | Cefcapene Pivoxil Hydrochloride Hydrate |                    |                    | S               | Oral                 | 3 Df                 |                 | Not Reported |                |
|                                                        | Pranlukast                              |                    |                    | S               | Oral                 | 4 Df                 |                 | Not Reported |                |
|                                                        | Besastar Sr                             |                    |                    | C               | Oral                 | 400 Mg               |                 | Not Reported |                |
|                                                        | Depas (Etizolam)                        |                    |                    | C               | Oral                 | 3 Mg                 |                 | Not Reported |                |

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

|               |   |      |         |              |
|---------------|---|------|---------|--------------|
| Minzain       | C | Oral | 0.25 Mg | Not Reported |
| Amlodipine Od | C | Oral |         | Not Reported |
| Calonal       | C | Oral |         | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Jul-2013              | 9391008       | EXPEDITED (15-DAY) |                    | DE              | FR-FRI-1000046462    |                      | 69 YR      | Male       | FRA            |

| <u>Preferred Term</u>            | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                          | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------|-----------------------|--------------|------------|-------------|---------------------------------------|--------------------|-----------------|--------------|
| Prothrombin Time Ratio Decreased | Escitalopram          |              |            | S           | Oral                                  | 1 Df               |                 | Forest       |
|                                  | Viread                |              |            | S           | Oral                                  | 1 Df               |                 | Not Reported |
|                                  | Aldactone             |              |            | S           | Oral                                  | 1 Df               |                 | Not Reported |
|                                  | Noroxine              |              |            | S           | Oral                                  | 1 Df               |                 | Not Reported |
|                                  | Eupantol              |              |            | S           | Other                                 | 2 Df               |                 | Not Reported |
|                                  | Ceftriaxone Panpharma |              |            | S           | Intravenous (not otherwise specified) |                    |                 | Not Reported |
|                                  | Avlocardyl            |              |            | C           | Oral                                  | 2 Df               |                 | Not Reported |
|                                  | Vitamin B1 And B6     |              |            | C           | Oral                                  | 60 Mg/500 Mg       |                 | Not Reported |
|                                  | Phosphoneuros         |              |            | C           |                                       | 150 Df             |                 | Not Reported |
|                                  | Lovenox               |              |            | C           | Subcutaneous                          | 40000 lu           |                 | Not Reported |
|                                  | Mag 2                 |              |            | C           | Oral                                  | 2 Df               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Jul-2013              | 9391546       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000046396    |                      | 89 YR      | Female     | FRA            |

| <u>Preferred Term</u>                              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Confusional State; Drug Interaction; Hyponatraemia | Escitalopram   |              |            | S           | Oral         | 1 Df               |                 | Forest       |
|                                                    | Bipreterax     |              |            | S           | Oral         | 4 Mg/1.25 Mg       |                 | Not Reported |
|                                                    | Xanax          |              |            | C           | Oral         | 3 Df               |                 | Not Reported |
|                                                    | Actonel        |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                    | Glucor         |              |            | C           | Oral         | 1 Df               |                 | Not Reported |

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

|                                                                             | Fixical Vitamin D3 |                    | C                  | Oral            | 1 Df                       |                      | Not Reported    |              |                |
|-----------------------------------------------------------------------------|--------------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
|                                                                             | Cosopt             |                    | C                  |                 | 20 Mg/5 Mg/MI Ocular       |                      | Not Reported    |              |                |
| <u>FDA Received Date</u>                                                    | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Jul-2013                                                                 | 9391815            | NON-EXPEDITED      |                    | LT, OT          | US-ASTRAZENECA-2013SE51162 |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                       | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Adverse Drug Reaction;<br>Suicide Attempt                                   | Seroquel           |                    |                    | S               | Oral                       |                      |                 | Zeneca       |                |
|                                                                             | Zoloft             |                    |                    | S               |                            |                      |                 | Not Reported |                |
|                                                                             | Lexapro            |                    |                    | S               |                            |                      |                 | Not Reported |                |
|                                                                             | Paxil              |                    |                    | S               |                            |                      |                 | Not Reported |                |
|                                                                             | Abilify            |                    |                    | S               |                            |                      |                 | Not Reported |                |
|                                                                             | Effexor            |                    |                    | S               |                            |                      |                 | Not Reported |                |
|                                                                             | Lamictal           |                    |                    | S               |                            |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                    | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Jul-2013                                                                 | 9393406            | DIRECT             |                    | OT              |                            |                      | 55 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                       | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Condition<br>Aggravated; Depression;<br>Product Substitution Issue | Escitalopram       |                    |                    | S               | Oral                       |                      |                 | Camber       |                |
|                                                                             | Epa-Dha            |                    |                    | C               |                            |                      |                 | Not Reported |                |
|                                                                             | Vitamins S, D, & B |                    |                    | C               |                            |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                    | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Jul-2013                                                                 | 8681330            | EXPEDITED (15-DAY) | Y                  | HO              | 2012153200                 |                      | 67 YR           | Female       | CHE            |
| <u>Preferred Term</u>                                                       | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Back Disorder; Blood Loss                                                   | Methotrexate       |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
| Anaemia;                                                                    | Fragmin            |                    |                    | S               | Subcutaneous               |                      |                 | Not Reported |                |
| Cytomegalovirus Test                                                        | Ibuprofen          |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
| Positive; Diverticulum;                                                     | Prednisone         |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
| Drug Interaction;                                                           | Klacid             |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
| Enterocolitis                                                               |                    |                    |                    |                 |                            |                      |                 |              |                |
| Haemorrhagic; Fractured                                                     |                    |                    |                    |                 |                            |                      |                 |              |                |
| Sacrum; Haemorrhoids;                                                       |                    |                    |                    |                 |                            |                      |                 |              |                |

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

|                                                                                |                                                      |   |                                          |              |
|--------------------------------------------------------------------------------|------------------------------------------------------|---|------------------------------------------|--------------|
| Lower Gastrointestinal<br>Haemorrhage; Pneumonia<br>Bacterial; Stress Fracture | Rocephin                                             | S | Intravenous (not<br>otherwise specified) | Not Reported |
|                                                                                | Ciprallex                                            | S | Oral                                     | Not Reported |
|                                                                                | Ramipril                                             | C |                                          | Not Reported |
|                                                                                | Pantozol (Pantoprazole Sodium)                       | C |                                          | Not Reported |
|                                                                                | Calcimagon-D3 (Calcium<br>Carbonate, Colecalciferol) | C |                                          | Not Reported |
|                                                                                |                                                      |   |                                          |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Jul-2013              | 9342442       | EXPEDITED (15-DAY) |                    | LT              | JP-FRI-1000045785    |                      | 75 YR      | Male       | JPN            |

| <u>Preferred Term</u>                                                                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardio-Respiratory Arrest;<br>Electrocardiogram Qt<br>Prolonged; Off Label Use;<br>Ventricular Tachycardia | Lexapro        |              |            | S           | Nasal        | 10 Mg              |                 | Forest       |
|                                                                                                            | Lexapro        |              |            | S           | Nasal        | 10 Mg              |                 | Forest       |
|                                                                                                            | Lexapro        |              |            | S           | Nasal        | 20 Mg              |                 | Not Reported |
|                                                                                                            | Aricept D      |              |            | S           | Nasal        | 2.5 Mg             |                 | Not Reported |
|                                                                                                            | Aricept D      |              |            | S           | Nasal        | 5 Mg               |                 | Not Reported |
|                                                                                                            | Daikenchuto    |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                            | Magmitt        |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                            | Zyprexa        |              |            | C           |              | 2.5 Mg             |                 | Not Reported |
|                                                                                                            | Zyprexa        |              |            | C           |              | 5 Mg               |                 | Not Reported |
|                                                                                                            | Zyprexa        |              |            | C           |              | 2.5 Mg             |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Jul-2013              | 9393076       | EXPEDITED (15-DAY) |                    | HO              | CA-FRI-1000046562    |                      | 63 YR      | Female     | CAN            |

| <u>Preferred Term</u> | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Urticarial Vasculitis | Escitalopram           |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                       | Calcium And Vitamine D |              |            | C           | Oral         | 500 Mg/400 Ui      |                 | Not Reported |

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

| <u>FDA Received Date</u>                                                                                                                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 10-Jul-2013                                                                                                                                              | 9393114        | EXPEDITED (15-DAY) |                    | HO, LT          | FR-JNJFOC-20130616728 |                      | 63 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                                                                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Coma; Disorientation;<br>Extrapyramidal Disorder;<br>Hallucination;<br>Hypertension;<br>Hypothermia; Sinus<br>Bradycardia; Toxicity To<br>Various Agents | Haldol         |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                                                                          | Lioresal       |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                                                                          | Tranxene       |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                                                                          | Seroplex       |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                                                                          | Tramadol       |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                                                                          | Lyrica         |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Jul-2013                                                                                                                                              | 9393138        | EXPEDITED (15-DAY) |                    | HO, LT          | FR-FRI-1000046565     |                      | 38 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyperthermia                                                                                                                                             | Escitalopram   |                    |                    | S               | Oral                  | 2 Df                 |                 | Forest       |                |
|                                                                                                                                                          | Alprazolam     |                    |                    | S               | Oral                  | 0.75 Mg              |                 | Not Reported |                |
|                                                                                                                                                          | Alprazolam     |                    |                    | S               | Oral                  | 1.5 Mg               |                 | Not Reported |                |
|                                                                                                                                                          | Alprazolam     |                    |                    | S               | Oral                  | 1.5 Mg               |                 | Not Reported |                |
|                                                                                                                                                          | Atarax         |                    |                    | S               | Oral                  | 100 Mg               |                 | Not Reported |                |
|                                                                                                                                                          | Atarax         |                    |                    | S               | Oral                  | 300 Mg               |                 | Not Reported |                |
|                                                                                                                                                          | Atarax         |                    |                    | S               | Oral                  | 400 Mg               |                 | Not Reported |                |
|                                                                                                                                                          | Atarax         |                    |                    | S               | Oral                  | 200 Df               |                 | Not Reported |                |
|                                                                                                                                                          | Atarax         |                    |                    | S               | Oral                  | 300 Mg               |                 | Not Reported |                |
|                                                                                                                                                          | Atarax         |                    |                    | S               | Oral                  | 250 Mg               |                 | Not Reported |                |
|                                                                                                                                                          | Atarax         |                    |                    | S               | Oral                  | 200 Mg               |                 | Not Reported |                |
|                                                                                                                                                          | Tercian        |                    |                    | S               | Oral                  | 40 Mg                |                 | Not Reported |                |
|                                                                                                                                                          | Tercian        |                    |                    | S               | Oral                  | 80 Dosage Form       |                 | Not Reported |                |
|                                                                                                                                                          | Ciprofloxacin  |                    |                    | S               | Intravenous (not      | 3 Df                 |                 | Not Reported |                |

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

|               |   |                                       |                |              |
|---------------|---|---------------------------------------|----------------|--------------|
|               |   | otherwise specified)                  |                |              |
| Bactrim Forte | C | 3 Df                                  |                | Not Reported |
| Fortum        | C | Intravenous (not otherwise specified) | 6500 Microgram | Not Reported |
| Paracetamol   | C | Intravenous (not otherwise specified) |                | Not Reported |
| Diffu K       | C |                                       |                | Not Reported |
| Paroxetine    | C | 20 Mg                                 |                | Not Reported |
| Dafalgan      | C |                                       |                | Not Reported |
| Contramal     | C |                                       |                | Not Reported |
| Scopoderm     | C | 1 Mg / 72 Hours                       |                | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 10-Jul-2013              | 9393827       | EXPEDITED (15-DAY) |                    | HO              | FR-PFIZER INC-2013201064 |                      | 39 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                          | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|---------------------------------------|---------------------------|-----------------|--------------|
| Hepatitis             | Lyrica         |              |            | S           | Oral                                  | 75 Mg, 2x/Day             |                 | Pfizer       |
|                       | Remicade       |              |            | S           | Intravenous (not otherwise specified) | Unk                       |                 | Not Reported |
|                       | Inexium        |              |            | S           | Oral                                  | 40 Mg Once Or Twice Daily |                 | Not Reported |
|                       | Seroplex       |              |            | S           | Oral                                  | 15 Mg, 1x/Day             |                 | Not Reported |
|                       | Adepal         |              |            | C           |                                       |                           |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Jul-2013              | 9399790       | EXPEDITED (15-DAY) | Y                  | HO, OT          | AUR-APL-2013-05812   |                      | 25 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Dysphoria;   | Escitalopram   |              |            | S           |              |                    |                 | Not Reported |
| Suicidal Ideation;    | Ketamine       |              |            | S           |              |                    |                 | Not Reported |
| Tearfulness           | Clomipramine   |              |            | S           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|-----------------|--------------|----------------|
| 11-Jul-2013                                                                                                                      | 9236494        | EXPEDITED (15-DAY) |                    | DS              | FR-FRI-1000042316              |                      | 75 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Haemorrhagic Stroke;<br>Macular Degeneration                                                                                     | Escitalopram   |                    |                    | S               | Oral                           | 5 Mg                 |                 | Forest       |                |
|                                                                                                                                  | Escitalopram   |                    |                    | S               | Oral                           | 10 Mg                |                 | Forest       |                |
|                                                                                                                                  | Kardegic       |                    |                    | S               | Oral                           | 75 Mg                |                 | Not Reported |                |
|                                                                                                                                  | Kardegic       |                    |                    | S               | Oral                           | 160 Mg               |                 | Not Reported |                |
|                                                                                                                                  | Kardegic       |                    |                    | S               | Oral                           | 75 Mg                |                 | Not Reported |                |
|                                                                                                                                  | Crestor        |                    |                    | C               | Oral                           |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Jul-2013                                                                                                                      | 9382255        | EXPEDITED (15-DAY) |                    | LT              | FR-FRI-1000046428              |                      | 63 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Coma; Extrapryramidal<br>Disorder; Hallucination;<br>Hypertension;<br>Hypothermia; Intentional<br>Overdose; Sinus<br>Bradycardia | Escitalopram   |                    |                    | S               | Oral                           |                      |                 | Forest       |                |
|                                                                                                                                  | Lioresal       |                    |                    | S               | Oral                           |                      |                 | Not Reported |                |
|                                                                                                                                  | Tranxene       |                    |                    | S               | Oral                           |                      |                 | Not Reported |                |
|                                                                                                                                  | Monocrixo      |                    |                    | S               | Oral                           |                      |                 | Not Reported |                |
|                                                                                                                                  | Lyrica         |                    |                    | S               | Oral                           |                      |                 | Not Reported |                |
|                                                                                                                                  | Haldol         |                    |                    | S               | Oral                           |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Jul-2013                                                                                                                      | 9385898        | EXPEDITED (15-DAY) |                    | HO, LT, OT      | TR-ASTRAZENECA-<br>2013SE50641 |                      | 29 YR           | Female       | TUR            |
| <u>Preferred Term</u>                                                                                                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Coma; Depressed Level<br>Of Consciousness;<br>Electrocardiogram Qrs<br>Complex Prolonged;<br>Hypotension; Overdose;              | Quetiapine     |                    |                    | S               | Oral                           | 9 Grams              |                 | Not Reported |                |
|                                                                                                                                  | Escitalopram   |                    |                    | S               | Oral                           | 280 Mg               |                 | Not Reported |                |
|                                                                                                                                  | Ibuprofen      |                    |                    | S               | Oral                           | 4 Grams              |                 | Not Reported |                |

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

|                                       |             |   |      |         |              |
|---------------------------------------|-------------|---|------|---------|--------------|
| Sinus Tachycardia;<br>Suicide Attempt | Amoxicillin | S | Oral | 5 Grams | Not Reported |
|---------------------------------------|-------------|---|------|---------|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Jul-2013              | 9396140       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000046560    |                      | 91 YR      | Female     | FRA            |

| <u>Preferred Term</u>                    | <u>Product</u>                                                                                                                     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Gastrointestinal<br>Haemorrhage; Melaena | Escitalopram                                                                                                                       |              |            | S           | Oral         | 2 Df               |                 | Forest       |
|                                          | Kardegic                                                                                                                           |              |            | S           | Oral         | 1 Df               |                 | Not Reported |
|                                          | Tareg                                                                                                                              |              |            | C           |              |                    |                 | Not Reported |
|                                          | Lasilix                                                                                                                            |              |            | C           |              |                    |                 | Not Reported |
|                                          | Xanax                                                                                                                              |              |            | C           |              |                    |                 | Not Reported |
|                                          | Tiapridal                                                                                                                          |              |            | C           |              |                    |                 | Not Reported |
|                                          | Loxen (Nicardipine<br>Hydrochloride)                                                                                               |              |            | C           |              |                    |                 | Not Reported |
|                                          | Transipeg (Polyethylene Glycol<br>3350\Potassium<br>Chloride\Sodium<br>Bicarbonate\Sodium<br>Chloride\Sodium Sulfate<br>Anhydrous) |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Jul-2013              | 9396144       | EXPEDITED (15-DAY) |                    | HO              | AU-FRI-1000046615    |                      | 54 YR      | Female     | AUS            |

| <u>Preferred Term</u>                                                       | <u>Product</u>   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------|------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Antipsychotic Drug Level<br>Increased;<br>Electrocardiogram Qt<br>Prolonged | Escitalopram     |              |            | S           |              | 5 Mg               |                 | Forest       |
|                                                                             | Clozapine        |              |            | S           | Oral         | 450 Mg             |                 | Not Reported |
|                                                                             | Thyroxine Sodium |              |            | S           |              | 75 Mg              |                 | Not Reported |
|                                                                             | Epilim           |              |            | C           |              | 500 Mg             |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Jul-2013              | 8599926       | EXPEDITED (15-DAY) |                    | HO              | JP-FRI-1000030944    |                      | 63 YR      | Male       | JPN            |

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



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

|                          |            |   |      |       |              |
|--------------------------|------------|---|------|-------|--------------|
| Epileptic Psychosis;     | Lexapro    | S | Oral | 10 Mg | Forest       |
| Hallucination; Insomnia; | Landsen    | C | Oral | 2 Mg  | Not Reported |
| Paranoia; Seizure        | Nizatidine | C | Oral | 75 Mg | Not Reported |

| <u>FDA Received Date</u>                                                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 12-Jul-2013                                                                                         | 9397542        | EXPEDITED (15-DAY) |                    | CA, OT          | US-PFIZER INC-2013202479 |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Congenital Anomaly;<br>Hypoplastic Left Heart<br>Syndrome; Maternal<br>Exposure During<br>Pregnancy | Zoloft         |                    |                    | S               | Transplacental           | Unk                  |                 | Pfizer       |                |
|                                                                                                     | Sertraline Hcl |                    |                    | S               | Transplacental           | Unk                  |                 | Pfizer       |                |
|                                                                                                     | Lexapro        |                    |                    | S               | Transplacental           | Unk                  |                 | Not Reported |                |

| <u>FDA Received Date</u>                | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|-----------------------------------------|----------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|-----------------|----------------|
| 12-Jul-2013                             | 9398346        | EXPEDITED (15-DAY) |                    | OT              | NL-GLAXOSMITHKLINE-B0907519A |                      | 45 YR           | Female          | NLD            |
| <u>Preferred Term</u>                   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Drug Interaction;<br>Serotonin Syndrome | Escitalopram   |                    |                    | S               | Oral                         | 10mg Per Day         |                 | Glaxosmithkline |                |
|                                         | Sumatriptan    |                    |                    | S               | Oral                         | 50mg Every Two Weeks |                 | Glaxosmithkline |                |
|                                         | Oxtripitan     |                    |                    | S               | Oral                         | 50mg Per Day         |                 | Not Reported    |                |

| <u>FDA Received Date</u>                          | <u>Case #</u>          | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------|------------------------|------------------|--------------------|-----------------|----------------------|------------------------------------------------------------|-----------------|--------------|----------------|
| 12-Jul-2013                                       | 9400447                | DIRECT           |                    |                 |                      |                                                            | 63 YR           | Female       | USA            |
| <u>Preferred Term</u>                             | <u>Product</u>         | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Crying; Depression;<br>Product Substitution Issue | Lexapro 10mg (Generic) |                  |                    | S               | Oral                 | Strength: 10mg Quantity: 90 (3 Mo) Frequency: Daily Orally | 90 DAY          | Not Reported |                |
|                                                   | Synthroid              |                  |                    | C               |                      |                                                            |                 | Not Reported |                |
|                                                   | Klonopin               |                  |                    | C               |                      |                                                            |                 | Not Reported |                |
|                                                   | Restasis               |                  |                    | C               |                      |                                                            |                 | Not Reported |                |
|                                                   | Gabapentin             |                  |                    | C               |                      |                                                            |                 | Not Reported |                |

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

|               |   |              |
|---------------|---|--------------|
| Cosamine Ds   | C | Not Reported |
| Tylenol       | C | Not Reported |
| Multivitamin  | C | Not Reported |
| L Lysine      | C | Not Reported |
| Vitamin D Nos | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Jul-2013              | 9400179       | EXPEDITED (15-DAY) |                    | CA, DE          | US-FRI-1000046578    |                      | < 1 DAY    | Female     | USA            |

| <u>Preferred Term</u>                                                                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|------------|
| Congenital Anomaly;<br>Hypoplastic Left Heart<br>Syndrome; Pulmonary<br>Hypertension | Lexapro        |              |            | S           | Transplacental |                    |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 15-Jul-2013              | 9400952       | EXPEDITED (15-DAY) |                    | OT              | GR-ACTAVIS-2013-12052 |                      | 63 YR      | Female     | GRC            |

| <u>Preferred Term</u>           | <u>Product</u>                     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>           |
|---------------------------------|------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------|
| Bruxism; Headache;<br>Toothache | Escitalopram (Unknown)             |              |            | S           | Unknown      | 60 Mg, Daily       |                 | Not Reported         |
|                                 | Escitalopram (Unknown)             |              |            | S           | Unknown      | 40 Mg, Daily       |                 | Not Reported         |
|                                 | Fluoxetine Hydrochloride (Unknown) |              |            | S           | Unknown      | 40 Mg, Daily       |                 | Actavis Mid Atlantic |
|                                 | Fluoxetine Hydrochloride (Unknown) |              |            | S           | Unknown      | 60 Mg, Daily       |                 | Actavis Mid Atlantic |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Jul-2013              | 9402545       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000046677    |                      | 78 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Confusional State;<br>Hyponatraemia;<br>Psychomotor Hyperactivity | Escitalopram   |              |            | S           |              | 1 Df               |                 | Forest       |
|                                                                   | Kardegic       |              |            | C           |              | 160 Mg             |                 | Not Reported |
|                                                                   | Xanax          |              |            | C           |              |                    |                 | Not Reported |
|                                                                   | Endotelon      |              |            | C           |              |                    |                 | Not Reported |
|                                                                   | Tanakan        |              |            | C           |              |                    |                 | Not Reported |

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

|                               |   |        |              |
|-------------------------------|---|--------|--------------|
| Mianserin                     | C | 1 Df   | Not Reported |
| Omeprazole                    | C |        | Not Reported |
| Azantac                       | C | 150 Mg | Not Reported |
| Simvastatin                   | C | 20 Mg  | Not Reported |
| Tareg                         | C | 1 Df   | Not Reported |
| Hydrochlorothiazide\Valsartan | C | 1 Df   | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Jul-2013              | 9402584       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000046680    |                      | 38 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                                                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Depression;<br>Hepatocellular Injury;<br>Neutropenia; Suicidal<br>Ideation;<br>Thrombocytopenia | Escitalopram   |              |            | S           | Oral         |                    |                 | Forest       |
|                                                                                                 | Pegasys        |              |            | S           | Subcutaneous | 90 Mcg Weekly      |                 | Not Reported |
|                                                                                                 | Paracetamol    |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                 | Prozac         |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                 | Xanax          |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                 | Stilnox        |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Jul-2013              | 9402709       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000046712    |                      | 39 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                             | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|------------------------------------------|--------------------|-----------------|--------------|
| Hepatitis             | Escitalopram   |              |            | S           | Oral                                     | 15 Mg              |                 | Forest       |
|                       | Remicade       |              |            | S           | Intravenous (not<br>otherwise specified) |                    |                 | Not Reported |
|                       | Inexium        |              |            | S           | Oral                                     | 40 To 80 Mg        |                 | Not Reported |
|                       | Lyrica         |              |            | S           | Oral                                     | 150 Mg             |                 | Not Reported |
|                       | Adepal         |              |            | C           |                                          |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Jul-2013              | 9403260       | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000046590    |                      | < 1 DAY    | Male       | USA            |

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

| <u>Preferred Term</u>                                                                                   | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------------------------------------------------------------|-----------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
| Congenital Anomaly;<br>Exomphalos;<br>Hydrocephalus; Patent<br>Ductus Arteriosus                        | Lexapro         |                    |                    | S               | Transplacental            |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Jul-2013                                                                                             | 9404082         | DIRECT             |                    | OT              |                           |                      | 37 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                   | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Headache;<br>Hyponatraemia; Loss Of<br>Consciousness; Pain;<br>Painful Ejaculation;<br>Seizure; Syncope | Escitalopram    |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                                                                                                         | Buspirone       |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Jul-2013                                                                                             | 9166364         | EXPEDITED (15-DAY) |                    | CA              | US-JNJFOC-<br>20111104297 |                      |                 | Male         | USA            |
| <u>Preferred Term</u>                                                                                   | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cleft Lip And Palate;<br>Dental Alveolar Anomaly;<br>Dysarthria; Social<br>Avoidant Behaviour           | Topamax         |                    |                    | S               | Transplacental            |                      |                 | Not Reported |                |
|                                                                                                         | Zantac          |                    |                    | S               | Transplacental            |                      |                 | Not Reported |                |
|                                                                                                         | Keppra          |                    |                    | S               | Transplacental            |                      |                 | Not Reported |                |
|                                                                                                         | Lexapro         |                    |                    | S               | Transplacental            |                      |                 | Not Reported |                |
|                                                                                                         | Azithromycin    |                    |                    | S               | Transplacental            |                      |                 | Not Reported |                |
|                                                                                                         | Sulphacetamide  |                    |                    | S               | Transplacental            |                      |                 | Not Reported |                |
|                                                                                                         | Phenergan       |                    |                    | S               | Transplacental            |                      |                 | Not Reported |                |
|                                                                                                         | Acebutolol      |                    |                    | S               | Transplacental            |                      |                 | Not Reported |                |
|                                                                                                         | Ferrous Sulfate |                    |                    | C               | Transplacental            |                      |                 | Not Reported |                |
|                                                                                                         | Folic Acid      |                    |                    | C               | Transplacental            |                      |                 | Not Reported |                |
| Prenatal Vitamins                                                                                       |                 |                    | C                  | Transplacental  |                           |                      | Not Reported    |              |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>                              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------|----------------|--------------------|--------------------|-----------------|---------------------------------------|---------------------------------------------------|-----------------|--------------|----------------|
| 17-Jul-2013                                      | 9404021        | EXPEDITED (15-DAY) |                    | HO              | FR-JNJFOC-20130706519                 |                                                   | 39 YR           | Female       | FRA            |
| <u>Preferred Term</u>                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>                                | <u>Duration</u> | <u>Mfr</u>   |                |
| Ankylosing Spondylitis;<br>Hepatitis Cholestatic | Remicade       |                    |                    | S               | Intravenous (not otherwise specified) |                                                   |                 | Not Reported |                |
|                                                  | Inexium        |                    |                    | S               | Oral                                  | 1 To 2 Df                                         |                 | Not Reported |                |
|                                                  | Lyrica         |                    |                    | S               | Oral                                  | 2 Df                                              |                 | Not Reported |                |
|                                                  | Seroplex       |                    |                    | S               | Oral                                  | 2 Df                                              |                 | Not Reported |                |
|                                                  | Adepal         |                    |                    | C               | Unknown                               | Started Approximately 4 Years Prior To The Report |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                     | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------|-----------------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| 17-Jul-2013                                                                                  | 9405343               | EXPEDITED (15-DAY) |                    | LT              | AU-009507513-1307AUS004521 |                      | 77 YR           | Male         | AUS            |
| <u>Preferred Term</u>                                                                        | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anal Incontinence; Coma<br>Scale Abnormal;<br>Haemorrhage Intracranial;<br>Pyrexia; Vomiting | Simvastatin           |                    |                    | S               | Oral                       | 40 Mg, Daily         |                 | Merck        |                |
|                                                                                              | Escitalopram          |                    |                    | S               |                            | 10 Mg, Daily         |                 | Not Reported |                |
|                                                                                              | Pradaxa               |                    |                    | S               |                            | 220 Mg, Daily        |                 | Not Reported |                |
|                                                                                              | Sotalol Hydrochloride |                    |                    | S               |                            | 80 Mg, Daily         |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| 17-Jul-2013              | 9406310        | EXPEDITED (15-DAY) |                    | HO              | FR-ABBOTT-13X-056-1120237-00 |                      | 88 YR           | Female       | FRA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Disorientation; Fall     | Depakote       |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                          | Risperdal      |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                          | Seroplex       |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                          | Kardegic       |                    |                    | C               |                              |                      |                 | Not Reported |                |
|                          | Sotalex        |                    |                    | C               |                              |                      |                 | Not Reported |                |
|                          | Coversyl       |                    |                    | C               |                              |                      |                 | Not Reported |                |

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|          |   |              |
|----------|---|--------------|
| Xalatan  | C | Not Reported |
| Azopt    | C | Not Reported |
| Dafalgan | C | Not Reported |
| Pariet   | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Jul-2013              | 9407919       | EXPEDITED (15-DAY) |                    | OT              | US-FRI-1000046701    |                      | 32 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Rheumatoid Arthritis  | Lexapro        |              |            | S           |              |                    |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Jul-2013              | 9361465       | EXPEDITED (15-DAY) |                    | DE, HO, OT      | JP-FRI-1000043168    |                      | 82 YR      | Male       | JPN            |

| <u>Preferred Term</u>                                                                                                        | <u>Product</u>   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------|------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Apathy; Decubitus Ulcer; Pneumonia Aspiration; Poriomania; Serotonin Syndrome; Treatment Noncompliance; Urinary Incontinence | Lexapro          |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                                                                                                              | Memary           |              |            | C           | Oral         | 5 Mg               |                 | Not Reported |
|                                                                                                                              | Memary           |              |            | C           | Oral         | 6 Df               |                 | Not Reported |
|                                                                                                                              | Memary           |              |            | C           | Oral         | 10 Mg              |                 | Not Reported |
|                                                                                                                              | Memary           |              |            | C           | Oral         | 5 Mg               |                 | Not Reported |
|                                                                                                                              | Desyrel          |              |            | C           | Oral         | 50 Mg              |                 | Not Reported |
|                                                                                                                              | Desyrel          |              |            | C           | Oral         | 6 Df               |                 | Not Reported |
|                                                                                                                              | Desyrel          |              |            | C           | Oral         | 25 Mg              |                 | Not Reported |
|                                                                                                                              | Rezaltas         |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                                              | Selumito         |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                                              | Loxoprofen       |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                              | Alesion          |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                                              | Ointment Bases   |              |            | C           | Topical      |                    |                 | Not Reported |
|                                                                                                                              | Vesicare         |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                                              | Depas (Etizolam) |              |            | C           | Oral         |                    |                 | Not Reported |
| Amoban                                                                                                                       |                  |              | C          | Oral        |              |                    | Not Reported    |              |

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

|                                         |                        |                    |                    |                 |                          |                                |                 |              |                |
|-----------------------------------------|------------------------|--------------------|--------------------|-----------------|--------------------------|--------------------------------|-----------------|--------------|----------------|
| Lendormin                               |                        |                    | C                  |                 | Oral                     |                                |                 | Not Reported |                |
| <u>FDA Received Date</u>                | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Jul-2013                             | 9372175                | EXPEDITED (15-DAY) |                    | LT, OT          | FR-PFIZER INC-2013191199 |                                | 88 YR           | Male         | FRA            |
| <u>Preferred Term</u>                   | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Asterixis; Clonus; Toxic Encephalopathy | Zyvoxid                |                    |                    | S               | Intravenous drip         | Unk                            |                 | Pfizer       |                |
|                                         | Zyvoxid                |                    |                    | S               | Oral                     | 600 Mg, 2x/Day                 |                 | Pfizer       |                |
|                                         | Flagyl                 |                    |                    | S               |                          | 500 Mg, 2x/Day                 |                 | Pfizer       |                |
|                                         | Seroplex               |                    |                    | S               | Oral                     | 10 Mg, 1x/Day                  |                 | Not Reported |                |
|                                         | Augmentin              |                    |                    | C               |                          | Unk                            |                 | Not Reported |                |
|                                         | Lantus                 |                    |                    | C               |                          | 10 lu, 1x/Day (In The Morning) |                 | Not Reported |                |
|                                         | Previscan (Fluindione) |                    |                    | C               | Oral                     | 1 Tablet Daily                 |                 | Not Reported |                |
|                                         | Pravastatin            |                    |                    | C               |                          | 20 Mg, 1x/Day                  |                 | Not Reported |                |
|                                         | Cardensiel             |                    |                    | C               |                          | 2.5 Mg, 1x/Day                 |                 | Not Reported |                |
|                                         | Lasilix                |                    |                    | C               |                          | 40 Mg                          |                 | Not Reported |                |
|                                         | Inexium                |                    |                    | C               |                          | 20 Mg, 1x/Day                  |                 | Not Reported |                |
|                                         | Levothyrox             |                    |                    | C               |                          | 1 Df, Daily                    |                 | Not Reported |                |
|                                         | Econazole              |                    |                    | C               |                          |                                |                 | Not Reported |                |
| <u>FDA Received Date</u>                | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Jul-2013                             | 9409209                | EXPEDITED (15-DAY) |                    | HO              | AU-ACCORD-018533         |                                | 21 YR           | Male         | AUS            |
| <u>Preferred Term</u>                   | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Purpura Fulminans                       | Escitalopram           |                    |                    | S               |                          |                                |                 | Accord       |                |
|                                         | Amoxicillin            |                    |                    | S               | Oral                     |                                |                 | Not Reported |                |
| <u>FDA Received Date</u>                | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Jul-2013                             | 9409347                | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2013211073 |                                | 58 YR           | Male         | USA            |

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| <u>Preferred Term</u>                                                                                     | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
|-----------------------------------------------------------------------------------------------------------|---------------------|--------------------|--------------------|-----------------|-----------------------------------------------------|----------------------|-----------------|-----------------|----------------|
| Drug Hypersensitivity                                                                                     | Zoloft              |                    |                    | S               |                                                     | Unk                  |                 | Pfizer          |                |
|                                                                                                           | Nefazodone          |                    |                    | S               |                                                     | Unk                  |                 | Not Reported    |                |
|                                                                                                           | Lexapro             |                    |                    | S               |                                                     | Unk                  |                 | Not Reported    |                |
|                                                                                                           | Allegra             |                    |                    | S               |                                                     | Unk                  |                 | Not Reported    |                |
|                                                                                                           | Hydrocodone         |                    |                    | S               |                                                     | Unk                  |                 | Not Reported    |                |
|                                                                                                           | Meloxicam           |                    |                    | S               |                                                     | Unk                  |                 | Not Reported    |                |
|                                                                                                           | Clarithromycin      |                    |                    | S               |                                                     | Unk                  |                 | Not Reported    |                |
|                                                                                                           | Acetaminophen       |                    |                    | S               |                                                     | Unk                  |                 | Not Reported    |                |
|                                                                                                           | Penicillin          |                    |                    | S               |                                                     | Unk                  |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                  | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 19-Jul-2013                                                                                               | 9410158             | EXPEDITED (15-DAY) |                    | OT              | AT-ROXANE<br>LABORATORIES, INC.-<br>2013-RO-01178RO |                      | 49 YR           | Female          | AUT            |
| <u>Preferred Term</u>                                                                                     | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Restless Legs Syndrome                                                                                    | Lorazepam           |                    |                    | S               |                                                     | 3.5 Mg               |                 | Roxane          |                |
|                                                                                                           | Quetiapine Fumarate |                    |                    | S               |                                                     | 100 Mg               |                 | Roxane          |                |
|                                                                                                           | Quetiapine Fumarate |                    |                    | S               |                                                     | 200 Mg               |                 | Roxane          |                |
|                                                                                                           | Escitalopram        |                    |                    | S               |                                                     | 20 Mg                |                 | Not Reported    |                |
|                                                                                                           | Mirtazapine         |                    |                    | S               |                                                     | 15 Mg                |                 | Not Reported    |                |
|                                                                                                           | Mirtazapine         |                    |                    | S               |                                                     | 30 Mg                |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                  | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 19-Jul-2013                                                                                               | 9410429             | EXPEDITED (15-DAY) |                    | HO              | FR-<br>GLAXOSMITHKLINE-<br>B0907669A                |                      | 42 YR           | Female          | FRA            |
| <u>Preferred Term</u>                                                                                     | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Cataract Cortical; Diplopia;<br>Discomfort; Headache;<br>Headache; Periorbital<br>Disorder; Visual Acuity | Lamictal            |                    |                    | S               | Oral                                                | 250mg Per Day        |                 | Glaxosmithkline |                |
|                                                                                                           | Seroplex            |                    |                    | S               | Oral                                                | 10mg Per Day         |                 | Unknown         |                |



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Reduced

| <u>FDA Received Date</u>                                                | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>              | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|-----------------------------------|----------------------|-----------------|--------------|----------------|
| 19-Jul-2013                                                             | 9410450                     | EXPEDITED (15-DAY) |                    | OT              | TR-US-EMD SERONO,<br>INC.-7224117 |                      |                 | Female       | TUR            |
| <u>Preferred Term</u>                                                   | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                      | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cervical Dysplasia;<br>Menstruation Irregular                           | Rebif                       |                    |                    | S               | Subcutaneous                      |                      |                 | Not Reported |                |
|                                                                         | Ciprallex                   |                    |                    | S               | Oral                              |                      |                 | Not Reported |                |
|                                                                         | Beloc /00376902/            |                    |                    | S               | Oral                              |                      |                 | Not Reported |                |
|                                                                         | Ecopirin                    |                    |                    | C               | Oral                              |                      |                 | Not Reported |                |
|                                                                         | Parol                       |                    |                    | C               | Oral                              |                      |                 | Not Reported |                |
|                                                                         | Parol                       |                    |                    | C               |                                   |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>              | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Jul-2013                                                             | 9412235                     | DIRECT             |                    |                 |                                   |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                   | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                      | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Depression; Drug<br>Ineffective; Product<br>Substitution Issue | Escitalopram                |                    |                    | S               | Oral                              | 1 1/2 Daily          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>              | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Jul-2013                                                             | 9416691                     | EXPEDITED (15-DAY) | Y                  | LT, RI          | TCI2013A04128                     |                      | 43 YR           | Male         | JPN            |
| <u>Preferred Term</u>                                                   | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                      | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;<br>Ventricular Fibrillation                           | Lansoprazole (Lansoprazole) |                    |                    | S               | Oral                              |                      |                 | Not Reported |                |
|                                                                         | Escitalopram Oxalate        |                    |                    | S               | Oral                              |                      |                 | Not Reported |                |
|                                                                         |                             |                    |                    |                 | Oral                              |                      |                 |              |                |
|                                                                         | Acetylsalicylic Acid        |                    |                    | C               |                                   |                      |                 | Not Reported |                |
|                                                                         | Clopidogrel Bisulfate       |                    |                    | C               |                                   |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <a href="#">FDA Received Date</a>                                                | <a href="#">Case #</a>      | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|----------------------------------------------------------------------------------|-----------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 22-Jul-2013                                                                      | 9411575                     | EXPEDITED (15-DAY)        |                             | HO                       | FR-ROCHE-1250388              |                               | 84 YR                    | Male                | FRA                     |
| <a href="#">Preferred Term</a>                                                   | <a href="#">Product</a>     | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Confusional State; Fall                                                          | Xeloda                      |                           |                             | S                        | Oral                          |                               |                          |                     | Not Reported            |
|                                                                                  | Seroplex                    |                           |                             | S                        | Oral                          |                               |                          |                     | Not Reported            |
|                                                                                  | Tramadol                    |                           |                             | S                        | Oral                          |                               |                          |                     | Not Reported            |
| <a href="#">FDA Received Date</a>                                                | <a href="#">Case #</a>      | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 22-Jul-2013                                                                      | 9422452                     | EXPEDITED (15-DAY)        | Y                           | HO                       | AU-MACLEODS<br>PHARMA-000112  |                               | 21 YR                    | Male                | AUS                     |
| <a href="#">Preferred Term</a>                                                   | <a href="#">Product</a>     | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Protein C Deficiency;<br>Purpura Fulminans; Upper<br>Respiratory Tract Infection | Escitalopram (Escitalopram) |                           |                             | S                        |                               |                               |                          |                     | Not Reported            |
|                                                                                  | Amoxicillin (Amoxicillin)   |                           |                             | S                        |                               |                               |                          |                     | Not Reported            |
| <a href="#">FDA Received Date</a>                                                | <a href="#">Case #</a>      | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 23-Jul-2013                                                                      | 9414676                     | EXPEDITED (15-DAY)        |                             | OT                       | AU-FRI-1000046888             |                               | 21 YR                    | Male                | AUS                     |
| <a href="#">Preferred Term</a>                                                   | <a href="#">Product</a>     | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Purpura Fulminans                                                                | Escitalopram                |                           |                             | S                        |                               |                               |                          |                     | Forest                  |
|                                                                                  | Amoxicillin                 |                           |                             | S                        | Oral                          |                               |                          |                     | Not Reported            |
| <a href="#">FDA Received Date</a>                                                | <a href="#">Case #</a>      | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 23-Jul-2013                                                                      | 9414821                     | EXPEDITED (15-DAY)        |                             | DE                       | NO-FRI-1000046890             |                               | 39 YR                    | Male                | NOR                     |
| <a href="#">Preferred Term</a>                                                   | <a href="#">Product</a>     | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Completed Suicide; Death                                                         | Escitalopram                |                           |                             | S                        | Oral                          | 10 Mg                         |                          |                     | Forest                  |
|                                                                                  | Xeplion                     |                           |                             | C                        | Oral                          | 150 Mg                        |                          |                     | Not Reported            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                                                                                         | <u>Case #</u>                                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------------------------|----------------|
| 23-Jul-2013                                                                                                                                                                                                                                                                      | 9414847                                                  | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000046814    |                      | < 1 DAY         | Female                       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                            | <u>Product</u>                                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Cerebral Palsy;<br>Microcephaly                                                                                                                                                                                                                                                  | Lexapro                                                  |                    |                    | S               |                      |                      |                 | Forest                       |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                         | <u>Case #</u>                                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 23-Jul-2013                                                                                                                                                                                                                                                                      | 9416347                                                  | DIRECT             |                    | OT              |                      |                      | 59 YR           | Female                       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                            | <u>Product</u>                                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Anxiety; Decreased<br>Appetite; Drug Withdrawal<br>Syndrome; Dyskinesia;<br>Feeling Abnormal;<br>Gastrointestinal Disorder;<br>Hypertension;<br>Nervousness; Product<br>Substitution Issue; Shock;<br>Therapeutic Response<br>Changed; Thinking<br>Abnormal; Weight<br>Decreased | Lexapro                                                  |                    |                    | S               | Oral                 | 1, Daily, Po         |                 | Teva                         |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                         | <u>Case #</u>                                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 23-Jul-2013                                                                                                                                                                                                                                                                      | 9419259                                                  | EXPEDITED (15-DAY) | Y                  | OT              | AUR-APL-2013-05874   |                      | 21 YR           | Male                         | AUS            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                            | <u>Product</u>                                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Protein C Decreased;<br>Purpura Fulminans;<br>Thrombocytopenia                                                                                                                                                                                                                   | Amoxicillin (Amoxicillin)<br>Escitalopram (Escitalopram) |                    |                    | S<br>S          | Oral                 |                      |                 | Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                         | <u>Case #</u>                                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 24-Jul-2013                                                                                                                                                                                                                                                                      | 9404623                                                  | EXPEDITED (15-DAY) |                    |                 | DE-FRI-1000046639    |                      | 42 YR           | Male                         | DEU            |

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

| <u>Preferred Term</u>                                                                                  | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|--------------------------------------------------------------------------------------------------------|----------------------------|--------------------|--------------------|-----------------|---------------------------------------|----------------------|-----------------|--------------|----------------|
| Drug Withdrawal Syndrome                                                                               | Escitalopram Oral Solution |                    |                    | S               | Oral                                  | 5 Mg                 |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                               | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Jul-2013                                                                                            | 9416997                    | EXPEDITED (15-DAY) |                    | LT              | FR-FRI-1000046975                     |                      | 88 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                  | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Asterixis; Clonus; Toxic Encephalopathy                                                                | Escitalopram               |                    |                    | S               | Oral                                  | 1 Df                 |                 | Forest       |                |
|                                                                                                        | Flagyl                     |                    |                    | S               | Oral                                  | 1000 Mg              |                 | Not Reported |                |
|                                                                                                        | Zyvoxid                    |                    |                    | S               | Intravenous (not otherwise specified) | 1200 Mg              |                 | Not Reported |                |
|                                                                                                        | Lantus                     |                    |                    | C               |                                       | 10 Df In The Morning |                 | Not Reported |                |
|                                                                                                        | Previscan (Fluindione)     |                    |                    | C               |                                       | 1 Df                 |                 | Not Reported |                |
|                                                                                                        | Pravastatine               |                    |                    | C               |                                       | 20 Mg                |                 | Not Reported |                |
|                                                                                                        | Cardensiel                 |                    |                    | C               |                                       | 2.5 Mg               |                 | Not Reported |                |
|                                                                                                        | Lasilix                    |                    |                    | C               |                                       |                      |                 | Not Reported |                |
|                                                                                                        | Inexium                    |                    |                    | C               |                                       | 1 Df                 |                 | Not Reported |                |
|                                                                                                        | Levothyrox                 |                    |                    | C               |                                       | 1 Df                 |                 | Not Reported |                |
| Econazole                                                                                              |                            |                    | C                  |                 |                                       |                      | Not Reported    |              |                |
| <u>FDA Received Date</u>                                                                               | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Jul-2013                                                                                            | 9419966                    | DIRECT             |                    | LT              |                                       |                      | 56 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                  | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Fatigue; Feeling Abnormal; Impaired Work Ability; Pain; Speech Disorder; Suicidal Ideation | Escitalopram 20mg          |                    |                    | S               |                                       |                      |                 | Aurobindo    |                |

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| <u>FDA Received Date</u>                                                                     | <u>Case #</u>                                                                                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>                 | <u>Mfr Control #</u> | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u>                                                                                           | <u>Country</u> |
|----------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------|--------------------|--------------------|---------------------------------|----------------------|---------------------------------------|-----------------|------------------------------------------------------------------------------------------------------|----------------|
| 24-Jul-2013                                                                                  | 9424813                                                                                       | EXPEDITED (15-DAY) |                    | DS, HO                          | SYM-2013-06292       |                                       | 39 YR           | Female                                                                                               | SWE            |
| <u>Preferred Term</u>                                                                        | <u>Product</u>                                                                                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                     | <u>Route</u>         | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>                                                                                           |                |
| Anaphylactic Reaction;<br>Paraesthesia; Weight<br>Decreased                                  | Voxra<br>Ciprallex<br>Antihistamines (Antihistamines)                                         |                    |                    | S<br>S<br>C                     |                      |                                       |                 | Not Reported<br>Not Reported<br>Not Reported                                                         |                |
| <u>FDA Received Date</u>                                                                     | <u>Case #</u>                                                                                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>                 | <u>Mfr Control #</u> | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u>                                                                                           | <u>Country</u> |
| 25-Jul-2013                                                                                  | 9137630                                                                                       | EXPEDITED (15-DAY) |                    | OT                              | US-TEVA-389158USA    |                                       | 51 YR           | Female                                                                                               | USA            |
| <u>Preferred Term</u>                                                                        | <u>Product</u>                                                                                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                     | <u>Route</u>         | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>                                                                                           |                |
| Contusion; Loss Of<br>Consciousness; Skin<br>Laceration; Syncope                             | Escitalopram<br>Terbinafine<br>Lorazepam<br>Bactrim Ds<br>Bisacodyl<br>Tramadol<br>Omeprazole |                    |                    | S<br>C<br>C<br>C<br>C<br>C<br>C |                      |                                       |                 | Ivax<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                     | <u>Case #</u>                                                                                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>                 | <u>Mfr Control #</u> | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u>                                                                                           | <u>Country</u> |
| 25-Jul-2013                                                                                  | 9400183                                                                                       | EXPEDITED (15-DAY) |                    | LT                              | AU-FRI-1000046638    |                                       | 77 YR           | Male                                                                                                 | AUS            |
| <u>Preferred Term</u>                                                                        | <u>Product</u>                                                                                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                     | <u>Route</u>         | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>                                                                                           |                |
| Anal Incontinence; Coma<br>Scale Abnormal;<br>Haemorrhage Intracranial;<br>Pyrexia; Vomiting | Escitalopram<br>Pradaxa<br>Simvastatin<br>Simvastatin<br>Sotalol Hydrochloride                |                    |                    | S<br>S<br>S<br>S<br>S           |                      | 10 Mg<br>220 Mg<br>40 Mg<br><br>80 Mg |                 | Forest<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported                               |                |
| <u>FDA Received Date</u>                                                                     | <u>Case #</u>                                                                                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>                 | <u>Mfr Control #</u> | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u>                                                                                           | <u>Country</u> |
| 25-Jul-2013                                                                                  | 9419115                                                                                       | EXPEDITED (15-DAY) |                    | HO                              | FR-NOVOPROD-383411   |                                       | 73 YR           | Female                                                                                               | FRA            |

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

| <u>Preferred Term</u>                                                                      | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                              | <u>Duration</u> | <u>Mfr</u>   |                |
|--------------------------------------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|------------------------------|-------------------------------------------------|-----------------|--------------|----------------|
| Agranulocytosis                                                                            | Novomix 30                  |                    |                    | S               | Subcutaneous                 |                                                 |                 | Novo Nordisk |                |
|                                                                                            | Aldactone /00006201/        |                    |                    | S               | Oral                         | 5 Mg, Qd                                        |                 | Not Reported |                |
|                                                                                            | Seroplex                    |                    |                    | S               | Oral                         | 5 Mg, Qd                                        |                 | Not Reported |                |
|                                                                                            | Ursolvan-200                |                    |                    | S               | Oral                         | 200 Mg, Qd                                      |                 | Not Reported |                |
|                                                                                            | Doliprane                   |                    |                    | S               | Oral                         | 2 G, Qd                                         |                 | Not Reported |                |
|                                                                                            | Previscan (Pentoxifylline)  |                    |                    | C               | Unknown                      | Unk                                             |                 | Not Reported |                |
|                                                                                            | Innohep                     |                    |                    | C               | Unknown                      | Unk                                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                   | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Jul-2013                                                                                | 9420531                     | NON-EXPEDITED      |                    |                 | US-ABBOTT-13P-163-1098937-00 |                                                 |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                      | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                              | <u>Duration</u> | <u>Mfr</u>   |                |
| Breath Odour; Drug Interaction; Malaise; Skin Odour Abnormal; Urinary Tract Infection      | Synthroid                   |                    |                    | S               |                              |                                                 |                 | Not Reported |                |
|                                                                                            | Amlodipine                  |                    |                    | S               |                              |                                                 |                 | Not Reported |                |
|                                                                                            | Lexapro Film-Coated Tablets |                    |                    | S               |                              |                                                 |                 | Not Reported |                |
|                                                                                            | Levothyroxine               |                    |                    | S               |                              | 50mcg: 5 Days A Week<br>And75mcg: 2 Days A Week |                 | Not Reported |                |
|                                                                                            | Levoxyl                     |                    |                    | S               |                              |                                                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                   | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Jul-2013                                                                                | 9421306                     | EXPEDITED (15-DAY) |                    | HO              | IT-ASTRAZENECA-2013SE54261   |                                                 | 91 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                                      | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                              | <u>Duration</u> | <u>Mfr</u>   |                |
| Electrocardiogram Qt Prolonged; Hypokalaemia; Hypomagnesaemia; Syncope; Torsade De Pointes | Seroquel                    |                    |                    | S               | Oral                         |                                                 |                 | Zeneca       |                |
|                                                                                            | Ciprallex                   |                    |                    | S               | Oral                         |                                                 |                 | Not Reported |                |
|                                                                                            | Pantorc                     |                    |                    | C               |                              |                                                 |                 | Not Reported |                |
|                                                                                            | Tavor (Lorazepam)           |                    |                    | C               |                              |                                                 |                 | Not Reported |                |
|                                                                                            | Enapren                     |                    |                    | C               |                              |                                                 |                 | Not Reported |                |

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

| <u>FDA Received Date</u>                                                                                                                             | <u>Case #</u>                                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------|--------------------|--------------------|-----------------|------------------------------------------|-------------------------------|-----------------|--------------|----------------|
| 26-Jul-2013                                                                                                                                          | 9242065                                                     | EXPEDITED (15-DAY) |                    | OT              | BE-FRI-1000044480                        |                               | 41 YR           | Female       | BEL            |
| <u>Preferred Term</u>                                                                                                                                | <u>Product</u>                                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Pituitary Tumour Benign                                                                                                                              | Escitalopram                                                |                    |                    | S               | Oral                                     | 10-15 Mg                      |                 | Forest       |                |
|                                                                                                                                                      | Escitalopram                                                |                    |                    | S               | Oral                                     | 5 Mg                          |                 | Forest       |                |
|                                                                                                                                                      | Uni-Tranxene                                                |                    |                    | C               | Oral                                     |                               |                 | Not Reported |                |
|                                                                                                                                                      | Nortrilen                                                   |                    |                    | C               |                                          |                               |                 | Not Reported |                |
|                                                                                                                                                      | Sostilar                                                    |                    |                    | C               | Oral                                     |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                             | <u>Case #</u>                                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Jul-2013                                                                                                                                          | 9416220                                                     | EXPEDITED (15-DAY) | Y                  | LT              | SYM-2013-06427                           |                               | 88 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                                                                | <u>Product</u>                                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Clonus;<br>Clostridium Test Positive;<br>Confusional State;<br>Encephalopathy; Hepatic<br>Failure; Overdose;<br>Thrombocytopenia;<br>Tremor | Flagyl                                                      |                    |                    | S               | Oral                                     | 2 Ut, Daily, Oral             |                 | Not Reported |                |
|                                                                                                                                                      | Zyvoxid                                                     |                    |                    | S               | Intravenous (not<br>otherwise specified) | 600mg 2 In 1 D<br>Intravenous |                 | Not Reported |                |
|                                                                                                                                                      |                                                             |                    |                    |                 | Oral                                     | 600mg, 2 In 1 D, Oral         |                 |              |                |
|                                                                                                                                                      | Seroplex                                                    |                    |                    | S               | Oral                                     |                               |                 | Not Reported |                |
|                                                                                                                                                      | Augmentin                                                   |                    |                    | C               |                                          |                               |                 | Not Reported |                |
|                                                                                                                                                      | Lantus (Insulin Glargine) (Insulin<br>Glargine)             |                    |                    | C               |                                          |                               |                 | Not Reported |                |
|                                                                                                                                                      | Previscan (Fluindione)                                      |                    |                    | C               |                                          |                               |                 | Not Reported |                |
|                                                                                                                                                      | Pravastatine )Pravastatin<br>Sodium) (Pravastatin Sodium)   |                    |                    | C               |                                          |                               |                 | Not Reported |                |
|                                                                                                                                                      | Cardensiel (Bisoprolol<br>Fumarate) (Bisoprolol Fumarate)   |                    |                    | C               |                                          |                               |                 | Not Reported |                |
|                                                                                                                                                      | Lasilix (Furosemide)<br>(Furosemide)                        |                    |                    | C               |                                          |                               |                 | Not Reported |                |
|                                                                                                                                                      | Inexium (Esomeprazole)                                      |                    |                    | C               |                                          |                               |                 | Not Reported |                |
|                                                                                                                                                      | Levothyrox (Levothyroxine<br>Sodium) (Levothyroxine Sodium) |                    |                    | C               |                                          |                               |                 | Not Reported |                |
|                                                                                                                                                      | Econazole (Econazole)<br>(Econazole)                        |                    |                    | C               |                                          |                               |                 | Not Reported |                |
|                                                                                                                                                      | Augmentin                                                   |                    |                    | C               |                                          |                               |                 | Not Reported |                |

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

| <u>FDA Received Date</u>                                                                                                                                                                                                      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| 26-Jul-2013                                                                                                                                                                                                                   | 9421768        | EXPEDITED (15-DAY) |                    | DE              | AU-ASTRAZENECA-2013SE56043 |                      | 152 DAY         | Unknown      | AUS            |
| <u>Preferred Term</u>                                                                                                                                                                                                         | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Escherichia Sepsis; Foetal Exposure During Pregnancy; Microencephaly; Necrotising Enterocolitis Neonatal; Peritoneal Haemorrhage; Peritonitis; Premature Delivery                                                             | Seroquel       |                    |                    | S               | Transplacental             |                      |                 | Zeneca       |                |
|                                                                                                                                                                                                                               | Lexapro        |                    |                    | S               | Transplacental             |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Jul-2013                                                                                                                                                                                                                   | 9422714        | EXPEDITED (15-DAY) |                    | OT              | CA-FRI-1000047223          |                      | 50 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                                                                                                                                                                                         | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Angle Closure Glaucoma                                                                                                                                                                                                        | Escitalopram   |                    |                    | S               | Oral                       |                      |                 | Forest       |                |
|                                                                                                                                                                                                                               | Saphris        |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Jul-2013                                                                                                                                                                                                                   | 9424225        | DIRECT             | Y                  | HO              |                            |                      | < 1 DAY         | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                         | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Blood Bilirubin Increased; Condition Aggravated; Drug-Induced Liver Injury; Fatigue; Influenza; Pain; Pyrexia | Escitalopram   |                    |                    | S               |                            |                      |                 | Not Reported |                |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
|---------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|---------------------------------------------|----------------------|-----------------|------------------|----------------|
| 27-Jul-2013                                                                           | 9423702        | EXPEDITED (15-DAY) |                    | HO, LT          | PHHY2013TR078641                            |                      | 29 YR           | Female           | TUR            |
| <u>Preferred Term</u>                                                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |
| Coma; Depressed Level Of Consciousness;                                               | Quetiapine     |                    |                    | S               |                                             | 9 G, Unk             |                 | Not Reported     |                |
| Disorientation;                                                                       | Escitalopram   |                    |                    | S               |                                             | 280 Mg, Unk          |                 | Not Reported     |                |
| Hypotension; Intentional Overdose; Sinus Tachycardia; Suicide Attempt                 | Amoxicillin    |                    |                    | S               |                                             | 5 G, Unk             |                 | Novartis         |                |
|                                                                                       | Ibuprofen      |                    |                    | S               |                                             | 4 G, Unk             |                 | Not Reported     |                |
| <u>FDA Received Date</u>                                                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 29-Jul-2013                                                                           | 9424725        | EXPEDITED (15-DAY) |                    | OT              | FR-ELI_LILLY_AND_COMP<br>ANY-FR201307006814 |                      | 42 YR           | Female           | FRA            |
| <u>Preferred Term</u>                                                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |
| Haemorrhage; Labelled Drug-Drug Interaction Medication Error                          | Zyprexa        |                    |                    | S               | Oral                                        | 5 Mg, Qd             |                 | Eli Lilly And Co |                |
|                                                                                       | Seroplex       |                    |                    | S               | Oral                                        | 10 Mg, Qd            |                 | Not Reported     |                |
|                                                                                       | Alprazolam     |                    |                    | C               | Unknown                                     | 2 Df, Qd             |                 | Not Reported     |                |
| <u>FDA Received Date</u>                                                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 29-Jul-2013                                                                           | 9426528        | DIRECT             |                    | LT              |                                             |                      | 55 YR           | Female           | USA            |
| <u>Preferred Term</u>                                                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |
| Anxiety; Depression; Disturbance In Attention; Product Substitution Issue; Somnolence | Escitalopram   |                    |                    | S               | Oral                                        | 15ms                 |                 | Unassigned       |                |
| <u>FDA Received Date</u>                                                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 29-Jul-2013                                                                           | 9426539        | DIRECT             |                    | LT              |                                             |                      | 55 YR           | Female           | USA            |
| <u>Preferred Term</u>                                                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |

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

|                                                                 |              |   |      |      |              |
|-----------------------------------------------------------------|--------------|---|------|------|--------------|
| Anxiety; Depression;<br>Disturbance In Attention;<br>Somnolence | Escitalopram | S | Oral | 15ms | Not Reported |
|-----------------------------------------------------------------|--------------|---|------|------|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 30-Jul-2013              | 9429140       | EXPEDITED (15-DAY) |                    | OT              | FR-JNJFOC-20130716654 |                      | 86 YR      | Female     | FRA            |

| <u>Preferred Term</u>      | <u>Product</u>  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                 | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|-----------------|--------------|------------|-------------|--------------|----------------------------------------------------|-----------------|--------------|
| Drug Interaction; Epilepsy | Ixprim          |              |            | S           | Oral         | 1 Dose In The Morning<br>And 1 Dose In The Evening |                 | Not Reported |
|                            | Seroplex        |              |            | S           | Oral         |                                                    |                 | Not Reported |
|                            | Dafalgan        |              |            | C           | Oral         |                                                    |                 | Not Reported |
|                            | Botulinum Toxin |              |            | C           | Unknown      |                                                    |                 | Not Reported |
|                            | Lyrica          |              |            | C           | Oral         |                                                    |                 | Not Reported |
|                            | Lyrica          |              |            | C           | Oral         |                                                    |                 | Not Reported |
|                            | Lyrica          |              |            | C           | Oral         |                                                    |                 | Not Reported |
|                            | Lyrica          |              |            | C           | Oral         |                                                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 30-Jul-2013              | 9431055       | EXPEDITED (15-DAY) |                    | OT              | CH-PFIZER INC-2013222301 |                      | 45 YR      | Female     | CHE            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Suicide Attempt       | Xanax          |              |            | S           | Oral         | 0.25 Mg, As Needed |                 | Pfizer       |
|                       | Xanax          |              |            | S           | Oral         | 5 Mg, Single       |                 | Pfizer       |
|                       | Cipralext      |              |            | S           | Oral         | 20 Mg, Once Daily  |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 30-Jul-2013              | 9431412       | EXPEDITED (15-DAY) |                    | OT              | AU-MYLANLABS-2013S1016174 |                      | 21 YR      | Male       | AUS            |

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

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

|                   |              |   |         |              |
|-------------------|--------------|---|---------|--------------|
| Purpura Fulminans | Amoxicillin  | S | Oral    | Not Reported |
|                   | Escitalopram | S | Unknown | Mylan        |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Jul-2013              | 9431468       | EXPEDITED (15-DAY) | CA                 |                 | US-FRI-1000046970    |                      | < 1 DAY    | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|------------|
| Atrial Septal Defect; | Celexa         |              |            | S           | Transplacental |                    |                 | Forest     |
| Fallot'S Tetralogy    | Lexapro        |              |            | S           | Transplacental |                    |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 30-Jul-2013              | 9431514       | EXPEDITED (15-DAY) | HO                 |                 | TR-MYLANLABS-2013S1016336 |                      | 29 YR      | Female     | TUR            |

| <u>Preferred Term</u>                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------|----------------|--------------|------------|-------------|--------------|------------------------------|-----------------|--------------|
| Coma; Hypotension;                      | Quetiapine     |              |            | S           | Oral         | Estimated Ingestion Of 9g    |                 | Not Reported |
| Intentional Overdose;                   | Amoxicillin    |              |            | S           | Oral         | Estimated Ingestion Of 5g    |                 | Not Reported |
| Suicide Attempt;                        | Escitalopram   |              |            | S           | Oral         | Estimated Ingestion Of 280mg |                 | Mylan        |
| Tachycardia; Toxicity To Various Agents | Ibuprofen      |              |            | S           | Oral         | Estimated Ingestion Of 4g    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Jul-2013              | 9435296       | EXPEDITED (15-DAY) | Y                  | OT              | 2013AP006871         |                      | 21 YR      | Male       | AUS            |

| <u>Preferred Term</u>               | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------|-----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Epidermal Necrosis;                 | Amoxicillin (Amoxicillin)   |              |            | S           |              |                    |                 | Not Reported |
| Purpura Fulminans; Skin Haemorrhage | Escitalopram (Escitalopram) |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 31-Jul-2013              | 9432098       | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2013221390 |                      | 55 YR      | Female     | USA            |

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

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

|                       |              |   |     |              |
|-----------------------|--------------|---|-----|--------------|
| Drug Hypersensitivity | Effexor      | S | Unk | Pfizer       |
|                       | Erythromycin | S | Unk | Not Reported |
|                       | Vicodin      | S | Unk | Not Reported |
|                       | Biaxin       | S | Unk | Not Reported |
|                       | Lexapro      | S | Unk | Not Reported |
|                       | Prozac       | S | Unk | Not Reported |
|                       | Synthroid    | S | Unk | Not Reported |
|                       | Paxil        | S | Unk | Not Reported |
|                       | Bactrim      | S | Unk | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-Jul-2013              | 9433218       | EXPEDITED (15-DAY) |                    | OT              | PHHY2013AU078535     |                      | 21 YR      | Male       | AUS            |

| <u>Preferred Term</u>                                                                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Epidermal Necrosis;<br>Purpura Fulminans; Rash;<br>Skin Haemorrhage; Skin<br>Lesion; Thrombosis | Amoxicillin    |              |            | S           | Oral         |                    |                 | Novartis     |
|                                                                                                 | Escitalopram   |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-Jul-2013              | 9434809       | DIRECT           |                    | OT              |                      |                      | 42 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Anxiety; Depression;<br>Disease Recurrence;<br>Product Substitution Issue | Escitalopram   |              |            | S           | Oral         |                    |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Aug-2013              | 9272097       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000044933    |                      | 66 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Nausea; Vomiting      | Escitalopram   |              |            | S           | Oral         | 1 Df               |                 | Forest     |

# FDA Adverse Event Reporting System

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| <u>FDA Received Date</u>                                                | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------|--------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 01-Aug-2013                                                             | 9434754                              | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000047325    |                      | 86 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                   | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Epilepsy                                              | Escitalopram                         |                    |                    | S               | Oral                 | 1 Df                 |                 | Forest       |                |
|                                                                         | Ixprim                               |                    |                    | S               | Oral                 | 2 Df                 |                 | Not Reported |                |
|                                                                         | Lyrica                               |                    |                    | C               |                      | 150 Mg               |                 | Not Reported |                |
|                                                                         | Lyrica                               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                         | Dafalgan                             |                    |                    | C               |                      | 1000 Mg              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Aug-2013                                                             | 9434756                              | EXPEDITED (15-DAY) |                    | HO, OT          | BE-FRI-1000047324    |                      | 58 YR           | Female       | BEL            |
| <u>Preferred Term</u>                                                   | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Diabetes Mellitus; Hyponatraemia; Weight Increased; Withdrawal Syndrome | Escitalopram                         |                    |                    | S               | Oral                 | 5 Mg                 |                 | Forest       |                |
|                                                                         | Escitalopram                         |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                                                         | Escitalopram                         |                    |                    | S               | Oral                 | 5 Mg                 |                 | Not Reported |                |
|                                                                         | Escitalopram                         |                    |                    | S               | Oral                 | 5 Mg                 |                 | Not Reported |                |
|                                                                         | Staurodorm                           |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |
|                                                                         | Haldol                               |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Aug-2013                                                             | 9434825                              | EXPEDITED (15-DAY) |                    | OT              | DE-FRI-1000047363    |                      | 36 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                                   | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Gestational Diabetes; Pregnancy; Premature Rupture Of Membranes         | Escitalopram                         |                    |                    | S               | Oral                 | 20 Mg                |                 | Forest       |                |
|                                                                         | Citalopram                           |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                                                         | Citalopram                           |                    |                    | S               | Oral                 | 30 Mg                |                 | Forest       |                |
|                                                                         | Femibion [Minerals Nos;Vitamins Nos] |                    |                    | C               |                      | 0.4 Mg               |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

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| <u>FDA Received Date</u>                                                                                                 | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------|--------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 01-Aug-2013                                                                                                              | 9435117                              | EXPEDITED (15-DAY) |                    | CA, HO          | DE-FRI-1000047364    |                      | 1 DAY           | Female       | DEU            |
| <u>Preferred Term</u>                                                                                                    | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrioventricular Septal Defect; Coarctation Of The Aorta; Foetal Exposure During Pregnancy                               | Escitalopram                         |                    |                    | S               | Transplacental       | 20 Mg                |                 | Forest       |                |
|                                                                                                                          | Citalopram                           |                    |                    | S               | Transplacental       | 10 Mg                |                 | Forest       |                |
|                                                                                                                          | Citalopram                           |                    |                    | S               | Transplacental       | 30 Mg                |                 | Forest       |                |
|                                                                                                                          | Femibion [Minerals Nos;Vitamins Nos] |                    |                    | C               | Transplacental       | 0.4 Mg               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                 | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Aug-2013                                                                                                              | 9436099                              | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000047394    |                      | 95 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                    | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Pruritus; Rash                                                                                                           | Escitalopram                         |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                                                                                                          | Temesta (Lorazepam)                  |                    |                    | S               | Oral                 | 3 Mg                 |                 | Not Reported |                |
|                                                                                                                          | Imovane                              |                    |                    | S               | Oral                 | 3.75 Mg              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                 | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Aug-2013                                                                                                              | 9441937                              | EXPEDITED (15-DAY) | Y                  | HO              | AXC-2013-000335      |                      | 73 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                    | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agranulocytosis; Ascites; Myelodysplastic Syndrome; Neutrophil Count Decreased; Oedema; White Blood Cell Count Decreased | Ursodeoxycholic Acid                 |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                          | Doliprane                            |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                          | Aldactone                            |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                          | Seroplex                             |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                          | Novomix                              |                    |                    | S               | Subcutaneous         |                      |                 | Not Reported |                |
|                                                                                                                          | Previscan (Fluindione)               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                          | Innohep (Tinzaparin Sodium)          |                    |                    | C               |                      |                      |                 | Not Reported |                |

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

| <u>FDA Received Date</u>                                                                                                                                          | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
| 02-Aug-2013                                                                                                                                                       | 9404701                | EXPEDITED (15-DAY) |                    | CA, DS          | DK-FRI-1000046759         |                      |                 | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                                                             | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Foetal Exposure During Pregnancy; Psychomotor Retardation                                                                                                         | Escitalopram           |                    |                    | S               | Transplacental            | 20 Mg                |                 | Forest       |                |
|                                                                                                                                                                   | Citalopram             |                    |                    | S               | Transplacental            | 40 Mg                |                 | Forest       |                |
|                                                                                                                                                                   | Noritren               |                    |                    | S               | Transplacental            | 60 Mg                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                          | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Aug-2013                                                                                                                                                       | 9437012                | EXPEDITED (15-DAY) |                    | OT              | US-TEVA-422527USA         |                      | 25 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                             | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Attention-Seeking Behaviour; Derealisation; Drug Interaction; Dysgeusia; Dysphoria; Illusion; Parosmia; Suicidal Ideation; Tearfulness; Trichotillomania | Clomipramine           |                    |                    | S               | Unknown                   |                      |                 | Not Reported |                |
|                                                                                                                                                                   | Escitalopram           |                    |                    | S               | Unknown                   |                      |                 | Not Reported |                |
|                                                                                                                                                                   | Ketamine               |                    |                    | S               | Intravenous drip          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                          | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Aug-2013                                                                                                                                                       | 9437544                | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2013S1016531 |                      | 40 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                             | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Exposure During Pregnancy                                                                                                                                         | Amnesteem Capsules     |                    |                    | S               |                           |                      |                 | Mylan        |                |
|                                                                                                                                                                   | Claravis               |                    |                    | S               |                           |                      |                 | Mylan        |                |
|                                                                                                                                                                   | Latisse                |                    |                    | S               |                           |                      |                 | Not Reported |                |
|                                                                                                                                                                   | Lexapro                |                    |                    | S               |                           |                      |                 | Not Reported |                |
|                                                                                                                                                                   | Oral Contraceptive Nos |                    |                    | C               | Oral                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                          | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Aug-2013                                                                                                                                                       | 9437683                | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000047439         |                      | 59 YR           | Female       | FRA            |

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| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|------------------------------------------|-----------------|--------------|
| Epilepsy              | Escitalopram   |              |            | S           | Oral         | 1 Df                                     |                 | Forest       |
|                       | Lioresal       |              |            | S           | Oral         | Progressive Titration Up To 150 Mg Daily |                 | Not Reported |
|                       | Lioresal       |              |            | S           | Oral         | 12 Df                                    |                 | Not Reported |
|                       | Seresta        |              |            | C           | Oral         | 3 Df                                     |                 | Not Reported |
|                       | Keppra         |              |            | C           |              | 2 Df                                     |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Aug-2013              | 9008251       | EXPEDITED (15-DAY) | Y                  | HO, OT          | THQ2012A11181        |                      | 41 YR      | Male       | JPN            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                    | <u>Product</u>                                                          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Acute Myocardial Infarction; Apathy; Blood Calcium Decreased; Blood Potassium Abnormal; Cardiac Failure; Coronary Artery Occlusion; Drug Interaction; Electrocardiogram R On T Phenomenon; Extrasystoles; Loss Of Consciousness; Torsade De Pointes; Ventricular Extrasystoles; Ventricular Fibrillation | Takepron (Lansoprazole)                                                 |              |            | S           | Oral         | 15 Mg (15 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                          | Lexapro                                                                 |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                          |                                                                         |              |            |             | Oral         | 10 Mg (10 Mg, 1 In 1 D), Oral |                 |              |
|                                                                                                                                                                                                                                                                                                          | Lamictal (Lamotrigine)                                                  |              |            | C           |              |                               |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                          | Landsen (Clonazepam)                                                    |              |            | C           |              |                               |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                          | Rivotril (Clonazepam)                                                   |              |            | C           |              |                               |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                          | Plavix (Clopidogrel Bisulfate)                                          |              |            | C           |              |                               |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                          | Bayaspirin (Acetylsalicylic Acid)                                       |              |            | C           |              |                               |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                          | (Acetylsalicylic Acid)                                                  |              |            |             |              |                               |                 |              |
|                                                                                                                                                                                                                                                                                                          | Crestor (Rosuvastatin Calcium)                                          |              |            | C           |              |                               |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                          | Nicorandis (Nicorandil)                                                 |              |            | C           |              |                               |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                          | Magnesium Oxide                                                         |              |            | C           |              |                               |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                          | Solita (Sodium Lactate, Potassium Chloride, Calcium Chloride Dihydrate) |              |            | C           |              |                               |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                          | Heparin Sodium                                                          |              |            | C           |              |                               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 05-Aug-2013              | 9429239       | EXPEDITED (15-DAY) |                    | HO, OT          | FR-PFIZER INC-2013218206 |                      | 65 YR      | Female     | FRA            |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                   | <u>Product</u>                                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------------------------------------------|------------------------------------------------|--------------------|--------------------|-----------------|-----------------------------------------------------|----------------------|-----------------|--------------|----------------|
| Hepatitis Cholestatic;<br>Hepatocellular Injury;<br>Jaundice; Pruritus  | Amlor                                          |                    |                    | S               | Oral                                                | 10 Mg, Daily         |                 | Pfizer       |                |
|                                                                         | Tahor                                          |                    |                    | S               | Oral                                                | 20 Mg, Daily         |                 | Pfizer       |                |
|                                                                         | Diamicron                                      |                    |                    | S               | Oral                                                | 60 Mg, Daily         |                 | Not Reported |                |
|                                                                         | Eucreas                                        |                    |                    | S               | Oral                                                | 2 Df, Daily          |                 | Not Reported |                |
|                                                                         | Coaprovel                                      |                    |                    | S               | Oral                                                | 1 Df Daily           |                 | Not Reported |                |
|                                                                         | Levothyrox                                     |                    |                    | S               | Oral                                                | 125 Ng, Daily        |                 | Not Reported |                |
|                                                                         | Seroplex                                       |                    |                    | S               | Oral                                                | 10 Mg, Daily         |                 | Not Reported |                |
|                                                                         | Ixprim                                         |                    |                    | S               | Oral                                                | Unk                  |                 | Not Reported |                |
|                                                                         | Doliprane                                      |                    |                    | S               | Oral                                                | Unk                  |                 | Not Reported |                |
|                                                                         | Voltarene (Diclofenac Sodium)                  |                    |                    | S               | Cutaneous                                           | Unk                  |                 | Not Reported |                |
|                                                                         | Voltarene (Diclofenac Sodium)                  |                    |                    | S               | Oral                                                | Unk                  |                 | Not Reported |                |
|                                                                         | Lamaline<br>(Acetaminophen\Caffeine\Opium<br>) |                    |                    | S               |                                                     | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                | <u>Case #</u>                                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Aug-2013                                                             | 9439847                                        | EXPEDITED (15-DAY) |                    | HO, LT          | TR-ROXANE<br>LABORATORIES, INC.-<br>2013-RO-01272RO |                      | 29 YR           | Female       | TUR            |
| <u>Preferred Term</u>                                                   | <u>Product</u>                                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Overdose;<br>Suicide Attempt; Toxicity<br>To Various Agents | Quetiapine Fumarate                            |                    |                    | S               | Oral                                                |                      |                 | Roxane       |                |
|                                                                         | Ibuprofen                                      |                    |                    | S               | Oral                                                |                      |                 | Not Reported |                |
|                                                                         | Amoxicillin                                    |                    |                    | S               | Oral                                                |                      |                 | Not Reported |                |
|                                                                         | Escitalopram                                   |                    |                    | S               | Oral                                                |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                | <u>Case #</u>                                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Aug-2013                                                             | 9441510                                        | EXPEDITED (15-DAY) |                    | HO              | TR-PERRIGO-<br>13TR007814                           |                      | 29 YR           | Female       | TUR            |
| <u>Preferred Term</u>                                                   | <u>Product</u>                                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Coma; Depressed Level                                                   | Ibuprofen 200 Mg 604                           |                    |                    | S               | Oral                                                | 4 G, Unk             |                 | Perrigo      |                |

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

|                                                   |              |   |      |             |              |
|---------------------------------------------------|--------------|---|------|-------------|--------------|
| Of Consciousness;                                 | Quetiapine   | S | Oral | 9 G, Unk    | Not Reported |
| Disorientation;                                   | Escitalopram | S | Oral | 280 Mg, Unk | Not Reported |
| Hypotension; Intentional<br>Overdose; Tachycardia | Amoxicillin  | S | Oral | 5 G, Unk    | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Aug-2013              | 9442189       | DIRECT           |                    | LT              |                      |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Overdose              | Lexapro        |              |            | S           | Oral         |                    | 1 MTH           | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Aug-2013              | 9442450       | DIRECT           |                    | DS              |                      |                      | 64 YR      | Female     | USA            |

| <u>Preferred Term</u>      | <u>Product</u>               | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abdominal Distension;      | Escitalopram Oxalate         |              |            | S           | Oral         |                    |                 | Not Reported |
| Abdominal Pain Upper;      | Metformin                    |              |            | C           |              |                    |                 | Not Reported |
| Condition Aggravated;      | Lisinopril                   |              |            | C           |              |                    |                 | Not Reported |
| Drug Ineffective; Fatigue; | Multiple Vitamin             |              |            | C           |              |                    |                 | Not Reported |
| Flatulence; Gastritis;     | Slo-Niacin                   |              |            | C           |              |                    |                 | Not Reported |
| Gastrointestinal Disorder; | Fish Oil                     |              |            | C           |              |                    |                 | Not Reported |
| Nausea; Pain; Product      | Devil Claw                   |              |            | C           |              |                    |                 | Not Reported |
| Substitution Issue;        | Vitamin C                    |              |            | C           |              |                    |                 | Not Reported |
| Vomiting                   | Vo Q 10 Plus Read Yeast Rice |              |            | C           |              |                    |                 | Not Reported |
|                            | Hyaluronic Acid              |              |            | C           |              |                    |                 | Not Reported |
|                            | Chrome-500                   |              |            | C           |              |                    |                 | Not Reported |
|                            | Advil                        |              |            | C           |              |                    |                 | Not Reported |
|                            | Aleve                        |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Aug-2013              | 9442964       | DIRECT           |                    | LT              |                      |                      | 60 YR      | Female     | USA            |

| <u>Preferred Term</u>                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u> |
|-----------------------------------------|----------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|------------|
| Blood Pressure<br>Decreased; Dizziness; | Escitalopram   |              |            | S           | Oral         | 15 Mg 1 Per Day Pill By<br>Mouth | 3 DAY           | Teva       |

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

|                                                                          |               |   |      |                                                            |       |              |
|--------------------------------------------------------------------------|---------------|---|------|------------------------------------------------------------|-------|--------------|
| Loss Of Consciousness;<br>Product Substitution Issue;<br>Syncope; Tremor | Escitalopram  | S | Oral | One 20 Mg Pill Cut As<br>Needed 1 Per Day Pill By<br>Mouth | 3 DAY | Mylan        |
|                                                                          | Singulair     | C |      |                                                            |       | Not Reported |
|                                                                          | Lexapro       | C |      |                                                            |       | Not Reported |
|                                                                          | Xanax         | C |      |                                                            |       | Not Reported |
|                                                                          | Probiotic     | C |      |                                                            |       | Not Reported |
|                                                                          | Vitamin D Nos | C |      |                                                            |       | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Aug-2013              | 9444877       | EXPEDITED (15-DAY) | Y                  | HO, OT          | 2013AP007020         |                      | 25 YR      | Female     | USA            |

| <u>Preferred Term</u>                                   | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>     | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------|---------------------|--------------|------------|-------------|------------------|--------------------|-----------------|--------------|
| Anxiety; Attention-Seeking<br>Behaviour; Derealisation; | Escitalopram        |              |            | S           |                  |                    |                 | Not Reported |
| Drug Interaction;                                       | Ketamine            |              |            | S           | Intravenous drip |                    |                 | Not Reported |
| Dysphoria; Illusion;                                    | Clomipramine        |              |            | S           |                  |                    |                 | Not Reported |
| Parosmia; Suicidal                                      | Selective Serotonin |              |            | C           |                  |                    |                 | Not Reported |
| Ideation; Taste Disorder;                               | Reuptake Inhibitors |              |            | C           |                  |                    |                 | Not Reported |
| Tearfulness                                             | Antipsychotics      |              |            | C           |                  |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Aug-2013              | 9442261       | EXPEDITED (15-DAY) |                    | OT              | TR-FRI-1000047502    |                      | 29 YR      | Female     | TUR            |

| <u>Preferred Term</u>                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------|----------------|--------------|------------|-------------|--------------|-------------------------|-----------------|--------------|
| Depressed Level Of<br>Consciousness;          | Escitalopram   |              |            | S           |              | Estimated Ingested Dose |                 | Forest       |
| Hypotension; Intentional<br>Overdose; Suicide | Quetiapine     |              |            | S           |              | Estimated Ingested Dose |                 | Not Reported |
| Attempt; Tachycardia                          | Amoxicillin    |              |            | S           |              | Estimated Ingested Dose |                 | Not Reported |
|                                               | Ibuprofen      |              |            | S           |              | Estimated Ingested Dose |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------------|----------------------|------------|------------|----------------|
| 06-Aug-2013              | 9443417       | EXPEDITED (15-DAY) |                    | HO              | ZA-<br>GLAXOSMITHKLINE-<br>B0912481A |                      |            | Male       | ZAF            |

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

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

|                                            |               |   |         |                     |                 |
|--------------------------------------------|---------------|---|---------|---------------------|-----------------|
| Fall; Seizure; Tremor;<br>Weight Increased | Lamictin      | S | Unknown | 100mg Twice Per Day | Glaxosmithkline |
|                                            | Epilim        | S | Unknown | 600mg Twice Per Day | Not Reported    |
|                                            | Escitalopram  | S | Unknown |                     | Glaxosmithkline |
|                                            | Levetiracetam | C | Unknown | 500mg Twice Per Day | Glaxosmithkline |

| <u>FDA Received Date</u>                 | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 06-Aug-2013                              | 9444176        | DIRECT           | Y                  | OT              |                      |                      | 40 YR           | Female       | USA            |
| <u>Preferred Term</u>                    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Diarrhoea; Product<br>Substitution Issue | Lexapro        |                  |                    | S               | Oral                 | 20mg Daily Po        |                 | Not Reported |                |
|                                          | Lexapro        |                  |                    | S               | Oral                 | 10mg Daily Po        |                 | Not Reported |                |
|                                          | Zyprexa        |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                          | Trazadone      |                  |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                           | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|----------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------------------|-----------------|------------|----------------|
| 06-Aug-2013                                        | 9444536        | DIRECT           |                    | LT, OT          |                      |                                  | 66 YR           | Female     | USA            |
| <u>Preferred Term</u>                              | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u> |                |
| Feelings Of<br>Worthlessness; Suicidal<br>Ideation | Escitalopram   |                  |                    | S               | Oral                 | One Once Daily Taken By<br>Mouth |                 | Aurobindo  |                |

| <u>FDA Received Date</u>                                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|-----------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|--------------------------------------|----------------------|-----------------|-----------------|----------------|
| 07-Aug-2013                                                           | 9347064        | EXPEDITED (15-DAY) |                    | HO              | JP-<br>GLAXOSMITHKLINE-<br>B0872038A |                      | 71 YR           | Female          | JPN            |
| <u>Preferred Term</u>                                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Affect Lability; Euphoric<br>Mood; Hyperkinesia;<br>Logorrhoea; Mania | Lamictal       |                    |                    | S               | Oral                                 | 50mg Per Day         |                 | Glaxosmithkline |                |
|                                                                       | Lamictal       |                    |                    | S               | Oral                                 |                      |                 | Glaxosmithkline |                |
|                                                                       | Lamictal       |                    |                    | S               | Oral                                 | 50mg Twice Per Day   |                 | Glaxosmithkline |                |
|                                                                       | Lamictal       |                    |                    | S               | Oral                                 | 75mg Twice Per Day   |                 | Glaxosmithkline |                |
|                                                                       | Lamictal       |                    |                    | S               | Oral                                 | 50mg Twice Per Day   |                 | Glaxosmithkline |                |

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

|  |                   |   |      |                    |                 |
|--|-------------------|---|------|--------------------|-----------------|
|  | Lexapro           | S | Oral | 10mg Per Day       | Not Reported    |
|  | Lithium Carbonate | S | Oral |                    | Glaxosmithkline |
|  | Lithium Carbonate | S | Oral |                    | Glaxosmithkline |
|  | Lithium Carbonate | S | Oral |                    | Glaxosmithkline |
|  | Solanax           | C | Oral | .4mg Twice Per Day | Glaxosmithkline |
|  | Palgin            | C | Oral | 1mg Per Day        | Not Reported    |
|  | Zolpidem Tartrate | C | Oral | 10mg Per Day       | Not Reported    |

| <u>FDA Received Date</u>                                                                   | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------|-------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 07-Aug-2013                                                                                | 9434806           | EXPEDITED (15-DAY) |                    | HO              | IT-FRI-1000047326    |                      | 90 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                                      | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Electrocardiogram Qt Prolonged; Hypokalaemia; Hypomagnesaemia; Syncope; Torsade De Pointes | Escitalopram      |                    |                    | S               | Oral                 |                      |                 | Forest       |                |
|                                                                                            | Seroquel          |                    |                    | S               | Oral                 | 1 Df                 |                 | Not Reported |                |
|                                                                                            | Pantorc           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                            | Tavor (Lorazepam) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                            | Enapren           |                    |                    | C               | Oral                 | 10 Mg                |                 | Not Reported |                |

| <u>FDA Received Date</u>    | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------|----------------|------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 07-Aug-2013                 | 9444570        | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2013228853 |                      | 58 YR           | Male         | USA            |
| <u>Preferred Term</u>       | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity; Rash | Effexor        |                  |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                             | Zoloft         |                  |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                             | Lexapro        |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 07-Aug-2013              | 9444889        | EXPEDITED (15-DAY) |                    | HO              | BE-FRI-1000047536    |                      | 83 YR           | Female     | BEL            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

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

|                                                               |              |   |      |        |              |
|---------------------------------------------------------------|--------------|---|------|--------|--------------|
| Barrett'S Oesophagus;<br>Gastric Ulcer; Rectal<br>Haemorrhage | Escitalopram | S | Oral | 150 Mg | Forest       |
|                                                               | Motifene     | S | Oral |        | Not Reported |
|                                                               | Asaflow      | S | Oral |        | Not Reported |
|                                                               | Bisoprolol   | C | Oral |        | Not Reported |
|                                                               | Perindopril  | C | Oral |        | Not Reported |
|                                                               | Crestor      | C | Oral |        | Not Reported |
|                                                               | Noctamid     | C | Oral |        | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Aug-2013              | 9444901       | EXPEDITED (15-DAY) |                    | HO              | SE-FRI-1000047568    |                      | 75 YR      | Male       | SWE            |

| <u>Preferred Term</u>                                     | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------|-------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Arrhythmia;<br>Electrocardiogram Qt<br>Prolonged; Syncope | Escitalopram      |              |            | S           | Oral         |                    |                 | Forest       |
|                                                           | Simvastatin       |              |            | C           |              |                    |                 | Not Reported |
|                                                           | Zolpidem          |              |            | C           |              |                    |                 | Not Reported |
|                                                           | Enalapril         |              |            | C           |              |                    |                 | Not Reported |
|                                                           | Dentan Mouth Wash |              |            | C           |              |                    |                 | Not Reported |
|                                                           | Tromblyl          |              |            | C           |              |                    |                 | Not Reported |
|                                                           | Xanor             |              |            | C           |              |                    |                 | Not Reported |
|                                                           | Selokenzoc        |              |            | C           |              |                    |                 | Not Reported |
|                                                           | Atacand           |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Aug-2013              | 9444912       | EXPEDITED (15-DAY) |                    | OT              | PHHY2013US081971     |                      | 25 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                             | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|------------------------------------------|--------------------|-----------------|--------------|
| Anhedonia; Anxiety;<br>Decreased Appetite;<br>Depressed Mood; Drug<br>Interaction; Dysphoria;<br>Sleep Disorder; Suicidal<br>Ideation | Ketamine       |              |            | S           | Intravenous (not<br>otherwise specified) |                    |                 | Not Reported |
|                                                                                                                                       | Clomipramine   |              |            | S           |                                          |                    |                 | Novartis     |
|                                                                                                                                       | Escitalopram   |              |            | S           |                                          |                    |                 | Not Reported |

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

| <u>FDA Received Date</u>                                                                                                                                          | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|-----------------|----------------|
| 07-Aug-2013                                                                                                                                                       | 9445106                       | EXPEDITED (15-DAY) |                    | HO              | US-MYLANLABS-2013S1016805    |                      | 25 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                                                                                                             | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Anxiety; Attention-Seeking<br>Behaviour; Derealisation;<br>Drug Interaction;<br>Dysgeusia; Dysphoria;<br>Illusion; Parosmia;<br>Suicidal Ideation;<br>Tearfulness | Ketamine                      |                    |                    | S               | Intravenous drip             |                      |                 | Not Reported    |                |
|                                                                                                                                                                   | Clomipramine                  |                    |                    | S               | Unknown                      |                      |                 | Mylan           |                |
|                                                                                                                                                                   | Escitalopram                  |                    |                    | S               | Unknown                      |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                                                          | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 07-Aug-2013                                                                                                                                                       | 9445201                       | EXPEDITED (15-DAY) |                    | DE, HO          | CH-GLAXOSMITHKLINE-B0891995A |                      | 44 YR           | Male            | CHE            |
| <u>Preferred Term</u>                                                                                                                                             | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Pyrexia; Sudden Death                                                                                                                                             | Dabrafenib                    |                    |                    | S               | Oral                         |                      |                 | Glaxosmithkline |                |
|                                                                                                                                                                   | Trametinib                    |                    |                    | S               | Oral                         |                      |                 | Glaxosmithkline |                |
|                                                                                                                                                                   | Cipralex                      |                    |                    | S               | Oral                         |                      |                 | Glaxosmithkline |                |
|                                                                                                                                                                   | Keppra                        |                    |                    | S               |                              |                      |                 | Glaxosmithkline |                |
|                                                                                                                                                                   | Novalgine (Metamizole Sodium) |                    |                    | S               |                              |                      |                 | Glaxosmithkline |                |
|                                                                                                                                                                   | Dexamethasone                 |                    |                    | C               | Oral                         |                      |                 | Glaxosmithkline |                |
|                                                                                                                                                                   | Valproic Acid                 |                    |                    | C               | Oral                         | 600mg Twice Per Day  |                 | Not Reported    |                |
|                                                                                                                                                                   | Fortecortin                   |                    |                    | C               |                              |                      |                 | Not Reported    |                |
|                                                                                                                                                                   | Orfiril                       |                    |                    | C               |                              |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                                                          | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 08-Aug-2013                                                                                                                                                       | 9432469                       | EXPEDITED (15-DAY) |                    | HO, LT, OT      | TR-RANBAXY-2013RR-71707      |                      | 29 YR           | Female          | TUR            |
| <u>Preferred Term</u>                                                                                                                                             | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Coma; Hypotension;<br>Intentional Overdose;<br>Suicide Attempt;                                                                                                   | Quetiapine                    |                    |                    | S               | Oral                         | 9g, Estimated Dose   |                 | Not Reported    |                |
|                                                                                                                                                                   | Amoxicillin                   |                    |                    | S               | Oral                         | 5 G, Estimated Dose  |                 | Ranbaxy         |                |

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

|             |              |   |      |                        |              |
|-------------|--------------|---|------|------------------------|--------------|
| Tachycardia | Escitalopram | S | Oral | 280 Mg, Estimated Dose | Not Reported |
|             | Ibuprofen    | S | Oral | 4 G, Estimated Dose    | Ranbaxy      |

| <u>FDA Received Date</u>                | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------|----------------|--------------------|--------------------|-----------------|------------------------------------------|----------------------|-----------------|--------------|----------------|
| 08-Aug-2013                             | 9447893        | EXPEDITED (15-DAY) |                    | HO              | PHHY2013FR082983                         |                      | 62 YR           | Female       | FRA            |
| <u>Preferred Term</u>                   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Haematoma; Purpura;<br>Thrombocytopenia | Ritaline       |                    |                    | S               | Oral                                     | 10 Mg, Qd            |                 | Novartis     |                |
|                                         | Carboplatin    |                    |                    | S               | Intravenous (not<br>otherwise specified) | 400 Mg, Per Course   |                 | Not Reported |                |
|                                         | Seroplex       |                    |                    | S               | Oral                                     | 10 Mg, Qd            |                 | Not Reported |                |

| <u>FDA Received Date</u>             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 08-Aug-2013                          | 9448225        | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000047505    |                      | < 1 DAY         | Male       | USA            |
| <u>Preferred Term</u>                | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Patent Ductus Arteriosus;<br>Talipes | Lexapro        |                    |                    | S               | Transplacental       |                      |                 | Forest     |                |

| <u>FDA Received Date</u>                                                      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|-------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 08-Aug-2013                                                                   | 9448293        | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000047524    |                      | < 1 DAY         | Female     | USA            |
| <u>Preferred Term</u>                                                         | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Fallot'S Tetralogy; Patent<br>Ductus Arteriosus;<br>Ventricular Septal Defect | Lexapro        |                    |                    | S               | Transplacental       |                      |                 | Forest     |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 08-Aug-2013              | 9448383        | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000047527    |                      | < 1 DAY         | Male       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Heart Disease Congenital | Lexapro        |                    |                    | S               | Transplacental       |                      |                 | Forest     |                |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

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| <u>FDA Received Date</u>                                                                                                                                  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|------------------------------------------|----------------------|-----------------|--------------|----------------|
| 09-Aug-2013                                                                                                                                               | 8961910              | EXPEDITED (15-DAY) |                    | OT              | CA-PFIZER INC-2012311529                 |                      | 58 YR           | Male         | CAN            |
| <u>Preferred Term</u>                                                                                                                                     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain Upper; Bradykinesia; Cogwheel Rigidity; Confusional State; Drug Ineffective; Drug Intolerance; Hyperhidrosis; Parkinsonism; Resting Tremor | Paroxetine           |                    |                    | S               |                                          | 5 And 10 Mg Per Day  |                 | Unknown      |                |
|                                                                                                                                                           | Sertraline Hcl       |                    |                    | S               |                                          | 50 Mg, Unk           |                 | Pfizer       |                |
|                                                                                                                                                           | Olanzapine           |                    |                    | S               | Oral                                     | 15 Mg Daily          |                 | Not Reported |                |
|                                                                                                                                                           | Quetiapine Fumarate  |                    |                    | S               |                                          | 25 Mg Daily          |                 | Not Reported |                |
|                                                                                                                                                           | Citalopram Hbr       |                    |                    | S               | Oral                                     | 10 Mg, 2x/Day        |                 | Not Reported |                |
|                                                                                                                                                           | Escitalopram Oxalate |                    |                    | S               |                                          | 10 Mg Daily          |                 | Not Reported |                |
|                                                                                                                                                           | Haloperidol          |                    |                    | S               |                                          | 1 Mg Daily           |                 | Pfizer       |                |
|                                                                                                                                                           | Clomipramine         |                    |                    | S               | Oral                                     | 25 Mg, Daily         |                 | Not Reported |                |
|                                                                                                                                                           | Clomipramine         |                    |                    | S               | Oral                                     | 100 Mg               |                 | Not Reported |                |
|                                                                                                                                                           | Valproic Acid        |                    |                    | S               |                                          | Unk                  |                 | Not Reported |                |
|                                                                                                                                                           | Trazodone            |                    |                    | S               |                                          | 100 Mg, Unk          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Aug-2013                                                                                                                                               | 9449387              | EXPEDITED (15-DAY) |                    | OT              | AU-LUPIN PHARMACEUTICALS INC.-2013-01461 |                      |                 | Female       | AUS            |
| <u>Preferred Term</u>                                                                                                                                     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective; Feeling Abnormal; Feeling Of Despair; Malaise; Nausea; Product Substitution Issue; Suicidal Ideation                                    | Escitalopram         |                    |                    | S               | Unknown                                  |                      |                 | Not Reported |                |
|                                                                                                                                                           | Escitalopram         |                    |                    | S               |                                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Aug-2013                                                                                                                                               | 9454318              | DIRECT             | Y                  | OT              |                                          |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

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|                                                              |                        |   |              |
|--------------------------------------------------------------|------------------------|---|--------------|
| Abdominal Discomfort;<br>Chills; Nausea; Tremor;<br>Vomiting | Lexapro 20mg - Generic | S | Not Reported |
|                                                              | Copaxone               | C | Not Reported |
|                                                              | Badofu                 | C | Not Reported |
|                                                              | Glucosamine            | C | Not Reported |
|                                                              | Vit D                  | C | Not Reported |
|                                                              | Percoet                | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Aug-2013              | 9454325       | DIRECT           |                    | OT              |                      |                      | 67 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                               | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------------------------------------|-----------------|--------------|
| Anxiety; Epistaxis    | Escitalopram   |              |            | S           | Oral         | Starting 1/2 Pill A Day 5mg<br>1 A Day - - Mouth |                 | Apotex       |
|                       | Omeprazole     |              |            | C           |              |                                                  |                 | Not Reported |
|                       | Advair         |              |            | C           |              |                                                  |                 | Not Reported |
|                       | Albuterol      |              |            | C           |              |                                                  |                 | Not Reported |
|                       | Multivitamin   |              |            | C           |              |                                                  |                 | Not Reported |
|                       | Vita D         |              |            | C           |              |                                                  |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Aug-2013              | 9025219       | EXPEDITED (15-DAY) |                    | HO              | FR-ROCHE-1181866     |                      | 17 YR      | Male       | FRA            |

| <u>Preferred Term</u>               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hepatitis; Hepatitis<br>Cholestatic | Rivotril       |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                     | Risperdal      |              |            | S           | Oral         |                    |                 | Not Reported |
|                                     | Risperdal      |              |            | S           | Oral         |                    |                 | Not Reported |
|                                     | Risperdal      |              |            | S           | Oral         |                    |                 | Not Reported |
|                                     | Tercian        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                     | Seroplex       |              |            | S           | Oral         |                    |                 | Not Reported |
|                                     | Solian         |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Aug-2013              | 9417871       | EXPEDITED (15-DAY) |                    | OT              | US-TEVA-420649USA    |                      |            | Unknown    | USA            |

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| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                              | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|----------------------|----------------|
| Coeliac Disease                                                                                                                                                                                                                                                                                                    | Ranitidine<br>Escitalopram             |                    |                    | S<br>S          |                      |                      |                 | Teva<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                           | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 12-Aug-2013                                                                                                                                                                                                                                                                                                        | 9452299                                | EXPEDITED (15-DAY) |                    | OT              | US-TEVA-424777       | USA                  |                 | Unknown              | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                              | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Decreased Appetite;<br>Dyskinesia;<br>Gastrointestinal Disorder;<br>Hypertension; Loss Of<br>Personal Independence In<br>Daily Activities; Morbid<br>Thoughts; Negative<br>Thoughts; Nervousness;<br>Paraesthesia; Social<br>Avoidant Behaviour;<br>Suicidal Ideation; Weight<br>Decreased; Withdrawal<br>Syndrome | Escitalopram                           |                    |                    | S               |                      |                      |                 | Ivax                 |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                           | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 12-Aug-2013                                                                                                                                                                                                                                                                                                        | 9457420                                | EXPEDITED (15-DAY) | Y                  | HO              | 2013000190           |                      | 75 YR           | Male                 | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                              | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Cardiomegaly; Fall; Head<br>Injury; Loss Of<br>Consciousness; Malaise;<br>Orthostatic Hypotension                                                                                                                                                                                                                  | Aceon (Perindopril Erbumine)<br>Tablet |                    |                    | S               | Oral                 |                      |                 | Not Reported         |                |
|                                                                                                                                                                                                                                                                                                                    | Temerit                                |                    |                    | S               | Oral<br>Oral         |                      |                 | Not Reported         |                |
|                                                                                                                                                                                                                                                                                                                    | Xatral                                 |                    |                    | S               | Oral                 |                      |                 | Not Reported         |                |
|                                                                                                                                                                                                                                                                                                                    | Seroplex                               |                    |                    | S               | Oral                 |                      |                 | Not Reported         |                |
|                                                                                                                                                                                                                                                                                                                    | Perindopril Arrow (Perindopril)        |                    |                    | C               |                      |                      |                 | Not Reported         |                |
|                                                                                                                                                                                                                                                                                                                    | Kardegic (Acetylsalicylate<br>Lysine)  |                    |                    | C               |                      |                      |                 | Not Reported         |                |
|                                                                                                                                                                                                                                                                                                                    | Tahor (Atorvastatin Calcium)           |                    |                    | C               |                      |                      |                 | Not Reported         |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                             | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| 13-Aug-2013                                                                                                                                                                                                                                                                                                                          | 9455512                              | EXPEDITED (15-DAY) |                    | DS, HO, LT      | FR-009507513-1308FRA001063 |                      | 41 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dyspnoea; Pulmonary Arterial Hypertension                                                                                                                                                                                                                                                                                            | Norset                               |                    |                    | S               | Oral                       | Unk                  |                 | Merck        |                |
|                                                                                                                                                                                                                                                                                                                                      | Prozac                               |                    |                    | S               | Oral                       | 20 Mg, Qd            |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                      | Seroplex                             |                    |                    | S               | Oral                       | 10 Mg, Qd            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                             | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Aug-2013                                                                                                                                                                                                                                                                                                                          | 9455706                              | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000047612          |                      | < 1 DAY         | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Congenital Anomaly; Craniosynostosis                                                                                                                                                                                                                                                                                                 | Lexapro                              |                    |                    | S               | Transplacental             |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                             | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Aug-2013                                                                                                                                                                                                                                                                                                                          | 7568634                              | EXPEDITED (15-DAY) |                    | HO, OT          | PHHY2010FR55134            |                      | 73 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Acute Kidney Injury; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Blood Bilirubin Increased; Blood Creatinine Increased; Drug Reaction With Eosinophilia And Systemic Symptoms; Eosinophil Count Increased; Purpura; Rash; Rash Erythematous; Vitamin D Decreased | Hydrochlorothiazide/Valsartan        |                    |                    | S               | Oral                       | 1 Df, Qd             |                 | Novartis     |                |
|                                                                                                                                                                                                                                                                                                                                      | Previscan (Fluindione)               |                    |                    | S               |                            | 20 Mg, Unk           |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                      | Seroplex                             |                    |                    | S               |                            | Unk Ukn, Unk         |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                      | Imovane                              |                    |                    | S               |                            | 1 Df, Qd             |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                      | Pariet                               |                    |                    | C               |                            | Unk Ukn, Unk         |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                      | Motilium                             |                    |                    | C               |                            | Unk Ukn, Unk         |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                      | Gaviscon                             |                    |                    | C               |                            | Unk Ukn, Unk         |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                      | Temerit                              |                    |                    | C               |                            | 5 Mg, Unk            |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                      | Ditropan                             |                    |                    | C               |                            | Unk Ukn, Unk         |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                      | Dextropropoxyphene Hcl W/Paracetamol |                    |                    | C               |                            | Unk Ukn, Unk         |                 | Not Reported |                |

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|       |   |              |              |
|-------|---|--------------|--------------|
| Tahor | C | Unk Ukn, Unk | Not Reported |
| Amlor | C | Unk Ukn, Unk | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 14-Aug-2013              | 8932192       | EXPEDITED (15-DAY) |                    | HO              | FR-JNJFOC-20121107729 |                      | 17 YR      | Male       | FRA            |

| <u>Preferred Term</u>            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------|----------------|--------------|------------|-------------|--------------|-----------------------------------|-----------------|--------------|
| Hepatitis; Hepatitis Cholestatic | Risperdal      |              |            | S           | Oral         |                                   |                 | Not Reported |
|                                  | Risperdal      |              |            | S           | Oral         |                                   |                 | Not Reported |
|                                  | Risperdal      |              |            | S           | Oral         |                                   |                 | Not Reported |
|                                  | Risperdal      |              |            | S           | Oral         |                                   |                 | Not Reported |
|                                  | Risperdal      |              |            | S           | Oral         |                                   |                 | Not Reported |
|                                  | Risperdal      |              |            | S           | Oral         |                                   |                 | Not Reported |
|                                  | Risperdal      |              |            | S           | Oral         |                                   |                 | Not Reported |
|                                  | Risperdal      |              |            | S           | Oral         |                                   |                 | Not Reported |
|                                  | Risperdal      |              |            | S           | Oral         |                                   |                 | Not Reported |
|                                  | Risperdal      |              |            | S           | Oral         |                                   |                 | Not Reported |
|                                  | Risperdal      |              |            | S           | Oral         |                                   |                 | Not Reported |
|                                  | Risperdal      |              |            | S           | Oral         |                                   |                 | Not Reported |
|                                  | Risperdal      |              |            | S           | Oral         |                                   |                 | Not Reported |
|                                  | Risperdal      |              |            | S           | Oral         |                                   |                 | Not Reported |
|                                  | Risperdal      |              |            | S           | Oral         |                                   |                 | Not Reported |
|                                  | Risperdal      |              |            | S           | Oral         |                                   |                 | Not Reported |
|                                  | Risperdal      |              |            | S           | Oral         |                                   |                 | Not Reported |
|                                  | Tercian        |              |            | S           | Oral         | Taken Occasionally If Needed      |                 | Not Reported |
|                                  | Solian         |              |            | S           | Oral         |                                   |                 | Not Reported |
|                                  | Seroplex       |              |            | S           | Oral         | Reintroduction On An Unknown Date |                 | Not Reported |
|                                  | Seroplex       |              |            | S           | Oral         |                                   |                 | Not Reported |
|                                  | Seroplex       |              |            | S           | Oral         |                                   |                 | Not Reported |

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

|          |   |         |                                   |              |
|----------|---|---------|-----------------------------------|--------------|
| Seroplex | S | Oral    |                                   | Not Reported |
| Seroplex | S | Oral    |                                   | Not Reported |
| Seroplex | S | Oral    | Reintroduction On An Unknown Date | Not Reported |
| Seroplex | S | Oral    |                                   | Not Reported |
| Seroplex | S | Oral    |                                   | Not Reported |
| Seroplex | S | Oral    | Reintroduction On An Unknown Date | Not Reported |
| Rivotril | S | Unknown |                                   | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Aug-2013              | 9242891       | EXPEDITED (15-DAY) | HO                 |                 | JP-FRI-1000044443    |                      | 81 YR      | Female     | JPN            |

| <u>Preferred Term</u>            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Seizure; Ventricular Tachycardia | Lexapro        |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                  | Rasilez        |              |            | C           | Oral         | 150 Mg             |                 | Not Reported |
|                                  | Norvasc        |              |            | C           | Oral         | 5 Mg               |                 | Not Reported |
|                                  | Bup-4          |              |            | C           | Oral         | 20 Mg              |                 | Not Reported |
|                                  | Protecadin     |              |            | C           | Oral         | 10 Mg              |                 | Not Reported |
|                                  | Reminyl Od     |              |            | C           | Oral         | 16 Mg              |                 | Not Reported |
|                                  | Nauzelin       |              |            | C           | Oral         | 20 Mg              |                 | Not Reported |
|                                  | Amitiza        |              |            | C           | Oral         | 24 Mg              |                 | Not Reported |
|                                  | Amlodipine     |              |            | C           | Oral         | 5 Mg               |                 | Not Reported |
|                                  | Mohrus         |              |            | C           | Transdermal  |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------|----------------------|------------|------------|----------------|
| 14-Aug-2013              | 9431733       | EXPEDITED (15-DAY) | OT                 |                 | AU-RANBAXY-2013RR-71654 |                      | 21 YR      | Male       | AUS            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Purpura Fulminans     | Amoxicillin    |              |            | S           | Oral         | Unk                |                 | Ranbaxy    |

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

| Escitalopram                                                                                                             |                |                    | S                  | Unknown         | Unk                      | Not Reported                                                                        |                 |              |                |
|--------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|--------------------------|-------------------------------------------------------------------------------------|-----------------|--------------|----------------|
| <u>FDA Received Date</u>                                                                                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                                                                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Aug-2013                                                                                                              | 9444780        | EXPEDITED (15-DAY) |                    | OT              | TW-RANBAXY-2013RR-71895  |                                                                                     |                 | Female       | TWN            |
| <u>Preferred Term</u>                                                                                                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                                                                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated;<br>Drug Ineffective; Nausea;<br>Obsessive-Compulsive<br>Disorder; Potentiating<br>Drug Interaction | Sertraline     |                    |                    | S               | Unknown                  | 300 Mg/Day                                                                          |                 | Ranbaxy      |                |
|                                                                                                                          | Sertraline     |                    |                    | S               | Unknown                  | 300 Mg/Day                                                                          |                 | Ranbaxy      |                |
|                                                                                                                          | Clozapine      |                    |                    | S               | Unknown                  | 400 Mg/Day                                                                          |                 | Not Reported |                |
|                                                                                                                          | Clozapine      |                    |                    | S               | Unknown                  | 350 Mg/Day                                                                          |                 | Not Reported |                |
|                                                                                                                          | Escitalopram   |                    |                    | S               | Unknown                  | 20 Mg/Day                                                                           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                                                                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Aug-2013                                                                                                              | 9458258        | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-2013233349 |                                                                                     | 57 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                                                                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Melanocytic Naevus;<br>Panic Attack                                                                                      | Neurontin      |                    |                    | S               | Oral                     | 600 Mg, 3x/Day                                                                      |                 | Pfizer       |                |
|                                                                                                                          | Gabapentin     |                    |                    | S               | Oral                     | 300 Mg, 3x/Day                                                                      |                 | Pfizer       |                |
|                                                                                                                          | Lyrica         |                    |                    | S               |                          | Unk                                                                                 |                 | Pfizer       |                |
|                                                                                                                          | Xanax          |                    |                    | S               |                          | Once A Day                                                                          |                 | Pfizer       |                |
|                                                                                                                          | Percocet       |                    |                    | S               | Oral                     | Oxycodone Hydrochloride<br>10 Mg, Paracetamol 325<br>Mg Take 1 Tab Every 4<br>Hours |                 | Not Reported |                |
|                                                                                                                          | Lexapro        |                    |                    | S               | Oral                     | 20 Mg, 1x/Day (Daily)                                                               |                 | Not Reported |                |
|                                                                                                                          | Prozac         |                    |                    | S               |                          | Unk                                                                                 |                 | Not Reported |                |
|                                                                                                                          | Cymbalta       |                    |                    | C               |                          |                                                                                     |                 | Not Reported |                |
|                                                                                                                          | Aspirin        |                    |                    | C               |                          |                                                                                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                                                                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Aug-2013                                                                                                              | 9458529        | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000047717        |                                                                                     | < 1 DAY         | Male         | USA            |

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

| <u>Preferred Term</u>                                                                                                                                                                                                           | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Aorta Hypoplasia; Aortic Valve Incompetence; Arteriovenous Malformation; Congenital Hydrocephalus; Hypoplastic Left Heart Syndrome; Mitral Valve Hypoplasia; Pulmonary Artery Stenosis Congenital; Tricuspid Valve Incompetence | Lexapro                            |                    |                    | S               |                      |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                        | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Aug-2013                                                                                                                                                                                                                     | 9458796                            | EXPEDITED (15-DAY) |                    | DS, HO, LT      | FR-FRI-1000047743    |                      | 41 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                                                           | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dyspnoea; Pulmonary Arterial Hypertension                                                                                                                                                                                       | Escitalopram                       |                    |                    | S               | Oral                 | 1 Df                 |                 | Forest       |                |
|                                                                                                                                                                                                                                 | Prozac                             |                    |                    | S               | Oral                 | 1 Df                 |                 | Not Reported |                |
|                                                                                                                                                                                                                                 | Norset                             |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                        | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Aug-2013                                                                                                                                                                                                                     | 9458967                            | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000047770    |                      | 62 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                                                           | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cholestasis; Hepatocellular Injury                                                                                                                                                                                              | Escitalopram                       |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                                                                                                                                                                                                                 | Loxen (Niacardipine Hydrochloride) |                    |                    | S               | Oral                 | 2 Df                 |                 | Not Reported |                |
|                                                                                                                                                                                                                                 | Hyperium                           |                    |                    | S               | Oral                 | 2 Df                 |                 | Not Reported |                |
|                                                                                                                                                                                                                                 | Propranolol                        |                    |                    | S               | Oral                 | 40 Mg                |                 | Not Reported |                |
|                                                                                                                                                                                                                                 | Solupred (Prednisolone)            |                    |                    | S               | Oral                 | 160 Mg               |                 | Not Reported |                |
|                                                                                                                                                                                                                                 | Atarax                             |                    |                    | S               | Oral                 | 25 Mg                |                 | Not Reported |                |
|                                                                                                                                                                                                                                 | Paracetamol                        |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|  |              |   |      |       |              |
|--|--------------|---|------|-------|--------------|
|  | Nebivolol    | C | Oral | 5 Mg  | Not Reported |
|  | Esomeprazole | C | Oral | 40 Mg | Not Reported |
|  | Iperfen      | C |      | 10 Mg | Not Reported |
|  | Tahor        | C |      | 40 Mg | Not Reported |
|  | Dafalgan     | C |      |       | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 14-Aug-2013              | 9459012        | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2013235313 |                      | 29 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity    | Zoloft         |                  |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                          | Effexor Xr     |                  |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                          | Zithromax      |                  |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                          | Amoxil         |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                          | Lexapro        |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|--------------------------|------------------|--------------------|-----------------|----------------------|----------------------------------|-----------------|------------|----------------|
| 14-Aug-2013              | 9461393                  | DIRECT           |                    | OT              |                      |                                  | 80 YR           | Male       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u> |                |
| Diarrhoea; Tremor        | Escitalopram 5 Mg Camber |                  |                    | S               | Oral                 | 5 Mg 1 Tablet A Bedtime By Mouth |                 | Camber     |                |

| <u>FDA Received Date</u>                                                                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 14-Aug-2013                                                                                                    | 9462744        | EXPEDITED (15-DAY) |                    | HO              | AUR-APL-2013-06606   |                      | 45 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Discomfort; Akathisia; Blood Pressure Increased; Fall; Insomnia; Nausea; Palpitations; Panic Attack; | Escitalopram   |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Restlessness; Suicidal  
Ideation; Tremor; Tremor;  
Weight Decreased

| <u>FDA Received Date</u>                    | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
|---------------------------------------------|-----------------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|------------------|----------------|
| 15-Aug-2013                                 | 9300903               | EXPEDITED (15-DAY) |                    | OT              | BE-<br>ELI_LILLY_AND_COMP<br>ANY-BE201305004233 |                      | 75 YR           | Female           | BEL            |
| <u>Preferred Term</u>                       | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |
| Balance Disorder; Drug<br>Interaction; Fall | Cymbalta              |                    |                    | S               | Oral                                            | 60 Mg, Qd            |                 | Eli Lilly And Co |                |
|                                             | Siprallexa /01588501/ |                    |                    | S               | Unknown                                         | Unk, Unknown         |                 | Not Reported     |                |
|                                             | Emconcor              |                    |                    | C               | Unknown                                         | Unk, Unknown         |                 | Not Reported     |                |
|                                             | Amlor                 |                    |                    | C               | Unknown                                         | Unk, Unknown         |                 | Not Reported     |                |

| <u>FDA Received Date</u>                                                                                                                                                        | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|--------------------------------------|-----------------|--------------|----------------|
| 15-Aug-2013                                                                                                                                                                     | 9379472        | EXPEDITED (15-DAY) |                    | CA, HO, OT      | US-FRI-1000046302    |                                      | 266 DAY         | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                           | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aortic Valve Atresia;<br>Coarctation Of The Aorta;<br>Failure To Thrive;<br>Hypoplastic Left Heart<br>Syndrome; Mitral Valve<br>Stenosis; Necrotising<br>Enterocolitis Neonatal | Lexapro        |                    |                    | S               | Transplacental       | 5 Mg                                 |                 | Forest       |                |
|                                                                                                                                                                                 | Lexapro        |                    |                    | S               | Transplacental       | 10 Mg                                |                 | Forest       |                |
|                                                                                                                                                                                 | Zoloft         |                    |                    | S               | Transplacental       | 50 Mg                                |                 | Not Reported |                |
|                                                                                                                                                                                 | Proventil Hfa  |                    |                    | C               |                      | 2 Puffs As Needed                    |                 | Not Reported |                |
|                                                                                                                                                                                 | Cefdinir       |                    |                    | C               |                      | 30 MI                                |                 | Not Reported |                |
|                                                                                                                                                                                 | Nitrofurantoin |                    |                    | C               |                      | 100 Mg Every 12 Hours                |                 | Not Reported |                |
|                                                                                                                                                                                 | Ibuprofen      |                    |                    | C               |                      | 600 Mg Four Times Daily<br>As Needed |                 | Not Reported |                |
|                                                                                                                                                                                 | Ondansetron    |                    |                    | C               |                      | 12 Mg                                |                 | Not Reported |                |
|                                                                                                                                                                                 | Ondansetron    |                    |                    | C               |                      |                                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|------------|------------|----------------|
| 15-Aug-2013              | 9459325       | EXPEDITED (15-DAY) |                    | OT              | CH-ASTRAZENECA-<br>2012SE76410 |                      | 21 YR      | Female     | CHE            |

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

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Bezoar; Overdose      | Quetiapine Xr  |              |            | S           | Oral         |                    |                 | Astrazeneca  |
|                       | Escitalopram   |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Pantoprazole   |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Topiramate     |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Aug-2013              | 9459730       | EXPEDITED (15-DAY) |                    | HO, OT          | FR-FRI-1000047623    |                      | 75 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Loss Of Consciousness;<br>Malaise; Orthostatic<br>Hypotension | Nebivolol      |              |            | S           | Oral         | 5 Mg               |                 | Forest       |
|                                                               | Nebivolol      |              |            | S           | Oral         | 2.5 Mg             |                 | Forest       |
|                                                               | Xatral         |              |            | S           | Oral         | 10 Mg              |                 | Not Reported |
|                                                               | Coversyl       |              |            | S           | Oral         | 15 Mg              |                 | Not Reported |
|                                                               | Escitalopram   |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                                               | Perindopril    |              |            | C           |              | 12 Mg              |                 | Not Reported |
|                                                               | Kardegic       |              |            | C           | Oral         | 75 Mg              |                 | Not Reported |
|                                                               | Tahor          |              |            | C           | Oral         | 40 Mg              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Aug-2013              | 9460371       | EXPEDITED (15-DAY) |                    | HO              | AU-FRI-1000047798    |                      | 65 YR      | Male       | AUS            |

| <u>Preferred Term</u>                                                       | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------|-----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Encephalitis Autoimmune;<br>Inappropriate Antidiuretic<br>Hormone Secretion | Escitalopram          |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                                                             | Nitrazepam            |              |            | S           | Oral         | 5 Mg               |                 | Not Reported |
|                                                                             | Sotalol Hydrochloride |              |            | C           | Oral         | 320 Mg             |                 | Not Reported |
|                                                                             | Candesartan           |              |            | C           | Oral         | 32 Mg              |                 | Not Reported |
|                                                                             | Hydrochlorothiazide   |              |            |             |              |                    |                 |              |
|                                                                             | Lansoprazole          |              |            | C           | Oral         | 30 Mg              |                 | Not Reported |
|                                                                             | Paracetamol-Codeine   |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Phosphate  
Warfarin Sodium

C

Oral

6.5 Mg

Not Reported

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 15-Aug-2013                       | 9460489                | EXPEDITED (15-DAY)        |                             | HO                       | AU-FRI-1000047851             |                               |                     | Female              | AUS                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Pregnancy; Premature Delivery  | Escitalopram            |                       |                     | S                    | Oral                  | 20 Mg                       |                          | Forest              |
|                                | Escitalopram            |                       |                     | S                    |                       | 200 Mg                      |                          | Not Reported        |
|                                | Seroquel                |                       |                     | S                    |                       |                             |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 15-Aug-2013                       | 9460520                | EXPEDITED (15-DAY)        |                             | DE, HO                   | AU-FRI-1000047852             |                               | < 1 DAY             | Female              | AUS                     |

| <a href="#">Preferred Term</a>                                                                                                        | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|---------------------------------------------------------------------------------------------------------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Escherichia Sepsis; Foetal Exposure During Pregnancy; Microencephaly; Necrotising Colitis; Peritoneal Haemorrhage; Premature Delivery | Escitalopram            |                       |                     | S                    | Transplacental        | 20 Mg                       |                          | Forest              |
|                                                                                                                                       | Seroquel                |                       |                     | S                    | Transplacental        |                             |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 16-Aug-2013                       | 9461368                | EXPEDITED (15-DAY)        |                             | OT                       | US-ACCORD-018968              |                               |                     | Unknown             | USA                     |

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

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 16-Aug-2013                       | 9461939                | EXPEDITED (15-DAY)        |                             | HO                       | GB-FRI-1000047794             |                               | 45 YR               | Female              | GBR                     |

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

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

|                                                                                                                                                                                                             |              |   |      |       |        |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|---|------|-------|--------|
| Abdominal Discomfort;<br>Akathisia; Blood Pressure<br>Increased; Condition<br>Aggravated; Insomnia;<br>Nausea; Palpitations;<br>Panic Attack; Suicidal<br>Ideation; Syncope;<br>Tremor; Weight<br>Decreased | Escitalopram | S | Oral | 10 Mg | Forest |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|---|------|-------|--------|

| <u>FDA Received Date</u>                                              | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|-----------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 16-Aug-2013                                                           | 9462742                       | EXPEDITED (15-DAY) |                    | HO, OT          | SI-ROXANE<br>LABORATORIES, INC.-<br>2013-RO-01336RO |                      | 79 YR           | Female       | SVN            |
| <u>Preferred Term</u>                                                 | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cystitis; Neutropenia;<br>Pancytopenia; Toxicity To<br>Various Agents | Methotrexate                  |                    |                    | S               |                                                     |                      |                 | Roxane       |                |
|                                                                       | Trimethoprim-Sulfamethoxazole |                    |                    | S               |                                                     |                      |                 | Not Reported |                |
|                                                                       | Folic Acid                    |                    |                    | S               |                                                     | 5 Mg                 |                 | Not Reported |                |
|                                                                       | Asasantin Retard              |                    |                    | S               |                                                     |                      |                 | Not Reported |                |
|                                                                       | Nifedipine                    |                    |                    | S               |                                                     |                      |                 | Not Reported |                |
|                                                                       | Escitalopram                  |                    |                    | S               |                                                     |                      |                 | Not Reported |                |
|                                                                       | Repaglinide                   |                    |                    | S               |                                                     |                      |                 | Not Reported |                |
|                                                                       | Bisoprolol                    |                    |                    | S               |                                                     |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>          | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------|---------------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|-----------------|--------------|----------------|
| 16-Aug-2013                       | 9462983             | EXPEDITED (15-DAY) |                    | HO              | SE-ASTRAZENECA-<br>2013SE63063 |                      | 27 YR           | Female       | SWE            |
| <u>Preferred Term</u>             | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Loss Of Consciousness;<br>Seizure | Seroquel            |                    |                    | S               | Oral                           |                      |                 | Zeneca       |                |
|                                   | Cipralex            |                    |                    | S               |                                |                      |                 | Not Reported |                |
|                                   | Ergenyl             |                    |                    | S               |                                |                      |                 | Not Reported |                |
|                                   | Temesta (Lorazepam) |                    |                    | S               |                                |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------------------------------------|----------------------|------------|------------|----------------|
| 16-Aug-2013              | 9463125       | EXPEDITED (15-DAY) |                    | HO, OT          | SI-B.I.<br>PHARMACEUTICALS,I<br>NC./RIDGEFIELD-2013-<br>RO-01 |                      | 79 YR      | Female     | SVN            |

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

| <u>Preferred Term</u>                                                 | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>           |
|-----------------------------------------------------------------------|-------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------|
| Cystitis; Neutropenia;<br>Pancytopenia; Toxicity To<br>Various Agents | Methotrexate                  |              |            | S           |              |                    |                 | Roxane               |
|                                                                       | Trimethoprim-Sulfamethoxazole |              |            | S           |              |                    |                 | Not Reported         |
|                                                                       | Folic Acid                    |              |            | S           |              | 5 Mg               |                 | Not Reported         |
|                                                                       | Asasantin Retard              |              |            | S           |              |                    |                 | Boehringer Ingelheim |
|                                                                       | Nifedipine                    |              |            | S           |              |                    |                 | Not Reported         |
|                                                                       | Escitalopram                  |              |            | S           |              |                    |                 | Not Reported         |
|                                                                       | Repaglinide                   |              |            | S           |              |                    |                 | Not Reported         |
|                                                                       | Bisoprolol                    |              |            | S           |              |                    |                 | Not Reported         |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Aug-2013              | 9471264       | EXPEDITED (15-DAY) | Y                  | HO              | 1844252              |                      | 25 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                  | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>     | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------|------------|-------------|------------------|--------------------|-----------------|--------------|
| Anhedonia; Anxiety;<br>Decreased Appetite;<br>Depressed Mood;<br>Derealisation; Drug<br>Interaction; Dysgeusia;<br>Dysphoria; Hyperphagia;<br>Hypersomnia; Illusion; Off<br>Label Use; Parosmia;<br>Poor Quality Sleep;<br>Suicidal Ideation;<br>Trichotillomania; Weight<br>Increased | Ketamine Hydrochloride |              |            | S           | Intravenous drip |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                        | Clomipramine           |              |            | S           |                  |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                        | Escitalopram           |              |            | S           |                  |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Aug-2013              | 9464416       | EXPEDITED (15-DAY) |                    | CA, DE          | US-FRI-1000047788    |                      | < 1 DAY    | Female     | USA            |

| <u>Preferred Term</u>             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|------------|
| Atrioventricular Septal<br>Defect | Lexapro        |              |            | S           | Transplacental |                    |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Aug-2013              | 9465124       | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000047850    |                      | < 1 DAY    | Female     | USA            |

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

| <u>Preferred Term</u>                                                               | <u>Product</u>                                       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>                                   |                |
|-------------------------------------------------------------------------------------|------------------------------------------------------|------------------|--------------------|-----------------|----------------------|------------------------------------------|-----------------|----------------------------------------------|----------------|
| Congenital Anomaly;<br>Fallot'S Tetralogy                                           | Lexapro                                              |                  |                    | S               | Transplacental       |                                          |                 | Forest                                       |                |
| <u>FDA Received Date</u>                                                            | <u>Case #</u>                                        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                     | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 19-Aug-2013                                                                         | 9467533                                              | DIRECT           | Y                  | HO              |                      |                                          | 17 YR           | Female                                       | USA            |
| <u>Preferred Term</u>                                                               | <u>Product</u>                                       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Haematocrit Decreased;<br>Haemoglobin Decreased;<br>Sepsis                          | Escitalopram<br>Piperacillin/Tazobactam<br>Ibuprofen |                  |                    | S<br>C<br>C     |                      |                                          |                 | Not Reported<br>Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                            | <u>Case #</u>                                        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                     | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 19-Aug-2013                                                                         | 9467610                                              | DIRECT           |                    |                 |                      |                                          | 43 YR           | Female                                       | USA            |
| <u>Preferred Term</u>                                                               | <u>Product</u>                                       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Anxiety; Dyspnoea;<br>Irritability; Palpitations;<br>Throat Tightness               | Escitalopram                                         |                  |                    | S               | Oral                 | 1 Tablet Once Daily Taken<br>By Mouth    |                 | Lupin                                        |                |
| <u>FDA Received Date</u>                                                            | <u>Case #</u>                                        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                     | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 19-Aug-2013                                                                         | 9467758                                              | DIRECT           |                    | DS              |                      |                                          | 32 YR           | Female                                       | USA            |
| <u>Preferred Term</u>                                                               | <u>Product</u>                                       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Anxiety; Confusional<br>State; Dizziness;<br>Hypokinesia; Hyporeflexia;<br>Migraine | Escitalopram                                         |                  |                    | S               | Oral                 | 10mg Once Daily Taken<br>By Mouth 7 Days |                 | Not Reported                                 |                |
| <u>FDA Received Date</u>                                                            | <u>Case #</u>                                        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                     | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 19-Aug-2013                                                                         | 9556405                                              | NON-EXPEDITED    | Y                  | OT              | 13DE007279           |                                          | 31 YR           | Female                                       | DEU            |
| <u>Preferred Term</u>                                                               | <u>Product</u>                                       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>                                   |                |

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

|                                                                           |            |   |      |  |  |  |  |              |
|---------------------------------------------------------------------------|------------|---|------|--|--|--|--|--------------|
| Inappropriate Antidiuretic<br>Hormone Secretion;<br>Nocturia; Pollakiuria | Paroxetine | S | Oral |  |  |  |  | Not Reported |
|                                                                           | Ciprallex  | S | Oral |  |  |  |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Aug-2013              | 9442435       | EXPEDITED (15-DAY) |                    | OT              | JP-FRI-1000047441    |                      |            | Female     | JPN            |

| <u>Preferred Term</u>                               | <u>Product</u>                            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------|-------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Agitation; Memory<br>Impairment; Suicide<br>Attempt | Lexapro                                   |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                                     | Paxil                                     |              |            | C           | Oral         | 3 Df               |                 | Not Reported |
|                                                     | Paxil                                     |              |            | C           | Oral         | 2 Df               |                 | Not Reported |
|                                                     | Paxil                                     |              |            | C           | Oral         | 1 Df               |                 | Not Reported |
|                                                     | Limas                                     |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                     | Lexotan                                   |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                     | Hypnotics And Sedatives,<br>Antianxietics |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Aug-2013              | 9465988       | EXPEDITED (15-DAY) |                    | OT              | US-FRI-1000030860    |                      | 20 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abdominal Pain Lower;<br>Bronchitis; Cellulitis;<br>Cubital Tunnel Syndrome;<br>Drug Ineffective; Exposure<br>During Pregnancy; Fall;<br>Foot Fracture; Genital<br>Herpes; Haematuria;<br>Ligament Sprain;<br>Menstruation Irregular;<br>Migraine; Otitis Externa;<br>Perinatal Depression;<br>Upper Respiratory Tract<br>Infection; Urinary Tract<br>Infection; Uterine Spasm;<br>Vaginal Abscess; Vaginal | Lexapro        |              |            | S           |              | 10 Mg              |                 | Forest       |
|                                                                                                                                                                                                                                                                                                                                                                                                             | Lexapro        |              |            | S           |              | 20 Mg              |                 | Forest       |
|                                                                                                                                                                                                                                                                                                                                                                                                             | Citalopram     |              |            | S           |              | 40 Mg              |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                             | Lexapro        |              |            | S           |              | 20 Mg              |                 | Forest       |
|                                                                                                                                                                                                                                                                                                                                                                                                             | Lexapro        |              |            | S           |              | 10 Mg              |                 | Forest       |
|                                                                                                                                                                                                                                                                                                                                                                                                             | Lexapro        |              |            | S           |              | 10 Mg              |                 | Forest       |
|                                                                                                                                                                                                                                                                                                                                                                                                             | Citalopram     |              |            | S           | Oral         | 40 Mg              |                 | Forest       |
|                                                                                                                                                                                                                                                                                                                                                                                                             | Lexapro        |              |            | S           |              | 10 Mg              |                 | Forest       |
|                                                                                                                                                                                                                                                                                                                                                                                                             | Lexapro        |              |            | S           |              | 20 Mg              |                 | Forest       |
|                                                                                                                                                                                                                                                                                                                                                                                                             | Aciphex        |              |            | C           |              | 20 Mg              |                 | Not Reported |



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|             |                  |   |      |                             |  |              |
|-------------|------------------|---|------|-----------------------------|--|--------------|
| Haemorrhage | Trinessa         | C |      |                             |  | Not Reported |
|             | Ortho Tri-Cyclen | C |      |                             |  | Not Reported |
|             | Advil            | C |      | As Needed                   |  | Not Reported |
|             | Vicodin          | C |      | 500/5 Mg Daily As Needed    |  | Not Reported |
|             | Nexium           | C | Oral | 20 Mg                       |  | Not Reported |
|             | Prenatal Vitamin | C |      |                             |  | Not Reported |
|             | Percocet         | C | Oral | 5/325 Mg 1-2 Tabs As Needed |  | Not Reported |
|             | Docusate         | C | Oral | 100 Mg                      |  | Not Reported |
|             | Amitriptyline    | C | Oral | 10 Mg                       |  | Not Reported |
|             | Folic Acid       | C |      |                             |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Aug-2013              | 9466963       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000047928    |                      | 93 YR      | Female     | FRA            |

| <u>Preferred Term</u>                         | <u>Product</u>                                   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------|--------------------------------------------------|--------------|------------|-------------|--------------|---------------------------------------|-----------------|--------------|
| Cerebral Haemorrhage;<br>Condition Aggravated | Escitalopram                                     |              |            | S           | Oral         | 1 Df                                  |                 | Forest       |
|                                               | Previscan (Fluindione)                           |              |            | S           | Oral         | 10 Mg Even Days/5 Mg<br>Odd Days      |                 | Not Reported |
|                                               | Aerius (Desloratadine)                           |              |            | C           |              | 1 Df                                  |                 | Not Reported |
|                                               | Hemigoxine                                       |              |            | C           |              | 1 Df                                  |                 | Not Reported |
|                                               | Inexium                                          |              |            | C           |              | 1 Df                                  |                 | Not Reported |
|                                               | Levemir                                          |              |            | C           |              | 20 Units                              |                 | Not Reported |
|                                               | Novorapid                                        |              |            | C           |              | Depending On Capillary<br>Glucose     |                 | Not Reported |
|                                               | Lasilix                                          |              |            | C           |              | 80 Mg On Morning And 40<br>Mg At Noon |                 | Not Reported |
|                                               | Nitriderm                                        |              |            | C           |              | 1 Df                                  |                 | Not Reported |
|                                               | Spasmine (Hawthorn Leaf With<br>Flower\Valerian) |              |            | C           |              | 2 Df                                  |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Aug-2013              | 9467131       | EXPEDITED (15-DAY) |                    | HO, OT          | US-B.I.              |                      | 10 YR      | Male       | USA            |

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

PHARMACEUTICALS,I  
NC./RIDGEFIELD-2013-  
BI-25

| <u>Preferred Term</u>                                     | <u>Product</u>                                          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>      | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                                                           |
|-----------------------------------------------------------|---------------------------------------------------------|--------------|------------|------------------|--------------|--------------------|-----------------|----------------------------------------------------------------------|
| Cardiac Arrest; Long Qt Syndrome; Ventricular Tachycardia | Clonidine<br>Methylphenidate<br>Lithium<br>Escitalopram |              |            | S<br>S<br>S<br>S |              |                    |                 | Boehringer Ingelheim<br>Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Aug-2013              | 9469836       | DIRECT           | Y                  | OT              |                      |                      | 46 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Feeling Abnormal; Panic Attack; Therapeutic Product Effect Decreased | Lexapro        |              |            | S           | Oral         | One Daily Oral     |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Aug-2013              | 8589038       | EXPEDITED (15-DAY) |                    | DE, HO, OT      | US-FRI-1000030861    |                      | 313 DAY    | Male       | USA            |

| <u>Preferred Term</u>                                                  | <u>Product</u>   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------|------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Acute Respiratory Failure;                                             | Lexapro          |              |            | S           |              | 10 Mg              |                 | Forest       |
| Atrial Septal Defect;                                                  | Lexapro          |              |            | S           |              | 20 Mg              |                 | Forest       |
| Atrioventricular Block Complete; Brain Injury;                         | Lexapro          |              |            | S           |              | 20 Mg              |                 | Not Reported |
| Bronchiolitis; Cardiac Failure Congestive;                             | Lexapro          |              |            | S           |              | 10 Mg              |                 | Not Reported |
| Cardiogenic Shock;                                                     | Lexapro          |              |            | S           |              | 10 Mg              |                 | Not Reported |
| Cardiomegaly;                                                          | Lexapro          |              |            | S           |              | 10 Mg              |                 | Not Reported |
| Cerebrovascular Accident;                                              | Citalopram       |              |            | C           |              | 40 Mg              |                 | Forest       |
| Clostridium Difficile Infection; Coagulopathy;                         | Citalopram       |              |            | C           |              | 40 Mg              |                 | Forest       |
| Conjunctivitis; Diarrhoea Haemorrhagic; Double Outlet Right Ventricle; | Aciphex          |              |            | C           |              | 20 Mg              |                 | Not Reported |
| Fallot'S Tetralogy;                                                    | Trinessa         |              |            | C           |              |                    |                 | Not Reported |
|                                                                        | Ortho Tri-Cyclen |              |            | C           |              |                    |                 | Not Reported |

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|                            |                  |   |      |                             |              |
|----------------------------|------------------|---|------|-----------------------------|--------------|
| Jaundice Neonatal;         | Advil            | C |      | As Needed                   | Not Reported |
| Multiple Organ             | Vicodin          | C |      | 500/5 Mg Daily As Needed    | Not Reported |
| Dysfunction Syndrome;      | Nexium           | C | Oral | 20 Mg                       | Not Reported |
| Nodal Rhythm; Oral         | Prenatal Vitamin | C |      |                             | Not Reported |
| Candidiasis; Otitis Media; | Percocet         | C | Oral | 5/325 Mg 1-2 Tabs As Needed | Not Reported |
| Pleural Effusion; Poor     |                  |   |      |                             |              |
| Feeding Infant; Pulmonary  |                  |   |      |                             |              |
| Hypertension; Serratia     | Docusate         | C | Oral | 100 Mg                      | Not Reported |
| Infection; Skin Disorder;  | Amitriptyline    | C | Oral | 10 Mg                       | Not Reported |
| Urinary Tract Infection;   | Folic Acid       | C |      |                             | Not Reported |
| Vomiting                   |                  |   |      |                             |              |

| <u>FDA Received Date</u>    | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------|----------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 21-Aug-2013                 | 8989355                    | EXPEDITED (15-DAY) |                    | HO              | IT-FRI-1000041218    |                      | 23 YR           | Male         | ITA            |
| <u>Preferred Term</u>       | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Psychomotor                 | Escitalopram Oral Solution |                    |                    | S               | Oral                 | 15 Gtt               |                 | Forest       |                |
| Hyperactivity; Tonic Clonic | Growth Hormone             |                    |                    | C               |                      | 0.4 lu               |                 | Not Reported |                |
| Movements                   | Valium                     |                    |                    | C               |                      | 30 Gtt               |                 | Not Reported |                |

| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 21-Aug-2013                | 9091737        | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000041624    |                      | 17 YR           | Male         | FRA            |
| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hepatitis; Hepatitis       | Escitalopram   |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
| Cholestatic; Off Label Use | Escitalopram   |                    |                    | S               | Oral                 | 15 Mg                |                 | Forest       |                |
|                            | Risperdal      |                    |                    | S               | Oral                 | 4 Mg                 |                 | Not Reported |                |
|                            | Risperdal      |                    |                    | S               | Oral                 | 6 Mg                 |                 | Not Reported |                |
|                            | Risperdal      |                    |                    | S               | Oral                 | 8 Mg                 |                 | Not Reported |                |
|                            | Risperdal      |                    |                    | S               | Oral                 | 6 Mg                 |                 | Not Reported |                |
|                            | Tercian        |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                            | Solian         |                    |                    | S               | Oral                 | 400 Mg               |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|------------------------------|-----------------------------------|-----------------|--------------|----------------|
| 21-Aug-2013                                                                            | 9353671        | EXPEDITED (15-DAY) |                    | LT              | FR-FRI-1000045962            |                                   |                 | Male         | FRA            |
| <u>Preferred Term</u>                                                                  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrioventricular Block<br>Second Degree                                                | Escitalopram   |                    |                    | S               | Oral                         | 1 Df                              |                 | Forest       |                |
|                                                                                        | Seresta        |                    |                    | C               |                              |                                   |                 | Not Reported |                |
|                                                                                        | Seresta        |                    |                    | C               |                              |                                   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Aug-2013                                                                            | 9468337        | NON-EXPEDITED      |                    |                 | US-PFIZER INC-<br>2013240669 |                                   | 51 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Decreased<br>Appetite; Dizziness;<br>Fatigue; Heart Rate<br>Decreased; Tremor | Xanax          |                    |                    | S               | Oral                         | 0.125 Mg, 4x/Day                  |                 | Pfizer       |                |
|                                                                                        | Lexapro        |                    |                    | S               |                              | 2.5 Mg, 1x/Day                    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Aug-2013                                                                            | 9472484        | DIRECT             | Y                  |                 |                              |                                   | 16 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |                |
| Feeling Abnormal;<br>Insomnia                                                          | Lexapro        |                    |                    | S               | Oral                         | 1 Tab (10 Mg)<br>Qhs/Bedtime Oral |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Aug-2013                                                                            | 9470203        | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000047893            |                                   | < 1 DAY         | Male         | USA            |
| <u>Preferred Term</u>                                                                  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |                |
| Talipes                                                                                | Lexapro        |                    |                    | S               | Transplacental               |                                   |                 | Forest       |                |
| <u>FDA Received Date</u>                                                               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Aug-2013                                                                            | 9471298        | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000015887            |                                   | 73 YR           | Female       | FRA            |

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| <u>Preferred Term</u>                                      | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|------------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Drug Reaction With Eosinophilia And Systemic Symptoms      | Escitalopram                  |                    |                    | S               | Oral                 | 1 Df                 |                 | Forest       |                |
|                                                            | Previscan (Fluindione)        |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                            | Hydrochlorothiazide\Valsartan |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                            | Imovane                       |                    |                    | S               | Oral                 | 7.5 Mg               |                 | Not Reported |                |
|                                                            | Tahor                         |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |
|                                                            | Amlor                         |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |
|                                                            | Temerit                       |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |
|                                                            | Diantalvic                    |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |
| Ditropan                                                   |                               |                    | C                  |                 |                      |                      | Not Reported    |              |                |
| <u>FDA Received Date</u>                                   | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Aug-2013                                                | 9471534                       | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000047895    |                      | < 1 DAY         | Female       | USA            |
| <u>Preferred Term</u>                                      | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Congenital Anomaly; Congenital Hydrocephalus; Spina Bifida | Lexapro                       |                    |                    | S               |                      |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                   | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Aug-2013                                                | 9471584                       | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000047901    |                      | < 1 DAY         | Male         | USA            |
| <u>Preferred Term</u>                                      | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Talipes                                                    | Lexapro                       |                    |                    | S               | Transplacental       |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                   | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Aug-2013                                                | 9471586                       | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000047903    |                      | < 1 DAY         | Male         | USA            |
| <u>Preferred Term</u>                                      | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Syndactyly                                                 | Lexapro                       |                    |                    | S               | Transplacental       |                      |                 | Forest       |                |

# FDA Adverse Event Reporting System

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| <u>FDA Received Date</u>                                                                             | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|------------------------------------------------------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|----------------------|----------------|
| 23-Aug-2013                                                                                          | 9400383                       | EXPEDITED (15-DAY) |                    | LT              | JP-FRI-1000046637                               |                      | 23 YR           | Male                 | JPN            |
| <u>Preferred Term</u>                                                                                | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Activation Syndrome;<br>Altered State Of<br>Consciousness; Hepatic<br>Function Abnormal;<br>Overdose | Lexapro                       |                    |                    | S               | Oral                                            | 10 Mg                |                 | Forest               |                |
|                                                                                                      | Meilax                        |                    |                    | C               | Oral                                            | 2 Mg                 |                 | Not Reported         |                |
|                                                                                                      | Vegetamin-B                   |                    |                    | C               | Oral                                            | 1 Df                 |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                                             | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 23-Aug-2013                                                                                          | 9473197                       | NON-EXPEDITED      |                    |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>18753756 |                      | 27 YR           | Male                 | USA            |
| <u>Preferred Term</u>                                                                                | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Dyspnoea; Fatigue                                                                                    | Sprycel (Cml) Tabs            |                    |                    | S               | Oral                                            |                      |                 | Bristol Myers Squibb |                |
|                                                                                                      | Lexapro                       |                    |                    | S               |                                                 |                      |                 | Not Reported         |                |
|                                                                                                      | Vitamin C                     |                    |                    | C               |                                                 |                      |                 | Not Reported         |                |
|                                                                                                      | Convallaria Majalis\Crataegus |                    |                    | C               |                                                 |                      |                 | Not Reported         |                |
|                                                                                                      | Laevigata Leaf\Proxyphylline  |                    |                    |                 |                                                 |                      |                 |                      |                |
|                                                                                                      | Vitamin B                     |                    |                    | C               |                                                 |                      |                 | Not Reported         |                |
|                                                                                                      | Calcium                       |                    |                    | C               |                                                 |                      |                 | Not Reported         |                |
|                                                                                                      | Magnesium                     |                    |                    | C               |                                                 |                      |                 | Not Reported         |                |
|                                                                                                      | Zinc                          |                    |                    | C               |                                                 |                      |                 | Not Reported         |                |
|                                                                                                      | Chlorella                     |                    |                    | C               |                                                 |                      |                 | Not Reported         |                |
|                                                                                                      | Zinc                          |                    |                    | C               |                                                 |                      |                 | Not Reported         |                |
|                                                                                                      | Zyrtec                        |                    |                    | C               |                                                 |                      |                 | Not Reported         |                |
|                                                                                                      | Tylenol                       |                    |                    | C               |                                                 |                      |                 | Not Reported         |                |
|                                                                                                      | Spirulina                     |                    |                    | C               |                                                 |                      |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                                             | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 23-Aug-2013                                                                                          | 9473613                       | EXPEDITED (15-DAY) |                    | OT              | US-TEVA-427810USA                               |                      |                 | Male                 | USA            |
| <u>Preferred Term</u>                                                                                | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Discomfort; Dizziness;<br>Drug Withdrawal                                                            | Escitalopram                  |                    |                    | S               |                                                 | 10 Milligram Daily;  |                 | Ivax                 |                |

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Syndrome; Feeling Hot;  
Malaise; Skin Burning  
Sensation

| <u>FDA Received Date</u>                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 23-Aug-2013                                           | 9474671        | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000048095    |                      | 35 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypotonic Urinary<br>Bladder; Urinary<br>Incontinence | Escitalopram   |                    |                    | S               |                      |                      |                 | Forest       |                |
|                                                       | Escitalopram   |                    |                    | S               |                      | 15 Mg                |                 | Not Reported |                |
|                                                       | Laroxyl        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                       | Risperidone    |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                       | Alprazolam     |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                       | Zopiclone      |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>          | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 26-Aug-2013                       | 9288161        | EXPEDITED (15-DAY) |                    |                 | JP-FRI-1000045083    |                      | 19 YR           | Female       | JPN            |
| <u>Preferred Term</u>             | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Electrocardiogram Qt<br>Prolonged | Lexapro        |                    |                    | S               | Oral                 |                      |                 | Forest       |                |
|                                   | Lexapro        |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                   | Horizon        |                    |                    | C               | Oral                 | 2 Mg                 |                 | Not Reported |                |

| <u>FDA Received Date</u>    | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------|-------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 26-Aug-2013                 | 9477434           | EXPEDITED (15-DAY) |                    | HO, OT          | DE-FRI-1000047498    |                      | 28 YR           | Female       | DEU            |
| <u>Preferred Term</u>       | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cystitis; Urinary Retention | Escitalopram      |                    |                    | S               | Oral                 | 20 Mg                |                 | Forest       |                |
|                             | Amitriptylinexide |                    |                    | S               |                      | 120 Mg               |                 | Not Reported |                |
|                             | L-Thyroxin        |                    |                    | C               | Oral                 | Changing Dosages     |                 | Not Reported |                |
|                             | Ramipril          |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |
|                             | Bisoprolol        |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 27-Aug-2013                                                      | 9460099        | EXPEDITED (15-DAY) |                    | OT              | US-FRI-1000047736    |                      | 76 YR           | Male         | USA            |
| <u>Preferred Term</u>                                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective;<br>Parkinson'S Disease;<br>Prescribed Overdose | Lexapro        |                    |                    | S               |                      | 20 Mg                |                 | Forest       |                |
|                                                                  | Viibryd        |                    |                    | C               | Oral                 | 10 Mg                |                 | Not Reported |                |
|                                                                  | Viibryd        |                    |                    | C               | Oral                 | 20 Mg                |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 27-Aug-2013              | 9479488          | EXPEDITED (15-DAY) |                    |                 | JP-FRI-1000048096    |                      | 29 YR           | Male         | JPN            |
| <u>Preferred Term</u>    | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Weight Increased         | Lexapro          |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                          | Dogmatyl         |                    |                    | S               | Oral                 | 200 Mg               |                 | Not Reported |                |
|                          | Dogmatyl         |                    |                    | S               | Oral                 | 100 Mg               |                 | Not Reported |                |
|                          | Meilax           |                    |                    | C               | Oral                 | 2 Mg                 |                 | Not Reported |                |
|                          | Depas (Etizolam) |                    |                    | C               | Oral                 | 0.5 Mg               |                 | Not Reported |                |
|                          | Depas            |                    |                    | C               | Oral                 | 1 Mg                 |                 | Not Reported |                |
|                          | Wypax            |                    |                    | C               | Oral                 | 1 Mg                 |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 27-Aug-2013              | 9485736        | DIRECT           |                    |                 |                      |                      | 13 YR           | Female     | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective         | Escitalopram   |                  |                    | S               | Oral                 | 1/2 Tab/Day          | 1 MTH           | Teva       |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 27-Aug-2013              | 9490541        | DIRECT           |                    |                 |                      |                      | 23 YR           | Male       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |



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

|                                                                                                                                                               |                |                            |                    |                 |                              |                                                                                                             |                 |              |                |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|----------------------------|--------------------|-----------------|------------------------------|-------------------------------------------------------------------------------------------------------------|-----------------|--------------|----------------|
| Anxiety; Cold Sweat;<br>Insomnia; Mydriasis;<br>Palpitations; Product<br>Substitution Issue;<br>Suicidal Ideation                                             |                | Escitalopram               |                    | S               | Oral                         | 30/Mo 10/Morning,<br>10/Night (Mg) Orally,<br>Swallowed 01/01/2009 -<br>N/A, Switched Back To<br>Name Brand |                 | Camber       |                |
|                                                                                                                                                               |                | Chewable Daily Gummy-Vites |                    | C               |                              |                                                                                                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                      | <u>Case #</u>  | <u>Case Type</u>           | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                                                                                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Aug-2013                                                                                                                                                   | 9395919        | EXPEDITED (15-DAY)         |                    | OT              | FR-FRI-1000046613            |                                                                                                             | 34 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                                         | <u>Product</u> | <u>Comp.</u>               | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                                                                                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Spontaneous Haematoma                                                                                                                                         | Escitalopram   |                            |                    | S               | Oral                         | 1 Df                                                                                                        |                 | Forest       |                |
|                                                                                                                                                               | Seresta        |                            |                    | C               | Oral                         | 1 Df                                                                                                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                      | <u>Case #</u>  | <u>Case Type</u>           | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                                                                                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Aug-2013                                                                                                                                                   | 9482732        | EXPEDITED (15-DAY)         |                    | CA, OT          | US-FRI-1000048065            |                                                                                                             | < 1 DAY         | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                         | <u>Product</u> | <u>Comp.</u>               | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                                                                                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Coarctation Of The Aorta;<br>Heart Disease Congenital                                                                                                         | Lexapro        |                            |                    | S               |                              |                                                                                                             |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                                                      | <u>Case #</u>  | <u>Case Type</u>           | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                                                                                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Aug-2013                                                                                                                                                   | 9485142        | EXPEDITED (15-DAY)         |                    | HO, OT          | FR-PFIZER INC-<br>2013246311 |                                                                                                             | 72 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                                         | <u>Product</u> | <u>Comp.</u>               | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                                                                                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Generalised Tonic-Clonic<br>Seizure; Hypokalaemia;<br>Hyponatraemia;<br>Phlebotomy; Polydipsia;<br>Suicide Attempt; Tendon<br>Rupture; Withdrawal<br>Syndrome | Effexor        |                            |                    | S               | Oral                         | Unk                                                                                                         |                 | Pfizer       |                |
|                                                                                                                                                               | Seroplex       |                            |                    | S               | Oral                         | 10 Mg, Daily                                                                                                |                 | Not Reported |                |
|                                                                                                                                                               | Coversyl       |                            |                    | C               | Oral                         | 2.5 Mg, Daily                                                                                               |                 | Not Reported |                |
|                                                                                                                                                               | Stilnox        |                            |                    | C               | Oral                         | 10 Mg, Daily                                                                                                |                 | Not Reported |                |
|                                                                                                                                                               | Theralene      |                            |                    | C               | Oral                         | 5 Mg, Daily                                                                                                 |                 | Not Reported |                |
|                                                                                                                                                               | Lysanxia       |                            |                    | C               | Oral                         | 10 Mg, Daily                                                                                                |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Aug-2013              | 9458833       | EXPEDITED (15-DAY) |                    | DE, HO          | CH-FRI-1000047683    |                      | 44 YR      | Male       | CHE            |

| <u>Preferred Term</u> | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                          | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-------------------------------|--------------|------------|-------------|---------------------------------------|-----------------------------|-----------------|--------------|
| Pyrexia; Sudden Death | Escitalopram                  |              |            | S           | Oral                                  | 10 Mg                       |                 | Forest       |
|                       | Dabrafenib                    |              |            | S           | Oral                                  | 300 Mg                      |                 | Not Reported |
|                       | Trametinib                    |              |            | S           | Oral                                  | 2 Mg                        |                 | Not Reported |
|                       | Novalgine (Metamizole Sodium) |              |            | S           | Oral                                  | 2000 Mg                     |                 | Not Reported |
|                       | Keppra                        |              |            | S           | Oral                                  | 1000 Mg                     |                 | Not Reported |
|                       | Fortecortin                   |              |            | S           | Oral                                  | Lower Dose Than 12 Mg Daily |                 | Not Reported |
|                       | Fortecortin                   |              |            | S           | Oral                                  | 12 Mg                       |                 | Not Reported |
|                       | Orfiril                       |              |            | S           | Oral                                  | 1200 Mg                     |                 | Not Reported |
|                       | Zelboraf                      |              |            | C           | Intravenous (not otherwise specified) |                             |                 | Not Reported |
|                       | Ipilimumab                    |              |            | C           |                                       |                             |                 | Not Reported |
|                       | Cisplatin                     |              |            | C           |                                       |                             |                 | Not Reported |
|                       | Temodal                       |              |            | C           |                                       | 300 Mg                      |                 | Not Reported |
|                       | Temodal                       |              |            | C           |                                       | 300 Mg                      |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Aug-2013              | 9485662       | EXPEDITED (15-DAY) |                    | OT              | CH-ROCHE-1265410     |                      | 51 YR      | Male       | CHE            |

| <u>Preferred Term</u>                              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------|----------------|--------------|------------|-------------|--------------|------------------------------------|-----------------|--------------|
| Depressed Level Of Consciousness; Drug Interaction | Valium         |              |            | S           | Oral         |                                    |                 | Not Reported |
|                                                    | Valium         |              |            | S           | Oral         | Dose Reduced                       |                 | Not Reported |
|                                                    | Cipralex       |              |            | S           | Unknown      | Form: Tablets, Tongue Soluble      |                 | Not Reported |
|                                                    | Lithiofor      |              |            | S           | Oral         | Freq: Every 2 Days, Dose Increased |                 | Not Reported |
|                                                    | Dipiperon      |              |            | S           | Oral         | Freq: Every 3 Days                 |                 | Not Reported |

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

|                        |   |              |              |
|------------------------|---|--------------|--------------|
| Clopin Eco             | S | Oral         | Not Reported |
| Psychopax              | S | Oral         | Not Reported |
| Pantozol (Switzerland) | C | Oral         | Not Reported |
| Atropine Sulfate       | C | Oral         | Not Reported |
| Orfiril Long           | C | Oral         | Not Reported |
| Fragmin                | C | Subcutaneous | Not Reported |

Drug Name: 'Bellafit N'

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Aug-2013              | 9486638       | EXPEDITED (15-DAY) | HO                 |                 | FR-FRI-1000048147    |                      | 59 YR      | Male       | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hepatocellular Injury | Escitalopram   |              |            | S           |              | 2 Df               |                 | Forest       |
|                       | Combivir       |              |            | C           | Oral         | 150 Mg / 300 Mg    |                 | Not Reported |
|                       | Norvir         |              |            | C           | Oral         | 2 Df               |                 | Not Reported |
|                       | Prezista       |              |            | C           | Oral         | 1200 Mg            |                 | Not Reported |
|                       | Gutron         |              |            | C           |              | 3 Df               |                 | Not Reported |
|                       | Bactrim Forte  |              |            | C           | Oral         | 1 Df               |                 | Not Reported |
|                       | Depakote       |              |            | C           | Oral         | 2 Df               |                 | Not Reported |
|                       | Seresta        |              |            | C           | Oral         | 3 Df               |                 | Not Reported |
|                       | Mirtazapine    |              |            | C           | Oral         | 15 Mg              |                 | Not Reported |
|                       | Zopiclone      |              |            | C           | Oral         |                    |                 | Not Reported |
|                       | Theralene      |              |            | C           | Oral         | 20 Gtt             |                 | Not Reported |
|                       | Gaviscon       |              |            | C           | Oral         | 3 Df               |                 | Not Reported |
|                       | Smecta         |              |            | C           | Oral         | 1 Df               |                 | Not Reported |
|                       | Clinutren      |              |            | C           |              |                    |                 | Not Reported |
|                       | Mouthwash      |              |            | C           |              | 3 Df               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Aug-2013              | 9249057       | EXPEDITED (15-DAY) | HO, LT             |                 | CA-FRI-1000044583    |                      | 36 YR      | Female     | CAN            |

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

| <u>Preferred Term</u>                                                                       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Angioedema; Carpal Tunnel Syndrome; Generalised Oedema; Pain; Urticaria Chronic             | Escitalopram         |                    |                    | S               | Oral                 | 20 Mg                |                 | Forest       |                |
|                                                                                             | Ativan               |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Aug-2013                                                                                 | 9249377              | EXPEDITED (15-DAY) |                    | OT              | CA-FRI-1000044575    |                      | 38 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                                                       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Depression; Drug Ineffective; Drug Withdrawal Syndrome; Mood Altered; Paraesthesia | Escitalopram         |                    |                    | S               |                      |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Aug-2013                                                                                 | 9249559              | EXPEDITED (15-DAY) |                    | OT              | CA-FRI-1000044579    |                      | 67 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                                                       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Chest Discomfort; Heart Rate Irregular; Palpitations                                        | Escitalopram         |                    |                    | S               | Oral                 | 20 Mg                |                 | Forest       |                |
|                                                                                             | Crestor              |                    |                    | C               | Oral                 | 40 Mg                |                 | Not Reported |                |
|                                                                                             | Acetylsalicylic Acid |                    |                    | C               | Oral                 | 81 Mg                |                 | Not Reported |                |
|                                                                                             | Coversyl             |                    |                    | C               | Oral                 | 4 Mg                 |                 | Not Reported |                |
|                                                                                             | Doxepin              |                    |                    | C               | Oral                 | 25 Mg                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Aug-2013                                                                                 | 9249797              | EXPEDITED (15-DAY) |                    | DS, OT          | CA-FRI-1000044570    |                      | 68 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                                                       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Prescribed Overdose; Urinary Incontinence                                                   | Escitalopram         |                    |                    | S               | Oral                 | 30 Mg                |                 | Forest       |                |
|                                                                                             | Celebrex             |                    |                    | C               | Oral                 | 200 Mg               |                 | Not Reported |                |

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

|            |   |      |        |              |
|------------|---|------|--------|--------------|
| Losec      | C | Oral | 40 Mg  | Not Reported |
| Tryptophan | C | Oral | 6 Gram | Not Reported |
| Tryptophan | C | Oral | 3 Gram | Not Reported |

| <u>FDA Received Date</u>               | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------|---------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 30-Aug-2013                            | 9249810                   | EXPEDITED (15-DAY) |                    | HO              | CA-FRI-1000044576    |                      | 36 YR           | Female       | CAN            |
| <u>Preferred Term</u>                  | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Crying; Intentional Overdose; Vomiting | Escitalopram              |                    |                    | S               | Oral                 |                      |                 | Forest       |                |
|                                        | Arthrotec                 |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                        | Ethanol                   |                    |                    | S               | Oral                 | 13 Alcoholic Drinks  |                 | Not Reported |                |
|                                        | Raspberry Ketone Plus     |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                        | Gravol Naturals Certified |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                        | Organic Ginger Tablet     |                    |                    |                 |                      |                      |                 |              |                |
|                                        | Oxycontin                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                        | Seroquel                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                        | Tylenol No.1 Caplets      |                    |                    | C               |                      | 300 Mg/8 Mg/15 Mg    |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 30-Aug-2013                                                                                                                            | 9251661        | EXPEDITED (15-DAY) |                    | LT, OT          | CA-FRI-1000044580    |                      | 21 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                                                                                                  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Decreased Appetite; Disturbance In Attention; Emotional Disorder; Fatigue; Feeling Of Despair; Irritability; Nausea; Suicidal Ideation | Escitalopram   |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                                                                                                                        | Escitalopram   |                    |                    | S               |                      |                      |                 | Forest       |                |
|                                                                                                                                        | Zdxf           |                    |                    | S               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 30-Aug-2013              | 9252065        | EXPEDITED (15-DAY) |                    | HO              | CA-FRI-1000044589    |                      | 67 YR           | Female     | CAN            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

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

|                                                                                                |                           |        |      |       |                        |
|------------------------------------------------------------------------------------------------|---------------------------|--------|------|-------|------------------------|
| Anxiety; Asthenia; Chest Discomfort; Chills; Dyspnoea; Headache; Malaise; Palpitations; Tremor | Escitalopram<br>Zopiclone | S<br>C | Oral | 10 Mg | Forest<br>Not Reported |
|------------------------------------------------------------------------------------------------|---------------------------|--------|------|-------|------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Aug-2013              | 9252089       | EXPEDITED (15-DAY) |                    | OT              | CA-FRI-1000044640    |                      | 76 YR      | Male       | CAN            |

| <u>Preferred Term</u>                                                                                                                                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Dyskinesia; Dyspnoea; Glassy Eyes; Hallucination; Heart Rate Decreased; Incoherent; Loss Of Consciousness; Restlessness; Somnolence; Tachyphrenia; Tremor | Escitalopram   |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                                                                                                                                           | Ativan         |              |            | C           | Oral         | 2-3 Times A Day    |                 | Not Reported |
|                                                                                                                                                           | Calcium        |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                           | Hyzaar         |              |            | C           | Oral         | 25 Mg              |                 | Not Reported |
|                                                                                                                                                           | Multivitamines |              |            | C           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Aug-2013              | 9440489       | EXPEDITED (15-DAY) |                    | HO, LT, OT      | PT-FRI-1000047440    |                      | 70 YR      | Male       | PRT            |

| <u>Preferred Term</u>                                                                          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Ecchymosis; Gingival Bleeding; Haematuria; Melaena; Platelet Count Decreased; Thrombocytopenia | Escitalopram   |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                                                                                | Selincro       |              |            | S           | Oral         | 18 Mg              |                 | Not Reported |
|                                                                                                | Topiramate     |              |            | S           | Oral         | 100 Mg             |                 | Not Reported |
|                                                                                                | Campral        |              |            | C           | Oral         | 1998 Mg            |                 | Not Reported |
|                                                                                                | Lyrica         |              |            | C           | Oral         | 100 Mg             |                 | Not Reported |
|                                                                                                | Simvastatin    |              |            | C           | Oral         | 20 Mg              |                 | Not Reported |
|                                                                                                | Naltrexone     |              |            | C           | Oral         | 50 Mg              |                 | Not Reported |
|                                                                                                | Naltrexone     |              |            | C           |              | 50 Mg              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------|----------------------|------------|------------|----------------|
| 30-Aug-2013              | 9490789       | EXPEDITED (15-DAY) |                    | HO, OT          | FR-MERCK-1308FRA009978 |                      | 51 YR      | Male       | FRA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                      | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Loss Of Consciousness;<br>Malaise; Vertigo | Aerius (Desloratadine) |              |            | S           | Oral         | 1 Df, Qd           |                 | Merck        |
|                                            | Klival                 |              |            | S           | Oral         |                    |                 | Not Reported |
|                                            | Pariet                 |              |            | S           | Oral         | 20 Mg, Qd          |                 | Not Reported |
|                                            | Seroplex               |              |            | S           | Oral         | 10 Mg, Qd          |                 | Not Reported |
|                                            | Alteis                 |              |            | S           | Oral         | 20 Mg, Qd          |                 | Not Reported |
|                                            | Cacit Vitamine D3      |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Aug-2013              | 9491606       | EXPEDITED (15-DAY) |                    | HO              | FR-NOVOPROD-386139   |                      | 59 YR      | Male       | FRA            |

| <u>Preferred Term</u>                       | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------|--------------------------|--------------|------------|-------------|--------------|-------------------------|-----------------|--------------|
| Headache; Loss Of<br>Consciousness; Malaise | Victoza                  |              |            | S           | Subcutaneous | 0.6 Mg, Qd              |                 | Novo Nordisk |
|                                             | Seroplex                 |              |            | S           | Unknown      | 5 Mg, Qd                |                 | Not Reported |
|                                             | Novorapid                |              |            | C           | Unknown      | Unk                     |                 | Novo Nordisk |
|                                             | Kardegic                 |              |            | C           |              |                         |                 | Not Reported |
|                                             | Inexium /01479302/       |              |            | C           |              |                         |                 | Not Reported |
|                                             | Glucophage               |              |            | C           |              | 3000 Mg, Qd             |                 | Not Reported |
|                                             | Tahor                    |              |            | C           |              | 40 Mg, Qd               |                 | Not Reported |
|                                             | Triatec /00116401/       |              |            | C           |              | 10 Mg, Qd               |                 | Not Reported |
|                                             | Cardensiel               |              |            | C           |              | 5 Mg, Qd                |                 | Not Reported |
|                                             | Zyloric                  |              |            | C           |              | 300 Mg, Qd              |                 | Not Reported |
|                                             | Amlor                    |              |            | C           |              | 10 Mg, Qd               |                 | Not Reported |
|                                             | Colchimax /00728901/     |              |            | C           |              |                         |                 | Not Reported |
|                                             | Tardyferon B9 /00023601/ |              |            | C           |              |                         |                 | Not Reported |
|                                             | Laroxyl                  |              |            | C           |              | 19 Drops In The Evening |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Aug-2013              | 9492026       | EXPEDITED (15-DAY) |                    | OT              | CH-FRI-1000048332    |                      |            | Male       | CHE            |

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

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                  |                        |   |              |          |  |              |
|----------------------------------|------------------------|---|--------------|----------|--|--------------|
| Depressed Level Of Consciousness | Escitalopram           | S | Oral         |          |  | Forest       |
|                                  | Escitalopram           | S | Oral         |          |  | Not Reported |
|                                  | Valium                 | S | Oral         |          |  | Not Reported |
|                                  | Valium                 | S | Oral         | 5 Mg     |  | Not Reported |
|                                  | Lithiofor              | S | Oral         |          |  | Not Reported |
|                                  | Lithiofor              | S | Oral         | 1320 Mg  |  | Not Reported |
|                                  | Dipiperon              | S | Oral         |          |  | Not Reported |
|                                  | Clopin Eco             | S | Oral         | 300 Mg   |  | Not Reported |
|                                  | Psychopax              | S | Oral         |          |  | Not Reported |
|                                  | Pantozol (Switzerland) | C | Oral         | 20 Mg    |  | Not Reported |
|                                  | Bellafit N             | C | Oral         | 15 Drops |  | Not Reported |
|                                  | Orfiril                | C | Oral         | 2000 Mg  |  | Not Reported |
|                                  | Fragmin                | C | Subcutaneous | 5000 Iu  |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|------------|------------|----------------|
| 30-Aug-2013              | 9492172       | EXPEDITED (15-DAY) |                    | HO              | FR-EISAI INC-E3810-06626-SPO-FR |                      | 51 YR      | Male       | FRA            |

| <u>Preferred Term</u>                   | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Loss Of Consciousness; Malaise; Vertigo | Pariet (Rabeprazole)   |              |            | S           | Oral         |                    |                 | Not Reported |
|                                         | Klipal                 |              |            | S           | Oral         | Unknown            |                 | Not Reported |
|                                         | Seroplex               |              |            | S           | Oral         |                    |                 | Not Reported |
|                                         | Alteis                 |              |            | S           | Oral         |                    |                 | Not Reported |
|                                         | Aerius (Desloratadine) |              |            | S           | Oral         | Unknown            |                 | Not Reported |
|                                         | Cacit Vitamine D3      |              |            | S           | Oral         | Unknown            |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------------------|----------------------|------------|------------|----------------|
| 30-Aug-2013              | 9492202       | EXPEDITED (15-DAY) |                    | OT              | CA-ELI_LILLY_AND_COMP<br>ANY-CA201305002094 |                      | 48 YR      | Male       | CAN            |

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



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

|                         |           |   |      |                      |                  |
|-------------------------|-----------|---|------|----------------------|------------------|
| Abnormal Dreams;        | Cymbalta  | S | Oral | 60 Mg, Qd            | Eli Lilly And Co |
| Anxiety; Condition      | Cymbalta  | S |      |                      | Eli Lilly And Co |
| Aggravated; Depressed   | Ciprallex | S |      | 10 Mg, Qd            | Not Reported     |
| Mood; Hallucination;    | Ciprallex | S |      |                      | Not Reported     |
| Hypervigilance; Injury; | Asa       | C |      | 325 Mg, Qd           | Not Reported     |
| Tremor; Vomiting        | Atenolol  | C | Oral | 25 Mg, Qd            | Not Reported     |
|                         | Multaq    | C | Oral |                      | Not Reported     |
|                         | Percocet  | C | Oral | 1 Df, Tid            | Not Reported     |
|                         | Synthroid | C |      | 0.1 Mg, Qd           | Not Reported     |
|                         | Zopiclone | C |      | 7.5 Mg, Each Evening | Not Reported     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Sep-2013              | 8613008       | EXPEDITED (15-DAY) |                    | HO, LT          | JP-FRI-1000031155    |                      | 20 YR      | Female     | JPN            |

| <u>Preferred Term</u>                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Overdose; Toxicity To Various Agents | Escitalopram   |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                      | Rohypnol       |              |            | S           | Oral         | 2 Mg               |                 | Not Reported |
|                                      | Myslee         |              |            | S           | Oral         | 10 Mg              |                 | Not Reported |
|                                      | Rize           |              |            | S           | Oral         | 15 Mg              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Sep-2013              | 9251573       | EXPEDITED (15-DAY) |                    | HO, OT          | CA-FRI-1000044584    |                      | 60 YR      | Male       | CAN            |

| <u>Preferred Term</u>                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Aggression; Blood Pressure Decreased;       | Escitalopram   |              |            | S           | Oral         | 20 Mg              |                 | Forest       |
| Diarrhoea; Drug Interaction; Hyperhidrosis; | Escitalopram   |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
| Influenza Like Illness;                     | Escitalopram   |              |            | S           | Oral         | 5 Mg               |                 | Not Reported |
| Pain; Serotonin Syndrome; Wound Infection   | Fluconazole    |              |            | S           | Oral         | 400 Mg             |                 | Not Reported |
|                                             | Mirtazapine    |              |            | S           | Oral         | 15 Mg              |                 | Not Reported |
|                                             | Zyvoxam        |              |            | S           | Oral         | 1200 Mg            |                 | Not Reported |

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

|                      |   |              |                                       |              |
|----------------------|---|--------------|---------------------------------------|--------------|
| Hydromorphone        | S | Subcutaneous | 1-2 Mg Every 4 Hours                  | Not Reported |
| Hydromorphone        | S | Oral         | 2-4mg Every 4 Hours                   | Not Reported |
| Acetaminophen        | C | Oral         |                                       | Not Reported |
| Atorvastatin Calcium | C | Oral         | 10 Mg                                 | Not Reported |
| Clonazepam           | C |              | 1 Mg                                  | Not Reported |
| Diazepam             | C | Oral         |                                       | Not Reported |
| Dimenhydrinate       | C | Oral         | 25-50 Mg Every 4-6 Hours              | Not Reported |
| Dimenhydrinate       | C | Other        | 25-50 Mg Every 4-6 Hours<br>As Needed | Not Reported |
| Ondansetron          | C | Other        | 4 Mg Every 8 Hours As                 | Not Reported |
| Pantoprazole         | C | Oral         | 40 Mg                                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Sep-2013              | 9440492       | EXPEDITED (15-DAY) |                    | HO, OT          | JP-FRI-1000047438    |                      | 92 YR      | Female     | JPN            |

| <u>Preferred Term</u>                                                                                                                     | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Decreased Appetite; Drug Interaction;<br>Electrocardiogram Qt Prolonged; Malaise;<br>Ventricular Fibrillation;<br>Ventricular Tachycardia | Lexapro                  |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                                                                                                                           | Lexapro                  |              |            | S           | Oral         | 5 Mg               |                 | Forest       |
|                                                                                                                                           | Lansoprazole-Od          |              |            | S           | Oral         | 15 Mg              |                 | Not Reported |
|                                                                                                                                           | Sulpiride                |              |            | S           | Oral         | 50 Mg              |                 | Not Reported |
|                                                                                                                                           | Cravit                   |              |            | S           | Oral         | 1 Df               |                 | Not Reported |
|                                                                                                                                           | Polyful                  |              |            | C           | Oral         | 1 Gram             |                 | Not Reported |
|                                                                                                                                           | Pollakisu                |              |            | C           | Oral         | 4 Mg               |                 | Not Reported |
|                                                                                                                                           | Dopacol                  |              |            | C           | Oral         | 100 Mg             |                 | Not Reported |
|                                                                                                                                           | Arotinolol Hydrochloride |              |            | C           | Oral         | 5 Mg               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|------------|------------|----------------|
| 03-Sep-2013              | 9451560       | EXPEDITED (15-DAY) |                    | HO, OT          | US-SANOFI-AVENTIS-2013SA079081 |                      | 77 YR      | Female     | USA            |

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

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

|                           |          |   |         |              |
|---------------------------|----------|---|---------|--------------|
| Cerebrovascular Accident; | Plavix   | S | Oral    | Not Reported |
| Contusion; Fall; Loss Of  | Plavix   | S | Oral    | Not Reported |
| Consciousness; Lung       | Lexapro  | S | Unknown | Not Reported |
| Disorder; Polyp           | Xanax    | S | Unknown | Not Reported |
|                           | Prilosec | C |         | Not Reported |
|                           | Oxygen   | C | Unknown | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Sep-2013              | 9495138       | EXPEDITED (15-DAY) |                    | DS              | FR-FRI-1000048334    |                      | 74 YR      | Female     | FRA            |

| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Camptocormia; Overdose | Escitalopram   |              |            | S           | Oral         | 30 Mg              |                 | Forest       |
|                        | Zyprexa        |              |            | S           | Oral         | 10 Mg              |                 | Not Reported |
|                        | Zyprexa        |              |            | S           | Oral         | 5 Mg               |                 | Not Reported |
|                        | Eupantol       |              |            | C           |              | 20 Mg              |                 | Not Reported |
|                        | Art            |              |            | C           |              | 50 Mg              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Sep-2013              | 9495769       | EXPEDITED (15-DAY) |                    | OT              | IT-TEVA-421313ISR    |                      | 64 YR      | Female     | ITA            |

| <u>Preferred Term</u>                                                                  | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------|-------------------|--------------|------------|-------------|--------------|-----------------------|-----------------|--------------|
| Drug Interaction;<br>Hallucination; Sleep-<br>Related Eating Disorder;<br>Somnambulism | Quetiapine        |              |            | S           | Oral         |                       |                 | Teva         |
|                                                                                        | Lamotrigine       |              |            | S           | Oral         |                       |                 | Teva         |
|                                                                                        | Stilnox           |              |            | S           | Oral         | 1 Dosage Forms Daily; |                 | Not Reported |
|                                                                                        | Cipralext 20mg/MI |              |            | S           | Oral         |                       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 04-Sep-2013              | 9236248       | EXPEDITED (15-DAY) |                    | DS, OT          | FR-<br>ELI_LILLY_AND_COMP<br>ANY-FR201304001718 |                      | 74 YR      | Female     | FRA            |

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

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

|              |          |   |      |           |                  |
|--------------|----------|---|------|-----------|------------------|
| Camptocormia | Zyprexa  | S | Oral | 10 Mg, Qd | Eli Lilly And Co |
|              | Zyprexa  | S |      | 5 Mg, Qd  | Eli Lilly And Co |
|              | Seroplex | S | Oral | 30 Mg, Qd | Not Reported     |
|              | Eupantol | C |      | 20 Mg, Qd | Not Reported     |
|              | Art      | C |      | 50 Mg, Qd | Not Reported     |

| <u>FDA Received Date</u>                             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 04-Sep-2013                                          | 9466953        | EXPEDITED (15-DAY) | CA                 |                 | NL-FRI-1000047987    |                      |                 | Unknown    | NLD            |
| <u>Preferred Term</u>                                | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Brain Malformation; Foetal Exposure During Pregnancy | Lexapro        |                    |                    | S               | Transplacental       | 10 Mg                |                 | Forest     |                |

| <u>FDA Received Date</u>                 | <u>Case #</u>                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------|--------------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 04-Sep-2013                              | 9496581                                    | EXPEDITED (15-DAY) | HO                 |                 | FR-FRI-1000048333    |                      | 59 YR           | Male         | FRA            |
| <u>Preferred Term</u>                    | <u>Product</u>                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Headache; Loss Of Consciousness; Malaise | Escitalopram                               |                    |                    | S               | Oral                 | 5 Mg                 |                 | Forest       |                |
|                                          | Victoza                                    |                    |                    | S               | Other                | 0.6 Mg               |                 | Not Reported |                |
|                                          | Kardegic                                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                          | Inexium                                    |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                          | Glucophage                                 |                    |                    | C               |                      | 3 Df                 |                 | Not Reported |                |
|                                          | Tahor                                      |                    |                    | C               |                      | 1 Df                 |                 | Not Reported |                |
|                                          | Triatec (Ramipril)                         |                    |                    | C               |                      | 1 Df                 |                 | Not Reported |                |
|                                          | Cardensiel                                 |                    |                    | C               |                      | 1 Df                 |                 | Not Reported |                |
|                                          | Zyloric                                    |                    |                    | C               |                      | 1 Df                 |                 | Not Reported |                |
|                                          | Amlor                                      |                    |                    | C               |                      | 1 Df                 |                 | Not Reported |                |
|                                          | Colchimax (France)                         |                    |                    | C               |                      | 1 Df                 |                 | Not Reported |                |
|                                          | Tardyferon B9 [Ferrous Sulfate;Folic Acid] |                    |                    | C               |                      | 1 Df                 |                 | Not Reported |                |
|                                          | Novorapid                                  |                    |                    | C               |                      |                      |                 | Not Reported |                |

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

|            |   |        |              |
|------------|---|--------|--------------|
| Laroxyl    | C | 19 Gtt | Not Reported |
| Gliclazide | C | 2 Df   | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 04-Sep-2013              | 9498492       | EXPEDITED (15-DAY) | OT                 |                 | BR-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>19214568 |                      | 41 YR      | Female     | BRA            |

| <u>Preferred Term</u>                                                   | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |
|-------------------------------------------------------------------------|-----------------------|--------------|------------|-------------|--------------|----------------------|-----------------|----------------------|
| Alanine Aminotransferase Increased; Drug Interaction; Virologic Failure | Baraclude Tabs 0.5 Mg |              |            | S           | Oral         | Conmeds-Herbal Drugs |                 | Bristol Myers Squibb |
|                                                                         | Acetaminophen         |              |            | S           |              |                      |                 | Cadence              |
|                                                                         | Ketorolac Trometamol  |              |            | S           |              |                      |                 | Not Reported         |
|                                                                         | Pristiq               |              |            | S           |              |                      |                 | Not Reported         |
|                                                                         | Tramadol Hcl          |              |            | S           |              |                      |                 | Not Reported         |
|                                                                         | Cyclobenzaprine       |              |            | S           |              |                      |                 | Sandoz               |
|                                                                         | Prednisone            |              |            | S           |              |                      |                 | Not Reported         |
|                                                                         | Depakote              |              |            | S           |              |                      |                 | Not Reported         |
|                                                                         | Fluoxetine            |              |            | S           |              |                      |                 | Not Reported         |
|                                                                         | Escitalopram Oxalate  |              |            | S           |              |                      |                 | Not Reported         |
|                                                                         | Gabapentin            |              |            | S           |              |                      |                 | Not Reported         |
|                                                                         | Vitamin D Nos         |              |            | C           |              |                      |                 | Not Reported         |
|                                                                         | Pantoprazole          |              |            | C           |              |                      |                 | Not Reported         |
|                                                                         | Bisoprolol            |              |            | C           |              |                      |                 | Not Reported         |
|                                                                         | Lactulona             |              |            | C           |              |                      |                 | Not Reported         |
|                                                                         | Calcium Polycarbophil |              |            | C           |              |                      |                 | Not Reported         |
| Macrogol 3350                                                           |                       |              | C          |             |              |                      | Not Reported    |                      |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Sep-2013              | 9499855       | DIRECT           | Y                  | OT              |                      |                      | 53 YR      | Female     | USA            |

| <u>Preferred Term</u>                                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Hot Flush; Mobility Decreased; Nausea; Unevaluable Event; Vertigo | Escitalopram   |              |            | S           | Oral         |                    |                 | Teva       |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 04-Sep-2013                       | 9500469                | DIRECT                    |                             | DS                       |                               |                               | 74 YR               | Female              | USA                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Gastrointestinal Disorder      | Escitalopram            |                       |                     | S                    | Oral                  |                             |                          | Aurobindo           |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 04-Sep-2013                       | 9506501                | EXPEDITED (15-DAY)        | Y                           | HO                       | DEM-2013-00786                |                               | 51 YR               | Male                | FRA                     |

| <a href="#">Preferred Term</a>                                                                                       | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a>      | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|----------------------------------------------------------------------------------------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|----------------------------------|--------------------------|---------------------|
| Asthenia; Dizziness;<br>Glomerular Filtration Rate<br>Decreased; Incorrect Dose<br>Administered; Malaise;<br>Syncope | Alteis                  |                       |                     | S                    | Oral                  |                                  |                          | Not Reported        |
|                                                                                                                      | Klipal Codeine          |                       |                     | S                    | Oral                  |                                  |                          | Not Reported        |
|                                                                                                                      | Pariet                  |                       |                     | S                    | Oral                  | (20 Mg, 1 In 1 D), Oral          |                          | Not Reported        |
|                                                                                                                      | Seroplex                |                       |                     | S                    | Oral                  | (10 Mg, 1 In 1 D), Oral          |                          | Not Reported        |
|                                                                                                                      | Aerius (Desloratadine)  |                       |                     | S                    | Oral                  | (1 Dosage Forms, 1 In 1 D), Oral |                          | Not Reported        |
|                                                                                                                      | Cacit D3                |                       |                     | S                    | Oral                  |                                  |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 05-Sep-2013                       | 9469377                | EXPEDITED (15-DAY)        |                             | HO                       | SE-FRI-1000047980             |                               | 27 YR               | Female              | SWE                     |

| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|-----------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Loss Of Consciousness;<br>Seizure | Escitalopram            |                       |                     | S                    |                       |                             |                          | Forest              |
|                                   | Seroquel                |                       |                     | C                    |                       |                             |                          | Not Reported        |
|                                   | Temesta (Lorazepam)     |                       |                     | C                    |                       |                             |                          | Not Reported        |
|                                   | Ergenyl                 |                       |                     | C                    |                       |                             |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 05-Sep-2013                       | 9503857                | DIRECT                    |                             | OT                       |                               |                               | 25 YR               | Female              | USA                     |

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

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

|                                             |                    |   |      |                                        |              |
|---------------------------------------------|--------------------|---|------|----------------------------------------|--------------|
| Dermatitis; Feeling Abnormal; Rash Pruritic | Escitalopram 10 Mg | S | Oral | Lexapro 10mg Once Daily Taken By Mouth | Not Reported |
|---------------------------------------------|--------------------|---|------|----------------------------------------|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Sep-2013              | 9240536       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000044441    |                      | 46 YR      | Male       | FRA            |

| <u>Preferred Term</u>                             | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Gastrointestinal Haemorrhage; Haematuria; Melaena | Escitalopram           |              |            | S           | Oral         | 1 Df               |                 | Forest       |
|                                                   | Previscan (Fluindione) |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                   | Imovane                |              |            | C           |              |                    |                 | Not Reported |
|                                                   | Alprazolam             |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Sep-2013              | 9371821       | EXPEDITED (15-DAY) |                    | OT              | DE-FRI-1000046213    |                      | 31 YR      | Female     | DEU            |

| <u>Preferred Term</u>                                               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Inappropriate Antidiuretic Hormone Secretion; Nocturia; Pollakiuria | Escitalopram   |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                                                     | Escitalopram   |              |            | S           | Oral         | 15 Mg              |                 | Forest       |
|                                                                     | Paroxetin      |              |            | S           | Oral         | 20 Mg              |                 | Not Reported |
|                                                                     | Paroxetin      |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Sep-2013              | 9465921       | EXPEDITED (15-DAY) |                    |                 | BR-FRI-1000047934    |                      |            | Female     | BRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Ineffective      | Lexapro        |              |            | S           | Oral         |                    |                 | Forest       |
|                       | Lexapro        |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                       | Lexapro        |              |            | S           | Oral         | 5 Mg               |                 | Not Reported |
|                       | Pristiq        |              |            | S           | Oral         | 25 Mg              |                 | Not Reported |
|                       | Synthroid      |              |            | C           | Oral         | 100 Mcg            |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                             | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------|----------------------------|--------------------|--------------------|-----------------|-------------------------|----------------------|-----------------|--------------|----------------|
| 06-Sep-2013                                          | 9496658                    | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000048356       |                      | 51 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Loss Of Consciousness;<br>Malaise; Vertigo           | Escitalopram               |                    |                    | S               | Oral                    | 1 Df                 |                 | Forest       |                |
|                                                      | Klupal Codein              |                    |                    | S               | Oral                    |                      |                 | Not Reported |                |
|                                                      | Pariet                     |                    |                    | S               | Oral                    | 1 Df                 |                 | Not Reported |                |
|                                                      | Alteis                     |                    |                    | S               | Oral                    | 1 Df                 |                 | Not Reported |                |
|                                                      | Aerius (Desloratadine)     |                    |                    | S               | Oral                    | 1 Df                 |                 | Not Reported |                |
|                                                      | Cacit Vitamine D3          |                    |                    | S               | Oral                    |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                             | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Sep-2013                                          | 9502421                    | EXPEDITED (15-DAY) |                    | DE, HO          | US-RANBAXY-2010US-38969 |                      | 58 YR           | Female       | USA            |
| <u>Preferred Term</u>                                | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest;<br>Electrocardiogram Qt<br>Prolonged | Escitalopram               |                    |                    | S               | Unknown                 | Unk                  |                 | Not Reported |                |
|                                                      | Fluoxetine                 |                    |                    | S               | Unknown                 | Unk                  |                 | Ranbaxy      |                |
|                                                      | Trazodone                  |                    |                    | S               | Unknown                 | Unk                  |                 | Not Reported |                |
|                                                      | Buspirone                  |                    |                    | S               | Unknown                 | Unk                  |                 | Not Reported |                |
|                                                      | Temazepam                  |                    |                    | S               | Unknown                 | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                             | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Sep-2013                                          | 9502987                    | EXPEDITED (15-DAY) |                    | OT              | IT-FRI-1000048462       |                      | 41 YR           | Male         | ITA            |
| <u>Preferred Term</u>                                | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Amnesia; Parosmia                                    | Escitalopram Oral Solution |                    |                    | S               | Oral                    | 1 Df                 |                 | Forest       |                |
| <u>FDA Received Date</u>                             | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Sep-2013                                          | 9503590                    | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000048376       |                      | < 1 DAY         | Male         | USA            |



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| <u>Preferred Term</u>                                                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|-----------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|------------------------------------------|----------------------|-----------------|--------------|----------------|
| Arnold-Chiari Malformation; Congenital Anomaly; Encephalocele; Klippel-Feil Syndrome; Renal Aplasia | Lexapro        |                    |                    | S               | Transplacental                           |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Sep-2013                                                                                         | 9504443        | EXPEDITED (15-DAY) |                    | OT              | CH-PFIZER INC-2013029204                 |                      |                 | Male         | CHE            |
| <u>Preferred Term</u>                                                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Withdrawal Syndrome Neonatal; Maternal Exposure Timing Unspecified; Premature Baby             | Xanax          |                    |                    | S               | Transplacental                           | Unk                  |                 | Pfizer       |                |
|                                                                                                     | Methadone      |                    |                    | S               | Transplacental                           | 26 Mg, 1x/Day        |                 | Not Reported |                |
|                                                                                                     | Ciprallex      |                    |                    | S               | Transplacental                           | 10 Mg, 1x/Day        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Sep-2013                                                                                         | 9504446        | EXPEDITED (15-DAY) |                    | HO, OT          | CH-PFIZER INC-2013257763                 |                      | 24 YR           | Female       | CHE            |
| <u>Preferred Term</u>                                                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Uterine Haemorrhage                                                                                 | Xanax          |                    |                    | S               |                                          | Unk                  |                 | Pfizer       |                |
|                                                                                                     | Methadone      |                    |                    | S               |                                          | 26 Mg, 1x/Day        |                 | Not Reported |                |
|                                                                                                     | Ciprallex      |                    |                    | S               |                                          | 10 Mg, 1x/Day        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Sep-2013                                                                                         | 9509051        | NON-EXPEDITED      |                    |                 | US-BRISTOL-MYERS SQUIBB COMPANY-17375569 |                      | 30 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Feeling Abnormal                                                                                    | Abilify        |                    |                    | S               | Oral                                     |                      |                 | Not Reported |                |
|                                                                                                     | Lexapro        |                    |                    | S               |                                          |                      |                 | Not Reported |                |

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| <u>FDA Received Date</u>            | <u>Case #</u>     | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------|-------------------|------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 09-Sep-2013                         | 9509057           | NON-EXPEDITED    |                    |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>17374935 |                      | 18 YR           | Male         | USA            |
| <u>Preferred Term</u>               | <u>Product</u>    | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Swollen Tongue                      | Abilify           |                  |                    | S               |                                                 | Red To 2mg           |                 | Not Reported |                |
|                                     | Lexapro           |                  |                    | S               |                                                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>            | <u>Case #</u>     | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Sep-2013                         | 9509059           | NON-EXPEDITED    |                    |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>17370867 |                      | 40 YR           | Female       | USA            |
| <u>Preferred Term</u>               | <u>Product</u>    | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Tremor                              | Abilify           |                  |                    | S               |                                                 | Also Taken 5 Mg      |                 | Not Reported |                |
|                                     | Lexapro           |                  |                    | S               |                                                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>            | <u>Case #</u>     | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Sep-2013                         | 9509177           | NON-EXPEDITED    |                    |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>17337718 |                      | 19 YR           | Female       | USA            |
| <u>Preferred Term</u>               | <u>Product</u>    | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Vision Blurred                      | Abilify Tabs 5 Mg |                  |                    | S               |                                                 |                      |                 | Not Reported |                |
|                                     | Lexapro           |                  |                    | S               |                                                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>            | <u>Case #</u>     | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Sep-2013                         | 9509232           | NON-EXPEDITED    |                    |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>19005867 |                      | 19 YR           | Female       | USA            |
| <u>Preferred Term</u>               | <u>Product</u>    | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| White Blood Cell Count<br>Decreased | Abilify           |                  |                    | S               |                                                 |                      |                 | Not Reported |                |
|                                     | Lexapro           |                  |                    | S               |                                                 |                      |                 | Not Reported |                |
|                                     | Remeron           |                  |                    | S               |                                                 |                      |                 | Not Reported |                |
|                                     | Cogentin          |                  |                    | S               |                                                 |                      |                 | Sandoz       |                |

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| <u>FDA Received Date</u>                                                                                                                                            | <u>Case #</u>                                      | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------|------------------|--------------------|-----------------|-------------------------------------------------|--------------------------------|-----------------|----------------------------------------------|----------------|
| 09-Sep-2013                                                                                                                                                         | 9509234                                            | NON-EXPEDITED    |                    | OT              | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>19005388 |                                |                 | Female                                       | USA            |
| <u>Preferred Term</u>                                                                                                                                               | <u>Product</u>                                     | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Suicidal Ideation                                                                                                                                                   | Abilify<br>Lexapro                                 |                  |                    | S<br>S          |                                                 |                                |                 | Not Reported<br>Not Reported                 |                |
| <u>FDA Received Date</u>                                                                                                                                            | <u>Case #</u>                                      | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 09-Sep-2013                                                                                                                                                         | 9509251                                            | NON-EXPEDITED    |                    |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>17329392 |                                | 6 YR            | Unknown                                      | USA            |
| <u>Preferred Term</u>                                                                                                                                               | <u>Product</u>                                     | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Back Pain; Corrective<br>Lens User; Depressive<br>Symptom; Disturbance In<br>Attention; Enuresis;<br>Fatigue; Night Sweats;<br>Somnolence; Tic; Weight<br>Decreased | Abilify<br><br>Lexapro<br>Guanfacine Hydrochloride |                  |                    | S<br><br>S<br>S |                                                 | Reduced To 5 Mg Twice A<br>Day |                 | Not Reported<br>Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                            | <u>Case #</u>                                      | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 09-Sep-2013                                                                                                                                                         | 9509426                                            | NON-EXPEDITED    |                    | OT              | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>17293515 |                                | 45 YR           | Female                                       | USA            |
| <u>Preferred Term</u>                                                                                                                                               | <u>Product</u>                                     | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Anxiety; Type 2 Diabetes<br>Mellitus; Weight Increased                                                                                                              | Abilify<br>Lexapro                                 |                  |                    | S<br>S          |                                                 |                                |                 | Not Reported<br>Not Reported                 |                |
| <u>FDA Received Date</u>                                                                                                                                            | <u>Case #</u>                                      | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 09-Sep-2013                                                                                                                                                         | 9509543                                            | NON-EXPEDITED    |                    |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>17250200 |                                |                 | Female                                       | USA            |
| <u>Preferred Term</u>                                                                                                                                               | <u>Product</u>                                     | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Anxiety; Lethargy                                                                                                                                                   | Abilify Tabs 5 Mg<br>Lexapro                       |                  |                    | S<br>S          |                                                 |                                |                 | Not Reported<br>Not Reported                 |                |

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| <u>FDA Received Date</u>                                           | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                                                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------|----------------------|------------------|--------------------|-----------------|-------------------------------------------------|---------------------------------------------------------------------|-----------------|--------------|----------------|
| 09-Sep-2013                                                        | 9509645              | NON-EXPEDITED    |                    |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>18904946 |                                                                     |                 | Female       | USA            |
| <u>Preferred Term</u>                                              | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Dystonia                                                           | Abilify              |                  |                    | S               |                                                 |                                                                     |                 | Not Reported |                |
|                                                                    | Concerta             |                  |                    | S               |                                                 |                                                                     |                 | Not Reported |                |
|                                                                    | Lexapro              |                  |                    | S               |                                                 |                                                                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                           | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                                                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Sep-2013                                                        | 9509702              | NON-EXPEDITED    |                    |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>17170143 |                                                                     | 39 YR           | Female       | USA            |
| <u>Preferred Term</u>                                              | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Fungal Infection                                                   | Abilify              |                  |                    | S               |                                                 |                                                                     |                 | Not Reported |                |
|                                                                    | Armour Thyroid       |                  |                    | S               | Oral                                            | Tablets; Aug-Oct2012<br>(30mg) Dose Increased To<br>60mg On Oct2012 |                 | Not Reported |                |
|                                                                    | Escitalopram         |                  |                    | S               |                                                 |                                                                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                           | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                                                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Sep-2013                                                        | 9509704              | NON-EXPEDITED    |                    |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>17169525 |                                                                     |                 | Male         | USA            |
| <u>Preferred Term</u>                                              | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Disturbance In<br>Attention; Drug Ineffective;<br>Tremor | Abilify              |                  |                    | S               |                                                 |                                                                     |                 | Not Reported |                |
|                                                                    | Escitalopram Oxalate |                  |                    | S               |                                                 |                                                                     |                 | Not Reported |                |
|                                                                    | Vyvanse              |                  |                    | S               |                                                 |                                                                     |                 | Not Reported |                |
|                                                                    | Lamictal             |                  |                    | S               |                                                 |                                                                     |                 | Not Reported |                |
|                                                                    | Flaxseed Oil         |                  |                    | S               |                                                 |                                                                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                           | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                                                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Sep-2013                                                        | 9509958              | NON-EXPEDITED    |                    |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>18788067 |                                                                     | 72 YR           | Male         | USA            |
| <u>Preferred Term</u>                                              | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                                  | <u>Duration</u> | <u>Mfr</u>   |                |

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|                          |                   |   |      |            |              |
|--------------------------|-------------------|---|------|------------|--------------|
| Fatigue; Feeling         | Abilify Tabs 2 Mg | S | Oral | 1-2mg Also | Not Reported |
| Abnormal; Influenza Like | Abilify Tabs 2 Mg | S | Oral | 1-2mg Also | Not Reported |
| Illness; Rash            | Lexapro           | S |      |            | Not Reported |
|                          | Carbamazepine     | S |      |            | Not Reported |
|                          | Klonopin          | S |      |            | Sandoz       |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------------------------------------|----------------------|------------|------------|----------------|
| 09-Sep-2013              | 9510513       | EXPEDITED (15-DAY) |                    | HO, OT          | US-B.I.<br>PHARMACEUTICALS,I<br>NC./RIDGEFIELD-2013-<br>BI-27 |                      |            | Male       | USA            |

| <u>Preferred Term</u>     | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u>           |
|---------------------------|--------------------|--------------|------------|-------------|--------------|---------------------|-----------------|----------------------|
| Aggression; Agitation;    | Amantadine         |              |            | S           |              |                     |                 | Not Reported         |
| Anxiety; Delusion; Drug   | Pramipexole        |              |            | S           |              | Up To 2.5 Mg        |                 | Boehringer Ingelheim |
| Ineffective; Gambling     | Carbidopa-Levodopa |              |            | S           |              | Levodopa-Equivalent |                 | Not Reported         |
| Disorder; Hypersexuality; |                    |              |            |             |              | Dose: 3140 Mg       |                 |                      |
| Impulsive Behaviour;      |                    |              |            |             |              | (Preoperatively)    |                 |                      |
| Jealous Delusion;         | Carbidopa-Levodopa |              |            | S           |              | Levodopa-Equivalent |                 | Not Reported         |
| Paranoia; Psychotic       |                    |              |            |             |              | Dose: 1048 Mg       |                 |                      |
| Disorder                  |                    |              |            |             |              | (Postperatively)    |                 |                      |
|                           | Entacapone         |              |            | S           |              |                     |                 | Not Reported         |
|                           | Selegiline         |              |            | S           |              |                     |                 | Not Reported         |
|                           | Baclofen           |              |            | S           |              |                     |                 | Not Reported         |
|                           | Escitalopram       |              |            | S           |              |                     |                 | Not Reported         |
|                           | Calcium Carbonate  |              |            | C           |              |                     |                 | Not Reported         |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Sep-2013              | 9462182       | EXPEDITED (15-DAY) |                    | HO              | JP-FRI-1000047793    |                      | 60 YR      | Male       | JPN            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hepatic Function      | Lexapro        |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
| Abnormal              | Myslee         |              |            | C           | Oral         |                    |                 | Not Reported |
|                       | Solanax        |              |            | C           | Oral         |                    |                 | Not Reported |
|                       | Dogmatyl       |              |            | C           | Oral         |                    |                 | Not Reported |

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### Detailed Report

| <u>FDA Received Date</u>                        | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------|----------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 10-Sep-2013                                     | 9492066                    | EXPEDITED (15-DAY) |                    | HO              | JP-FRI-1000048320    |                      | 33 YR           | Female       | JPN            |
| <u>Preferred Term</u>                           | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Altered State Of Consciousness; Overdose        | Lexapro                    |                    |                    | S               | Oral                 | 6 Tablets            |                 | Forest       |                |
|                                                 | Isocline                   |                    |                    | C               | Oral                 | 15 Tablets           |                 | Not Reported |                |
|                                                 | Ravona                     |                    |                    | C               | Oral                 | 17 Tablets           |                 | Not Reported |                |
|                                                 | Lobu                       |                    |                    | C               | Oral                 | 2 Tablets            |                 | Not Reported |                |
|                                                 | Domperidone                |                    |                    | C               | Oral                 | 8 Tablets            |                 | Not Reported |                |
|                                                 | Lansoprazole               |                    |                    | C               | Oral                 | 4 Tablets            |                 | Not Reported |                |
| <u>FDA Received Date</u>                        | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Sep-2013                                     | 9492096                    | EXPEDITED (15-DAY) |                    | OT              | DE-FRI-1000048319    |                      | 55 YR           | Male         | DEU            |
| <u>Preferred Term</u>                           | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Epidermolysis                                   | Escitalopram Oral Solution |                    |                    | S               | Oral                 | 5 Mg                 |                 | Forest       |                |
|                                                 | Insulin                    |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                 | Asthma-Spray               |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                        | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Sep-2013                                     | 9511756                    | EXPEDITED (15-DAY) |                    | HO              | DE-FRI-1000048494    |                      | 31 YR           | Female       | DEU            |
| <u>Preferred Term</u>                           | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Caesarean Section; Obstructed Labour; Pregnancy | Escitalopram               |                    |                    | S               | Oral                 | 20 Mg                |                 | Forest       |                |
|                                                 | Escitalopram Oral Solution |                    |                    | S               | Oral                 | 1 Mg                 |                 | Forest       |                |
|                                                 | Citadura                   |                    |                    | C               | Oral                 | 30 Mg                |                 | Not Reported |                |
| <u>FDA Received Date</u>                        | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Sep-2013                                     | 9513850                    | EXPEDITED (15-DAY) |                    | OT              | PHEH2013US018891     |                      |                 | Female       | USA            |

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| <u>Preferred Term</u>                                                             | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u>      | <u>Mfr</u>   |              |                |
|-----------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|------------------------------------------|----------------------|----------------------|--------------|--------------|----------------|
| Diabetes Mellitus;<br>Musculoskeletal<br>Discomfort; Myocardial<br>Infarction     | Diovan         |                    |                    | S               |                                          | 160 Mg, Unk          |                      | Novartis     |              |                |
|                                                                                   | Lexapro        |                    |                    | S               |                                          |                      |                      |              | Not Reported |                |
| <u>FDA Received Date</u>                                                          | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> |                                          | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>   | <u>Sex</u>   | <u>Country</u> |
| 11-Sep-2013                                                                       | 9517438        | EXPEDITED (15-DAY) |                    | HO              |                                          | IE-FRI-1000048686    |                      | 20 YR        | Female       | IRL            |
| <u>Preferred Term</u>                                                             | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u>      | <u>Mfr</u>   |              |                |
| Hypotension; Hypotonia;<br>Muscle Rigidity;<br>Tachycardia                        | Escitalopram   |                    |                    | S               | Intravenous (not<br>otherwise specified) |                      |                      | Forest       |              |                |
|                                                                                   | Fentanyl       |                    |                    | S               |                                          |                      |                      | Not Reported |              |                |
|                                                                                   | Dexamethasone  |                    |                    | C               |                                          |                      |                      | Not Reported |              |                |
|                                                                                   | Co-Amoxiclav   |                    |                    | C               |                                          |                      |                      | Not Reported |              |                |
|                                                                                   | Ephedrine      |                    |                    | C               |                                          |                      |                      | Not Reported |              |                |
|                                                                                   | Sevoflurane    |                    |                    | C               |                                          |                      |                      | Not Reported |              |                |
|                                                                                   | Remifentanyl   |                    |                    | C               |                                          |                      |                      | Not Reported |              |                |
|                                                                                   | Propofol       |                    |                    | C               |                                          |                      |                      | Not Reported |              |                |
| <u>FDA Received Date</u>                                                          | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> |                                          | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>   | <u>Sex</u>   | <u>Country</u> |
| 11-Sep-2013                                                                       | 9519213        | DIRECT             |                    | OT              |                                          |                      |                      | 40 YR        | Female       | USA            |
| <u>Preferred Term</u>                                                             | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u>      | <u>Mfr</u>   |              |                |
| Anxiety; Asthma; Drug<br>Ineffective; Panic Attack;<br>Product Substitution Issue | Escitalopram   |                    |                    | S               | Oral                                     |                      | 2 WEEK               | Mylan        |              |                |
|                                                                                   | Bupropion      |                    |                    | C               |                                          |                      |                      | Not Reported |              |                |
|                                                                                   | Multivitamin   |                    |                    | C               |                                          |                      |                      | Not Reported |              |                |
| <u>FDA Received Date</u>                                                          | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> |                                          | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>   | <u>Sex</u>   | <u>Country</u> |
| 11-Sep-2013                                                                       | 9519289        | DIRECT             | Y                  |                 |                                          |                      |                      | 11 YR        | Female       | USA            |
| <u>Preferred Term</u>                                                             | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u>      | <u>Mfr</u>   |              |                |
| Drug Ineffective; Product<br>Substitution Issue                                   | Escitalopram   |                    |                    | S               |                                          |                      |                      | Not Reported |              |                |

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| <u>FDA Received Date</u>                                               | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------|----------------------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| 12-Sep-2013                                                            | 9417834                    | EXPEDITED (15-DAY) |                    | HO              | IT-FRI-1000046991          |                      | 7 YR            | Male         | ITA            |
| <u>Preferred Term</u>                                                  | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Accidental Exposure To Product By Child; Bradycardia; Medication Error | Escitalopram Oral Solution |                    |                    | S               | Oral                       | Overdose: 10 Drops   |                 | Forest       |                |
| <u>FDA Received Date</u>                                               | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Sep-2013                                                            | 9524117                    | DIRECT             |                    | HO, OT          |                            |                      | 26 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                  | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Endometriosis; Fibromyalgia; Gait Disturbance; Speech Disorder         | Lexapro                    |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                               | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Sep-2013                                                            | 9438827                    | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2013222315   |                      | 59 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                  | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Dry Mouth; Enuresis; Urinary Incontinence            | Lyrica                     |                    |                    | S               | Oral                       | 100 Mg, 3x/Day       |                 | Pfizer       |                |
|                                                                        | Lyrica                     |                    |                    | S               |                            |                      |                 | Pfizer       |                |
|                                                                        | Lyrica                     |                    |                    | S               |                            |                      |                 | Pfizer       |                |
|                                                                        | Omeprazole                 |                    |                    | S               |                            | 40 Mg, 1x/Day        |                 | Not Reported |                |
|                                                                        | Lexapro                    |                    |                    | S               |                            | 10 Mg, 1x/Day        |                 | Not Reported |                |
|                                                                        | Felodipine                 |                    |                    | S               |                            | 2.5 Mg, 1x/Day       |                 | Not Reported |                |
|                                                                        | Ambien                     |                    |                    | S               |                            | 5 Mg, 1x/Day         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                               | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Sep-2013                                                            | 9520530                    | EXPEDITED (15-DAY) |                    | OT              | CH-ASTRAZENECA-2013SE67811 |                      | 56 YR           | Female       | CHE            |



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| <u>Preferred Term</u>                                                                                            | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|------------------------------------------------------------------------------------------------------------------|---------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Agitation; Condition Aggravated; Disturbance In Attention                                                        | Seroquel Xr         |                    |                    | S               | Oral                 |                      |                 | Zeneca       |                |
|                                                                                                                  | Cipralext           |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                  | Cipralext           |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                  | Cipralext           |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                  | Cipralext           |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                  | Temesta (Lorazepam) |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                         | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Sep-2013                                                                                                      | 9531111             | DIRECT             |                    | OT              |                      |                      | 70 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                            | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Depression; Heart Rate Irregular; Insomnia; Panic Attack; Product Substitution Issue; Suicidal Ideation | Escitalopram        |                    |                    | S               | Oral                 | 1; Once Daily        |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                         | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Sep-2013                                                                                                      | 8626962             | EXPEDITED (15-DAY) |                    | LT              | PT-FRI-1000027206    |                      | 85 YR           | Male         | PRT            |
| <u>Preferred Term</u>                                                                                            | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Angioedema; Dizziness; Dyspnoea; Mouth Swelling; Oropharyngeal Pain; Swollen Tongue                              | Escitalopram        |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                                                                                                  | Coaprovel           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                  | Lorenin             |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                         | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Sep-2013                                                                                                      | 9458925             | EXPEDITED (15-DAY) |                    | HO              | JP-FRI-1000047739    |                      | 46 YR           | Male         | JPN            |
| <u>Preferred Term</u>                                                                                            | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Activation Syndrome; Disturbance In Attention; Head Discomfort; Hyperhidrosis; Tension                           | Lexapro             |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                                                                                                  | Flunitrazepam       |                    |                    | C               | Oral                 | 1 Mg                 |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                         | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
| 17-Sep-2013                                                                      | 9459006                 | EXPEDITED (15-DAY) |                    | HO              | JP-FRI-1000047740         |                      | 55 YR           | Male         | JPN            |
| <u>Preferred Term</u>                                                            | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Activation Syndrome;<br>Anxiety; Malaise; Suicide<br>Attempt                     | Lexapro                 |                    |                    | S               | Oral                      | 10 Mg                |                 | Forest       |                |
|                                                                                  | Rivotril                |                    |                    | C               | Oral                      | 1 mg                 |                 | Not Reported |                |
|                                                                                  | Depas (Etizolam)        |                    |                    | C               | Oral                      | 0.5 Mg               |                 | Not Reported |                |
|                                                                                  | Reslin                  |                    |                    | C               | Oral                      | 25 Mg                |                 | Not Reported |                |
|                                                                                  | Yokukansankachimpihange |                    |                    | C               | Oral                      | 7.5 Gram             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                         | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Sep-2013                                                                      | 9459101                 | EXPEDITED (15-DAY) |                    | HO              | JP-FRI-1000047742         |                      | 52 YR           | Male         | JPN            |
| <u>Preferred Term</u>                                                            | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain; Activation<br>Syndrome; Autonomic<br>Nervous System<br>Imbalance | Lexapro                 |                    |                    | S               | Oral                      | 10 Mg                |                 | Forest       |                |
|                                                                                  | Remeron                 |                    |                    | C               | Oral                      | 15 Mg                |                 | Not Reported |                |
|                                                                                  | Lexotan                 |                    |                    | C               | Oral                      | 15 Mg                |                 | Not Reported |                |
|                                                                                  | Silece                  |                    |                    | C               | Oral                      | 4 Mg                 |                 | Not Reported |                |
|                                                                                  | Seroquel                |                    |                    | C               | Oral                      | 75 Mg                |                 | Not Reported |                |
|                                                                                  | Seroquel                |                    |                    | C               | Oral                      | 100 Mg               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                         | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Sep-2013                                                                      | 9493680                 | EXPEDITED (15-DAY) |                    | OT              | IT-JNJFOC-<br>20130814909 |                      | 28 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                            | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Abuse; Intentional<br>Self-Injury; Sopor                                    | Risperdal               |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                                                                                  | Entact                  |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |

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|--------------------------------------------------------------|-----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 17-Sep-2013                                                  | 9529141               | EXPEDITED (15-DAY) |                    | OT              | JP-FRI-1000024486    |                      | 32 YR           | Male         | JPN            |
| <u>Preferred Term</u>                                        | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Seizure                                                      | Lexapro               |                    |                    | S               |                      | 10 Mg                |                 | Forest       |                |
|                                                              | Amoxan                |                    |                    | S               | Oral                 | 75 Mg                |                 | Not Reported |                |
|                                                              | Lexotan               |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |
|                                                              | Flunitrazepam         |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |
|                                                              | Irribow               |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |
|                                                              | Benzalin (Nitrazepam) |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |
|                                                              | Ravona                |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |
|                                                              | Cymbalta              |                    |                    | C               | Oral                 | 60 Mg                |                 | Not Reported |                |
|                                                              | Seniran               |                    |                    | C               |                      | 6 Mg                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Sep-2013                                                  | 9529968               | EXPEDITED (15-DAY) |                    | DE              | US-FRI-1000048571    |                      | < 1 DAY         | Female       | USA            |
| <u>Preferred Term</u>                                        | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Congenital Anomaly;<br>Heart Disease Congenital              | Lexapro               |                    |                    | S               | Transplacental       |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Sep-2013                                                  | 9529998               | EXPEDITED (15-DAY) |                    | HO              | CH-FRI-1000042460    |                      |                 | Female       | CHE            |
| <u>Preferred Term</u>                                        | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Caesarean Section;<br>Haemorrhage In<br>Pregnancy; Pregnancy | Escitalopram          |                    |                    | S               |                      | 10 Mg                |                 | Forest       |                |
|                                                              | Escitalopram          |                    |                    | S               |                      | 10 Mg                |                 | Forest       |                |
|                                                              | Methadone             |                    |                    | S               |                      | 26 Mg                |                 | Not Reported |                |
|                                                              | Alprazolam            |                    |                    | S               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Sep-2013              | 9530043       | EXPEDITED (15-DAY) |                    | OT              | CH-FRI-1000048804    |                      |            | Female     | CHE            |

| <u>Preferred Term</u>                                          | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------|---------------------|--------------|------------|-------------|--------------|----------------------|-----------------|--------------|
| Agitation; Condition Aggravated; Disturbance In Sexual Arousal | Escitalopram        |              |            | S           | Oral         | 15 Mg                |                 | Forest       |
|                                                                | Escitalopram        |              |            | S           | Oral         | 25 Mg                |                 | Forest       |
|                                                                | Escitalopram        |              |            | S           |              | 10 Mg Qod            |                 | Not Reported |
|                                                                | Escitalopram        |              |            | S           |              | 5 Mg Qod             |                 | Not Reported |
|                                                                | Seroquel Xr         |              |            | S           | Oral         | 50 Mg In The Evening |                 | Not Reported |
|                                                                | Temesta (Lorazepam) |              |            | C           |              | 0.5 Mg               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 17-Sep-2013              | 9530187       | EXPEDITED (15-DAY) |                    | HO              | FR-PFIZER INC-2013263670 |                      | 77 YR      | Female     | FRA            |

| <u>Preferred Term</u>                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                              | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------|----------------|--------------|------------|-------------|--------------|-----------------------------------------------------------------|-----------------|--------------|
| Chest Pain; Dizziness; Pulmonary Embolism | Caduet         |              |            | S           | Oral         | Amlodipine Besilate 5 Mg/Atorvastatin Calcium 10 Mg, 1 Df Daily |                 | Pfizer       |
|                                           | Ebixa          |              |            | S           | Oral         | 20 Mg, Daily                                                    |                 | Not Reported |
|                                           | Reminyl        |              |            | S           | Oral         | 16 Mg, Daily                                                    |                 | Not Reported |
|                                           | Seroplex       |              |            | S           | Oral         | 5 Mg, Daily                                                     |                 | Not Reported |
|                                           | Atarax         |              |            | S           | Oral         | 25 Mg, Daily                                                    |                 | Not Reported |
|                                           | Nisisco        |              |            | S           | Oral         | Valsartan 80 Mg/ Hydrochlorothiazide 12.5 Mg,1 Df Daily         |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Sep-2013              | 9531596       | DIRECT           | Y                  |                 |                      |                      | 14 YR      | Female     | USA            |

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

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

|                                       |         |   |      |              |
|---------------------------------------|---------|---|------|--------------|
| Product Substitution Issue;<br>Tremor | Lexapro | S | Oral | Not Reported |
|---------------------------------------|---------|---|------|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Sep-2013              | 9536426       | DIRECT           |                    | DS, HO          |                      |                      | 19 YR      | Male       | USA            |

| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|----------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Glucose Tolerance Impaired | Lexapro        |              |            | S           |              | 10 Dose Once Daily |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Sep-2013              | 9459007       | EXPEDITED (15-DAY) |                    | HO              | US-FRI-1000047790    |                      | 25 YR      | Female     | USA            |

| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anhedonia; Anxiety;        | Lexapro        |              |            | S           |              |                    |                 | Forest       |
| Decreased Appetite;        | Ketamine       |              |            | S           |              |                    |                 | Not Reported |
| Depressed Mood;            | Clomipramine   |              |            | S           |              |                    |                 | Not Reported |
| Derealisation; Drug        |                |              |            |             |              |                    |                 |              |
| Interaction; Hyperphagia;  |                |              |            |             |              |                    |                 |              |
| Hypersomnia; Illusion;     |                |              |            |             |              |                    |                 |              |
| Sleep Disorder; Suicidal   |                |              |            |             |              |                    |                 |              |
| Ideation; Therapeutic      |                |              |            |             |              |                    |                 |              |
| Product Effect Incomplete; |                |              |            |             |              |                    |                 |              |
| Trichotillomania; Weight   |                |              |            |             |              |                    |                 |              |
| Increased                  |                |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 18-Sep-2013              | 9531588       | EXPEDITED (15-DAY) |                    | HO              | CH-JNJFOC-20130907197 |                      | 17 YR      | Female     | CHE            |

| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Panic Attack; Product Use | Topiramate     |              |            | S           | Oral         |                    |                 | Not Reported |
| In Unapproved Indication  | Topiramate     |              |            | S           | Oral         |                    |                 | Not Reported |
|                           | Topiramate     |              |            | S           | Oral         |                    |                 | Not Reported |
|                           | Topiramate     |              |            | S           | Oral         |                    |                 | Not Reported |

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

| Escitalopram                                                                                                                              |                               |                    | S                  |                 | Unknown              |                      |                 | Not Reported |                |
|-------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| <u>FDA Received Date</u>                                                                                                                  | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Sep-2013                                                                                                                               | 9532705                       | EXPEDITED (15-DAY) |                    | HO, OT          | CH-FRI-1000048921    |                      |                 | Male         | CHE            |
| <u>Preferred Term</u>                                                                                                                     | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Premature Baby; Retroplacental Haematoma; Umbilical Cord Abnormality | Escitalopram                  |                    |                    | S               | Transplacental       | 10 Mg                |                 | Forest       |                |
|                                                                                                                                           | Methadone                     |                    |                    | S               | Transplacental       | 26 Mg                |                 | Not Reported |                |
|                                                                                                                                           | Alprazolam                    |                    |                    | S               | Transplacental       |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                  | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Sep-2013                                                                                                                               | 9533239                       | EXPEDITED (15-DAY) |                    | OT              | US-FRI-1000048699    |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                     | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Off Label Use; Schizophrenia                                                                                                              | Lexapro                       |                    |                    | S               |                      |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                                  | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Sep-2013                                                                                                                               | 9535078                       | EXPEDITED (15-DAY) |                    | DE, HO          | CH-UCBSA-098016      |                      | 44 YR           | Male         | CHE            |
| <u>Preferred Term</u>                                                                                                                     | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Neoplasm Progression; Pyrexia                                                                                                             | Keppra                        |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                                           | Dabrafenib                    |                    |                    | S               | Oral                 | 300 Mg/Day           |                 | Not Reported |                |
|                                                                                                                                           | Trametinib                    |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                                           | Cipralex                      |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                                           | Novalgine (Metamizole Sodium) |                    |                    | S               | Oral                 | 1500-2000 Mg/Day     |                 | Not Reported |                |
|                                                                                                                                           | Fortecortin                   |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                                           | Fortecortin                   |                    |                    | S               | Oral                 | 12 Mg/Day            |                 | Not Reported |                |
|                                                                                                                                           | Orfiril                       |                    |                    | S               | Oral                 | 1000-1200 Mg         |                 | Not Reported |                |

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

|            |   |                                                       |              |
|------------|---|-------------------------------------------------------|--------------|
| Orfirl     | S | Oral                                                  | Not Reported |
| Ipilimumab | C | Cycle                                                 | Not Reported |
| Cisplatin  | C | Intravenous (not otherwise specified) 2 Cycles, 90 Mg | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Sep-2013              | 9536674       | DIRECT           | Y                  |                 |                      |                      | 14 YR      | Female     | USA            |

| <u>Preferred Term</u>              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Product Substitution Issue; Tremor | Lexapro        |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Sep-2013              | 9537176       | DIRECT           |                    |                 |                      |                      | 45 YR      | Unknown    | USA            |

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

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 19-Sep-2013              | 9160718       | NON-EXPEDITED    |                    | CA, DE, HO      | US-JNJFOC-20130306472 |                      | 94 DAY     | Male       | USA            |

| <u>Preferred Term</u>       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------|----------------|--------------|------------|-------------|----------------|----------------------|-----------------|--------------|
| Atrial Septal Defect;       | Topamax        |              |            | S           | Transplacental | 200-500 Mg Every Day |                 | Not Reported |
| Cardiac Failure             | Lamictal       |              |            | S           | Transplacental |                      |                 | Not Reported |
| Congestive; Chromosomal     | Xanax          |              |            | S           | Transplacental |                      |                 | Not Reported |
| Deletion; Cytogenetic       | Ambien         |              |            | S           | Transplacental |                      |                 | Not Reported |
| Abnormality; Double         | Trazodone      |              |            | S           | Transplacental |                      |                 | Not Reported |
| Outlet Right Ventricle;     | Lexapro        |              |            | S           | Transplacental |                      |                 | Not Reported |
| Factor V Leiden Mutation;   | Zoloft         |              |            | S           | Transplacental |                      |                 | Not Reported |
| Hypospadias; Lung           | Dilantin       |              |            | S           | Transplacental |                      |                 | Not Reported |
| Disorder; Necrotising       |                |              |            |             |                |                      |                 |              |
| Colitis; Patent Ductus      |                |              |            |             |                |                      |                 |              |
| Arteriosus; Periventricular |                |              |            |             |                |                      |                 |              |

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

|                                                                                                                     |           |   |                |              |
|---------------------------------------------------------------------------------------------------------------------|-----------|---|----------------|--------------|
| Leukomalacia; Premature Baby; Respiratory Failure; Sepsis;                                                          | Z-Pack    | S | Transplacental | Not Reported |
| Thrombocytopenia; Tracheitis; Transposition Of The Great Vessels; Vascular Skin Disorder; Ventricular Septal Defect | Metformin | S | Transplacental | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Sep-2013              | 9319286       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000045448    |                      | 29 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Galactorrhoea         | Escitalopram            |              |            | S           | Oral         |                    |                 | Forest       |
|                       | Citalopram              |              |            | S           | Oral         | 20 Mg              |                 | Forest       |
|                       | Effexor                 |              |            | S           | Oral         | 75 Mg              |                 | Not Reported |
|                       | Cerazette (Desogestrel) |              |            | C           | Oral         |                    |                 | Not Reported |
|                       | Lexomil                 |              |            | C           | Oral         | 1 Df               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 19-Sep-2013              | 9517177       | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2013260096 |                      | 41 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Hypersensitivity | Zoloft                 |              |            | S           |              | Unk                |                 | Pfizer       |
|                       | Xanax                  |              |            | S           |              | Unk                |                 | Pfizer       |
|                       | Neurontin              |              |            | S           |              | Unk                |                 | Pfizer       |
|                       | Morphine Sulfate       |              |            | S           |              | Unk                |                 | Pfizer       |
|                       | Robaxin                |              |            | S           |              | Unk                |                 | Pfizer       |
|                       | Etodolac               |              |            | S           |              | Unk                |                 | Pfizer       |
|                       | Tramadol Hydrochloride |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Wellbutrin             |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Prozac                 |              |            | S           |              | Unk                |                 | Not Reported |



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

|          |   |     |              |
|----------|---|-----|--------------|
| Flexeril | S | Unk | Not Reported |
| Ambien   | S | Unk | Not Reported |
| Celexa   | S | Unk | Not Reported |
| Cymbalta | S | Unk | Not Reported |
| Lexapro  | S | Unk | Not Reported |
| Lunesta  | S | Unk | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 19-Sep-2013              | 9536586       | NON-EXPEDITED    |                    | OT              | US-JNJFOC-20130306471 |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                                                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|---------------------------|-----------------|--------------|
| Emotional Disorder; Exposure During Pregnancy; Perinatal Depression; Premature Labour | Topamax        |              |            | S           | Oral         | 200-500 Mg Every Day      |                 | Not Reported |
|                                                                                       | Lamictal       |              |            | S           | Oral         | 600-800 Mg Every Day      |                 | Not Reported |
|                                                                                       | Xanax          |              |            | S           | Oral         | 0.25 Mg To 1 Mg Every Day |                 | Not Reported |
|                                                                                       | Ambien         |              |            | S           | Oral         | 50 Mg Every Day           |                 | Not Reported |
|                                                                                       | Trazodone      |              |            | S           | Oral         | 100-200 Mg Every Day      |                 | Not Reported |
|                                                                                       | Lexapro        |              |            | S           | Oral         | 25 Mg Every Day           |                 | Not Reported |
|                                                                                       | Lexapro        |              |            | S           | Oral         | 25 Mg Every Day           |                 | Not Reported |
|                                                                                       | Zoloft         |              |            | S           | Oral         | 2010 Till Present         |                 | Not Reported |
|                                                                                       | Zoloft         |              |            | S           | Oral         | 2010 Till Present         |                 | Not Reported |
|                                                                                       | Dilantin       |              |            | S           | Oral         |                           |                 | Not Reported |
|                                                                                       | Z-Pack         |              |            | S           | Unknown      |                           |                 | Not Reported |
|                                                                                       | Metformin      |              |            | S           | Unknown      |                           |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Sep-2013              | 9537405       | EXPEDITED (15-DAY) |                    | DS              | FR-FRI-1000048942    |                      | 88 YR      | Male       | FRA            |

| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Confusional State; Fall; | Escitalopram   |              |            | S           | Oral         | 10 Mg              |                 | Forest     |

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

|                        |            |   |      |      |              |
|------------------------|------------|---|------|------|--------------|
| Hemianopia             | Furosemide | S | Oral | 1 Df | Not Reported |
| Homonymous;            | Alprazolam | S | Oral | 1 Df | Not Reported |
| Hemiparesis; Ischaemic | Foradil    | C |      |      | Not Reported |
| Stroke; Seizure        |            |   |      |      |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Sep-2013              | 9541950       | DIRECT           |                    |                 |                      |                      | 62 YR      | Unknown    | USA            |

| <u>Preferred Term</u>                                                                                        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|---------------------------------|-----------------|--------------|
| Product Contamination<br>Physical; Product<br>Substitution Issue;<br>Therapeutic Product Effect<br>Decreased | Escitalopram   |              |            | S           |              | 1.5, Once Daily, Taken By Mouth | 10 YR           | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 20-Sep-2013              | 9310380       | EXPEDITED (15-DAY) |                    | OT              | FR-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>18910620 |                      | 40 YR      | Male       | FRA            |

| <u>Preferred Term</u>                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Asphyxia; Rash; Sleep<br>Apnoea Syndrome | Abilify        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                          | Seroplex       |              |            | S           | Oral         |                    |                 | Not Reported |
|                                          | Zyprexa        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Sep-2013              | 9539082       | EXPEDITED (15-DAY) |                    | DE              | FR-FRI-1000048936    |                      | 76 YR      | Male       | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cerebral Haemorrhage  | Escitalopram   |              |            | S           | Oral         | 1 Df               |                 | Forest       |
|                       | Xarelto        |              |            | S           | Oral         | 1 Df               |                 | Not Reported |
|                       | Xanax          |              |            | C           | Oral         | 1 Df               |                 | Not Reported |
|                       | Flecaine       |              |            | C           | Oral         | 1 Df               |                 | Not Reported |
|                       | Inexium        |              |            | C           | Oral         | 1 Df               |                 | Not Reported |

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|                          |                |                    |                    |                 |                                                |                      |                 |              |                |
|--------------------------|----------------|--------------------|--------------------|-----------------|------------------------------------------------|----------------------|-----------------|--------------|----------------|
| Seresta                  |                |                    | C                  |                 | 10 Mg                                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Sep-2013              | 9539093        | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000048937                              |                      | 45 YR           | Female       | FRA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Pancytopenia             | Escitalopram   |                    |                    | S               | Oral                                           | 1 Df                 |                 | Forest       |                |
|                          | Carboplatine   |                    |                    | C               |                                                |                      |                 | Not Reported |                |
|                          | Etoposide      |                    |                    | C               |                                                |                      |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Sep-2013              | 9543138        | EXPEDITED (15-DAY) |                    | HO, LT          | FR-JHP<br>PHARMACEUTICALS,<br>LLC-JHP201300564 |                      | 45 YR           | Male         | FRA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Serotonin Syndrome       | Dantrium       |                    |                    | S               |                                                | Unk Unk, Single      |                 | Jhp          |                |
|                          | Seroplex       |                    |                    | S               | Oral                                           | 20 Mg, Unk           |                 | Not Reported |                |
|                          | Laroxyl        |                    |                    | S               |                                                | 50 Mg, Daily         |                 | Not Reported |                |
|                          | Lyrica         |                    |                    | C               |                                                | 75 Mg, Bid           |                 | Not Reported |                |
|                          | Urbanyl        |                    |                    | C               |                                                | 420 Mg, Tid          |                 | Not Reported |                |
|                          | Doliprane      |                    |                    | C               |                                                | 1 G, Qid             |                 | Not Reported |                |
|                          | Rivotril       |                    |                    | C               |                                                | 15 Df, Daily         |                 | Not Reported |                |
|                          | Baclofen       |                    |                    | C               |                                                | 9 Df, Daily          |                 | Not Reported |                |
|                          | Ditropan       |                    |                    | C               |                                                | 1.5 Df, Daily        |                 | Not Reported |                |
|                          | Neurontin      |                    |                    | C               |                                                | 1200 Mg, Tid         |                 | Not Reported |                |
|                          | Xanax          |                    |                    | C               |                                                | 0.5 Mg, Qhs          |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Sep-2013              | 9548777        | DIRECT             |                    | DS, OT          |                                                |                      | 47 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

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

|                                                                                                                                                                                        |                                                                                                                                                                          |                                                               |                    |                                                                                                                                                                                                              |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------|--------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Blood Disorder;<br>Hypophagia; Insomnia;<br>Intentional Self-Injury;<br>Mental Disorder; Migraine;<br>Nausea; Product<br>Substitution Issue;<br>Suicidal Ideation; Weight<br>Decreased | Escitalopram<br>Lexapro<br>Propranolol<br>Piroxicam<br>Diazepam<br>Tizanidine<br>Ketorolac<br>Sumatriptan<br>Vitamin B2<br>Magnesium<br>Vitamins<br>Coq10<br>Acidophilus | S<br>C<br>C<br>C<br>C<br>C<br>C<br>C<br>C<br>C<br>C<br>C<br>C | 1 Pill; Once Daily | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------|--------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|------------|------------|----------------|
| 24-Sep-2013              | 9547495       | EXPEDITED (15-DAY) |                    | DE, HO          | ES-SANOFI-AVENTIS-2013SA092934 |                      | 92 YR      | Female     | ESP            |

| <u>Preferred Term</u>               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                          | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------|----------------|--------------|------------|-------------|---------------------------------------|--------------------|-----------------|--------------|
| Anuria; Blood Loss<br>Anaemia; Coma | Clexane        |              |            | S           | Subcutaneous                          | 40mg               |                 | Not Reported |
|                                     | Escitalopram   |              |            | S           | Oral                                  | 10mg En Desayuno   |                 | Not Reported |
|                                     | Dexketoprofen  |              |            | S           | Intravenous (not otherwise specified) | 50mg/8h            |                 | Not Reported |
|                                     | Haloperidol    |              |            | C           | Intravenous (not otherwise specified) | 5mg/8h             |                 | Not Reported |
|                                     | Risperidone    |              |            | C           | Oral                                  | 1mg En Cena        |                 | Not Reported |
|                                     | Omeprazole     |              |            | C           | Oral                                  | 20mg               |                 | Not Reported |
|                                     | Oxycodone      |              |            | C           | Oral                                  | 5mg/8h             |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 24-Sep-2013              | 9549868       | EXPEDITED (15-DAY) |                    | DE, OT          | US-ACTAVIS-2013-16626 |                      | 42 YR      | Female     | USA            |

| <u>Preferred Term</u>                                        | <u>Product</u>                         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>           |
|--------------------------------------------------------------|----------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------|
| Drug Interaction;<br>Overdose; Toxicity To<br>Various Agents | Cyproheptadine Hydrochloride (Amallic) |              |            | S           | Unknown      | Unk                |                 | Actavis Mid Atlantic |

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|                                                                                                                                           | Citalopram Hydrobromide<br>(Watson Laboratories)<br>Lexapro |                    | S                  | Unknown         | Unk                   |                      |                 | Watson       |                |
|-------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
|                                                                                                                                           |                                                             |                    | S                  | Unknown         | Unk                   |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                  | <u>Case #</u>                                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Sep-2013                                                                                                                               | 9553573                                                     | DIRECT             |                    | DS              |                       |                      | 46 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                     | <u>Product</u>                                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Dizziness; Drug Withdrawal Syndrome; Impaired Driving Ability; Product Dose Omission; Wrong Technique In Product Usage Process | Lexapro                                                     |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                  | <u>Case #</u>                                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Sep-2013                                                                                                                               | 9100164                                                     | EXPEDITED (15-DAY) |                    | HO              | JP-FRI-1000042573     |                      | < 1 DAY         | Female       | JPN            |
| <u>Preferred Term</u>                                                                                                                     | <u>Product</u>                                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy                                                                       | Lexapro                                                     |                    |                    | S               | Transplacental        | 20 Mg                |                 | Forest       |                |
|                                                                                                                                           | Remeron                                                     |                    |                    | C               | Transplacental        |                      |                 | Not Reported |                |
|                                                                                                                                           | Rhythmy                                                     |                    |                    | C               | Transplacental        |                      |                 | Not Reported |                |
|                                                                                                                                           | Myslee                                                      |                    |                    | C               | Transplacental        |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                  | <u>Case #</u>                                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Sep-2013                                                                                                                               | 9552970                                                     | EXPEDITED (15-DAY) |                    | HO              | FR-JNJFOC-20130910076 |                      | 73 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                                                     | <u>Product</u>                                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Drug Interaction; Orthostatic Hypotension                                                                                      | Haldol                                                      |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                                                           | Lexomil                                                     |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                                                           | Seroplex                                                    |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                               | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 25-Sep-2013                                                            | 9553007                 | EXPEDITED (15-DAY) |                    | HO              | JP-FRI-1000042572    |                      |                 | Female       | JPN            |
| <u>Preferred Term</u>                                                  | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Pregnancy; Subchorionic Haematoma; Threatened Labour; Weight Increased | Lexapro                 |                    |                    | S               | Oral                 | 20 Mg                |                 | Forest       |                |
|                                                                        | Remeron                 |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |
|                                                                        | Rhythmy                 |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |
|                                                                        | Myslee                  |                    |                    | C               | Oral                 | 1 Df                 |                 | Not Reported |                |
|                                                                        | Cercine                 |                    |                    | C               | Oral                 | 3 Df                 |                 | Not Reported |                |
|                                                                        | Gasmotin                |                    |                    | C               | Oral                 | 3 Df                 |                 | Not Reported |                |
|                                                                        | Silece                  |                    |                    | C               | Oral                 | 1 Df                 |                 | Not Reported |                |
|                                                                        | Vegetamin-B             |                    |                    | C               | Oral                 | 1 Df                 |                 | Not Reported |                |
|                                                                        | Risperdal               |                    |                    | C               | Transdermal          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                               | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Sep-2013                                                            | 9553578                 | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000048968    |                      | 72 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                  | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Withdrawal Syndrome                                                    | Escitalopram            |                    |                    | S               | Oral                 |                      |                 | Forest       |                |
|                                                                        | Solian                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                        | Metformine              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                        | Repaglinide             |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                        | Parkinane               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                        | Buspirone Hydrochloride |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                        | Chondrosulf             |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                               | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Sep-2013                                                            | 9553950                 | EXPEDITED (15-DAY) |                    | OT              | IT-FRI-1000049036    |                      | 28 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                  | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Self-Injury;                                               | Escitalopram            |                    |                    | S               |                      |                      |                 | Forest       |                |

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|                                                                                                                        |                      |                    |                    |                 |                      |                      |                 |              |                |
|------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Sopor                                                                                                                  | Risperdal            |                    |                    | S               |                      |                      |                 |              | Not Reported   |
| <u>FDA Received Date</u>                                                                                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Sep-2013                                                                                                            | 9554325              | EXPEDITED (15-DAY) |                    | HO, OT          | JP-FRI-1000048416    |                      | 64 YR           | Female       | JPN            |
| <u>Preferred Term</u>                                                                                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Decreased Appetite;<br>Dehydration;<br>Hyponatraemia; Off Label<br>Use; Urinary Retention                              | Lexapro              |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                                                                                                        | Gasmotin             |                    |                    | S               | Oral                 | 15 Mg                |                 | Not Reported |                |
|                                                                                                                        | Constan [Alprazolam] |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                        | Lendormin            |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                        | Lendormin            |                    |                    | S               | Oral                 | 0.25 Mg              |                 | Not Reported |                |
|                                                                                                                        | Olmetec              |                    |                    | C               | Oral                 | 40 Mg                |                 | Not Reported |                |
|                                                                                                                        | Methycobal           |                    |                    | C               | Oral                 | 1500 Mg              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Sep-2013                                                                                                            | 9554375              | EXPEDITED (15-DAY) |                    | HO, OT          | US-FRI-1000047482    |                      | 56 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Breast Cancer; Myocardial<br>Infarction                                                                                | Escitalopram         |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                                                                                                        | Escitalopram         |                    |                    | S               | Oral                 | 20 Mg                |                 | Forest       |                |
|                                                                                                                        | Xanax                |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Sep-2013                                                                                                            | 9554404              | EXPEDITED (15-DAY) |                    | CA, HO          | DE-FRI-1000049037    |                      | 1 DAY           | Male         | DEU            |
| <u>Preferred Term</u>                                                                                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrial Septal Defect; Foetal<br>Exposure During<br>Pregnancy; Selective<br>Eating Disorder; Urinary<br>Tract Infection | Escitalopram         |                    |                    | S               | Transplacental       | 10 Mg                |                 | Forest       |                |
|                                                                                                                        | Edronax              |                    |                    | S               | Transplacental       | 4 Mg                 |                 | Not Reported |                |
|                                                                                                                        | Diclofenac           |                    |                    | C               | Transplacental       |                      |                 | Not Reported |                |
|                                                                                                                        | Folic Acid           |                    |                    | C               | Transplacental       | 0.8 Mg               |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                           | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 25-Sep-2013                                                                        | 9554452        | EXPEDITED (15-DAY) |                    | CA              | FR-FRI-1000049146     |                      |                 | Unknown      | FRA            |
| <u>Preferred Term</u>                                                              | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Congenital Umbilical Hernia; Exposure During Pregnancy                             | Escitalopram   |                    |                    | S               | Transplacental        |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                           | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Sep-2013                                                                        | 8193189        | EXPEDITED (15-DAY) |                    | HO              | FR-JNJFOC-20111007241 |                      | 43 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                              | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alcoholism; Generalised Tonic-Clonic Seizure; Hyponatraemia; Loss Of Consciousness | Haldol         |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                    | Contramal      |                    |                    | S               | Oral                  | Twice Daily          |                 | Not Reported |                |
|                                                                                    | Seroplex       |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                    | Seroplex       |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                    | Zyprexa        |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                    | Seresta        |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |
|                                                                                    | Vitamin B1     |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |
|                                                                                    | Vitamin B6     |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |
|                                                                                    | Nicobion       |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |
|                                                                                    | Imovane        |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                           | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Sep-2013                                                                        | 9585903        | NON-EXPEDITED      |                    | DE              | 2013-00621            |                      | 46 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                              | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                                                  | Valproic Acid  |                    |                    | S               |                       |                      |                 | Not Reported |                |
|                                                                                    | Escitalopram   |                    |                    | S               |                       |                      |                 | Not Reported |                |
|                                                                                    | Hydroxyzine    |                    |                    | S               |                       |                      |                 | Not Reported |                |
|                                                                                    | Ibuprofen      |                    |                    | S               |                       |                      |                 | Not Reported |                |



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|                             |                |                    |                    |                 |                      |                      |                 |              |                |
|-----------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Cyclobenzaprine             |                |                    | S                  |                 |                      | Not Reported         |                 |              |                |
| <u>FDA Received Date</u>    | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Sep-2013                 | 8941819        | EXPEDITED (15-DAY) |                    | OT              | CH-FRI-1000040751    |                      |                 | Male         | CHE            |
| <u>Preferred Term</u>       | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Haematuria; Renal Cyst      | Escitalopram   |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
| <u>FDA Received Date</u>    | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Sep-2013                 | 9530062        | EXPEDITED (15-DAY) |                    | OT              | JP-FRI-1000045958    |                      | 51 YR           | Male         | JPN            |
| <u>Preferred Term</u>       | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Decreased Appetite;         | Lexapro        |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
| Depression; Nausea; Off     | Lyrica         |                    |                    | S               | Oral                 | 150 Mg               |                 | Not Reported |                |
| Label Use; Poor Quality     | Methycobal     |                    |                    | S               | Oral                 | 3 Df                 |                 | Not Reported |                |
| Sleep; Thirst; Urine Output | Anplag         |                    |                    | S               | Oral                 | 3 Df                 |                 | Not Reported |                |
| Decreased; Vision Blurred   |                |                    |                    |                 |                      |                      |                 |              |                |
| <u>FDA Received Date</u>    | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Sep-2013                 | 9554012        | EXPEDITED (15-DAY) |                    |                 | JP-FRI-1000049043    |                      |                 | Female       | JPN            |
| <u>Preferred Term</u>       | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Feeling Hot;                | Lexapro        |                    |                    | S               | Oral                 |                      |                 | Forest       |                |
| Hyperhidrosis; Palpitations | Lunesta        |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |
|                             | Etizolam       |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>    | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Sep-2013                 | 9560372        | EXPEDITED (15-DAY) |                    | HO              | CN-FRI-1000049264    |                      | 53 YR           | Female       | CHN            |
| <u>Preferred Term</u>       | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Back Pain; Back Pain;       | Lexapro        |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
| Blood Pressure Increased;   |                |                    |                    |                 |                      |                      |                 |              |                |

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|                                                                                           |         |   |      |                                 |              |
|-------------------------------------------------------------------------------------------|---------|---|------|---------------------------------|--------------|
| Chest Discomfort;<br>Decreased Appetite;<br>Discomfort; Insomnia;<br>Palpitations; Tremor | Lexapro | S | Oral | 1 Tab/2 Days To 1 Tab/5<br>Days | Forest       |
|                                                                                           | Lexapro | S | Oral | 1 Tab/5days                     | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Sep-2013              | 9562285       | EXPEDITED (15-DAY) | HO                 |                 | FR-FRI-1000049272    |                      | 73 YR      | Male       | FRA            |

  

| <u>Preferred Term</u>                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Dizziness; Drug<br>Interaction; Orthostatic<br>Hypotension | Escitalopram   |              |            | S           | Oral         | 1 Df               |                 | Forest       |
|                                                            | Lexomil Roche  |              |            | S           | Oral         | 3 Df               |                 | Not Reported |
|                                                            | Haldol         |              |            | S           | Oral         | 2 Df               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Sep-2013              | 9563034       | EXPEDITED (15-DAY) | CA, DE             |                 | US-FRI-1000049050    |                      | < 1 DAY    | Male       | USA            |

  

| <u>Preferred Term</u>                                                                                                                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|------------|
| Atrioventricular Septal<br>Defect; Hypoplastic Left<br>Heart Syndrome;<br>Pulmonary Hypertension;<br>Pulmonary Vein Stenosis;<br>Ventricular Septal Defect | Lexapro        |              |            | S           | Transplacental |                    |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Sep-2013              | 9563377       | EXPEDITED (15-DAY) | OT                 |                 | PHHY2013AU105976     |                      |            | Female     | AUS            |

  

| <u>Preferred Term</u>                  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Antipsychotic Drug Level<br>Increased; | Clozapine      |              |            | S           |              | Unk                |                 | Novartis     |
| Electrocardiogram Qt<br>Prolonged      | Escitalopram   |              |            | S           |              | Unk                |                 | Not Reported |
|                                        | Thyroxin       |              |            | S           |              | Unk                |                 | Not Reported |
|                                        | Epilim         |              |            | C           |              | Unk                |                 | Not Reported |

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| <u>FDA Received Date</u>                | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------|---------------------|--------------------|--------------------|-----------------|-----------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 30-Sep-2013                             | 9564996             | EXPEDITED (15-DAY) |                    | HO              | FR-JNJFOC-20130916638                               |                      | 89 YR           | Female       | FRA            |
| <u>Preferred Term</u>                   | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Disturbance In Attention;<br>Somnolence | Contramal           |                    |                    | S               | Oral                                                |                      |                 | Not Reported |                |
|                                         | Seroplex            |                    |                    | S               | Oral                                                |                      |                 | Not Reported |                |
|                                         | Trolamine           |                    |                    | C               | Topical                                             |                      |                 | Not Reported |                |
|                                         | Loperamide          |                    |                    | C               | Oral                                                |                      |                 | Not Reported |                |
|                                         | Atarax              |                    |                    | C               | Oral                                                |                      |                 | Not Reported |                |
|                                         | Lovenox             |                    |                    | C               | Parenteral                                          |                      |                 | Not Reported |                |
|                                         | Mopral              |                    |                    | C               | Oral                                                |                      |                 | Not Reported |                |
|                                         | Diprosone           |                    |                    | C               | Topical                                             |                      |                 | Not Reported |                |
|                                         | Diffu K             |                    |                    | C               | Oral                                                |                      |                 | Not Reported |                |
|                                         | Gutron              |                    |                    | C               | Oral                                                |                      |                 | Not Reported |                |
|                                         | Fludrocortisone     |                    |                    | C               | Oral                                                |                      |                 | Not Reported |                |
|                                         | Dafalgan            |                    |                    | C               | Oral                                                |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Sep-2013                             | 9565958             | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000049245                                   |                      | 85 YR           | Male         | FRA            |
| <u>Preferred Term</u>                   | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;<br>Hyponatraemia      | Escitalopram        |                    |                    | S               | Oral                                                | 1 Df                 |                 | Forest       |                |
|                                         | Fludex (Indapamide) |                    |                    | S               | Oral                                                | 1 Df                 |                 | Not Reported |                |
|                                         | Valdoxan            |                    |                    | S               | Oral                                                | 2 Df                 |                 | Not Reported |                |
|                                         | Seresta             |                    |                    | C               | Oral                                                | 3 Df                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Sep-2013                             | 9566306             | EXPEDITED (15-DAY) |                    | HO, LT, OT      | DE-ROXANE<br>LABORATORIES, INC.-<br>2013-RO-01596RO |                      | 31 YR           | Male         | DEU            |

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| <u>Preferred Term</u>                                                                                                                                                                                               | <u>Product</u>   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                             | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|--------------|------------|-------------|------------------------------------------|--------------------|-----------------|--------------|
| Abdominal Pain Upper;<br>Electrocardiogram Qt<br>Prolonged; Faecaloma;<br>Generalised Tonic-Clonic<br>Seizure; Hypokalaemia;<br>Hypomagnesaemia; Pulse<br>Absent; Torsade De<br>Pointes; Ventricular<br>Tachycardia | Methadone        |              |            | S           | Oral                                     |                    |                 | Roxane       |
|                                                                                                                                                                                                                     | Ondansetron      |              |            | S           | Intravenous (not<br>otherwise specified) |                    |                 | Not Reported |
|                                                                                                                                                                                                                     | Escitalopram     |              |            | S           |                                          |                    |                 | Not Reported |
|                                                                                                                                                                                                                     | Esomeprazole     |              |            | C           | Intravenous (not<br>otherwise specified) |                    |                 | Not Reported |
|                                                                                                                                                                                                                     | Butylscopolamine |              |            | C           | Intravenous (not<br>otherwise specified) |                    |                 | Not Reported |
|                                                                                                                                                                                                                     | Metamizole       |              |            | C           | Intravenous (not<br>otherwise specified) |                    |                 | Not Reported |
|                                                                                                                                                                                                                     | Paracetamol      |              |            | C           | Intravenous (not<br>otherwise specified) |                    |                 | Not Reported |
|                                                                                                                                                                                                                     | Pethidine        |              |            | C           | Intravenous (not<br>otherwise specified) |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Sep-2013              | 9573331       | DIRECT           | Y                  | HO              |                      |                      | 64 YR      | Female     | USA            |

| <u>Preferred Term</u>                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction; Torsade<br>De Pointes | Lexapro        |              |            | S           | Oral         | 1 Tablet           |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Sep-2013              | 9579977       | DIRECT           |                    | OT              |                      |                      | 39 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Depression; Disease<br>Recurrence; Panic Attack;<br>Product Substitution Issue | Escitalopram   |              |            | S           | Oral         | 1 Pill             |                 | Teva       |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Sep-2013              | 9580235       | EXPEDITED (15-DAY) | Y                  | OT              | 2013P1019558         |                      |            | Unknown    | FRA            |

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| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Adverse Drug Reaction; | Escitalopram   |              |            | S           |              |                    |                 | Not Reported |
| Drug Interaction       | Furosemide     |              |            | S           |              |                    |                 | Not Reported |
|                        | Bromazepam     |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------------|----------------------|------------|------------|----------------|
| 01-Oct-2013              | 9070945       | EXPEDITED (15-DAY) |                    | HO              | JP-<br>GLAXOSMITHKLINE-<br>B0845771A |                      | 78 YR      | Female     | JPN            |

| <u>Preferred Term</u>       | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u>      |
|-----------------------------|---------------------------|--------------|------------|-------------|--------------|---------------------|-----------------|-----------------|
| Alanine Aminotransferase    | Lamictal                  |              |            | S           | Oral         | 25mg Per Day        |                 | Glaxosmithkline |
| Increased; Arthralgia;      | Lamictal                  |              |            | S           | Oral         | 50mg Per Day        |                 | Glaxosmithkline |
| Aspartate                   | Paxil                     |              |            | S           | Oral         | 12.5mg Per Day      |                 | Glaxosmithkline |
| Aminotransferase            | Tramcet                   |              |            | S           | Oral         |                     |                 | Not Reported    |
| Increased; Blood Creatine   | Tramcet                   |              |            | S           | Oral         |                     |                 | Not Reported    |
| Phosphokinase Increased;    | Lexapro                   |              |            | S           | Oral         | 10mg Per Day        |                 | Not Reported    |
| Decreased Appetite; Drug    | Lyrica                    |              |            | C           | Oral         | 75mg Twice Per Day  |                 | Not Reported    |
| Eruption; Drug Interaction; | Milmag                    |              |            | C           | Oral         |                     |                 | Glaxosmithkline |
| Drug Reaction With          | Gasrick D                 |              |            | C           | Oral         |                     |                 | Not Reported    |
| Eosinophilia And Systemic   | Meilax                    |              |            | C           | Oral         |                     |                 | Not Reported    |
| Symptoms; Erythema          | Lithium Carbonate         |              |            | C           | Oral         | 100mg Twice Per Day |                 | Glaxosmithkline |
| Multiforme; Gait            | Rilmazafone Hydrochloride |              |            | C           | Oral         | 2mg Per Day         |                 | Not Reported    |
| Disturbance; Generalised    | Thyradin S                |              |            | C           | Oral         | 75mcg Per Day       |                 | Glaxosmithkline |
| Erythema;                   |                           |              |            |             |              |                     |                 |                 |
| Hypersensitivity;           |                           |              |            |             |              |                     |                 |                 |
| Inappropriate Schedule Of   |                           |              |            |             |              |                     |                 |                 |
| Product Administration;     |                           |              |            |             |              |                     |                 |                 |
| Malaise; Nasopharyngitis;   |                           |              |            |             |              |                     |                 |                 |
| Nausea; Ocular              |                           |              |            |             |              |                     |                 |                 |
| Hyperaemia;                 |                           |              |            |             |              |                     |                 |                 |
| Oropharyngeal Pain; Pain    |                           |              |            |             |              |                     |                 |                 |
| In Extremity; Pruritus;     |                           |              |            |             |              |                     |                 |                 |
| Pyrexia; Rash; Rash         |                           |              |            |             |              |                     |                 |                 |
| Generalised; Red Blood      |                           |              |            |             |              |                     |                 |                 |
| Cell Count Decreased;       |                           |              |            |             |              |                     |                 |                 |
| Restlessness; Skin          |                           |              |            |             |              |                     |                 |                 |
| Disorder; Urticaria;        |                           |              |            |             |              |                     |                 |                 |
| Vomiting; White Blood Cell  |                           |              |            |             |              |                     |                 |                 |
| Count Decreased             |                           |              |            |             |              |                     |                 |                 |

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| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Oct-2013              | 9499091       | EXPEDITED (15-DAY) |                    | HO, OT          | US-RB-057907-13      |                      | 21 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>             | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>        |
|-------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------------------|-------------------------------|-----------------|-------------------|
| Affect Lability; Anxiety; Depression; Drug Abuse; Drug Dependence; Insomnia; Overdose; Seizure; Suicidal Ideation | Suboxone Film  |              |            | S           | Sublingual               | Suboxone Film                 |                 | Reckitt Benckiser |
|                                                                                                                   | Suboxone Film  |              |            | S           | Sublingual               | Suboxone Film                 |                 | Reckitt Benckiser |
|                                                                                                                   | Xanax          |              |            | S           | Unknown                  | Dosing Details Unknown        |                 | Not Reported      |
|                                                                                                                   | Ambien         |              |            | S           | Oral                     | Dosing Details Unknown; Daily |                 | Not Reported      |
|                                                                                                                   | Marijuana      |              |            | S           | Respiratory (inhalation) | Dosing Details Unknown        |                 | Not Reported      |
|                                                                                                                   | Klonopin       |              |            | S           | Oral                     |                               |                 | Not Reported      |
|                                                                                                                   | Prozac         |              |            | S           | Unknown                  | Dosing Details Unknown        |                 | Not Reported      |
|                                                                                                                   | Lexapro        |              |            | S           | Unknown                  | Dosing Details Unknown        |                 | Not Reported      |
|                                                                                                                   | Cymbalta       |              |            | S           | Unknown                  | Dosing Details Unknown        |                 | Not Reported      |
|                                                                                                                   | Zoloft         |              |            | S           | Oral                     | Dosing Details Unknown;       |                 | Not Reported      |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Oct-2013              | 9510469       | EXPEDITED (15-DAY) |                    | HO              | CH-TEVA-428982ISR    |                      | 83 YR      | Female     | CHE            |

| <u>Preferred Term</u>           | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                 | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------|------------------------|--------------|------------|-------------|--------------|----------------------------------------------------|-----------------|--------------|
| Drug Interaction; Hyponatraemia | Comiloid-Mepha         |              |            | S           | Oral         | 1 Dosage Forms Daily; Dosing Regimen: 1-0-0-0      |                 | Barr         |
|                                 | Remeron                |              |            | S           | Oral         | 45 Milligram Daily;                                |                 | Not Reported |
|                                 | Cipralex               |              |            | S           | Oral         | 20 Milligram Daily;                                |                 | Not Reported |
|                                 | Pantozol (Switzerland) |              |            | C           | Unknown      |                                                    |                 | Not Reported |
|                                 | Pradif                 |              |            | C           | Unknown      | Pradif Was Discontinued During The Hospitalization |                 | Not Reported |
|                                 | Ciproxin               |              |            | C           | Unknown      |                                                    |                 | Not Reported |
|                                 | Lyrica                 |              |            | C           | Unknown      |                                                    |                 | Not Reported |

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

|                                          |   |         |              |
|------------------------------------------|---|---------|--------------|
| Aspirin                                  | C | Unknown | Not Reported |
| Imovane                                  | C | Unknown | Not Reported |
| Calcium + D3                             | C | Unknown | Not Reported |
| Paspertin [Metoclopramide Hydrochloride] | C | Unknown | Not Reported |
| Perenterol                               | C | Unknown | Not Reported |

| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 01-Oct-2013                | 9580214        | DIRECT           | Y                  |                 |                      |                      | 55 YR           | Female       | USA            |
| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Product Substitution Issue | Escitalopram   |                  |                    | S               | Oral                 | 1/2 Tabl             | 1 YR            | Not Reported |                |
|                            | Oxycontin      |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                            | Ibuprofen      |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                            | Ranitidine     |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                            | Albuterol      |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                            | Vicodin        |                  |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 01-Oct-2013                                                             | 9580904        | DIRECT           |                    | OT              |                      |                      | 21 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Condition Aggravated; Depression; Hallucination; Sleep Talking | Escitalopram   |                  |                    | S               |                      | 1 Once Daily         |                 | Not Reported |                |

| <u>FDA Received Date</u>                    | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------|----------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 02-Oct-2013                                 | 9031974        | EXPEDITED (15-DAY) |                    | CA, DE, LT, OT  | US-PFIZER INC-2013030509 |                      |                 | Male         | USA            |
| <u>Preferred Term</u>                       | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrial Septal Defect; Cleft Lip And Palate; | Zoloft         |                    |                    | S               | Transplacental           | Unk                  |                 | Pfizer       |                |
| Cytogenetic Abnormality;                    | Lexapro        |                    |                    | S               | Transplacental           | Unk                  |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Double Outlet Right Ventricle; Exomphalos; Maternal Exposure Timing Unspecified; Neonatal Aspiration; Neural Tube Defect; Newborn Persistent Pulmonary Hypertension; Pulmonary Valve Stenosis; Talipes; Transposition Of The Great Vessels; Ventricular Septal Defect

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Oct-2013              | 9507389       | EXPEDITED (15-DAY) |                    | OT              | CA-FRI-1000048443    |                      | 4 YR       | Male       | CAN            |

| <u>Preferred Term</u>                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u> |
|-----------------------------------------|----------------|--------------|------------|-------------|--------------|---------------------------------------|-----------------|------------|
| Accidental Exposure To Product By Child | Escitalopram   |              |            | S           | Oral         | Overdose: Escitalopram (Around 50 Mg) |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Oct-2013              | 9580161       | EXPEDITED (15-DAY) |                    | OT              | PHHY2013US107278     |                      | 30 YR      | Male       | USA            |

| <u>Preferred Term</u>                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Akathisia; Drug Interaction; Dysstasia; Insomnia | Aripiprazole   |              |            | S           |              | 25 Mg, Unk         |                 | Not Reported |
|                                                  | Quetiapine     |              |            | S           |              | 450 Mg, Unk        |                 | Novartis     |
|                                                  | Buspirone      |              |            | S           |              | 30 Mg, Unk         |                 | Not Reported |
|                                                  | Clonazepam     |              |            | S           |              | 3 Mg, Unk          |                 | Not Reported |
|                                                  | Lexapro        |              |            | S           |              | 20 Mg, Unk         |                 | Not Reported |
|                                                  | Asenapine      |              |            | S           | Sublingual   | 5 Mg, Bid          |                 | Not Reported |
|                                                  | Asenapine      |              |            | S           |              | 5 M Daily          |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Oct-2013              | 9581393       | EXPEDITED (15-DAY) |                    | OT              | US-FRI-1000049275    |                      |            | Male       | USA            |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                                                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|-----------------------------------|-----------------|--------------|----------------|
| Atrial Septal Defect;<br>Congenital Vesicoureteric<br>Reflux; Ectopic Kidney;<br>Single Functional Kidney                           | Lexapro        |                    |                    | S               | Transplacental       |                                   |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Oct-2013                                                                                                                         | 9431470        | EXPEDITED (15-DAY) |                    | HO, OT          | US-FRI-1000046980    |                                   | < 1 DAY         | Male         | USA            |
| <u>Preferred Term</u>                                                                                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |                |
| Anaemia Neonatal;                                                                                                                   | Lexapro        |                    |                    | S               |                      |                                   |                 | Forest       |                |
| Bradycardia; Bronchiolitis;                                                                                                         | Prilosec       |                    |                    | C               | Transplacental       |                                   |                 | Not Reported |                |
| Croup Infectious;                                                                                                                   | Macrobid       |                    |                    | C               | Transplacental       |                                   |                 | Not Reported |                |
| Laryngomalacia; Metabolic<br>Acidosis; Nasopharyngitis;<br>Neurogenic Bladder;<br>Spina Bifida; Talipes;<br>Urinary Tract Infection | Tylenol        |                    |                    | C               | Transplacental       |                                   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Oct-2013                                                                                                                         | 9586383        | EXPEDITED (15-DAY) |                    | HO, OT          | PHHY2013GR106282     |                                   | 42 YR           | Female       | GRC            |
| <u>Preferred Term</u>                                                                                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Anxiety;                                                                                                                | Oxcarbazepine  |                    |                    | S               |                      | Unk                               |                 | Novartis     |                |
| Confusional State;                                                                                                                  | Oxcarbazepine  |                    |                    | S               |                      | 1200 Mg, Unk                      |                 | Novartis     |                |
| Depression; Fear;                                                                                                                   | Clozapine      |                    |                    | S               |                      | 300 Mg, Unk                       |                 | Not Reported |                |
| Generalised Tonic-Clonic<br>Seizure; Hallucination,<br>Auditory; Obsessive<br>Thoughts; Obsessive-<br>Compulsive Disorder;          | Clomipramine   |                    |                    | S               |                      | Unk                               |                 | Not Reported |                |
| Persecutory Delusion;                                                                                                               | Valproic Acid  |                    |                    | S               |                      |                                   |                 | Not Reported |                |
| Self-Injurious Ideation;                                                                                                            | Maprotiline    |                    |                    | S               |                      |                                   |                 | Not Reported |                |
| Suicidal Ideation; Suicide<br>Attempt                                                                                               | Paroxetine     |                    |                    | S               |                      | Unk Unk, Unk                      |                 | Not Reported |                |
|                                                                                                                                     | Venlafaxine    |                    |                    | S               |                      |                                   |                 | Not Reported |                |
|                                                                                                                                     | Propranolol    |                    |                    | S               |                      | 20 Df, Unk                        |                 | Not Reported |                |
|                                                                                                                                     | Quetiapine     |                    |                    | S               |                      | Unk 600 To 800 Mg For 2<br>Months |                 | Not Reported |                |

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

|                             |   |                                                 |              |
|-----------------------------|---|-------------------------------------------------|--------------|
| Lorazepam                   | S | Unk Unk, Unk                                    | Not Reported |
| Risperidone                 | S | Unk 2 To 4 Mg For Short<br>Periods              | Not Reported |
| Ziprasidone                 | S |                                                 | Not Reported |
| Amitriptyline, Perphenazine | S | Unk                                             | Not Reported |
| Escitalopram                | S | Unk                                             | Not Reported |
| Fluoxetine                  | S | Unk                                             | Not Reported |
| Fluoxetine                  | S | 40 Mg, Upto                                     | Not Reported |
| Gabapentin                  | S | Unk                                             | Not Reported |
| Pregabalin                  | S | Unk Unk, Unk                                    | Not Reported |
| Pregabalin                  | S | 225 Mg, Upto                                    | Not Reported |
| Pregabalin                  | S | 300 Mg, Unk                                     | Not Reported |
| Amisulpride                 | S | 100 Mg, Unk                                     | Not Reported |
| Sertraline                  | S | 150 Mg, Unk                                     | Not Reported |
| Sertraline                  | S | 300 Mg, Unk                                     | Not Reported |
| Mirtazapine                 | S | Unk                                             | Not Reported |
| Topiramate                  | S | 200 Mg, Unk                                     | Not Reported |
| Alprazolam                  | S |                                                 | Not Reported |
| Haloperidol                 | S | Unk                                             | Not Reported |
| Diazepam                    | S | Unk                                             | Not Reported |
| Thioridazine                | S | Unk                                             | Not Reported |
| Trifluoperazine             | S | Unk Unk, Unk                                    | Not Reported |
| Nefazodone                  | S | Unk                                             | Not Reported |
| Fluvoxamine                 | S | Unk                                             | Not Reported |
| Olanzapine                  | S | Unk                                             | Not Reported |
| Levomepromazine             | S | Intravenous (not<br>otherwise specified)<br>Unk | Not Reported |
| Duloxetine                  | S | Unk                                             | Not Reported |
| Zuclopenthixol              | S | Unk                                             | Not Reported |
| Biperiden                   | S | Unk                                             | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                                                        |                |                    |                    |                 |                            |                      |                 |            |                |  |
|----------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|------------|----------------|--|
| Clorazepate                                                                            |                |                    | S                  |                 |                            | Unk                  |                 |            | Not Reported   |  |
| <u>FDA Received Date</u>                                                               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |  |
| 03-Oct-2013                                                                            | 9586402        | EXPEDITED (15-DAY) |                    | HO              | FR-ASTRAZENECA-2013SE72343 |                      | 31 YR           | Female     | FRA            |  |
| <u>Preferred Term</u>                                                                  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |  |
| Hypoalbuminaemia;<br>Hypogammaglobulinaemia<br>; Pancreatitis Acute;<br>Thrombocytosis | Entocort       |                    |                    | S               | Oral                       |                      |                 |            | Not Reported   |  |
|                                                                                        | Seroplex       |                    |                    | S               | Oral                       |                      |                 |            | Not Reported   |  |
|                                                                                        | Imurel         |                    |                    | S               | Oral                       |                      |                 |            | Not Reported   |  |
|                                                                                        | Pentasa        |                    |                    | S               | Oral                       |                      |                 |            | Not Reported   |  |
|                                                                                        | Biprofenid     |                    |                    | S               | Oral                       |                      |                 |            | Not Reported   |  |
| <u>FDA Received Date</u>                                                               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |  |
| 03-Oct-2013                                                                            | 9587645        | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000049277          |                      | < 1 DAY         | Male       | USA            |  |
| <u>Preferred Term</u>                                                                  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |  |
| Aortic Valve Disease;<br>Atrial Septal Defect;<br>Ventricular Septal Defect            | Lexapro        |                    |                    | S               | Transplacental             |                      |                 |            | Forest         |  |
| <u>FDA Received Date</u>                                                               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |  |
| 03-Oct-2013                                                                            | 9587786        | EXPEDITED (15-DAY) |                    | HO, OT          | US-FRI-1000046979          |                      | 31 YR           | Female     | USA            |  |
| <u>Preferred Term</u>                                                                  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |  |
| Breech Presentation;<br>Exposure During<br>Pregnancy; Hypertension;<br>Oligohydramnios | Lexapro        |                    |                    | S               |                            |                      |                 |            | Forest         |  |
|                                                                                        | Prilosec       |                    |                    | C               |                            |                      |                 |            | Not Reported   |  |
|                                                                                        | Macrobid       |                    |                    | C               |                            |                      |                 |            | Not Reported   |  |
|                                                                                        | Tylenol        |                    |                    | C               |                            |                      |                 |            | Not Reported   |  |
| <u>FDA Received Date</u>                                                               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |  |
| 04-Oct-2013                                                                            | 9565067        | EXPEDITED (15-DAY) |                    | OT              | JP-FRI-1000049260          |                      | 30 YR           | Male       | JPN            |  |
| <u>Preferred Term</u>                                                                  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |  |

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

|                            |          |   |      |                  |              |
|----------------------------|----------|---|------|------------------|--------------|
| Overdose; Physical Assault | Lexapro  | S | Oral | 210 Mg           | Forest       |
|                            | Depakene | C | Oral | Overdose: 800 Mg | Not Reported |
|                            | Silece   | C |      | Overdose: 2 Mg   | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Oct-2013              | 9596902       | EXPEDITED (15-DAY) |                    | OT              | GB-FRI-1000049458    |                      | 22 YR      | Female     | GBR            |

| <u>Preferred Term</u>                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>  | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------|----------------|--------------|------------|-------------|---------------|--------------------|-----------------|--------------|
| Abnormal Dreams;                         | Escitalopram   |              |            | S           | Oral          | 10 Mg              |                 | Forest       |
| Agitation; Confusional State; Dizziness; | Depo-Provera   |              |            | C           | Intramuscular |                    |                 | Not Reported |
| Hyperhidrosis; Mydriasis; Paraesthesia;  |                |              |            |             |               |                    |                 |              |
| Restlessness; Vaginal Haemorrhage        |                |              |            |             |               |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Oct-2013              | 9601850       | EXPEDITED (15-DAY) |                    | OT              | IT-ACCORD-019666     |                      |            | Unknown    | ITA            |

| <u>Preferred Term</u>                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Foetal Exposure During Pregnancy; Underweight | Alprazolam     |              |            | S           | Transplacental |                    |                 | Not Reported |
|                                               | Escitalopram   |              |            | S           | Transplacental |                    |                 | Accord       |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Oct-2013              | 9603363       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000049608    |                      | 29 YR      | Male       | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Ischaemic Stroke      | Escitalopram   |              |            | S           | Oral         |                    |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Oct-2013              | 9603374       | EXPEDITED (15-DAY) |                    | DE              | FR-FRI-1000049609    |                      | 40 YR      | Male       | FRA            |

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

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

|                        |                         |   |      |                                    |              |
|------------------------|-------------------------|---|------|------------------------------------|--------------|
| Labelled Drug-Drug     | Escitalopram            | S | Oral | 20 Mg                              | Forest       |
| Interaction Medication | Kestine                 | S |      |                                    | Not Reported |
| Error; Sudden Death    | Psychotropic Agents Nos | C |      | Psychotropic Agent<br>Overdose Nos | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 08-Oct-2013              | 9170541       | EXPEDITED (15-DAY) |                    | CA, HO, OT      | US-JNJFOC-20130310451 |                      |            | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Chordee; Deformity;<br>Developmental Delay;<br>Drug Withdrawal<br>Syndrome Neonatal;<br>Emotional Distress;<br>Encephalopathy;<br>Eustachian Tube<br>Dysfunction; Muscular<br>Weakness; Otitis Media<br>Acute; Pain; Penile<br>Torsion; Periventricular<br>Leukomalacia; Premature<br>Baby; Prepuce<br>Redundant; Skull<br>Malformation; Social<br>Avoidant Behaviour;<br>Tachypnoea | Topamax           |              |            | S           | Transplacental |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                      | Miralax           |              |            | S           | Transplacental |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                      | Dulcolax          |              |            | S           | Transplacental |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                      | Lexapro           |              |            | S           | Transplacental |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                      | Reglan            |              |            | S           | Transplacental |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                      | Zofran            |              |            | S           | Transplacental |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                      | Methadone         |              |            | S           | Transplacental |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                      | Percocet          |              |            | S           | Transplacental |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                      | Lortab            |              |            | S           | Transplacental |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                      | Cymbalta          |              |            | S           | Transplacental |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                      | Stadol            |              |            | S           | Transplacental |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                      | Dilaudid          |              |            | S           | Transplacental |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                      | Neurontin         |              |            | S           | Transplacental |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                      | Protonix          |              |            | S           | Transplacental |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                      | Bentyl            |              |            | S           | Transplacental |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                      | Prenatal Vitamins |              |            | C           | Transplacental |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Oct-2013              | 9499006       | EXPEDITED (15-DAY) |                    | LT              | JP-FRI-1000048361    |                      | 67 YR      | Female     | JPN            |

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

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

|                      |            |   |      |        |              |
|----------------------|------------|---|------|--------|--------------|
| Electrocardiogram Qt | Lexapro    | S | Oral | 10 Mg  | Forest       |
| Prolonged; Loss Of   | Rize       | C | Oral | 15 Mg  | Not Reported |
| Consciousness;       | Crestor    | C | Oral | 2.5 Mg | Not Reported |
| Respiratory Arrest   | Co-Dio     | C | Oral | 1 Df   | Not Reported |
|                      | Alinamin-F | C | Oral | 50 Mg  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------------------------------------|----------------------|------------|------------|----------------|
| 08-Oct-2013              | 9605677       | EXPEDITED (15-DAY) |                    | OT              | BR-B.I.<br>PHARMACEUTICALS,I<br>NC./RIDGEFIELD-2013-<br>BI-31 |                      | 85 YR      | Male       | BRA            |

| <u>Preferred Term</u>       | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>           |
|-----------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------|
| Sialoceles; Suicide Attempt | Secotex                   |              |            | S           | Oral         |                    |                 | Boehringer Ingelheim |
|                             | Escitalopram              |              |            | S           | Oral         | 240 Mg             |                 | Not Reported         |
|                             | Oxibutinina Hydrochloride |              |            | S           | Oral         |                    |                 | Not Reported         |
|                             | Valsatana                 |              |            | S           |              |                    |                 | Not Reported         |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Oct-2013              | 9605928       | EXPEDITED (15-DAY) |                    | DS, HO          | FI-FRI-1000049751    |                      | 27 YR      | Female     | FIN            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Withdrawal Syndrome   | Escitalopram   |              |            | S           | Oral         | 2.5 - 15 Mg Daily  |                 | Forest     |
|                       | Escitalopram   |              |            | S           |              |                    |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Oct-2013              | 9607877       | DIRECT           |                    | OT              |                      |                      | 33 YR      | Female     | USA            |

| <u>Preferred Term</u>                   | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------|-------------------|--------------|------------|-------------|--------------|---------------------------------------|-----------------|--------------|
| Migraine; Product<br>Substitution Issue | Escitalopram 20mg |              |            | S           | Oral         | 45 Pills Once Daily Taken<br>By Mouth |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <a href="#">FDA Received Date</a>                                                                                                       | <a href="#">Case #</a>                     | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 08-Oct-2013                                                                                                                             | 9611777                                    | NON-EXPEDITED             | Y                           | OT                       | 2013-0007                     |                               |                          | Unknown             | TUR                     |
| <a href="#">Preferred Term</a>                                                                                                          | <a href="#">Product</a>                    | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Blood Triglycerides Increased                                                                                                           | Escitalopram                               |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                                       | <a href="#">Case #</a>                     | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 08-Oct-2013                                                                                                                             | 9612518                                    | EXPEDITED (15-DAY)        | Y                           | HO, OT                   | AUR-APL-2013-08321            |                               | 54 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                                                                          | <a href="#">Product</a>                    | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Condition Aggravated; Depression                                                                                                        | Escitalopram (Escitalopram)                |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
|                                                                                                                                         | Topiramate (Topiramate)                    |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
|                                                                                                                                         | Valproate (Valproate Sodium)               |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
|                                                                                                                                         | Flunarizine (Flunarizine)                  |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                                       | <a href="#">Case #</a>                     | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 08-Oct-2013                                                                                                                             | 9613517                                    | EXPEDITED (15-DAY)        | Y                           | OT                       | AUR-APL-2013-08060            |                               | 22 YR                    | Female              | GBR                     |
| <a href="#">Preferred Term</a>                                                                                                          | <a href="#">Product</a>                    | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Abnormal Dreams; Agitation; Confusional State; Dizziness; Erythema; Hyperhidrosis; Mydriasis; Restlessness; Tremor; Vaginal Haemorrhage | Escitalopram                               |                           |                             | S                        | Oral                          |                               |                          | Not Reported        |                         |
|                                                                                                                                         | Depo-Provera (Medroxyprogesterone Acetate) |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                                       | <a href="#">Case #</a>                     | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 09-Oct-2013                                                                                                                             | 9609318                                    | EXPEDITED (15-DAY)        |                             | HO                       | US-FRI-1000049715             |                               |                          | Male                | USA                     |
| <a href="#">Preferred Term</a>                                                                                                          | <a href="#">Product</a>                    | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Abscess Limb; Cellulitis                                                                                                                | Lexapro                                    |                           |                             | S                        | Oral                          | 10 Mg                         |                          | Forest              |                         |

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

|                                                |                                   |                    |                    |                 |                                       |                      |                 |                        |                |
|------------------------------------------------|-----------------------------------|--------------------|--------------------|-----------------|---------------------------------------|----------------------|-----------------|------------------------|----------------|
| Sotalol                                        |                                   |                    | C                  |                 |                                       | 160 Mg               |                 |                        | Not Reported   |
| <u>FDA Received Date</u>                       | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>             | <u>Country</u> |
| 09-Oct-2013                                    | 9610017                           | EXPEDITED (15-DAY) |                    | OT              | AU-FRI-1000049832                     |                      |                 | Male                   | AUS            |
| <u>Preferred Term</u>                          | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>             |                |
| Seizure                                        | Escitalopram<br>Quetiapine        |                    |                    | S<br>S          |                                       |                      |                 | Forest<br>Not Reported |                |
| <u>FDA Received Date</u>                       | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>             | <u>Country</u> |
| 09-Oct-2013                                    | 9610642                           | EXPEDITED (15-DAY) |                    | HO              | PHHY2013FR111389                      |                      | 73 YR           | Female                 | FRA            |
| <u>Preferred Term</u>                          | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>             |                |
| Blister; Rash Maculo-Papular; Skin Exfoliation | Loxen (Nicardipine Hydrochloride) |                    |                    | S               | Oral                                  | 20 Mg, Tid           |                 | Not Reported           |                |
|                                                | Paracetamol Sandoz                |                    |                    | S               | Oral                                  | 1 G, Tid             |                 | Not Reported           |                |
|                                                | Inexium//Esomeprazole             |                    |                    | S               | Oral                                  | 20 Mg, Qd            |                 | Not Reported           |                |
|                                                | Magnesium Lasilix                 |                    |                    | S               | Oral                                  | 20 Mg, Qd            |                 | Not Reported           |                |
|                                                | Seroplex                          |                    |                    | S               | Oral                                  | 10 Mg, Qd            |                 | Not Reported           |                |
|                                                | Atarax                            |                    |                    | S               | Oral                                  | 100 Mg, Qd           |                 | Not Reported           |                |
|                                                | Heparine                          |                    |                    | S               | Intravenous (not otherwise specified) | 170 Mg, Daily        |                 | Not Reported           |                |
|                                                | Umuline                           |                    |                    | S               | Subcutaneous                          | Unk Unk, Unk         |                 | Not Reported           |                |
| <u>FDA Received Date</u>                       | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>             | <u>Country</u> |
| 09-Oct-2013                                    | 9610924                           | EXPEDITED (15-DAY) |                    | OT              | DE-FRI-1000049831                     |                      |                 | Male                   | DEU            |
| <u>Preferred Term</u>                          | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>             |                |
| Coma                                           | Escitalopram                      |                    |                    | S               | Oral                                  | 1 Df                 |                 | Forest                 |                |



# FDA Adverse Event Reporting System

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| <u>FDA Received Date</u>                                                                                                                                                 | <u>Case #</u>                                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>                            | <u>Age</u>      | <u>Sex</u>               | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------|--------------------|--------------------|-----------------|------------------------------------------|-------------------------------------------------|-----------------|--------------------------|----------------|
| 09-Oct-2013                                                                                                                                                              | 9610960                                                | EXPEDITED (15-DAY) |                    | HO, OT          | BR-FRI-1000049833                        |                                                 | 25 YR           | Female                   | BRA            |
| <u>Preferred Term</u>                                                                                                                                                    | <u>Product</u>                                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>                              | <u>Duration</u> | <u>Mfr</u>               |                |
| Asthenia; Hypothermia;<br>Somnolence; Syncope;<br>Tremor                                                                                                                 | Lexapro<br>Diazepam                                    |                    |                    | S<br>C          | Oral<br>Oral                             | 5 Mg<br>5 Mg                                    |                 | Forest<br>Not Reported   |                |
| <u>FDA Received Date</u>                                                                                                                                                 | <u>Case #</u>                                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>                            | <u>Age</u>      | <u>Sex</u>               | <u>Country</u> |
| 09-Oct-2013                                                                                                                                                              | 9614750                                                | DIRECT             |                    |                 |                                          |                                                 | 44 YR           | Female                   | USA            |
| <u>Preferred Term</u>                                                                                                                                                    | <u>Product</u>                                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>                              | <u>Duration</u> | <u>Mfr</u>               |                |
| Abnormal Dreams;<br>Affective Disorder;<br>Anxiety; Gastrointestinal<br>Disorder; Nausea; Night<br>Sweats; Poor Quality<br>Sleep; Product<br>Substitution Issue; Vertigo | Escitalopram                                           |                    |                    | S               | Oral                                     | 1 Pill Once Daily Taken By<br>Mouth             |                 | Mylan                    |                |
| <u>FDA Received Date</u>                                                                                                                                                 | <u>Case #</u>                                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>                            | <u>Age</u>      | <u>Sex</u>               | <u>Country</u> |
| 09-Oct-2013                                                                                                                                                              | 9617795                                                | EXPEDITED (15-DAY) | Y                  | OT              | IT-MACLEODS<br>PHARMA-000143             |                                                 |                 | Unknown                  | ITA            |
| <u>Preferred Term</u>                                                                                                                                                    | <u>Product</u>                                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>                              | <u>Duration</u> | <u>Mfr</u>               |                |
| Low Birth Weight Baby;<br>Maternal Drugs Affecting<br>Foetus                                                                                                             | Escitalopram (Escitalopram)<br>Alprazolam (Alprazolam) |                    |                    | S<br>S          | Transplacental<br>Transplacental         |                                                 |                 | Macleods<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                 | <u>Case #</u>                                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>                            | <u>Age</u>      | <u>Sex</u>               | <u>Country</u> |
| 10-Oct-2013                                                                                                                                                              | 7943324                                                | EXPEDITED (15-DAY) |                    | HO, OT          | CA-ROCHE-624758                          |                                                 | 31 YR           | Female                   | CAN            |
| <u>Preferred Term</u>                                                                                                                                                    | <u>Product</u>                                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>                              | <u>Duration</u> | <u>Mfr</u>               |                |
| Bradycardia; Neutropenia;<br>Pleural Effusion                                                                                                                            | Bevacizumab                                            |                    |                    | S               | Intravenous (not<br>otherwise specified) | Form: Vial. Total Dose:<br>960 Mg. Date Of Last |                 | Not Reported             |                |

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|                   |   |                                          |                                                                                                          |              |
|-------------------|---|------------------------------------------|----------------------------------------------------------------------------------------------------------|--------------|
|                   |   |                                          | Dose Prior To Sae: 18<br>March 2009.                                                                     |              |
| Trastuzumab       | S | Intravenous (not<br>otherwise specified) | Form: Vial. Total Dose:<br>512 Mg. Date Of Last<br>Dose Prior To Sae: 18<br>March 2009. Loading<br>Dose. | Not Reported |
| Trastuzumab       | S | Intravenous (not<br>otherwise specified) |                                                                                                          | Not Reported |
| Docetaxel         | S | Intravenous (not<br>otherwise specified) | Form: Vial. Total Dose:<br>126.8 Mg. Date Of Last<br>Dose Prior To Sae: 18<br>March 2009.                | Not Reported |
| Docetaxel         | S | Intravenous (not<br>otherwise specified) |                                                                                                          | Not Reported |
| Carboplatin       | S | Intravenous (not<br>otherwise specified) | Dose: 6 Auc. Form:Vial.<br>Total Dose: 852 Mg.Date<br>Of Last Dose Prior To<br>Sae:18 Mar 09.            | Not Reported |
| Carboplatin       | S | Intravenous (not<br>otherwise specified) |                                                                                                          | Not Reported |
| Tylenol           | S | Unknown                                  |                                                                                                          | Not Reported |
| Morphine          | S | Unknown                                  | Frequency: Q 4 Hrs Prn                                                                                   | Not Reported |
| Cipralext         | S | Unknown                                  |                                                                                                          | Not Reported |
| Ciprofloxacin     | S | Oral                                     |                                                                                                          | Not Reported |
| Ammonium Chloride | C |                                          |                                                                                                          | Not Reported |
| Ceftazidime       | C | Unknown                                  |                                                                                                          | Not Reported |
| Codeine           | C | Unknown                                  |                                                                                                          | Not Reported |
| Trazodone         | C | Unknown                                  |                                                                                                          | Not Reported |
| Escitalopram      | C | Unknown                                  |                                                                                                          | Not Reported |
| Docusate          | C | Unknown                                  | Dose: 2 To 6                                                                                             | Not Reported |
| Senna             | C | Unknown                                  | Dose: 2to 6                                                                                              | Not Reported |
| Lactulose         | C | Unknown                                  | Dose: 15 To 30 MI                                                                                        | Not Reported |
| Mouthwash Nos     | C | Unknown                                  | Drug Name: Cci Mouth                                                                                     | Not Reported |

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

|         |   |         |                     |              |
|---------|---|---------|---------------------|--------------|
| Gravol  | C | Unknown | Wash. Dosage: 30 Cc | Not Reported |
| Codeine | C |         |                     | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Oct-2013              | 9537938       | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000048966    |                      | 77 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                                                                                                                    | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction;<br>Haemarthrosis;<br>Haematoma; Inflammatory<br>Marker Increased;<br>International Normalised<br>Ratio Increased; Oedema;<br>Synovitis | Escitalopram            |              |            | S           | Oral         | 5 Mg               |                 | Forest       |
|                                                                                                                                                          | Escitalopram            |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                                                                                                                                          | Previscan (Fluindione)  |              |            | S           | Oral         | 3 Or 4 Df Daily    |                 | Not Reported |
|                                                                                                                                                          | Previscan (Fluindione)  |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                          | Previscan (Fluindione)  |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                          | Solupred (Prednisolone) |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                          | Sotalex                 |              |            | C           |              | 80 Mg              |                 | Not Reported |
|                                                                                                                                                          | Aldactone               |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                          | Sinemet                 |              |            | C           | Oral         | 8 Df               |                 | Not Reported |
|                                                                                                                                                          | Modopar                 |              |            | C           | Oral         | 1 Df               |                 | Not Reported |
|                                                                                                                                                          | Alprazolam              |              |            | C           | Oral         | 0.50 Mg            |                 | Not Reported |
|                                                                                                                                                          | Doliprane               |              |            | C           |              | 4 Df               |                 | Not Reported |
|                                                                                                                                                          | Mianserin               |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                          | Zolpidem                |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                          | Aprovel                 |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                          | Finasteride             |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 10-Oct-2013              | 9611460       | EXPEDITED (15-DAY) |                    | HO              | FR-ASTRAZENECA-2013SE73220 |                      | 73 YR      | Female     | FRA            |

| <u>Preferred Term</u>                          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blister; Rash Maculo-Papular; Skin Exfoliation | Inexium        |              |            | S           | Oral         |                    |                 | Astrazeneca  |
|                                                | Seroplex       |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                | Paracetamol    |              |            | S           | Oral         |                    |                 | Not Reported |

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

|  |                                    |   |                                       |              |
|--|------------------------------------|---|---------------------------------------|--------------|
|  | Contramal                          | S | Oral                                  | Not Reported |
|  | Lasilix                            | S | Oral                                  | Not Reported |
|  | Atarax                             | S | Oral                                  | Not Reported |
|  | Heparine Sodique                   | S | Intravenous (not otherwise specified) | Not Reported |
|  | Loxen (Niacardipine Hydrochloride) | S | Oral                                  | Not Reported |
|  | Umuline                            | S | Subcutaneous                          | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Oct-2013              | 9612005       | EXPEDITED (15-DAY) |                    | HO              | NO-FRI-1000049868    |                      | 46 YR      | Female     | NOR            |

| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                               | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------|----------------|--------------|------------|-------------|--------------|------------------------------------------------------------------|-----------------|--------------|
| Economic Problem; Mania | Escitalopram   |              |            | S           |              | 10 Mg Daily, Dose Decreased /Jan/2013 And Discontinued /Feb/2013 |                 | Forest       |
|                         | Remeron-S      |              |            | S           |              | 0.25 Mg                                                          |                 | Not Reported |
|                         | Remeron        |              |            | S           |              | 15 Mg                                                            |                 | Not Reported |
|                         | Remeron Triobe |              |            | S           |              |                                                                  |                 | Not Reported |
|                         |                |              |            | C           |              | 1 Df                                                             |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 10-Oct-2013              | 9612117       | NON-EXPEDITED    |                    |                 | US-ASTELLAS-2013US009593 |                      |            | Male       | USA            |

| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Drug Interaction | Myrbetriq      |              |            | S           | Oral         | 25 Mg, Unknown/D   |                 | Astellas     |
|                           | Lexapro        |              |            | S           | Unknown      | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Oct-2013              | 9432546       | EXPEDITED (15-DAY) |                    | HO              | PHHY2013FR080067     |                      | 65 YR      | Female     | FRA            |

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

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

|                                              |                                                |   |      |                                                   |              |
|----------------------------------------------|------------------------------------------------|---|------|---------------------------------------------------|--------------|
| Hepatitis Cholestatic;<br>Jaundice; Pruritus | Eucreas                                        | S | Oral | Unk Unk, Bid                                      | Not Reported |
|                                              | Voltarene Lp                                   | S | Oral | 100 Mg                                            | Novartis     |
|                                              | Voltarene Emulgel                              | S |      |                                                   | Not Reported |
|                                              | Diamicron                                      | S | Oral | 60 Mg, Bid                                        | Not Reported |
|                                              | Coaprovel                                      | S | Oral | 1 Df (300 Mg Irbe And<br>12.5 Mg Hydrochloro), Qd | Not Reported |
|                                              | Amlor                                          | S | Oral | 10 Mg, Qd                                         | Not Reported |
|                                              | Tahor                                          | S | Oral | 20 Mg, Qd                                         | Not Reported |
|                                              | Levothyrox                                     | S | Oral | 125 Ug, Qd                                        | Not Reported |
|                                              | Levothyrox                                     | S | Oral | 100 Ug, Qd                                        | Not Reported |
|                                              | Seroplex                                       | S | Oral | 10 Mg, Qd                                         | Not Reported |
|                                              | Ixprim                                         | S | Oral | 10 Mg, Qd                                         | Not Reported |
|                                              | Doliprane                                      | S | Oral | Unk Unk, Unk                                      | Not Reported |
|                                              | Lamaline<br>(Acetaminophen\Caffeine\Opium<br>) | S |      | Unk Unk, Unk                                      | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 11-Oct-2013              | 9454847       | EXPEDITED (15-DAY) |                    | HO              | JP-MERCK-<br>1308JPN003890 |                      | 59 YR      | Female     | JPN            |

| <u>Preferred Term</u> | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Parkinson'S Disease   | Reflex            |              |            | S           | Oral         | 30mg Daily         |                 | Merck        |
|                       | Reflex            |              |            | S           | Oral         | 15mg Daily         |                 | Merck        |
|                       | Reflex            |              |            | S           | Oral         | 30mg Daily         |                 | Merck        |
|                       | Remeron           |              |            | S           | Oral         | Unk                |                 | Merck        |
|                       | Lexapro           |              |            | S           | Oral         | 10 Mg Daily Dose   |                 | Not Reported |
|                       | Lexapro           |              |            | S           | Oral         | 5 Mg Daily Dose    |                 | Not Reported |
|                       | Lexapro           |              |            | S           | Oral         | 10 Mg Daily Dose   |                 | Not Reported |
|                       | Flunitrazepam     |              |            | C           | Oral         | 1mg                |                 | Not Reported |
|                       | Flunitrazepam     |              |            | C           |              |                    |                 | Not Reported |
|                       | Zolpidem Tartrate |              |            | C           | Oral         | 10 Mg              |                 | Not Reported |

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

|  |                           |   |             |                |  |              |
|--|---------------------------|---|-------------|----------------|--|--------------|
|  | Zolpidem Tartrate         | C |             |                |  | Not Reported |
|  | Eszopiclone               | C | Oral        | 3mg            |  | Not Reported |
|  | Eszopiclone               | C |             |                |  | Not Reported |
|  | Rabeprazole Sodium        | C | Oral        | 10mg           |  | Not Reported |
|  | Etizolam                  | C | Oral        | 0.5 Mg         |  | Not Reported |
|  | Etizolam                  | C |             |                |  | Not Reported |
|  | Hydroxyzine               | C | Oral        | 50mg           |  | Not Reported |
|  | Hydroxyzine               | C |             |                |  | Not Reported |
|  | Metformin Hydrochloride   | C | Oral        | 750ng          |  | Not Reported |
|  | Mosapride Citrate         | C | Oral        | 15mg           |  | Not Reported |
|  | Mecobalamin               | C | Oral        | 1500 Microgram |  | Not Reported |
|  | Pregabalin                | C | Oral        | 300 Mg         |  | Not Reported |
|  | Sennosides                | C | Oral        | 1.0g           |  | Not Reported |
|  | Doxazosin Mesylate        | C | Oral        | 4mg            |  | Not Reported |
|  | Doxazosin Mesylate        | C | Oral        | 2mg            |  | Not Reported |
|  | Azilsartan                | C | Oral        | 20mg           |  | Not Reported |
|  | Dorzolamide Hydrochloride | C | Intraocular | 3 Drops        |  | Merck        |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Oct-2013              | 9474675       | EXPEDITED (15-DAY) |                    | HO              | IT-FRI-1000048021    |                      | 48 YR      | Female     | ITA            |

  

| <u>Preferred Term</u>                              | <u>Product</u>             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------|----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Coma; Intentional Overdose; Sopor; Suicide Attempt | Escitalopram Oral Solution |              |            | S           | Oral         | Overdose: 300 Mg   |                 | Forest       |
|                                                    | Lexotan                    |              |            | S           | Oral         | Overdose: 30 Mg    |                 | Not Reported |
|                                                    | Tavor (Lorazepam)          |              |            | S           | Oral         | Overdose: 25 Mg    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 11-Oct-2013              | 9614662       | EXPEDITED (15-DAY) |                    | HO              | FR-JNJFOC-20131000223 |                      | 88 YR      | Female     | FRA            |

  

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Disorientation; Fall  | Risperdaloro   |              |            | S           | Oral         |                    |                 | Not Reported |

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

|              |   |         |              |
|--------------|---|---------|--------------|
| Risperdaloro | S | Oral    | Not Reported |
| Risperdaloro | S | Oral    | Not Reported |
| Depakote     | S | Oral    | Not Reported |
| Depakote     | S | Oral    | Not Reported |
| Depakote     | S | Oral    | Not Reported |
| Seroplex     | S | Oral    | Not Reported |
| Kardegic     | C | Unknown | Not Reported |
| Sotalex      | C | Unknown | Not Reported |
| Coversyl     | C | Unknown | Not Reported |
| Xalatan      | C | Unknown | Not Reported |
| Azopt        | C | Unknown | Not Reported |
| Dafalgan     | C | Unknown | Not Reported |
| Pariet       | C | Unknown | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Oct-2013              | 9617225       | DIRECT           |                    | DS              |                      |                      | 36 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u> |
|-------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|------------------------------------|-----------------|------------|
| Confusional State; Erectile Dysfunction; Genital Paraesthesia; Hypoaesthesia; Libido Decreased; Memory Impairment | Lexapro        |              |            | S           | Oral         | 1 Pill, Once Daily, Taken By Mouth | 8 YR            | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Oct-2013              | 9617774       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000049926    |                      | 73 YR      | Female     | FRA            |

| <u>Preferred Term</u>                          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blister; Rash Maculo-Papular; Skin Exfoliation | Escitalopram   |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                                | Contramal      |              |            | S           | Oral         | 150 Mg             |                 | Not Reported |

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

|  |                                    |   |                                       |        |              |
|--|------------------------------------|---|---------------------------------------|--------|--------------|
|  | Inexium                            | S | Oral                                  | 20 Mg  | Not Reported |
|  | Lasilix                            | S | Oral                                  | 20 Mg  | Not Reported |
|  | Atarax                             | S | Oral                                  | 100 Mg | Not Reported |
|  | Heparine Sodique                   | S | Intravenous (not otherwise specified) | 170 Mg | Not Reported |
|  | Loxen (Niacardipine Hydrochloride) | S | Oral                                  | 60 Mg  | Not Reported |
|  | Paracetamol                        | S | Oral                                  | 3 Gram | Not Reported |
|  | Umuline                            | S | Subcutaneous                          |        | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 14-Oct-2013              | 9618668        | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2013293171 |                      | 58 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity    | Zoloft         |                  |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                          | Citalopram     |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                          | Lexapro        |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                          | Paxil          |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                          | Wellbutrin     |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                                | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 14-Oct-2013                                                                                                                                             | 9619548        | EXPEDITED (15-DAY) |                    | HO, LT, OT      | FR-PFIZER INC-2013290004 |                      | 21 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                                   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bradycardia; Cardiac Disorder; Hypotension; Hypotonia; Left Ventricular Dysfunction; Overdose; Sinoatrial Block; Somnolence; Toxicity To Various Agents | Xanax          |                    |                    | S               | Oral                     | 12 Mg, Single        |                 | Pfizer       |                |
|                                                                                                                                                         | Theralene      |                    |                    | S               | Oral                     | 135 Mg, Single       |                 | Not Reported |                |
|                                                                                                                                                         | Risperdal      |                    |                    | S               | Oral                     | 20 Mg, Single        |                 | Not Reported |                |
|                                                                                                                                                         | Seroplex       |                    |                    | S               | Oral                     | 420 Mg, Single       |                 | Not Reported |                |
|                                                                                                                                                         | Imovane        |                    |                    | S               | Oral                     | 22.5 Mg, Single      |                 | Not Reported |                |



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

| <u>FDA Received Date</u>      | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------|-----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 14-Oct-2013                   | 9619765         | EXPEDITED (15-DAY) |                    | OT              | FI-TEVA-2010R0503588 |                      |                 | Male         | FIN            |
| <u>Preferred Term</u>         | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Discomfort;         | Amoxin          |                    |                    | S               | Oral                 |                      |                 | Teva         |                |
| Acute Sinusitis;              | Amoxin          |                    |                    | S               |                      |                      |                 | Teva         |                |
| Adjustment Disorder With      | Champix         |                    |                    | S               | Oral                 | .5 Milligram Daily;  |                 | Not Reported |                |
| Mixed Anxiety And             | Champix         |                    |                    | S               | Oral                 | 1 Milligram Daily;   |                 | Not Reported |                |
| Depressed Mood;               | Champix         |                    |                    | S               | Oral                 | 2 Milligram Daily;   |                 | Not Reported |                |
| Aggression; Anxiety;          | Champix         |                    |                    | S               | Oral                 | 2 Milligram Daily;   |                 | Not Reported |                |
| Blood Cholesterol             | Nicorette Gum   |                    |                    | S               | Oral                 | 2 Milligram Daily;   |                 | Not Reported |                |
| Increased; Blood Glucose      | Rinexin         |                    |                    | S               | Oral                 | 50 Milligram Daily;  |                 | Not Reported |                |
| Increased; Confusional        | Nicorette Patch |                    |                    | S               | Transdermal          |                      |                 | Not Reported |                |
| State; Depression;            | Sertralin Orion |                    |                    | S               | Oral                 | 25 Milligram Daily;  |                 | Not Reported |                |
| Dizziness; Drug               | Cipralax        |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Interaction; Dyspnoea;        | Azithromycin    |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Erythema; Euphoric Mood;      | Doximycin       |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Fatigue; Fear; Feeling        | Klacid          |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Abnormal; Hallucination;      | Havrix          |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Hepatic Steatosis;            | Toclase         |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Hypersensitivity;             |                 |                    |                    |                 |                      |                      |                 |              |                |
| Hyposmia;                     |                 |                    |                    |                 |                      |                      |                 |              |                |
| Hypothyroidism; Increased     |                 |                    |                    |                 |                      |                      |                 |              |                |
| Appetite; Infection;          |                 |                    |                    |                 |                      |                      |                 |              |                |
| Influenza; Irritability; Loss |                 |                    |                    |                 |                      |                      |                 |              |                |
| Of Personal Independence      |                 |                    |                    |                 |                      |                      |                 |              |                |
| In Daily Activities; Lower    |                 |                    |                    |                 |                      |                      |                 |              |                |
| Respiratory Tract             |                 |                    |                    |                 |                      |                      |                 |              |                |
| Infection; Medication         |                 |                    |                    |                 |                      |                      |                 |              |                |
| Error; Memory                 |                 |                    |                    |                 |                      |                      |                 |              |                |
| Impairment; Mood Swings;      |                 |                    |                    |                 |                      |                      |                 |              |                |
| Musculoskeletal               |                 |                    |                    |                 |                      |                      |                 |              |                |
| Discomfort; Nausea;           |                 |                    |                    |                 |                      |                      |                 |              |                |
| Nightmare; Overweight;        |                 |                    |                    |                 |                      |                      |                 |              |                |
| Palpitations; Panic           |                 |                    |                    |                 |                      |                      |                 |              |                |
| Reaction; Personality         |                 |                    |                    |                 |                      |                      |                 |              |                |
| Change; Restlessness;         |                 |                    |                    |                 |                      |                      |                 |              |                |
| Sense Of Oppression;          |                 |                    |                    |                 |                      |                      |                 |              |                |
| Sleep Disorder; Swelling;     |                 |                    |                    |                 |                      |                      |                 |              |                |
| Tinnitus; Upper               |                 |                    |                    |                 |                      |                      |                 |              |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Respiratory Tract  
Infection; Vasodilatation;  
Vertigo; Weight Increased;  
Withdrawal Syndrome

| <u>FDA Received Date</u>       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------|----------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| 14-Oct-2013                    | 9619951        | NON-EXPEDITED      |                    |                 | US-PFIZER INC-<br>2013292748 |                      |                 | Female       | USA            |
| <u>Preferred Term</u>          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Crying; Diarrhoea;<br>Insomnia | Xanax          |                    |                    | S               |                              | Unk                  |                 | Pfizer       |                |
|                                | Lexapro        |                    |                    | S               |                              | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Oct-2013                    | 9535018        | EXPEDITED (15-DAY) |                    | HO              | FR-PFIZER INC-<br>2013264690 |                      | 35 YR           | Male         | FRA            |
| <u>Preferred Term</u>          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Pyrexia; Rash Generalised      | Lyrica         |                    |                    | S               | Oral                         | 25 Mg, 2x/Day        |                 | Pfizer       |                |
|                                | Bactrim        |                    |                    | S               | Oral                         | 2 G, 3x/Day          |                 | Not Reported |                |
|                                | Bactrim        |                    |                    | S               | Oral                         | 800 Mg, Daily        |                 | Not Reported |                |
|                                | Seroplex       |                    |                    | S               | Oral                         | 5 Mg, Daily          |                 | Not Reported |                |
|                                | Loxapac        |                    |                    | S               | Oral                         | 25 Mg, Daily         |                 | Not Reported |                |
|                                | Truvada        |                    |                    | C               |                              | Unk                  |                 | Not Reported |                |
|                                | Prezista       |                    |                    | C               |                              | Unk                  |                 | Not Reported |                |
|                                | Norvir         |                    |                    | C               |                              | Unk                  |                 | Not Reported |                |
|                                | Rovalcyte      |                    |                    | C               |                              |                      |                 | Not Reported |                |
|                                | Xanax          |                    |                    | C               |                              |                      |                 | Not Reported |                |
|                                | Paracetamol    |                    |                    | C               |                              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Oct-2013                    | 9625119        | DIRECT             | Y                  |                 |                              |                      | 30 YR           | Female       | USA            |
| <u>Preferred Term</u>          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

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

|                                                                          |                                                                       |                    |                    |                  |                              |                                      |                 |                                                        |                |
|--------------------------------------------------------------------------|-----------------------------------------------------------------------|--------------------|--------------------|------------------|------------------------------|--------------------------------------|-----------------|--------------------------------------------------------|----------------|
| Abdominal Pain Upper;<br>Abdominal Pain Upper                            |                                                                       | Escitalopram 10 Mg |                    | S                |                              | Not Reported                         |                 |                                                        |                |
| <u>FDA Received Date</u>                                                 | <u>Case #</u>                                                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u>         | <u>503B Facility</u>                 | <u>Age</u>      | <u>Sex</u>                                             | <u>Country</u> |
| 15-Oct-2013                                                              | 9626164                                                               | DIRECT             |                    |                  |                              |                                      | 57 YR           | Female                                                 | USA            |
| <u>Preferred Term</u>                                                    | <u>Product</u>                                                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>                 | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>                                             |                |
| Drug Ineffective; Product<br>Substitution Issue                          | Escitalopram                                                          |                    |                    | S                | Oral                         | 3 Pills Once Daily Taken<br>By Mouth |                 | Mylan                                                  |                |
| <u>FDA Received Date</u>                                                 | <u>Case #</u>                                                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u>         | <u>503B Facility</u>                 | <u>Age</u>      | <u>Sex</u>                                             | <u>Country</u> |
| 16-Oct-2013                                                              | 9468437                                                               | EXPEDITED (15-DAY) |                    | DE               | IE-PFIZER INC-<br>2013241955 |                                      | 65 YR           | Female                                                 | IRL            |
| <u>Preferred Term</u>                                                    | <u>Product</u>                                                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>                 | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>                                             |                |
| Completed Suicide;<br>Product Use In<br>Unapproved Indication            | Lyrica<br>Lexapro                                                     |                    |                    | S<br>S           |                              | Unk<br>Unk                           |                 | Pfizer<br>Not Reported                                 |                |
| <u>FDA Received Date</u>                                                 | <u>Case #</u>                                                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u>         | <u>503B Facility</u>                 | <u>Age</u>      | <u>Sex</u>                                             | <u>Country</u> |
| 16-Oct-2013                                                              | 9627143                                                               | EXPEDITED (15-DAY) |                    | HO               | FR-FRI-1000049994            |                                      | 92 YR           | Female                                                 | FRA            |
| <u>Preferred Term</u>                                                    | <u>Product</u>                                                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>                 | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>                                             |                |
| Agitation; Confusional<br>State; Withdrawal<br>Syndrome                  | Escitalopram<br>Hydrochlorothiazide/Valsartan<br>Vastarel<br>Kardegic |                    |                    | S<br>C<br>C<br>C | Oral                         | 1 Df                                 |                 | Forest<br>Not Reported<br>Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                 | <u>Case #</u>                                                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u>         | <u>503B Facility</u>                 | <u>Age</u>      | <u>Sex</u>                                             | <u>Country</u> |
| 16-Oct-2013                                                              | 9627965                                                               | EXPEDITED (15-DAY) |                    | OT               | PHHY2013AU113251             |                                      |                 | Male                                                   | AUS            |
| <u>Preferred Term</u>                                                    | <u>Product</u>                                                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>                 | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>                                             |                |
| Hallucination, Visual;<br>Hypernatraemia; Partial<br>Seizures; Sedation; | Valproic Acid<br>Escitalopram                                         |                    |                    | S<br>S           |                              |                                      |                 | Novartis<br>Not Reported                               |                |

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

|         |             |   |                      |              |
|---------|-------------|---|----------------------|--------------|
| Seizure | Quetiapine  | S | Unk Ukn, Unk         | Not Reported |
|         | Quetiapine  | S | Unk (Dose Increased) | Not Reported |
|         | Mirtazapine | S |                      | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Oct-2013              | 9630616       | DIRECT           |                    |                 |                      |                      | 64 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Diarrhoea; Dry Mouth;<br>Electrolyte Imbalance;<br>Hypertension;<br>Paraesthesia; Syncope | Escitalopram   |              |            | S           | Oral         | 1 Dose             |                 | Torrent    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Oct-2013              | 9442231       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000047499    |                      | 65 YR      | Female     | FRA            |

| <u>Preferred Term</u>                        | <u>Product</u>                                  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------|-------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hepatitis Cholestatic;<br>Jaundice; Pruritus | Escitalopram                                    |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                              | Diamicron                                       |              |            | S           | Oral         | 120 Mg             |                 | Not Reported |
|                                              | Eucreas                                         |              |            | S           | Oral         | 2 Df               |                 | Not Reported |
|                                              | Coaprovel                                       |              |            | S           | Oral         | 300/12.5 Mg        |                 | Not Reported |
|                                              | Amlor                                           |              |            | S           | Oral         | 1 Df               |                 | Not Reported |
|                                              | Tahor                                           |              |            | S           | Oral         | 1 Df               |                 | Not Reported |
|                                              | Levothyrox                                      |              |            | S           | Oral         | 125 Mcg            |                 | Not Reported |
|                                              | Ixprim                                          |              |            | S           | Oral         |                    |                 | Not Reported |
|                                              | Doliprane                                       |              |            | S           | Oral         |                    |                 | Not Reported |
|                                              | Voltarene (Diclofenac Sodium)                   |              |            | S           | Cutaneous    |                    |                 | Not Reported |
|                                              | Voltarene Lp                                    |              |            | S           | Oral         |                    |                 | Not Reported |
|                                              | Lamalaine<br>(Acetaminophen\Caffeine\Opium<br>) |              |            | S           |              |                    |                 | Not Reported |

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

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Oct-2013              | 9628526       | EXPEDITED (15-DAY) |                    | OT              | US-ACCORD-019927     |                      | 54 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                             | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|------------------------------------------|--------------------|-----------------|--------------|
| Abnormal Behaviour;<br>Decreased Appetite;<br>Depression; Disturbance<br>In Attention; Drug<br>Ineffective; Insomnia;<br>Memory Impairment; Off<br>Label Use; Suicidal<br>Ideation; Weight<br>Decreased | Topiramate     |              |            | S           |                                          |                    |                 | Accord       |
|                                                                                                                                                                                                         | Escitalopram   |              |            | S           |                                          |                    |                 | Accord       |
|                                                                                                                                                                                                         | Flunarizine    |              |            | S           | Oral                                     |                    |                 | Not Reported |
|                                                                                                                                                                                                         | Valproate      |              |            | C           | Intravenous (not<br>otherwise specified) |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 17-Oct-2013              | 9628535       | EXPEDITED (15-DAY) |                    | OT              | MX-SHIRE-ALL1-2013-<br>06948 |                      |            | Female     | MEX            |

| <u>Preferred Term</u> | <u>Product</u>                               | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Glaucoma              | Blinded 489 (Lisdexamfetamine<br>Dimesylate) |              |            | S           | Oral         | Unk, 1x/Day:Qd     |                 | Shire        |
|                       | Blinded Duloxetine<br>Hydrochloride          |              |            | S           | Oral         | Unk, 1x/Day:Qd     |                 | Shire        |
|                       | Blinded Escitalopram Oxalate                 |              |            | S           | Oral         | Unk, 1x/Day:Qd     |                 | Shire        |
|                       | Blinded Placebo                              |              |            | S           | Oral         | Unk, 1x/Day:Qd     |                 | Shire        |
|                       | Blinded Sertraline Hydrochloride             |              |            | S           | Oral         | Unk, 1x/Day:Qd     |                 | Shire        |
|                       | Blinded Venlafaxine<br>Hydrochloride         |              |            | S           | Oral         | Unk, 1x/Day:Qd     |                 | Shire        |
|                       | Duloxetine Hydrochloride                     |              |            | S           | Oral         | 90 Mg, 2x/Day:Bid  |                 | Unknown      |
|                       | Duloxetine Hydrochloride                     |              |            | S           | Oral         | 60 Mg, 2x/Day:Bid  |                 | Unknown      |
|                       | Ketorolac                                    |              |            | C           | Unknown      | Unk, Unknown       |                 | Not Reported |
|                       | Neo Melubrina                                |              |            | C           | Unknown      | Unk, Unknown       |                 | Not Reported |
|                       | Neo Melubrina                                |              |            | C           | Unknown      | Unk, Unknown       |                 | Not Reported |
|                       | Neo Melubrina                                |              |            | C           | Unknown      | Unk, Unknown       |                 | Not Reported |

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

|               |   |         |                  |              |
|---------------|---|---------|------------------|--------------|
| Neo Melubrina | C | Unknown | Unk, Unknown     | Not Reported |
| Neo Melubrina | C | Unknown | Unk, Unknown     | Not Reported |
| Neo Melubrina | C | Unknown | Unk, Unknown     | Not Reported |
| Neo Melubrina | C | Unknown | Unk, Unknown     | Not Reported |
| Neo Melubrina | C | Unknown | Unk, Unknown     | Not Reported |
| Neo Melubrina | C | Unknown | Unk Unk, Unknown | Not Reported |
| Neo Melubrina | C | Unknown | Unk, Unknown     | Not Reported |
| Paracetamol   | C | Unknown | Unk, Unknown     | Not Reported |
| Nepafenac     | C | Unknown | Unk, Unknown     | Not Reported |
| Timolol       | C | Unknown | Unk, Unknown     | Not Reported |

| <u>FDA Received Date</u>                   | <u>Case #</u>    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------|------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
| 17-Oct-2013                                | 9628756          | EXPEDITED (15-DAY) |                    | OT              | AU-MYLANLABS-2013S1022622 |                      |                 | Male         | AUS            |
| <u>Preferred Term</u>                      | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypernatraemia; Partial Seizures; Sedation | Escitalopram     |                    |                    | S               | Unknown                   |                      |                 | Not Reported |                |
|                                            | Quetiapine       |                    |                    | S               | Unknown                   | Increasing Doses     |                 | Not Reported |                |
|                                            | Sodium Valproate |                    |                    | S               | Unknown                   |                      |                 | Mylan        |                |
|                                            | Mirtazapine      |                    |                    | C               | Unknown                   |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------|----------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 17-Oct-2013                                          | 9629933        | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-2013293820 |                      | 56 YR           | Female       | USA            |
| <u>Preferred Term</u>                                | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anaemia; Large Intestinal Haemorrhage; Off Label Use | Advil          |                    |                    | S               |                          | Unk, As Needed       |                 | Pfizer       |                |
|                                                      | Advil          |                    |                    | S               |                          |                      |                 | Pfizer       |                |
|                                                      | Lexapro        |                    |                    | S               |                          | 10 Mg, 1x/Day        |                 | Not Reported |                |
|                                                      | Synthroid      |                    |                    | C               |                          | 0.125 Mg, 2x/Day     |                 | Not Reported |                |
|                                                      | Benicar        |                    |                    | C               |                          | 40 Mg, 1x/Day        |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------|--------------------------------|--------------------|--------------------|-----------------|------------------------------|------------------------|-----------------|--------------|----------------|
| 17-Oct-2013                                             | 9630999                        | EXPEDITED (15-DAY) | Y                  | OT              | AUR-APL-2013-08394           |                        | 30 YR           | Male         | USA            |
| <u>Preferred Term</u>                                   | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Akathisia; Dysstasia; Initial<br>Insomnia; Restlessness | Quetiapine                     |                    |                    | S               |                              |                        |                 | Not Reported |                |
|                                                         | Asenapine                      |                    |                    | S               | Sublingual                   | 10 Mg (5 Mg, 2 In 1 D) |                 | Not Reported |                |
|                                                         | Aripiprazole                   |                    |                    | S               |                              |                        |                 | Not Reported |                |
|                                                         | Clonazepam                     |                    |                    | S               |                              |                        |                 | Not Reported |                |
|                                                         | Buspirone                      |                    |                    | S               |                              |                        |                 | Not Reported |                |
|                                                         | Lexapro (Escitalopram Oxalate) |                    |                    | S               |                              |                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Oct-2013                                             | 9633799                        | EXPEDITED (15-DAY) | Y                  | DE              | 2013AP008644                 |                        | 66 YR           | Unknown      | USA            |
| <u>Preferred Term</u>                                   | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardio-Respiratory Arrest;<br>Completed Suicide         | Lithium Carbonate Capsules     |                    |                    | S               | Oral                         |                        |                 | Not Reported |                |
|                                                         | Oxycodone                      |                    |                    | S               | Oral                         |                        |                 | Not Reported |                |
|                                                         | Escitalopram Oxalate           |                    |                    | S               | Oral                         |                        |                 | Not Reported |                |
|                                                         | Methylphenidate                |                    |                    | S               | Oral                         |                        |                 | Not Reported |                |
|                                                         | Aripiprazole                   |                    |                    | S               | Oral                         |                        |                 | Not Reported |                |
|                                                         | Simvastatin                    |                    |                    | S               | Oral                         |                        |                 | Not Reported |                |
|                                                         | Valaciclovir                   |                    |                    | S               | Oral                         |                        |                 | Not Reported |                |
|                                                         | Propoxyphene                   |                    |                    | S               | Oral                         |                        |                 | Not Reported |                |
|                                                         | Hydrocodone                    |                    |                    | S               | Oral                         |                        |                 | Not Reported |                |
|                                                         | Triazolam                      |                    |                    | S               | Oral                         |                        |                 | Not Reported |                |
|                                                         | Acetaminophen                  |                    |                    | S               | Oral                         |                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Oct-2013                                             | 8898735                        | EXPEDITED (15-DAY) |                    | HO              | ES-PFIZER INC-<br>2012278694 |                        | 52 YR           | Male         | ESP            |
| <u>Preferred Term</u>                                   | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |

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

|                                                                      |                      |   |      |                |              |
|----------------------------------------------------------------------|----------------------|---|------|----------------|--------------|
| Drug Interaction;<br>Dyspnoea; Respiratory<br>Depression; Somnolence | Atenolol             | S | Oral | 50 Mg, Daily   | Pfizer       |
|                                                                      | Escitalopram Oxalate | S |      | 20 Mg, Daily   | Not Reported |
|                                                                      | Seroquel             | S | Oral | 400 Mg, 2x/Day | Not Reported |
|                                                                      | Lormetazepam         | S | Oral | 2 Mg, Daily    | Not Reported |
|                                                                      | Artane               | S | Oral | 2 Mg, Daily    | Not Reported |
|                                                                      | Hidrosaluretil       | C | Oral | 25 Mg, Daily   | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Oct-2013              | 9447463       | EXPEDITED (15-DAY) | Y                  | HO              | 7226731              |                      | 65 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                                            | <u>Product</u>                                                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------|---------------------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cell Death; Headache;<br>Hepatitis Cholestatic;<br>Hepatotoxicity; Neck Pain;<br>Self-Medication | Levothyrox                                                    |              |            | S           | Oral         | 1 In 1 D           |                 | Not Reported |
|                                                                                                  | Daimicron                                                     |              |            | S           | Oral         | 2 Df In 1 D        |                 | Not Reported |
|                                                                                                  | Eucreas                                                       |              |            | S           | Oral         | 2 In 1 D           |                 | Not Reported |
|                                                                                                  | Coaprovel                                                     |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                  | Amlor                                                         |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                  | Tahor                                                         |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                  | Seroplex                                                      |              |            | S           | Oral         |                    | 4 MTH           | Not Reported |
|                                                                                                  | Ixprim                                                        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                  | Doliprane                                                     |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                  | Voltarene (Diclofenac Sodium)                                 |              |            | S           |              | Cutaneous          |                 | Not Reported |
|                                                                                                  | Voltarene (Diclofenac Sodium)                                 |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                  | Lamaline<br>(Acetaminophen\Belladonna<br>Leaf\Caffeine\Opium) |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 18-Oct-2013              | 9449735       | EXPEDITED (15-DAY) |                    | HO              | FR-JNJFOC-<br>20130801355 |                      | 65 YR      | Female     | FRA            |

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



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

|                                                           |                                                |   |              |              |
|-----------------------------------------------------------|------------------------------------------------|---|--------------|--------------|
| Hepatitis Cholestatic;<br>Jaundice; Overdose;<br>Pruritus | Ixprim                                         | S | Oral         | Not Reported |
|                                                           | Diamicron                                      | S | Oral         | Not Reported |
|                                                           | Lamaline<br>(Acetaminophen\Caffeine\Opium<br>) | S | Oral         | Not Reported |
|                                                           | Voltarene (Diclofenac Sodium)                  | S | Cutaneous    | Not Reported |
|                                                           | Doliprane                                      | S | Oral         | Not Reported |
|                                                           | Coaprovel                                      | S | Oral         | Not Reported |
|                                                           | Amlor                                          | S | Oral         | Not Reported |
|                                                           | Tahor                                          | S | Oral         | Not Reported |
|                                                           | Levothyrox                                     | S | Oral         | Not Reported |
|                                                           | Seroplex                                       | S | Oral         | Not Reported |
|                                                           | Voltarene (Diclofenac Sodium)                  | S | Oral         | Not Reported |
|                                                           | Eucreas                                        | S | Oral         | Not Reported |
|                                                           | Tramadol                                       | C | Unknown      | Not Reported |
|                                                           | Humalog                                        | C | Subcutaneous | Not Reported |
|                                                           | Questran                                       | C | Oral         | Not Reported |
|                                                           | Lantus                                         | C | Subcutaneous | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Oct-2013              | 9631400       | EXPEDITED (15-DAY) |                    | DS              | FR-FRI-1000050139    |                      |            | Male       | FRA            |

| <u>Preferred Term</u>                                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|------------|
| Foetal Exposure During<br>Pregnancy; Psychomotor<br>Retardation | Escitalopram   |              |            | S           | Transplacental | 20 Mg              |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 18-Oct-2013              | 9631604       | NON-EXPEDITED    |                    |                 | US-PFIZER INC-<br>2013297318 |                      | 96 YR      | Female     | USA            |

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

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

|                                                                   |            |   |                                                           |              |
|-------------------------------------------------------------------|------------|---|-----------------------------------------------------------|--------------|
| Dizziness; Drug Ineffective; Product Use In Unapproved Indication | Gabapentin | S | 3x/Day, 300mg In Morning And Afternoon And 600mg At Night | Pfizer       |
|                                                                   | Effexor    | S | 75 Mg, Daily                                              | Pfizer       |
|                                                                   | Effexor    | S | 150 Mg, Daily                                             | Pfizer       |
|                                                                   | Effexor    | S |                                                           | Pfizer       |
|                                                                   | Lexapro    | S | 30 Mg, 1x/Day                                             | Not Reported |
|                                                                   | Maxalt     | C | 2.5 Mg, As Needed                                         | Not Reported |
|                                                                   | Lorazepam  | C | 1 Mg, As Needed                                           | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Oct-2013              | 9632905       | EXPEDITED (15-DAY) | HO                 |                 | NO-FRI-1000050216    |                      | 80 YR      | Male       | NOR            |

| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug-Induced Liver Injury | Escitalopram   |              |            | S           |              | 5 Mg               |                 | Forest       |
|                           | Heminevrin     |              |            | C           |              | 300 Mg             |                 | Not Reported |
|                           | Paracetamol    |              |            | C           | Oral         | 1 Gram             |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Oct-2013              | 9633231       | DIRECT           |                    |                 |                      |                      | 23 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Abdominal Pain Upper; Anxiety; Headache; Insomnia; Panic Attack; Product Substitution Issue | Escitalopram   |              |            | S           | Oral         | 1 Pill             |                 | Aurobindo  |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Oct-2013              | 9633467       | DIRECT           |                    | OT              |                      |                      | 58 YR      | Female     | USA            |

| <u>Preferred Term</u>                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Depression; Drug Withdrawal Syndrome; | Escitalopram   |              |            | S           | Oral         |                    |                 | Mylan      |

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

|                            |                   |   |              |
|----------------------------|-------------------|---|--------------|
| Product Substitution Issue | Lexpro            | C | Not Reported |
|                            | Albuterol Inhaler | C | Not Reported |
|                            | Lamictal          | C | Not Reported |
|                            | Tylenol           | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------------------------------------|----------------------|------------|------------|----------------|
| 19-Oct-2013              | 9633132       | EXPEDITED (15-DAY) |                    | HO              | FR-B.I.<br>PHARMACEUTICALS,I<br>NC./RIDGEFIELD-2013-<br>BI-33 |                      | 86 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u>                       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>           |
|-----------------------|--------------------------------------|--------------|------------|-------------|--------------|--------------------------|-----------------|----------------------|
| Fall; Hyponatraemia   | Telmisartan +<br>Hydrochlorothiazide |              |            | S           | Oral         | Daily Dose: 80/12.5 1 Df |                 | Boehringer Ingelheim |
|                       | Lasilix                              |              |            | S           | Oral         | 20 Mg                    |                 | Not Reported         |
|                       | Seroplex                             |              |            | S           | Oral         | 5 Mg                     |                 | Not Reported         |
|                       | Minisintrom (Acenocoumarol)          |              |            | C           |              |                          |                 | Not Reported         |
|                       | Ikorel (Nicorandil)                  |              |            | C           |              |                          |                 | Not Reported         |
|                       | Temerit (Nebivolol)                  |              |            | C           |              |                          |                 | Not Reported         |
|                       | Kaleorid (Potassium Chloride)        |              |            | C           |              |                          |                 | Not Reported         |
|                       | Monuril (Fosfomycin                  |              |            | C           |              |                          |                 | Not Reported         |
|                       | Trometamol)                          |              |            |             |              |                          |                 |                      |
|                       | Pentasa (Mesalazine)                 |              |            | C           |              |                          |                 | Not Reported         |
|                       | Requip (Ropinirole                   |              |            | C           |              |                          |                 | Not Reported         |
|                       | Hydrochloride)                       |              |            |             |              |                          |                 |                      |
|                       | Oroken                               |              |            | C           |              |                          |                 | Not Reported         |
|                       | Lactulose (Lactulose)                |              |            | C           |              |                          |                 | Not Reported         |
|                       | Dafalgan (Paracetamol)               |              |            | C           |              |                          |                 | Not Reported         |
|                       | Lactulose (Lactulose)                |              |            | C           |              |                          |                 | Not Reported         |
|                       | Aerius (Desloratadine)               |              |            | C           |              |                          |                 | Not Reported         |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 21-Oct-2013              | 9633434       | EXPEDITED (15-DAY) |                    | HO              | FR-<br>ELI_LILLY_AND_COMP<br>ANY-FR201310001888 |                      | 73 YR      | Female     | FRA            |

| <u>Preferred Term</u>                              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>       |
|----------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------------|
| Blister; Rash Maculo-<br>Papular; Skin Exfoliation | Umuline        |              |            | S           | Subcutaneous | Unk                |                 | Eli Lilly And Co |
|                                                    | Contramal      |              |            | S           | Oral         | 50 Mg, Tid         |                 | Not Reported     |

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

|                                    |   |                                       |            |              |
|------------------------------------|---|---------------------------------------|------------|--------------|
| Inexium                            | S | Oral                                  | 20 Mg, Qd  | Not Reported |
| Lasilix                            | S | Oral                                  | 20 Mg, Qd  | Not Reported |
| Seroplex                           | S | Oral                                  | 10 Mg, Qd  | Not Reported |
| Atarax                             | S | Oral                                  | 100 Mg, Qd | Not Reported |
| Heparina Sodica                    | S | Intravenous (not otherwise specified) | 170 Mg, Qd | Not Reported |
| Loxen (Niacardipine Hydrochloride) | S | Oral                                  | 20 Mg, Tid | Not Reported |
| Paracetamol                        | S | Oral                                  | 1 G, Tid   | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 21-Oct-2013              | 9634326       | EXPEDITED (15-DAY) |                    | HO, LT          | FR-JNJFOC-20131006399 |                      | 21 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiac Disorder;<br>Hypotension; Hypotonia;<br>Intentional Overdose;<br>Somnolence | Risperdal      |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                     | Risperdal      |              |            | S           | Oral         | 20 Tablets         |                 | Not Reported |
|                                                                                     | Theralene      |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                     | Theralene      |              |            | S           | Oral         | 27 Tablets         |                 | Not Reported |
|                                                                                     | Xanax          |              |            | S           | Oral         | 24 Tablets         |                 | Not Reported |
|                                                                                     | Xanax          |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                     | Seroplex       |              |            | S           | Oral         | 28 Tablets         |                 | Not Reported |
|                                                                                     | Seroplex       |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                     | Imovane        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                     | Imovane        |              |            | S           | Oral         | 3 Tablets          |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Oct-2013              | 9636395       | EXPEDITED (15-DAY) |                    | DE              | FR-FRI-1000050323    |                      | 38 YR      | Female     | FRA            |

| <u>Preferred Term</u>                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Completed Suicide; Drug Level Above Therapeutic | Escitalopram   |              |            | S           | Oral         | 1 Df               |                 | Forest     |

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

|  |               |   |                                       |                    |              |
|--|---------------|---|---------------------------------------|--------------------|--------------|
|  | Dropleptan    | S | Intravenous (not otherwise specified) | 1 Mg At 03:00 A.M. | Not Reported |
|  | Dexamethasone | S | Intravenous (not otherwise specified) | 4 Mg               | Not Reported |
|  | Myolastan     | S | Oral                                  |                    | Not Reported |

| <u>FDA Received Date</u>                                                                                                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| 21-Oct-2013                                                                                                                              | 9636480        | EXPEDITED (15-DAY) |                    | OT              | GB-MALLINCKRODT-T201103057 |                      | 60 YR           | Male         | GBR            |
| <u>Preferred Term</u>                                                                                                                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Arthropathy; C-Reactive Protein Increased; Drug Resistance; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Synovitis | Pennsaid       |                    |                    | S               | Unknown                    | Unk                  |                 | Tyco         |                |
|                                                                                                                                          | Sulfasalazine  |                    |                    | S               | Unknown                    | Unk                  |                 | Not Reported |                |
|                                                                                                                                          | Methotrexate   |                    |                    | S               | Unknown                    | 3 In 1 Week          |                 | Not Reported |                |
|                                                                                                                                          | Escitalopram   |                    |                    | S               | Unknown                    | 10 Mg, Qd            |                 | Not Reported |                |
|                                                                                                                                          | Risperidone    |                    |                    | S               | Unknown                    | 1 Mg, Qd             |                 | Not Reported |                |
|                                                                                                                                          | Aspirin        |                    |                    | S               | Unknown                    | 75 Mg, Unk           |                 | Not Reported |                |
|                                                                                                                                          | Simvastatin    |                    |                    | S               | Unknown                    | 40 Mg, Unk           |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                    | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 22-Oct-2013                                                                 | 9637181        | EXPEDITED (15-DAY) |                    | OT              | US-JNJFOC-20131009794 |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                       | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Adverse Event; Arrhythmia; Drug Interaction; Electrocardiogram Qt Prolonged | Levaquin       |                    |                    | S               | Unknown               |                      |                 | Not Reported |                |
|                                                                             | Zofran         |                    |                    | S               | Unknown               |                      |                 | Not Reported |                |
|                                                                             | Lexapro        |                    |                    | S               | Unknown               |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|------------|----------------|
| 23-Oct-2013              | 9640128        | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2013297291 |                      | 49 YR           | Female     | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

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

|                       |                 |   |     |              |
|-----------------------|-----------------|---|-----|--------------|
| Drug Hypersensitivity | Effexor         | S | Unk | Pfizer       |
|                       | Zoloft          | S | Unk | Pfizer       |
|                       | Naproxen Sodium | S | Unk | Pfizer       |
|                       | Prozac          | S | Unk | Not Reported |
|                       | Lexapro         | S | Unk | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|------------------------------|--------------------|--------------------|-----------------|-------------------------|----------------------|-----------------|--------------|----------------|
| 23-Oct-2013              | 9641653                      | EXPEDITED (15-DAY) |                    | HO              | US-TAKEDA-TPA2013A07609 |                      | 49 YR           | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Depression      | Blinded Escitalopram Oxalate |                    |                    | S               | Oral                    | Unk, Qd              |                 | Takeda       |                |
|                          | Blinded Vortioxetine         |                    |                    | S               | Oral                    | Unk, Qd              |                 | Takeda       |                |
|                          | Blinded Escitalopram Oxalate |                    |                    | S               | Oral                    | Unk, Qd              |                 | Takeda       |                |
|                          | Blinded Vortioxetine         |                    |                    | S               | Oral                    | Unk, Qd              |                 | Takeda       |                |
|                          | Pariet                       |                    |                    | C               | Oral                    | 20 Mg, Qd            |                 | Not Reported |                |
|                          | Apo-Quinine                  |                    |                    | C               | Oral                    | 200 Mg, Qd           |                 | Not Reported |                |
|                          | Telmisartan                  |                    |                    | C               | Oral                    | 12.5 Mg, Qd          |                 | Not Reported |                |
|                          | Cipralelex                   |                    |                    | C               | Oral                    | 10 Mg, Prn           |                 | Not Reported |                |
|                          | Cipralelex                   |                    |                    | C               | Oral                    | 20 Mg, Prn           |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 23-Oct-2013              | 9642053        | EXPEDITED (15-DAY) |                    | OT              | CA-ROCHE-1290749     |                      | 44 YR           | Female       | CAN            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Ecchymosis               | Rivotril       |                    |                    | S               | Unknown              |                      |                 | Not Reported |                |
|                          | Cipralelex     |                    |                    | S               | Unknown              |                      |                 | Not Reported |                |
|                          | Cipralelex     |                    |                    | S               | Unknown              |                      |                 | Not Reported |                |
|                          | Cipralelex     |                    |                    | S               | Unknown              |                      |                 | Not Reported |                |
|                          | Cipralelex     |                    |                    | S               | Unknown              |                      |                 | Not Reported |                |
|                          | Omega-3        |                    |                    | S               | Unknown              |                      |                 | Not Reported |                |

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| <u>FDA Received Date</u> | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 23-Oct-2013              | 9643913                    | EXPEDITED (15-DAY) | Y                  | OT              | AUR-APL-2013-08673       |                      |                 | Male         | AUS            |
| <u>Preferred Term</u>    | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Convulsive    | Quetiapine                 |                    |                    | S               |                          |                      |                 | Not Reported |                |
| Threshold Lowered;       | Mirtazapine                |                    |                    | S               |                          |                      |                 | Not Reported |                |
| Hallucination, Visual;   | Escitalopram               |                    |                    | S               |                          |                      |                 | Not Reported |                |
| Hypernatraemia; Partial  | Sodium Valproate           |                    |                    | S               |                          |                      |                 | Not Reported |                |
| Seizures; Sedation       |                            |                    |                    |                 |                          |                      |                 |              |                |
| <u>FDA Received Date</u> | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Oct-2013              | 8774328                    | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2012215878 |                      | 43 YR           | Unknown      | USA            |
| <u>Preferred Term</u>    | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity    | Effexor                    |                    |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                          | Neurontin                  |                    |                    | S               | Oral                     | 600 Mg, 3x/Day       |                 | Pfizer       |                |
|                          | Amoxicillin                |                    |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                          | Ibuprofen                  |                    |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                          | Phenytoin                  |                    |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                          | Fexofenadine Hydrochloride |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                          | Flurbiprofen               |                    |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                          | Ketoprofen                 |                    |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                          | Ketorolac Tromethamine     |                    |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                          | Lodine                     |                    |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                          | Meclofenamate Sodium       |                    |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                          | Meclomen                   |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                          | Mefenamic Acid             |                    |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                          | Methocarbamol              |                    |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                          | Momentum                   |                    |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                          | Motrin                     |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |

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

|                    |     |     |              |
|--------------------|-----|-----|--------------|
| Nabumetone         | S   | Unk | Pfizer       |
| Naproxen Sodium    | S   | Unk | Pfizer       |
| Omnicef            | S   | Unk | Pfizer       |
| Ponstel            | S   | Unk | Pfizer       |
| Pravastatin Sodium | S   | Unk | Not Reported |
| Effexor Xr         | S   | Unk | Pfizer       |
| Valerian Root      | S   | Unk | Unknown      |
| Advil              | S   | Unk | Pfizer       |
| Anacin             | S   | Unk | Pfizer       |
| Ansaid             | S   | Unk | Pfizer       |
| Celebrex           | S   | Unk | Pfizer       |
| Diclofenac         | S   | Unk | Pfizer       |
| Dimetapp Sinus     | S   | Unk | Pfizer       |
| Cefadroxil         | S   | Unk | Not Reported |
| Dristan            | Y S | Unk | Pfizer       |
| Daypro             | S   | Unk | Pfizer       |
| Ceclor             | S   | Unk | Not Reported |
| Keflex             | S   | Unk | Not Reported |
| Aspirin            | S   | Unk | Not Reported |
| Lexapro            | S   | Unk | Not Reported |
| Augmentin          | S   | Unk | Not Reported |
| Quinidine          | S   | Unk | Not Reported |
| Pravachol          | S   | Unk | Not Reported |
| Tizanidine         | S   | Unk | Not Reported |
| Zanaflex           | S   | Unk | Not Reported |
| Cymbalta           | S   | Unk | Not Reported |
| Allegra            | S   | Unk | Not Reported |
| Maxzide            | C   | Unk | Not Reported |
| Acular             | S   | Unk | Not Reported |



**FDA Adverse Event Reporting System  
Freedom of Information Act (FOIA)  
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|                 |   |     |              |
|-----------------|---|-----|--------------|
| Aleve           | S | Unk | Not Reported |
| Alka-Seltzer    | S | Unk | Not Reported |
| Anaprox         | S | Unk | Not Reported |
| Ascriptin       | S | Unk | Not Reported |
| Aspirin "Bayer" | S | Unk | Not Reported |
| Bufferin        | S | Unk | Not Reported |
| Cama            | S | Unk | Not Reported |
| Cataflam        | S | Unk | Not Reported |
| Cefaclor        | S | Unk | Not Reported |
| Cephalexin      | S | Unk | Not Reported |
| Feldine         | S | Unk | Not Reported |
| Fenoprofen      | S | Unk | Not Reported |
| Fiorinal        | S | Unk | Not Reported |
| Haltran         | S | Unk | Not Reported |
| Ibuprin         | S | Unk | Not Reported |
| Indocin         | S | Unk | Not Reported |
| Indomethacin    | S | Unk | Not Reported |
| Medipren        | S | Unk | Not Reported |
| Moxatag         | S | Unk | Not Reported |
| Nalfon          | S | Unk | Not Reported |
| Naprelan        | S | Unk | Not Reported |
| Naprosyn        | S | Unk | Not Reported |
| Naproxen        | S | Unk | Not Reported |
| Norflex         | S | Unk | Not Reported |
| Norgesic        | S | Unk | Not Reported |
| Nuprin          | S | Unk | Not Reported |
| Ocufen          | S | Unk | Not Reported |
| Orphenadrine    | S | Unk | Not Reported |
| Orudis          | S | Unk | Not Reported |

**FDA Adverse Event Reporting System  
Freedom of Information Act (FOIA)  
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|              |   |     |              |
|--------------|---|-----|--------------|
| Oruvail      | S | Unk | Not Reported |
| Pamprin      | S | Unk | Not Reported |
| Pepto-Bismol | S | Unk | Not Reported |
| Percodan     | S | Unk | Not Reported |
| Principen    | S | Unk | Not Reported |
| Profenal     | S | Unk | Not Reported |
| Propoxyphene | S | Unk | Not Reported |
| Equagesic    | S | Unk | Not Reported |
| Ecotrin      | S | Unk | Not Reported |
| Empirin      | S | Unk | Not Reported |
| Clinoril     | S | Unk | Not Reported |
| Ceftin       | S | Unk | Not Reported |
| Aggrenox     | S | Unk | Not Reported |
| Combunox     | S | Unk | Not Reported |
| Congespirin  | S | Unk | Not Reported |
| Darvon       | S | Unk | Not Reported |
| Duloxetine   | S | Unk | Not Reported |
| Nexium       | C | Unk | Not Reported |
| Ventolin     | C | Unk | Not Reported |
| Loratadine   | C | Unk | Not Reported |
| Maxalt       | C | Unk | Not Reported |
| Trazodone    | C | Unk | Not Reported |
| Omeprazole   | C | Unk | Not Reported |
| Advair       | C | Unk | Not Reported |
| Fluoxetine   | C | Unk | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Oct-2013              | 9086045       | EXPEDITED (15-DAY) |                    | CA, OT          | US-FRI-1000042156    |                      | < 1 DAY    | Male       | USA            |

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

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

|                                                                                                                                                   |         |   |                |        |
|---------------------------------------------------------------------------------------------------------------------------------------------------|---------|---|----------------|--------|
| Atrial Septal Defect;<br>Hypoplastic Left Heart<br>Syndrome; Patent Ductus<br>Arteriosus; Pulmonary<br>Hypertension; Ventricular<br>Septal Defect | Lexapro | S | Transplacental | Forest |
|---------------------------------------------------------------------------------------------------------------------------------------------------|---------|---|----------------|--------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 24-Oct-2013              | 9524482       | NON-EXPEDITED    |                    |                 | US-PFIZER INC-<br>2013265665 |                      | 75 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|----------------------|-----------------|--------------|
| Arthropathy; Drug<br>Ineffective For<br>Unapproved Indication;<br>Drug Interaction; Fatigue;<br>Gait Disturbance; Product<br>Use In Unapproved<br>Indication; Somnolence | Lyrica         |              |            | S           |              | Unknown Dose, 1x/Day |                 | Pfizer       |
|                                                                                                                                                                          | Lyrica         |              |            | S           |              |                      |                 | Pfizer       |
|                                                                                                                                                                          | Lexapro        |              |            | S           |              | 10 Mg, 1x/Day        |                 | Not Reported |
|                                                                                                                                                                          | Dicyclomine    |              |            | C           |              | 10 Mg, As Needed     |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Oct-2013              | 9642974       | EXPEDITED (15-DAY) |                    | HO              | FR-SA-2013SA104942   |                      | 50 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                                                              | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Coma; Hepatocellular<br>Injury;<br>Hyperphosphataemia;<br>Intentional Overdose;<br>Lactic Acidosis | Paracetamol               |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                    | Zolpidem Tartrate         |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                    | Tercian                   |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                    | Venlafaxine Hydrochloride |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                    | Seroplex                  |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 24-Oct-2013              | 9643034       | EXPEDITED (15-DAY) |                    | DE, OT          | AT-JNJFOC-<br>20131008865 |                      | 24 YR      | Female     | AUT            |

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

**FDA Adverse Event Reporting System  
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|                                      |                     |   |         |              |
|--------------------------------------|---------------------|---|---------|--------------|
| Hyperprolactinaemia;<br>Hypophysitis | Risperdal           | S | Unknown | Not Reported |
|                                      | Risperdal           | S | Unknown | Not Reported |
|                                      | Risperdal           | S | Unknown | Not Reported |
|                                      | Risperdal           | S | Unknown | Not Reported |
|                                      | Risperdal           | S | Unknown | Not Reported |
|                                      | Risperdal           | S | Unknown | Not Reported |
|                                      | Risperdal           | S | Unknown | Not Reported |
|                                      | Risperdal           | S | Unknown | Not Reported |
|                                      | Zyprexa             | S | Unknown | Not Reported |
|                                      | Zyprexa             | S | Unknown | Not Reported |
|                                      | Zyprexa             | S | Unknown | Not Reported |
|                                      | Zyprexa             | S | Unknown | Not Reported |
|                                      | Temesta (Lorazepam) | S | Unknown | Not Reported |
|                                      | Temesta             | S | Unknown | Not Reported |
|                                      | Temesta             | S | Unknown | Not Reported |
|                                      | Temesta             | S | Unknown | Not Reported |
|                                      | Temesta             | S | Unknown | Not Reported |
|                                      | Temesta             | S | Unknown | Not Reported |
|                                      | Temesta             | S | Unknown | Not Reported |
|                                      | Temesta             | S | Unknown | Not Reported |
|                                      | Temesta             | S | Unknown | Not Reported |
|                                      | Temesta             | S | Unknown | Not Reported |
|                                      | Temesta             | S | Unknown | Not Reported |
|                                      | Temesta             | S | Unknown | Not Reported |
|                                      | Cipralex            | S | Unknown | Not Reported |
|                                      | Cipralex            | S | Unknown | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                             | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|---------------------------------------|------------------------------|-----------------|--------------|----------------|
| 24-Oct-2013                                                                          | 9644221                | EXPEDITED (15-DAY) |                    | HO              | CA-ROCHE-1292120                      |                              | 47 YR           | Male         | CAN            |
| <u>Preferred Term</u>                                                                | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Coma; Dizziness;<br>Intentional Overdose;<br>Prescribed Overdose;<br>Suicide Attempt | Rivotril               |                    |                    | S               | Oral                                  | Therapy Duration: 1.0 Days   |                 | Not Reported |                |
|                                                                                      | Cipralext              |                    |                    | S               | Oral                                  |                              |                 | Not Reported |                |
|                                                                                      | Cipralext              |                    |                    | S               | Oral                                  | Therapy Duration: 4.0 Months |                 | Not Reported |                |
|                                                                                      | Ethanol                |                    |                    | S               | Oral                                  | Therapy Duration: 1.0 Days   |                 | Not Reported |                |
|                                                                                      | Wellbutrin Sr          |                    |                    | S               | Oral                                  | Therapy Duration: 4.0 Months |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                             | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Oct-2013                                                                          | 9820228                | NON-EXPEDITED      | Y                  | HO, LT          | 2013-01691                            |                              | 29 YR           | Female       | TUR            |
| <u>Preferred Term</u>                                                                | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Overdose; Suicide Attempt; Toxicity To Various Agents                                | Quetiapine             |                    |                    | S               |                                       |                              |                 | Not Reported |                |
|                                                                                      | Escitalopram (Unknown) |                    |                    | S               |                                       |                              |                 | Not Reported |                |
|                                                                                      | Ibuprofen (Unknown)    |                    |                    | S               |                                       |                              |                 | Not Reported |                |
|                                                                                      | Amoxicillin            |                    |                    | S               |                                       |                              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                             | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Oct-2013                                                                          | 9517196                | EXPEDITED (15-DAY) |                    | DE, HO          | FR-PFIZER INC-2013255250              |                              | 41 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Toxic Epidermal Necrolysis                                                           | Solu-Medrol            |                    |                    | S               | Intravenous (not otherwise specified) | 140 Mg, 1x/Day               |                 | Pfizer       |                |
|                                                                                      | Atarax                 |                    |                    | S               | Oral                                  | 50 Mg, 1x/Day                |                 | Pfizer       |                |
|                                                                                      | Fortum                 |                    |                    | S               | Intravenous (not otherwise specified) | 1 G, 4x/Day                  |                 | Not Reported |                |

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|                                                   |   |                                       |                        |              |
|---------------------------------------------------|---|---------------------------------------|------------------------|--------------|
| Flagyl                                            | S | Oral                                  | 500 Mg, 3x/Day         | Not Reported |
| Gentamycin Pnapharma                              | S | Intravenous (not otherwise specified) | 210 Mg, 1x/Day         | Not Reported |
| Noxafil                                           | S | Oral                                  | 200 Mg, 3x/Day         | Not Reported |
| Cancidas                                          | S | Intravenous (not otherwise specified) | Unk                    | Not Reported |
| Ambisome                                          | S | Intravenous (not otherwise specified) | 180 Mg, 1x/Day         | Not Reported |
| Bactrim                                           | S | Intravenous (not otherwise specified) | 2 Df, 3 Times In Week  | Not Reported |
| Folinic Acid                                      | S | Intravenous (not otherwise specified) | 50 Mg, 3 Times In Week | Not Reported |
| Zelitrex                                          | S | Intravenous (not otherwise specified) | 500 Mg, 2x/Day         | Not Reported |
| Cymevene                                          | S | Intravenous (not otherwise specified) | 350 Mg, 2x/Day         | Not Reported |
| Foscavir                                          | S | Intravenous (not otherwise specified) | 1 Df, 2x/Day           | Not Reported |
| Clairyg                                           | S | Intravenous (not otherwise specified) | Unk                    | Not Reported |
| Granocyte                                         | S | Intravenous (not otherwise specified) | Unk                    | Not Reported |
| Heparin Sodium                                    | S | Intravenous (not otherwise specified) | 7000 Iu, 1x/Day        | Not Reported |
| Inexium                                           | S | Intravenous (not otherwise specified) | 40 Mg, 1x/Day          | Not Reported |
| Spasfon (Phloroglucinol, Trimethylphloroglucinol) | S | Intravenous (not otherwise specified) | 2 Df, 3x/Day           | Not Reported |
| Delursan                                          | S | Oral                                  | 3 Df, 2x/Day           | Not Reported |
| Defibrotide                                       | S | Intravenous (not otherwise specified) | 25 Mg/Kg, 1x/Day       | Not Reported |
| Largactil                                         | S | Intravenous (not otherwise specified) | 1 Df, 1x/Day           | Not Reported |
| Largactil                                         | S | Intravenous (not otherwise specified) | 1 Df, 1x/Day           | Not Reported |

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

|                       |   |                                       |                         |              |
|-----------------------|---|---------------------------------------|-------------------------|--------------|
|                       |   | otherwise specified)                  |                         |              |
| Tranxene              | S | Oral                                  | 5 Mg, As Needed (1df 4) | Not Reported |
| Oxynorm               | S | Intravenous (not otherwise specified) | Unk                     | Not Reported |
| Exacyl                | S | Intravenous (not otherwise specified) | 1 Df, 3x/Day            | Not Reported |
| Perfalgan             | S | Intravenous (not otherwise specified) | 1 G, 3x/Day             | Not Reported |
| Droleptan             | S | Intravenous (not otherwise specified) | 0.625 Mg, 4x/Day        | Not Reported |
| Ultiva                | S | Intravenous (not otherwise specified) | 100 Gbq , 1 In 1 Hour   | Not Reported |
| Lasilix               | S | Intravenous (not otherwise specified) | 40 Mg, 2x/Day           | Not Reported |
| Seroplex              | S | Oral                                  | 10 Mg, 1x/Day           | Not Reported |
| Ceris                 | S | Oral                                  | 20 Mg, 2x/Day           | Not Reported |
| Noctamide             | S | Oral                                  | 2 Mg, 1x/Day            | Not Reported |
| Noctamide             | S | Oral                                  | Scored Tablet, 1x/Day   | Not Reported |
| Gentamycin            | C |                                       | 2 Df, 3x/Day            | Not Reported |
| Colistimethate Sodium | C |                                       | 2 Df, 3x/Day            | Not Reported |
| Vancomycin Mylan      | C |                                       | 1 G, 1x/Day             | Not Reported |
| Ciflox                | C |                                       | 400 Mg, 2x/Day          | Not Reported |
| Targocid              | C |                                       | 400 Mg, 2x/Day          | Not Reported |
| Mycostatine           | C |                                       | 2 Df, 1x/Day (Vials)    | Not Reported |
| Triflucan             | C |                                       | 200 Mg, 1x/Day          | Not Reported |
| Zovirax               | C |                                       | 250 Mg, 3x/Day          | Not Reported |
| Methotrexate Mylan    | C |                                       | 18 Mg, 1x/Day           | Not Reported |
| Elvorine              | C |                                       | 18.4 Mg, 1x/Day         | Not Reported |
| Sandimmun             | C |                                       | 210 Mg, 1x/Day          | Not Reported |
| Mopral                | C |                                       | 20 Mg, 1x/Day           | Not Reported |
| Ogastro               | C |                                       | 30 Mg, 1x/Day           | Not Reported |

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

|            |   |                         |              |
|------------|---|-------------------------|--------------|
| Gelox      | C | 1 Df, 3x/Day            | Not Reported |
| Smecta     | C | 6 Bags/Day              | Not Reported |
| Luteran    | C | Unk, One A Day          | Not Reported |
| Lexomil    | C | 0.5 Df, 1x/Day          | Not Reported |
| Zophren    | C | 2 Df, 1x/Day (Vials)    | Not Reported |
| Primperan  | C | 6 Df, 1x/Day (Vials)    | Not Reported |
| Acupan     | C | 6 Df, As Needed (Vials) | Not Reported |
| Tiorfan    | C | Unk                     | Not Reported |
| Levocarnil | C | 1 G, 3x/Day             | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 25-Oct-2013              | 9519934       | EXPEDITED (15-DAY) |                    | DE, HO, LT      | FR-ASTRAZENECA-2013SE67508 |                      | 41 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                                                                                                              | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                             | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|--------------|------------|-------------|------------------------------------------|--------------------------------|-----------------|--------------|
| Acute Kidney Injury;<br>General Physical Health<br>Deterioration; Hepatitis<br>Fulminant; Multiple Organ<br>Dysfunction Syndrome;<br>Toxic Epidermal<br>Necrolysis | Inexium               |              |            | S           | Intravenous (not<br>otherwise specified) |                                |                 | Not Reported |
|                                                                                                                                                                    | Seroplex              |              |            | S           | Oral                                     |                                |                 | Not Reported |
|                                                                                                                                                                    | Perfalgan             |              |            | S           | Intravenous (not<br>otherwise specified) |                                |                 | Not Reported |
|                                                                                                                                                                    | Ultiva                |              |            | S           | Intravenous (not<br>otherwise specified) | 2400 Gbq (100 Gbq Per<br>Hour) |                 | Not Reported |
|                                                                                                                                                                    | Fortum                |              |            | S           | Intravenous (not<br>otherwise specified) |                                |                 | Not Reported |
|                                                                                                                                                                    | Flagyl                |              |            | S           | Oral                                     |                                |                 | Not Reported |
|                                                                                                                                                                    | Gentamicine Panpharma |              |            | S           | Intravenous (not<br>otherwise specified) |                                |                 | Not Reported |
|                                                                                                                                                                    | Noxafil               |              |            | S           | Oral                                     |                                |                 | Not Reported |
|                                                                                                                                                                    | Candidas              |              |            | S           | Intravenous (not<br>otherwise specified) |                                |                 | Not Reported |
|                                                                                                                                                                    | Ambisome              |              |            | S           | Intravenous (not<br>otherwise specified) |                                |                 | Not Reported |



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

|                                                   |   |                                                                      |              |
|---------------------------------------------------|---|----------------------------------------------------------------------|--------------|
| Bactrim                                           | S | Intravenous (not otherwise specified)                                | Not Reported |
| Acide Folinique                                   | S | Intravenous (not otherwise specified)                                | Not Reported |
| Zelitrex                                          | S | Intravenous (not otherwise specified)                                | Not Reported |
| Cymevene                                          | S | Intravenous (not otherwise specified)                                | Not Reported |
| Foscavir                                          | S | Intravenous (not otherwise specified) 6g/250ml, 1 Df Two Times A Day | Not Reported |
| Clairyg                                           | S | Intravenous (not otherwise specified)                                | Not Reported |
| Granocyte                                         | S | Intravenous (not otherwise specified)                                | Not Reported |
| Heparine Sodique                                  | S | Intravenous (not otherwise specified)                                | Not Reported |
| Spasfon (Phloroglucinol, Trimethylphloroglucinol) | S | Intravenous (not otherwise specified)                                | Not Reported |
| Delursan                                          | S | Oral                                                                 | Not Reported |
| Defibrotide                                       | S | Intravenous (not otherwise specified) 25 Mg/Kg Every Day             | Not Reported |
| Largactil                                         | S | Intravenous (not otherwise specified)                                | Not Reported |
| Tranxene                                          | S | Oral 5 Mg Four Times A Day, On Demand                                | Not Reported |
| Oxynorm                                           | S | Intravenous (not otherwise specified)                                | Not Reported |
| Exacyl                                            | S | Intravenous (not otherwise specified)                                | Not Reported |
| Solumedrol                                        | S | Intravenous (not otherwise specified)                                | Not Reported |
| Droleptan                                         | S | Intravenous (not otherwise specified)                                | Not Reported |
| Atarax                                            | S | Oral                                                                 | Not Reported |

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

|                         |   |                                       |              |
|-------------------------|---|---------------------------------------|--------------|
| Lasilix                 | S | Intravenous (not otherwise specified) | Not Reported |
| Ceris                   | S | Oral                                  | Not Reported |
| Noctamide               | S |                                       | Not Reported |
| Noctamide               | S | Oral                                  | Not Reported |
| Gentamicine + Colistine | C |                                       | Not Reported |
| Vancomycine Mylan       | C |                                       | Not Reported |
| Ciflox                  | C |                                       | Not Reported |
| Targocid                | C |                                       | Not Reported |
| Mycostatine             | C | 2 Flasks A Day                        | Not Reported |
| Triflucan               | C |                                       | Not Reported |
| Zovirax                 | C |                                       | Not Reported |
| Methotrexate            | C |                                       | Not Reported |
| Methotrexate            | C | Mylan                                 | Not Reported |
| Elvorine                | C |                                       | Not Reported |
| Sandimmun               | C |                                       | Not Reported |
| Mopral                  | C |                                       | Not Reported |
| Ogastoro                | C |                                       | Not Reported |
| Gelox                   | C | 1 Sachet Three Times A Day            | Not Reported |
| Smecta                  | C | 6 Sachets Every Day                   | Not Reported |
| Luteran                 | C |                                       | Not Reported |
| Lexomil                 | C |                                       | Not Reported |
| Zophren                 | C | 2 Bulbs Every Day                     | Not Reported |
| Primperan               | C | 6 Bulbs Every Day                     | Not Reported |
| Acupan                  | C | 6 Amps Every Day, On Demand           | Not Reported |
| Tiorfan                 | C |                                       | Not Reported |
| Levocarnil              | C |                                       | Not Reported |
| Endoxan                 | C |                                       | Not Reported |
| Busulvex                | C |                                       | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 25-Oct-2013              | 9644782       | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2013302115 |                      |            | Male       | USA            |

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

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

|         |         |   |      |                |              |
|---------|---------|---|------|----------------|--------------|
| Myalgia | Zoloft  | S | Oral | 100 Mg, 1x/Day | Pfizer       |
|         | Lexapro | S |      | Unk            | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Oct-2013              | 9645293       | EXPEDITED (15-DAY) |                    | OT              | US-FRI-1000050414    |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                                                                        | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>             |
|--------------------------------------------------------------------------------------------------------------|-----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------------------|
| Abdominal Discomfort;<br>Abdominal Pain Upper;<br>Gastrointestinal<br>Haemorrhage; Intestinal<br>Haemorrhage | Lexapro<br>Prednisone |              |            | S<br>C      |              |                    |                 | Forest<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------------|----------------------|------------|------------|----------------|
| 25-Oct-2013              | 9646481       | EXPEDITED (15-DAY) | Y                  | HO              | FR-ABBVIE-13P-056-<br>1161789-00 |                      | 1 DAY      | Male       | FRA            |

| <u>Preferred Term</u>                                                                                                          | <u>Product</u>                    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                                       | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                                   |
|--------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|--------------|------------|-------------|----------------------------------------------------|--------------------|-----------------|----------------------------------------------|
| Bradycardia; Crying;<br>Foetal Exposure During<br>Pregnancy; Portal Vein<br>Thrombosis;<br>Restlessness;<br>Tachycardia Foetal | Depakote<br>Theralite<br>Seroplex |              |            | S<br>S<br>S | Transplacental<br>Transplacental<br>Transplacental |                    |                 | Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Oct-2013              | 9648351       | DIRECT           |                    |                 |                      |                      | 41 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Drug Ineffective; Drug<br>Withdrawal Syndrome;<br>Product Substitution Issue | Escitalopram   |              |            | S           | Oral         | 1 Pill Once Daily  |                 | Mylan      |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Oct-2013              | 9648460       | DIRECT           |                    |                 |                      |                      | 45 YR      | Male       |                |

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

| <u>Preferred Term</u>                                   | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------------|---------------------------------|--------------------|--------------------|-----------------|---------------------------------------|----------------------|-----------------|--------------|----------------|
| Amnesia; Disturbance In Attention; Premature Ageing     | Lexapro                         |                    |                    | S               | Oral                                  | 1 Pill Once Daily    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Oct-2013                                             | 9649623                         | EXPEDITED (15-DAY) | Y                  | OT              | 2013P1020261                          |                      | 1 DAY           | Unknown      | ITA            |
| <u>Preferred Term</u>                                   | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Foetal Exposure During Pregnancy; Low Birth Weight Baby | Escitalopram                    |                    |                    | S               | Intra-uterine                         |                      | 40 WEEK         | Not Reported |                |
| <u>FDA Received Date</u>                                | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Oct-2013                                             | 9820314                         | NON-EXPEDITED      | Y                  | DE              | 2103-00321                            |                      | 23 YR           | Female       | USA            |
| <u>Preferred Term</u>                                   | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                       | Quetiapine (Unknown)            |                    |                    | S               |                                       |                      |                 | Not Reported |                |
|                                                         | Escitalopram (Unknown)          |                    |                    | S               |                                       |                      |                 | Not Reported |                |
|                                                         | Acetaminophen/Codeine (Unknown) |                    |                    | S               |                                       |                      |                 | Not Reported |                |
|                                                         | Metaxalone                      |                    |                    | S               |                                       |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Oct-2013                                             | 9521172                         | EXPEDITED (15-DAY) |                    | HO, OT          | FR-MERCK-1309FRA002229                |                      | 41 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                   | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Toxic Epidermal Necrolysis                              | Candidas                        |                    |                    | S               | Intravenous (not otherwise specified) | Unk                  |                 | Merck        |                |
|                                                         | Fortum                          |                    |                    | S               |                                       | 1 Df, Qid            |                 | Not Reported |                |
|                                                         | Flagyl                          |                    |                    | S               | Oral                                  | 1 Df, Tid            |                 | Not Reported |                |
|                                                         | Gentamicin                      |                    |                    | S               | Intravenous (not otherwise specified) | 210 Mg, Qd           |                 | Not Reported |                |

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

|                                                   |   |                                       |              |              |
|---------------------------------------------------|---|---------------------------------------|--------------|--------------|
| Noxafil                                           | S | Oral                                  | 200 Mg, Tid  | Merck        |
| Ambisome                                          | S | Intravenous (not otherwise specified) | 180 Mg, Qd   | Not Reported |
| Bactrim                                           | S | Intravenous (not otherwise specified) | 2 Df, Tiw    | Not Reported |
| Folic Acid                                        | S | Intravenous (not otherwise specified) | 50 Mg, Tiw   | Not Reported |
| Zelitrex                                          | S | Intravenous (not otherwise specified) | 500 Mg, Bid  | Not Reported |
| Cymevan Iv                                        | S | Intravenous (not otherwise specified) | 350 Mg, Bid  | Not Reported |
| Foscavir                                          | S | Intravenous (not otherwise specified) | 1 Df, Bid    | Not Reported |
| Clairyg                                           | S | Intravenous (not otherwise specified) | Unk          | Not Reported |
| Granocyte                                         | S | Intravenous (not otherwise specified) | Unk          | Not Reported |
| Heparin Sodium                                    | S | Intravenous (not otherwise specified) | 7000 Iu, Qd  | Not Reported |
| Inexium                                           | S | Intravenous (not otherwise specified) | 1 Df, Qd     | Not Reported |
| Spasfon (Phloroglucinol, Trimethylphloroglucinol) | S | Intravenous (not otherwise specified) | 2 Df, Tid    | Not Reported |
| Delursan                                          | S | Oral                                  | 3 Df, Bid    | Not Reported |
| Defibrotide                                       | S | Intravenous (not otherwise specified) | 25 Mg/Kg, Qd | Not Reported |
| Largactil                                         | S | Intravenous (not otherwise specified) | 1 Df, Qd     | Not Reported |
| Tranxene                                          | S | Oral                                  | 4 Df, Prn    | Not Reported |
| Oxynorm                                           | S | Intravenous (not otherwise specified) | Unk          | Not Reported |
| Exacyl                                            | S | Intravenous (not otherwise specified) | 1 Df, Tid    | Not Reported |
| Perfalgan                                         | S | Intravenous (not                      | 1 G, Tid     | Not Reported |

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

|                                      |   |                                       |               |              |
|--------------------------------------|---|---------------------------------------|---------------|--------------|
|                                      |   | otherwise specified)                  |               |              |
| Solu-Medrol                          | S | Intravenous (not otherwise specified) | 140 Mg, Qd    | Not Reported |
| Drolectan                            | S | Intravenous (not otherwise specified) | 0.625 Mg, Qid | Not Reported |
| Ultiva                               | S | Intravenous (not otherwise specified) | 100 Gbq, Qh   | Not Reported |
| Atarax (Alprazolam)                  | S | Oral                                  | 0.5 Df, Qd    | Not Reported |
| Lasilix                              | S | Intravenous (not otherwise specified) | 40 Mg, Bid    | Not Reported |
| Seroplex                             | S | Oral                                  | 10 Mg, Qd     | Not Reported |
| Ceris                                | S | Oral                                  | 2 Df, Qd      | Not Reported |
| Noctamide                            | S | Oral                                  | 1 Df, Qd      | Not Reported |
| Gentamicin                           | C |                                       | 2 Df, Tid     | Not Reported |
| Colistin                             | C |                                       | 2 Df, Tid     | Not Reported |
| Vancomycin Mylan                     | C |                                       | 1 G, Qd       | Not Reported |
| Ciflox (Ciprofloxacin Hydrochloride) | C |                                       | 400 Mg, Bid   | Not Reported |
| Targocid                             | C |                                       | 400 Mg, Bid   | Not Reported |
| Mycostatine                          | C |                                       | 2 Df, Qd      | Not Reported |
| Triflucan                            | C |                                       | 200 Mg, Qd    | Not Reported |
| Zovirax                              | C |                                       | 250 Mg, Tid   | Not Reported |
| Methotrexate                         | C |                                       | 18 Mg, Qd     | Not Reported |
| Elvorine                             | C |                                       | 18.4 Mg, Qd   | Not Reported |
| Sandimmun                            | C |                                       | 210 Mg, Qd    | Not Reported |
| Mopral (Omeprazole Sodium)           | C |                                       | 20 Mg, Qd     | Not Reported |
| Ogastoro                             | C |                                       | 30 Mg, Qd     | Not Reported |
| Gelox (Aluminum Hydroxide)           | C |                                       | 1 Df, Tid     | Not Reported |
| Smecta                               | C |                                       | 6 Df, Qd      | Not Reported |
| Luteran                              | C |                                       | 1 Df, Qd      | Not Reported |
| Lexomil                              | C |                                       | 0.5 Df, Qd    | Not Reported |

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

|                       |   |           |              |
|-----------------------|---|-----------|--------------|
| Noctamide             | C | 1 Df, Qd  | Not Reported |
| Zophren (Ondansetron) | C | 2 Df, Qd  | Not Reported |
| Primperan             | C | 6 Df, Qd  | Not Reported |
| Acupan                | C | 6 Df, Prn | Not Reported |
| Tiorfan               | C | Unk       | Not Reported |
| Levocarnil            | C | 1 G, Tid  | Not Reported |

| <u>FDA Received Date</u>                                                                                                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|------------------------------|-----------------------|-----------------|-----------------|----------------|
| 28-Oct-2013                                                                                                                                         | 9649275        | EXPEDITED (15-DAY) |                    | HO              | FR-GLAXOSMITHKLINE-B0932294A |                       | 84 YR           | Female          | FRA            |
| <u>Preferred Term</u>                                                                                                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>      |                |
| Abdominal Pain; Anaemia; Cholelithiasis; Flatulence; Gastric Haemorrhage; Gastrointestinal Haemorrhage; Haematemesis; Inflammation; Nephrolithiasis | Arixtra        |                    |                    | S               | Subcutaneous                 |                       |                 | Glaxosmithkline |                |
|                                                                                                                                                     | Pradaxa        |                    |                    | S               | Oral                         | 110mg See Dosage Text |                 | Unknown         |                |
|                                                                                                                                                     | Seroplex       |                    |                    | S               | Oral                         | 1unit Per Day         |                 | Unknown         |                |
|                                                                                                                                                     | Ebixa          |                    |                    | C               |                              |                       |                 | Glaxosmithkline |                |
|                                                                                                                                                     | Ramipril       |                    |                    | C               |                              |                       |                 | Glaxosmithkline |                |
|                                                                                                                                                     | Dafalgan       |                    |                    | C               |                              |                       |                 | Glaxosmithkline |                |

| <u>FDA Received Date</u>                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|------------------------|-----------------|--------------|----------------|
| 28-Oct-2013                                                         | 9649643        | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000050540    |                        | 30 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Disturbance In Attention; Intentional Overdose; Irregular Breathing | Escitalopram   |                    |                    | S               | Oral                 | Overdose Of 84 Tablets |                 | Forest       |                |
|                                                                     | Theralene      |                    |                    | S               | Oral                 | Overdose Of 75 Tablets |                 | Not Reported |                |
|                                                                     | Diazepam       |                    |                    | S               | Oral                 | Overdose Of 20 Tablets |                 | Not Reported |                |
|                                                                     | Actiskenan     |                    |                    | S               | Oral                 | Overdose Of 7 Capsules |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Oct-2013              | 9631448       | EXPEDITED (15-DAY) |                    | HO, LT          | FR-FRI-1000050158    |                      | 21 YR      | Female     | FRA            |

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

| <u>Preferred Term</u>                                               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|------------------------|-----------------|--------------|
| Cardiac Disorder;<br>Hypotonia; Intentional<br>Overdose; Somnolence | Escitalopram   |              |            | S           | Oral         |                        |                 | Forest       |
|                                                                     | Escitalopram   |              |            | S           | Oral         | Overdose Of 28 Tablets |                 | Not Reported |
|                                                                     | Theralene      |              |            | S           | Oral         |                        |                 | Not Reported |
|                                                                     | Theralene      |              |            | S           | Oral         | Overdose Of 27 Tablets |                 | Not Reported |
|                                                                     | Xanax          |              |            | S           | Oral         |                        |                 | Not Reported |
|                                                                     | Xanax          |              |            | S           | Oral         | Overdose Of 24 Tablets |                 | Not Reported |
|                                                                     | Risperdal      |              |            | S           | Oral         |                        |                 | Not Reported |
|                                                                     | Risperdal      |              |            | S           | Oral         | Overdose Of 20 Tablets |                 | Not Reported |
|                                                                     | Imovane        |              |            | S           | Oral         |                        |                 | Not Reported |
|                                                                     | Imovane        |              |            | S           | Oral         | Overdose Of 3 Tablets  |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>              | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------------------|----------------------|------------|------------|----------------|
| 29-Oct-2013              | 9654961       | EXPEDITED (15-DAY) |                    | OT              | US-NAPPMUNDI-USA-<br>2012-0091804 |                      | 79 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                            | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                             | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------|------------------------|--------------|------------|-------------|------------------------------------------|--------------------|-----------------|--------------|
| Crying; Hallucination,<br>Auditory; Hallucination,<br>Visual; Prescribed<br>Overdose; Somnolence | Oxycontin (Nda 22-272) |              |            | S           |                                          |                    |                 | Purdue       |
|                                                                                                  | Oxycontin (Nda 22-272) |              |            | S           | Oral                                     | 40 Mg, Tid         |                 | Purdue       |
|                                                                                                  | Morphine /00036302/    |              |            | S           | Intravenous (not<br>otherwise specified) | Unk                |                 | Not Reported |
|                                                                                                  | Lexapro                |              |            | S           | Oral                                     | 20 Mg, Unk         |                 | Not Reported |
|                                                                                                  | Lunesta                |              |            | S           |                                          | 3 Mg, Hs           |                 | Not Reported |
|                                                                                                  | Vicodin                |              |            | C           |                                          | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------------|----------------------|------------|------------|----------------|
| 30-Oct-2013              | 9519448       | EXPEDITED (15-DAY) |                    | DE, HO          | FR-<br>GLAXOSMITHKLINE-<br>B0920180A |                      | 41 YR      | Female     | FRA            |

| <u>Preferred Term</u>                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                             | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>      |
|-----------------------------------------------|----------------|--------------|------------|-------------|------------------------------------------|-----------------------|-----------------|-----------------|
| Acute Kidney Injury;<br>Haematuria; Hepatitis | Fortum         |              |            | S           | Intravenous (not<br>otherwise specified) | 1g Four Times Per Day |                 | Glaxosmithkline |



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

|                                                                            |                                                   |   |                                       |                            |                 |
|----------------------------------------------------------------------------|---------------------------------------------------|---|---------------------------------------|----------------------------|-----------------|
| Fulminant; Multiple Organ Dysfunction Syndrome; Toxic Epidermal Necrolysis | Flagyl                                            | S | Oral                                  | 500mg Three Times Per Day  | Unknown         |
|                                                                            | Gentamycine                                       | S | Intravenous (not otherwise specified) | 210mg Per Day              | Unknown         |
|                                                                            | Noxafil                                           | S | Oral                                  | 200mg Three Times Per Day  | Unknown         |
|                                                                            | Candidas                                          | S | Intravenous (not otherwise specified) |                            | Unknown         |
|                                                                            | Ambisome                                          | S | Intravenous (not otherwise specified) | 180mg Per Day              | Unknown         |
|                                                                            | Bactrim                                           | S | Intravenous (not otherwise specified) | 2unit Three Times Per Week | Unknown         |
|                                                                            | Acid Folinic                                      | S | Intravenous (not otherwise specified) | 50mg Three Times Per Week  | Unknown         |
|                                                                            | Zelitrex                                          | S | Intravenous (not otherwise specified) | 500mg Twice Per Day        | Glaxosmithkline |
|                                                                            | Cymevene                                          | S | Intravenous (not otherwise specified) | 350mg Twice Per Day        | Unknown         |
|                                                                            | Foscavir                                          | S | Intravenous (not otherwise specified) | 1unit Twice Per Day        | Otsuka          |
|                                                                            | Human Immunoglobulin A\Human Immunoglobulin G     | S | Intravenous (not otherwise specified) |                            | Unknown         |
|                                                                            | Granocyte                                         | S | Intravenous (not otherwise specified) |                            | Unknown         |
|                                                                            | Heparin                                           | S | Intravenous (not otherwise specified) | 7000iu Per Day             | Unknown         |
|                                                                            | Inexium                                           | S | Intravenous (not otherwise specified) | 40mg Per Day               | Unknown         |
|                                                                            | Spasfon (Phloroglucinol, Trimethylphloroglucinol) | S | Intravenous (not otherwise specified) | 2unit Three Times Per Day  | Unknown         |
|                                                                            | Delursan                                          | S | Oral                                  | 3unit Twice Per Day        | Unknown         |
|                                                                            | Defibrotide                                       | S | Intravenous (not otherwise specified) | 25mgk Per Day              | Unknown         |
|                                                                            | Largactil                                         | S | Intravenous (not                      | 1unit Per Day              | Unknown         |

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

|              |     |                                       |                           |  |                 |
|--------------|-----|---------------------------------------|---------------------------|--|-----------------|
|              |     |                                       | otherwise specified)      |  |                 |
| Tranxene     | S   | Oral                                  | 4unit Per Day             |  | Unknown         |
| Oxynorm      | S   | Intravenous (not otherwise specified) |                           |  | Unknown         |
| Exacyl       | S   | Intravenous (not otherwise specified) | 1unit Three Times Per Day |  | Unknown         |
| Perfalgan    | Y S | Intravenous (not otherwise specified) | 1g Three Times Per Day    |  | Unknown         |
| Solumedrol   | S   | Intravenous (not otherwise specified) | 140mg Per Day             |  | Unknown         |
| Droleptan    | S   | Intravenous (not otherwise specified) | .625mg Four Times Per Day |  | Unknown         |
| Ultiva       | S   |                                       |                           |  | Unknown         |
| Atarax       | S   | Oral                                  | 50mg Per Day              |  | Unknown         |
| Lasilix      | S   | Intravenous (not otherwise specified) | 40mg Twice Per Day        |  | Unknown         |
| Seroplex     | S   | Oral                                  | 10mg Per Day              |  | Unknown         |
| Ceris        | S   | Oral                                  | 20mg Twice Per Day        |  | Unknown         |
| Noctamide    | S   | Oral                                  | 2mg Per Day               |  | Unknown         |
| Vancomycin   | C   | Unknown                               | 1g Per Day                |  | Unknown         |
| Ciflox       | C   | Unknown                               | 400mg Twice Per Day       |  | Glaxosmithkline |
| Targocid     | C   | Unknown                               | 400mg Twice Per Day       |  | Not Reported    |
| Mycostatine  | C   | Unknown                               | 2bt Per Day               |  | Glaxosmithkline |
| Triflucan    | C   | Unknown                               | 200mg Per Day             |  | Glaxosmithkline |
| Zovirax      | C   | Unknown                               | 250mg Three Times Per Day |  | Glaxosmithkline |
| Methotrexate | C   | Unknown                               | 18mg Per Day              |  | Glaxosmithkline |
| Elvorine     | C   | Unknown                               | 18.4mg Per Day            |  | Glaxosmithkline |
| Sandimmun    | C   | Unknown                               | 210mg Per Day             |  | Glaxosmithkline |
| Mopral       | C   | Unknown                               | 20mg Per Day              |  | Glaxosmithkline |
| Ogast        | C   | Oral                                  | 30mg Per Day              |  | Glaxosmithkline |
| Gelox        | C   | Oral                                  | 1sac Three Times Per Day  |  | Glaxosmithkline |

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

|            |   |         |                          |                 |
|------------|---|---------|--------------------------|-----------------|
| Smecta     | C | Oral    | 6sac Per Day             | Not Reported    |
| Luteran    | C |         | 1unit Per Day            | Not Reported    |
| Lexomil    | C |         | .5unit Per Day           | Glaxosmithkline |
| Zophren    | C | Oral    | 2amp Per Day             | Glaxosmithkline |
| Primperan  | C |         | 6amp Per Day             | Glaxosmithkline |
| Acupan     | C |         | 6amp Per Day             | Not Reported    |
| Tiorfan    | C | Unknown |                          | Glaxosmithkline |
| Levocarnil | C | Unknown | 1g Three Times Per Day   | Glaxosmithkline |
| Gentamicin | C | Oral    | 2cap Three Times Per Day | Glaxosmithkline |
| Colistine  | C | Oral    | 2cap Three Times Per Day | Not Reported    |
| Endoxan    | C |         |                          | Not Reported    |
| Busulfan   | C |         |                          | Glaxosmithkline |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 30-Oct-2013              | 9523685       | EXPEDITED (15-DAY) |                    | DE, HO          | FR-ALLERGAN-1313978US |                      | 41 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                                      | <u>Product</u>                                       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                             | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------|------------------------------------------------------|--------------|------------|-------------|------------------------------------------|---------------------|-----------------|--------------|
| Acute Kidney Injury;<br>Hepatitis Fulminant; Organ<br>Failure; Toxic Epidermal<br>Necrosis | Trospium Chloride Unk                                |              |            | S           | Oral                                     | 1 Df, Bid           |                 | Indevus      |
|                                                                                            | Clairyg                                              |              |            | S           | Intravenous (not<br>otherwise specified) | Unk                 |                 | Not Reported |
|                                                                                            | Heparin Sodium                                       |              |            | S           | Intravenous (not<br>otherwise specified) | 1 X 1 Df / 1 Day(S) |                 | Not Reported |
|                                                                                            | Delursan                                             |              |            | S           | Oral                                     | 2 Df, Tid           |                 | Not Reported |
|                                                                                            | Defibrotide                                          |              |            | S           | Intravenous (not<br>otherwise specified) | 25 Mg/Kg, Qd        |                 | Not Reported |
|                                                                                            | Noxafil                                              |              |            | S           | Oral                                     | 200 Mg, Tid         |                 | Not Reported |
|                                                                                            | Spasfon (Phloroglucinol,<br>Trimethylphloroglucinol) |              |            | S           | Intravenous (not<br>otherwise specified) | 2 Df, Tid           |                 | Not Reported |
|                                                                                            | Largactil                                            |              |            | S           | Intravenous (not<br>otherwise specified) | 1 Df, Qd            |                 | Not Reported |
|                                                                                            | Oxynorm                                              |              |            | S           | Intravenous (not<br>otherwise specified) | Unknown             |                 | Not Reported |

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

|              |   |                                       |                |              |
|--------------|---|---------------------------------------|----------------|--------------|
| Fortum       | S | Intravenous (not otherwise specified) | 1 Df, Qid      | Not Reported |
| Tranxene     | S | Oral                                  | 4 X 1 Df, Prn  | Not Reported |
| Candidas     | S | Intravenous (not otherwise specified) | Unk            | Not Reported |
| Ambisome     | S | Intravenous (not otherwise specified) | 180 Mg, Qd     | Not Reported |
| Zelitrex     | S | Intravenous (not otherwise specified) | 500 Mg, Bid    | Not Reported |
| Inexium      | S | Intravenous (not otherwise specified) | 1 Df, Qd       | Not Reported |
| Solumedrol   | S | Intravenous (not otherwise specified) | 140 Mg, Qd     | Not Reported |
| Perfalgan    | S | Intravenous (not otherwise specified) | 1 G, Tid       | Not Reported |
| Flagyl       | S | Oral                                  | 500 Mg, Tid    | Not Reported |
| Droleptan    | S | Intravenous (not otherwise specified) | 0.625 Mg, Qid  | Not Reported |
| Ultiva       | S | Intravenous (not otherwise specified) | 100 Gbq, Q1hr  | Not Reported |
| Atarax       | S | Oral                                  | 0.5 Df, Qd     | Not Reported |
| Lasilix      | S | Intravenous (not otherwise specified) | 40 Mg, Bid     | Not Reported |
| Seroplex     | S | Oral                                  | 10 Mg, Qd      | Not Reported |
| Bactrim      | S | Intravenous (not otherwise specified) | 2 Df, Tid      | Not Reported |
| Folinic Acid | S | Intravenous (not otherwise specified) | 150 Mg, Q Week | Not Reported |
| Cymevene     | S | Intravenous (not otherwise specified) | 350 Mg, Bid    | Not Reported |
| Exacyl       | S | Intravenous (not otherwise specified) | 1 Df, Tid      | Not Reported |
| Granocyte    | S | Intravenous (not otherwise specified) | Unk            | Not Reported |

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

|                       |   |                                       |            |              |
|-----------------------|---|---------------------------------------|------------|--------------|
| Foscavir              | S | Intravenous (not otherwise specified) | 1 Df, Bid  | Not Reported |
| Noctamide             | S | Oral                                  | 2 Mg, Qd   | Not Reported |
| Gentamicine Panpharma | S | Intravenous (not otherwise specified) | 210 Mg, Qd | Not Reported |
| Gentamicin/Colistine  | C |                                       | Unk        | Not Reported |
| Vancomycin Mylan      | C |                                       | Unk        | Not Reported |
| Mycostatine           | C |                                       | Unk        | Not Reported |
| Triflucan             | C |                                       | Unk        | Not Reported |
| Zovirax               | C |                                       | Unk        | Not Reported |
| Methotrexate Mylan    | C |                                       | Unk        | Not Reported |
| Elvorine              | C |                                       | Unk        | Not Reported |
| Mopral                | C |                                       | Unk        | Not Reported |
| Gelox                 | C |                                       | Unk        | Not Reported |
| Luteran               | C |                                       | Unk        | Not Reported |
| Lexomil               | C |                                       | Unk        | Not Reported |
| Noctamide             | C |                                       | Unk        | Not Reported |
| Zophren               | C |                                       | Unk        | Not Reported |
| Sandimmun             | C |                                       | Unk        | Not Reported |
| Ogastoro              | C |                                       | Unk        | Not Reported |
| Smecta                | C |                                       | Unk        | Not Reported |
| Primperan             | C |                                       | Unk        | Not Reported |
| Acupan                | C |                                       | Unk        | Not Reported |
| Tiorfan               | C |                                       | Unk        | Not Reported |
| Ciflox                | C |                                       | Unk        | Not Reported |
| Levocarnil            | C |                                       | Unk        | Not Reported |
| Targocid              | C |                                       | Unk        | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 30-Oct-2013              | 9614481       | EXPEDITED (15-DAY) |                    | DE, HO          | FR-PFIZER INC-2013291087 |                      | 86 YR      | Male       | FRA            |

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

| <u>Preferred Term</u>                                                                                                                 | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction;<br>Glomerular Filtration Rate<br>Decreased; International<br>Normalised Ratio<br>Increased; Pneumonia<br>Aspiration | Cordarone              |              |            | S           | Oral         | 200 Mg, Daily      |                 | Pfizer       |
|                                                                                                                                       | Amiodarone Hcl         |              |            | S           | Oral         | 400 Mg, Daily      |                 | Pfizer       |
|                                                                                                                                       | Doliprane              |              |            | S           | Oral         | 1 Unit, Daily      |                 | Not Reported |
|                                                                                                                                       | Seroplex               |              |            | S           | Oral         | 15 Mg, Daily       |                 | Not Reported |
|                                                                                                                                       | Previscan (Fluindione) |              |            | S           | Oral         | 20 Mg, Daily       |                 | Not Reported |
|                                                                                                                                       | Furosemide             |              |            | C           |              | Unk                |                 | Not Reported |
|                                                                                                                                       | Lasilix                |              |            | C           |              | Unk                |                 | Not Reported |
|                                                                                                                                       | Ebixa                  |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                       | Mecir                  |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                       | Debridat               |              |            | C           |              | Unk                |                 | Not Reported |
|                                                                                                                                       | Lysanxia               |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                       | Kaleorid               |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                       | Permixon               |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                       | Xanax                  |              |            | C           |              | Unk                |                 | Not Reported |
|                                                                                                                                       | Valsartan              |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                       | Poly Karaya            |              |            | C           |              | Unk                |                 | Not Reported |
|                                                                                                                                       | Movicol                |              |            | C           |              | Unk                |                 | Not Reported |
|                                                                                                                                       | Tiapridal              |              |            | C           |              | Unk                |                 | Not Reported |
|                                                                                                                                       | Augmentin              |              |            | C           |              | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 30-Oct-2013              | 9656147       | EXPEDITED (15-DAY) |                    | HO              | US-JNJFOC-20131013655 |                      | 16 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Electrocardiogram Qrs<br>Complex Prolonged;<br>Electrocardiogram Qt<br>Prolonged; Hypotension;<br>Lethargy; Overdose; Sinus<br>Bradycardia; Skin<br>Laceration; Syncope;<br>Vomiting | Tramadol/Paracetamol      |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                                                      | Escitalopram              |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                                                      | Acetaminophen\Hydrocodone |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                                                      | Bitartrate                |              |            |             |              |                    |                 |              |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|--------------------------|-----------------|--------------|----------------|
| 30-Oct-2013                                                                                                                                           | 9656528        | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000050554    |                          | 50 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                                                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Coma; Hepatocellular Injury; Hyperphosphataemia; Lactic Acidosis                                                                                      | Escitalopram   |                    |                    | S               | Oral                 | Overdose With 10 Tablets |                 | Forest       |                |
|                                                                                                                                                       | Paracetamol    |                    |                    | S               | Oral                 | Overdose With 50 Grams   |                 | Not Reported |                |
|                                                                                                                                                       | Zolpidem       |                    |                    | S               | Oral                 | Overdose With 14 Tablets |                 | Not Reported |                |
|                                                                                                                                                       | Tercian        |                    |                    | S               | Oral                 | Overdose With 45 Tablets |                 | Not Reported |                |
|                                                                                                                                                       | Venlafaxine    |                    |                    | S               | Oral                 | Overdose With 10 Tablets |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Oct-2013                                                                                                                                           | 9657133        | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000050548    |                          | < 1 DAY         | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrial Septal Defect; Congenital Anomaly; Heart Disease Congenital; Pulmonary Valve Stenosis; Right Atrial Enlargement; Right Ventricular Enlargement | Lexapro        |                    |                    | S               | Transplacental       |                          |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Oct-2013                                                                                                                                           | 9663776        | DIRECT             |                    | HO              |                      |                          | 47 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Mania; Product Substitution Issue; Suicide Attempt                                                                                                    | Lexapro        |                    |                    | S               | Oral                 |                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Oct-2013                                                                                                                                           | 9663779        | DIRECT             |                    | HO              |                      |                          | 58 YR           | Male         | USA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                                                                   | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------------------------------------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|--------------------------------|-------------------------------------|-----------------|--------------|----------------|
| Product Substitution Issue;<br>Therapeutic Response<br>Changed                                                          | Bupropion XI                |                    |                    | S               |                                | Taken By Mouth                      |                 | Teva         |                |
|                                                                                                                         | Escitalopram                |                    |                    | S               |                                | Taken By Mouth                      |                 | Teva         |                |
| <u>FDA Received Date</u>                                                                                                | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Oct-2013                                                                                                             | 9663793                     | DIRECT             |                    |                 |                                |                                     | 45 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                   | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Diarrhoea;<br>Fatigue; Flatulence;<br>Gastrointestinal Disorder;<br>Headache; Insomnia;<br>Weight Decreased | Escitalopram                |                    |                    | S               | Oral                           | 1 Dose Once Daily Taken<br>By Mouth |                 | Accord       |                |
| <u>FDA Received Date</u>                                                                                                | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Oct-2013                                                                                                             | 9664176                     | DIRECT             | Y                  |                 |                                |                                     |                 | Male         | USA            |
| <u>Preferred Term</u>                                                                                                   | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Product Substitution Issue;<br>Therapy Non-Responder                                                                    | Escitalopram                |                    |                    | S               |                                |                                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Oct-2013                                                                                                             | 9664551                     | DIRECT             |                    |                 |                                |                                     | 42 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                   | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Product<br>Substitution Issue;<br>Restlessness; Stress                                                       | Escitalopram 10mg Aurobiudo |                    |                    | S               | Oral                           |                                     |                 | Not Reported |                |
|                                                                                                                         | Pharma<br>Sertraline        |                    |                    | S               |                                |                                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-Oct-2013                                                                                                             | 8681116                     | EXPEDITED (15-DAY) |                    | HO, LT, OT      | CH-009507513-<br>1207CHE007059 |                                     | 73 YR           | Male         | CHE            |
| <u>Preferred Term</u>                                                                                                   | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |



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

|                                                                                                 |                |   |              |                   |              |
|-------------------------------------------------------------------------------------------------|----------------|---|--------------|-------------------|--------------|
| Acute Kidney Injury; Blood Loss Anaemia; Hypotonia; Lower Gastrointestinal Haemorrhage; Melaena | Remeron        | S | Oral         | 30 Mg, Qd         | Merck        |
|                                                                                                 | Plavix         | S | Oral         | 75 Mg, Qd         | Not Reported |
|                                                                                                 | Aspirin Cardio | S | Oral         | 100 Mg, Qd        | Not Reported |
|                                                                                                 | Cipralext      | S | Oral         | 10 Mg, Qd         | Not Reported |
|                                                                                                 | Glucophage     | S |              | 850 Mg, Qd        | Not Reported |
|                                                                                                 | Flector        | S | Cutaneous    | 1 Df, Unk         | Not Reported |
|                                                                                                 | Concor         | C | Oral         | 10 Mg, Qd         | Not Reported |
|                                                                                                 | Triatec Comp   | C | Oral         | 2.5/12.5mg, Qd    | Not Reported |
|                                                                                                 | Sortis         | C | Oral         | 40 Mg, Qd         | Not Reported |
|                                                                                                 | Seroquel       | C |              | 25 Mg, Qd         | Not Reported |
|                                                                                                 | Lantus         | C | Subcutaneous | 4 lu              | Not Reported |
|                                                                                                 | Pradif         | C |              | 400 Microgram, Qd | Not Reported |
|                                                                                                 | Haldol         | C | Oral         | Unk, Prn          | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 31-Oct-2013              | 8780945       | EXPEDITED (15-DAY) |                    | OT              | US-009507513-1209USA003695 |                      | 33 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                   | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abdominal Pain; Amylase Increased; Biliary Dilatation; Lipase Increased | Isentress            |              |            | S           | Oral         |                    |                 | Merck        |
|                                                                         | Escitalopram Oxalate |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                         | Truvada              |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                         | Tercian              |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                         | Irbesartan           |              |            | C           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 31-Oct-2013              | 8784739       | EXPEDITED (15-DAY) |                    | OT              | ES-009507513-1209ESP005286 |                      | 71 YR      | Male       | ESP            |

| <u>Preferred Term</u> | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Acute Psychosis       | Carbidopa (+) Levodopa |              |            | S           | Oral         |                    |                 | Merck        |
|                       | Zyprexa                |              |            | S           | Oral         |                    |                 | Not Reported |

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

|  |                                  |   |      |              |
|--|----------------------------------|---|------|--------------|
|  | Deprax (Trazodone Hydrochloride) | S | Oral | Not Reported |
|  | Stelara                          | C | Oral | Not Reported |
|  | Escitalopram                     | S | Oral | Not Reported |
|  | Omeprazole                       | C | Oral | Not Reported |

| <u>FDA Received Date</u>                                           | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| 31-Oct-2013                                                        | 8795304                  | EXPEDITED (15-DAY) |                    | DE, OT          | US-009507513-1209USA006060 |                      | 65 YR           | Female       | USA            |
| <u>Preferred Term</u>                                              | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bipolar I Disorder;                                                | Saphris                  |                    |                    | S               | Oral                       | 5 Mg, Qd             |                 | Merck        |                |
| Cardiomegaly; Completed Suicide; Left Ventricular Hypertrophy;     | Lexapro                  |                    |                    | S               | Oral                       | 10 Mg, Qd            |                 | Not Reported |                |
| Nephrosclerosis;                                                   | Lexapro                  |                    |                    | S               | Oral                       | 20 Mg, Qd            |                 | Not Reported |                |
| Pneumoconiosis;                                                    | Xanax                    |                    |                    | S               | Oral                       | 1 Mg, Qd             |                 | Not Reported |                |
| Pulmonary Congestion; Self-Medication; Toxicity To Various Agents; | Vicodin                  |                    |                    | S               | Oral                       | Unk                  |                 | Not Reported |                |
| Visceral Congestion                                                | Triamterene              |                    |                    | C               |                            |                      |                 | Not Reported |                |
|                                                                    | Atacand                  |                    |                    | C               |                            |                      |                 | Not Reported |                |
|                                                                    | Simvastatin Tablets, Usp |                    |                    | C               |                            |                      |                 | Merck        |                |
|                                                                    | Famotidine               |                    |                    | C               |                            |                      |                 | Merck        |                |

| <u>FDA Received Date</u>                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------------|-------------------------------|-----------------|--------------|----------------|
| 31-Oct-2013                                                    | 9659155        | EXPEDITED (15-DAY) |                    | OT              | CH-009507513-1310CHE011726 |                               | 39 YR           | Female       | CHE            |
| <u>Preferred Term</u>                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation;                                                     | Remeron        |                    |                    | S               | Oral                       | 10 Dosage Units, Once         |                 | Merck        |                |
| Electrocardiogram Qt Prolonged; Hypokalaemia;                  | Lorazepam      |                    |                    | S               | Oral                       | 10 Dosage Units, Once         |                 | Not Reported |                |
| Intentional Overdose; Somnolence; Suicide Attempt; Tachycardia | Escitalopram   |                    |                    | S               | Oral                       | Number Of Units Unknown, Once |                 | Not Reported |                |
|                                                                | Trimipramine   |                    |                    | S               | Oral                       | 10 Dosage Units, Once         |                 | Not Reported |                |
|                                                                | Alcohol        |                    |                    | S               | Oral                       | 2 Bottles, Once               |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                       | <u>Case #</u>                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u>                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------|------------------------------------------|--------------------|--------------------|-----------------|-------------------------------|-------------------------------------------|-----------------|--------------|----------------|
| 31-Oct-2013                                                                                    | 9660224                                  | EXPEDITED (15-DAY) |                    | DE              | US-NAPPMUNDI-USA-2011-0066313 |                                           | 26 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                          | <u>Product</u>                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>                        | <u>Duration</u> | <u>Mfr</u>   |                |
| Accidental Overdose;<br>Substance Abuse                                                        | Oxycontin Tablets                        |                    |                    | S               |                               |                                           |                 | Purdue       |                |
|                                                                                                | Morphine Sulfate (Similar To Nda 19-516) |                    |                    | S               |                               |                                           |                 | Purdue       |                |
|                                                                                                | Xanax                                    |                    |                    | S               |                               |                                           |                 | Not Reported |                |
|                                                                                                | Cocaine                                  |                    |                    | S               |                               |                                           |                 | Not Reported |                |
|                                                                                                | Cannabis                                 |                    |                    | S               |                               |                                           |                 | Not Reported |                |
|                                                                                                | Hydroxyzine                              |                    |                    | S               |                               |                                           |                 | Not Reported |                |
|                                                                                                | Escitalopram                             |                    |                    | S               |                               |                                           |                 | Not Reported |                |
|                                                                                                | Ibuprofen                                |                    |                    | S               |                               |                                           |                 | Not Reported |                |
|                                                                                                | Quetiapine                               |                    |                    | S               |                               |                                           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                       | <u>Case #</u>                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u>                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-Oct-2013                                                                                    | 9661103                                  | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000050681             |                                           | < 1 DAY         | Male         | FRA            |
| <u>Preferred Term</u>                                                                          | <u>Product</u>                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>                        | <u>Duration</u> | <u>Mfr</u>   |                |
| Foetal Exposure During Pregnancy; Portal Vein Thrombosis; Product Use In Unapproved Indication | Escitalopram                             |                    |                    | S               | Transplacental                | 5 Mg                                      |                 | Forest       |                |
|                                                                                                | Depakote                                 |                    |                    | S               | Transplacental                | 250 Mg                                    |                 | Not Reported |                |
|                                                                                                | Teralithe                                |                    |                    | S               | Transplacental                | 125 Mg                                    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                       | <u>Case #</u>                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u>                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-Oct-2013                                                                                    | 9661259                                  | EXPEDITED (15-DAY) |                    | OT              | US-FRI-1000050468             |                                           |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                          | <u>Product</u>                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>                        | <u>Duration</u> | <u>Mfr</u>   |                |
| Anaemia; Blood Pressure Increased; Large Intestinal Haemorrhage                                | Lexapro                                  |                    |                    | S               | Oral                          | 10 Mg                                     |                 | Forest       |                |
|                                                                                                | Lexapro                                  |                    |                    | S               |                               |                                           |                 | Forest       |                |
|                                                                                                | Advil                                    |                    |                    | S               |                               | 2-3 Times Daily Prn (Up To 6 Times Daily) |                 | Not Reported |                |
|                                                                                                | Advil                                    |                    |                    | S               |                               |                                           |                 | Not Reported |                |
|                                                                                                | Synthroid                                |                    |                    | C               |                               | 0.25 Mg                                   |                 | Not Reported |                |

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

|                                                                                                                            |                   |                    |                    |                 |                                       |                                        |                 |              |                |
|----------------------------------------------------------------------------------------------------------------------------|-------------------|--------------------|--------------------|-----------------|---------------------------------------|----------------------------------------|-----------------|--------------|----------------|
| Benicar                                                                                                                    |                   |                    | C                  |                 | 40 Mg                                 |                                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                   | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-Oct-2013                                                                                                                | 9665753           | DIRECT             |                    |                 |                                       |                                        | 27 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                      | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Anger; Condition Aggravated; Crying; Drug Ineffective; Product Substitution Issue                                          | Escitalopram 20mg |                    |                    | S               | Oral                                  | 1 Pill Once Daily Taken By 1 MTH Mouth |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                   | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Nov-2013                                                                                                                | 8818333           | NON-EXPEDITED      |                    |                 | US-009507513-1209USA004813            |                                        |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                      | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Insomnia; Muscle Twitching                                                                                        | Januvia           |                    |                    | S               | Oral                                  | 50 Mg, Qd                              |                 | Merck        |                |
|                                                                                                                            | Lexapro           |                    |                    | S               |                                       | 20 Mg, Unk                             |                 | Not Reported |                |
|                                                                                                                            | Lexapro           |                    |                    | S               |                                       | 10 Unk, Unk                            |                 | Not Reported |                |
|                                                                                                                            | Lorazepam         |                    |                    | C               |                                       | Unk                                    |                 | Not Reported |                |
|                                                                                                                            | Metformin         |                    |                    | C               |                                       | 500 Mg, Bid                            |                 | Not Reported |                |
|                                                                                                                            | Glyburide         |                    |                    | C               |                                       | 5 Mg, Unk                              |                 | Not Reported |                |
|                                                                                                                            | Trimethoprim      |                    |                    | C               |                                       | 100 Mg, Unk                            |                 | Not Reported |                |
|                                                                                                                            | Simvastatin       |                    |                    | C               |                                       | Unk                                    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                   | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Nov-2013                                                                                                                | 9531902           | EXPEDITED (15-DAY) |                    | DE, HO, OT      | FR-SANOFI-AVENTIS-2013SA091919        |                                        | 41 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                      | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Acute Kidney Injury; Bladder Disorder; Blister; Graft Versus Host Disease In Gastrointestinal Tract; Haematuria; Hepatitis | Flagyl            |                    |                    | S               | Oral                                  |                                        |                 | Not Reported |                |
|                                                                                                                            | Heparin Sodium    |                    |                    | S               | Intravenous (not otherwise specified) |                                        |                 | Not Reported |                |

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|                                                                                                                   |                                                   |   |                                       |               |              |
|-------------------------------------------------------------------------------------------------------------------|---------------------------------------------------|---|---------------------------------------|---------------|--------------|
| Fulminant; Multiple Organ Dysfunction Syndrome; Oedema; Skin Exfoliation; Skin Lesion; Toxic Epidermal Necrolysis | Largactil                                         | S | Intravenous (not otherwise specified) | Form:Infusion | Not Reported |
|                                                                                                                   | Exacyl                                            | S | Intravenous (not otherwise specified) | Form:Infusion | Not Reported |
|                                                                                                                   | Lasilix                                           | S | Intravenous (not otherwise specified) |               | Not Reported |
|                                                                                                                   | Granocyte                                         | S | Intravenous (not otherwise specified) | Form:Infusion | Not Reported |
|                                                                                                                   | Delursan                                          | S | Oral                                  |               | Not Reported |
|                                                                                                                   | Gentamicin                                        | S | Intravenous (not otherwise specified) | Form:Infusion | Not Reported |
|                                                                                                                   | Noxafil                                           | S | Oral                                  |               | Not Reported |
|                                                                                                                   | Candidas                                          | S | Intravenous (not otherwise specified) | Form:Infusion | Not Reported |
|                                                                                                                   | Ambisome                                          | S | Intravenous (not otherwise specified) | Form:Infusion | Not Reported |
|                                                                                                                   | Bactrim                                           | S | Intravenous (not otherwise specified) |               | Not Reported |
|                                                                                                                   | Folinic Acid                                      | S | Intravenous (not otherwise specified) |               | Not Reported |
|                                                                                                                   | Zelitrex                                          | S | Intravenous (not otherwise specified) | Form:Infusion | Not Reported |
|                                                                                                                   | Cymevene                                          | S | Intravenous (not otherwise specified) | Form:Infusion | Not Reported |
|                                                                                                                   | Foscavir                                          | S | Intravenous (not otherwise specified) |               | Not Reported |
|                                                                                                                   | Clairyg                                           | S | Intravenous (not otherwise specified) | Form:Infusion | Not Reported |
|                                                                                                                   | Inexium                                           | S | Intravenous (not otherwise specified) |               | Not Reported |
|                                                                                                                   | Spasfon (Phloroglucinol, Trimethylphloroglucinol) | S | Intravenous (not otherwise specified) |               | Not Reported |
|                                                                                                                   | Defibrotide                                       | S | Intravenous (not otherwise specified) |               | Not Reported |

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

|                          |   |                                                     |              |
|--------------------------|---|-----------------------------------------------------|--------------|
| Tranxene                 | S | Oral                                                | Not Reported |
| Perfalgan                | S | Intravenous (not otherwise specified)               | Not Reported |
| Solumedrol               | S | Intravenous (not otherwise specified) Form:Infusion | Not Reported |
| Droleptan                | S | Intravenous (not otherwise specified)               | Not Reported |
| Ultiva                   | S | Intravenous (not otherwise specified)               | Not Reported |
| Atarax                   | S | Oral                                                | Not Reported |
| Seroplex                 | S | Oral                                                | Not Reported |
| Ceris                    | S | Oral                                                | Not Reported |
| Noctamide                | S | Oral                                                | Not Reported |
| Noctamide                | S | Oral                                                | Not Reported |
| Oxynorm                  | S | Intravenous (not otherwise specified) Form:Infusion | Not Reported |
| Fortum                   | S | Intravenous (not otherwise specified)               | Not Reported |
| Vancomycin Hydrochloride | C |                                                     | Not Reported |
| Ciflox                   | C |                                                     | Not Reported |
| Targocid                 | C |                                                     | Not Reported |
| Mycostatin               | C |                                                     | Not Reported |
| Triflucan                | C |                                                     | Not Reported |
| Zovirax                  | C |                                                     | Not Reported |
| Methotrexate             | C |                                                     | Not Reported |
| Elvorine                 | C |                                                     | Not Reported |
| Sandimmune               | C |                                                     | Not Reported |
| Mopral                   | C |                                                     | Not Reported |
| Ogastoro                 | C |                                                     | Not Reported |
| Gelox                    | C |                                                     | Not Reported |
| Smecta                   | C |                                                     | Not Reported |
| Luteran                  | C |                                                     | Not Reported |
| Lexomil                  | C |                                                     | Not Reported |
| Primperan                | C |                                                     | Not Reported |
| Acupan                   | C |                                                     | Not Reported |
| Tiorfan                  | C |                                                     | Not Reported |
| Levocarnil               | C |                                                     | Not Reported |

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| Zophren                                                                                                                                                                           |                                 |                    | C                  |                                          |                                          |                                | Not Reported    |              |                |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|--------------------|--------------------|------------------------------------------|------------------------------------------|--------------------------------|-----------------|--------------|----------------|
| <u>FDA Received Date</u>                                                                                                                                                          | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>                          | <u>Mfr Control #</u>                     | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Nov-2013                                                                                                                                                                       | 9549251                         | EXPEDITED (15-DAY) | Y                  | DE, HO, OT                               | AXC-2013-000466                          |                                | 41 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                                                             | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                              | <u>Route</u>                             | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Acute Kidney Injury;<br>Bladder Disorder; Graft<br>Versus Host Disease In<br>Gastrointestinal Tract;<br>Haematuria; Hepatitis<br>Fulminant; Oedema; Toxic<br>Epidermal Necrolysis | Delursan (Ursodeoxycholic Acid) |                    |                    | S                                        | Oral                                     | 3 Df, Bid, Oral                |                 |              | Not Reported   |
|                                                                                                                                                                                   | Tablet                          |                    |                    |                                          |                                          |                                |                 |              |                |
|                                                                                                                                                                                   | Fortum                          |                    |                    | S                                        | Intravenous (not<br>otherwise specified) | 1 Df, Qid, Intravenous         |                 |              | Not Reported   |
|                                                                                                                                                                                   | Flagyl                          |                    |                    | S                                        | Oral                                     |                                |                 |              | Not Reported   |
|                                                                                                                                                                                   | Gentamicine                     |                    |                    | S                                        | Intravenous (not<br>otherwise specified) |                                |                 |              | Not Reported   |
|                                                                                                                                                                                   | Ambisome                        |                    |                    | S                                        | Intravenous (not<br>otherwise specified) |                                |                 |              | Not Reported   |
|                                                                                                                                                                                   | Bactrim                         |                    |                    | S                                        | Intravenous (not<br>otherwise specified) | 2 Df, 3x/Weekly,<br>Itravenous |                 |              | Not Reported   |
|                                                                                                                                                                                   | Noxafil                         |                    |                    | S                                        | Oral                                     |                                |                 |              | Not Reported   |
|                                                                                                                                                                                   | Cancidas                        |                    |                    | S                                        | Intravenous (not<br>otherwise specified) |                                |                 |              | Not Reported   |
|                                                                                                                                                                                   | Folinic Acid                    |                    |                    | S                                        | Intravenous (not<br>otherwise specified) | 50mg, 3x/Wk, Intravenous       |                 |              | Not Reported   |
|                                                                                                                                                                                   | Zelitrex                        |                    |                    | S                                        | Intravenous (not<br>otherwise specified) |                                |                 |              | Not Reported   |
|                                                                                                                                                                                   | Cymevene                        |                    |                    | S                                        | Intravenous (not<br>otherwise specified) |                                |                 |              | Not Reported   |
|                                                                                                                                                                                   | Foscavir                        |                    |                    | S                                        | Intravenous (not<br>otherwise specified) | 1 Df, Bid, Intravenous         |                 |              | Not Reported   |
|                                                                                                                                                                                   | Clairyg                         |                    |                    | S                                        | Intravenous (not<br>otherwise specified) |                                |                 |              | Not Reported   |
|                                                                                                                                                                                   | Granocyte                       |                    |                    | S                                        |                                          |                                |                 |              | Not Reported   |
| Sodium Heparin                                                                                                                                                                    |                                 |                    | S                  | Intravenous (not<br>otherwise specified) | 7000 Lu, Qd, Intravenous                 |                                |                 | Not Reported |                |
| Inexium (Esomeprazole Sodium)                                                                                                                                                     |                                 |                    | S                  | Intravenous (not                         |                                          |                                |                 | Not Reported |                |

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

|                                              |   |                                       |                            |              |
|----------------------------------------------|---|---------------------------------------|----------------------------|--------------|
|                                              |   | otherwise specified)                  |                            |              |
| Spasfon /00765801/                           | S |                                       | 2 Df, Tid, Intravenous     | Not Reported |
| Defibrotide                                  | S | Intravenous (not otherwise specified) | 25 Mg/Kg, Qd, Intravenous  | Not Reported |
| Largactil                                    | S | Intravenous (not otherwise specified) | 1 Df, Qd, Intravenous      | Not Reported |
| Tranxene                                     | S | Oral                                  | 5 Mg, Qid Pm, Oral         | Not Reported |
| Oxynorm                                      | S | Intravenous (not otherwise specified) |                            | Not Reported |
| Exacyl                                       | S | Intravenous (not otherwise specified) | 1 Df, Tid, Intravenous     | Not Reported |
| Perfalgan                                    | S | Intravenous (not otherwise specified) | 1 G, Tid, Intravenous      | Not Reported |
| Solumedrol                                   | S | Intravenous (not otherwise specified) |                            | Not Reported |
| Droleptan                                    | S | Intravenous (not otherwise specified) | 0.625 Mg, Qid, Intravenous | Not Reported |
| Ultiva                                       | S | Intravenous (not otherwise specified) | 100gbq, Q1h, Intravenous   | Not Reported |
| Atarax                                       | S | Oral                                  |                            | Not Reported |
| Lasilix                                      | S | Intravenous (not otherwise specified) | 40mg, Bid, Intravenous     | Not Reported |
| Seroplex                                     | S | Oral                                  |                            | Not Reported |
| Ceris                                        | S | Oral                                  |                            | Not Reported |
| Noctamide                                    | S | Oral                                  | 1 Df, Qd, Oral             | Not Reported |
| Gentamicin +Colistin (Gentamicin + Colistin) | C |                                       |                            | Not Reported |
| Vancomycine Mylan 9vancomycin Hydrochloride) | C |                                       |                            | Not Reported |
| Ciflox/00697201/(Ciprofloxacin)              | C |                                       |                            | Not Reported |
| Targocid (Teicoplanin)                       | C |                                       |                            | Not Reported |
| Mycostatin (Nystatin)                        | C |                                       |                            | Not Reported |
| Triflucan (Teicoplanin)                      | C |                                       |                            | Not Reported |
| Zovirax                                      | C |                                       |                            | Not Reported |
| Methotrexate Mylan                           | C |                                       |                            | Not Reported |



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

|                                                                                                                                      |   |              |
|--------------------------------------------------------------------------------------------------------------------------------------|---|--------------|
| (Methotrexate Mylan)                                                                                                                 |   |              |
| Elvorine (Calcium Levofolinate)                                                                                                      | C | Not Reported |
| Sandimmun (Ciclosporin)                                                                                                              | C | Not Reported |
| Infusion                                                                                                                             |   |              |
| Mopral/006661201/(Omeprazole )                                                                                                       | C | Not Reported |
| Ogastoro (Lansoprazole)                                                                                                              | C | Not Reported |
| Gelox (Aluminum Hydroxide, Aluminum Silicate, Magnesium Hydroxide)                                                                   | C | Not Reported |
| Smecta / 00837601/(Aluminum Hydroxide-Magnesium Carbonate Gel, Aluminum Magnesium Silicate, Glucose Monohydrate, Glycyrrhiza Glabra) | C | Not Reported |
| Magnesium Silicate, Glucose Monohydrate, Glycyrrhiza Glabra)                                                                         | C | Not Reported |
| Luteran (Chlormadinone Acetate)                                                                                                      | C | Not Reported |
| Lexomil (Bromazepam)                                                                                                                 | C | Not Reported |
| Zophren / 00955301/ (Ondansetron)                                                                                                    | C | Not Reported |
| Primperan (Metoclopramide Hydrochloride)                                                                                             | C | Not Reported |
| Acupan (Nefopam Hydrochloride)                                                                                                       | C | Not Reported |
| Tiorfan (Acetorphan) Unknown                                                                                                         | C | Not Reported |
| Levocarnil (Levocarnitine)                                                                                                           | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Nov-2013              | 9605857       | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000049746    |                      | 61 YR      | Female     | FRA            |

| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Carotid Artery Dissection | Escitalopram   |              |            | S           | Oral         | 1 Df               |                 | Forest       |
|                           | Levothyrox     |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Nov-2013              | 9636391       | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000050357    |                      | 58 YR      | Female     | FRA            |

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| <u>Preferred Term</u>                                                                                                       | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|-----------------------------------------------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|--------------|----------------|
| Hypersensitivity; Lip Swelling; Oropharyngeal Swelling; Swollen Tongue                                                      | Escitalopram           |                    |                    | S               | Oral                                            | 10 Mg                |                 | Forest       |                |
|                                                                                                                             | Xanax                  |                    |                    | C               |                                                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                    | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Nov-2013                                                                                                                 | 9636411                | EXPEDITED (15-DAY) |                    | CA, DE          | IE-FRI-1000050219                               |                      |                 | Male         | IRL            |
| <u>Preferred Term</u>                                                                                                       | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Congenital Heart Valve Disorder; Foetal Death; Foetal Exposure During Pregnancy; Hydrops Foetalis; Multiple Cardiac Defects | Lexapro                |                    |                    | S               | Transplacental                                  |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                    | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Nov-2013                                                                                                                 | 9645594                | EXPEDITED (15-DAY) |                    |                 | CH-FRI-1000050248                               |                      | 25 YR           | Male         | CHE            |
| <u>Preferred Term</u>                                                                                                       | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Prescribed Overdose                                                                                                         | Escitalopram           |                    |                    | S               | Oral                                            | 30 Mg                |                 | Forest       |                |
|                                                                                                                             | Escitalopram           |                    |                    | S               |                                                 |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                    | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Nov-2013                                                                                                                 | 9663503                | NON-EXPEDITED      |                    |                 | US-ENDO<br>PHARMACEUTICALS<br>INC.-LISI20110018 |                      | 76 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                       | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Memory Impairment; Nausea                                                                                                   | Lisinopril Tablets 5mg |                    |                    | S               | Oral                                            |                      |                 | Not Reported |                |
|                                                                                                                             | Lexapro                |                    |                    | S               | Oral                                            |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                    | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Nov-2013                                                                                                                 | 9664360                | EXPEDITED (15-DAY) |                    | OT              | US-TEVA-441709USA                               |                      |                 | Female       | USA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                                                                                                   | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |
|---------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|------------------|----------------|
| Coeliac Disease                                                                                                                                         | Escitalopram                            |                    |                    | S               |                                                 |                      |                 | Ivax             |                |
| <u>FDA Received Date</u>                                                                                                                                | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 01-Nov-2013                                                                                                                                             | 9665305                                 | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000050116                               |                      | 65 YR           | Male             | FRA            |
| <u>Preferred Term</u>                                                                                                                                   | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |
| Atrioventricular<br>Dissociation; Bradycardia;<br>Electrocardiogram Qt<br>Prolonged                                                                     | Escitalopram                            |                    |                    | S               | Oral                                            | 1 Df                 |                 | Forest           |                |
|                                                                                                                                                         | Sifrol                                  |                    |                    | C               | Oral                                            | 1 Df                 |                 | Not Reported     |                |
|                                                                                                                                                         | Bactrim                                 |                    |                    | C               |                                                 |                      |                 | Not Reported     |                |
|                                                                                                                                                         | Zelitrex                                |                    |                    | C               |                                                 |                      |                 | Not Reported     |                |
|                                                                                                                                                         | Loxan                                   |                    |                    | C               |                                                 |                      |                 | Not Reported     |                |
|                                                                                                                                                         | Lederfoline                             |                    |                    | C               |                                                 |                      |                 | Not Reported     |                |
| <u>FDA Received Date</u>                                                                                                                                | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 03-Nov-2013                                                                                                                                             | 9566038                                 | EXPEDITED (15-DAY) |                    | OT              | GB-<br>ELI_LILLY_AND_COMP<br>ANY-GB201309007991 |                      |                 | Female           | GBR            |
| <u>Preferred Term</u>                                                                                                                                   | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |
| Abdominal Pain; Chest<br>Discomfort; Dyspepsia;<br>Hypoaesthesia; Multiple<br>Sclerosis Relapse;<br>Product Dispensing Error;<br>Product Name Confusion | Cialis                                  |                    |                    | S               | Oral                                            | 5 Mg, Qd             |                 | Eli Lilly And Co |                |
|                                                                                                                                                         | Cipralext                               |                    |                    | S               | Unknown                                         | 5 Mg, Unknown        |                 | Not Reported     |                |
| <u>FDA Received Date</u>                                                                                                                                | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 03-Nov-2013                                                                                                                                             | 9665168                                 | EXPEDITED (15-DAY) |                    | HO              | US-MYLANLABS-<br>2013S1023812                   |                      | 16 YR           | Female           | USA            |
| <u>Preferred Term</u>                                                                                                                                   | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |
| Bundle Branch Block<br>Right; Electrocardiogram<br>Qrs Complex Prolonged;<br>Electrocardiogram Qt<br>Prolonged; Overdose                                | Escitalopram                            |                    |                    | S               | Oral                                            | Df = 10mg            |                 | Mylan            |                |
|                                                                                                                                                         | Paracetamol W/Tramadol<br>Hydrochloride |                    |                    | S               | Oral                                            |                      |                 | Not Reported     |                |
|                                                                                                                                                         | Procet /01554201/                       |                    |                    | S               | Oral                                            | Unknown Amount       |                 | Not Reported     |                |

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| <u>FDA Received Date</u>                                                                                                                                                                           | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|--------------------|--------------------|-----------------|---------------------------------------|----------------------|-----------------|--------------|----------------|
| 03-Nov-2013                                                                                                                                                                                        | 9665171                         | EXPEDITED (15-DAY) |                    | OT              | TR-US-EMD SERONO,<br>INC.-7246479     |                      |                 | Female       | TUR            |
| <u>Preferred Term</u>                                                                                                                                                                              | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Epilepsy; Toothache                                                                                                                                                                                | Rebif                           |                    |                    | S               | Subcutaneous                          |                      |                 | Not Reported |                |
|                                                                                                                                                                                                    | Tamol                           |                    |                    | S               | Oral                                  |                      |                 | Not Reported |                |
|                                                                                                                                                                                                    | Tamol                           |                    |                    | S               |                                       |                      |                 | Not Reported |                |
|                                                                                                                                                                                                    | Cipralext                       |                    |                    | S               | Oral                                  |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                           | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Nov-2013                                                                                                                                                                                        | 9560190                         | EXPEDITED (15-DAY) | Y                  | DE, HO          | 2013CP000111                          |                      | 41 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                              | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Acute Kidney Injury; Bone Marrow Transplant; Graft Versus Host Disease In Gastrointestinal Tract; Haematuria; Hepatitis Fulminant; Multiple Organ Dysfunction Syndrome; Toxic Epidermal Necrolysis | Perfalgan                       |                    |                    | S               | Intravenous (not otherwise specified) |                      |                 | Not Reported |                |
|                                                                                                                                                                                                    | Heparin Sodium                  |                    |                    | S               | Intravenous (not otherwise specified) |                      |                 | Not Reported |                |
|                                                                                                                                                                                                    | Ceftazidime (Ceftazidime)       |                    |                    | S               | Intravenous (not otherwise specified) |                      |                 | Not Reported |                |
|                                                                                                                                                                                                    | Gentamicine                     |                    |                    | S               | Intravenous (not otherwise specified) |                      |                 | Not Reported |                |
|                                                                                                                                                                                                    | Ambisome                        |                    |                    | S               | Intravenous (not otherwise specified) |                      |                 | Not Reported |                |
|                                                                                                                                                                                                    | Bactrim                         |                    |                    | S               | Intravenous (not otherwise specified) |                      |                 | Not Reported |                |
|                                                                                                                                                                                                    | Folinic Acid                    |                    |                    | S               |                                       |                      |                 | Not Reported |                |
|                                                                                                                                                                                                    | Zelitrext                       |                    |                    | S               | Oral                                  |                      |                 | Not Reported |                |
|                                                                                                                                                                                                    | Cymevene                        |                    |                    | S               |                                       |                      |                 | Not Reported |                |
|                                                                                                                                                                                                    | Foscavir                        |                    |                    | S               | Intravenous (not otherwise specified) |                      |                 | Not Reported |                |
|                                                                                                                                                                                                    | Esomeprazole (Esomeprazole)     |                    |                    | S               |                                       |                      |                 | Not Reported |                |
|                                                                                                                                                                                                    | Phloroglucinol (Phloroglucinol) |                    |                    | S               | Intravenous (not                      |                      |                 | Not Reported |                |

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

|                              |   |                                                       |              |
|------------------------------|---|-------------------------------------------------------|--------------|
|                              |   | otherwise specified)                                  |              |
| Defibrotide                  | S | Intravenous (not otherwise specified)                 | Not Reported |
| Chlorpromazine Hydrochloride | S | Intravenous (not otherwise specified)                 | Not Reported |
| Tranexamic Acid              | S | Intravenous (not otherwise specified)                 | Not Reported |
| Methylprednisolone           | S | Intravenous (not otherwise specified)                 | Not Reported |
| Droperidol                   | S | Intravenous (not otherwise specified)                 | Not Reported |
| Ultiva                       | S | Intravenous (not otherwise specified) 100 Gbq; Qh; Iv | Not Reported |
| Furosemide                   | S | Intravenous (not otherwise specified)                 | Not Reported |
| Metronidazole                | S | Oral                                                  | Not Reported |
| Noxafil                      | S | Oral                                                  | Not Reported |
| Delursan                     | S | Oral                                                  | Not Reported |
| Tranxene                     | S | Oral                                                  | Not Reported |
| Hydroxyzine                  | S | Oral                                                  | Not Reported |
| Seroplex                     | S | Oral                                                  | Not Reported |
| Ceris                        | S | Oral                                                  | Not Reported |
| Noctamide                    | S | Oral                                                  | Not Reported |
| Granocyte                    | S | Intravenous (not otherwise specified)                 | Not Reported |
| Oxynorm                      | S | Intravenous (not otherwise specified)                 | Not Reported |
| Gentamicine                  | C |                                                       | Not Reported |
| Colistin                     | C |                                                       | Not Reported |
| Vancomycin                   | C |                                                       | Not Reported |
| Ciprofloxacin Hcl            | C |                                                       | Not Reported |
| Acyclovir                    | C |                                                       | Not Reported |
| Cyclosporine                 | C |                                                       | Not Reported |
| Ogastoro                     | C |                                                       | Not Reported |

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

|                 |   |              |
|-----------------|---|--------------|
| Smectite        | C | Not Reported |
| Luteran         | C | Not Reported |
| Lexomil         | C | Not Reported |
| Noctamide       | C | Not Reported |
| Ondansetron Hcl | C | Not Reported |
| Primperan       | C | Not Reported |
| Acupan          | C | Not Reported |
| Levocarnil      | C | Not Reported |
| Racecadotril    | C | Not Reported |
| Targocid        | C | Not Reported |
| Gelox           | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Nov-2013              | 9621143       | EXPEDITED (15-DAY) |                    | DE              | FR-FRI-1000050027    |                      | 86 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                            | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|------------------------|-----------------|--------------|
| Drug Interaction;<br>International Normalised<br>Ratio Increased | Escitalopram           |              |            | S           | Oral         | 1 Df                   |                 | Forest       |
|                                                                  | Previscan (Fluindione) |              |            | S           |              | 0.75 Df                |                 | Not Reported |
|                                                                  | Previscan (Fluindione) |              |            | S           |              | Daily Dose Reduced Nos |                 | Not Reported |
|                                                                  | Cordarone              |              |            | S           | Oral         | 1 Df                   |                 | Not Reported |
|                                                                  | Doliprane              |              |            | S           | Oral         | 1 Df                   |                 | Not Reported |
|                                                                  | Lasilix                |              |            | C           | Oral         | 1 Df                   |                 | Not Reported |
|                                                                  | Lasilix                |              |            | C           | Oral         | 4 Df                   |                 | Not Reported |
|                                                                  | Lasilix                |              |            | C           | Oral         | 1 Df                   |                 | Not Reported |
|                                                                  | Ebixa                  |              |            | C           | Oral         | 1.5 Df                 |                 | Not Reported |
|                                                                  | Mecir                  |              |            | C           | Oral         | 1 Df                   |                 | Not Reported |
|                                                                  | Debridat               |              |            | C           |              | 3 Df                   |                 | Not Reported |
|                                                                  | Lysanxia               |              |            | C           | Oral         | 1 Df                   |                 | Not Reported |
|                                                                  | Kaleorid               |              |            | C           | Oral         | 3 Df                   |                 | Not Reported |
|                                                                  | Permixon               |              |            | C           | Oral         | 2 Df                   |                 | Not Reported |
|                                                                  | Xanax                  |              |            | C           | Oral         |                        |                 | Not Reported |
|                                                                  | Valsartan              |              |            | C           | Oral         | 1 Df                   |                 | Not Reported |
|                                                                  | Poly-Karaya            |              |            | C           |              |                        |                 | Not Reported |

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

|                                                                                                                 | Movicol              |                    | C                  |                 |                      |                                       |                 |              | Not Reported   |
|-----------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|---------------------------------------|-----------------|--------------|----------------|
|                                                                                                                 | Tiapridal            |                    | C                  | Oral            | 2 Df                 |                                       |                 |              | Not Reported   |
|                                                                                                                 | Augmentin            |                    | C                  |                 | 3 Grams              |                                       |                 |              | Not Reported   |
| <u>FDA Received Date</u>                                                                                        | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Nov-2013                                                                                                     | 9665631              | EXPEDITED (15-DAY) |                    | DE, HO          | US-FRI-1000050704    |                                       | 45 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                           | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Posterior Reversible Encephalopathy Syndrome; Reversible Cerebral Vasoconstriction Syndrome; Serotonin Syndrome | Escitalopram         |                    |                    | S               |                      | 10 Mg                                 |                 | Forest       |                |
|                                                                                                                 | Dihydroergotamine    |                    |                    | S               |                      |                                       |                 | Not Reported |                |
|                                                                                                                 | Hydrocodone          |                    |                    | S               |                      |                                       |                 | Not Reported |                |
|                                                                                                                 | Hydromorphone        |                    |                    | S               |                      |                                       |                 | Not Reported |                |
|                                                                                                                 | Tetrahydrocannabinol |                    |                    | S               |                      |                                       |                 | Not Reported |                |
|                                                                                                                 | Anticoagulation      |                    |                    | C               |                      |                                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                        | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Nov-2013                                                                                                     | 9665940              | EXPEDITED (15-DAY) |                    | OT              | PHHY2013BR121015     |                                       |                 | Male         | BRA            |
| <u>Preferred Term</u>                                                                                           | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Cholesterol Increased; Dementia Alzheimer'S Type; Gait Disturbance;                                       | Galvus Met           |                    |                    | S               | Oral                 | 2 Df, (Metf 850 Mg/ Vild 50 Mg) Daily |                 | Not Reported |                |
| Hydrocephalus; Mood Altered; Parkinson'S Disease; Screaming; Speech Disorder; Thyroid Disorder; Tremor          | Metformin            |                    |                    | S               | Oral                 | 850 Mg, Daily                         |                 | Novartis     |                |
|                                                                                                                 | Atenolol             |                    |                    | S               | Oral                 | 2 Df, (25 Mg) Daily                   |                 | Not Reported |                |
|                                                                                                                 | Lexapro              |                    |                    | S               | Oral                 | 1 Df (15mg), Daily                    |                 | Not Reported |                |
|                                                                                                                 | Diamicron            |                    |                    | S               | Oral                 | 1 Df (60mg), Daily                    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                        | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Nov-2013                                                                                                     | 9665960              | EXPEDITED (15-DAY) |                    | DE, HO          | FR-FRI-1000048785    |                                       | 41 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                           | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Toxic Epidermal Necrolysis                                                                                      | Escitalopram         |                    |                    | S               | Oral                 |                                       |                 | Forest       |                |

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

|                                                   |   |                                       |                      |              |
|---------------------------------------------------|---|---------------------------------------|----------------------|--------------|
| Fortum                                            | S | Intravenous (not otherwise specified) | 4 Df                 | Not Reported |
| Flagyl                                            | S | Oral                                  | 3 Df                 | Not Reported |
| Gentamicine Panpharma                             | S | Intravenous (not otherwise specified) | 1 Df                 | Not Reported |
| Noxafil                                           | S |                                       | 3 Df                 | Not Reported |
| Candidas                                          | S | Intracavernous                        |                      | Not Reported |
| Ambisome                                          | S | Intravenous (not otherwise specified) | 1 Df                 | Not Reported |
| Bactrim                                           | S | Intravenous (not otherwise specified) | 0.8571 Df            | Not Reported |
| Acide Folinique                                   | S | Intravenous (not otherwise specified) | 21.4286 Mg           | Not Reported |
| Zelitrex                                          | S | Intravenous (not otherwise specified) | 2 Df                 | Not Reported |
| Cymevene                                          | S | Intravenous (not otherwise specified) | 700 Mg               | Not Reported |
| Foscavir                                          | S | Intravenous (not otherwise specified) | 12 Gram/500 MI Daily | Not Reported |
| Clairyg                                           | S | Intravenous (not otherwise specified) |                      | Not Reported |
| Granocyte                                         | S | Intravenous (not otherwise specified) |                      | Not Reported |
| Heparin Sodique                                   | S | Intravenous (not otherwise specified) | 7000 lu              | Not Reported |
| Inexium                                           | S | Intravenous (not otherwise specified) | 1 Df                 | Not Reported |
| Spasfon (Phloroglucinol, Trimethylphloroglucinol) | S | Intravenous (not otherwise specified) | 6 Df                 | Not Reported |
| Delursan                                          | S | Oral                                  | 6 Df                 | Not Reported |
| Defibrotide                                       | S | Intravenous (not otherwise specified) | 25 Mg/Kg Daily       | Not Reported |
| Largactil                                         | S | Intravenous (not otherwise specified) | 1 Df                 | Not Reported |



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

|                    |   |                                       |                 |              |
|--------------------|---|---------------------------------------|-----------------|--------------|
| Tranxene           | S | Oral                                  |                 | Not Reported |
| Oxynorm            | S | Intravenous (not otherwise specified) |                 | Not Reported |
| Exacyl             | S |                                       | 3 Df            | Not Reported |
| Perfalgan          | S |                                       | 3 Df            | Not Reported |
| Solumedrol         | S | Intravenous (not otherwise specified) | 1 Df            | Not Reported |
| Droleptan          | S |                                       | 4 Df            | Not Reported |
| Ultiva             | S | Endocervical                          | 24 Df           | Not Reported |
| Atarax             | S | Oral                                  | 0.5 Df          | Not Reported |
| Lasilix            | S | Intravenous (not otherwise specified) | 2 Df            | Not Reported |
| Ceris              | S | Oral                                  | 2 Df            | Not Reported |
| Noctamide          | S | Oral                                  | 1 Df            | Not Reported |
| Gentamicine        | C | Oral                                  | 6 Df            | Not Reported |
| Colistine          | C | Oral                                  | 6 Df            | Not Reported |
| Vancomycine Mylan  | C |                                       | 1 Df            | Not Reported |
| Ciflox             | C |                                       | 2 Df            | Not Reported |
| Targocid           | C |                                       | 2 Df            | Not Reported |
| Mycostatine        | C |                                       | 2 Bottles Daily | Not Reported |
| Triflucan          | C |                                       | 1 Df            | Not Reported |
| Zovirax            | C |                                       | 3 Df            | Not Reported |
| Methotrexate Mylan | C |                                       | 1 Df            | Not Reported |
| Elvorine           | C |                                       | 1 Df            | Not Reported |
| Sandimmun          | C |                                       | 1 Df            | Not Reported |
| Mopral             | C |                                       | 1 Df            | Not Reported |
| Ogastoro           | C |                                       | 1 Df            | Not Reported |
| Gelox              | C |                                       | 1 Packed Tid    | Not Reported |
| Smecta             | C |                                       | 6 Packets Daily | Not Reported |
| Luteran            | C |                                       | 1 Df            | Not Reported |

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

|            |   |                             |              |
|------------|---|-----------------------------|--------------|
| Lexomil    | C | 0.5 Df                      | Not Reported |
| Noctamide  | C | 1 Df                        | Not Reported |
| Zophren    | C | 2 Ampoules Daily            | Not Reported |
| Primperan  | C | 6 Ampoules Daily            | Not Reported |
| Acupan     | C | 6 Ampoules Daily On Request | Not Reported |
| Tiorfan    | C |                             | Not Reported |
| Levocarnil | C | 3 Df                        | Not Reported |

| <u>FDA Received Date</u>                                                                                     | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 04-Nov-2013                                                                                                  | 9667831                   | EXPEDITED (15-DAY) |                    | HO, OT          | US-TEVA-441607USA    |                      | 16 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                        | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bundle Branch Block Right; Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Overdose | Escitalopram              |                    |                    | S               | Oral                 | Df = 10mg            |                 | Ivax         |                |
|                                                                                                              | Tramadol + Paracetamol    |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                              | Hydrocodone + Paracetamol |                    |                    | S               | Oral                 | Unknown Amount       |                 | Not Reported |                |

| <u>FDA Received Date</u>                                              | <u>Case #</u>   | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|-----------------------------------------------------------------------|-----------------|------------------|--------------------|-----------------|----------------------|----------------------------------------|-----------------|------------|----------------|
| 04-Nov-2013                                                           | 9669615         | DIRECT           |                    | HO              |                      |                                        | 54 YR           | Unknown    | USA            |
| <u>Preferred Term</u>                                                 | <u>Product</u>  | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u> |                |
| Burning Sensation; Chest Pain; Chromaturia; Dyspepsia; Dysuria; Ulcer | Escitalopram    |                  |                    | S               | Oral                 | 20 Mg 1 Pill At Bedtime Taken By Mouth |                 | Camber     |                |
|                                                                       | Cyclobenzaprine |                  |                    | S               | Oral                 |                                        |                 | Cadista    |                |

| <u>FDA Received Date</u>         | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------|-----------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 04-Nov-2013                      | 9669920                     | EXPEDITED (15-DAY) | Y                  | HO              | AUR-APL-2013-09110   |                      | 16 YR           | Female       | USA            |
| <u>Preferred Term</u>            | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Pressure Decreased; Bundle | Escitalopram (Escitalopram) |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                  | Tramadol/Paracetamol        |                    |                    | S               |                      |                      |                 | Not Reported |                |

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

|                                                                                                                                                                                         |         |   |      |              |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|---|------|--------------|
| Branch Block Right;<br>Electrocardiogram Qrs<br>Complex Prolonged;<br>Electrocardiogram Qt<br>Prolonged; Intentional<br>Overdose; Lethargy;<br>Presyncope; Skin<br>Laceration; Vomiting | Vicodin | S | Oral | Not Reported |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|---|------|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------|----------------------|------------|------------|----------------|
| 05-Nov-2013              | 8794234       | EXPEDITED (15-DAY) |                    | OT              | US-MERCK-1209USA005725 |                      | 65 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Inappropriate Schedule Of<br>Product Administration;<br>Mania; Oedema<br>Peripheral | Saphris        |              |            | S           | Sublingual   | 20 Mg, Qpm         |                 | Merck        |
|                                                                                     | Wellbutrin     |              |            | S           |              |                    |                 | Not Reported |
|                                                                                     | Lexapro        |              |            | S           |              |                    |                 | Not Reported |
|                                                                                     | Alprazolam     |              |            | C           |              | 4 Mg, Qpm          |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Nov-2013              | 9648261       | EXPEDITED (15-DAY) |                    | OT              | CA-FRI-1000050519    |                      | 54 YR      | Male       | CAN            |

| <u>Preferred Term</u>                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u> |
|-----------------------------------------|----------------|--------------|------------|-------------|--------------|-------------------------|-----------------|------------|
| Nephrolithiasis; Prescribed<br>Overdose | Escitalopram   |              |            | S           | Oral         | Overdose: (30 Mg Daily) |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------------|----------------------|------------|------------|----------------|
| 05-Nov-2013              | 9668454       | EXPEDITED (15-DAY) |                    | HO              | US-MICRO LABS<br>LIMITED-BB2013-01089 |                      | 16 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                      | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Bundle Branch Block<br>Right; Electrocardiogram<br>Qrs Complex Prolonged;<br>Electrocardiogram Qt<br>Interval; Lethargy;<br>Overdose; Presyncope;<br>Skin Laceration; Skin | Tramadol + Paracetamol  |              |            | S           | Oral         | 25 Tablets         |                 | Micro Labs   |
|                                                                                                                                                                            | Escitalopram            |              |            | S           | Unknown      | 50 Tablets         |                 | Not Reported |
|                                                                                                                                                                            | Hydrocodone/Paracetamol |              |            | S           | Unknown      |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Laceration; Vomiting

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 05-Nov-2013                       | 9669697                | EXPEDITED (15-DAY)        |                             | HO                       | FR-FRI-1000050744             |                               | 79 YR               | Male                | FRA                     |

| <a href="#">Preferred Term</a>            | <a href="#">Product</a>                             | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|-------------------------------------------|-----------------------------------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Cerebral Haemorrhage;<br>Drug Interaction | Escitalopram                                        |                       |                     | S                    | Oral                  | 1 Df                        |                          | Forest              |
|                                           | Xarelto                                             |                       |                     | S                    | Oral                  | 1 Df                        |                          | Not Reported        |
|                                           | Tanakan                                             |                       |                     | S                    | Oral                  | 3 Df                        |                          | Not Reported        |
|                                           | Doliprane                                           |                       |                     | C                    | Oral                  |                             |                          | Not Reported        |
|                                           | Transilane (Potassium<br>Bicarbonate\Psyllium Husk) |                       |                     | C                    | Oral                  |                             |                          | Not Reported        |
|                                           | Gutron                                              |                       |                     | C                    | Oral                  | 6 Df                        |                          | Not Reported        |
|                                           | Flecaine                                            |                       |                     | C                    | Oral                  | 1 Df                        |                          | Not Reported        |
|                                           | Seresta                                             |                       |                     | C                    | Oral                  | 2 Df                        |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 05-Nov-2013                       | 9670122                | EXPEDITED (15-DAY)        |                             | OT                       | FR-FRI-1000050742             |                               | 47 YR               | Female              | FRA                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Amaurosis                      | Escitalopram            |                       |                     | S                    | Oral                  | 10 Mg                       |                          | Forest              |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 05-Nov-2013                       | 9671316                | DIRECT                    |                             |                          |                               |                               | 52 YR               | Female              | USA                     |

| <a href="#">Preferred Term</a>              | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|---------------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Condition Aggravated;<br>Migraine With Aura | Escitalopram            |                       |                     | S                    |                       | Taken By Mouth              |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 05-Nov-2013                       | 9676239                | EXPEDITED (15-DAY)        | Y                           | HO                       | 2013AP009311                  |                               | 16 YR               | Female              | USA                     |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                                           | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                 | <u>Duration</u> | <u>Mfr</u>       |                |
|-------------------------------------------------------------------------------------------------|-----------------------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------------------------------------|-----------------|------------------|----------------|
| Bundle Branch Block<br>Right; Electrocardiogram<br>Qt Prolonged; Overdose;<br>Qrs Axis Abnormal | Escitalopram Oxalate                    |                    |                    | S               | Oral                                            |                                                    |                 | Apotex           |                |
|                                                                                                 | Paracetamol W/Tramadol<br>Hydrochloride |                    |                    | S               | Oral                                            |                                                    |                 | Not Reported     |                |
|                                                                                                 | Acetaminophen\Hydrocodone               |                    |                    | S               | Oral                                            |                                                    |                 | Not Reported     |                |
|                                                                                                 | Acetaminophen W/<br>Hydrocodone         |                    |                    | C               |                                                 |                                                    |                 | Not Reported     |                |
| <u>FDA Received Date</u>                                                                        | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                               | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 06-Nov-2013                                                                                     | 9643352                                 | EXPEDITED (15-DAY) |                    | OT              | JP-<br>ELI_LILLY_AND_COMP<br>ANY-JP201310004590 |                                                    | 40 YR           | Female           | JPN            |
| <u>Preferred Term</u>                                                                           | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                 | <u>Duration</u> | <u>Mfr</u>       |                |
| Syncope                                                                                         | Cymbalta                                |                    |                    | S               | Oral                                            | 20 Mg, Qd                                          |                 | Eli Lilly And Co |                |
|                                                                                                 | Lexapro                                 |                    |                    | S               | Oral                                            | 10 Unk, Unk                                        |                 | Not Reported     |                |
|                                                                                                 | Lexapro                                 |                    |                    | S               | Oral                                            | Unk                                                |                 | Not Reported     |                |
|                                                                                                 | Lonasen                                 |                    |                    | C               | Oral                                            | 4 Mg, Unk                                          |                 | Not Reported     |                |
|                                                                                                 | Levotomin /00038602/                    |                    |                    | C               | Oral                                            | 75 Mg, Unk                                         |                 | Not Reported     |                |
|                                                                                                 | Depas (Etizolam)                        |                    |                    | C               | Oral                                            | 3 Mg, Unk                                          |                 | Not Reported     |                |
|                                                                                                 | Flunitrazepam                           |                    |                    | C               | Oral                                            | Unk                                                |                 | Not Reported     |                |
|                                                                                                 | Goodmin                                 |                    |                    | C               | Oral                                            | Unk                                                |                 | Not Reported     |                |
|                                                                                                 | Allorin                                 |                    |                    | C               | Oral                                            | Unk                                                |                 | Not Reported     |                |
|                                                                                                 | Mucosta                                 |                    |                    | C               | Oral                                            | Unk                                                |                 | Not Reported     |                |
|                                                                                                 | Loxonin                                 |                    |                    | C               | Oral                                            | Unk                                                |                 | Not Reported     |                |
| <u>FDA Received Date</u>                                                                        | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                               | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 06-Nov-2013                                                                                     | 9674688                                 | DIRECT             |                    | OT              |                                                 |                                                    | 39 YR           | Female           | USA            |
| <u>Preferred Term</u>                                                                           | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                 | <u>Duration</u> | <u>Mfr</u>       |                |
| Dizziness; Headache;<br>Nausea; Presyncope;<br>Product Substitution Issue                       | Escitalopram                            |                    |                    | S               | Oral                                            | 1/2 Pill (About 5 Mg) Once<br>Daily Taken By Mouth |                 | Not Reported     |                |

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

| <u>FDA Received Date</u>                                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|------------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 06-Nov-2013                                                           | 9674696        | DIRECT             |                    |                 |                                                      |                      | 42 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Headache; Heart Rate Increased; Product Substitution Issue   | Escitalopram   |                    |                    | S               | Oral                                                 | 1 Pill; Once Daily   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Nov-2013                                                           | 9675097        | DIRECT             |                    |                 |                                                      |                      | 58 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Glucose Increased; Drug Ineffective; Product Substitution Issue | Simvastatin    |                    |                    | S               |                                                      |                      |                 | Not Reported |                |
|                                                                       | Levothyroxine  |                    |                    | S               |                                                      |                      |                 | Not Reported |                |
|                                                                       | Irbesartan     |                    |                    | S               |                                                      |                      |                 | Not Reported |                |
|                                                                       | Escitalopram   |                    |                    | S               |                                                      |                      |                 | Not Reported |                |
|                                                                       | Novolog        |                    |                    | S               |                                                      |                      |                 | Not Reported |                |
|                                                                       | Multivitamin   |                    |                    | C               |                                                      |                      |                 | Not Reported |                |
|                                                                       | Calcium        |                    |                    | C               |                                                      |                      |                 | Not Reported |                |
|                                                                       | Zyrtec         |                    |                    | C               |                                                      |                      |                 | Not Reported |                |
|                                                                       | Apidra         |                    |                    | S               |                                                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Nov-2013                                                           | 9675437        | EXPEDITED (15-DAY) |                    | OT              | US-FRI-1000050828                                    |                      | 12 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Failure To Thrive; Off Label Use                                      | Escitalopram   |                    |                    | S               |                                                      |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Nov-2013                                                           | 9676304        | EXPEDITED (15-DAY) |                    | LT              | FR-B.I. PHARMACEUTICALS, I NC./RIDGEFIELD-2013-FF-02 |                      | 64 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

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

|                                              |                   |   |                          |                      |
|----------------------------------------------|-------------------|---|--------------------------|----------------------|
| Inappropriate Antidiuretic Hormone Secretion | Spiriva           | S | Respiratory (inhalation) | Boehringer Ingelheim |
|                                              | Seroplex          | S |                          | Not Reported         |
|                                              | Haldol            | C | Oral                     | Not Reported         |
|                                              | Sulfarlem         | C | Oral                     | Not Reported         |
|                                              | Lepticur          | C | Oral                     | Not Reported         |
|                                              | Miflonil          | C | Respiratory (inhalation) | Not Reported         |
|                                              | Onbrez Breezhaler | C | Respiratory (inhalation) | Not Reported         |
|                                              | Onbrez Breezhaler | C | Oral                     | Not Reported         |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|---------------------------|--------------------------------|-----------------|--------------|----------------|
| 08-Nov-2013              | 8774272        | EXPEDITED (15-DAY) |                    | HO              | JP-009507513-2012SP014090 |                                | 49 YR           | Female       | JPN            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Dizziness      | Pegintron      |                    |                    | S               | Subcutaneous              | 1.3 Microgram Per Kilogram, Qw |                 | Merck        |                |
|                          | Pegintron      |                    |                    | S               | Subcutaneous              | 1.5 Microgram Per Kilogram, Qw |                 | Merck        |                |
|                          | Pegintron      |                    |                    | S               | Subcutaneous              | 1.5 Microgram Per Kilogram, Qw |                 | Merck        |                |
|                          | Pegintron      |                    |                    | S               | Subcutaneous              | 40 Microgram Per Kilogram, Qw  |                 | Merck        |                |
|                          | Pegintron      |                    |                    | S               | Subcutaneous              | 60 Microgram Per Kilogram, Qw  |                 | Merck        |                |
|                          | Pegintron      |                    |                    | S               | Subcutaneous              | 80 Microgram Per Kilogram, Qw  |                 | Merck        |                |
|                          | Rebetol        |                    |                    | S               | Oral                      | 800 Mg, Qd                     |                 | Merck        |                |
|                          | Rebetol        |                    |                    | S               | Oral                      | 400 Mg, Qd                     |                 | Merck        |                |
|                          | Rebetol        |                    |                    | S               | Oral                      | 800 Mg, Qd                     |                 | Merck        |                |
|                          | Telavic        |                    |                    | S               | Oral                      | 2250 Mg, Qd                    |                 | Not Reported |                |

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

|                        |   |                                          |                               |              |
|------------------------|---|------------------------------------------|-------------------------------|--------------|
| Telavic                | S | Oral                                     | 1500 Mg, Qd                   | Not Reported |
| Telavic                | S | Oral                                     | Daily Dose Unknown            | Not Reported |
| Desyrel                | S | Oral                                     | 50 Mg, Qd,<br>Formulation:Por | Not Reported |
| Lexapro                | S | Oral                                     | 10 Mg, Qd,<br>Formulation:Por | Not Reported |
| Mucosta                | C | Oral                                     | 300 Mg, Qd                    | Not Reported |
| Loxonin                | C | Oral                                     | Prn, Formulation: Por         | Not Reported |
| Aphtasolon             | C | Parenteral                               | Prn, Formulation:Ext          | Not Reported |
| Hachiazule Gargle      | C | Parenteral                               | Prn, Formulation: Ext         | Not Reported |
| Pursennid (Sennosides) | C | Oral                                     | Prn, Formulation:Por          | Not Reported |
| Celestoderm V          | C | Topical                                  | 1 G, Qd                       | Not Reported |
| Fulmeta                | C | Topical                                  | Unk Unk, Prn                  | Not Reported |
| Nauzelin               | C | Oral                                     | 3 Df, Qd                      | Not Reported |
| Lac-B                  | C | Oral                                     | 3 G, Qd, Formulation: Por     | Not Reported |
| Primperan              | C | Intravenous (not<br>otherwise specified) | 1 Df, Qd                      | Not Reported |
| Vitamedin Capsules     | C |                                          | 3 Df, Qd                      | Not Reported |

| <u>FDA Received Date</u>    | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------|----------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|-----------------|--------------|----------------|
| 08-Nov-2013                 | 8995914        | EXPEDITED (15-DAY) |                    | DS, HO, OT      | US-009507513-<br>2010SP063654 |                      |                 | Female       | USA            |
| <u>Preferred Term</u>       | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Acute Sinusitis; Back Pain; | Nuvaring       |                    |                    | S               | Vaginal                       |                      |                 | Merck        |                |
| Breast Disorder; Bursitis;  | Nuvaring       |                    |                    | S               |                               |                      |                 | Merck        |                |
| Cerebellar Haemorrhage;     | Nuvaring       |                    |                    | S               |                               |                      |                 | Merck        |                |
| Concussion; Depression;     | Nuvaring       |                    |                    | S               |                               |                      |                 | Merck        |                |
| Drug Hypersensitivity;      | Lexapro        |                    |                    | S               |                               |                      |                 | Not Reported |                |
| Drug Intolerance;           | Reglan         |                    |                    | S               |                               |                      |                 | Not Reported |                |
| Dyspnoea; Dystonia;         | Coumadin       |                    |                    | S               |                               |                      |                 | Not Reported |                |
| Epstein-Barr Virus          | Coumadin       |                    |                    | S               |                               |                      |                 | Not Reported |                |
| Infection; Fatigue; Feeling |                |                    |                    |                 |                               |                      |                 |              |                |
| Jittery; Fibromyalgia;      |                |                    |                    |                 |                               |                      |                 |              |                |
| Folate Deficiency;          |                |                    |                    |                 |                               |                      |                 |              |                |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Gastroesophageal Reflux  
Disease; Headache;  
Herpes Simplex;  
Hypercoagulation;  
Inappropriate Schedule Of  
Product Administration;  
Influenza Like Illness;  
Insomnia; Iron Deficiency  
Anaemia; Lichenoid  
Keratosi; Loss Of  
Consciousness;  
Lymphadenectomy;  
Mastoptosis; Metrorrhagia;  
Migraine; Muscle Strain;  
Off Label Use; Ovarian  
Cyst; Pain; Pelvic Pain;  
Pharyngitis; Pulmonary  
Emboli; Sleep Apnoea  
Syndrome; Sleep Apnoea  
Syndrome; Vaginal  
Discharge; Vertigo; Viral  
Infection; Vitamin B12  
Deficiency

| <u>FDA Received Date</u>                                               | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------|---------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 08-Nov-2013                                                            | 9678769             | EXPEDITED (15-DAY) |                    | DE, OT          | US-TEVA-443306USA    |                      | 29 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                  | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Brain Injury; Cardiac<br>Arrest; Haemodynamic<br>Instability; Overdose | Bupropion           |                    |                    | S               | Unknown              |                      |                 | Teva         |                |
|                                                                        | Escitalopram        |                    |                    | S               | Unknown              |                      |                 | Ivax         |                |
|                                                                        | Quetiapine Fumarate |                    |                    | S               | Unknown              |                      |                 | Teva         |                |
|                                                                        | Desvenlafaxine      |                    |                    | S               | Unknown              |                      |                 | Not Reported |                |
|                                                                        | Ibuprofen           |                    |                    | S               | Unknown              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                               | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Nov-2013                                                            | 9678943             | EXPEDITED (15-DAY) |                    | OT              | US-FRI-1000050941    |                      | 12 YR           | Male         | USA            |

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

| <u>Preferred Term</u>                                                                               | <u>Product</u>                                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|-----------------------------------------------------------------------------------------------------|-------------------------------------------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
| Off Label Use; Pleuritic Pain                                                                       | Escitalopram                                                |                    |                    | S               |                           | 10 Or 20 Mg          |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                            | <u>Case #</u>                                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Nov-2013                                                                                         | 9680751                                                     | DIRECT             |                    |                 |                           |                      | 43 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                               | <u>Product</u>                                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Loss Of Libido; Product Substitution Issue; Weight Increased                             | Escitalopram                                                |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                            | <u>Case #</u>                                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Nov-2013                                                                                         | 9684672                                                     | EXPEDITED (15-DAY) | Y                  | HO, LT, OT      | 2013HINLIT0216            |                      | 16 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                               | <u>Product</u>                                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bundle Branch Block Right; Electrocardiogram Abnormal; Lethargy; Overdose; Skin Laceration; Syncope | Escitalopram                                                |                    |                    | S               |                           | 500 Mg, Unk, Unknown |                 | Not Reported |                |
|                                                                                                     | Tramadol+Paracetamol                                        |                    |                    | C               |                           |                      |                 | Not Reported |                |
|                                                                                                     | (Tramadol+Paracetamol) Acetaminophen\Hydrocodone Bitartrate |                    |                    | C               |                           |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                            | <u>Case #</u>                                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Nov-2013                                                                                         | 9619349                                                     | EXPEDITED (15-DAY) |                    | OT              | NZ-MYLANLABS-2013S1021874 |                      | 17 YR           | Female       | NZL            |
| <u>Preferred Term</u>                                                                               | <u>Product</u>                                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abortion Spontaneous; Depression; Exposure During Pregnancy; Off Label Use                          | Escitalopram                                                |                    |                    | S               | Oral                      |                      |                 | Mylan        |                |
| <u>FDA Received Date</u>                                                                            | <u>Case #</u>                                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Nov-2013                                                                                         | 9671782                                                     | EXPEDITED (15-DAY) |                    | OT              | NO-PFIZER INC-2013S15841  |                      | 35 YR           | Male         | NOR            |

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

| <u>Preferred Term</u>                                                                                                                                                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Crying; Drug Dependence;<br>Epilepsy; Fatigue; Feeling<br>Of Despair; Frustration<br>Tolerance Decreased;<br>Insomnia; Irritability;<br>Malaise; Thinking<br>Abnormal | Neurontin      |              |            | S           |              | 300 Mg, Unk        |                 | Pfizer       |
|                                                                                                                                                                       | Sobril         |              |            | S           |              | 10 Mg, Unk         |                 | Pfizer       |
|                                                                                                                                                                       | Paralgin Forte |              |            | S           |              | 30 Mg, Unk         |                 | Not Reported |
|                                                                                                                                                                       | Imovane        |              |            | S           |              | 7.5 Mg, Unk        |                 | Not Reported |
|                                                                                                                                                                       | Vallergan      |              |            | S           |              | 10 Mg, Unk         |                 | Not Reported |
|                                                                                                                                                                       | Ciprallex      |              |            | S           |              | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 11-Nov-2013              | 9680370       | EXPEDITED (15-DAY) |                    | HO              | CH-MERCK-<br>1311CHE002410 |                      | 72 YR      | Female     | CHE            |

| <u>Preferred Term</u>                                  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>      | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------|----------------|--------------|------------|-------------|-------------------|--------------------|-----------------|--------------|
| Confusional State;<br>Disorientation;<br>Hyponatraemia | Remeron        |              |            | S           | Oral              | 30 Mg, Qd          |                 | Merck        |
|                                                        | Remeron        |              |            | S           | Oral              | Unk                |                 | Merck        |
|                                                        | Torem          |              |            | S           | Oral              | 5 Mg, Qd           |                 | Not Reported |
|                                                        | Ciprallex      |              |            | S           | Oral              | 10 Mg, Qd          |                 | Not Reported |
|                                                        | Ciprallex      |              |            | S           | Oral              | Unk                |                 | Not Reported |
|                                                        | Concor         |              |            | C           | Oral              | 1.25 Mg, Qd        |                 | Not Reported |
|                                                        | Norvasc        |              |            | C           | Oral              | 10 Mg, Qd          |                 | Not Reported |
|                                                        | Pantoprazole   |              |            | C           | Oral              | 40 Mg, Qd          |                 | Not Reported |
|                                                        | Duphalac       |              |            | C           | Oral              | 20 Ml, Prn         |                 | Not Reported |
|                                                        | Benerva        |              |            | C           | Oral              | 100 Mg, Tid        |                 | Not Reported |
|                                                        | Becozym        |              |            | C           | Oral              | 1 Df, Qd           |                 | Not Reported |
|                                                        | Konakion       |              |            | C           | Intravenous bolus | 10 Mg, Qd          |                 | Not Reported |
|                                                        | Nicotinell     |              |            | C           | Transdermal       | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------------------------------------|----------------------|------------|------------|----------------|
| 11-Nov-2013              | 9681257       | EXPEDITED (15-DAY) |                    | HO              | FR-B.I.<br>PHARMACEUTICALS,I<br>NC./RIDGEFIELD-2013-<br>FF-02 |                      | 88 YR      | Female     | FRA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                                                        | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>           |                |
|--------------------------------------------------------------------------------------------------------------|-----------------------|--------------------|--------------------|-----------------|----------------------|----------------------------------|-----------------|----------------------|----------------|
| Iron Deficiency Anaemia                                                                                      | Pradaxa               |                    |                    | S               | Oral                 |                                  |                 | Boehringer Ingelheim |                |
|                                                                                                              | Seroplex              |                    |                    | S               | Oral                 |                                  |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                                                     | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 11-Nov-2013                                                                                                  | 9681648               | EXPEDITED (15-DAY) |                    | HO              | US-FRI-1000050818    |                                  | 53 YR           | Male                 | USA            |
| <u>Preferred Term</u>                                                                                        | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>           |                |
| Cholelithiasis;<br>Hallucination, Auditory;<br>Hallucination, Visual                                         | Escitalopram          |                    |                    | S               | Oral                 | 10 Mg                            |                 | Forest               |                |
|                                                                                                              | Risperidone           |                    |                    | C               |                      | 6 Mg                             |                 | Not Reported         |                |
|                                                                                                              | Benzotropine          |                    |                    | C               |                      | 4 Mg                             |                 | Not Reported         |                |
|                                                                                                              | Valium                |                    |                    | C               |                      | 5 Mg                             |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                                                     | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 12-Nov-2013                                                                                                  | 9684153               | EXPEDITED (15-DAY) |                    | CA, HO          | FR-FRI-1000050999    |                                  | 1 DAY           | Unknown              | FRA            |
| <u>Preferred Term</u>                                                                                        | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>           |                |
| Exposure During<br>Pregnancy; Hypotonia<br>Neonatal; Poor Feeding<br>Infant; Ventricular Septal<br>Defect    | Escitalopram          |                    |                    | S               | Transplacental       |                                  |                 | Forest               |                |
|                                                                                                              | Largactil             |                    |                    | S               | Transplacental       |                                  |                 | Not Reported         |                |
|                                                                                                              | Atarax                |                    |                    | S               | Transplacental       |                                  |                 | Not Reported         |                |
|                                                                                                              | Lexomil               |                    |                    | S               | Transplacental       |                                  |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                                                     | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 12-Nov-2013                                                                                                  | 9685218               | DIRECT             |                    |                 |                      |                                  | 69 YR           | Female               | USA            |
| <u>Preferred Term</u>                                                                                        | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>           |                |
| Blepharospasm; Choking;<br>Drooling; Facial Spasm;<br>Lip Disorder; Nightmare;<br>Product Substitution Issue | Escitalopram Tab 10mg |                    |                    | S               | Oral                 | 10 Mg 1 Tab Everyday By<br>Mouth |                 | Aurobindo            |                |
|                                                                                                              | Levothyroxin          |                    |                    | C               |                      |                                  |                 | Not Reported         |                |
|                                                                                                              | Metoprolol            |                    |                    | C               |                      |                                  |                 | Not Reported         |                |
|                                                                                                              | Lexapro               |                    |                    | C               |                      |                                  |                 | Not Reported         |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                   |   |              |
|-------------------|---|--------------|
| Vit D             | C | Not Reported |
| Hydrocorothiazide | C | Not Reported |
| Compazine         | C | Not Reported |
| Sirnethecone      | C | Not Reported |
| Prilosec          | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Nov-2013              | 9685423       | DIRECT           |                    | LT              |                      |                      | 56 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u> |
|-------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|------------|
| Anxiety; Condition Aggravated; Irritability; Product Substitution Issue; Suicidal Ideation; Tic | Escitalopram   |              |            | S           | Oral         | 1 Dose Once Daily Taken By Mouth |                 | Teva       |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Nov-2013              | 9636353       | EXPEDITED (15-DAY) |                    | HO, LT          | AU-FRI-1000050319    |                      | 42 YR      | Female     | AUS            |

| <u>Preferred Term</u>                                        | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------|--------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Depressed Level Of Consciousness; Drug Interaction; Overdose | Lexapro            |              |            | S           | Oral         | 30 Mg              |                 | Forest       |
|                                                              | Alprazolam         |              |            | S           | Oral         | 1 Mg               |                 | Not Reported |
|                                                              | Methylprednisolone |              |            | S           | Other        | 40 Mg              |                 | Not Reported |
|                                                              | Sodium Valproate   |              |            | S           | Oral         | 1.5 Gram           |                 | Not Reported |
|                                                              | Mirtazapine        |              |            | C           | Oral         | 75 Mg              |                 | Not Reported |
|                                                              | Rabeprazole        |              |            | C           | Oral         | 20 Mg              |                 | Not Reported |
|                                                              | Salbutamol         |              |            | C           |              | 6 Df               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Nov-2013              | 9636367       | EXPEDITED (15-DAY) |                    | HO              | AU-FRI-1000050324    |                      | 57 YR      | Female     | AUS            |

| <u>Preferred Term</u>                       | <u>Product</u>   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------|------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cogwheel Rigidity; Extrapyramidal Disorder; | Escitalopram     |              |            | S           |              |                    |                 | Forest       |
|                                             | Sodium Valproate |              |            | S           |              |                    |                 | Not Reported |

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

|                    |           |   |      |      |              |
|--------------------|-----------|---|------|------|--------------|
| Petit Mal Epilepsy | Edronax   | S | Oral | 4 Mg | Not Reported |
|                    | Moduretic | C |      |      | Not Reported |
|                    | Nexium    | C |      |      | Not Reported |
|                    | Aspirin   | C |      |      | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Nov-2013              | 9636409       | EXPEDITED (15-DAY) |                    | LT, OT          | AU-FRI-1000050321    |                      | 42 YR      | Female     | AUS            |

| <u>Preferred Term</u>  | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------|--------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Agitation; Depression; | Escitalopram       |              |            | S           | Oral         | 30 Mg              |                 | Forest       |
| Drug Interaction;      | Methylprednisolone |              |            | S           |              | 40 Mg              |                 | Not Reported |
| Homicidal Ideation;    | Champix            |              |            | S           | Oral         | 1 Df               |                 | Not Reported |
| Suicidal Behaviour     | Sodium Valproate   |              |            | S           | Oral         | 1.5 Gram           |                 | Not Reported |
|                        | Alprazolam         |              |            | C           | Oral         |                    |                 | Not Reported |
|                        | Rabeprazole Sodium |              |            | C           | Oral         | 20 Mg              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 13-Nov-2013              | 9671224       | EXPEDITED (15-DAY) |                    | DE              | ES-JNJFOC-20131019370 |                      |            | Male       | ESP            |

| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>  | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|----------------|--------------|------------|-------------|---------------|--------------------|-----------------|--------------|
| Cardiac Arrest; Infarction | Xeplion        |              |            | S           | Intramuscular |                    |                 | Not Reported |
|                            | Escitalopram   |              |            | S           | Unknown       |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------------------------|----------------------|------------|------------|----------------|
| 13-Nov-2013              | 9685418       | EXPEDITED (15-DAY) |                    | OT              | KR-ROXANE LABORATORIES, INC.-2013-RO-01798RO |                      | 57 YR      | Female     | KOR            |

| <u>Preferred Term</u>                                      | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|------------------------------------------------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Dysarthria; Limb Discomfort; Sleep-Related Eating Disorder | Diazepam            |              |            | S           |              | 20 Mg              |                 | Roxane     |
|                                                            | Zolpidem Tartrate   |              |            | S           |              | 10 Mg              |                 | Roxane     |
|                                                            | Quetiapine Fumarate |              |            | S           |              | 25 Mg              |                 | Roxane     |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                  |   |       |              |
|------------------|---|-------|--------------|
| Lorazepam        | S | 2 Mg  | Roxane       |
| Escitalopram     | S | 20 Mg | Not Reported |
| Propylthiouracil | S | 50 Mg | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 13-Nov-2013              | 9686119        | EXPEDITED (15-DAY) |                    | OT              | DE-FRI-1000051051    |                      |                 | Female     | DEU            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Colitis; Vasculitis      | Escitalopram   |                    |                    | S               |                      |                      |                 | Forest     |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 13-Nov-2013              | 9686842        | EXPEDITED (15-DAY) |                    | OT              | IT-PFIZER INC-2013323307 |                      | 22 YR           | Male         | ITA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Abuse               | Xanax          |                    |                    | S               | Oral                     | 50 Gtt, Total        |                 | Pfizer       |                |
|                          | Antabuse       |                    |                    | S               | Oral                     | 800 Mg, Daily        |                 | Not Reported |                |
|                          | Cipralext      |                    |                    | S               | Oral                     | 10 Mg, Daily         |                 | Not Reported |                |

| <u>FDA Received Date</u>    | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------|----------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 14-Nov-2013                 | 9176567        | EXPEDITED (15-DAY) |                    | DE              | US-JNJFOC-20130306847 |                      |                 | Male         | USA            |
| <u>Preferred Term</u>       | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Overdose | Concerta       |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                             | Adderall       |                    |                    | S               | Unknown               |                      |                 | Not Reported |                |
|                             | Lexapro        |                    |                    | S               | Unknown               |                      |                 | Not Reported |                |
|                             | Vyvanse        |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|------------|----------------|
| 14-Nov-2013              | 9181563        | NON-EXPEDITED    |                    | OT              | US-PFIZER INC-2013091534 |                      | 49 YR           | Female     | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                                                 |               |   |                                                             |              |
|---------------------------------------------------------------------------------|---------------|---|-------------------------------------------------------------|--------------|
| Asthenia; Glucose Tolerance Impaired; Increased Appetite; Muscle Spasms; Oedema | Zoloft        | S | 100 Mg, Unk                                                 | Pfizer       |
| Peripheral; Weight Increased                                                    | Lexapro       | S | 10 Mg, Unk                                                  | Not Reported |
|                                                                                 | Amitriptyline | S | 25 Mg, Unk                                                  | Not Reported |
|                                                                                 | Warfarin      | C | 8 Mg, Every Tuesday, Wednesday, Friday, Saturday And Sunday | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Nov-2013              | 9478493       | EXPEDITED (15-DAY) |                    | HO, OT          | US-FRI-1000047984    |                      | 59 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Appendicectomy; Depression; Drug Ineffective; Knee Arthroplasty; Prescribed Overdose | Escitalopram   |              |            | S           | Oral         | 20 Mg              |                 | Forest       |
|                                                                                      | Escitalopram   |              |            | S           | Oral         | 40 Mg              |                 | Forest       |
|                                                                                      | Escitalopram   |              |            | S           | Oral         | 20 Mg              |                 | Not Reported |
|                                                                                      | Levothyroxine  |              |            | C           |              | 50 Mcg             |                 | Not Reported |
|                                                                                      | Insulin        |              |            | C           |              |                    |                 | Not Reported |
|                                                                                      | Simvastatin    |              |            | C           |              | 20 Mg              |                 | Not Reported |
|                                                                                      | Omeprazole     |              |            | C           |              | 20 Mg              |                 | Not Reported |
|                                                                                      | Diazepam       |              |            | C           |              | 10 Mg              |                 | Not Reported |
|                                                                                      | Oxycontin      |              |            | C           |              | 120 Mg             |                 | Not Reported |
|                                                                                      | Phenergan      |              |            | C           |              |                    |                 | Not Reported |
|                                                                                      | Lasix          |              |            | C           |              | 40 Mg              |                 | Not Reported |
|                                                                                      | Potassium      |              |            | C           |              | 20 Meq             |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Nov-2013              | 9612008       | EXPEDITED (15-DAY) |                    | OT              | GB-FRI-1000049869    |                      |            | Female     | GBR            |

| <u>Preferred Term</u>                                                                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abdominal Pain; Chest Discomfort; Dyspepsia; Hypoaesthesia; Multiple Sclerosis Relapse; | Escitalopram   |              |            | S           |              | 5 Mg               |                 | Forest       |
|                                                                                         | Cialis         |              |            | S           | Oral         | 5 Mg               |                 | Not Reported |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Product Dispensing Error;  
Product Name Confusion

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Nov-2013              | 9648169       | EXPEDITED (15-DAY) |                    | HO              | PHEH2013US022324     |                      |            | Female     | USA            |

| <u>Preferred Term</u>                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Blood Thyroid Stimulating Hormone | Combipatch     |              |            | S           | Transdermal  | Unk Ukn, Unk       |                 | Novartis     |
| Decreased; Merycism;                       | Combipatch     |              |            | S           | Transdermal  | Unk Ukn, Unk       |                 | Novartis     |
| Speech Disorder; Tremor                    | Lexapro        |              |            | S           |              | Unk Ukn, Unk       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 14-Nov-2013              | 9687969       | EXPEDITED (15-DAY) |                    | DE, HO          | US-MYLANLABS-2013S1024797 |                      | 29 YR      | Female     | USA            |

| <u>Preferred Term</u>                                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Brain Injury; Cardiac Arrest; Haemodynamic Instability; Overdose | Bupropion      |              |            | S           | Unknown      |                    |                 | Mylan        |
|                                                                  | Desvenlafaxine |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                  | Escitalopram   |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                  | Ibuprofen      |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                  | Quetiapine     |              |            | S           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Nov-2013              | 9688386       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000051173    |                      | 88 YR      | Female     | FRA            |

| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Iron Deficiency Anaemia | Escitalopram   |              |            | S           | Oral         | 1 Df               |                 | Forest       |
|                         | Pradaxa        |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Nov-2013              | 9690123       | DIRECT           |                    |                 |                      |                      | 43 YR      | Female     | USA            |

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

| <u>Preferred Term</u>                                                                                                 | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>             |                |
|-----------------------------------------------------------------------------------------------------------------------|-----------------------|--------------------|--------------------|-----------------|----------------------|---------------------------------------|-----------------|------------------------|----------------|
| Dizziness; Loss Of Libido;<br>Product Substitution Issue;<br>Weight Increased                                         | Escitalopram          |                    |                    | S               | Oral                 |                                       |                 | Not Reported           |                |
| <u>FDA Received Date</u>                                                                                              | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u>             | <u>Country</u> |
| 14-Nov-2013                                                                                                           | 9690182               | DIRECT             |                    |                 |                      |                                       | 33 YR           | Female                 | USA            |
| <u>Preferred Term</u>                                                                                                 | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>             |                |
| Anxiety; Panic Attack;<br>Product Substitution Issue                                                                  | Escitalopram 20mg     |                    |                    | S               | Oral                 | 1 Pill, Once Daily, Taken<br>By Mouth |                 | Not Reported           |                |
| <u>FDA Received Date</u>                                                                                              | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u>             | <u>Country</u> |
| 14-Nov-2013                                                                                                           | 9690261               | DIRECT             |                    | OT              |                      |                                       | 61 YR           | Female                 | USA            |
| <u>Preferred Term</u>                                                                                                 | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>             |                |
| Anxiety; Hyperhidrosis;<br>Muscle Twitching; Panic<br>Disorder; Product<br>Substitution Issue;<br>Withdrawal Syndrome | Escitalopram<br>Zocor |                    |                    | S<br>C          |                      |                                       |                 | Camber<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                                              | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u>             | <u>Country</u> |
| 15-Nov-2013                                                                                                           | 9526444               | EXPEDITED (15-DAY) |                    | DS, HO          | US-TEVA-432072USA    |                                       | 65 YR           | Male                   | USA            |
| <u>Preferred Term</u>                                                                                                 | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>             |                |
| Akathisia; Cogwheel                                                                                                   | Clozapine             |                    |                    | S               |                      |                                       |                 | Ivax                   |                |
| Rigidity; Drug Interaction;                                                                                           | Luvox                 |                    |                    | S               |                      |                                       |                 | Not Reported           |                |
| Obsessive-Compulsive                                                                                                  | Lexapro               |                    |                    | S               |                      |                                       |                 | Not Reported           |                |
| Disorder; Parkinsonism;                                                                                               | Benzatropine Mesilate |                    |                    | C               |                      |                                       |                 | Not Reported           |                |
| Toxicity To Various Agents                                                                                            | Depakote              |                    |                    | C               |                      |                                       |                 | Not Reported           |                |
|                                                                                                                       | Prilosec              |                    |                    | C               |                      |                                       |                 | Not Reported           |                |
|                                                                                                                       | Antidepressant        |                    |                    | C               |                      |                                       |                 | Not Reported           |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                          | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|------------------------------|---------------------------|-----------------|-----------------|----------------|
| 15-Nov-2013                                                                                                                       | 9632557        | EXPEDITED (15-DAY) |                    | HO, LT          | IT-ABBVIE-13P-083-1159125-00 |                           | 55 YR           | Male            | ITA            |
| <u>Preferred Term</u>                                                                                                             | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>      |                |
| Drug Abuse; Sopor                                                                                                                 | Depakin        |                    |                    | S               | Oral                         |                           |                 | Not Reported    |                |
|                                                                                                                                   | Depakin        |                    |                    | S               |                              |                           |                 | Not Reported    |                |
|                                                                                                                                   | Entact         |                    |                    | S               | Oral                         |                           |                 | Not Reported    |                |
|                                                                                                                                   | Entact         |                    |                    | S               |                              |                           |                 | Not Reported    |                |
|                                                                                                                                   | Xanax          |                    |                    | S               | Oral                         |                           |                 | Not Reported    |                |
|                                                                                                                                   | Cardioaspirin  |                    |                    | C               |                              |                           |                 | Not Reported    |                |
|                                                                                                                                   | Torvast        |                    |                    | C               |                              |                           |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                          | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 15-Nov-2013                                                                                                                       | 9691147        | EXPEDITED (15-DAY) |                    | DE, HO          | FR-GLAXOSMITHKLINE-B0941072A |                           | 85 YR           | Female          | FRA            |
| <u>Preferred Term</u>                                                                                                             | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>      |                |
| Anaemia; Duodenal Ulcer Haemorrhage; Fall; Gastrointestinal Haemorrhage; Haematoma; Haematoma Muscle; Melaena; Shock Haemorrhagic | Arixtra        |                    |                    | S               | Subcutaneous                 | 7.5mg Per Day             |                 | Glaxosmithkline |                |
|                                                                                                                                   | Ibuprofen      |                    |                    | S               | Oral                         | 400mg Three Times Per Day |                 | Unknown         |                |
|                                                                                                                                   | Seroplex       |                    |                    | S               | Oral                         | 15mg Per Day              |                 | Unknown         |                |
|                                                                                                                                   | Pyostacine     |                    |                    | S               | Oral                         | 2g Per Day                |                 | Unknown         |                |
|                                                                                                                                   | Xanax          |                    |                    | C               |                              |                           |                 | Glaxosmithkline |                |
|                                                                                                                                   | Parlodel       |                    |                    | C               |                              |                           |                 | Not Reported    |                |
|                                                                                                                                   | Vesicare       |                    |                    | C               |                              |                           |                 | Not Reported    |                |
|                                                                                                                                   | Nuctalon       |                    |                    | C               |                              |                           |                 | Not Reported    |                |
|                                                                                                                                   | Omeprazole     |                    |                    | C               |                              |                           |                 | Glaxosmithkline |                |
|                                                                                                                                   | Dafalgan       |                    |                    | C               |                              |                           |                 | Glaxosmithkline |                |
|                                                                                                                                   | Macrogol       |                    |                    | C               |                              |                           |                 | Glaxosmithkline |                |
| <u>FDA Received Date</u>                                                                                                          | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 15-Nov-2013                                                                                                                       | 9696009        | EXPEDITED (15-DAY) | Y                  | HO, LT          | 2013P1020943                 |                           | 16 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                                                                             | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>      |                |

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

|                          |                           |   |      |            |              |
|--------------------------|---------------------------|---|------|------------|--------------|
| Blood Glucose Increased; | Escitalopram              | S | Oral | 500 Mg; Po | Not Reported |
| Blood Potassium          | Tramadol/Acetaminophen    | S |      |            | Not Reported |
| Decreased; Blood         | Acetaminophen\Hydrocodone | S |      |            | Not Reported |
| Pressure Decreased;      | Bitartrate                |   |      |            |              |
| Bundle Branch Block      |                           |   |      |            |              |
| Right; Cardiotoxicity;   |                           |   |      |            |              |
| Electrocardiogram Qrs    |                           |   |      |            |              |
| Complex Prolonged;       |                           |   |      |            |              |
| Lethargy; Overdose;      |                           |   |      |            |              |
| Presyncope; Sinus        |                           |   |      |            |              |
| Bradycardia; Vomiting    |                           |   |      |            |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Nov-2013              | 9698514       | EXPEDITED (15-DAY) | Y                  | DE, HO          | 2013P1020897         |                      | 45 YR      | Female     | USA            |

| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|----------------------|--------------|------------|-------------|----------------------|--------------------|-----------------|--------------|
| International Normalised | Escitalopram         |              |            | S           |                      |                    |                 | Not Reported |
| Ratio Increased;         | Hydromorphone        |              |            | S           |                      |                    |                 | Not Reported |
| Ischaemic Cerebral       | Dihydroergotamine    |              |            | S           | Intravenous (not     |                    |                 | Not Reported |
| Infarction; Pyrexia;     |                      |              |            |             | otherwise specified) |                    |                 |              |
| Reversible Cerebral      | Hydrocodone          |              |            | S           |                      |                    |                 | Not Reported |
| Vasoconstriction         | Tetrahydrocannabinol |              |            | S           |                      |                    |                 | Not Reported |
| Syndrome; Serotonin      | Anticoagulant (S)    |              |            | C           |                      |                    |                 | Not Reported |
| Syndrome; Subarachnoid   |                      |              |            |             |                      |                    |                 |              |
| Haemorrhage              |                      |              |            |             |                      |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Nov-2013              | 9433007       | EXPEDITED (15-DAY) | Y                  | OT              | AUR-APL-2013-06299   |                      | 64 YR      | Female     | ITA            |

| <u>Preferred Term</u>    | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|---------------------------|--------------|------------|-------------|--------------|------------------------|-----------------|--------------|
| Drug Interaction;        | Lamotrigine (Lamotrigine) |              |            | S           | Oral         |                        |                 | Not Reported |
| Hallucination; Sleep-    | Quetiapine (Quetiapine)   |              |            | S           | Oral         |                        |                 | Not Reported |
| Related Eating Disorder; | Stilnox                   |              |            | S           | Oral         | )1 Dosage Forms), Oral |                 | Not Reported |
| Somnambulism             | Ciprallex                 |              |            | S           | Oral         |                        |                 | Not Reported |

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| <u>FDA Received Date</u>    | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------|-------------------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| 18-Nov-2013                 | 9693371                       | EXPEDITED (15-DAY) |                    | OT              | CA-ROCHE-1301791             |                      | 56 YR           | Male         | CAN            |
| <u>Preferred Term</u>       | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Constipation; Depression;   | Clonazepam                    |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
| Dizziness; Dry Mouth;       | Ciprallex                     |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
| Erection Increased;         | Seroquel                      |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
| Fatigue; Increased          | Wellbutrin XL                 |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
| Appetite; Muscular          | Echinacea                     |                    |                    | C               | Oral                         |                      |                 | Not Reported |                |
| Weakness; Nausea;           | Horse Chestnut Extract        |                    |                    | C               | Oral                         |                      |                 | Not Reported |                |
| Somnolence; Suicidal        | Milk Thistle                  |                    |                    | C               | Oral                         |                      |                 | Not Reported |                |
| Ideation; Tinnitus; Tremor; |                               |                    |                    |                 |                              |                      |                 |              |                |
| Weight Increased            |                               |                    |                    |                 |                              |                      |                 |              |                |
| <u>FDA Received Date</u>    | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Nov-2013                 | 9693503                       | EXPEDITED (15-DAY) |                    | OT              | AU-ABBVIE-13P-008-1157517-00 |                      | 57 YR           | Female       | AUS            |
| <u>Preferred Term</u>       | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cogwheel Rigidity;          | Sodium Valproate              |                    |                    | S               | Unknown                      |                      |                 | Not Reported |                |
| Extrapyramidal Disorder;    | Lexapro                       |                    |                    | S               | Unknown                      |                      |                 | Not Reported |                |
| Petit Mal Epilepsy          | Edronax                       |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                             | Moduretic                     |                    |                    | C               |                              |                      |                 | Not Reported |                |
|                             | Nexium I.V.                   |                    |                    | C               |                              |                      |                 | Not Reported |                |
|                             | Aspirin                       |                    |                    | C               |                              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>    | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Nov-2013                 | 9693779                       | EXPEDITED (15-DAY) |                    | HO              | IT-PFIZER INC-2013326671     |                      | 77 YR           | Male         | ITA            |
| <u>Preferred Term</u>       | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Sopor                       | Alprazolam                    |                    |                    | S               | Oral                         | 1 Df, 1x/Day         |                 | Pfizer       |                |
|                             | Control (Phenylpropanolamine) |                    |                    | S               | Oral                         | 2.5 Mg, 1x/Day       |                 | Not Reported |                |
|                             | Entact                        |                    |                    | S               | Oral                         | 10 Mg, 1x/Day        |                 | Not Reported |                |

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

|                                                                                   |                      |                    |                    |                 |                              |                      |                 |            |                |  |
|-----------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|------------|----------------|--|
| Lormetazepam                                                                      |                      |                    | S                  |                 | Oral                         |                      | 1 Df, 1x/Day    |            | Not Reported   |  |
| <u>FDA Received Date</u>                                                          | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |  |
| 18-Nov-2013                                                                       | 9694022              | EXPEDITED (15-DAY) |                    | OT              | AU-ABBVIE-13P-008-1157813-00 |                      | 42 YR           | Female     | AUS            |  |
| <u>Preferred Term</u>                                                             | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |  |
| Depressed Level Of Consciousness; Drug Interaction; Overdose                      | Sodium Valproate     |                    |                    | S               |                              |                      |                 |            | Not Reported   |  |
|                                                                                   | Alprazolam           |                    |                    | S               |                              |                      |                 |            | Not Reported   |  |
|                                                                                   | Escitalopram         |                    |                    | S               |                              |                      |                 |            | Not Reported   |  |
|                                                                                   | Methylprednisolone   |                    |                    | S               |                              |                      |                 |            | Not Reported   |  |
|                                                                                   | Mirtazapine          |                    |                    | C               |                              |                      |                 |            | Not Reported   |  |
|                                                                                   | Rabeprazole Sodium   |                    |                    | C               |                              |                      |                 |            | Not Reported   |  |
|                                                                                   | Salbutamol           |                    |                    | C               |                              |                      |                 |            | Not Reported   |  |
| <u>FDA Received Date</u>                                                          | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |  |
| 18-Nov-2013                                                                       | 9695392              | DIRECT             |                    | OT              |                              |                      | 40 YR           | Female     | USA            |  |
| <u>Preferred Term</u>                                                             | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |  |
| Abulia; Hypersensitivity; Mood Swings; Product Substitution Issue; Sleep Disorder | Lexapro              |                    |                    | S               |                              |                      |                 |            | Not Reported   |  |
|                                                                                   | Escitalopram Oxalate |                    |                    | S               |                              |                      |                 |            | Not Reported   |  |
| <u>FDA Received Date</u>                                                          | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |  |
| 18-Nov-2013                                                                       | 9695818              | DIRECT             |                    | OT              |                              |                      | 77 YR           | Female     | USA            |  |
| <u>Preferred Term</u>                                                             | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |  |
| Anxiety; Dyspnoea; Hypertension; Palpitations; Product Substitution Issue         | Escitalopram 20mg    |                    |                    | S               | Oral                         | 1 Pill               |                 |            | Aurobindo      |  |
| <u>FDA Received Date</u>                                                          | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |  |
| 18-Nov-2013                                                                       | 9695850              | DIRECT             |                    |                 |                              |                      | 37 YR           | Female     | USA            |  |
| <u>Preferred Term</u>                                                             | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |  |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                        |                   |   |      |                   |         |
|----------------------------------------|-------------------|---|------|-------------------|---------|
| Depression; Product Substitution Issue | Escitalopram 20mg | S | Oral | 1 Pill 20mg Daily | Walmart |
|----------------------------------------|-------------------|---|------|-------------------|---------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Nov-2013              | 9698842       | EXPEDITED (15-DAY) | Y                  | HO              | 2013110041           |                      | 72 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                     | <u>Product</u>                                                                                                              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Anxiety; Confusional State; Delirium; Disorientation; Disturbance In Attention; Drug Interaction; Hyponatraemia; Slow Response To Stimuli | Torem                                                                                                                       |              |            | S           | Oral         | 1-0-0 (5 Mg, 1 In 1 D), Oral  |                 | Not Reported |
|                                                                                                                                           | Remeron                                                                                                                     |              |            | S           | Oral         | 0-0-1 (30 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                                                                                                                           | Ciprallex                                                                                                                   |              |            | S           | Oral         | 1-0-0 (10 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                                                                                                                           | Concor (Bisoprolol Fumarate)                                                                                                |              |            | C           |              |                               |                 | Not Reported |
|                                                                                                                                           | Norvasc (Amlodipine Besilate)                                                                                               |              |            | C           |              |                               |                 | Not Reported |
|                                                                                                                                           | Pantoprazol (Pantoprazole)                                                                                                  |              |            | C           |              |                               |                 | Not Reported |
|                                                                                                                                           | Duphalac (Galactose, Lactulose, Lactose)                                                                                    |              |            | C           |              |                               |                 | Not Reported |
|                                                                                                                                           | Nicotinell                                                                                                                  |              |            | C           |              |                               |                 | Not Reported |
|                                                                                                                                           | Benerva (Thiamine Hydrochloride)                                                                                            |              |            | C           |              |                               |                 | Not Reported |
|                                                                                                                                           | Becozym Forte (Pyridoxine Hydrochloride, Biotin, Cyanocobalamin, Riboflavin, Thiamine Hydrochloride, Calcium Pantiothenate) |              |            | C           |              |                               |                 | Not Reported |
| Konakion (Phytomenadione)                                                                                                                 |                                                                                                                             |              | C          |             |              |                               | Not Reported    |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Nov-2013              | 9648345       | EXPEDITED (15-DAY) |                    | HO, LT          | IT-FRI-1000050520    |                      | 55 YR      | Male       | ITA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|-----------------------------------|-----------------|--------------|
| Overdose; Sopor       | Escitalopram   |              |            | S           | Oral         | 280 Mg At Once                    |                 | Forest       |
|                       | Depakin        |              |            | S           |              | Overdose: 60 Dosage Forms At Once |                 | Not Reported |
|                       | Xanax          |              |            | S           |              | Overdose: 40 Dosage               |                 | Not Reported |

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

|                                                                                                                     |                                     | Cardioaspirin      | C                  | Oral            | Forms At Once        |                      | Not Reported    |              |                |
|---------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
|                                                                                                                     |                                     | Torvast            | C                  | Oral            |                      |                      | Not Reported    |              |                |
| <u>FDA Received Date</u>                                                                                            | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Nov-2013                                                                                                         | 9670036                             | EXPEDITED (15-DAY) |                    | HO              | IT-FRI-1000050768    |                      | 71 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                                                               | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State;<br>Electrolyte Imbalance;<br>Inappropriate Antidiuretic<br>Hormone Secretion;<br>Muscle Rigidity | Escitalopram                        |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                                                                                                     | Clonazepam                          |                    |                    | C               | Oral                 | 10 Drops             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                            | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Nov-2013                                                                                                         | 9696342                             | EXPEDITED (15-DAY) |                    | DS, OT          | GB-FRI-1000051460    |                      | 73 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                                                               | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain Upper;<br>Bedridden; Nausea                                                                          | Escitalopram                        |                    |                    | S               | Oral                 | 5 Mg                 |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                            | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Nov-2013                                                                                                         | 9696377                             | EXPEDITED (15-DAY) |                    | LT              | ES-FRI-1000051462    |                      | 84 YR           | Female       | ESP            |
| <u>Preferred Term</u>                                                                                               | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardio-Respiratory Arrest;<br>Electrocardiogram Qt<br>Prolonged; Ventricular<br>Tachycardia                         | Escitalopram                        |                    |                    | S               | Oral                 |                      |                 | Forest       |                |
|                                                                                                                     | Ebastine                            |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                     | Deprax (Trazodone<br>Hydrochloride) |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                     | Atarax                              |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                            | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Nov-2013                                                                                                         | 9529797                             | EXPEDITED (15-DAY) |                    | DE, HO          | FR-ROCHE-1270915     |                      | 41 YR           | Female       | FRA            |



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

| <u>Preferred Term</u>                                                                                                                                                                                                                                                         | <u>Product</u>   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                             | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|--------------|------------|-------------|------------------------------------------|--------------------|-----------------|--------------|
| Acute Kidney Injury;<br>Blister; Eschar; Graft<br>Versus Host Disease In<br>Gastrointestinal Tract;<br>Haematuria; Hepatitis<br>Fulminant; Mucosal<br>Erosion; Multiple Organ<br>Dysfunction Syndrome;<br>Oedema; Skin Erosion;<br>Skin Lesion; Toxic<br>Epidermal Necrolysis | Bactrim          |              |            | S           | Intravenous drip                         |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                               | Cymevene         |              |            | S           | Intravenous (not<br>otherwise specified) |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                               | Fortum           |              |            | S           | Intravenous (not<br>otherwise specified) | 1 G                |                 | Not Reported |
|                                                                                                                                                                                                                                                                               | Flagyl           |              |            | S           | Oral                                     | 500 Mg             |                 | Not Reported |
|                                                                                                                                                                                                                                                                               | Zelitrex         |              |            | S           | Intravenous (not<br>otherwise specified) |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                               | Foscavir         |              |            | S           | Intravenous (not<br>otherwise specified) |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                               | Clairyg          |              |            | S           | Intravenous (not<br>otherwise specified) |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                               | Granocyte        |              |            | S           | Intravenous (not<br>otherwise specified) |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                               | Heparine Sodique |              |            | S           | Intravenous (not<br>otherwise specified) |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                               | Inexium          |              |            | S           | Intravenous (not<br>otherwise specified) | 40 Mg Once Per Day |                 | Not Reported |
|                                                                                                                                                                                                                                                                               | Spasfon (France) |              |            | S           | Intravenous (not<br>otherwise specified) |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                               | Delursan         |              |            | S           | Oral                                     |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                               | Defibrotide      |              |            | S           | Intravenous (not<br>otherwise specified) |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                               | Largactil        |              |            | S           | Intravenous (not<br>otherwise specified) |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                               | Tranxene         |              |            | S           | Oral                                     | As Required        |                 | Not Reported |
|                                                                                                                                                                                                                                                                               | Oxynorm          |              |            | S           | Intravenous (not<br>otherwise specified) |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                               | Exacyl           |              |            | S           | Intravenous (not<br>otherwise specified) |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                               | Perfalgan        |              |            | S           | Intravenous (not<br>otherwise specified) |                    |                 | Not Reported |

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

|                 |   |                                       |                                    |              |
|-----------------|---|---------------------------------------|------------------------------------|--------------|
| Solu-Medrol     | S | Intravenous (not otherwise specified) |                                    | Not Reported |
| Drolectan       | S | Intravenous (not otherwise specified) |                                    | Not Reported |
| Ultiva          | S | Intravenous (not otherwise specified) |                                    | Not Reported |
| Atarax (France) | S | Oral                                  | 100 Mg                             | Not Reported |
| Lasilix         | S | Intravenous (not otherwise specified) |                                    | Not Reported |
| Seroplex        | S | Oral                                  | Dose Increased On Unspecified Date | Not Reported |
| Ceris           | S | Oral                                  | 20 Mg                              | Not Reported |
| Noctamide       | S | Oral                                  | 2 Mg                               | Not Reported |
| Noctamide       | S | Oral                                  |                                    | Not Reported |
| Gentamicin      | S | Intravenous (not otherwise specified) |                                    | Not Reported |
| Noxafil         | S | Oral                                  |                                    | Not Reported |
| Cancidas        | S | Intravenous (not otherwise specified) |                                    | Not Reported |
| Folinic Acid    | S | Intravenous (not otherwise specified) |                                    | Not Reported |
| Ambisome        | S | Intravenous (not otherwise specified) |                                    | Not Reported |
| Endoxan         | C |                                       |                                    | Not Reported |
| Busulfex        | C |                                       |                                    | Not Reported |
| Methotrexate    | C | Unknown                               |                                    | Not Reported |
| Vancomycine     | C | Unknown                               |                                    | Not Reported |
| Ciflox (France) | C | Unknown                               |                                    | Not Reported |
| Targocid        | C | Unknown                               |                                    | Not Reported |
| Mycostatine     | C | Unknown                               | 2 Vial                             | Not Reported |
| Triflucan       | C | Unknown                               |                                    | Not Reported |
| Zovirax         | C | Unknown                               |                                    | Not Reported |

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

|                    |   |         |                    |              |
|--------------------|---|---------|--------------------|--------------|
| Elvorine           | C | Unknown |                    | Not Reported |
| Sandimmun          | C | Unknown |                    | Not Reported |
| Mopral (France)    | C | Unknown |                    | Not Reported |
| Ogastoro           | C | Unknown |                    | Not Reported |
| Gelox              | C | Unknown |                    | Not Reported |
| Smecta (France)    | C | Unknown |                    | Not Reported |
| Luteran            | C | Unknown |                    | Not Reported |
| Zophren            | C | Unknown | One Tablet Per Day | Not Reported |
| Primperan (France) | C | Unknown |                    | Not Reported |
| Acupan             | C | Unknown | If Needed          | Not Reported |
| Tiorfan            | C | Unknown |                    | Not Reported |
| Levocarnil         | C | Unknown |                    | Not Reported |
| Colistine          | C | Unknown |                    | Not Reported |
| Lexomil            | C | Unknown |                    | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 20-Nov-2013              | 9681870       | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-2013320824 |                      | 51 YR      | Female     | USA            |

| <u>Preferred Term</u>       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Chest Discomfort;  | Lyrica         |              |            | S           |              | 75 Mg, Daily       |                 | Pfizer       |
| Depression; Dyspnoea;       | Lyrica         |              |            | S           |              | 50 Mg, 2x/Day      |                 | Pfizer       |
| Feeling Hot; Heart Rate     | Lyrica         |              |            | S           |              |                    |                 | Pfizer       |
| Increased; Myalgia;         | Lexapro        |              |            | S           |              | Unk                |                 | Not Reported |
| Palpitations; Panic Attack; | Lexapro        |              |            | S           |              |                    |                 | Not Reported |
| Product Use In              |                |              |            |             |              |                    |                 |              |
| Unapproved Indication;      |                |              |            |             |              |                    |                 |              |
| Vision Blurred              |                |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Nov-2013              | 9698023       | EXPEDITED (15-DAY) |                    | DE, HO          | FR-FRI-1000051491    |                      | 85 YR      | Female     | FRA            |

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

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

|                                                                   |              |   |              |               |              |
|-------------------------------------------------------------------|--------------|---|--------------|---------------|--------------|
| Gastrointestinal<br>Haemorrhage;<br>Haematoma Muscle;<br>Overdose | Escitalopram | S | Oral         | 1 Df          | Forest       |
|                                                                   | Arixtra      | S | Subcutaneous | 7.5 Mg/0.6 MI | Not Reported |
|                                                                   | Ibuprofen    | S | Oral         | 3 Df          | Not Reported |
|                                                                   | Pyostacine   | S | Oral         | 4 Df          | Not Reported |
|                                                                   | Xanax        | C |              |               | Not Reported |
|                                                                   | Parlodel     | C |              |               | Not Reported |
|                                                                   | Vesicare     | C |              |               | Not Reported |
|                                                                   | Nuctalon     | C |              |               | Not Reported |
|                                                                   | Omeprazole   | C |              |               | Not Reported |
|                                                                   | Dafalgan     | C |              |               | Not Reported |
|                                                                   | Macrogol     | C |              |               | Not Reported |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 20-Nov-2013                       | 9700959                | DIRECT                    |                             | OT                       |                               |                               | 52 YR               | Female              | USA                     |

| <a href="#">Preferred Term</a>                                                                  | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|-------------------------------------------------------------------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Anxiety; Depression; Drug Ineffective; Product Substitution Issue; Therapeutic Response Changed | Lexapro                 |                       |                     | S                    |                       | Generic Lexapro Twice Daily | 2 MTH                    | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 20-Nov-2013                       | 9701510                | DIRECT                    |                             |                          |                               |                               | 31 YR               | Female              | USA                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a>             |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------------------|
| Amnesia; Impaired Work Ability | Escitalopram            |                       |                     | S                    | Oral                  | 1 Once Daily Taken By Mouth |                          | Legacy Pharmaceutical Packaging |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 20-Nov-2013                       | 9701915                | DIRECT                    | Y                           |                          |                               |                               | 16 YR               | Female              | USA                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Drug Ineffective; Product      | Escitalopram            |                       |                     | S                    | Oral                  |                             |                          | Not Reported        |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Substitution Issue

| <u>FDA Received Date</u>      | <u>Case #</u>                                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------|--------------------------------------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
| 20-Nov-2013                   | 9701919                                                | DIRECT             |                    | OT              |                           |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>         | <u>Product</u>                                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Night Sweats; Pain | Escitalopram                                           |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>      | <u>Case #</u>                                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Nov-2013                   | 9701999                                                | EXPEDITED (15-DAY) | Y                  | OT              | TR-MACLEODS PHARMA-000165 |                      | 29 YR           | Male         | TUR            |
| <u>Preferred Term</u>         | <u>Product</u>                                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Parkinsonism                  | Escitalopram                                           |                    |                    | S               |                           | 10.00-Mg-1.0days     |                 | Not Reported |                |
| <u>FDA Received Date</u>      | <u>Case #</u>                                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Nov-2013                   | 9826626                                                | NON-EXPEDITED      |                    | OT              | 1000044743                |                      | 71 YR           | Female       | USA            |
| <u>Preferred Term</u>         | <u>Product</u>                                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hot Flush; Insomnia           | Viibryd                                                |                    |                    | S               | Oral                      | 10 Mg, 1 In 1 D      |                 | Not Reported |                |
|                               | Lexapro (Escitalopram Oxalate) (10 Milligram, Tablets) |                    |                    | S               | Oral                      | (10 Mg, 1 In 1 D)    |                 | Not Reported |                |
|                               | Alprazolam (Alprazolam) (Alprazolam)                   |                    |                    | C               |                           |                      |                 | Not Reported |                |
|                               | Lisinopril (Lisinopril) (Lisinopril)                   |                    |                    | C               |                           |                      |                 | Not Reported |                |
|                               | Amlodipine (Amlodipine) (Amlodipine)                   |                    |                    | C               |                           |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>      | <u>Case #</u>                                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Nov-2013                   | 9836662                                                | NON-EXPEDITED      |                    |                 | 1000049313                |                      | 65 YR           | Female       | USA            |
| <u>Preferred Term</u>         | <u>Product</u>                                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Muscle Twitching              | Viibryd (Vilazodone Hydrochloride)                     |                    |                    | S               | Oral                      | 10 Mg, 1 In1 D       |                 | Not Reported |                |

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|  |                                        |   |      |                 |  |  |  |  |              |
|--|----------------------------------------|---|------|-----------------|--|--|--|--|--------------|
|  | Lexapro (Escitalopram Oxalate) Tablets | S | Oral | 20 Mg, 1 In 1 D |  |  |  |  |              |
|  | Crestor                                | C | Oral | 10 Mg, 1 In 1 D |  |  |  |  | Not Reported |
|  | Vitamin D Nos                          | C |      |                 |  |  |  |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Nov-2013              | 9382003       | EXPEDITED (15-DAY) |                    | CA, OT          | JP-FRI-1000046398    |                      | 38 YR      | Male       | JPN            |

| <u>Preferred Term</u>                                                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Sperm Concentration Decreased; Spermatozoa Progressive Motility Decreased | Lexapro        |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                                                           | Lexapro        |              |            | S           | Oral         | 20 Mg              |                 | Forest       |
|                                                                           | Lexapro        |              |            | S           | Oral         | 20 Mg              |                 | Forest       |
|                                                                           | Meilax         |              |            | C           | Oral         | 2 Mg               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Nov-2013              | 9537936       | EXPEDITED (15-DAY) |                    | HO              | IT-FRI-1000048938    |                      | 33 YR      | Female     | ITA            |

| <u>Preferred Term</u>       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Abuse; Overdose; Sopor | Escitalopram   |              |            | S           | Oral         | 200 Mg             |                 | Forest       |
|                             | Delorazepam    |              |            | S           | Oral         | 20 MI              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Nov-2013              | 9686102       | EXPEDITED (15-DAY) |                    | OT              | CA-FRI-1000051049    |                      |            | Male       | CAN            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Renal Impairment      | Escitalopram   |              |            | S           | Oral         |                    |                 | Forest       |
|                       | Escitalopram   |              |            | S           |              |                    |                 | Forest       |
|                       | Escitalopram   |              |            | S           | Oral         | 20 Mg              |                 | Forest       |
|                       | Escitalopram   |              |            | S           |              | 10 Mg              |                 | Forest       |
|                       | Metoprolol     |              |            | C           | Oral         | 50 Mg              |                 | Not Reported |

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| <u>FDA Received Date</u>                                                                                                                                              | <u>Case #</u>    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>        | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|-------------------|----------------|
| 21-Nov-2013                                                                                                                                                           | 9689326          | EXPEDITED (15-DAY) |                    | OT              | NO-FRI-1000051375            |                      | 35 YR           | Male              | NOR            |
| <u>Preferred Term</u>                                                                                                                                                 | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>        |                |
| Crying; Drug Dependence;<br>Epilepsy; Fatigue; Feeling<br>Of Despair; Frustration<br>Tolerance Decreased;<br>Insomnia; Irritability;<br>Malaise; Thinking<br>Abnormal | Escitalopram     |                    |                    | S               |                              |                      |                 | Forest            |                |
|                                                                                                                                                                       | Vallergan        |                    |                    | S               |                              | 10 Mg                |                 | Not Reported      |                |
|                                                                                                                                                                       | Neurontin        |                    |                    | S               |                              | 300 Mg               |                 | Not Reported      |                |
|                                                                                                                                                                       | Paralgin Forte   |                    |                    | S               |                              | 30 Mg                |                 | Not Reported      |                |
|                                                                                                                                                                       | Sobril           |                    |                    | S               |                              | 10 Mg                |                 | Not Reported      |                |
|                                                                                                                                                                       | Imovane          |                    |                    | S               |                              | 7.5 Mg               |                 | Not Reported      |                |
| <u>FDA Received Date</u>                                                                                                                                              | <u>Case #</u>    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>        | <u>Country</u> |
| 21-Nov-2013                                                                                                                                                           | 9700549          | NON-EXPEDITED      |                    |                 | US-PFIZER INC-<br>2013331159 |                      | 48 YR           | Male              | USA            |
| <u>Preferred Term</u>                                                                                                                                                 | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>        |                |
| Drug Hypersensitivity                                                                                                                                                 | Effexor          |                    |                    | S               |                              | Unk                  |                 | Pfizer            |                |
|                                                                                                                                                                       | Lexapro          |                    |                    | S               |                              | Unk                  |                 | Not Reported      |                |
|                                                                                                                                                                       | Wellbutrin       |                    |                    | S               |                              | Unk                  |                 | Not Reported      |                |
| <u>FDA Received Date</u>                                                                                                                                              | <u>Case #</u>    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>        | <u>Country</u> |
| 21-Nov-2013                                                                                                                                                           | 9701746          | EXPEDITED (15-DAY) |                    | OT              | DK-ACTAVIS-2013-<br>21289    |                      | 36 YR           | Male              | DNK            |
| <u>Preferred Term</u>                                                                                                                                                 | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>        |                |
| Altered State Of<br>Consciousness;<br>Diarrhoea; Dizziness;<br>Drug Interaction;<br>Hyperhidrosis; Malaise;<br>Muscle Spasticity;<br>Serotonin Syndrome               | Tramadol Actavis |                    |                    | S               | Unknown                      | Unk                  |                 | Actavis Elizabeth |                |
|                                                                                                                                                                       | Cipralext        |                    |                    | S               | Oral                         | 20 Mg, Daily         |                 | Not Reported      |                |

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| <u>FDA Received Date</u>                                                     | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------|-----------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 22-Nov-2013                                                                  | 9703303               | EXPEDITED (15-DAY) |                    | HO              | US-JNJFOC-20131107934 |                      | 14 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                        | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Amnesia; Product Use In Unapproved Indication; Tremor                        | Risperdal             |                    |                    | S               | Unknown               |                      |                 | Not Reported |                |
|                                                                              | Escitalopram Oxalate  |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                              | Abilify               |                    |                    | S               | Unknown               |                      |                 | Not Reported |                |
|                                                                              | Synthroid             |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                     | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Nov-2013                                                                  | 9703970               | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000051629     |                      | 63 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                        | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Haematoma                                                  | Escitalopram          |                    |                    | S               | Oral                  | 1 Df                 |                 | Forest       |                |
|                                                                              | Biprofenid            |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                              | Lyrica                |                    |                    | C               | Oral                  | 2 Df                 |                 | Not Reported |                |
|                                                                              | Oxynorm               |                    |                    | C               | Oral                  |                      |                 | Not Reported |                |
|                                                                              | Seresta               |                    |                    | C               |                       | 1 Df                 |                 | Not Reported |                |
|                                                                              | Baclofene             |                    |                    | C               |                       | 3 Df                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                     | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Nov-2013                                                                  | 9705436               | EXPEDITED (15-DAY) |                    | OT              | IT-ACTAVIS-2013-21216 |                      | 64 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                        | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Hallucination; Sleep-Related Eating Disorder; Somnambulism | Quetiapine (Unknown)  |                    |                    | S               | Oral                  | Unk                  |                 | Actavis      |                |
|                                                                              | Lamotrigine (Unknown) |                    |                    | S               | Oral                  | Unk                  |                 | Watson       |                |
|                                                                              | Stilnox               |                    |                    | S               | Oral                  | 1 Df, Qpm            |                 | Not Reported |                |
|                                                                              | Cipralext             |                    |                    | S               | Oral                  | 20 Mg/MI, Unk        |                 | Not Reported |                |



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| <a href="#">FDA Received Date</a>                                                  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>             | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|------------------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------------------|--------------------------|---------------------|-------------------------|
| 22-Nov-2013                                                                        | 9706810                 | DIRECT                    |                             | LT                       |                               |                                           | 46 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>                                                     | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>               | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Anxiety; Condition Aggravated; Depression; Hypersomnia; Product Substitution Issue | Lexapro 10mg (Generic)  |                           |                             | S                        | Oral                          | 1 Pill Once Daily Taken By 30 DAY Mouth   |                          | Forest              |                         |
| <a href="#">FDA Received Date</a>                                                  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>             | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 25-Nov-2013                                                                        | 9690943                 | EXPEDITED (15-DAY)        |                             | OT                       | US-PFIZER INC-2013326280      |                                           | 75 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                     | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>               | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Hip Fracture; Intentional Product Misuse; Mental Disorder                          | Xanax                   |                           |                             | S                        |                               | 0.5 Mg In The Morning And 1.5 Mg At Night |                          | Pfizer              |                         |
|                                                                                    | Preparation H           |                           | Y                           | S                        |                               | Unk, As Needed                            |                          | Pfizer              |                         |
|                                                                                    | Remeron                 |                           |                             | S                        |                               | 30 Mg, Daily                              |                          | Not Reported        |                         |
|                                                                                    | Lexapro                 |                           |                             | S                        |                               | 25 Mg, Daily                              |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>             | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 25-Nov-2013                                                                        | 9708559                 | EXPEDITED (15-DAY)        |                             | HO                       | IT-FRI-1000051678             |                                           | 45 YR                    | Female              | ITA                     |
| <a href="#">Preferred Term</a>                                                     | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>               | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Confusional State; Intentional Overdose; Poisoning; Sopor                          | Escitalopram            |                           |                             | S                        | Oral                          | Overdose:560 Mg Once                      |                          | Forest              |                         |
|                                                                                    | En                      |                           |                             | C                        | Oral                          |                                           |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>             | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 25-Nov-2013                                                                        | 9708803                 | EXPEDITED (15-DAY)        |                             | OT                       | CH-FRI-1000051733             |                                           | 49 YR                    | Female              | CHE                     |
| <a href="#">Preferred Term</a>                                                     | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>               | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Hypoacusis; Nasal                                                                  | Escitalopram            |                           |                             | S                        | Oral                          | 10 Mg                                     |                          | Forest              |                         |

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|                                                                                                                |                                   |                    |                    |                 |                      |                                        |                 |              |                |
|----------------------------------------------------------------------------------------------------------------|-----------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------------------------|-----------------|--------------|----------------|
| Obstruction                                                                                                    | Trittico                          |                    | C                  | Oral            | 50 Mg                |                                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                       | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Nov-2013                                                                                                    | 9711819                           | DIRECT             |                    |                 |                      |                                        | 49 YR           | Unknown      | USA            |
| <u>Preferred Term</u>                                                                                          | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Dreams; Drug Ineffective; Nasal Ulcer; Nightmare; Product Substitution Issue                          | Escitalopram                      |                    |                    | S               | Oral                 | 1 Pill Once Daily Taken By 6 MTH Mouth |                 | Torrent      |                |
| <u>FDA Received Date</u>                                                                                       | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Nov-2013                                                                                                    | 9716799                           | EXPEDITED (15-DAY) |                    | OT              | BR-TORRENT-00001828  |                                        | 69 YR           | Female       | BRA            |
| <u>Preferred Term</u>                                                                                          | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Hemiparesis; Tremor                                                                                            | Espran (Inn:Escitalopram Oxalate) |                    |                    | S               | Oral                 | Once Daily/Oral                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                       | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Nov-2013                                                                                                    | 9718948                           | EXPEDITED (15-DAY) | Y                  | DE, HO          | 2013P1021126         |                                        | 29 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                          | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Brain Injury; Cardiac Arrest; Circulatory Collapse; Overdose; Pulseless Electrical Activity; Sinus Tachycardia | Escitalopram                      |                    |                    | S               |                      | ; X1;                                  |                 | Not Reported |                |
|                                                                                                                | Bupropion                         |                    |                    | S               |                      | ; X1 ;                                 |                 | Not Reported |                |
|                                                                                                                | Quetiapine                        |                    |                    | S               |                      | ; X1 ;                                 |                 | Not Reported |                |
|                                                                                                                | Desvenlafaxine                    |                    |                    | S               |                      | ; X1 ;                                 |                 | Not Reported |                |
|                                                                                                                | Ibuprofen                         |                    |                    | S               |                      | ; X 1 ;                                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                       | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Nov-2013                                                                                                    | 9537853                           | EXPEDITED (15-DAY) |                    | HO, OT          | JP-FRI-1000040028    |                                        | 68 YR           | Female       | JPN            |
| <u>Preferred Term</u>                                                                                          | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |                |

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|                                                                            |            |   |      |        |              |
|----------------------------------------------------------------------------|------------|---|------|--------|--------------|
| Dizziness; Dyspnoea;<br>Feeling Hot; Nausea;<br>Palpitations; Paraesthesia | Lexapro    | S | Oral | 10 Mg  | Forest       |
|                                                                            | Adetphos   | C | Oral | 300 Mg | Not Reported |
|                                                                            | Rebamipide | C | Oral | 300 Mg | Not Reported |
|                                                                            | Gasmotin   | C | Oral | 15 Mg  | Not Reported |
|                                                                            | Alositol   | C | Oral | 100 Mg | Not Reported |
|                                                                            | Takepron   | C | Oral | 15 Mg  | Not Reported |
|                                                                            | Myslee     | C | Oral | 10 Mg  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 26-Nov-2013              | 9665401       | EXPEDITED (15-DAY) |                    | DE, OT          | US-JNJFOC-20131100280 |                      | 29 YR      | Female     | USA            |

| <u>Preferred Term</u>        | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Areflexia; Brain Injury;     | Ibuprofen                |              |            | S           | Unknown      |                    |                 | Not Reported |
| Circulatory Collapse;        | Bupropion                |              |            | S           | Unknown      |                    |                 | Not Reported |
| Coma Scale Abnormal;         | Escitalopram Oxalate     |              |            | S           | Unknown      |                    |                 | Not Reported |
| Dry Skin; Gastrointestinal   | Desvenlafaxine Succinate |              |            | S           | Unknown      |                    |                 | Not Reported |
| Sounds Abnormal;             | Monohydrate              |              |            |             |              |                    |                 |              |
| Hypotension; Overdose;       | Quetiapine Fumarate      |              |            | S           | Unknown      |                    |                 | Not Reported |
| Pulseless Electrical         |                          |              |            |             |              |                    |                 |              |
| Activity; Pupil Fixed; Sinus |                          |              |            |             |              |                    |                 |              |
| Tachycardia                  |                          |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                        | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------------------|----------------------|------------|------------|----------------|
| 26-Nov-2013              | 9709415       | EXPEDITED (15-DAY) |                    | DE, HO          | US-SUN<br>PHARMACEUTICAL<br>INDUSTRIES LTD-<br>2013SUN05051 |                      | 29 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Brain Injury; Cardiac | Bupropion Hydrochloride       |              |            | S           | Unknown      |                    |                 | Not Reported |
| Arrest; Circulatory   | Extended-Release Tablets, Usp |              |            |             |              |                    |                 |              |
| Collapse; Intentional | (Sr) 100mg                    |              |            |             |              |                    |                 |              |
| Overdose              | Quetiapine Fumarate 25mg      |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Tablets                       |              |            |             |              |                    |                 |              |
|                       | Escitalopram 1mg/ML Oral      |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Solution                      |              |            |             |              |                    |                 |              |

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

|                                                                                                                         |                |                    |                    |                 |                              |                      |                 |              |                |
|-------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
|                                                                                                                         |                | Desvenlafaxine     |                    | S               | Unknown                      |                      |                 |              | Not Reported   |
|                                                                                                                         |                | Ibuprofen          |                    | S               | Unknown                      | Unk                  |                 |              | Not Reported   |
| <u>FDA Received Date</u>                                                                                                | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Nov-2013                                                                                                             | 9714335        | EXPEDITED (15-DAY) |                    | OT              | IT-FRI-1000041360            |                      |                 | Female       | ITA            |
| <u>Preferred Term</u>                                                                                                   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Gestational Diabetes;<br>Pregnancy                                                                                      | Escitalopram   |                    |                    | S               |                              | 10 Mg                |                 | Forest       |                |
|                                                                                                                         | Escitalopram   |                    |                    | S               |                              | 20 Mg                |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Nov-2013                                                                                                             | 9715894        | DIRECT             |                    | OT              |                              |                      | 60 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Depression;<br>Drug Ineffective                                                                               | Escitalopram   |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Nov-2013                                                                                                             | 9722873        | EXPEDITED (15-DAY) | Y                  | DE, HO          | 2013P1021124                 |                      | 29 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Brain Injury; Circulatory<br>Collapse; Hypotension;<br>Overdose; Pulseless<br>Electrical Activity; Sinus<br>Tachycardia | Bupropion      |                    |                    | S               |                              | X1                   |                 | Not Reported |                |
|                                                                                                                         | Quetiapin      |                    |                    | S               |                              | X1                   |                 | Not Reported |                |
|                                                                                                                         | Desvenlafaxine |                    |                    | S               |                              | X1                   |                 | Not Reported |                |
|                                                                                                                         | Escitalopram   |                    |                    | S               |                              | X1                   |                 | Not Reported |                |
|                                                                                                                         | Ibuprofen      |                    |                    | S               |                              | X1                   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Nov-2013                                                                                                             | 9716625        | NON-EXPEDITED      |                    |                 | US-PFIZER INC-<br>2013338910 |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

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

|           |         |   |     |              |
|-----------|---------|---|-----|--------------|
| Contusion | Zoloft  | S | Unk | Pfizer       |
|           | Lexapro | S | Unk | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Nov-2013              | 9718723       | EXPEDITED (15-DAY) |                    | OT              | CH-FRI-1000051795    |                      |            | Female     | CHE            |

| <u>Preferred Term</u>                                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Nausea; Serotonin Syndrome; Sleep Disorder; Tachycardia; Tremor | Escitalopram   |              |            | S           | Oral         | 5 Mg               |                 | Forest       |
|                                                                 | Trittico       |              |            | C           | Oral         | 25 Mg              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Nov-2013              | 9719242       | EXPEDITED (15-DAY) |                    | HO, OT          | PHHY2013BE119304     |                      | 32 YR      | Female     | BEL            |

| <u>Preferred Term</u>                                                                                                                | <u>Product</u>                        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Asthenia; Depression; Hypokinesia; Increased Appetite; Multiple Sclerosis Relapse; Urine Output Decreased; Weight Increased | Gilenya                               |              |            | S           | Oral         | 0.5 Mg, Qd         |                 | Novartis     |
|                                                                                                                                      | Remergon                              |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                      | Sipralexa                             |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                      | Nitrofurantoin                        |              |            | C           |              | 150 Mg, Qd         |                 | Not Reported |
|                                                                                                                                      | Zopiclone                             |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                      | Lyrica                                |              |            | C           |              | 300 Mg, Bid        |                 | Not Reported |
|                                                                                                                                      | Magnespasmyl                          |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                      | Serlain                               |              |            | C           |              | 50 Mg, Unk         |                 | Not Reported |
|                                                                                                                                      | Befact                                |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                      | (Cyanocobalamin\Pyridoxine\Thi amine) |              |            |             |              |                    |                 |              |
|                                                                                                                                      | Omnibionta                            |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                      | Tri Minulet                           |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Nov-2013              | 9601207       | EXPEDITED (15-DAY) |                    | OT              | FI-JNJFOC-2010012535 |                      | 46 YR      | Male       | FIN            |

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

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

|                                                                                                                                                                                                                                                                                                                                                                                                                   |                       |   |   |               |                                          |              |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|---|---|---------------|------------------------------------------|--------------|
| Abdominal Discomfort;                                                                                                                                                                                                                                                                                                                                                                                             | Nicorette Patch       | Y | S | Transdermal   |                                          | Not Reported |
| Acute Sinusitis;                                                                                                                                                                                                                                                                                                                                                                                                  | Nicorette Patch       |   | S | Transdermal   | Daily Dose Text: Unknown                 | Not Reported |
| Adjustment Disorder With Mixed Anxiety And Depressed Mood;                                                                                                                                                                                                                                                                                                                                                        | Nicorette Gum         | Y | S | Oral          | 1/2 Tablet Daily;                        | Not Reported |
| Aggression; Agitation;                                                                                                                                                                                                                                                                                                                                                                                            |                       |   |   |               | Daily Dose Text: 2mg And 4mg Unspecified | Not Reported |
| Anosmia; Anxiety; Blood Cholesterol Increased;                                                                                                                                                                                                                                                                                                                                                                    | Champix               |   | S | Oral          | Daily Dose Text: 1mg, 2x/Day             | Not Reported |
| Blood Glucose Increased;                                                                                                                                                                                                                                                                                                                                                                                          | Champix               |   | S | Oral          | Daily Dose Text: 0.5mg, 1x/Day           | Not Reported |
| Confusional State;                                                                                                                                                                                                                                                                                                                                                                                                | Champix               |   | S | Oral          | Daily Dose Text: 0.5mg, 2x/Day           | Not Reported |
| Confusional State;                                                                                                                                                                                                                                                                                                                                                                                                |                       |   |   |               |                                          |              |
| Depression; Dizziness;                                                                                                                                                                                                                                                                                                                                                                                            | Champix               |   | S | Oral          |                                          | Not Reported |
| Drug Dependence; Drug Interaction; Dyspnoea;                                                                                                                                                                                                                                                                                                                                                                      | Amoxin                |   | S | Oral          |                                          | Not Reported |
| Dyspnoea; Erythema;                                                                                                                                                                                                                                                                                                                                                                                               | Rinexin               |   | S | Oral          |                                          | Not Reported |
| Euphoric Mood; Fatigue;                                                                                                                                                                                                                                                                                                                                                                                           | Cipralext             |   | S | Unknown       |                                          | Not Reported |
| Fear; Feeling Abnormal;                                                                                                                                                                                                                                                                                                                                                                                           | Pentoxyverine Citrate |   | C | Unknown       |                                          | Not Reported |
| Hallucination; Hepatic Steatosis;                                                                                                                                                                                                                                                                                                                                                                                 | Clarithromycin        |   | C | Unknown       |                                          | Not Reported |
| Hypersensitivity;                                                                                                                                                                                                                                                                                                                                                                                                 | Doximycin             |   | C | Unknown       |                                          | Not Reported |
| Hyposmia;                                                                                                                                                                                                                                                                                                                                                                                                         | Azithromycin          |   | C | Unknown       |                                          | Not Reported |
| Hypothyroidism; Increased Appetite; Infection;                                                                                                                                                                                                                                                                                                                                                                    | Havrix                |   | C | Intramuscular | Daily Dose Text: Unknown                 | Not Reported |
| Influenza; Irritability; Loss Of Personal Independence In Daily Activities; Lower Respiratory Tract Infection; Medication Error; Memory Impairment; Mood Swings; Musculoskeletal Discomfort; Nausea; Nightmare; Overdose; Overweight; Palpitations; Panic Reaction; Personality Change; Restlessness; Sense Of Oppression; Sleep Disorder; Swelling; Tinnitus; Upper Respiratory Tract Infection; Vasodilatation; |                       |   |   |               |                                          |              |

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

Vertigo; Weight Increased;  
Withdrawal Syndrome

| <u>FDA Received Date</u>                     | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------|-------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 29-Nov-2013                                  | 9720141                 | EXPEDITED (15-DAY) |                    | DE              | US-INDICUS PHARMA-000181 |                      | 31 YR           | Female       | USA            |
| <u>Preferred Term</u>                        | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Exposure Via Ingestion | Metformin Hydrochloride |                    |                    | S               | Oral                     |                      |                 | Indicus      |                |
|                                              | Metoprolol              |                    |                    | S               | Oral                     | Extended Release     |                 | Not Reported |                |
|                                              | Escitalopram            |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                                              | Esomeprazole            |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                                              | Acetaminophen/Opioid    |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>        | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------|----------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 29-Nov-2013                     | 9720538        | EXPEDITED (15-DAY) |                    | OT              | FR-JNJFOC-20131118003 |                      | 83 YR           | Female       | FRA            |
| <u>Preferred Term</u>           | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State;<br>Myoclonus | Ixprim         |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                 | Seroplex       |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                 | Keppra         |                    |                    | C               | Oral                  |                      |                 | Not Reported |                |
|                                 | Keppra         |                    |                    | C               | Oral                  |                      |                 | Not Reported |                |
|                                 | Keppra         |                    |                    | C               | Oral                  |                      |                 | Not Reported |                |
|                                 | Keppra         |                    |                    | C               | Oral                  |                      |                 | Not Reported |                |
|                                 | Keppra         |                    |                    | C               | Oral                  |                      |                 | Not Reported |                |
|                                 | Keppra         |                    |                    | C               | Oral                  |                      |                 | Not Reported |                |
|                                 | Keppra         |                    |                    | C               | Oral                  |                      |                 | Not Reported |                |
|                                 | Omeprazole     |                    |                    | C               | Oral                  |                      |                 | Not Reported |                |
|                                 | Actonel        |                    |                    | C               | Oral                  |                      |                 | Not Reported |                |
|                                 | Methotrexate   |                    |                    | C               | Oral                  |                      |                 | Not Reported |                |
|                                 | Acide Folique  |                    |                    | C               | Oral                  |                      |                 | Not Reported |                |

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

|          |   |      |              |
|----------|---|------|--------------|
| Tahor    | C | Oral | Not Reported |
| Amlor    | C | Oral | Not Reported |
| Kardegic | C | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 02-Dec-2013              | 9373064        | EXPEDITED (15-DAY) |                    |                 | AT-FRI-1000046249    |                      |                 | Male         | AUT            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenospermia;          | Escitalopram   |                    |                    | S               |                      | 10 Mg                |                 | Forest       |                |
| Oligospermia;            | Escitalopram   |                    |                    | S               |                      | 20 Mg                |                 | Forest       |                |
| Teratospermia            | Escitalopram   |                    |                    | S               |                      | 2.5 Mg               |                 | Not Reported |                |

| <u>FDA Received Date</u>                         | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 02-Dec-2013                                      | 9659822                  | EXPEDITED (15-DAY) |                    | DE, OT          | US-PFIZER INC-2013308507 |                      | 29 YR           | Female       | USA            |
| <u>Preferred Term</u>                            | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Areflexia; Brain Injury;                         | Quetiapine Fumarate      |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
| Cardiac Arrest; Circulatory Collapse; Coma Scale | Escitalopram Oxalate     |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
| Abnormal; Dry Skin;                              | Ibuprofen                |                    |                    | S               |                          | Unk                  |                 | Pfizer       |                |
| Gastrointestinal Sounds                          | Desvenlafaxine Succinate |                    |                    | S               |                          | Unk                  |                 | Pfizer       |                |
| Abnormal; Hypotension;                           | Monohydrate              |                    |                    |                 |                          |                      |                 |              |                |
| Overdose; Pupil Fixed;                           | Bupropion                |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
| Tachycardia                                      |                          |                    |                    |                 |                          |                      |                 |              |                |

| <u>FDA Received Date</u>          | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------|-------------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 02-Dec-2013                       | 9698558                       | EXPEDITED (15-DAY) |                    | HO              | IT-PFIZER INC-2013329226 |                      | 77 YR           | Male         | ITA            |
| <u>Preferred Term</u>             | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Sopor; Toxicity To Various Agents | Xanax                         |                    |                    | S               | Oral                     | 1 Df, Daily          |                 | Pfizer       |                |
|                                   | Lormetazepam                  |                    |                    | S               | Oropharyngeal            | 1 Df, Unk            |                 | Pfizer       |                |
|                                   | Control (Phenylpropanolamine) |                    |                    | S               | Oral                     | 2.5 Mg, Daily        |                 | Not Reported |                |



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

|                                                                                                                                           |                  |                    |                    |                 |                      |                                     |                 |              |                |  |
|-------------------------------------------------------------------------------------------------------------------------------------------|------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------------|-----------------|--------------|----------------|--|
| Entact                                                                                                                                    |                  |                    | S                  |                 | Oral                 |                                     | 10 Mg, Daily    |              | Not Reported   |  |
| <u>FDA Received Date</u>                                                                                                                  | <u>Case #</u>    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |  |
| 02-Dec-2013                                                                                                                               | 9725252          | DIRECT             |                    |                 |                      |                                     | 71 YR           | Male         | USA            |  |
| <u>Preferred Term</u>                                                                                                                     | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |  |
| Depression; Muscle Twitching; Nightmare; Product Substitution Issue                                                                       | Escitalopram     |                    |                    | S               | Oral                 | 1 Once Daily Taken By Mouth         | 100 DAY         | Aurobindo    |                |  |
| <u>FDA Received Date</u>                                                                                                                  | <u>Case #</u>    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |  |
| 02-Dec-2013                                                                                                                               | 9725302          | DIRECT             |                    | OT              |                      |                                     | 32 YR           | Female       | USA            |  |
| <u>Preferred Term</u>                                                                                                                     | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |  |
| Abdominal Pain Upper; Anxiety; Depression; Panic Attack; Product Substitution Issue                                                       | Escitalopram     |                    |                    | S               |                      | 2 Pills, Once Daily, Taken By Mouth | 2 MTH           | Teva         |                |  |
| <u>FDA Received Date</u>                                                                                                                  | <u>Case #</u>    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |  |
| 02-Dec-2013                                                                                                                               | 9730459          | EXPEDITED (15-DAY) |                    | HO              | JP-FRI-1000045325    |                                     | 77 YR           | Female       | JPN            |  |
| <u>Preferred Term</u>                                                                                                                     | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |  |
| Abdominal Pain Upper; Blood Bilirubin Increased; Blood Glucose Increased; Headache; Muscular Weakness; Nausea; Serotonin Syndrome; Thirst | Lexapro          |                    |                    | S               | Oral                 | 10 Mg                               |                 | Forest       |                |  |
|                                                                                                                                           | Opalmon          |                    |                    | C               | Oral                 |                                     |                 | Not Reported |                |  |
|                                                                                                                                           | Myslee           |                    |                    | C               | Oral                 |                                     |                 | Not Reported |                |  |
|                                                                                                                                           | Depas (Etizolam) |                    |                    | C               | Oral                 |                                     |                 | Not Reported |                |  |
|                                                                                                                                           | Amlodin Od       |                    |                    | C               | Oral                 |                                     |                 | Not Reported |                |  |
|                                                                                                                                           | Onealfa          |                    |                    | C               | Oral                 |                                     |                 | Not Reported |                |  |
|                                                                                                                                           | Bayaspirin       |                    |                    | C               | Oral                 |                                     |                 | Not Reported |                |  |
|                                                                                                                                           | Crestor          |                    |                    | C               | Oral                 |                                     |                 | Not Reported |                |  |
|                                                                                                                                           | Omepral          |                    |                    | C               | Oral                 |                                     |                 | Not Reported |                |  |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|--------------------------|---------------------------------------|-----------------|--------------|----------------|
| 02-Dec-2013                                                                                                  | 9730739        | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000051810        |                                       | 83 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State; Drug Interaction; Myoclonus                                                               | Escitalopram   |                    |                    | S               | Oral                     | 1 Df                                  |                 | Forest       |                |
|                                                                                                              | Ixprim         |                    |                    | S               | Oral                     | 3 Df                                  |                 | Not Reported |                |
|                                                                                                              | Amlor          |                    |                    | C               |                          |                                       |                 | Not Reported |                |
|                                                                                                              | Tahor          |                    |                    | C               |                          |                                       |                 | Not Reported |                |
|                                                                                                              | Kardegic       |                    |                    | C               |                          |                                       |                 | Not Reported |                |
|                                                                                                              | Omeprazole     |                    |                    | C               |                          |                                       |                 | Not Reported |                |
|                                                                                                              | Actonel        |                    |                    | C               |                          |                                       |                 | Not Reported |                |
|                                                                                                              | Methotrexate   |                    |                    | C               |                          |                                       |                 | Not Reported |                |
|                                                                                                              | Acide Folique  |                    |                    | C               |                          |                                       |                 | Not Reported |                |
|                                                                                                              | Levetiracetam  |                    |                    | C               |                          | 500 Mg                                |                 | Not Reported |                |
|                                                                                                              | Levetiracetam  |                    |                    | C               |                          | 1000 Mg                               |                 | Not Reported |                |
|                                                                                                              | Levetiracetam  |                    |                    | C               |                          | 1500 Mg                               |                 | Not Reported |                |
|                                                                                                              | Levetiracetam  |                    |                    | C               |                          | 2000 Mg                               |                 | Not Reported |                |
|                                                                                                              | Levetiracetam  |                    |                    | C               |                          | 1000 Mg                               |                 | Not Reported |                |
|                                                                                                              | Levetiracetam  |                    |                    | C               |                          | 500 Mg                                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Dec-2013                                                                                                  | 9012610        | EXPEDITED (15-DAY) |                    | OT              | DK-PFIZER INC-2013013843 |                                       | 38 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Chest Pain; Coordination Abnormal; Drug Interaction; Dysstasia; Hot Flush; Laboratory Test Abnormal; Malaise | Relpax         |                    |                    | S               | Oral                     | 1 Tablet Of 20mg Per Day For Migraine |                 | Pfizer       |                |
|                                                                                                              | Relpax         |                    |                    | S               | Oral                     | 40 Mg, In Case Of Migraine Attacks    |                 | Pfizer       |                |
|                                                                                                              | Cipralext      |                    |                    | S               | Oral                     | 20 Mg, 1x/Day                         |                 | Not Reported |                |
|                                                                                                              | Cipralext      |                    |                    | S               |                          |                                       |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                    | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 03-Dec-2013                                                                 | 9726120                | EXPEDITED (15-DAY) |                    | HO              | FI-FRI-1000051814                               |                      | 43 YR           | Male         | FIN            |
| <u>Preferred Term</u>                                                       | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dyskinesia; Speech Disorder; Suicide Attempt                                | Escitalopram           |                    |                    | S               | Oral                                            |                      |                 | Forest       |                |
|                                                                             | Citalopram             |                    |                    | S               |                                                 |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                    | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Dec-2013                                                                 | 9727542                | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000051819                               |                      | 80 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                       | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Haematemesis; Rectal Haemorrhage                          | Escitalopram           |                    |                    | S               | Oral                                            | 1 Df                 |                 | Forest       |                |
|                                                                             | Eliquis                |                    |                    | S               | Oral                                            | 2 Df                 |                 | Not Reported |                |
|                                                                             | Levothyrox             |                    |                    | C               | Oral                                            | 37.5 Mcg             |                 | Not Reported |                |
|                                                                             | Cokenzen               |                    |                    | C               | Oral                                            | 1 Df                 |                 | Not Reported |                |
|                                                                             | Omeprazole             |                    |                    | C               | Oral                                            | 1 Df                 |                 | Not Reported |                |
|                                                                             | Singulair              |                    |                    | C               | Oral                                            | 1 Df                 |                 | Not Reported |                |
|                                                                             | Seretide               |                    |                    | C               | Respiratory (inhalation)                        | 2 Df                 |                 | Not Reported |                |
|                                                                             | Airomir Autohaler      |                    |                    | C               | Respiratory (inhalation)                        | 2 Puffs              |                 | Not Reported |                |
|                                                                             | Alprazolam             |                    |                    | C               | Oral                                            | 1 Df                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                    | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Dec-2013                                                                 | 9727766                | NON-EXPEDITED      |                    | OT              | US-ENDO<br>PHARMACEUTICALS<br>INC.-AMIT20130011 |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                       | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Gait Disturbance; Glucose Tolerance Impaired; Increased Appetite; | Amitriptyline Hcl 25mg |                    |                    | S               | Oral                                            |                      |                 | Not Reported |                |
|                                                                             | Lexapro                |                    |                    | S               | Oral                                            |                      |                 | Not Reported |                |
|                                                                             | Zoloft                 |                    |                    | S               | Oral                                            |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Muscle Spasms; Oedema  
Peripheral; Weight  
Increased

Warfarin

C

Oral

Not Reported

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Dec-2013              | 9732023       | EXPEDITED (15-DAY) | Y                  | DE              | US-ALKEM-000361      |                      | 35 YR      | Female     | USA            |

| <u>Preferred Term</u>                                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Exposure Via Ingestion;<br>Toxicity To Various Agents | Gabapentin     |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                       | Quetiapine     |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                       | Escitalopram   |              |            | S           | Oral         | Oral               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Dec-2013              | 8504859       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000029721    |                      | 52 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                                              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Condition Aggravated;<br>Hepatic Enzyme<br>Increased; Hepatic<br>Failure; Jaundice | Escitalopram   |              |            | S           | Oral         | 20 Mg              |                 | Forest       |
|                                                                                    | Zyprexa        |              |            | S           | Oral         | 5 Mg               |                 | Not Reported |
|                                                                                    | Rasilez Hct    |              |            | S           | Oral         | 150 Mg/12.5 Mg     |                 | Not Reported |
|                                                                                    | Anafranil      |              |            | S           | Oral         | 37.5 Mg            |                 | Not Reported |
|                                                                                    | Alprazolam     |              |            | S           | Oral         | 0.75 Mg            |                 | Not Reported |
|                                                                                    | Prazepam       |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 04-Dec-2013              | 9054756       | EXPEDITED (15-DAY) |                    | HO              | IT-PFIZER INC-<br>2013042222 |                      | 56 YR      | Female     | ITA            |

| <u>Preferred Term</u>                                                              | <u>Product</u>  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------|-----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Intentional Overdose;<br>Respiratory Acidosis;<br>Respiratory Depression;<br>Sopor | Venlafaxine Hcl |              |            | S           | Oral         | 21 Df, Total Dose  |                 | Pfizer       |
|                                                                                    | Lexotan         |              |            | S           | Oral         | 51 Df, Total Dose  |                 | Not Reported |
|                                                                                    | Patrol          |              |            | S           | Oral         | 4 Df, Total Dose   |                 | Not Reported |
|                                                                                    | Moment 200      |              |            | S           | Oral         | 18 Df, Total Dose  |                 | Not Reported |

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

|             |   |      |                   |              |
|-------------|---|------|-------------------|--------------|
| Ciprallex   | S | Oral | 18 Mg, Total Dose | Not Reported |
| Paracetamol | S | Oral | 28 Df, Total Dose | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Dec-2013              | 9540200       | EXPEDITED (15-DAY) | HO                 |                 | BE-FRI-1000049086    |                      | 26 YR      | Male       | BEL            |

| <u>Preferred Term</u>                  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                     | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------------------------------------------|-----------------|--------------|
| Gastrointestinal Necrosis;<br>Overdose | Escitalopram   |              |            | S           |              | 10 Mg                                                  |                 | Forest       |
|                                        | Escitalopram   |              |            | S           |              | Overdose Of Unknown Amount                             |                 | Not Reported |
|                                        | Clopidol       |              |            | S           |              | 200 Mg Once Every 15th Day                             |                 | Not Reported |
|                                        | Clopidol       |              |            | S           |              | Overdose Of Unknown Amount                             |                 | Not Reported |
|                                        | Etumine        |              |            | S           |              | 40 Mg                                                  |                 | Not Reported |
|                                        | Etumine        |              |            | S           |              | Overdose Of Unknown Amount                             |                 | Not Reported |
|                                        | Doctrazodone   |              |            | S           |              | 200 Mg                                                 |                 | Not Reported |
|                                        | Doctrazodone   |              |            | S           |              | Overdose Of Unknown Amount                             |                 | Not Reported |
|                                        | Lambipol       |              |            | S           |              | 200 Mg                                                 |                 | Not Reported |
|                                        | Lambipol       |              |            | S           |              | Overdose Of Unknown Amount                             |                 | Not Reported |
|                                        | Lorazepam      |              |            | S           |              | 2.5 Mg                                                 |                 | Not Reported |
|                                        | Lorazepam      |              |            | S           |              | Overdose Of Unknown Amount                             |                 | Not Reported |
|                                        | Seroquel       |              |            | S           |              | 600 Mg                                                 |                 | Not Reported |
|                                        | Seroquel       |              |            | S           |              | Overdose Of Unknown Amount (300 Mg Middy And At 17 Pm) |                 | Not Reported |

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

| <u>FDA Received Date</u>      | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|-------------------------------|-----------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|-----------------|----------------|
| 04-Dec-2013                   | 9610959               | EXPEDITED (15-DAY) |                    | OT              | FI-GLAXOSMITHKLINE-A1044399A |                      | 46 YR           | Male            | FIN            |
| <u>Preferred Term</u>         | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Abdominal Discomfort;         | Nicorette Patch       |                    |                    | S               | Transdermal                  |                      |                 | Glaxosmithkline |                |
| Acute Sinusitis;              | Nicorette Gum         |                    |                    | S               | Oral                         |                      |                 | Glaxosmithkline |                |
| Adjustment Disorder With      | Champix               |                    |                    | S               | Oral                         |                      |                 | Not Reported    |                |
| Mixed Anxiety And             | Champix               |                    |                    | S               | Oral                         |                      |                 | Not Reported    |                |
| Depressed Mood;               | Champix               |                    |                    | S               | Oral                         |                      |                 | Not Reported    |                |
| Aggression; Agitation;        | Champix               |                    |                    | S               | Oral                         |                      |                 | Not Reported    |                |
| Anosmia; Anxiety; Blood       | Amoxin                |                    |                    | S               | Oral                         | .5mg Per Day         |                 | Glaxosmithkline |                |
| Cholesterol Increased;        | Rinexin               |                    |                    | S               | Oral                         |                      |                 | Glaxosmithkline |                |
| Blood Glucose Increased;      | Cipralext             |                    |                    | S               | Unknown                      |                      |                 | Glaxosmithkline |                |
| Confusional State;            | Pentoxyverine Citrate |                    |                    | C               | Unknown                      |                      |                 | Glaxosmithkline |                |
| Confusional State;            | Clarithromycin        |                    |                    | C               | Unknown                      |                      |                 | Glaxosmithkline |                |
| Depression; Dizziness;        | Doximycin             |                    |                    | C               | Unknown                      |                      |                 | Glaxosmithkline |                |
| Drug Dependence; Drug         | Azithromycin          |                    |                    | C               | Unknown                      |                      |                 | Glaxosmithkline |                |
| Interaction; Dyspnoea;        | Havrix                |                    |                    | C               | Intramuscular                |                      |                 | Glaxosmithkline |                |
| Dyspnoea; Erythema;           |                       |                    |                    |                 |                              |                      |                 |                 |                |
| Euphoric Mood; Fatigue;       |                       |                    |                    |                 |                              |                      |                 |                 |                |
| Fear; Feeling Abnormal;       |                       |                    |                    |                 |                              |                      |                 |                 |                |
| Hallucination; Hepatic        |                       |                    |                    |                 |                              |                      |                 |                 |                |
| Steatosis;                    |                       |                    |                    |                 |                              |                      |                 |                 |                |
| Hypersensitivity;             |                       |                    |                    |                 |                              |                      |                 |                 |                |
| Hyposmia;                     |                       |                    |                    |                 |                              |                      |                 |                 |                |
| Hypothyroidism; Increased     |                       |                    |                    |                 |                              |                      |                 |                 |                |
| Appetite; Infection;          |                       |                    |                    |                 |                              |                      |                 |                 |                |
| Influenza; Irritability; Loss |                       |                    |                    |                 |                              |                      |                 |                 |                |
| Of Personal Independence      |                       |                    |                    |                 |                              |                      |                 |                 |                |
| In Daily Activities; Lower    |                       |                    |                    |                 |                              |                      |                 |                 |                |
| Respiratory Tract             |                       |                    |                    |                 |                              |                      |                 |                 |                |
| Infection; Medication         |                       |                    |                    |                 |                              |                      |                 |                 |                |
| Error; Memory                 |                       |                    |                    |                 |                              |                      |                 |                 |                |
| Impairment; Mood Swings;      |                       |                    |                    |                 |                              |                      |                 |                 |                |
| Musculoskeletal               |                       |                    |                    |                 |                              |                      |                 |                 |                |
| Discomfort; Nausea;           |                       |                    |                    |                 |                              |                      |                 |                 |                |
| Nightmare; Overdose;          |                       |                    |                    |                 |                              |                      |                 |                 |                |
| Overweight; Palpitations;     |                       |                    |                    |                 |                              |                      |                 |                 |                |
| Panic Reaction;               |                       |                    |                    |                 |                              |                      |                 |                 |                |
| Personality Change;           |                       |                    |                    |                 |                              |                      |                 |                 |                |

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

Restlessness; Sense Of  
Oppression; Sleep  
Disorder; Swelling;  
Tinnitus; Upper  
Respiratory Tract  
Infection; Vasodilatation;  
Vertigo; Weight Increased;  
Withdrawal Syndrome

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 04-Dec-2013              | 9729276       | EXPEDITED (15-DAY) |                    | HO              | FR-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>19864289 |                      | 80 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                | <u>Dosage Text</u>                                                | <u>Duration</u> | <u>Mfr</u>           |
|----------------------------------------------------------|----------------|--------------|------------|-------------|-----------------------------|-------------------------------------------------------------------|-----------------|----------------------|
| Drug Interaction;<br>Haematemesis; Rectal<br>Haemorrhage | Eliquis        |              |            | S           | Oral                        | Eliquis 2.5 Mg Film-Coated Tablet                                 |                 | Bristol Myers Squibb |
|                                                          | Seroplex       |              |            | S           | Oral                        |                                                                   |                 | Not Reported         |
|                                                          | Seroplex       |              |            | S           | Oral                        |                                                                   |                 | Not Reported         |
|                                                          | Levothyrox     |              |            | C           | Oral                        | 75 Micro G Scored Tablet.<br>1df= Half Tablet.                    |                 | Not Reported         |
|                                                          | Cokenzen       |              |            | C           | Oral                        | 1df= 1 Tablet.                                                    |                 | Not Reported         |
|                                                          | Omeprazole     |              |            | C           | Oral                        | 1df= 1 Tablet.                                                    |                 | Not Reported         |
|                                                          | Singulair      |              |            | C           | Oral                        | 10 Mg Film-Coated Tablet                                          |                 | Not Reported         |
|                                                          | Seretide       |              |            | C           | Respiratory<br>(inhalation) | 1df= 1 Puff                                                       |                 | Not Reported         |
|                                                          | Airomir        |              |            | C           |                             | Autohaler 100<br>Micrograms/Dose.                                 |                 | Not Reported         |
|                                                          | Salbutamol     |              |            | C           |                             | Suspension For<br>Pressurized Inhalation<br>1df= 2 Puff On Demand |                 | Not Reported         |
|                                                          | Alprazolam     |              |            | C           | Oral                        | 0.25mg 1df= 1tablet.                                              |                 | Not Reported         |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Dec-2013              | 9730352       | EXPEDITED (15-DAY) |                    | OT              | CA-ROCHE-1308075     |                      | 56 YR      | Female     | CAN            |

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

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Abdominal Discomfort;<br>Anxiety; Asthenia; Balance<br>Disorder; Diarrhoea;<br>Disorientation;<br>Disturbance In Attention;<br>Dizziness; Drug<br>Interaction; Dyspnoea;<br>Euphoric Mood; Gait<br>Disturbance; Hallucination;<br>Headache; Hypopnoea;<br>Muscle Spasms;<br>Palpitations; Pulse<br>Pressure Increased;<br>Somnolence; Urinary Tract<br>Infection; Vomiting | Clonazepam     |              |            | S           | Oral         |                               |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                            | Baclofen       |              |            | S           | Unknown      |                               |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                            | Baclofen       |              |            | S           | Unknown      |                               |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                            | Butrans        |              |            | S           | Transdermal  | Therapy Duration: 7.0<br>Days |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                            | Butrans        |              |            | S           | Transdermal  |                               |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                            | Butrans        |              |            | S           | Transdermal  |                               |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                            | Butrans        |              |            | S           | Transdermal  |                               |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                            | Cesamet        |              |            | S           | Oral         |                               |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                            | Cipralelex     |              |            | S           | Oral         |                               |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                            | Cipralelex     |              |            | S           | Oral         |                               |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                            | Bisoprolol     |              |            | C           | Unknown      |                               |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                            | Cipro          |              |            | C           | Unknown      |                               |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                            | Furosemide     |              |            | C           | Unknown      |                               |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                            | Wellbutrin XI  |              |            | C           | Unknown      |                               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Dec-2013              | 9731856       | DIRECT           |                    |                 |                      |                      | 54 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                                                  | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|--------------------------|--------------|------------|-------------|--------------|-----------------------------------------------------------------------------------------------------|-----------------|--------------|
| Nausea; Vomiting      | Escitalopram             |              |            | S           | Oral         | 1 Tablet, Then Decreased<br>To 1/4 Tablet--Symptoms<br>Persisted ; Bedtime, Then<br>Tried At Dinner |                 | Camber       |
|                       | Enalapril Maleate W/Hctz |              |            | C           |              |                                                                                                     |                 | Not Reported |
|                       | Zegrid                   |              |            | C           |              |                                                                                                     |                 | Not Reported |
|                       | Restasis                 |              |            | C           |              |                                                                                                     |                 | Not Reported |
|                       | Simvastatin              |              |            | C           |              |                                                                                                     |                 | Not Reported |
|                       | Vivelle                  |              |            | C           |              |                                                                                                     |                 | Not Reported |
|                       | Progesterone             |              |            | C           |              |                                                                                                     |                 | Not Reported |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                  | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|---------------------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 04-Dec-2013                                               | 9733096                     | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000051866                                             |                      | 28 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                     | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Extrasystoles                                             | Escitalopram                |                    |                    | S               | Oral                                                          | 10 Mg                |                 | Forest       |                |
| <u>FDA Received Date</u>                                  | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Dec-2013                                               | 9735564                     | EXPEDITED (15-DAY) | Y                  | DE              | US-ALKEM-000331                                               |                      | 54 YR           | Female       | USA            |
| <u>Preferred Term</u>                                     | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardio-Respiratory Arrest;<br>Completed Suicide           | Gabapentin (Gabapentin)     |                    |                    | S               | Oral                                                          | Oral                 |                 | Not Reported |                |
|                                                           | Quetiapine (Quetiapine)     |                    |                    | S               | Oral                                                          | Oral                 |                 | Not Reported |                |
|                                                           | Escitalopram (Escitalopram) |                    |                    | S               | Oral                                                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                  | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Dec-2013                                               | 9736341                     | EXPEDITED (15-DAY) | Y                  | DE              | US-ALKEM-000302                                               |                      | 65 YR           | Male         | USA            |
| <u>Preferred Term</u>                                     | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Exposure Via Ingestion;<br>Overdose | Gabapentin                  |                    |                    | S               | Oral                                                          |                      |                 | Not Reported |                |
|                                                           | Acetaminophen W/Codeine     |                    |                    | S               | Oral                                                          |                      |                 | Not Reported |                |
|                                                           | Metoprolol                  |                    |                    | S               | Oral                                                          |                      |                 | Not Reported |                |
|                                                           | Simvastatin                 |                    |                    | S               | Oral                                                          |                      |                 | Not Reported |                |
|                                                           | Escitalopram                |                    |                    | S               |                                                               |                      |                 | Not Reported |                |
|                                                           | Quetiapine                  |                    |                    | S               | Oral                                                          |                      |                 | Not Reported |                |
|                                                           | Eszopiclone                 |                    |                    | S               |                                                               |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                  | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Dec-2013                                               | 9580879                     | EXPEDITED (15-DAY) |                    | HO              | JP-B.I.<br>PHARMACEUTICALS,I<br>NC./RIDGEFIELD-2013-<br>BI-30 |                      | 65 YR           | Female       | JPN            |

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

| <u>Preferred Term</u> | <u>Product</u>                                      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>           |
|-----------------------|-----------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------|
| Pancytopenia          | Trazenta                                            |              |            | S           | Oral         | 5 Mg               |                 | Boehringer Ingelheim |
|                       | Xarelto / Rivaroxaban                               |              |            | S           | Oral         | 10 Mg              |                 | Not Reported         |
|                       | Plavix                                              |              |            | S           | Oral         | 75 Mg              |                 | Not Reported         |
|                       | Diart                                               |              |            | S           | Oral         | 60 Mg              |                 | Not Reported         |
|                       | Samsca                                              |              |            | S           | Oral         | 15 Mg              |                 | Not Reported         |
|                       | Maintate                                            |              |            | S           | Oral         | 5 Mg               |                 | Not Reported         |
|                       | Risperdal Od                                        |              |            | S           | Oral         | 1 Mg               |                 | Not Reported         |
|                       | Lexapro                                             |              |            | S           | Oral         | 10 Mg              |                 | Not Reported         |
|                       | Acinon / Nizatidine                                 |              |            | C           | Oral         | 300 Mg             |                 | Not Reported         |
|                       | Vasolan / Verapamil Hydrochloride                   |              |            | C           | Oral         | 80 Mg              |                 | Not Reported         |
|                       | Predonine / Prednisolone                            |              |            | C           | Oral         | 10 Mg              |                 | Not Reported         |
|                       | Novorapid / Insulin Aspart(Genetical Recombination) |              |            | C           | Subcutaneous | 24 U               |                 | Not Reported         |
|                       | Lantus                                              |              |            | C           | Subcutaneous | 14 U               |                 | Not Reported         |
|                       | Omnipaque 140 / Iohexol                             |              |            | C           |              |                    |                 | Not Reported         |
|                       | Nexium / Esomeprazole                               |              |            | C           |              |                    |                 | Not Reported         |
|                       | Magnesium Hydrate                                   |              |            |             |              |                    |                 |                      |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Dec-2013              | 9684631       | EXPEDITED (15-DAY) | Y                  | DE, OT          | AUR-APL-2013-09280   |                      | 29 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                               | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Areflexia; Blood Lactic Acid Increased; Body Temperature Decreased; Brain Injury; Cardiac Arrest; Circulatory Collapse; Coma Scale Abnormal; Dry Skin; Gastrointestinal Sounds Abnormal; Heart Rate | Quetiapine                  |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                     | Escitalopram (Escitalopram) |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                     | Ibuprofen (Ibuprofen)       |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                     | Desvenlafaxine Succinate    |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                     | Bupropion                   |              |            | S           |              |                    |                 | Not Reported |

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

Increased; Hypotension;  
Mydriasis; Overdose;  
Oxygen Saturation  
Increased; Peripheral  
Coldness; Ph Body Fluid  
Abnormal; Pulseless  
Electrical Activity; Sinus  
Tachycardia; Tachycardia

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Dec-2013              | 9699566       | EXPEDITED (15-DAY) |                    | HO              | PHHY2013IT131932     |                      | 77 YR      | Male       | ITA            |

| <u>Preferred Term</u> | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>  | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|---------------------|--------------|------------|-------------|---------------|--------------------|-----------------|--------------|
| Sopor                 | Lormetazepam        |              |            | S           | Oropharyngeal | 1 U, Qd            |                 | Not Reported |
|                       | Lormetazepam        |              |            | S           | Oropharyngeal | 1 Mg, Unk          |                 | Not Reported |
|                       | Entact              |              |            | S           | Oral          | 10 Mg, Qd          |                 | Not Reported |
|                       | Control (Lorazepam) |              |            | S           | Oral          | 2.5 Mg, Qd         |                 | Not Reported |
|                       | Xanax               |              |            | S           | Oral          | 1 U, Qd            |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|------------|------------|----------------|
| 05-Dec-2013              | 9721584       | EXPEDITED (15-DAY) |                    | OT              | US-009507513-<br>1311USA012141 |                      |            | Female     | USA            |

| <u>Preferred Term</u>                             | <u>Product</u>                         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                          | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------|----------------------------------------|--------------|------------|-------------|--------------|-------------------------------------------------------------|-----------------|--------------|
| Hip Fracture; Off Label<br>Use; Unevaluable Event | Remeron                                |              |            | S           | Oral         | 30 Mg, Qd                                                   |                 | Merck        |
|                                                   | Lexapro                                |              |            | S           |              | 25 Mg, Qd                                                   |                 | Not Reported |
|                                                   | Xanax                                  |              |            | S           |              | Dose Of 0.5mg In The<br>Morning And 1.5mg At<br>Night , Bid |                 | Not Reported |
|                                                   | Preparation H Hemorrhoidal<br>Ointment |              |            | S           |              | Unk, Prn                                                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Dec-2013              | 9732655       | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000051873    |                      | < 1 DAY    | Female     | USA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                                                              | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>   |                |
|--------------------------------------------------------------------------------------------------------------------|---------------------|--------------------|--------------------|-----------------|----------------------|--------------------------------------|-----------------|--------------|----------------|
| Talipes                                                                                                            | Lexapro             |                    |                    | S               | Transplacental       |                                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                           | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Dec-2013                                                                                                        | 9734105             | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000051854    |                                      | < 1 DAY         | Male         | USA            |
| <u>Preferred Term</u>                                                                                              | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anal Atresia; Congenital Ectopic Bladder; Epispadias; Inguinal Hernia; Perineal Fistula; Ventricular Septal Defect | Lexapro             |                    |                    | S               | Transplacental       |                                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                           | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Dec-2013                                                                                                        | 9627774             | EXPEDITED (15-DAY) |                    | DE              | FR-FRI-1000050115    |                                      | 31 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                              | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Suicidal Behaviour                                                                              | Escitalopram        |                    |                    | S               | Oral                 | 1 Df                                 |                 | Forest       |                |
|                                                                                                                    | Baclofene Zentiva   |                    |                    | S               | Oral                 | Progressive Titration To 60 Mg Daily |                 | Not Reported |                |
|                                                                                                                    | Diazepam Ratiopharm |                    |                    | S               | Oral                 | 3 Df                                 |                 | Not Reported |                |
|                                                                                                                    | Zopiclone           |                    |                    | C               |                      |                                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                           | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Dec-2013                                                                                                        | 9708616             | EXPEDITED (15-DAY) |                    | HO              | IT-FRI-1000051674    |                                      | 77 YR           | Male         | ITA            |
| <u>Preferred Term</u>                                                                                              | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Sopor                                                                                                              | Escitalopram        |                    |                    | S               | Oral                 | 10 Mg                                |                 | Forest       |                |
|                                                                                                                    | Lormetazepam        |                    |                    | S               | Oropharingeal        | 1 Df                                 |                 | Not Reported |                |
|                                                                                                                    | Xanax               |                    |                    | S               | Oral                 | 1 Df                                 |                 | Not Reported |                |
|                                                                                                                    | Control (Lorazepam) |                    |                    | S               | Oral                 |                                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                    | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------------------------------------------------|-----------------|--------------|----------------|
| 09-Dec-2013                                                                                                                 | 9052854        | EXPEDITED (15-DAY) |                    | HO              | IT-FRI-1000042489    |                                                                | 56 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                                                                       | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                             | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Overdose;<br>Respiratory Acidosis;<br>Respiratory Depression;<br>Sopor                                          | Escitalopram   |                    |                    | S               | Oral                 | 18 Tablets Taken At Once<br>As An Overdose.                    |                 | Forest       |                |
|                                                                                                                             | Paracetamol    |                    |                    | S               | Oral                 | 28 Tablets Taken At Once<br>As An Overdose.                    |                 | Not Reported |                |
|                                                                                                                             | Venlafaxine    |                    |                    | S               | Oral                 | 21 Tablets Taken At Once<br>As An Overdose.                    |                 | Not Reported |                |
|                                                                                                                             | Patrol         |                    |                    | S               | Oral                 | (37.5 Mg/325 Mg) 4<br>Tablets Taken At Once As<br>An Overdose. |                 | Not Reported |                |
|                                                                                                                             | Moment         |                    |                    | S               | Oral                 | 18 Tablets Taken At Once<br>As An Overdose.                    |                 | Not Reported |                |
|                                                                                                                             | Lexotan        |                    |                    | S               | Oral                 | 51 Tablets Taken At Once<br>As An Overdose.                    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                    | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Dec-2013                                                                                                                 | 9708787        | EXPEDITED (15-DAY) |                    | OT              | JP-FRI-1000051631    |                                                                | 70 YR           | Male         | JPN            |
| <u>Preferred Term</u>                                                                                                       | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                             | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness Postural                                                                                                          | Lexapro        |                    |                    | S               | Oral                 | 10 Mg                                                          |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                    | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Dec-2013                                                                                                                 | 9741177        | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000051979    |                                                                | 18 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                       | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                             | <u>Duration</u> | <u>Mfr</u>   |                |
| Brief Psychotic Disorder<br>With Marked Stressors;<br>Chest Pain; Hallucination;<br>Major Depression; Petit<br>Mal Epilepsy | Escitalopram   |                    |                    | S               |                      |                                                                |                 | Forest       |                |
|                                                                                                                             | Contramal      |                    |                    | S               |                      |                                                                |                 | Not Reported |                |
|                                                                                                                             | Epitomax       |                    |                    | S               |                      |                                                                |                 | Not Reported |                |
|                                                                                                                             | Tercian        |                    |                    | S               |                      |                                                                |                 | Not Reported |                |
|                                                                                                                             |                |                    |                    |                 |                      | 15 Drops Once                                                  |                 |              |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                                                              |                           |                    |                    |                 |                                                 |                      |                 |              |                |
|----------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|--------------|----------------|
| Modiodal                                                                                     |                           |                    | C                  |                 |                                                 | Not Reported         |                 |              |                |
| <u>FDA Received Date</u>                                                                     | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Dec-2013                                                                                  | 9746325                   | DIRECT             |                    |                 |                                                 |                      | 55 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                        | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Depression;<br>Disturbance In Attention;<br>Dizziness; Memory<br>Impairment; Nausea | Escitalopram              |                    |                    | S               | Oral                                            |                      | 1 YR            | Mylan        |                |
| <u>FDA Received Date</u>                                                                     | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Dec-2013                                                                                  | 9099878                   | EXPEDITED (15-DAY) |                    | HO              | IT-JNJFOC-<br>20130203452                       |                      | 56 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                                        | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;                                                                            | Patrol                    |                    |                    | S               | Oral                                            | 150 Mg + 1300 Mg     |                 | Not Reported |                |
| Dyspnoea; Intentional                                                                        | Lexotan                   |                    |                    | S               | Oral                                            | 76.5 Mg              |                 | Not Reported |                |
| Overdose; Loss Of                                                                            | Cipralext                 |                    |                    | S               | Oral                                            | 180 Mg               |                 | Not Reported |                |
| Consciousness;                                                                               | Moment 200                |                    |                    | S               | Oral                                            | 3600 Mg              |                 | Not Reported |                |
| Respiratory Acidosis;                                                                        | Venlafaxine Hydrochloride |                    |                    | S               | Oral                                            |                      |                 | Not Reported |                |
| Respiratory Depression;                                                                      | Paracetamol               |                    |                    | S               | Oral                                            |                      |                 | Not Reported |                |
| Sopor; Suicidal Ideation;                                                                    |                           |                    |                    |                 |                                                 |                      |                 |              |                |
| Toxicity To Various Agents                                                                   |                           |                    |                    |                 |                                                 |                      |                 |              |                |
| <u>FDA Received Date</u>                                                                     | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Dec-2013                                                                                  | 9632673                   | EXPEDITED (15-DAY) |                    | HO, OT          | ES-<br>ELI_LILLY_AND_COMP<br>ANY-ES201310005292 |                      | 57 YR           | Female       | ESP            |
| <u>Preferred Term</u>                                                                        | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression;                                                                                  | Olanzapine                |                    |                    | S               | Unknown                                         | 5 Mg, Qd             |                 | Unknown      |                |
| Hyponatraemia; Suicidal                                                                      | Haloperidol               |                    |                    | S               | Unknown                                         | 20 Gtt, Qd           |                 | Not Reported |                |
| Behaviour                                                                                    | Haloperidol               |                    |                    | S               |                                                 | 10 Gtt, Qd           |                 | Not Reported |                |
|                                                                                              | Clorazepate Dipotassium   |                    |                    | C               | Unknown                                         | 3 Df, Qd             |                 | Not Reported |                |
|                                                                                              | Clorazepate Dipotassium   |                    |                    | C               |                                                 | 10 Mg, Qd            |                 | Not Reported |                |

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

|  |              |   |         |           |  |              |
|--|--------------|---|---------|-----------|--|--------------|
|  | Enalapril    | S | Unknown |           |  | Not Reported |
|  | Escitalopram | S | Unknown | 10 Mg, Qd |  | Not Reported |
|  | Agomelatine  | C | Unknown | 25 Mg, Qd |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Dec-2013              | 9636031       | EXPEDITED (15-DAY) |                    | DE              | FR-TEVA-437289ISR    |                      | 31 YR      | Male       | FRA            |

| <u>Preferred Term</u>                    | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------|--------------------------|--------------|------------|-------------|--------------|-----------------------------------|-----------------|--------------|
| Completed Suicide;<br>Suicidal Behaviour | Diazepam Ratiopharm 10mg |              |            | S           | Oral         | 3 Dosage Forms Daily;             |                 | Barr         |
|                                          | Baclofene Zentiva 10mg   |              |            | S           | Oral         | Progressive Increase To<br>60mg/D |                 | Not Reported |
|                                          | Seroplex 10mg            |              |            | S           | Oral         | 1 Dosage Forms Daily;             |                 | Not Reported |
|                                          | Zopiclone Ratiopharm     |              |            | C           |              | 1 Dosage Forms Daily;             |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Dec-2013              | 9703299       | EXPEDITED (15-DAY) |                    | OT              | US-ACCORD-020406     |                      | 16 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                      | <u>Product</u>             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------|----------------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Electrocardiogram Qrs<br>Complex Prolonged;<br>Electrocardiogram Qt<br>Prolonged; Overdose | Dihydrocodeine/Paracetamol |              |            | C           |              |                               |                 | Not Reported |
|                                                                                            | Escitalopram               |              |            | S           |              | Took Escitalopram<br>Overdose |                 | Accord       |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 10-Dec-2013              | 9735284       | EXPEDITED (15-DAY) |                    | HO              | FR-PFIZER INC-<br>2013345324 |                      | 86 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Subdural Haematoma    | Amlor                  |              |            | S           | Oral         | 5 Mg, 1x/Day       |                 | Pfizer       |
|                       | Furosemide             |              |            | S           | Oral         | 20 Mg, 1x/Day      |                 | Not Reported |
|                       | Previscan (Fluindione) |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                       | Previscan              |              |            | S           | Oral         | Unk                |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|  |            |   |      |                |              |
|--|------------|---|------|----------------|--------------|
|  | Seroplex   | S | Oral | 10 Mg, 1x/Day  | Not Reported |
|  | Levothyrox | S | Oral | 150 Ug, 1x/Day | Not Reported |
|  | Contramal  | S | Oral |                | Not Reported |

| <u>FDA Received Date</u>                                           | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 11-Dec-2013                                                        | 9729924        | EXPEDITED (15-DAY) | Y                  | OT              | AUR-APL-2013-09871   |                      |                 | Unknown      | ITA            |
| <u>Preferred Term</u>                                              | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Withdrawal Syndrome Neonatal; Maternal Drugs Affecting Foetus | Paroxetine     |                    |                    | S               | Transplacental       |                      |                 | Not Reported |                |
|                                                                    | Escitalopram   |                    |                    | S               | Transplacental       |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|------------------------|--------------------|--------------------|-----------------|------------------------|----------------------|-----------------|--------------|----------------|
| 11-Dec-2013              | 9745755                | EXPEDITED (15-DAY) |                    | HO              | FR-MERCK-1312FRA001020 |                      | 75 YR           | Male         | FRA            |
| <u>Preferred Term</u>    | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Subdural Haematoma       | Zocor 20mg             |                    |                    | S               | Oral                   | 20 Mg, Qd            |                 | Merck        |                |
|                          | Seroplex               |                    |                    | S               | Oral                   | 10 Mg, Qd            |                 | Not Reported |                |
|                          | Previscan (Fluindione) |                    |                    | S               | Oral                   | Unk                  |                 | Not Reported |                |
|                          | Triatec (Ramipril)     |                    |                    | C               | Oral                   | 5 Mg, Qd             |                 | Not Reported |                |
|                          | Triatec (Ramipril)     |                    |                    | C               | Oral                   | 5 Mg, Qd             |                 | Not Reported |                |
|                          | Zanidip                |                    |                    | C               | Oral                   | 10 Mg, Qd            |                 | Not Reported |                |
|                          | Betaserc               |                    |                    | C               | Oral                   | Unk                  |                 | Not Reported |                |

| <u>FDA Received Date</u>      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|-------------------------------|----------------|--------------------|--------------------|-----------------|--------------------------|----------------------------|-----------------|------------|----------------|
| 11-Dec-2013                   | 9746368        | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-2013351465 |                            | 62 YR           | Female     | USA            |
| <u>Preferred Term</u>         | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u> |                |
| Coma; Logorrhoea; Neck Injury | Xanax          |                    |                    | S               | Oral                     | 0.5 Mg, Unk                |                 | Pfizer     |                |
|                               | Xanax          |                    |                    | S               | Oral                     | 0.25 Mg, Unk (Splitting It |                 | Pfizer     |                |



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

|            |   |                            |              |
|------------|---|----------------------------|--------------|
| Effexor Xr | S | Into Half)                 | Pfizer       |
| Lexapro    | S | 37.5 Mg, Unk<br>40 Mg, Unk | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Dec-2013              | 9841712       | NON-EXPEDITED    |                    | OT              | ALL1-2012-02058      |                      | 63 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                      | <u>Product</u>                                   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------|--------------|------------|-------------|--------------|---------------------------------------------|-----------------|--------------|
| Chills; Depression;<br>Disturbance In Attention;<br>Drug Ineffective; Product<br>Prescribing Error; Product<br>Quality Issue; Pyrexia;<br>Sluggishness; Tremor;<br>Yawning | Vyvanse (Lisdexamfetamine<br>Dimesylate) Capsule |              |            | S           | Oral         | 50 Mg, 3-4 Times Per<br>Week As Req'D, Oral |                 | Not Reported |
|                                                                                                                                                                            | Amoxapine (Amoxapine)                            |              |            | S           | Oral         |                                             |                 | Not Reported |
|                                                                                                                                                                            | Wellbutrin (Bupropion<br>Hydrochloride)          |              |            | S           | Oral         |                                             |                 | Not Reported |
|                                                                                                                                                                            | Lexapro (Escitalopram Oxalate)                   |              |            | S           | Oral         |                                             |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Dec-2013              | 8505660       | EXPEDITED (15-DAY) |                    | HO, OT          | PHHY2012FR029732     |                      | 52 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                                                                                                                                                                                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|------------------------------------|-----------------|--------------|
| Alcoholic Liver Disease;<br>Ascites; Condition<br>Aggravated;<br>Gynaecomastia; Hepatic<br>Cirrhosis; Hepatic Enzyme<br>Increased; Hepatic<br>Failure; Hepatocellular<br>Injury; Hepatomegaly;<br>Jaundice; Liver Injury | Rasilez Hct    |              |            | S           | Oral         | 1 Df, (150 Mg Ali/ 12.5 Mg<br>Hct) |                 | Novartis     |
|                                                                                                                                                                                                                          | Anafranil      |              |            | S           |              | 37.5 Mg, Qd                        |                 | Not Reported |
|                                                                                                                                                                                                                          | Alprazolam     |              |            | S           |              | 0.25 Mg, Tid                       |                 | Not Reported |
|                                                                                                                                                                                                                          | Seroplex       |              |            | S           |              | 20 Mg, Qd                          |                 | Not Reported |
|                                                                                                                                                                                                                          | Zyprexa        |              |            | S           |              | 5 Mg, Qd                           |                 | Not Reported |
|                                                                                                                                                                                                                          | Prazepam       |              |            | C           |              |                                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>        | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------------|----------------------|------------|------------|----------------|
| 12-Dec-2013              | 9059642       | EXPEDITED (15-DAY) |                    | HO              | IT-RANBAXY-2013R1-<br>65084 |                      | 56 YR      | Female     | ITA            |

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

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

|                                                                                         |             |   |   |      |                              |              |
|-----------------------------------------------------------------------------------------|-------------|---|---|------|------------------------------|--------------|
| Intentional Overdose;<br>Respiratory Acidosis;<br>Respiratory Depression;<br>Somnolence | Venlafaxine |   | S | Oral | 21 Dosage Units,<br>Complete | Not Reported |
|                                                                                         | Paracetamol | Y | S | Oral | 28 Dosage Units,<br>Complete | Ohm Lab      |
|                                                                                         | Cipralext   |   | S | Oral | 18 Dosage Units,<br>Complete | Not Reported |
|                                                                                         | Patrol      |   | S | Oral | 4 Dosage Units, Complete     | Not Reported |
|                                                                                         | Moment      |   | S | Oral | 18 Dosage Units,<br>Complete | Not Reported |
|                                                                                         | Lexotan     |   | S | Oral | 51 Dosage Units,<br>Complete | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Dec-2013              | 9249438       | EXPEDITED (15-DAY) |                    | DE              | CA-FRI-1000044577    |                      | 68 YR      | Male       | CAN            |

| <u>Preferred Term</u>                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Completed<br>Suicide; Depression | Escitalopram   |              |            | S           | Oral         |                    |                 | Forest       |
|                                           | Escitalopram   |              |            | S           | Oral         | 20 Mg              |                 | Forest       |
|                                           | Seroquel       |              |            | C           | Oral         | 25 Mg              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Dec-2013              | 9698963       | EXPEDITED (15-DAY) | Y                  | HO              | AUR-APL-2013-08972   |                      | 59 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                            | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|-----------------------------|--------------------|-----------------|--------------|
| Discomfort; Drug<br>Interaction; Dysuria;<br>International Normalised<br>Ratio Fluctuation; Urinary<br>Retention | Escitalopram            |              |            | S           |                             |                    |                 | Not Reported |
|                                                                                                                  | Ipratropium Bromide     |              |            | S           | Respiratory<br>(inhalation) | Nebulizer          |                 | Not Reported |
|                                                                                                                  | Cephalexin (Cefalexin)  |              |            | C           |                             |                    |                 | Not Reported |
|                                                                                                                  | Metoprolol (Metoprolol) |              |            | C           |                             |                    |                 | Not Reported |
|                                                                                                                  | Amiodarone (Amiodarone) |              |            | C           |                             |                    |                 | Not Reported |
|                                                                                                                  | Ranitidine (Ranitidine) |              |            | C           |                             |                    |                 | Not Reported |
|                                                                                                                  | Furosemide (Furosemide) |              |            | C           |                             |                    |                 | Not Reported |
|                                                                                                                  | Digoxin (Digoxin)       |              |            | C           |                             |                    |                 | Not Reported |
|                                                                                                                  | Lisinopril (Lisinopril) |              |            | C           |                             |                    |                 | Not Reported |

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

|                                        |   |              |
|----------------------------------------|---|--------------|
| Nystop (Nystatin)                      | C | Not Reported |
| Nystatin (Nystatin)                    | C | Not Reported |
| Combivent (Combivent)                  | C | Not Reported |
| Insulin Lispro (Insulin Lispro)        | C | Not Reported |
| Warfarin (Warfarin)                    | C | Not Reported |
| Acetaminophen (Paracetamol)            | C | Not Reported |
| Milk Of Magnesia (Magnesium Hydroxide) | C | Not Reported |
| Bisacodyl (Bisacodyl)                  | C | Not Reported |
| Omeprazole (Omeprazole)                | C | Not Reported |
| Mucinex                                | C | Not Reported |
| Diphenhydramine (Diphenhydramine)      | C | Not Reported |
| Docusate W/Senna (Docusate W/Senna)    | C | Not Reported |
| Triamcinolone (Triamcinolone)          | C | Not Reported |
| Fluticasone Propionate                 | C | Not Reported |
| Ondansetron (Ondansetron)              | C | Not Reported |
| Albuterol (Salbutamol)                 | C | Not Reported |
| Omeprazole (Omeprazole)                | C | Not Reported |
| Dimethicone (Dimeticone)               | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Dec-2013              | 9750336       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000052172    |                      | 75 YR      | Male       | FRA            |

| <u>Preferred Term</u>                | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction; Subdural Haematoma | Escitalopram           |              |            | S           | Oral         | 1 Df               |                 | Forest       |
|                                      | Zocor                  |              |            | S           | Oral         | 1 Df               |                 | Not Reported |
|                                      | Previscan (Fluindione) |              |            | S           | Oral         |                    |                 | Not Reported |
|                                      | Triatec (Ramipril)     |              |            | C           | Oral         | 1 Df               |                 | Not Reported |
|                                      | Zanidip                |              |            | C           | Oral         | 1 Df               |                 | Not Reported |
|                                      | Betaserc               |              |            | C           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Dec-2013              | 9752020       | DIRECT           |                    | OT              |                      |                      |            | Male       | USA            |

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

| <u>Preferred Term</u>                                                                                                                                                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>   |                |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|------------------------------------------|-----------------|--------------|----------------|
| Anxiety; Panic Reaction                                                                                                                                                        | Lexapro              |                    |                    | S               |                      |                                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Dec-2013                                                                                                                                                                    | 9752167              | DIRECT             |                    | OT              |                      |                                          | 33 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective;<br>Economic Problem;<br>Product Substitution Issue                                                                                                           | Escitalopram         |                    |                    | S               | Oral                 | 1 1/2 Pills Once Daily<br>Taken By Mouth | 2 MTH           | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Dec-2013                                                                                                                                                                    | 9752175              | DIRECT             |                    | DS, OT          |                      |                                          | 52 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated;<br>Generalised Anxiety<br>Disorder; Headache;<br>Product Substitution Issue                                                                              | Lexapro Generic 10mg |                    |                    | S               |                      | Lexapro/30                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Dec-2013                                                                                                                                                                    | 9252916              | EXPEDITED (15-DAY) |                    | DE, OT          | CA-FRI-1000044638    |                                          | 58 YR           | Male         | CAN            |
| <u>Preferred Term</u>                                                                                                                                                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain Upper;<br>Bradykinesia; Cogwheel<br>Rigidity; Confusional<br>State; Drug Ineffective;<br>Drug Intolerance;<br>Hyperhidrosis;<br>Parkinsonism; Resting<br>Tremor | Citalopram           |                    |                    | S               | Oral                 | 10 Mg                                    |                 | Forest       |                |
|                                                                                                                                                                                | Citalopram           |                    |                    | S               | Oral                 | 20 Mg                                    |                 | Not Reported |                |
|                                                                                                                                                                                | Escitalopram         |                    |                    | S               |                      | 10 Mg                                    |                 | Forest       |                |
|                                                                                                                                                                                | Clomipramine         |                    |                    | S               | Oral                 | 25 Mg                                    |                 | Not Reported |                |
|                                                                                                                                                                                | Clomipramine         |                    |                    | S               | Oral                 |                                          |                 | Not Reported |                |
|                                                                                                                                                                                | Haloperidol          |                    |                    | S               |                      | 1 Mg                                     |                 | Not Reported |                |
|                                                                                                                                                                                | Olanzapine           |                    |                    | S               | Oral                 | 15 Mg                                    |                 | Not Reported |                |
|                                                                                                                                                                                | Paroxetine           |                    |                    | S               |                      | 5 Mg                                     |                 | Not Reported |                |

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

|               |   |       |              |
|---------------|---|-------|--------------|
| Paroxetine    | S | 10 Mg | Not Reported |
| Quetiapine    | S | 25 Mg | Not Reported |
| Sertraline    | S |       | Not Reported |
| Trazodone     | S |       | Not Reported |
| Valproic Acid | S |       | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 13-Dec-2013              | 9752609       | EXPEDITED (15-DAY) | HO                 |                 | IT-JNJFOC-20131204888 |                      | 86 YR      | Female     | ITA            |

| <u>Preferred Term</u>                                               | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|---------------------------------------------------|-----------------|--------------|
| Bradycardia; Intentional Overdose; Psychomotor Hyperactivity; Sopor | Serenase (Haloperidol) |              |            | S           | Oral         |                                                   |                 | Not Reported |
|                                                                     | Serenase               |              |            | S           | Oral         | 0.5 Unspecified Units Twice An Unspecified Period |                 | Not Reported |
|                                                                     | Serenase               |              |            | S           | Oral         |                                                   |                 | Not Reported |
|                                                                     | Serenase               |              |            | S           | Oral         | 0.5 Unspecified Units Twice An Unspecified Period |                 | Not Reported |
|                                                                     | Cipralelex             |              |            | S           | Oral         |                                                   |                 | Not Reported |
|                                                                     | Cipralelex             |              |            | S           | Oral         |                                                   |                 | Not Reported |
|                                                                     | Cipralelex             |              |            | S           | Oral         |                                                   |                 | Not Reported |
|                                                                     | Cipralelex             |              |            | S           | Oral         |                                                   |                 | Not Reported |
|                                                                     | Metformina             |              |            | S           | Oral         | Once An Unspecified Period                        |                 | Not Reported |
|                                                                     | Metformina             |              |            | S           | Oral         |                                                   |                 | Not Reported |
|                                                                     | Metformina             |              |            | S           | Oral         | Once An Unspecified Period                        |                 | Not Reported |
|                                                                     | Metformina             |              |            | S           | Oral         |                                                   |                 | Not Reported |
|                                                                     | Bisoprolol             |              |            | S           | Oral         |                                                   |                 | Not Reported |
|                                                                     | Bisoprolol             |              |            | S           | Oral         | 2.5 Unspecified Units Twice An Unspecified Period |                 | Not Reported |
|                                                                     | Bisoprolol             |              |            | S           | Oral         |                                                   |                 | Not Reported |

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

|                   |   |         |                                                         |              |
|-------------------|---|---------|---------------------------------------------------------|--------------|
| Bisoprolol        | S | Oral    | 2.5 Unspecified Units<br>Twice An Unspecified<br>Period | Not Reported |
| Tavor (Lorazepam) | S | Oral    |                                                         | Not Reported |
| Diamicon          | S | Oral    | 30 Unspecified Units<br>Thrice An Unspecified<br>Period | Not Reported |
| Diamicon          | S | Oral    |                                                         | Not Reported |
| Diamicon          | S | Oral    |                                                         | Not Reported |
| Diamicon          | S | Oral    | 30 Unspecified Units<br>Thrice An Unspecified<br>Period | Not Reported |
| Tachipirina       | S | Oral    |                                                         | Not Reported |
| Coumadin          | C | Unknown |                                                         | Not Reported |
| Dibase            | C | Unknown | 100 Unspecified Units                                   | Not Reported |
| Nexium            | C | Unknown |                                                         | Not Reported |
| Isoptin           | C | Unknown |                                                         | Not Reported |
| Macrogol          | C | Unknown | 20 Unspecified Units Once<br>An Unspecified Period      | Not Reported |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 13-Dec-2013                       | 9752725                | EXPEDITED (15-DAY)        |                             | OT                       | CH-FRI-1000052207             |                               |                     | Female              | CHE                     |

| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|-----------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Dizziness; Withdrawal<br>Syndrome | Escitalopram            |                       |                     | S                    | Oral                  | 3.75 Mg                     |                          | Forest              |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 13-Dec-2013                       | 9752760                | EXPEDITED (15-DAY)        |                             | HO                       | FR-FRI-1000052209             |                               | 86 YR               | Female              | FRA                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Subdural Haematoma             | Escitalopram            |                       |                     | S                    | Oral                  | 1 Df                        |                          | Forest              |

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

|  |                        |   |      |         |  |              |
|--|------------------------|---|------|---------|--|--------------|
|  | Previscan (Fluindione) | S | Oral |         |  | Not Reported |
|  | Amlor                  | S | Oral | 1 Df    |  | Not Reported |
|  | Furosemide             | S | Oral | 1 Df    |  | Not Reported |
|  | Levothyrox             | S | Oral | 150 Mcg |  | Not Reported |
|  | Contramal              | S | Oral |         |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 13-Dec-2013              | 9752785        | EXPEDITED (15-DAY) |                    | HO              | NL-FRI-1000052208    |                      | 60 YR           | Female     | NLD            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Epilepsy                 | Lexapro        |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest     |                |
|                          | Lexapro        |                    |                    | S               |                      |                      |                 | Forest     |                |
|                          | Lexapro        |                    |                    | S               |                      |                      |                 | Forest     |                |

| <u>FDA Received Date</u>                                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 13-Dec-2013                                               | 9756642        | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000052211    |                      |                 | Female       | FRA            |
| <u>Preferred Term</u>                                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Decreased Appetite;<br>Dementia; Haemorrhage;<br>Insomnia | Escitalopram   |                    |                    | S               |                      |                      |                 | Forest       |                |
|                                                           | Propranolol    |                    |                    | S               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 13-Dec-2013                                  | 9756662        | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000052206    |                      | 68 YR           | Male         | FRA            |
| <u>Preferred Term</u>                        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;<br>Orthostatic Hypotension | Escitalopram   |                    |                    | S               | Oral                 | 1 Df                 |                 | Forest       |                |
|                                              | Fluanxol       |                    |                    | S               | Oral                 | 120 Df               |                 | Not Reported |                |
|                                              | Leponex        |                    |                    | S               | Oral                 | 1 Df                 |                 | Not Reported |                |
|                                              | Xatral         |                    |                    | S               | Oral                 | 1 Df                 |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Dec-2013              | 9756668       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000052210    |                      | 82 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Pemphigoid            | Escitalopram              |              |            | S           | Oral         | 1 Df               |                 | Forest       |
|                       | Escitalopram              |              |            | S           |              |                    |                 | Forest       |
|                       | Risperdal                 |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Risperdal                 |              |            | S           |              |                    |                 | Not Reported |
|                       | Eucreas                   |              |            | S           | Oral         | 100/1700 Mg        |                 | Not Reported |
|                       | Kardegic                  |              |            | C           |              |                    |                 | Not Reported |
|                       | Ikorel                    |              |            | C           |              |                    |                 | Not Reported |
|                       | Crestor                   |              |            | C           |              |                    |                 | Not Reported |
|                       | Duphalac                  |              |            | C           |              |                    |                 | Not Reported |
|                       | Cacit [Calcium Carbonate] |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 13-Dec-2013              | 9756677       | EXPEDITED (15-DAY) |                    | HO              | IT-ACTAVIS-2013-22321 |                      | 56 YR      | Female     | ITA            |

| <u>Preferred Term</u>                                                              | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>           |
|------------------------------------------------------------------------------------|-----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------|
| Intentional Overdose;<br>Respiratory Acidosis;<br>Respiratory Depression;<br>Sopor | Venlafaxine (Unknown) |              |            | S           | Oral         | 21 Df, Single      |                 | Not Reported         |
|                                                                                    | Paracetamol (Unknown) |              |            | S           | Oral         | 28 Df, Single      |                 | Actavis Mid Atlantic |
|                                                                                    | Ciprallex             |              |            | S           | Oral         | 18 Df, Single      |                 | Not Reported         |
|                                                                                    | Lexotan               |              |            | S           | Oral         | 51 Df, Single      |                 | Not Reported         |
|                                                                                    | Moment 200            |              |            | S           | Oral         | 18 Df, Single      |                 | Not Reported         |
|                                                                                    | Patrol                |              |            | S           | Oral         | 4 Df, Single       |                 | Not Reported         |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------|----------------------|------------|------------|----------------|
| 13-Dec-2013              | 10022181      | EXPEDITED (15-DAY) |                    | OT              | BR-TORRENT-00001828-01 |                      | 69 YR      | Female     | BRA            |

| <u>Preferred Term</u> | <u>Product</u>                    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-----------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hemiparesis; Tremor   | Espran (Inn:Escitalopram Oxalate) |              |            | S           | Oral         | Once Daily/Oral    |                 | Not Reported |



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|               |   |              |
|---------------|---|--------------|
| Amato         | C | Not Reported |
| Glucovance    | C | Not Reported |
| Enalabal      | C | Not Reported |
| Simvastatin   | C | Not Reported |
| Stugeron      | C | Not Reported |
| Amiodarone    | C | Not Reported |
| Levothyroxine | C | Not Reported |
| Bromazepam    | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 16-Dec-2013              | 9757907       | EXPEDITED (15-DAY) |                    | HO              | FR-JNJFOC-20131207327 |                      | 86 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Subdural Haematoma    | Contramal              |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Furosemide             |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Seroplex               |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Amlor                  |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Levothyrox             |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Previscan (Fluindione) |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 16-Dec-2013              | 9757914       | EXPEDITED (15-DAY) |                    | HO              | FR-JNJFOC-20131202220 |                      | 82 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Pemphigoid            | Risperdal      |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Risperdal      |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Seroplex       |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Seroplex       |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Eucreas        |              |            | S           | Oral         | 50 Mg/850 Mg       |                 | Not Reported |
|                       | Kardegic       |              |            | C           | Unknown      | 160                |                 | Not Reported |
|                       | Ikorel         |              |            | C           | Unknown      |                    |                 | Not Reported |
|                       | Crestor        |              |            | C           | Unknown      |                    |                 | Not Reported |

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

|           |   |         |              |
|-----------|---|---------|--------------|
| Duphalac  | C | Unknown | Not Reported |
| Cacit Nos | C | Unknown | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Dec-2013              | 9759504       | EXPEDITED (15-DAY) | LT                 |                 | FR-FRI-1000052254    |                      | 67 YR      | Male       | FRA            |

| <u>Preferred Term</u>         | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Mood Altered; Suicide Attempt | Escitalopram        |              |            | S           | Oral         | 1 Df               |                 | Forest       |
|                               | Temesta (Lorazepam) |              |            | S           | Oral         |                    |                 | Not Reported |
|                               | Coaprovel           |              |            | C           |              |                    |                 | Not Reported |
|                               | Lercan              |              |            | C           |              |                    |                 | Not Reported |
|                               | Zyloric             |              |            | C           |              |                    |                 | Not Reported |
|                               | Praxilene           |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Dec-2013              | 9759593       | EXPEDITED (15-DAY) | HO                 |                 | FR-FRI-1000052257    |                      | 35 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                               | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------------------------------------|-----------------|--------------|
| Disturbance In Attention; Hypothermia; Intentional Overdose; Toxic Encephalopathy | Escitalopram   |              |            | S           | Oral         | Overdose With One Intake Of 14 Tablets Of 20 Mg  |                 | Forest       |
|                                                                                   | Baclofene      |              |            | S           | Oral         | Overdose With One Intake Of 20 Df                |                 | Not Reported |
|                                                                                   | Seresta        |              |            | S           | Oral         | Overdose With One Intake Of 100 Tablets Of 50 Mg |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Dec-2013              | 9762023       | EXPEDITED (15-DAY) | OT                 |                 | US-FRI-1000052291    |                      | 54 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Asthenia; Food Craving; Impaired Driving Ability; Inappropriate Affect; Obsessive-Compulsive | Lexapro        |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                                                                              | Lexapro        |              |            | S           | Oral         | 5 Mg               |                 | Forest       |
|                                                                                              | Lexapro        |              |            | S           | Oral         | 2.5 Mg             |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Disorder; Paraesthesia;  
Suicidal Ideation; Weight  
Increased

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Dec-2013              | 9762785       | EXPEDITED (15-DAY) |                    | HO              | IT-FRI-1000052282    |                      | 86 YR      | Female     | ITA            |

| <u>Preferred Term</u>                                                     | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>  | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|---------------|--------------------|-----------------|--------------|
| Bradycardia; Intentional<br>Overdose; Psychomotor<br>Hyperactivity; Sopor | Escitalopram            |              |            | S           | Oral          |                    |                 | Forest       |
|                                                                           | Metformin               |              |            | S           | Oral          |                    |                 | Not Reported |
|                                                                           | Bisoprolol Hemifumarate |              |            | S           | Oral          |                    |                 | Not Reported |
|                                                                           | Tavor (Lorazepam)       |              |            | S           |               |                    |                 | Not Reported |
|                                                                           | Diamicron               |              |            | S           | Oral          |                    |                 | Not Reported |
|                                                                           | Tachipirina             |              |            | S           | Oral          |                    |                 | Not Reported |
|                                                                           | Serenase (Haloperidol)  |              |            | S           | Oral          |                    |                 | Not Reported |
|                                                                           | Coumadin                |              |            | C           |               |                    |                 | Not Reported |
|                                                                           | Dibase                  |              |            | C           | Intramuscular | 1 Vial / Month     |                 | Not Reported |
|                                                                           | Nexium                  |              |            | C           |               |                    |                 | Not Reported |
|                                                                           | Isoptin                 |              |            | C           |               |                    |                 | Not Reported |
|                                                                           | Onligol                 |              |            | C           |               |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Dec-2013              | 9767710       | EXPEDITED (15-DAY) |                    | HO              | PHHY2013IT145616     |                      |            | Female     | ITA            |

| <u>Preferred Term</u>                                                          | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|----------------------|-----------------|--------------|
| Bradycardia; Intentional<br>Overdose; Psychomotor<br>Hyperactivity; Somnolence | Metformin              |              |            | S           | Oral         | 1500 Mg, Once/Single |                 | Novartis     |
|                                                                                | Bisoprolol             |              |            | S           | Oral         | 3 Df, Once/Single    |                 | Not Reported |
|                                                                                | Tavor (Lorazepam)      |              |            | S           | Oral         | 6 Df, Once/Single    |                 | Not Reported |
|                                                                                | Cipralex//Escitalopram |              |            | S           | Oral         | 3 Df, Once/Single    |                 | Not Reported |
|                                                                                | Diamicron              |              |            | S           | Oral         | 3 Df, Once/Single    |                 | Not Reported |
|                                                                                | Tachipirina            |              |            | S           | Oral         | 3 Df, Once/Single    |                 | Not Reported |
|                                                                                | Serenase (Haloperidol) |              |            | S           | Oral         | 2 Df, Once/Single    |                 | Not Reported |

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

|  |                             |   |               |            |  |  |  |              |
|--|-----------------------------|---|---------------|------------|--|--|--|--------------|
|  | Coumadin//Warfarin Sodium   | C |               |            |  |  |  | Not Reported |
|  | Dibase                      | C | Intramuscular | 1 Ukn, Qmo |  |  |  | Not Reported |
|  | Nexium//Esomeprazole Sodium | C |               |            |  |  |  | Not Reported |
|  | Isoptin                     | C |               |            |  |  |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Dec-2013              | 9768251       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000052313    |                      | 59 YR      | Male       | FRA            |

| <u>Preferred Term</u>                      | <u>Product</u>                                                                                                      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------|---------------------------------------------------------------------------------------------------------------------|--------------|------------|-------------|--------------|------------------------------------------|-----------------|--------------|
| Generalised Tonic-Clonic Seizure; Overdose | Escitalopram                                                                                                        |              |            | S           | Oral         | Titration Up To 35 Mg Daily              |                 | Forest       |
|                                            | Escitalopram                                                                                                        |              |            | S           | Oral         | 30 Mg                                    |                 | Not Reported |
|                                            | Theralene                                                                                                           |              |            | S           | Oral         | 15 Df                                    |                 | Not Reported |
|                                            | Mianserine                                                                                                          |              |            | S           |              | 30 Mg                                    |                 | Not Reported |
|                                            | Xeroquel                                                                                                            |              |            | S           | Oral         | Progressive Titration Up To 200 Mg Daily |                 | Not Reported |
|                                            | Imovane                                                                                                             |              |            | C           | Oral         | 7.5 Mg                                   |                 | Not Reported |
|                                            | Transipeg (Polyethylene Glycol 3350\Potassium Chloride\Sodium Bicarbonate\Sodium Chloride\Sodium Sulfate Anhydrous) |              |            | C           | Oral         | 2 Df                                     |                 | Not Reported |
|                                            | Seresta                                                                                                             |              |            | C           | Oral         | 3 Df                                     |                 | Not Reported |
|                                            | Xarelto                                                                                                             |              |            | C           | Oral         | 1 Df                                     |                 | Not Reported |
|                                            | Propranolol                                                                                                         |              |            | C           |              | 80 Mg                                    |                 | Not Reported |
|                                            | Inexium                                                                                                             |              |            | C           | Oral         | 20 Mg                                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Dec-2013              | 9768274       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000052284    |                      | 64 YR      | Male       | FRA            |

| <u>Preferred Term</u>                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Condition Aggravated; Subdural Haematoma | Escitalopram   |              |            | S           | Oral         |                    |                 | Forest     |

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

|                                                                                                                                                      |                |                    |                    |                 |                      |                      |                 |              |                |
|------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Aspegic [Acetylsalicylate Lysine]                                                                                                                    |                |                    | S                  | Oral            | 1 Df                 |                      | Not Reported    |              |                |
| <u>FDA Received Date</u>                                                                                                                             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Dec-2013                                                                                                                                          | 9768295        | EXPEDITED (15-DAY) |                    | OT              | CA-FRI-1000052285    |                      |                 | Male         | CAN            |
| <u>Preferred Term</u>                                                                                                                                | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Coordination Abnormal;<br>Diarrhoea; Diarrhoea<br>Haemorrhagic; Emotional<br>Disorder; Fatigue; Feeling<br>Abnormal; Insomnia;<br>Sexual Dysfunction | Escitalopram   |                    |                    | S               | Oral                 |                      |                 | Forest       |                |
|                                                                                                                                                      | Escitalopram   |                    |                    | S               | Oral                 |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                                             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Dec-2013                                                                                                                                          | 9768319        | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000052287    |                      | 67 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                                | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyperreflexia; Hypertonia;<br>Hyponatraemia; Mydriasis;<br>Prescribed Overdose                                                                       | Escitalopram   |                    |                    | S               | Oral                 | 20 Mg                |                 | Forest       |                |
|                                                                                                                                                      | Escitalopram   |                    |                    | S               | Oral                 | 30 Mg                |                 | Forest       |                |
|                                                                                                                                                      | Escitalopram   |                    |                    | S               | Oral                 | 20 Mg                |                 | Forest       |                |
|                                                                                                                                                      | Seresta        |                    |                    | C               | Oral                 | 70 Mg                |                 | Not Reported |                |
|                                                                                                                                                      | Imovane        |                    |                    | C               | Oral                 | 7.5 Mg               |                 | Not Reported |                |
|                                                                                                                                                      | Levothyrox     |                    |                    | C               | Oral                 | 12.5 Mcg             |                 | Not Reported |                |
|                                                                                                                                                      | Vogalene       |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Dec-2013                                                                                                                                          | 9768332        | EXPEDITED (15-DAY) |                    | HO              | AU-FRI-1000052288    |                      | 71 YR           | Male         | AUS            |
| <u>Preferred Term</u>                                                                                                                                | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Seizure                                                                                                                                              | Escitalopram   |                    |                    | S               |                      | 15 Mg                |                 | Forest       |                |
|                                                                                                                                                      | Progout        |                    |                    | C               |                      | 300 Mg               |                 | Not Reported |                |
|                                                                                                                                                      | Temaze         |                    |                    | C               |                      | 10 Mg                |                 | Not Reported |                |

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

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 17-Dec-2013                       | 9769044                | DIRECT                    |                             | OT                       |                               |                               |                     | Female              | USA                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Depression; Suicidal Behaviour | Lexapro                 |                       |                     | S                    | Oral                  | 2 Tabs. Qd.                 |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 17-Dec-2013                       | 9772505                | EXPEDITED (15-DAY)        | Y                           | HO                       | 7255301                       |                               | 85 YR               | Female              | FRA                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a>             | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a>                        | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------------------|-----------------------|---------------------|----------------------|-----------------------|----------------------------------------------------|--------------------------|---------------------|
| Subdural Haematoma             | Previscan (Fluindione) (Fluindione) |                       |                     | S                    | Oral                  | Renewed As Home Discharge Treatment                |                          | Not Reported        |
|                                | Levothroxine Sodium                 |                       |                     | S                    | Oral                  | 150 Mcg (150 Mcg, 1 In 1 D), Oral Long Term        |                          | Not Reported        |
|                                | Seroplex                            |                       |                     | S                    | Oral                  | 10 Mg (10 Mg, 1 In 1 D), Oral                      |                          | Not Reported        |
|                                | Amlor                               |                       |                     | S                    | Oral                  | 5 Mg (5 Mg, 1 In 1 D), Oral                        |                          | Not Reported        |
|                                | Furosemide                          |                       |                     | S                    | Oral                  | 20 Mg (20 Mg, 1 In 1 D), Oral, Ongoing (Long Term) |                          | Not Reported        |
|                                | Contramal                           |                       |                     | S                    | Oral                  | Ongoing (Long Term)                                |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 18-Dec-2013                       | 8466572                | EXPEDITED (15-DAY)        |                             | HO                       | AU-PFIZER INC-2012063736      |                               | 40 YR               | Female              | AUS                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Migraine                       | Varenicline Tartrate    |                       |                     | S                    | Oral                  | 0.5 Mg, 1x/Day              |                          | Pfizer              |
|                                | Varenicline Tartrate    |                       |                     | S                    | Oral                  | 0.5 Mg, 2x/Day              |                          | Pfizer              |
|                                | Varenicline Tartrate    |                       |                     | S                    | Oral                  | 0.5 Mg (2 Tablets) 2x/Day   |                          | Pfizer              |

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

|              |   |               |                     |              |
|--------------|---|---------------|---------------------|--------------|
| Depo-Provera | S | Intramuscular | Unk, Every 3 Months | Pfizer       |
| Lexapro      | S | Oral          | 20 Mg, Daily        | Not Reported |
| Cymbalta     | S | Oral          | 30 Mg, Daily        | Not Reported |
| Thyroxine    | C | Oral          | 50 Mg, Daily        | Not Reported |
| Esomeprazole | C | Oral          | 20 Mg, As Needed    | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 18-Dec-2013              | 9769107              | EXPEDITED (15-DAY) | HO                 |                 | US-JNJFOC-20131207478 |                      | 15 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Amnesia; Tremor          | Risperdal            |                    |                    | S               | Unknown               |                      |                 | Not Reported |                |
|                          | Escitalopram Oxalate |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                          | Escitalopram Oxalate |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                          | Abilify              |                    |                    | S               | Unknown               |                      |                 | Not Reported |                |
|                          | Synthroid            |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 18-Dec-2013              | 9770961        | EXPEDITED (15-DAY) | OT                 |                 | IT-FRI-1000041373    |                      |                 | Female       | ITA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Pre-Eclampsia; Pregnancy | Escitalopram   |                    |                    | S               |                      | 10 Mg                |                 | Forest       |                |
|                          | Escitalopram   |                    |                    | S               |                      | 10 Mg                |                 | Forest       |                |
|                          | Alprazolam     |                    |                    | C               |                      | 0.25 Mg              |                 | Not Reported |                |
|                          | Levothyroxine  |                    |                    | C               |                      | 125 Mcg              |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 18-Dec-2013              | 9771217        | EXPEDITED (15-DAY) | HO                 |                 | FR-FRI-1000052349    |                      | 86 YR           | Male       | FRA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Abnormal Dreams; Ataxia; | Escitalopram   |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest     |                |

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

|                                                     |                   |   |      |      |              |
|-----------------------------------------------------|-------------------|---|------|------|--------------|
| Behaviour Disorder; Drug Interaction; Hallucination | Escitalopram      | S | Oral | 5 Mg | Not Reported |
|                                                     | Tramadol Biogaran | S | Oral | 2 Df | Not Reported |
|                                                     | Paracetamol       | C | Oral |      | Not Reported |
|                                                     | Kardegic          | C | Oral | 1 Df | Not Reported |
|                                                     | Amlor             | C | Oral | 1 Df | Not Reported |
|                                                     | Tahor             | C | Oral | 1 Df | Not Reported |
|                                                     | Xanax             | C | Oral | 1 Df | Not Reported |
|                                                     | Allopurinol       | C | Oral |      | Not Reported |

|                          |               |                  |                    |                 |                      |                      |            |            |                |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
| 18-Dec-2013              | 9772420       | DIRECT           | Y                  | HO              |                      |                      | 89 YR      | Female     | USA            |

|                                      |                |              |            |             |              |                                 |                 |              |
|--------------------------------------|----------------|--------------|------------|-------------|--------------|---------------------------------|-----------------|--------------|
| <u>Preferred Term</u>                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |
| Angioedema; Dyspnoea; Swollen Tongue | Lexapro        |              |            | S           | Oral         | 1 Tablet                        |                 | Not Reported |
|                                      | Lisinopril     |              |            | S           | Oral         | Past 10 Years 1 Tablet Bid Oral |                 | Not Reported |

|                          |               |                    |                    |                 |                                          |                      |            |            |                |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------------------|----------------------|------------|------------|----------------|
| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
| 19-Dec-2013              | 9773150       | EXPEDITED (15-DAY) |                    | DS              | US-BRISTOL-MYERS SQUIBB COMPANY-19828367 |                      | 17 YR      | Male       | USA            |

|                           |                |              |            |             |              |                                                  |                 |              |
|---------------------------|----------------|--------------|------------|-------------|--------------|--------------------------------------------------|-----------------|--------------|
| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                               | <u>Duration</u> | <u>Mfr</u>   |
| Nystagmus; Vision Blurred | Abilify        |              |            | S           | Oral         | Dose Increased To 15 Mg<br>Later Reduced To 5 Mg |                 | Not Reported |
|                           | Lexapro        |              |            | S           | Oral         |                                                  |                 | Not Reported |
|                           | Adderall Xr    |              |            | C           | Oral         |                                                  |                 | Not Reported |

|                          |               |                    |                    |                 |                      |                      |            |            |                |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
| 19-Dec-2013              | 9773604       | EXPEDITED (15-DAY) |                    | CA, DE          | US-FRI-1000052256    |                      | < 1 DAY    | Female     | USA            |

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



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

|                                                                                             |         |   |                |        |
|---------------------------------------------------------------------------------------------|---------|---|----------------|--------|
| Congenital Anomaly;<br>Hypoplastic Left Heart<br>Syndrome; Neonatal Multi-<br>Organ Failure | Lexapro | S | Transplacental | Forest |
|---------------------------------------------------------------------------------------------|---------|---|----------------|--------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 20-Dec-2013              | 9637906       | EXPEDITED (15-DAY) |                    |                 | JP-<br>ELI_LILLY_AND_COMP<br>ANY-JP201309008372 |                      | 48 YR      | Female     | JPN            |

| <u>Preferred Term</u> | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>       |
|-----------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------------|
| Hyperprolactinaemia   | Cymbalta            |              |            | S           | Oral         | 20 Mg, Qd          |                 | Eli Lilly And Co |
|                       | Lexapro             |              |            | S           | Oral         | 10 Mg, Qd          |                 | Not Reported     |
|                       | Primperan           |              |            | S           | Oral         | 1 Df, Bid          |                 | Not Reported     |
|                       | Sepazon             |              |            | C           | Oral         | 1 Mg, Bid          |                 | Not Reported     |
|                       | Magmitt             |              |            | C           | Oral         | 660 Mg, Qd         |                 | Not Reported     |
|                       | Cepharanthin        |              |            | C           | Oral         | 1 Mg, Bid          |                 | Not Reported     |
|                       | Promac /01312301/   |              |            | C           | Oral         | 75 Mg, Bid         |                 | Not Reported     |
|                       | Ferromia /00023520/ |              |            | C           | Oral         | 50 Mg, Bid         |                 | Not Reported     |
|                       | Selbex              |              |            | C           | Oral         | 100 Mg, Qd         |                 | Not Reported     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Dec-2013              | 9776270       | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000052341    |                      | < 1 DAY    | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|------------|
| Talipes               | Lexapro        |              |            | S           | Transplacental |                    |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|------------|------------|----------------|
| 20-Dec-2013              | 9776356       | EXPEDITED (15-DAY) |                    | HO              | IT-MYLANLABS-<br>113AS20130478 |                      | 86 YR      | Female     | ITA            |

| <u>Preferred Term</u>                                            | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Bradycardia; Drug Abuse;<br>Intentional Overdose;<br>Psychomotor | Metformin               |              |            | S           | Oral         | 1500 Mg Total      |                 | Mylan        |
|                                                                  | Bisoprolol Hemifumarate |              |            | S           | Oral         | 3 Df Total         |                 | Not Reported |

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

|                      |                           |   |      |            |              |
|----------------------|---------------------------|---|------|------------|--------------|
| Hyperactivity; Sopor | Tavor (Lorazepam)         | S | Oral | 6 Df Total | Not Reported |
|                      | Cipralex                  | S | Oral | 3 Df Total | Not Reported |
|                      | Diamicron                 | S | Oral | 3 Df Total | Not Reported |
|                      | Tachipirina               | S | Oral | 3 Df Total | Not Reported |
|                      | Serenase /00027401/       | S | Oral | 2 Df Total | Not Reported |
|                      | Coumadin - 5 Mg Compresse | C |      |            | Not Reported |
|                      | Dibase                    | C |      |            | Not Reported |
|                      | Nexium                    | C |      |            | Not Reported |
|                      | Isoptin - 80 Mg Compresse | C |      |            | Not Reported |
|                      | Rivestite Con Film        |   |      |            | Not Reported |
|                      | Onligol                   | C |      |            | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Dec-2013              | 8385704       | NON-EXPEDITED    |                    |                 | 2012SP002852         |                      | 48 YR      | Female     | USA            |

| <u>Preferred Term</u>                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Arthritis; Drug Interaction;<br>Hypoaesthesia | Meloxicam      |              |            | S           |              |                    |                 | Not Reported |
|                                               | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 23-Dec-2013              | 9779100       | EXPEDITED (15-DAY) |                    | LT, OT          | GB-<br>ELI_LILLY_AND_COMP<br>ANY-GB201312005528 |                      |            | Male       | GBR            |

| <u>Preferred Term</u>                    | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>       |
|------------------------------------------|--------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------------|
| General Physical Health<br>Deterioration | Zyprexa            |              |            | S           | Unknown      | 15 Mg, Unknown     |                 | Eli Lilly And Co |
|                                          | Escitalopram       |              |            | S           | Unknown      | 30 Mg, Unknown     |                 | Not Reported     |
|                                          | Priadel /00033702/ |              |            | S           | Unknown      | 1000 G, Unknown    |                 | Not Reported     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 23-Dec-2013              | 9779455       | EXPEDITED (15-DAY) |                    | HO, OT          | FR-PFIZER INC-<br>2013364530 |                      | 33 YR      | Female     | FRA            |

| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Agitation; Confusional | Lyrca          |              |            | S           | Oral         | 21 Df, Single      |                 | Pfizer     |

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

|                           |            |   |      |                      |              |
|---------------------------|------------|---|------|----------------------|--------------|
| State; Depressed Level Of | Olanzapine | S | Oral | Unk                  | Not Reported |
| Consciousness; Drug       | Olanzapine | S | Oral | 28 Df, Single 7.5 Mg | Not Reported |
| Screen Positive;          | Lexomil    | S | Oral | Unk                  | Not Reported |
| Intentional Overdose;     | Lexomil    | S | Oral | 15 Df, Single        | Not Reported |
| Somnolence; Toxicity To   | Seroplex   | S | Oral |                      | Not Reported |
| Various Agents            | Seroplex   | S | Oral | 12 Df, Single 20 Mg  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Dec-2013              | 9781185       | DIRECT           |                    | OT              |                      |                      | 41 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Balance Disorder; Blood Cholesterol Increased; Blood Triglycerides Increased; Dizziness; Drug Withdrawal Syndrome; Extrasystoles; Paraesthesia; Weight Increased | Lexapro        |              |            | S           | Oral         | Taken By Mouth     |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Dec-2013              | 9781233       | DIRECT           |                    | OT              |                      |                      | 5 YR       | Male       | USA            |

| <u>Preferred Term</u>                        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|----------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Drug Ineffective; Product Substitution Issue | Lexapro        |              |            | S           | Oral         |                    |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Dec-2013              | 9783589       | EXPEDITED (15-DAY) | Y                  | HO              | 2013AP010571         |                      | 78 YR      | Female     | USA            |

| <u>Preferred Term</u>                    | <u>Product</u>                  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------|---------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cerebral Small Vessel Ischaemic Disease; | Gabapentin                      |              |            | S           |              |                    |                 | Not Reported |
| Electroencephalogram                     | Trazodone Hydrochloride Tablets |              |            | S           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                          |                      |   |           |              |
|--------------------------|----------------------|---|-----------|--------------|
| Abnormal; Off Label Use; | Escitalopram Oxalate | S | 20 Mg, Am | Not Reported |
| Thalamic Infarction      | Levetiracetam        | S |           | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------|----------------------|------------|------------|----------------|
| 24-Dec-2013              | 9780677       | EXPEDITED (15-DAY) |                    | OT              | ES-RANBAXY-2013RR-74017 |                      | 57 YR      | Female     | ESP            |

| <u>Preferred Term</u>           | <u>Product</u>                    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------|-----------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hyperkalaemia;<br>Hyponatraemia | Venlafaxine                       |              |            | S           | Unknown      | 150 Mg/D           |                 | Not Reported |
|                                 | Escitalopram                      |              |            | S           | Unknown      | 10 Mg/Day          |                 | Not Reported |
|                                 | Olanzapine                        |              |            | S           | Unknown      | 5 Mg/Day           |                 | Not Reported |
|                                 | Haloperidol                       |              |            | S           | Unknown      | 20 Drops/Day       |                 | Not Reported |
|                                 | Haloperidol                       |              |            | S           | Unknown      | 10 Drops/Day       |                 | Not Reported |
|                                 | Enalapril                         |              |            | S           | Unknown      | Unk                |                 | Ranbaxy      |
|                                 | Amiloride                         |              |            | S           | Unknown      | 5/50 G (1c/D)      |                 | Not Reported |
|                                 | Hydrochloride/Hydrochlorothiazide |              |            |             |              |                    |                 |              |
|                                 | Citalopram                        |              |            | C           | Unknown      | 20 Mg/Day          |                 | Not Reported |
|                                 | Agomelatine                       |              |            | C           | Unknown      | 25 Mg/Day          |                 | Not Reported |
|                                 | Clorazepate Dipotasium            |              |            | C           | Unknown      | 10mg (3c/D)        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Dec-2013              | 9848542       | NON-EXPEDITED    | Y                  | OT              | PHEH2013US004433     |                      | 16 YR      | Female     | USA            |

| <u>Preferred Term</u>     | <u>Product</u>                  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|---------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hypertension; Tachycardia | Clozaril                        |              |            | S           | Oral         |                    |                 | Not Reported |
|                           | Lexapro (Escitalopram Oxalate)  |              |            | S           |              |                    |                 | Not Reported |
|                           | Eskalith Cr (Lithium Carbonate) |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|------------|------------|----------------|
| 26-Dec-2013              | 9525982       | EXPEDITED (15-DAY) |                    | DE, HO          | FR-SANOFI-AVENTIS-2013SA090853 |                      | 41 YR      | Female     | FRA            |

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

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

|                                                                                                                                                                                                                                                                           |                             |   |                                          |                        |              |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|---|------------------------------------------|------------------------|--------------|
| Acute Kidney Injury;<br>Blister; Eschar; Graft<br>Versus Host Disease In<br>Gastrointestinal Tract;<br>Haematuria; Hepatitis<br>Acute; Mucosal Erosion;<br>Multiple Organ<br>Dysfunction Syndrome;<br>Oedema; Skin Erosion;<br>Skin Lesion; Toxic<br>Epidermal Necrolysis | Granocyte                   | S | Intravenous (not<br>otherwise specified) |                        | Not Reported |
|                                                                                                                                                                                                                                                                           | Heparin Sodium              | S | Intravenous (not<br>otherwise specified) | Dose:7000 Milliunit(S) | Not Reported |
|                                                                                                                                                                                                                                                                           | Lasilix                     | S | Intravenous (not<br>otherwise specified) |                        | Not Reported |
|                                                                                                                                                                                                                                                                           | Largactil                   | S | Intravenous (not<br>otherwise specified) |                        | Not Reported |
|                                                                                                                                                                                                                                                                           | Exacyl                      | S | Intravenous (not<br>otherwise specified) |                        | Not Reported |
|                                                                                                                                                                                                                                                                           | Flagyl                      | S | Oral                                     |                        | Not Reported |
|                                                                                                                                                                                                                                                                           | Fortum                      | S | Intravenous (not<br>otherwise specified) |                        | Not Reported |
|                                                                                                                                                                                                                                                                           | Gentamicin Sulfate          | S | Intravenous (not<br>otherwise specified) |                        | Not Reported |
|                                                                                                                                                                                                                                                                           | Noxafil                     | S | Oral                                     |                        | Not Reported |
|                                                                                                                                                                                                                                                                           | Candidas                    | S | Intravenous (not<br>otherwise specified) |                        | Not Reported |
|                                                                                                                                                                                                                                                                           | Ambisome                    | S | Intravenous (not<br>otherwise specified) |                        | Not Reported |
|                                                                                                                                                                                                                                                                           | Bactrim                     | S | Intravenous (not<br>otherwise specified) |                        | Not Reported |
|                                                                                                                                                                                                                                                                           | Folinic Acid                | S | Intravenous (not<br>otherwise specified) |                        | Not Reported |
|                                                                                                                                                                                                                                                                           | Zelitrex                    | S | Intravenous (not<br>otherwise specified) |                        | Not Reported |
|                                                                                                                                                                                                                                                                           | Cymevene                    | S | Intravenous (not<br>otherwise specified) |                        | Not Reported |
|                                                                                                                                                                                                                                                                           | Foscavir                    | S | Intravenous (not<br>otherwise specified) |                        | Not Reported |
|                                                                                                                                                                                                                                                                           | Immunoglobulin Human Normal | S | Intravenous (not<br>otherwise specified) |                        | Not Reported |
|                                                                                                                                                                                                                                                                           | Inexium                     | S | Intravenous (not<br>otherwise specified) |                        | Not Reported |

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

|                                                      |   |                                          |              |
|------------------------------------------------------|---|------------------------------------------|--------------|
| Spasfon (Phloroglucinol,<br>Trimethylphloroglucinol) | S | Intravenous (not<br>otherwise specified) | Not Reported |
| Delursan                                             | S | Oral                                     | Not Reported |
| Defibrotide                                          | S | Intravenous (not<br>otherwise specified) | Not Reported |
| Tranxene                                             | S | Oral                                     | Not Reported |
| Oxynorm                                              | S | Intravenous (not<br>otherwise specified) | Not Reported |
| Perfalgan                                            | S | Intravenous (not<br>otherwise specified) | Not Reported |
| Solumedrol                                           | S | Intravenous (not<br>otherwise specified) | Not Reported |
| Droleptan                                            | S | Intravenous (not<br>otherwise specified) | Not Reported |
| Ultiva                                               | S | Intravenous (not<br>otherwise specified) | Not Reported |
| Atarax                                               | S | Oral                                     | Not Reported |
| Seroplex                                             | S | Oral                                     | Not Reported |
| Ceris                                                | S | Oral                                     | Not Reported |
| Noctamide                                            | S | Oral                                     | Not Reported |
| Colistin                                             | C |                                          | Not Reported |
| Vancomycine                                          | C |                                          | Not Reported |
| Ciflox                                               | C |                                          | Not Reported |
| Targocid                                             | C |                                          | Not Reported |
| Mycostatine                                          | C |                                          | Not Reported |
| Triflucan                                            | C |                                          | Not Reported |
| Zovirax                                              | C |                                          | Not Reported |
| Methotrexate                                         | C |                                          | Not Reported |
| Elvorine                                             | C |                                          | Not Reported |
| Sandimmun                                            | C |                                          | Not Reported |
| Mopral                                               | C |                                          | Not Reported |
| Ogastoro                                             | C |                                          | Not Reported |
| Gelox                                                | C |                                          | Not Reported |
| Smecta                                               | C |                                          | Not Reported |
| Luteran                                              | C |                                          | Not Reported |
| Lexomil                                              | C |                                          | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                                                               | Noctamide              |                    |                    | C               |                          |                      |                 |              | Not Reported   |
|-----------------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
|                                                                                               | Zophren                |                    |                    | C               |                          |                      |                 |              | Not Reported   |
|                                                                                               | Primperan              |                    |                    | C               |                          |                      |                 |              | Not Reported   |
| <u>FDA Received Date</u>                                                                      | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Dec-2013                                                                                   | 9549603                | EXPEDITED (15-DAY) |                    | HO, OT          | JP-PFIZER INC-2013269020 |                      | 78 YR           | Female       | JPN            |
| <u>Preferred Term</u>                                                                         | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Fall; Inappropriate Antidiuretic Hormone Secretion; Nausea; Radius Fracture | Sertraline Hcl         |                    |                    | S               | Oral                     | 25 Mg, Daily         |                 | Pfizer       |                |
|                                                                                               | Luvox                  |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                                                                                               | Luvox                  |                    |                    | S               |                          | 50 Mg, Unk           |                 | Not Reported |                |
|                                                                                               | Luvox                  |                    |                    | S               |                          | 75 Mg/Day            |                 | Not Reported |                |
|                                                                                               | Mirtazapine            |                    |                    | S               |                          | 7.5 Mg/Day           |                 | Not Reported |                |
|                                                                                               | Escitalopram Oxalate   |                    |                    | S               |                          | 15 Mg/Day            |                 | Not Reported |                |
|                                                                                               | Duloxetine             |                    |                    | S               |                          | 40 Mg/Day            |                 | Not Reported |                |
|                                                                                               | Benzalin (Nitrazepam)  |                    |                    | S               | Oral                     | 25 Mg/Day            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                      | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Dec-2013                                                                                   | 9783971                | EXPEDITED (15-DAY) |                    | OT              | FR-PFIZER INC-2013363260 |                      | 64 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                         | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Neutropenia                                                                                   | Xanax                  |                    |                    | S               |                          | 0.5 Mg, 3x/Day       |                 | Pfizer       |                |
|                                                                                               | Seroplex               |                    |                    | S               | Oral                     | 40 Mg, 1x/Day        |                 | Not Reported |                |
|                                                                                               | Noctamide              |                    |                    | S               | Oral                     | 2 Mg, 1x/Day         |                 | Not Reported |                |
|                                                                                               | Lovenox                |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                      | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Dec-2013                                                                                   | 9785223                | DIRECT             |                    |                 |                          |                      | 38 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                         | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Headache; Product                                                                             | Lexapro 10mg (Generic) |                    |                    | S               | Oral                     |                      | 1 MTH           | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Substitution Issue

| <u>FDA Received Date</u>                                                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
| 27-Dec-2013                                                                           | 9060917        | EXPEDITED (15-DAY) |                    | HO              | IT-MYLANLABS-2013S1002558 |                      | 56 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Intentional Overdose; Respiratory Acidosis; Respiratory Depression; Sopor | Venlafaxine    |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                                                                                       | Paracetamol    |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                                                                                       | Lexotan        |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                                                                                       | Cipralex       |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                                                                                       | Patrol         |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                                                                                       | Moment         |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                          | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|---------------------------------------------------|---------------------|--------------------|--------------------|-----------------|------------------------------------------------------|----------------------|-----------------|----------------------|----------------|
| 27-Dec-2013                                       | 9785978             | EXPEDITED (15-DAY) |                    | DE              | IE-B.I. PHARMACEUTICALS, I NC./RIDGEFIELD-2013-BI-43 |                      | 69 YR           | Female               | IRL            |
| <u>Preferred Term</u>                             | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Haematemesis; Haematemesis; Haemoglobin Decreased | Persantin Retard    |                    |                    | S               |                                                      | 15 MI                |                 | Boehringer Ingelheim |                |
|                                                   | Aspirin             |                    |                    | S               |                                                      | 75 Mg                |                 | Not Reported         |                |
|                                                   | Lexapro             |                    |                    | S               |                                                      | 10 Mg                |                 | Not Reported         |                |
|                                                   | Lansoprazole        |                    |                    | C               |                                                      | 30 Mg                |                 | Not Reported         |                |
|                                                   | Sitagliptin         |                    |                    | C               |                                                      | 100 Mg               |                 | Not Reported         |                |
|                                                   | Levetiracetam       |                    |                    | C               | Oral                                                 | 1500 Mg              |                 | Not Reported         |                |
|                                                   | Alprazolam          |                    |                    | C               |                                                      | 1 MI                 |                 | Not Reported         |                |
|                                                   | Ondansetron         |                    |                    | C               |                                                      | Route: Peg           |                 | Not Reported         |                |
|                                                   | Zopiclone           |                    |                    | C               |                                                      | Route: Peg           |                 | Not Reported         |                |
|                                                   | Calogen             |                    |                    | C               |                                                      | 90 MI                |                 | Not Reported         |                |
|                                                   | Metoprolol Tartrate |                    |                    | C               |                                                      | 25 Mg                |                 | Not Reported         |                |
|                                                   | Cyclizine           |                    |                    | C               |                                                      | 150 Mg               |                 | Not Reported         |                |



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

|                 |   |      |                           |              |
|-----------------|---|------|---------------------------|--------------|
| Gaviscon Liquid | C |      | Route: Peg, Dose: 10-25ml | Not Reported |
| Lyrica          | C |      | 25 Mg                     | Not Reported |
| Pharmaton Kiddi | C |      | 15 MI                     | Not Reported |
| Perindopril     | C | Oral | 5 Mg                      | Not Reported |
| Lactulose       | C |      | 30 MI                     | Not Reported |
| Paracetamol     | C | Oral | 4 G                       | Not Reported |
| Risperidone     | C |      | 0.5 Mg                    | Not Reported |
| Procal          | C |      | 90 MI                     | Not Reported |
| Nutrison        | C |      | 1000 MI                   | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Dec-2013              | 9786047       | EXPEDITED (15-DAY) |                    | OT              | FR-SA-2013SA132694   |                      | 64 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Neutropenia           | Lovenox        |              |            | S           | Subcutaneous |                    |                 | Not Reported |
|                       | Xanax          |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Noctamide      |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Seroplex       |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Dec-2013              | 9786410       | EXPEDITED (15-DAY) |                    | HO              | JP-FRI-1000052466    |                      | 70 YR      | Male       | JPN            |

| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hepatic Function Abnormal | Lexapro        |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                           | Contomin       |              |            | C           | Oral         | 50 Mg              |                 | Not Reported |
|                           | Contomin       |              |            | C           | Oral         |                    |                 | Not Reported |
|                           | Contomin       |              |            | C           | Oral         |                    |                 | Not Reported |
|                           | Contomin       |              |            | C           | Oral         |                    |                 | Not Reported |
|                           | Risperdal      |              |            | C           | Oral         | 2 Mg               |                 | Not Reported |

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

|                                                        |   |      |         |              |
|--------------------------------------------------------|---|------|---------|--------------|
| Risperidone                                            | C | Oral | 3 Mg    | Not Reported |
| Tasmolin                                               | C | Oral | 3 Mg    | Not Reported |
| Tasmolin                                               | C | Oral | 3 Mg    | Not Reported |
| Tasmolin                                               | C | Oral | 6 Mg    | Not Reported |
| Tasmolin                                               | C | Oral | 5 Mg    | Not Reported |
| Tasmolin                                               | C | Oral | 4 Mg    | Not Reported |
| Tasmolin                                               | C | Oral | 3 Mg    | Not Reported |
| Tasmolin                                               | C | Oral | 2 Mg    | Not Reported |
| Eurodin (Estazolam)                                    | C | Oral | 1 Mg    | Not Reported |
| Eurodin (Estazolam)                                    | C | Oral | 2 Mg    | Not Reported |
| Memary                                                 | C | Oral | 20 Mg   | Not Reported |
| Eticalm                                                | C | Oral | 0.5 Mg  | Not Reported |
| Tsumura Yokukansan Extract<br>Granules For Ethical Use | C | Oral | 3 Df    | Not Reported |
| Solita-T No.3                                          | C |      | 1000 MI | Not Reported |
| Solita-T No.3                                          | C |      | 1500 MI | Not Reported |
| Solita-T No.3                                          | C |      | 500 MI  | Not Reported |
| C-Para                                                 | C |      | 2 MI    | Not Reported |
| Tarivid                                                | C |      |         | Not Reported |
| Racol                                                  | C |      |         | Not Reported |
| Akineton                                               | C | Oral | 3 Mg    | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Dec-2013              | 9786434       | EXPEDITED (15-DAY) |                    | DE              | FR-FRI-1000052478    |                      | 67 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiac Arrest;<br>Electrocardiogram Qt<br>Prolonged | Escitalopram        |              |            | S           |              |                    |                 | Forest       |
|                                                      | Sotalol             |              |            | S           |              | 2 Df               |                 | Not Reported |
|                                                      | Fludex (Indapamide) |              |            | S           | Oral         | 1.5 Mg             |                 | Not Reported |
|                                                      | Hexaquine           |              |            | S           |              | 1 Df               |                 | Not Reported |
|                                                      | Rilmenidine         |              |            | C           |              | 2 Mg               |                 | Not Reported |

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

|  |                        |   |         |              |
|--|------------------------|---|---------|--------------|
|  | Praxilene              | C | 400 Mg  | Not Reported |
|  | Onglyza                | C | 5 Mg    | Not Reported |
|  | Previscan (Fluindione) | C | 1.25 Df | Not Reported |
|  | Coversyl               | C |         | Not Reported |
|  | Baclofene              | C | 30 Mg   | Not Reported |
|  | Lexomil                | C | 1 Df    | Not Reported |
|  | Doliprane Codeine      | C |         | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Dec-2013              | 9786532       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000052434    |                      | 18 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Labelled Drug-Drug<br>Interaction Medication<br>Error; Overdose; Urinary<br>Retention | Escitalopram   |              |            | S           | Oral         |                    |                 | Forest       |
|                                                                                       | Stilnox        |              |            | S           |              |                    |                 | Not Reported |
|                                                                                       | Xeroquel       |              |            | S           |              |                    |                 | Not Reported |
|                                                                                       | Moclamine      |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 27-Dec-2013              | 9786592       | NON-EXPEDITED    |                    |                 | US-PFIZER INC-<br>2013368806 |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Speech Disorder       | Lipitor        |              |            | S           |              | Unk                |                 | Pfizer       |
|                       | Ogen           |              |            | S           |              | Unk                |                 | Pfizer       |
|                       | Provera        |              |            | S           |              | Unk                |                 | Pfizer       |
|                       | Victoza        |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Abilify        |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Cymbalta       |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Diovan         |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Lexapro        |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Potassium      |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Synthroid      |              |            | S           |              | Unk                |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                                                              | <u>Case #</u>                                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>                                                                                                                                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------|--------------------|--------------------|-----------------|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|--------------|----------------|
| 27-Dec-2013                                                                                                                                                                                                                                           | 9787855                                          | DIRECT             |                    | OT              |                       |                                                                                                                                                          |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                 | <u>Product</u>                                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>                                                                                                                                       | <u>Duration</u> | <u>Mfr</u>   |                |
| Dyspepsia; Weight Decreased; Weight Gain Poor                                                                                                                                                                                                         | Escitalopram Teva Ritecol May Have -301-267-2955 |                    |                    | S               | Oral                  | Ndc # 10mg-00093585101<br>20mg 0009358201<br>Strength:10 Mg 1 Week 20<br>Mg Quantity:1 Month<br>Frequency:Once Ady How<br>Was It Taken Or Used:<br>Mouth |                 | Teva         |                |
|                                                                                                                                                                                                                                                       | Lorezepam                                        |                    |                    | C               |                       |                                                                                                                                                          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                       | Wellbutrin                                       |                    |                    | C               |                       |                                                                                                                                                          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                       | Geodon                                           |                    |                    | C               |                       |                                                                                                                                                          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                       | Famitodore                                       |                    |                    | C               |                       |                                                                                                                                                          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                       | Protonix                                         |                    |                    | C               |                       |                                                                                                                                                          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                       | Vit. K                                           |                    |                    | C               |                       |                                                                                                                                                          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                       | Fish Oil                                         |                    |                    | C               |                       |                                                                                                                                                          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                       | Multivitamins                                    |                    |                    | C               |                       |                                                                                                                                                          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                       | Calcium                                          |                    |                    | C               |                       |                                                                                                                                                          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                       | Antiosidents                                     |                    |                    | C               |                       |                                                                                                                                                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                              | <u>Case #</u>                                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>                                                                                                                                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Dec-2013                                                                                                                                                                                                                                           | 9274773                                          | EXPEDITED (15-DAY) |                    | CA, OT          | US-JNJFOC-20130417571 |                                                                                                                                                          |                 | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                 | <u>Product</u>                                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>                                                                                                                                       | <u>Duration</u> | <u>Mfr</u>   |                |
| Adhesion; Caesarean Section; Choking; Cleft Lip; Cleft Palate; Cough; Dacryostenosis Acquired; Dental Caries; Developmental Delay; Dysphagia; Jaundice Neonatal; Maternal Drugs Affecting Foetus; Nasal Disorder; Otitis Media Acute; Pilonidal Cyst; | Topamax                                          |                    |                    | S               | Transplacental        |                                                                                                                                                          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                       | Topamax                                          |                    |                    | S               | Transplacental        |                                                                                                                                                          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                       | Topamax                                          |                    |                    | S               | Transplacental        |                                                                                                                                                          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                       | Phenobarbital                                    |                    |                    | S               | Transplacental        |                                                                                                                                                          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                       | Depakote                                         |                    |                    | S               | Transplacental        |                                                                                                                                                          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                       | Neurontin                                        |                    |                    | S               | Unknown               |                                                                                                                                                          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                       | Lexapro                                          |                    |                    | S               | Transplacental        |                                                                                                                                                          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                       | Lorazepam                                        |                    |                    | S               | Transplacental        |                                                                                                                                                          |                 | Not Reported |                |

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

|                          |                |   |                |              |
|--------------------------|----------------|---|----------------|--------------|
| Psychomotor              | Promethazine   | S | Transplacental | Not Reported |
| Hyperactivity; Sensory   | Nitrofurantoin | S | Transplacental | Not Reported |
| Disturbance; Sleep       | Cefaclor       | S | Transplacental | Not Reported |
| Apnoea Syndrome; Sleep   | Fluconazole    | S | Transplacental | Not Reported |
| Terror; Snoring;         | Fluoxetine     | S | Transplacental | Not Reported |
| Somnambulism; Spina      | Vitamin B2     | C | Transplacental | Not Reported |
| Bifida; Umbilical Hernia |                |   |                |              |

| <u>FDA Received Date</u> | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 30-Dec-2013              | 9773307                 | EXPEDITED (15-DAY) | HO                 |                 | IT-FRI-1000052315    |                      | 92 YR           | Male         | ITA            |
| <u>Preferred Term</u>    | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Injury;        | Escitalopram            |                    |                    | S               | Oral                 | 1 Df                 |                 | Forest       |                |
| Presyncope; Wound        | Coumadin 5 Mg Compresse |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|---------------------------|-----------------|------------|----------------|
| 30-Dec-2013              | 9776253        | EXPEDITED (15-DAY) | OT                 |                 | DE-FRI-1000052396    |                           |                 | Male       | DEU            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u> |                |
| Blood Glucose Decreased; | Escitalopram   |                    |                    | S               | Oral                 | Gradually Increased To 25 |                 | Forest     |                |
| Pancreatic Failure;      |                |                    |                    |                 |                      | Mg/Day                    |                 |            |                |
| Prescribed Overdose      |                |                    |                    |                 |                      |                           |                 |            |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 30-Dec-2013              | 9787783        | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2013368490 |                      | 53 YR           | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity    | Procardia      |                  |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                          | Norvasc        |                  |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                          | Vasotec        |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                          | Lexapro        |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 30-Dec-2013              | 9787841        | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2013370940 |                      | 43 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity    | Zoloft         |                  |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                          | Celexa         |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                          | Lexapro        |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 30-Dec-2013              | 9788642        | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000052448    |                      |                 | Male       | FRA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Myocarditis              | Escitalopram   |                    |                    | S               |                      |                      |                 | Forest     |                |

| <u>FDA Received Date</u> | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 30-Dec-2013              | 9788646                | EXPEDITED (15-DAY) |                    | LT              | FR-FRI-1000052458    |                      | 60 YR           | Male         | FRA            |
| <u>Preferred Term</u>    | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Shock Haemorrhagic       | Escitalopram           |                    |                    | S               | Oral                 |                      |                 | Forest       |                |
|                          | Plavix                 |                    |                    | S               | Oral                 | 75 Mg                |                 | Not Reported |                |
|                          | Previscan (Fluindione) |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                          | Lovenox                |                    |                    | S               |                      | 14000 lu             |                 | Not Reported |                |
|                          | Triatec (Ramipril)     |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Amlor                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Depamide               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Inexium                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Cordarone              |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 30-Dec-2013              | 9788708        | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000052461    |                      | 64 YR           | Female     | FRA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                       |              |   |      |                                           |              |
|-----------------------|--------------|---|------|-------------------------------------------|--------------|
| Neutropenia; Overdose | Escitalopram | S | Oral | Overdose With 40 Mg Daily Of Escitalopram | Forest       |
|                       | Noctamide    | S | Oral | 2 Mg                                      | Not Reported |
|                       | Xanax        | S | Oral | 1.5 Mg                                    | Not Reported |
|                       | Lovenox      | S | Oral | Not Specified                             | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Dec-2013              | 9788735       | EXPEDITED (15-DAY) | HO                 |                 | IT-FRI-1000052490    |                      | 73 YR      | Male       | ITA            |

| <u>Preferred Term</u>                                                  | <u>Product</u>             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|------------------------------------------------------------------------|----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Confusional State; Hyperpyrexia; Off Label Use; Rhabdomyolysis; Tremor | Escitalopram Oral Solution |              |            | S           | Oral         | 5 Mg               |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Dec-2013              | 9788747       | EXPEDITED (15-DAY) | DE                 |                 | FR-FRI-1000052455    |                      | 68 YR      | Female     | FRA            |

| <u>Preferred Term</u>     | <u>Product</u>                                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|------------------------------------------------|--------------|------------|-------------|--------------|-----------------------------------|-----------------|--------------|
| Cardio-Respiratory Arrest | Escitalopram                                   |              |            | S           | Oral         | 1 Df                              |                 | Forest       |
|                           | Trazolan                                       |              |            | S           | Oral         | 1 Df                              |                 | Not Reported |
|                           | Sectral                                        |              |            | S           | Oral         | 1 Df                              |                 | Not Reported |
|                           | Ixprim                                         |              |            | C           | Oral         | 112.50/975 Mg Daily               |                 | Not Reported |
|                           | Ebixa                                          |              |            | C           | Oral         |                                   |                 | Not Reported |
|                           | Alprazolam                                     |              |            | C           | Oral         | 3 Df                              |                 | Not Reported |
|                           | Calcium/Vitamin D3                             |              |            | C           | Oral         | 500 Mg/400 Iu - 12 Tablets Weekly |                 | Not Reported |
|                           | Azopt                                          |              |            | C           |              | 10 Mg/MI Twice Daily              |                 | Not Reported |
|                           | Ogastoro                                       |              |            | C           | Oral         | 1 Df                              |                 | Not Reported |
|                           | Acide Alendronique                             |              |            | C           | Oral         | 10 Mg                             |                 | Not Reported |
|                           | Transipeg (Polyethylene Glycol 3350)\Potassium |              |            | C           | Oral         | 1 Df                              |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Chloride\Sodium  
Bicarbonate\Sodium  
Chloride\Sodium Sulfate  
Anhydrous)

| <u>FDA Received Date</u>                                                           | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|---------------------------|--------------------------------|-----------------|--------------|----------------|
| 30-Dec-2013                                                                        | 9789186        | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000052492         |                                | 33 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                              | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State;<br>Depressed Level Of<br>Consciousness;<br>Overdose; Somnolence | Escitalopram   |                    |                    | S               | Oral                      | Drug Overdose Of 12<br>Tablets |                 | Forest       |                |
|                                                                                    | Lexomil        |                    |                    | S               | Oral                      | Drug Overdose Of 15<br>Tablets |                 | Not Reported |                |
|                                                                                    | Lyrica         |                    |                    | S               | Oral                      | Drug Overdose Of Of 21<br>Df   |                 | Not Reported |                |
|                                                                                    | Olanzapine     |                    |                    | S               | Oral                      | Drug Overdose Of 28<br>Tablets |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                           | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Dec-2013                                                                        | 9789995        | DIRECT             |                    | DS              |                           |                                | 53 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                              | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Bone Disorder; Fracture;<br>Impaired Work Ability                                  | Lexapro        |                    |                    | S               | Oral                      |                                | 8 YR            | Not Reported |                |
| <u>FDA Received Date</u>                                                           | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-Dec-2013                                                                        | 8471999        | EXPEDITED (15-DAY) |                    | HO, OT          | US-JNJFOC-<br>20111109040 |                                |                 | Female       | USA            |
| <u>Preferred Term</u>                                                              | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Amniotic Cavity Infection;                                                         | Topamax        |                    |                    | S               | Oral                      |                                |                 | Not Reported |                |
| Bipolar Disorder;                                                                  | Topamax        |                    |                    | S               | Oral                      |                                |                 | Not Reported |                |
| Emotional Distress;                                                                | Topamax        |                    |                    | S               | Oral                      |                                |                 | Not Reported |                |
| Exposure During<br>Pregnancy; Premature<br>Delivery; Premature                     | Topamax        |                    |                    | S               | Oral                      |                                |                 | Not Reported |                |



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

|                                                              |                   |   |         |              |
|--------------------------------------------------------------|-------------------|---|---------|--------------|
| Rupture Of Membranes;<br>Premature Separation Of<br>Placenta | Clindamycin       | S | Vaginal | Not Reported |
|                                                              | Terbutaline       | S | Oral    | Not Reported |
|                                                              | Prometrium        | S | Oral    | Not Reported |
|                                                              | Lexapro           | S | Oral    | Not Reported |
|                                                              | Lithium Carbonate | S | Oral    | Not Reported |
|                                                              | Zithromax         | S | Unknown | Not Reported |
|                                                              | Betamethasone     | S | Unknown | Not Reported |
|                                                              | Nifedipine        | S | Unknown | Not Reported |
|                                                              | Ampicillin        | S | Unknown | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-Dec-2013              | 9603368       | EXPEDITED (15-DAY) |                    | HO              | CH-FRI-1000049606    |                      |            | Female     | CHE            |

| <u>Preferred Term</u>                                                                                  | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------|-------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Loss Anaemia;<br>Gastrointestinal<br>Haemorrhage;<br>International Normalised<br>Ratio Increased | Escitalopram Oral Solution    |              |            | S           | Oral         | 20 Mg              |                 | Forest       |
|                                                                                                        | Xarelto                       |              |            | S           | Oral         | 20 Mg              |                 | Not Reported |
|                                                                                                        | Xarelto                       |              |            | S           | Oral         | 15 Mg              |                 | Not Reported |
|                                                                                                        | Flector                       |              |            | S           |              | 1 Df               |                 | Not Reported |
|                                                                                                        | Nebilet                       |              |            | C           |              | 5 Mg               |                 | Not Reported |
|                                                                                                        | Mephanol                      |              |            | C           |              | 300 Mg             |                 | Not Reported |
|                                                                                                        | Marcoumar                     |              |            | C           |              | 3 Mg               |                 | Not Reported |
|                                                                                                        | Vitamin D3                    |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                        | Trittico                      |              |            | C           |              | 100 Mg             |                 | Not Reported |
|                                                                                                        | Atorvastatin                  |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                        | Novalgine (Metamizole Sodium) |              |            | C           |              | 1000 Mg            |                 | Not Reported |
|                                                                                                        | Traumanase                    |              |            | C           | Oral         | 3 Df               |                 | Not Reported |
|                                                                                                        | Nopil Forte                   |              |            | C           | Oral         | 2 Df               |                 | Not Reported |
|                                                                                                        | Glaupax                       |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                        | Cosopt                        |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                        | Kimzalplus                    |              |            | C           |              |                    |                 | Not Reported |

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

| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                     | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| 31-Dec-2013                                                                                                                                                                                                                                                                                                  | 9776777                         | EXPEDITED (15-DAY) |                    | OT              | US-ASTRAZENECA-2013SE89265 |                      | 71 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                        | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Faeces;                                                                                                                                                                                                                                                                                             | Faslodex                        |                    |                    | S               | Intramuscular              |                      |                 | Not Reported |                |
| Adverse Drug Reaction;                                                                                                                                                                                                                                                                                       | Faslodex                        |                    |                    | S               | Intramuscular              |                      |                 | Not Reported |                |
| Agitation; Arthralgia;                                                                                                                                                                                                                                                                                       | Lexapro                         |                    |                    | S               | Unknown                    |                      |                 | Not Reported |                |
| Asthenia; Back Pain; Bone Pain; Breast Cancer;                                                                                                                                                                                                                                                               | Letrozol                        |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
| Constipation; Cough;                                                                                                                                                                                                                                                                                         | Lyrica                          |                    |                    | S               | Unknown                    |                      |                 | Not Reported |                |
| Decreased Appetite;                                                                                                                                                                                                                                                                                          | Gabapentin                      |                    |                    | S               | Unknown                    |                      |                 | Not Reported |                |
| Discomfort; Diverticulitis;                                                                                                                                                                                                                                                                                  | Unspecified Steroid Type        |                    |                    | S               | Unknown                    |                      |                 | Not Reported |                |
| Dizziness; Drug Hypersensitivity; Fatigue;                                                                                                                                                                                                                                                                   | Medication                      |                    |                    |                 |                            |                      |                 | Not Reported |                |
| Fatigue; Feeling Abnormal; Hepatic Steatosis; Hypoaesthesia;                                                                                                                                                                                                                                                 | Xegva                           |                    |                    | C               |                            |                      |                 | Not Reported |                |
| Hypothyroidism; Injection Site Pain; Injection Site Reaction; Intentional Product Misuse;                                                                                                                                                                                                                    | Another Unidentified Medication |                    |                    | C               |                            |                      |                 | Not Reported |                |
| Laryngitis; Lethargy; Limb Discomfort; Listless; Mental Impairment; Muscle Atrophy; Muscle Spasms; Musculoskeletal Stiffness; Myalgia; Nausea; Nerve Injury; Pain; Quality Of Life Decreased; Respiratory Tract Infection; Sedation; Skin Odour Abnormal; Urine Odour Abnormal; Vomiting; Weight Fluctuation |                                 |                    |                    |                 |                            |                      |                 |              |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                     | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-Dec-2013                                                                                                                                                                                                                                                                                                  | 9790140                         | EXPEDITED (15-DAY) |                    | HO              | CH-FRI-1000052484          |                      |                 | Male         | CHE            |

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

| <u>Preferred Term</u>                                  | <u>Product</u>                                                                                                                     | <u>Comp.</u>  | <u>OTC</u>         | <u>Role</u>        | <u>Route</u>    | <u>Dosage Text</u>   | <u>Duration</u>      | <u>Mfr</u>   |            |                |
|--------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|--------------|------------|----------------|
| Cholestatic Liver Injury;<br>Jaundice                  | Escitalopram                                                                                                                       |               |                    | S                  | Oral            | 10 Mg                |                      | Forest       |            |                |
|                                                        | Urispas                                                                                                                            |               |                    | S                  | Oral            | 200 Mg               |                      | Not Reported |            |                |
|                                                        | Urispas                                                                                                                            |               |                    | S                  | Oral            | 400 Mg               |                      | Not Reported |            |                |
|                                                        | Tasmar                                                                                                                             |               |                    | S                  | Oral            | 200 Mg               |                      | Not Reported |            |                |
|                                                        | Motilium                                                                                                                           |               |                    | S                  | Oral            | 40 Mg                |                      | Not Reported |            |                |
|                                                        | Motilium                                                                                                                           |               |                    | S                  |                 |                      |                      | Not Reported |            |                |
|                                                        | Transipeg (Polyethylene Glycol<br>3350\Potassium<br>Chloride\Sodium<br>Bicarbonate\Sodium<br>Chloride\Sodium Sulfate<br>Anhydrous) |               |                    | S                  |                 |                      |                      | Not Reported |            |                |
|                                                        | Becosym Forte                                                                                                                      |               |                    | C                  |                 |                      |                      | Not Reported |            |                |
|                                                        | Exelon Patch                                                                                                                       |               |                    | C                  |                 |                      |                      | Not Reported |            |                |
|                                                        | Gutron                                                                                                                             |               |                    | C                  |                 |                      |                      | Not Reported |            |                |
|                                                        | Madopar                                                                                                                            |               |                    | C                  |                 |                      |                      | Not Reported |            |                |
|                                                        | Remeron                                                                                                                            |               |                    | C                  |                 |                      |                      | Not Reported |            |                |
|                                                        | Rivotril                                                                                                                           |               |                    | C                  |                 |                      |                      | Not Reported |            |                |
|                                                        | Seroquel                                                                                                                           |               |                    | C                  |                 |                      |                      | Not Reported |            |                |
|                                                        | Sinemet Cr                                                                                                                         |               |                    | C                  |                 |                      |                      | Not Reported |            |                |
|                                                        | <u>FDA Received Date</u>                                                                                                           | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>   | <u>Sex</u> | <u>Country</u> |
|                                                        | 31-Dec-2013                                                                                                                        | 9790179       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000052452    |                      | 83 YR        | Male       | FRA            |
| <u>Preferred Term</u>                                  | <u>Product</u>                                                                                                                     | <u>Comp.</u>  | <u>OTC</u>         | <u>Role</u>        | <u>Route</u>    | <u>Dosage Text</u>   | <u>Duration</u>      | <u>Mfr</u>   |            |                |
| Drug Interaction;<br>Haematoma; Traumatic<br>Haematoma | Escitalopram                                                                                                                       |               |                    | S                  | Oral            | 5 Mg                 |                      | Forest       |            |                |
|                                                        | Xarelto                                                                                                                            |               |                    | S                  | Oral            | 15 Mg                |                      | Not Reported |            |                |
|                                                        | Kardegic                                                                                                                           |               |                    | S                  | Oral            | 75 Mg                |                      | Not Reported |            |                |
|                                                        | Inexium                                                                                                                            |               |                    | C                  |                 |                      |                      | Not Reported |            |                |
|                                                        | Mono-Tildiem                                                                                                                       |               |                    | C                  |                 |                      |                      | Not Reported |            |                |
|                                                        | Simvastatine                                                                                                                       |               |                    | C                  |                 |                      |                      | Not Reported |            |                |
|                                                        | Temesta (Lorazepam)                                                                                                                |               |                    | C                  |                 |                      |                      | Not Reported |            |                |

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| <u>FDA Received Date</u>                                                                           | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u>                                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|--------------------------------|-----------------------------------------------------|-----------------|--------------|----------------|
| 01-Jan-2014                                                                                        | 9785448              | EXPEDITED (15-DAY) |                    | HO, OT          | CH-009507513-1312CHE010276     |                                                     | 55 YR           | Male         | CHE            |
| <u>Preferred Term</u>                                                                              | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>                                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Lactic Acid Increased; Coma; Electrocardiogram Qt Prolonged; Rhabdomyolysis; Suicide Attempt | Remeron              |                    |                    | S               | Oral                           | Frequency: 39 Df At Once                            |                 | Merck        |                |
|                                                                                                    | Lorazepam            |                    |                    | S               | Oral                           | 37 Df At Once                                       |                 | Not Reported |                |
|                                                                                                    | Quetiapine Fumarate  |                    |                    | S               | Oral                           | Dose: 1.8-18 Mg; Frequency 6-60 Df At One           |                 | Not Reported |                |
|                                                                                                    | Janumet              |                    |                    | S               | Oral                           | Total Daily Dose: 1.25/25 G; Frequency 25 Df At One |                 | Merck        |                |
|                                                                                                    | Escitalopram         |                    |                    | S               | Oral                           | 700 Mg, Unk                                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                           | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u>                                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Jan-2014                                                                                        | 9791547              | EXPEDITED (15-DAY) |                    | HO              | TR-US-EMD SERONO, INC.-7259696 |                                                     | 21 YR           | Female       | TUR            |
| <u>Preferred Term</u>                                                                              | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>                                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Headache; Multiple Sclerosis Relapse; Nausea; Toxicity To Various Agents; Vomiting                 | Rebif                |                    |                    | S               | Subcutaneous                   |                                                     |                 | Not Reported |                |
|                                                                                                    | Ciprallex /01588501/ |                    |                    | S               | Oral                           |                                                     |                 | Not Reported |                |
|                                                                                                    | Brufen /00109201/    |                    |                    | S               | Oral                           |                                                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                           | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u>                                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Jan-2014                                                                                        | 9336706              | EXPEDITED (15-DAY) |                    | DS, OT          | JP-FRI-1000045731              |                                                     | 30 YR           | Female       | JPN            |
| <u>Preferred Term</u>                                                                              | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>                                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Cerebral Haemorrhage; Pancytopenia; Renal Impairment                                               | Lexapro              |                    |                    | S               | Oral                           | 20 Mg                                               |                 | Forest       |                |
|                                                                                                    | Meilax               |                    |                    | C               | Oral                           | 1 Mg                                                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                           | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u>                                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Jan-2014                                                                                        | 9779308              | EXPEDITED (15-DAY) |                    | DE              | CH-FRI-1000052398              |                                                     | 55 YR           | Male         | CHE            |

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| <u>Preferred Term</u>                                   | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------------|---------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Drug Abuse; Overdose;<br>Sudden Death                   | Escitalopram        |                    |                    | S               |                      | Overdose 30 Mg Daily |                 | Forest       |                |
|                                                         | Methadone           |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                         | Atazanavir          |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                         | Levomepromazine     |                    |                    | S               |                      | 50 Mg                |                 | Not Reported |                |
|                                                         | Zidovudine          |                    |                    | S               |                      | 600 Mg               |                 | Not Reported |                |
|                                                         | Lamivudine          |                    |                    | S               |                      | 300 Mg               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Jan-2014                                             | 9793261             | EXPEDITED (15-DAY) |                    | DE              | IE-FRI-1000052610    |                      | 69 YR           | Female       | IRL            |
| <u>Preferred Term</u>                                   | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Haematemesis;<br>Haematemesis;<br>Haemoglobin Decreased | Escitalopram        |                    |                    | S               | Oral                 |                      |                 | Forest       |                |
|                                                         | Aspirin             |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                         | Persantin Retard    |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                         | Gaviscon            |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                         | Lansoprazole        |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |
|                                                         | Sitagliptin         |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |
|                                                         | Levetiracetam       |                    |                    | C               |                      | 1500 Mg              |                 | Not Reported |                |
|                                                         | Alprazolam          |                    |                    | C               |                      | 1000 Mcg             |                 | Not Reported |                |
|                                                         | Ondansetron         |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                         | Zopiclone           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                         | Calogen             |                    |                    | C               |                      | 90 MI                |                 | Not Reported |                |
|                                                         | Metoprolol Tartrate |                    |                    | C               |                      | 25 Mg                |                 | Not Reported |                |
|                                                         | Cyclizine           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                         | Lyrica              |                    |                    | C               |                      | 25 Mg                |                 | Not Reported |                |
|                                                         | Pharmaton Kiddi     |                    |                    | C               |                      | 15 MI                |                 | Not Reported |                |
|                                                         | Perindopril         |                    |                    | C               | Oral                 | 5 Mg                 |                 | Not Reported |                |
|                                                         | Lactulose           |                    |                    | C               |                      | 30 MI                |                 | Not Reported |                |
|                                                         | Paracetamol         |                    |                    | C               |                      | 0.5 Mg               |                 | Not Reported |                |
|                                                         | Risperidone         |                    |                    | C               |                      | 0.5 Mg               |                 | Not Reported |                |

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|                                                                                                                                          | Procal                 |                    | C                  |                 | 90 MI                                           |                      |                 | Not Reported     |                |
|------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|------------------|----------------|
|                                                                                                                                          | Nutrison               |                    | C                  |                 | 1000 MI                                         |                      |                 | Not Reported     |                |
| <u>FDA Received Date</u>                                                                                                                 | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 02-Jan-2014                                                                                                                              | 9797486                | DIRECT             |                    | OT              |                                                 |                      | 44 YR           | Male             | USA            |
| <u>Preferred Term</u>                                                                                                                    | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |
| Headache; Hot Flush;<br>Influenza; Neuralgia                                                                                             | Lexapro 10mg (Generic) |                    |                    | S               | Oral                                            |                      |                 | Teva             |                |
| <u>FDA Received Date</u>                                                                                                                 | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 03-Jan-2014                                                                                                                              | 8563320                | EXPEDITED (15-DAY) |                    | HO, OT          | FR-<br>ELI_LILLY_AND_COMP<br>ANY-FR201205000922 |                      | 52 YR           | Male             | FRA            |
| <u>Preferred Term</u>                                                                                                                    | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |
| Hepatic Failure                                                                                                                          | Zyprexa                |                    |                    | S               | Oral                                            | 5 Mg, Qd             |                 | Eli Lilly And Co |                |
|                                                                                                                                          | Seroplex               |                    |                    | S               |                                                 | 20 Mg, Unk           |                 | Not Reported     |                |
|                                                                                                                                          | Rasilez Hct            |                    |                    | S               |                                                 | Unk                  |                 | Not Reported     |                |
|                                                                                                                                          | Anafranil              |                    |                    | S               |                                                 | 37.5 Mg, Qd          |                 | Not Reported     |                |
|                                                                                                                                          | Alprazolam             |                    |                    | S               |                                                 | 0.75 Mg, Qd          |                 | Not Reported     |                |
|                                                                                                                                          | Prazepam               |                    |                    | C               |                                                 |                      |                 | Not Reported     |                |
| <u>FDA Received Date</u>                                                                                                                 | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 03-Jan-2014                                                                                                                              | 9798824                | DIRECT             | Y                  | OT              |                                                 |                      | 41 YR           | Female           | USA            |
| <u>Preferred Term</u>                                                                                                                    | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |
| Anxiety; Arthralgia;<br>Depression; Disturbance<br>In Attention; Memory<br>Impairment; Rash; Sexual<br>Dysfunction; Suicidal<br>Ideation | Escitalopram Oxalate   |                    |                    | S               | Oral                                            |                      |                 | Aurobindo        |                |

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| <u>FDA Received Date</u>                        | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u>                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------|----------------------------|--------------------|--------------------|-----------------|----------------------------------|------------------------------------------|-----------------|--------------|----------------|
| 06-Jan-2014                                     | 9798148                    | EXPEDITED (15-DAY) |                    | DE, HO, OT      | US-UCBSA-108005                  |                                          | 45 YR           | Female       | USA            |
| <u>Preferred Term</u>                           | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                     | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardio-Respiratory Arrest;<br>Completed Suicide | Alprazolam                 |                    |                    | S               | Oral                             | Ingestion                                |                 | Not Reported |                |
|                                                 | Escitalopram               |                    |                    | S               | Oral                             | Ingestion                                |                 | Not Reported |                |
|                                                 | Zolpidem                   |                    |                    | S               | Oral                             | Ingestion                                |                 | Not Reported |                |
| <u>FDA Received Date</u>                        | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u>                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Jan-2014                                     | 9799318                    | EXPEDITED (15-DAY) |                    | OT              | RS-FRI-1000052635                |                                          |                 | Female       | SRB            |
| <u>Preferred Term</u>                           | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                     | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>   |                |
| Night Sweats                                    | Escitalopram               |                    |                    | S               | Oral                             | 10 Mg                                    |                 | Forest       |                |
|                                                 | Escitalopram               |                    |                    | S               | Oral                             | 5 Mg                                     |                 | Forest       |                |
|                                                 | Rivotril                   |                    |                    | C               |                                  |                                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                        | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u>                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Jan-2014                                     | 9802983                    | DIRECT             |                    |                 |                                  |                                          | 60 YR           | Female       | USA            |
| <u>Preferred Term</u>                           | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                     | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Product<br>Substitution Issue       | Escitalopram 10 Mg         |                    |                    | S               | Oral                             |                                          |                 | Torrent      |                |
| <u>FDA Received Date</u>                        | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u>                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Jan-2014                                     | 9720883                    | EXPEDITED (15-DAY) |                    | HO              | IT-ABBVIE-13P-083-<br>1174304-00 |                                          | 17 YR           | Male         | ITA            |
| <u>Preferred Term</u>                           | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                     | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Abuse; Nausea;<br>Suicide Attempt; Tremor  | Depakin Chrono             |                    |                    | S               | Oral                             | Extended-Release Tablet:<br>600 Mg Total |                 | Not Reported |                |
|                                                 | Depakin (Valproate Sodium) |                    |                    | S               | Oral                             |                                          |                 | Not Reported |                |

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|                            |   |      |                                |              |
|----------------------------|---|------|--------------------------------|--------------|
| Depakin (Valproate Sodium) | S | Oral | 1000 Mg Total                  | Not Reported |
| Ciprallex                  | S | Oral | Solution: 20 Drops Total       | Not Reported |
| En                         | S | Oral | 20 Drops Total                 | Not Reported |
| En                         | S | Oral | Solution Drops: 24 Drops Total | Not Reported |
| Sertraline Hydrochloride   | C |      |                                | Not Reported |

| <u>FDA Received Date</u>                                                           | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|------------------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|------------------------------------|-----------------|------------|----------------|
| 07-Jan-2014                                                                        | 9803058        | DIRECT           |                    | LT              |                      |                                    | 31 YR           | Male       | USA            |
| <u>Preferred Term</u>                                                              | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u> |                |
| Anxiety; Drug Ineffective; Dyspnoea; Product Substitution Issue; Suicidal Ideation | Escitalopram   |                  |                    | S               | Oral                 | 1/2 Pill Once Daily Taken By Mouth |                 | Aurobindo  |                |

| <u>FDA Received Date</u>                                                | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|-------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 07-Jan-2014                                                             | 9803220        | DIRECT           |                    | OT              |                      |                      | 51 YR           | Female     | USA            |
| <u>Preferred Term</u>                                                   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Anxiety; Drug Ineffective; Feeling Abnormal; Product Substitution Issue | Escitalopram   |                  |                    | S               | Oral                 |                      |                 | Teva       |                |

| <u>FDA Received Date</u>                                                                                                           | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 08-Jan-2014                                                                                                                        | 9936775        | NON-EXPEDITED    |                    | OT              | E2B_00001438         |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                              | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Depression; Drug Ineffective; Heart Rate Irregular; Insomnia; Panic Attack; Product Substitution Issue; Suicidal Ideation | Escitalopram   |                  |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                                    | Atenolol       |                  |                    | C               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                                    | Lisinopril     |                  |                    | C               |                      |                      |                 | Not Reported |                |



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| <u>FDA Received Date</u>                | <u>Case #</u>          | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>                    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------|------------------------|------------------|--------------------|-----------------|---------------------------------------|-----------------------------------------|-----------------|--------------|----------------|
| 08-Jan-2014                             | 9936776                | NON-EXPEDITED    | Y                  | HO, LT          | 2013-01953                            |                                         | 65 YR           | Female       | IND            |
| <u>Preferred Term</u>                   | <u>Product</u>         | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>                      | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;<br>Serotonin Syndrome | Escitalopram (Unknown) |                  |                    | S               |                                       |                                         |                 | Not Reported |                |
|                                         | Linezolid              |                  |                    | S               | Intravenous (not otherwise specified) | 1200 Mg (600 Mg, 2 In 1 D), Intravenous |                 | Not Reported |                |
|                                         | Clonazepam (Unknown)   |                  |                    | C               |                                       |                                         |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                                       | <u>Case #</u>                                                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>                                             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------|--------------------|--------------------|-----------------|---------------------------------------|------------------------------------------------------------------|-----------------|--------------|----------------|
| 09-Jan-2014                                                                                                                                                    | 9547651                                                       | EXPEDITED (15-DAY) | Y                  | DE, HO, OT      | SYM-2013-10767                        |                                                                  | 41 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                                          | <u>Product</u>                                                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>                                               | <u>Duration</u> | <u>Mfr</u>   |                |
| Acute Kidney Injury; Graft Versus Host Disease In Gastrointestinal Tract; Hepatitis Fulminant; Multiple Organ Dysfunction Syndrome; Toxic Epidermal Necrolysis | Flagyl                                                        |                    |                    | S               | Intravenous (not otherwise specified) |                                                                  |                 | Not Reported |                |
|                                                                                                                                                                | Largactil (Chlorpromazine) (Chlorpromazine)                   |                    |                    | S               |                                       | 1 Dosage Forms, Daily                                            |                 | Not Reported |                |
|                                                                                                                                                                | Exacyl (Tranexamic Acid) (Tranexamic Acid)                    |                    |                    | S               |                                       | 1 Dosage Forms, 3 In 1 D                                         |                 | Not Reported |                |
|                                                                                                                                                                | Fortum (Ceftazidime) (Injection) (Ceftazidime)                |                    |                    | S               |                                       | 1 Dosage Forms, 4 In 1 D                                         |                 | Not Reported |                |
|                                                                                                                                                                | Gentamicin Sulfate (Gentamicin Sulfate) (Gentamicin Sulfate)  |                    |                    | S               | Intravenous (not otherwise specified) |                                                                  |                 | Not Reported |                |
|                                                                                                                                                                | Noxafil (Posaconazole) (Posaconazole)                         |                    |                    | S               | Oral                                  |                                                                  |                 | Not Reported |                |
|                                                                                                                                                                | Cancidas (Caspofungin Acetate) (Caspofungin Acetate)          |                    |                    | S               | Intravenous (not otherwise specified) | Iv (Not Otherwise Specified)                                     |                 | Not Reported |                |
|                                                                                                                                                                | Ambisome (Amphotericin B Liposome) (Amphotericin B, Liposome) |                    |                    | S               | Intravenous (not otherwise specified) | 1i80 Mg, Daily, Intravenous (Not Otherwise Specified)            |                 | Not Reported |                |
|                                                                                                                                                                | Bactrim (Bactrim) (Sulfamethoxazole, Trimethoprim)            |                    |                    | S               | Intravenous (not otherwise specified) | 2 Dosage Forms, 3 In 1 Wk, Intravenous (Not Otherwise Specified) |                 | Not Reported |                |
|                                                                                                                                                                | Folinic Acid (Folinic Acid) (Folinic Acid)                    |                    |                    | S               | Intravenous (not otherwise specified) | 50 Mg, 3 In 1 Wk, Intravenous (Not                               |                 | Not Reported |                |

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

|                                                                                         |   |                                       |                                                                  |              |
|-----------------------------------------------------------------------------------------|---|---------------------------------------|------------------------------------------------------------------|--------------|
|                                                                                         |   |                                       | Otherwise Specified)                                             |              |
| Zelitrex (Valaciclovir Hydrochloride) (Valaciclovir Hydrochloride)                      | S | Intravenous (not otherwise specified) | 500 Mg, 2 In 1 D, Intravenous (Not Otherwise Specified)          | Not Reported |
| Cymevan (Ganciclovir Sodium) (Ganciclovir Sodium)                                       | S | Intravenous (not otherwise specified) | 350 Mg, 2 In 1 D, Intravenous (Not Otherwise Specified)          | Not Reported |
| Foscavir (Foscarnet Sodium ) (Solution For Infusion) (Foscarnet Sodium)                 | S |                                       | 1 Dosage Forms, 2 In 1 D, Bid                                    | Not Reported |
| Clairyg                                                                                 | S | Intravenous (not otherwise specified) | Intravenous (Not Otherwise Specified)                            | Not Reported |
| Inexium (Esomeprazole Magnesium)                                                        | S | Intravenous (not otherwise specified) |                                                                  | Not Reported |
| Spasfon (Phloroglucinol)                                                                | S | Intravenous (not otherwise specified) | 2 Dosages Forms, 3 In 1 D, Intravenous (Not Otherwise Specified) | Not Reported |
| Delursan (Ursodeoxycholic Acid) Tablet                                                  | S | Oral                                  | 3 Dosages Forms, 2 In 1 D, Oral                                  | Not Reported |
| Defibrotide (Defibrotide) (Defibrotide)                                                 | S | Intravenous (not otherwise specified) |                                                                  | Not Reported |
| Tranxene (Clorazepate Dipotassium) (Capsules) (Clorazepate Dipotassium)                 | S | Oral                                  |                                                                  | Not Reported |
| Oxynorm (Oxycodone Hydrochloride) (Oxycodone Hydrochloride)                             | S | Intravenous (not otherwise specified) | Intravenous (Not Otherwise Specified)                            | Not Reported |
| Perfalgan                                                                               | S | Intravenous (not otherwise specified) |                                                                  | Not Reported |
| Solumedrol (Methylprednisolone Sodium Succinate ) (Methylprednisolone Sodium Succinate) | S | Intravenous (not otherwise specified) | 140 Mg, Daily, Intravenous (Not Otherwise Specified)             | Not Reported |
| Ultiva (Remifentanyl Hydrochloride) (Remifentanyl Hydrochloride)                        | S |                                       |                                                                  | Not Reported |
| Noctamide                                                                               | S | Oral<br>Oral                          |                                                                  | Not Reported |

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

|                                                                           |   |                                       |                |              |
|---------------------------------------------------------------------------|---|---------------------------------------|----------------|--------------|
| Lasilix (Furosemide)                                                      | S | Oral                                  |                | Not Reported |
| (Furosemide)                                                              |   |                                       |                |              |
| Heparin Sodium (Heparin Sodium)                                           | S |                                       | 7000 Milliunit | Not Reported |
| Granocyte (Lenograstim) (Injection) (Lenograstime)                        | S | Intravenous (not otherwise specified) |                | Not Reported |
| Colistin                                                                  | C |                                       |                | Not Reported |
| Vancomycin Hydrochloride                                                  | C |                                       |                | Not Reported |
| Ciflox (Ciprofloxacin) (Ciprofloxacin)                                    | C |                                       |                | Not Reported |
| Targocid (Teicoplanin) (Teicoplanin)                                      | C |                                       |                | Not Reported |
| Mycostatine (Nystatin) (Nystatin)                                         | C |                                       |                | Not Reported |
| Triflucan (Fluconazole) (Fluconazole)                                     | C |                                       |                | Not Reported |
| Zovirax (Aciclovir) (Aciclovir)                                           | C |                                       |                | Not Reported |
| Methotrexate (Methotrexate) (Methotrexate)                                | C |                                       |                | Not Reported |
| Elvorine (Calcium Levofolinate) (Calcium Levofolinate)                    | C |                                       |                | Not Reported |
| Sandimmun (Ciclosporin) (Ciclosporin)                                     | C |                                       |                | Not Reported |
| Mopral (Omeprazole) (Omeprazole)                                          | C |                                       |                | Not Reported |
| Ogastoro (Lansoprazole) (Lansoprazole)                                    | C |                                       |                | Not Reported |
| Gelox (Gelox) (Magnesium Hydroxide, Montmorillonite, Aluminium Hydroxide) | C |                                       |                | Not Reported |
| Smecta (Diosmectite) (Diosmectite)                                        | C |                                       |                | Not Reported |
| Luteran (Chlormadinone Acetate) (Chlormadinone Acetate)                   | C |                                       |                | Not Reported |
| Lexomil (Bromazepam) (Bromazepam)                                         | C |                                       |                | Not Reported |
| Zophren (Ondansetron Hydrochloride ) (Ondansetron Hydrochloride)          | C |                                       |                | Not Reported |
| Primperan (Metoclopramide Hydrochloride) (Metoclopramide Hydrochloride)   | C |                                       |                | Not Reported |

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

|                                                           |   |      |              |
|-----------------------------------------------------------|---|------|--------------|
| Acupan (Nefopam) (Nefopam)                                | C |      | Not Reported |
| Tiorfan (Acetorphan)<br>(Acetorphan)                      | C |      | Not Reported |
| Levocarnil (Levocarnitine)<br>(Levocarnitine)             | C |      | Not Reported |
| Atarax                                                    | S | Oral | Not Reported |
| Seroplex (Escitalopram Oxalate)<br>(Escitalopram Oxalate) | S | Oral | Not Reported |
| Ceris                                                     | S | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Jan-2014              | 9805415       | EXPEDITED (15-DAY) |                    | DE, OT          | US-UCBSA-108463      |                      | 86 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------------|--------------|------------|-------------|--------------|----------------------------------------|-----------------|--------------|
| Completed Suicide     | Acetaminophen /Hydrocodone |              |            | S           | Oral         | Route: Ingestion                       |                 | Not Reported |
|                       | Isosorbide Mononitrate     |              |            | S           | Oral         | Route: Ingestion                       |                 | Not Reported |
|                       | Amlodipine                 |              |            | S           | Oral         | Route: Ingestion                       |                 | Not Reported |
|                       | Doxazosin                  |              |            | S           | Oral         | Route : Ingestion,<br>Extended Release |                 | Not Reported |
|                       | Escitalopram               |              |            | S           | Oral         | Route: Ingestion                       |                 | Not Reported |
|                       | Warfarin                   |              |            | S           | Oral         | Route: Ingestion                       |                 | Not Reported |
|                       | Furosemide                 |              |            | S           | Oral         | Route: Ingestion                       |                 | Not Reported |
|                       | Levothyroxine              |              |            | S           | Oral         | Route: Ingestion                       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Jan-2014              | 9805882       | EXPEDITED (15-DAY) |                    | DE, OT          | US-UCBSA-108321      |                      | 55 YR      | Male       | USA            |

| <u>Preferred Term</u>                                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardio-Respiratory Arrest;<br>Completed Suicide;<br>Hyperthermia | Alprazolam     |              |            | S           |              |                    |                 | Not Reported |
|                                                                  | Vilazodone     |              |            | S           |              | Extended Release   |                 | Not Reported |
|                                                                  | Salicylate     |              |            | S           |              | Extended Release   |                 | Not Reported |
|                                                                  | Escitalopram   |              |            | S           |              |                    |                 | Not Reported |
|                                                                  | Duloxetine     |              |            | S           |              |                    |                 | Not Reported |

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

|                                                                                                                                                   |                               |                    |                    |                 |                      |                      |                 |              |                |
|---------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Clonazepam                                                                                                                                        |                               |                    | C                  |                 |                      | Not Reported         |                 |              |                |
| <u>FDA Received Date</u>                                                                                                                          | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Jan-2014                                                                                                                                       | 9690854                       | EXPEDITED (15-DAY) |                    | OT              | US-FRI-1000051153    |                      |                 | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                             | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Amnesia; Depression;<br>Dizziness; Emotional<br>Disorder; Hallucination;<br>Homicide; Hostility; Skin<br>Burning Sensation;<br>Suicidal Behaviour | Lexapro                       |                    |                    | S               |                      |                      |                 | Forest       |                |
|                                                                                                                                                   | Xanax                         |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                   | Klonopin                      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                   |                               |                    |                    |                 |                      |                      |                 |              |                |
| <u>FDA Received Date</u>                                                                                                                          | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Jan-2014                                                                                                                                       | 9807748                       | EXPEDITED (15-DAY) |                    | DE, OT          | US-UCBSA-108245      |                      | 47 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                             | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardio-Respiratory Arrest;<br>Completed Suicide                                                                                                   | Acetaminophen/Hydrocodone     |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                   | Alprazolam                    |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                   | Amlodipine                    |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                   | Carvedilol                    |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                   | Bupropion                     |                    |                    | S               |                      | Extended Release     |                 | Not Reported |                |
|                                                                                                                                                   | Citalopram                    |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                   | Escitalopram                  |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                          | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Jan-2014                                                                                                                                       | 9808808                       | EXPEDITED (15-DAY) |                    | DE              | US-BAYER-2014-004062 |                      | 55 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                             | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Toxicity To Various Agents                                                                                                                        | Paracetamol + Diphenhydramine | Y                  |                    | S               | Oral                 |                      |                 | Bayer        |                |
|                                                                                                                                                   | Citalopram                    |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                                                   | Escitalopram                  |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                                                   | Bupropion                     |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                            | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------|---------------------|--------------------|--------------------|-----------------|--------------------------|----------------------------------------|-----------------|--------------|----------------|
| 10-Jan-2014                                                                                         | 9813236             | DIRECT             |                    | OT              |                          |                                        | 48 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                               | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Disease Recurrence; Feeling Abnormal; Insomnia; Product Substitution Issue                 | Escitalopram        |                    |                    | S               | Oral                     | 1 Pill Once Daily Taken By 6 MTH Mouth |                 | Mylan        |                |
| <u>FDA Received Date</u>                                                                            | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Jan-2014                                                                                         | 9812582             | EXPEDITED (15-DAY) |                    | OT              | AU-ROCHE-1331759         |                                        | 46 YR           | Female       | AUS            |
| <u>Preferred Term</u>                                                                               | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Diabetes Mellitus; Hepatic Function Abnormal; Hepatic Steatosis; Renal Impairment; Weight Increased | Diazepam            |                    |                    | S               | Unknown                  |                                        |                 | Not Reported |                |
|                                                                                                     | Clopine             |                    |                    | S               | Oral                     |                                        |                 | Not Reported |                |
|                                                                                                     | Levetiracetam       |                    |                    | S               | Unknown                  |                                        |                 | Not Reported |                |
|                                                                                                     | Risperidone         |                    |                    | S               | Unknown                  |                                        |                 | Not Reported |                |
|                                                                                                     | Escitalopram        |                    |                    | S               | Unknown                  |                                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                            | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Jan-2014                                                                                         | 9812959             | EXPEDITED (15-DAY) |                    | DE              | US-PFIZER INC-2014006713 |                                        | 93 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                               | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                                                                   | Amlodipine Besilate |                    |                    | S               | Oral                     | Unk                                    |                 | Pfizer       |                |
|                                                                                                     | Escitalopram        |                    |                    | S               | Oral                     | Unk                                    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                            | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Jan-2014                                                                                         | 9813608             | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000052769        |                                        | < 1 DAY         | Female       | USA            |
| <u>Preferred Term</u>                                                                               | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |                |

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

|                                                        |         |   |                |        |
|--------------------------------------------------------|---------|---|----------------|--------|
| Congenital Anomaly;<br>Congenital Hand<br>Malformation | Lexapro | S | Transplacental | Forest |
|--------------------------------------------------------|---------|---|----------------|--------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Jan-2014              | 9814620       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000052791    |                      | 37 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                                               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                  | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|-----------------------------------------------------|-----------------|--------------|
| Depressed Level Of<br>Consciousness;<br>Electrocardiogram Qt<br>Prolonged; Overdose | Escitalopram   |              |            | S           | Oral         | 1 Df                                                |                 | Forest       |
|                                                                                     | Escitalopram   |              |            | S           | Oral         | Escitalopram 20 Mg<br>Overdose: 42 Tablets<br>Once. |                 | Not Reported |
|                                                                                     | Zopiclone      |              |            | S           | Oral         | 1 Df                                                |                 | Not Reported |
|                                                                                     | Zopiclone      |              |            | S           | Oral         | Zopiclone Overdose: 42<br>Tablets Once.             |                 | Not Reported |
|                                                                                     | Baclofen       |              |            | S           | Oral         | 1 Df                                                |                 | Not Reported |
|                                                                                     | Baclofen       |              |            | S           | Oral         | Baclofen Overdose: 20<br>Tablets Once.              |                 | Not Reported |
|                                                                                     | Alcohol        |              |            | S           |              |                                                     |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Jan-2014              | 9814623       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000052784    |                      | 87 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                              | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                        | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------|--------------------|--------------|------------|-------------|--------------|-------------------------------------------|-----------------|--------------|
| International Normalised<br>Ratio Increased; Subdural<br>Haematoma | Escitalopram       |              |            | S           | Oral         | 1 Df                                      |                 | Forest       |
|                                                                    | Minisintrom        |              |            | S           |              | 1 Mg On Even Days And 2<br>Mg On Odd Days |                 | Not Reported |
|                                                                    | Actiskenan         |              |            | C           |              | 5 Mg                                      |                 | Not Reported |
|                                                                    | Triatec (Ramipril) |              |            | C           |              | 5 Mg                                      |                 | Not Reported |
|                                                                    | Seresta            |              |            | C           |              | 10 Mg                                     |                 | Not Reported |
|                                                                    | Primperan          |              |            | C           |              | 30 Mg                                     |                 | Not Reported |
|                                                                    | Atarax             |              |            | C           |              | 75 Mg                                     |                 | Not Reported |

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

|            |   |                      |              |
|------------|---|----------------------|--------------|
| Cacit D3   | C | 1 Df                 | Not Reported |
| Cardensiel | C | 3.75 Mg              | Not Reported |
| Dafalgan   | C | 3 Grams (Systematic) | Not Reported |
| Lantus     | C | 600 Iu/MI            | Not Reported |
| Lasilix    | C | 375 Mg               | Not Reported |
| Macrogol   | C | 2 Df (Systematic)    | Not Reported |
| Polaramine | C | 6 Mg                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Jan-2014              | 9814642       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000052785    |                      | 85 YR      | Female     | FRA            |

| <u>Preferred Term</u>                   | <u>Product</u>                                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------|------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cerebral Haematoma;<br>Drug Interaction | Escitalopram                                   |              |            | S           | Oral         | 1 Df               |                 | Forest       |
|                                         | Pradaxa                                        |              |            | S           | Oral         | 2 Df               |                 | Not Reported |
|                                         | Meteospasmyl (Alverine<br>Citrate\Dimethicone) |              |            | C           | Oral         | 2 Df               |                 | Not Reported |
|                                         | Forlax                                         |              |            | C           | Oral         | 4 Gram             |                 | Not Reported |
|                                         | Furosemide                                     |              |            | C           | Oral         | 40 Mg              |                 | Not Reported |
|                                         | Hemigoxine Nativelle                           |              |            | C           | Oral         |                    |                 | Not Reported |
|                                         | Kaleorid                                       |              |            | C           | Oral         | 1 Df               |                 | Not Reported |
|                                         | Zolpidem                                       |              |            | C           | Oral         | 1 Df               |                 | Not Reported |
|                                         | Doliprane                                      |              |            | C           | Oral         | 3 Df               |                 | Not Reported |
|                                         | Exelon                                         |              |            | C           | Transdermal  | 1 Df               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 14-Jan-2014              | 9814750       | EXPEDITED (15-DAY) |                    | DE              | US-PFIZER INC-<br>2014006378 |                      | 55 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiac Arrest; Completed<br>Suicide; Overdose;<br>Respiratory Arrest | Alprazolam     |              |            | S           |              | Unk                |                 | Pfizer       |
|                                                                       | Vilazodone     |              |            | S           |              | Unk                |                 | Not Reported |



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

|              |   |     |              |
|--------------|---|-----|--------------|
| Salicylate   | S | Unk | Not Reported |
| Escitalopram | S | Unk | Not Reported |
| Duloxetine   | S | Unk | Not Reported |

| <u>FDA Received Date</u>                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------|----------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 14-Jan-2014                                           | 9815834        | EXPEDITED (15-DAY) |                    | DE              | US-PFIZER INC-2014006473 |                      | 45 YR           | Female       | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Completed Suicide; Respiratory Arrest | Alprazolam     |                    |                    | S               | Oral                     | Unk                  |                 | Pfizer       |                |
|                                                       | Escitalopram   |                    |                    | S               | Oral                     | Unk                  |                 | Not Reported |                |
|                                                       | Zolpidem       |                    |                    | S               | Oral                     | Unk                  |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 14-Jan-2014              | 9816088                    | EXPEDITED (15-DAY) |                    | DE              | US-PFIZER INC-2014006827 |                      | 86 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide        | Amlodipine Besilate        |                    |                    | S               | Oral                     | Unk                  |                 | Pfizer       |                |
|                          | Doxazosin Mesilate         |                    |                    | S               | Oral                     | Unk                  |                 | Pfizer       |                |
|                          | Furosemide                 |                    |                    | S               | Oral                     | Unk                  |                 | Unknown      |                |
|                          | Levothyroxine Sodium       |                    |                    | S               | Oral                     | Unk                  |                 | Pfizer       |                |
|                          | Acetaminophen/ Hydrocodone |                    |                    | S               | Oral                     | Unk                  |                 | Not Reported |                |
|                          | Isosorbide Mononitrate     |                    |                    | S               | Oral                     | Unk                  |                 | Not Reported |                |
|                          | Escitalopram               |                    |                    | S               | Oral                     | Unk                  |                 | Not Reported |                |
|                          | Warfarin                   |                    |                    | S               | Oral                     | Unk                  |                 | Not Reported |                |
|                          | Potassium                  |                    |                    | S               | Oral                     | Unk                  |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|------------|----------------|
| 14-Jan-2014              | 9816391        | EXPEDITED (15-DAY) |                    | HO              | FR-ABBVIE-14P-056-1187902-00 |                      | 42 YR           | Male       | FRA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

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

|                                     |           |   |      |              |
|-------------------------------------|-----------|---|------|--------------|
| Coma; Intentional Overdose; Seizure | Depakote  | S | Oral | Not Reported |
|                                     | Depakote  | S | Oral | Not Reported |
|                                     | Tercian   | S | Oral | Not Reported |
|                                     | Tercian   | S | Oral | Not Reported |
|                                     | Teralithe | S | Oral | Not Reported |
|                                     | Teralithe | S | Oral | Not Reported |
|                                     | Theralene | S | Oral | Not Reported |
|                                     | Theralene | S | Oral | Not Reported |
|                                     | Seroplex  | S | Oral | Not Reported |
|                                     | Seroplex  | S | Oral | Not Reported |
|                                     | Xanax     | S | Oral | Not Reported |
|                                     | Abilify   | S | Oral | Not Reported |
|                                     | Lysanxia  | C |      | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------------------|----------------------|------------|------------|----------------|
| 14-Jan-2014              | 9816649       | EXPEDITED (15-DAY) | HO                 |                 | FR-ELI_LILLY_AND_COMP<br>ANY-FR201401000023 |                      | 58 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                                                                                                            | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>       |
|--------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------------|
| Hypocalcaemia;<br>Hyponatraemia;<br>Inappropriate Antidiuretic<br>Hormone Secretion;<br>Nausea; Sleep Disorder;<br>Thrombocytopenia;<br>Vomiting | Cymbalta            |              |            | S           | Oral         | Unk, Unknown       |                 | Eli Lilly And Co |
|                                                                                                                                                  | Seroplex            |              |            | S           | Oral         | Unk, Unknown       |                 | Not Reported     |
|                                                                                                                                                  | Atarax /00595201/   |              |            | S           | Oral         | Unk, Unknown       |                 | Not Reported     |
|                                                                                                                                                  | Diffu K             |              |            | C           | Unknown      | Unk, Unknown       |                 | Not Reported     |
|                                                                                                                                                  | Lamaline /01708901/ |              |            | C           | Unknown      | Unk, Unknown       |                 | Not Reported     |
|                                                                                                                                                  | Lercanidipine       |              |            | C           | Unknown      | Unk, Unknown       |                 | Not Reported     |
|                                                                                                                                                  | Esomeprazole        |              |            | C           | Unknown      | Unk, Unknown       |                 | Not Reported     |
|                                                                                                                                                  | Bisoprolol          |              |            | C           | Unknown      | Unk, Unknown       |                 | Not Reported     |
|                                                                                                                                                  | Aotal               |              |            | C           | Unknown      | Unk, Unknown       |                 | Not Reported     |
|                                                                                                                                                  | Alfuzosine L.P.     |              |            | C           | Unknown      | Unk, Unknown       |                 | Not Reported     |
|                                                                                                                                                  | Uvedose             |              |            | C           | Unknown      | Unk, Unknown       |                 | Not Reported     |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                              | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------|----------------------------|--------------------|--------------------|-----------------|--------------------------|-----------------------------------------|-----------------|--------------|----------------|
| 14-Jan-2014                                           | 9816731                    | EXPEDITED (15-DAY) |                    | DE              | US-PFIZER INC-2014007226 |                                         | 47 YR           | Female       | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                      | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Completed Suicide; Respiratory Arrest | Amlodipine Besilate        |                    |                    | S               | Oral                     | Unk                                     |                 | Pfizer       |                |
|                                                       | Alprazolam                 |                    |                    | S               | Oral                     | Unk                                     |                 | Pfizer       |                |
|                                                       | Carvedilol                 |                    |                    | S               | Oral                     | Unk                                     |                 | Not Reported |                |
|                                                       | Bupropion                  |                    |                    | S               | Oral                     | Unk                                     |                 | Not Reported |                |
|                                                       | Acetaminophen/ Hydrocodone |                    |                    | S               | Oral                     | Unk                                     |                 | Not Reported |                |
|                                                       | Citalopram                 |                    |                    | S               | Oral                     | Unk                                     |                 | Not Reported |                |
|                                                       | Escitalopram               |                    |                    | S               | Oral                     | Unk                                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Jan-2014                                           | 9816917                    | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000052854        |                                         | 42 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                 | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                      | <u>Duration</u> | <u>Mfr</u>   |                |
| Coma; Intentional Overdose; Seizure                   | Escitalopram               |                    |                    | S               | Oral                     | 10 Mg                                   |                 | Forest       |                |
|                                                       | Escitalopram               |                    |                    | S               | Oral                     | Overdose :22 Tablets (220 Mg ) Once     |                 | Forest       |                |
|                                                       | Theralene                  |                    |                    | S               | Oral                     | 20 Drops On Evening                     |                 | Not Reported |                |
|                                                       | Theralene                  |                    |                    | S               | Oral                     | Overdose : 1 Bottle Once                |                 | Not Reported |                |
|                                                       | Tercian                    |                    |                    | S               | Oral                     | 20 Df                                   |                 | Not Reported |                |
|                                                       | Tercian                    |                    |                    | S               | Oral                     | Overdose : 1 Bottle Once                |                 | Not Reported |                |
|                                                       | Depakote                   |                    |                    | S               | Oral                     | 1000 Mg                                 |                 | Not Reported |                |
|                                                       | Depakote                   |                    |                    | S               | Oral                     | Overdose : 60 Tablets (30 Grams ) Once  |                 | Not Reported |                |
|                                                       | Theralithe Lp              |                    |                    | S               | Oral                     |                                         |                 | Not Reported |                |
|                                                       | Theralithe Lp              |                    |                    | S               | Oral                     | Overdose : 210 Tablets (84 Grams ) Once |                 | Not Reported |                |
|                                                       | Xanax                      |                    |                    | S               | Oral                     | Overdose : 100 Df Once                  |                 | Not Reported |                |

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

|          |   |      |                  |              |
|----------|---|------|------------------|--------------|
| Abilify  | S | Oral | Overdose : 14 Df | Not Reported |
| Lysanxia | C |      | 10 Mg            | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Jan-2014              | 9816935       | EXPEDITED (15-DAY) |                    | HO, OT          | PHHY2014BR002544     |                      | 74 YR      | Male       | BRA            |

| <u>Preferred Term</u>                                                                                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|---------------------|-----------------|--------------|
| Blood Sodium Decreased;<br>Depression; Dizziness;<br>Haemorrhage Urinary<br>Tract; Urinary Tract<br>Infection | Exelon Patch   |              |            | S           | Transdermal  | 9.5 Mg, Daily       |                 | Not Reported |
|                                                                                                               | Enalapril      |              |            | S           |              | Unk Ukn, Unk        |                 | Novartis     |
|                                                                                                               | Lexapro        |              |            | S           |              | 1 Df, Qd (At Night) |                 | Not Reported |
|                                                                                                               | Prolopa        |              |            | C           |              | Unk Ukn, Unk        |                 | Not Reported |
|                                                                                                               | Losartan       |              |            | C           |              | Unk Ukn, Unk        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Jan-2014              | 9820461       | EXPEDITED (15-DAY) | Y                  | HO              | 2014HINLIT0002       |                      | 65 YR      | Female     | IND            |

| <u>Preferred Term</u>                                   | <u>Product</u>                          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                             | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------|-----------------------------------------|--------------|------------|-------------|------------------------------------------|--------------------|-----------------|--------------|
| Drug Interaction;<br>Pneumonitis; Serotonin<br>Syndrome | Escitalopram                            |              |            | S           | Intravenous (not<br>otherwise specified) |                    |                 | Not Reported |
|                                                         | Linezolid                               |              |            | S           |                                          |                    |                 | Not Reported |
|                                                         | Clonazepam (Clonazepam)<br>(Clonazepam) |              |            | C           |                                          |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Jan-2014              | 9818294       | EXPEDITED (15-DAY) |                    | LT, OT          | GB-FRI-1000052810    |                      |            | Male       | GBR            |

| <u>Preferred Term</u>                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| General Physical Health<br>Deterioration | Escitalopram   |              |            | S           | Oral         | 30 Mg              |                 | Forest       |
|                                          | Priadel        |              |            | S           |              | 1000 Mg            |                 | Not Reported |
|                                          | Zyprexa        |              |            | S           |              | 15 Mg              |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                            | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------|-----------------------|--------------------|--------------------|-----------------|------------------------------------------|----------------------|-----------------|--------------|----------------|
| 15-Jan-2014                                                                                                         | 9819598               | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000052763                        |                      | < 1 DAY         | Unknown      | USA            |
| <u>Preferred Term</u>                                                                                               | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Congenital Anomaly;<br>Gastroschisis                                                                                | Lexapro               |                    |                    | S               | Transplacental                           |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                            | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Jan-2014                                                                                                         | 9822192               | EXPEDITED (15-DAY) | Y                  | HO              | MAC2014000828                            |                      | 65 YR           | Female       | IND            |
| <u>Preferred Term</u>                                                                                               | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State; Drug<br>Interaction; Hyperhidrosis;<br>Hypoxia; Myoclonus;<br>Pneumonitis; Serotonin<br>Syndrome | Escitalopram Oxalate  |                    |                    | S               | Intravenous (not<br>otherwise specified) |                      |                 | Not Reported |                |
|                                                                                                                     | Linezolid             |                    |                    | S               |                                          |                      |                 | Not Reported |                |
|                                                                                                                     | Clonazepam            |                    |                    | C               |                                          |                      |                 | Not Reported |                |
|                                                                                                                     | Etofylline            |                    |                    | C               |                                          |                      |                 | Not Reported |                |
|                                                                                                                     | Guaifenesin           |                    |                    | C               |                                          |                      |                 | Not Reported |                |
|                                                                                                                     | Ambroxol              |                    |                    | C               |                                          |                      |                 | Not Reported |                |
|                                                                                                                     | Amoxicillin           |                    |                    | C               |                                          |                      |                 | Not Reported |                |
|                                                                                                                     | Clavulanate Potassium |                    |                    | C               |                                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                            | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Jan-2014                                                                                                         | 9825394               | DIRECT             | Y                  | OT              |                                          |                      | 56 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                               | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Product<br>Substitution Issue                                                                           | Escitalopram          |                    |                    | S               |                                          |                      | 1 MTH           | Not Reported |                |
|                                                                                                                     | Cymbalta              |                    |                    | C               |                                          |                      |                 | Not Reported |                |
|                                                                                                                     | Buspar                |                    |                    | C               |                                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                            | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Jan-2014                                                                                                         | 9434810               | EXPEDITED (15-DAY) |                    | HO, LT          | FR-FRI-1000047327                        |                      | 86 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                               | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

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

|                                  |              |   |      |      |              |
|----------------------------------|--------------|---|------|------|--------------|
| Haematoma; Subdural<br>Haematoma | Escitalopram | S | Oral | 1 Df | Forest       |
|                                  | Plavix       | S | Oral |      | Not Reported |
|                                  | Ramipril     | C |      |      | Not Reported |
|                                  | Furosemide   | C |      |      | Not Reported |
|                                  | Diffu K      | C |      |      | Not Reported |
|                                  | Norset       | C |      |      | Not Reported |
|                                  | Imovane      | C |      |      | Not Reported |
|                                  | Lexomil      | C |      |      | Not Reported |
|                                  | Tramadol     | C |      |      | Not Reported |
|                                  | Paracetamol  | C |      |      | Not Reported |
|                                  | Diclofenac   | C |      |      | Not Reported |
|                                  | Aranesp      | C |      |      | Not Reported |
|                                  | Movicol      | C |      |      | Not Reported |
|                                  | Uvedose      | C |      |      | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Jan-2014              | 9814579       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000052782    |                      | 26 YR      | Male       | FRA            |

| <u>Preferred Term</u>         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                        | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------|----------------|--------------|------------|-------------|--------------|-------------------------------------------|-----------------|--------------|
| Coma; Intentional<br>Overdose | Escitalopram   |              |            | S           | Oral         |                                           |                 | Forest       |
|                               | Escitalopram   |              |            | S           | Oral         | Escitalopram Overdose:<br>Unknown Amount. |                 | Not Reported |
|                               | Bromazepam     |              |            | S           | Oral         |                                           |                 | Not Reported |
|                               | Bromazepam     |              |            | S           | Oral         | Bromazepam Overdose:<br>Unknown Amount.   |                 | Not Reported |
|                               | Zopiclone      |              |            | S           | Oral         |                                           |                 | Not Reported |
|                               | Zopiclone      |              |            | S           | Oral         | Zopiclone Overdose:<br>Unknown Amount.    |                 | Not Reported |
|                               | Tercian        |              |            | S           | Oral         |                                           |                 | Not Reported |
|                               | Tercian        |              |            | S           | Oral         | Cyamemazine Overdose:<br>Unknown Amount.  |                 | Not Reported |
|                               | Alcohol        |              |            | S           |              |                                           |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 16-Jan-2014              | 9821769       | NON-EXPEDITED    |                    |                 | US-PFIZER INC-<br>2014012703 |                      | 84 YR      | Female     | USA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                                                                                                                                                  | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| Drug Hypersensitivity                                                                                                                                                                                  | Lipitor             |                    |                    | S               |                            | Unk                  |                 | Pfizer       |                |
|                                                                                                                                                                                                        | Fosamax             |                    |                    | S               |                            | Unk                  |                 | Not Reported |                |
|                                                                                                                                                                                                        | Lexapro             |                    |                    | S               |                            | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                               | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Jan-2014                                                                                                                                                                                            | 9821899             | EXPEDITED (15-DAY) |                    | HO, OT          | CA-ASTRAZENECA-2014SE02626 |                      |                 | Female       | CAN            |
| <u>Preferred Term</u>                                                                                                                                                                                  | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Electrocardiogram Qt Prolonged; Fibula Fracture; Syncope; Tibia Fracture                                                                                                                               | Seroquel            |                    |                    | S               | Oral                       |                      |                 | Zeneca       |                |
|                                                                                                                                                                                                        | Ciprallex           |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                                                                                                                                                                        | Ethanol             |                    |                    | C               |                            |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                               | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Jan-2014                                                                                                                                                                                            | 9821923             | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000052856          |                      | 46 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                                  | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Amnesia; Suicide Attempt; Urinary Tract Disorder                                                                                                                                                       | Escitalopram        |                    |                    | S               | Oral                       |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                                                                                               | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Jan-2014                                                                                                                                                                                            | 9822088             | EXPEDITED (15-DAY) |                    | HO              | PHHY2013CA149171           |                      | 83 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                                                                                                                                                                  | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain Upper; Balance Disorder; Bradycardia; Dizziness; Drug Ineffective; Fall; Headache; Hypotension; Mobility Decreased; Nausea; Orthostatic Hypotension; Pain; Panic Attack; Sleep Disorder | Metoprolol          |                    |                    | S               |                            | 50 Mg, Per Day       |                 | Novartis     |                |
|                                                                                                                                                                                                        | Metoprolol          |                    |                    | S               |                            | 25 Mg, Qd            |                 | Novartis     |                |
|                                                                                                                                                                                                        | Amlodipine          |                    |                    | S               |                            | 2.5 Mg, Bid          |                 | Not Reported |                |
|                                                                                                                                                                                                        | Amlodipine          |                    |                    | S               |                            | 2.5 Mg, Daily        |                 | Not Reported |                |
|                                                                                                                                                                                                        | Ramipril            |                    |                    | S               |                            | 5 Mg, Qd             |                 | Not Reported |                |
|                                                                                                                                                                                                        | Glyceryl Trinitrate |                    |                    | S               | Transdermal                | 0.4 Mg, Bid (Patch)  |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                     |   |                             |              |
|---------------------|---|-----------------------------|--------------|
| Glyceryl Trinitrate | S | 0.4 Mg, Qd                  | Not Reported |
| Escitalopram        | S | 10 Mg, Qd                   | Not Reported |
| Escitalopram        | S |                             | Not Reported |
| Zopiclone           | S | 5 Mg, Qd                    | Not Reported |
| Zopiclone           | S | 2.5 Mg, Qd                  | Not Reported |
| Furosemide          | S | 40 Mg, Qd                   | Not Reported |
| Furosemide          | S | 20 Mg, Daily                | Not Reported |
| Oxazepam            | S | 10 Mg, Bid                  | Not Reported |
| Codeine Phosphate   | S | 30 Mg, Bid                  | Not Reported |
| Codeine Phosphate   | S | 30 Mg, Tid                  | Not Reported |
| Clopidogrel         | C | 75 Mg, Qd                   | Not Reported |
| Clopidogrel         | C |                             | Not Reported |
| Clopidogrel         | C |                             | Not Reported |
| Atorvastatin        | C | 80 Mg, Qd                   | Not Reported |
| Atorvastatin        | C |                             | Not Reported |
| Vitamin D Nos       | C | 1000 Iu, Unk                | Not Reported |
| Vitamin D           | C | 1000 Iu, Tid                | Not Reported |
| Acetaminophen       | C | 500 Mg, Bid                 | Not Reported |
| Acetaminophen       | C | 500 Mg, Qid                 | Not Reported |
| Polyethylene Glycol | C |                             | Not Reported |
| Pure Vitamin C      | C |                             | Not Reported |
| Rabeprazole         | C | 10 Mg, Per Day, For 2 Weeks | Not Reported |
| Pantoprazole        | C | 40 Mg, Qd                   | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Jan-2014              | 9822384       | EXPEDITED (15-DAY) |                    | CA, DE          | US-FRI-1000052761    |                      | < 1 DAY    | Female     | USA            |

| <u>Preferred Term</u>                                                                              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|----------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|------------|
| Atrial Septal Defect; Atrial Septal Defect; Coarctation Of The Aorta; Left Ventricle Outflow Tract | Lexapro        |              |            | S           | Transplacental |                    |                 | Forest     |



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

Obstruction; Patent  
Ductus Arteriosus;  
Pulmonary Hypertension;  
Right Ventricle Outflow  
Tract Obstruction;  
Ventricular Septal Defect

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Jan-2014              | 9822946       | EXPEDITED (15-DAY) |                    | DE, LT          | NO-FRI-1000052849    |                      | 20 YR      | Female     | NOR            |

| <u>Preferred Term</u>                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------|----------------|--------------|------------|-------------|--------------|-------------------------------------|-----------------|--------------|
| Completed Suicide;<br>Intentional Self-Injury | Escitalopram   |              |            | S           | Oral         | Strength: 50 Mg-200 Mg              |                 | Forest       |
|                                               | Citalopram     |              |            | S           |              |                                     |                 | Forest       |
|                                               | Nobligan       |              |            | S           |              |                                     |                 | Not Reported |
|                                               | Imovane        |              |            | S           |              |                                     |                 | Not Reported |
|                                               | Lamictal       |              |            | S           |              | Strength: 25 Mg, 50 Mg,<br>100 Mg   |                 | Not Reported |
|                                               | Pinex Forte    |              |            | S           |              | Strength: 500/30 Mg And<br>Pandeine |                 | Not Reported |
|                                               | Seroquel       |              |            | S           |              | Strength: 5 Mg-10 Mg                |                 | Not Reported |
|                                               | Sobril         |              |            | S           |              |                                     |                 | Not Reported |
|                                               | Oxynorm        |              |            | S           |              |                                     |                 | Not Reported |
|                                               | Remeron        |              |            | S           |              |                                     |                 | Not Reported |
|                                               | Sarotex        |              |            | S           |              | Strength: 600 Mg-1200 Mg            |                 | Not Reported |
|                                               | Rivotril       |              |            | S           |              |                                     |                 | Not Reported |
|                                               | Orfiril        |              |            | S           |              |                                     |                 | Not Reported |
|                                               | Atarax         |              |            | S           |              | Strength: 25 Mg To 50 Mg            |                 | Not Reported |
|                                               | Tramadol       |              |            | S           |              |                                     |                 | Not Reported |
|                                               | Vival          |              |            | S           |              |                                     |                 | Not Reported |
|                                               | Nozinan        |              |            | S           |              |                                     |                 | Not Reported |
|                                               | Truxal         |              |            | S           |              |                                     |                 | Not Reported |
|                                               | Catapresan     |              |            | S           |              |                                     |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Jan-2014              | 9823240       | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000052793    |                      | < 1 DAY    | Female     | USA            |

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

| <u>Preferred Term</u>                                                                                        | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
|--------------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|--------------------------------------|----------------------|-----------------|-----------------|----------------|
| Congenital Torticollis;<br>Deafness; Heart Disease<br>Congenital; Plagiocephaly;<br>Spine Malformation       | Lexapro                 |                    |                    | S               | Transplacental                       |                      |                 | Forest          |                |
| <u>FDA Received Date</u>                                                                                     | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 16-Jan-2014                                                                                                  | 9824192                 | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000052795                    |                      | < 1 DAY         | Male            | USA            |
| <u>Preferred Term</u>                                                                                        | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Congenital Anomaly;<br>Transposition Of The<br>Great Vessels                                                 | Lexapro                 |                    |                    | S               | Transplacental                       |                      |                 | Forest          |                |
| <u>FDA Received Date</u>                                                                                     | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 16-Jan-2014                                                                                                  | 9825761                 | DIRECT             |                    | LT              |                                      |                      | 43 YR           | Male            | USA            |
| <u>Preferred Term</u>                                                                                        | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Dizziness; Drug<br>Ineffective; Nausea                                                                       | Lexapro Or Escitalopram |                    |                    | S               |                                      |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                     | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 17-Jan-2014                                                                                                  | 9809023                 | EXPEDITED (15-DAY) |                    | HO              | FR-<br>GLAXOSMITHKLINE-<br>B0957260A |                      | 91 YR           | Female          | FRA            |
| <u>Preferred Term</u>                                                                                        | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Anaemia; Drug Interaction;<br>Dyspnoea; Ecchymosis;<br>Fatigue; Haematoma;<br>Incorrect Dose<br>Administered | Arixtra                 |                    |                    | S               | Subcutaneous                         | 5mg Per Day          |                 | Glaxosmithkline |                |
|                                                                                                              | Plavix                  |                    |                    | S               | Oral                                 | 75mg Per Day         |                 | Unknown         |                |
|                                                                                                              | Seroplex                |                    |                    | S               | Oral                                 | 10mg Per Day         |                 | Unknown         |                |
|                                                                                                              | Celluvisc               |                    |                    | C               | Ophthalmic                           |                      |                 | Not Reported    |                |
|                                                                                                              | Cordarone               |                    |                    | C               | Oral                                 |                      |                 | Not Reported    |                |
|                                                                                                              | Tardyferon              |                    |                    | C               |                                      |                      |                 | Not Reported    |                |
|                                                                                                              | Alprazolam              |                    |                    | C               |                                      |                      |                 | Glaxosmithkline |                |
|                                                                                                              | Amlor                   |                    |                    | C               |                                      |                      |                 | Glaxosmithkline |                |

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

|                                                                                                                     |      |                 |
|---------------------------------------------------------------------------------------------------------------------|------|-----------------|
| Cetirizine Dichlorhydrate                                                                                           | C    | Glaxosmithkline |
| Mestinon                                                                                                            | C    | Not Reported    |
| Ebixa                                                                                                               | C    | Glaxosmithkline |
| Furadantine                                                                                                         | C    | Glaxosmithkline |
| Dafalgan                                                                                                            | C    | Glaxosmithkline |
| Transipeg (Polyethylene Glycol 3350\Potassium Chloride\Sodium Bicarbonate\Sodium Chloride\Sodium Sulfate Anhydrous) | C    | Not Reported    |
| Inexium                                                                                                             | C    | Glaxosmithkline |
|                                                                                                                     | Oral |                 |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 17-Jan-2014              | 9827187       | EXPEDITED (15-DAY) |                    | DS              | CA-009507513-1401CAN005496 |                      | 83 YR      | Female     | CAN            |

| <u>Preferred Term</u>                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                         | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------|----------------|--------------|------------|-------------|--------------|------------------------------------------------------------|-----------------|--------------|
| Dizziness; Fall; Orthostatic Hypotension | Nitro-Dur      |              |            | S           | Unknown      | 0.4 Mg Patch, 2 On At 9 Am And Off At 10 Pm, Rotating Site |                 | Merck        |
|                                          | Nitro-Dur      |              |            | S           | Unknown      | Single 0.4 Microgram Patch On For 12 H, Off For 12 H       |                 | Merck        |
|                                          | Metoprolol     |              |            | S           | Oral         | Half A 50 Mg Tablet Twice Daily                            |                 | Not Reported |
|                                          | Metoprolol     |              |            | S           | Oral         | 25 Mg, Qd                                                  |                 | Not Reported |
|                                          | Metoprolol     |              |            | S           | Oral         | 12.5 Mg, Bid                                               |                 | Not Reported |
|                                          | Amlodipine     |              |            | S           | Oral         | Half A 5 Mg Tablet Twice Daily                             |                 | Not Reported |
|                                          | Amlodipine     |              |            | S           | Oral         | 2.5 Mg, Qd                                                 |                 | Not Reported |
|                                          | Furosemide     |              |            | S           | Oral         | 40 Mg Every Morning                                        |                 | Merck        |
|                                          | Furosemide     |              |            | S           | Oral         | 20 Mg/Daily For 1 Week                                     |                 | Merck        |
|                                          | Escitalopram   |              |            | S           | Unknown      | 10 Mg, Every Morning                                       |                 | Not Reported |
|                                          | Escitalopram   |              |            | S           |              |                                                            |                 | Not Reported |
|                                          | Zopiclone      |              |            | S           | Unknown      | 5 Mg At Bedtime                                            |                 | Not Reported |

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

|                                     |   |         |                                                    |              |
|-------------------------------------|---|---------|----------------------------------------------------|--------------|
| Zopiclone                           | S | Unknown | 2.5 Mg, Every Night For 3 Weeks                    | Not Reported |
| Oxazepam                            | S | Oral    | 2, 10 Mg At Bedtime                                | Not Reported |
| Oxazepam                            | S | Oral    | 15 Mg, Every Night For 2}3 Weeks                   | Not Reported |
| Oxazepam                            | S | Oral    | 10 Mg, Every Night For 2}3 Weeks                   | Not Reported |
| Oxazepam                            | S | Oral    | 5 Mg, Every Night For 2}3 Weeks                    | Not Reported |
| Oxazepam                            | S | Oral    | 5 Mg, Every Other Day Or As Needed Nutil Able Stop | Not Reported |
| Ramipril                            | C | Unknown | 5 Mg, Every Morning                                | Not Reported |
| Atorvastatin                        | C |         | 80 Mg, At Bedtime                                  | Not Reported |
| Atorvastatin                        | C |         |                                                    | Not Reported |
| Atorvastatin                        | C |         |                                                    | Not Reported |
| Vitamin D (Unspecified)             | C | Unknown | 1000 Iu, Qd                                        | Not Reported |
| Vitamin D (Unspecified)             | C | Unknown | 3000 Iu, Qd                                        | Not Reported |
| Clopidogrel                         | C | Unknown | 75 Mg, Every Morning                               | Not Reported |
| Clopidogrel                         | C |         |                                                    | Not Reported |
| Clopidogrel                         | C |         |                                                    | Not Reported |
| Hydroxychloroquine Sulfate          | C | Unknown | 200 Mg, At Supper                                  | Not Reported |
| Pantoprazole                        | C | Unknown | 40 Mg, Every Morning                               | Not Reported |
| Pantoprazole                        | C | Unknown | 40 Mg, Qd                                          | Not Reported |
| Polyethylene Glycol                 | C | Unknown | Eye Drops As Needed                                | Not Reported |
| Acetaminophen (+) Codeine Phosphate | C | Unknown | 30 Mg, Bid As Needed                               | Not Reported |
| Acetaminophen                       | C | Oral    | 500 Mg, 4 Times A Day                              | Not Reported |
| Acetaminophen                       | C |         | 1000 Mg, Unk                                       | Not Reported |
| Codeine                             | C | Unknown | 30 Mg, 3 Times Daily As Needed                     | Not Reported |
| Codeine                             | C |         | 30 Mg, 3 Times Daily Regularly                     | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                             | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|-----------------------|-----------------------------|-----------------|--------------|----------------|
| 17-Jan-2014                                                          | 9837548                       | DIRECT             |                    | OT              |                       |                             | 31 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Heart Rate Increased; Hyperventilation; Panic Attack        | Lexapro                       |                    |                    | S               | Oral                  | 1 Pill Taken By Mouth       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                             | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Jan-2014                                                          | 9837618                       | DIRECT             |                    | OT              |                       |                             | 49 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Anger; Anxiety; Crying; Drug Ineffective; Product Substitution Issue | Escitalopram                  |                    |                    | S               | Oral                  | 1 Once Daily Taken By Mouth |                 | Mylan        |                |
| <u>FDA Received Date</u>                                             | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Jan-2014                                                          | 9828833                       | EXPEDITED (15-DAY) |                    | DE              | US-JNJFOC-20140108717 |                             | 55 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Toxicity To Various Agents                        | Acetaminophen/Diphenhydramine |                    | Y                  | S               | Oral                  |                             |                 | Not Reported |                |
|                                                                      | Citalopram                    |                    |                    | S               | Oral                  |                             |                 | Not Reported |                |
|                                                                      | Escitalopram                  |                    |                    | S               | Oral                  |                             |                 | Not Reported |                |
|                                                                      | Bupropion                     |                    |                    | S               | Oral                  |                             |                 | Not Reported |                |
|                                                                      | Clonazepam                    |                    |                    | S               | Oral                  |                             |                 | Not Reported |                |
|                                                                      | Tadalafil                     |                    |                    | S               | Oral                  |                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                             | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Jan-2014                                                          | 8260806                       | EXPEDITED (15-DAY) |                    | CA, HO, OT      | US-JNJFOC-20111107265 |                             |                 | Female       | USA            |

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

| <u>Preferred Term</u>                                                                                                                                                                                                                                         | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Bradycardia; Cleft Palate;<br>Conductive Deafness;<br>Eustachian Tube<br>Dysfunction; Feeding<br>Disorder; Fistula; Infantile<br>Apnoea; Jaundice<br>Neonatal; Motor<br>Developmental Delay;<br>Otitis Media Chronic;<br>Speech Disorder; Weight<br>Decreased | Topamax           |              |            | S           | Transplacental |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                               | Paracetamol       |              | Y          | S           | Transplacental |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                               | Paracetamol       |              |            | S           | Transplacental |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                               | Lexapro           |              |            | S           | Transplacental |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                               | Levothyroxine     |              |            | S           | Transplacental |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                               | Vicodin           |              |            | S           | Transplacental |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                               | Suboxone          |              |            | S           | Transplacental |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                               | Prenatal Vitamins |              |            | S           | Transplacental |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                               | Opioids Nos       |              |            | S           | Transplacental |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                               | Subutex           |              |            | S           | Transplacental |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Jan-2014              | 9829728       | EXPEDITED (15-DAY) |                    | HO, OT          | IN-ACCORD-021279     |                      | 65 YR      | Female     | IND            |

| <u>Preferred Term</u>                                  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                             | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------|----------------|--------------|------------|-------------|------------------------------------------|--------------------|-----------------|--------------|
| Drug Interaction;<br>Serotonin Syndrome;<br>Somnolence | Clonazepam     |              |            | S           | Intravenous (not<br>otherwise specified) |                    |                 | Accord       |
|                                                        | Escitalopram   |              |            | S           |                                          |                    |                 | Accord       |
|                                                        | Linezolid      |              |            | S           |                                          |                    |                 | Not Reported |
|                                                        | Guaifenesin    |              |            | C           |                                          |                    |                 | Not Reported |
|                                                        | Paracetamol    |              |            | C           |                                          |                    |                 | Not Reported |
|                                                        | Ambroxol       |              |            | C           |                                          |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Jan-2014              | 9830976       | EXPEDITED (15-DAY) |                    | OT              | PHHY2014CH005599     |                      | 43 YR      | Female     | CHE            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Weight Increased      | Gilenya        |              |            | S           | Oral         | 0.5 Mg, Qd         |                 | Novartis     |
|                       | Cipralex       |              |            | S           | Oral         | 10 Mg, Qd          |                 | Not Reported |

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

| <u>FDA Received Date</u>                                                                                             | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|------------------|----------------|
| 21-Jan-2014                                                                                                          | 9628820                  | EXPEDITED (15-DAY) |                    |                 | JP-<br>ELI_LILLY_AND_COMP<br>ANY-JP201310003334 |                      | 40 YR           | Male             | JPN            |
| <u>Preferred Term</u>                                                                                                | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |
| Hepatic Function Abnormal;<br>Hypertriglyceridaemia                                                                  | Cymbalta                 |                    |                    | S               | Oral                                            | 20 Mg, Qd            |                 | Eli Lilly And Co |                |
|                                                                                                                      | Lexapro                  |                    |                    | S               | Oral                                            | Unk                  |                 | Not Reported     |                |
|                                                                                                                      | Lipidil                  |                    |                    | C               | Oral                                            | Unk                  |                 | Not Reported     |                |
| <u>FDA Received Date</u>                                                                                             | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 21-Jan-2014                                                                                                          | 9831486                  | EXPEDITED (15-DAY) |                    | DE              | US-JNJFOC-<br>20140110556                       |                      | 55 YR           | Male             | USA            |
| <u>Preferred Term</u>                                                                                                | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |
| Arrhythmia; Bradycardia;<br>Completed Suicide;<br>Hyperthermia;<br>Hypotension; Overdose;<br>Ventricular Tachycardia | Salicylate               |                    | Y                  | S               | Unknown                                         |                      |                 | Not Reported     |                |
|                                                                                                                      | Vilazodone               |                    |                    | S               | Unknown                                         |                      |                 | Not Reported     |                |
|                                                                                                                      | Alprazolam               |                    |                    | S               | Unknown                                         |                      |                 | Not Reported     |                |
|                                                                                                                      | Escitalopram             |                    |                    | S               | Unknown                                         |                      |                 | Not Reported     |                |
|                                                                                                                      | Duloxetine               |                    |                    | S               | Unknown                                         |                      |                 | Not Reported     |                |
| <u>FDA Received Date</u>                                                                                             | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 21-Jan-2014                                                                                                          | 9831801                  | EXPEDITED (15-DAY) |                    | OT              | BR-<br>ELI_LILLY_AND_COMP<br>ANY-BR201401004836 |                      |                 | Male             | BRA            |
| <u>Preferred Term</u>                                                                                                | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |
| Asthenia; Drug Dependence; Panic Disorder; Visual Impairment                                                         | Fluoxetine Hydrochloride |                    |                    | S               | Unknown                                         | Unk, Unknown         |                 | Unknown          |                |
|                                                                                                                      | Tranxilene               |                    |                    | S               | Unknown                                         | Unk, Unknown         |                 | Not Reported     |                |
|                                                                                                                      | Lorax//Lorazepam         |                    |                    | S               | Unknown                                         | Unk, Unknown         |                 | Not Reported     |                |
|                                                                                                                      | Escitalopram             |                    |                    | S               | Unknown                                         | Unk, Unknown         |                 | Not Reported     |                |
|                                                                                                                      | Amitriptilina            |                    |                    | S               | Unknown                                         | Unk, Unknown         |                 | Not Reported     |                |
|                                                                                                                      | Venlafaxine              |                    |                    | S               | Unknown                                         | Unk, Unknown         |                 | Not Reported     |                |

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

|                                                                      | Anafranil                    | S                  | Unknown            | Unk, Unknown    |                      | Not Reported         |                 |                        |                |
|----------------------------------------------------------------------|------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------------------|----------------|
|                                                                      | Tofranil                     | S                  | Unknown            | Unk, Unknown    |                      | Not Reported         |                 |                        |                |
|                                                                      | Risperidona                  | S                  | Unknown            | Unk, Unknown    |                      | Not Reported         |                 |                        |                |
|                                                                      | Rivotril                     | S                  | Unknown            | 2 Mg, Bid       |                      | Not Reported         |                 |                        |                |
| <u>FDA Received Date</u>                                             | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>             | <u>Country</u> |
| 21-Jan-2014                                                          | 9832922                      | EXPEDITED (15-DAY) |                    | CA, DS, HO      | BE-FRI-1000052946    |                      |                 | Male                   | BEL            |
| <u>Preferred Term</u>                                                | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>             |                |
| Congenital Megacolon;<br>Foetal Exposure During<br>Pregnancy; Sepsis | Escitalopram                 |                    |                    | S               | Transplacental       | 5 Mg                 |                 | Forest                 |                |
| <u>FDA Received Date</u>                                             | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>             | <u>Country</u> |
| 21-Jan-2014                                                          | 9832997                      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000052950    |                      | 68 YR           | Male                   | FRA            |
| <u>Preferred Term</u>                                                | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>             |                |
| Drug Interaction; Tremor                                             | Escitalopram<br>Teralithe Lp |                    |                    | S<br>S          | Oral                 | 1 Df                 |                 | Forest<br>Not Reported |                |
| <u>FDA Received Date</u>                                             | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>             | <u>Country</u> |
| 22-Jan-2014                                                          | 9523058                      | EXPEDITED (15-DAY) |                    | DS, OT          | CA-FRI-1000048781    |                      | 47 YR           | Female                 | CAN            |
| <u>Preferred Term</u>                                                | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>             |                |
| Stress Fracture; Weight<br>Increased                                 | Escitalopram                 |                    |                    | S               | Oral                 | 20 Mg                |                 | Forest                 |                |
| <u>FDA Received Date</u>                                             | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>             | <u>Country</u> |
| 22-Jan-2014                                                          | 9523371                      | EXPEDITED (15-DAY) |                    | HO, OT          | CA-FRI-1000048783    |                      | 14 YR           | Female                 | CAN            |
| <u>Preferred Term</u>                                                | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>             |                |
| Headache; Intracranial                                               | Escitalopram                 |                    |                    | S               | Oral                 |                      |                 | Forest                 |                |



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

Pressure Increased; Off Label Use; Papilloedema; Vision Blurred      Tetracycline      S      Oral      Not Reported

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 22-Jan-2014              | 9834231       | EXPEDITED (15-DAY) |                    | HO              | FR-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>20032579 |                      | 62 YR      | Female     | FRA            |

| <u>Preferred Term</u>  | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>           |
|------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------|
| Pancreatitis           | Baraclude Tabs 0.5 Mg  |              |            | S           | Oral         |                    |                 | Bristol Myers Squibb |
|                        | Mabthera               |              |            | S           |              | 03jul2007          |                 | Not Reported         |
|                        | Tercian                |              |            | S           | Oral         |                    |                 | Not Reported         |
|                        | Noctran                |              |            | S           | Oral         |                    |                 | Not Reported         |
|                        | Seroplex               |              |            | S           | Oral         |                    |                 | Not Reported         |
|                        | Durogesic              |              |            | S           | Transdermal  | 1df: 50mcg/Hour    |                 | Not Reported         |
|                        | Dulcolax               |              |            | C           |              | 1df: 1suppository  |                 | Not Reported         |
|                        | Previscan (Fluindione) |              |            | C           |              | 1df: 0.5 Unit Nos  |                 | Not Reported         |
| Aerius (Desloratadine) |                        |              | C          |             |              |                    | Not Reported    |                      |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Jan-2014              | 9835873       | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000052982    |                      | 50 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Colitis Microscopic   | Escitalopram   |              |            | S           |              |                    |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Jan-2014              | 9844682       | EXPEDITED (15-DAY) | Y                  | HO              | VAL_02907_2014       |                      | 83 YR      | Female     | CAN            |

| <u>Preferred Term</u>                                                                         | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Arthralgia; Back Pain; Fall; Headache; Hypotension; Mobility Decreased; Musculoskeletal Chest | Metoprolol Tartrate     |              |            | S           |              | 50 Mg Day          |                 | Not Reported |
|                                                                                               | Amlodipine (Amlodipine) |              |            | S           |              |                    |                 | Not Reported |
|                                                                                               | Ramipril (Ramipril)     |              |            | S           |              |                    |                 | Not Reported |
|                                                                                               | Glyceryl Trinitrate     |              |            | S           | Transdermal  |                    |                 | Not Reported |

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

|                           |                                       |   |              |
|---------------------------|---------------------------------------|---|--------------|
| Pain; Musculoskeletal     | Escitalopram (Escitalopram)           | S | Not Reported |
| Pain; Nausea; Neck Pain;  | Zopiclone (Zopiclone)                 | S | Not Reported |
| Oedema Peripheral;        | Furosemide (Furosemide)               | S | Not Reported |
| Orthostatic Hypotension;  | Praxiten Pliva (Oxazepam)             | S | Not Reported |
| Serum Ferritin Decreased; | (Oxazepam)                            |   |              |
| Sleep Disorder            | Codeine Phosphate (Codeine Phosphate) | S | Not Reported |
|                           | Clopidogrel                           | C | Not Reported |
|                           | Atorvastatin                          | C | Not Reported |
|                           | Vitamin D2                            | C | Not Reported |
|                           | Acetaminophen                         | C | Not Reported |
|                           | Polyethylene Glycol                   | C | Not Reported |
|                           | Vitamin-C                             | C | Not Reported |
|                           | Rabeprazole                           | C | Not Reported |
|                           | Pantoprazole                          | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Jan-2014              | 9844719       | EXPEDITED (15-DAY) |                    | OT              | 7260901              |                      | 95 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Thrombocytopenia      | Levothyrox     |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Alteis         |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Furosemide     |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Seroplex       |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Nebivolol      |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Zopiclone      |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Diffu K        |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Jan-2014              | 9844840       | EXPEDITED (15-DAY) | Y                  | HO, LT, OT      | AUR-APL-2014-00197   |                      | 65 YR      | Female     | IND            |

| <u>Preferred Term</u>                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction; Hypoxia;                 | Escitalopram   |              |            | S           |              | 1 D                |                 | Not Reported |
| Pneumonia; Serotonin Syndrome; Somnolence; | Linezolid      |              |            | S           |              | 1 D                |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                       |                                   |   |              |
|-----------------------|-----------------------------------|---|--------------|
| Therapy Non-Responder | Etophylline (Etofylline)          | C | Not Reported |
|                       | Guaiphenesin (Guaifenesin)        | C | Not Reported |
|                       | Ambroxol                          | C | Not Reported |
|                       | Amoxicillin (Amoxicillin)         | C | Not Reported |
|                       | Clavulanic Acid (Clavulanci Acid) | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Jan-2014              | 9845061       | EXPEDITED (15-DAY) | Y                  | OT              | DSM-2014-00019       |                      | 95 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------------------|-----------------|--------------|
| Thrombocytopenia      | Alteis         |              |            | S           | Oral         | 40mg (40mg, 1 In 1 D)<br>Oral  |                 | Not Reported |
|                       | Nebivolol      |              |            | S           | Oral         | 5mg (5mg, 1 In 1 D, Oral)      |                 | Not Reported |
|                       | Furosemide     |              |            | S           | Oral         | 40mg (40mg, 1 In 1d) Oral      |                 | Not Reported |
|                       | Seroplex       |              |            | S           | Oral         | 15mg, (15mg, 1 In 1 D)<br>Oral |                 | Not Reported |
|                       | Amlodipine     |              |            | S           | Oral         | 5mg (5mg, 1 In 1 D) Oral       |                 | Not Reported |
|                       | Levothyrox     |              |            | S           |              | 125mcg, (125mcg, 1 In 1        |                 | Not Reported |
|                       | Zopiclone      |              |            | S           | Oral         |                                |                 | Not Reported |
|                       | Diffu K        |              |            | S           | Oral         |                                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Jan-2014              | 9523017       | EXPEDITED (15-DAY) |                    | OT              | CA-FRI-1000048775    |                      | 19 YR      | Male       | CAN            |

| <u>Preferred Term</u>                                                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|----------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Abnormal Behaviour;<br>Dizziness; Nausea;<br>Unresponsive To Stimuli | Escitalopram   |              |            | S           | Oral         | 10 Mg              |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Jan-2014              | 9523060       | EXPEDITED (15-DAY) |                    | DE              | CA-FRI-1000048780    |                      | 20 YR      | Male       | CAN            |

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

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

|                                                                     |              |   |      |                                        |        |
|---------------------------------------------------------------------|--------------|---|------|----------------------------------------|--------|
| Anxiety; Completed<br>Suicide; Irritability;<br>Prescribed Overdose | Escitalopram | S | Oral | 20 Mg                                  | Forest |
|                                                                     | Escitalopram | S | Oral | Overdose: Escitalopram<br>40 Mg Daily. | Forest |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Jan-2014              | 9530037       | EXPEDITED (15-DAY) |                    | OT              | CA-FRI-1000048800    |                      | 55 YR      | Female     | CAN            |

  

| <u>Preferred Term</u>                                                                                                                                                                                                                                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Asthenia; Chest<br>Pain; Depressed Mood;<br>Diarrhoea; Dizziness;<br>Dyspepsia; Dyspnoea;<br>Emotional Disorder;<br>Fatigue; Headache;<br>Irritability; Nausea; Off<br>Label Use; Pallor;<br>Pharyngeal Swelling;<br>Rash; Throat Irritation;<br>Throat Tightness | Escitalopram   |              |            | S           | Oral         | 5 Mg               |                 | Forest       |
|                                                                                                                                                                                                                                                                            | Estrogel       |              |            | C           | Transdermal  |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                            | Lamisil        |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                            | Prometrium     |              |            | C           |              | 100 Mg             |                 | Not Reported |
|                                                                                                                                                                                                                                                                            | Zopiclone      |              |            | C           |              | 0.5357 Mg          |                 | Not Reported |
|                                                                                                                                                                                                                                                                            | Zopiclone      |              |            | C           |              | 7.5 Mg             |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Jan-2014              | 9530052       | EXPEDITED (15-DAY) |                    | DS, HO, LT      | CA-FRI-1000048778    |                      | 77 YR      | Female     | CAN            |

  

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Agitation; Arthralgia;<br>Asthenia; Confusional<br>State; Coordination<br>Abnormal; Dyspnoea;<br>Fatigue; Headache; Joint<br>Stiffness; Loss Of<br>Consciousness;<br>Musculoskeletal Stiffness;<br>Myalgia; Off Label Use;<br>Pharyngeal Disorder;<br>Seizure; Urinary<br>Incontinence; Urinary<br>Retention; Wrist Fracture;<br>Yellow Skin | Escitalopram   |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                                                                                                                                                                                                                                                                                                                              | Norvasc        |              |            | C           | Oral         | 5 Mg               |                 | Not Reported |

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

| <u>FDA Received Date</u>                      | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|-----------------------------------------------|---------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------------|-----------------|----------------------|----------------|
| 23-Jan-2014                                   | 9646375             | EXPEDITED (15-DAY) |                    | DE, LT          | NO-WATSON-2013-19200 |                                     | 20 YR           | Female               | NOR            |
| <u>Preferred Term</u>                         | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>           |                |
| Completed Suicide;<br>Intentional Self-Injury | Vival               |                    |                    | S               | Unknown              | Unk                                 |                 | Watson               |                |
|                                               | Pinex Forte         |                    |                    | S               | Unknown              | Unk                                 |                 | Actavis Mid Atlantic |                |
|                                               | Tramadol (Unknown)  |                    |                    | S               | Unknown              | Unk                                 |                 | Actavis Elizabeth    |                |
|                                               | Rivotril            |                    |                    | S               | Unknown              | Unk                                 |                 | Not Reported         |                |
|                                               | Sobril              |                    |                    | S               | Unknown              | Unk                                 |                 | Not Reported         |                |
|                                               | Cipramil /00582602/ |                    |                    | S               | Unknown              | Unk                                 |                 | Not Reported         |                |
|                                               | Nobligan            |                    |                    | S               | Unknown              | Unk; Strength: 50 Mg-200 Mg         |                 | Not Reported         |                |
|                                               | Cipralext           |                    |                    | S               | Unknown              | Unk                                 |                 | Not Reported         |                |
|                                               | Catapresan          |                    |                    | S               | Unknown              | Unk; Strength: 25 Mg To 50 Mg       |                 | Not Reported         |                |
|                                               | Orfiril             |                    |                    | S               | Unknown              | Unk; Strength: 600 Mg-1200 Mg       |                 | Not Reported         |                |
|                                               | Seroquel            |                    |                    | S               | Unknown              | Unk                                 |                 | Not Reported         |                |
|                                               | Lamictal            |                    |                    | S               | Unknown              | Unk; Strength: 25 Mg, 50 Mg, 100 Mg |                 | Not Reported         |                |
|                                               | Nozinan /00038601/  |                    |                    | S               | Unknown              | Unk                                 |                 | Not Reported         |                |
|                                               | Sarotex             |                    |                    | S               | Unknown              | Unk                                 |                 | Not Reported         |                |
|                                               | Truxal              |                    |                    | S               | Unknown              | Unk                                 |                 | Not Reported         |                |
|                                               | Atarax /00058402/   |                    |                    | S               | Unknown              | Unk                                 |                 | Not Reported         |                |
|                                               | Imovane             |                    |                    | S               | Oral                 | Unk                                 |                 | Not Reported         |                |
|                                               | Oxynorm             |                    |                    | S               | Unknown              | Unk; Strength: 5 Mg-10 Mg           |                 | Not Reported         |                |
|                                               | Remeron             |                    |                    | S               | Unknown              | Unk                                 |                 | Not Reported         |                |
|                                               | Diamorphine         |                    |                    | C               | Unknown              | Unk                                 |                 | Not Reported         |                |
|                                               | Cyanocobalamin      |                    |                    | C               | Unknown              | Unk; According To Mah               |                 | Not Reported         |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Product Name Is "Forte"

| <a href="#">FDA Received Date</a>                                                                  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>    | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|----------------------------------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|----------------------------------|--------------------------|---------------------|-------------------------|
| 23-Jan-2014                                                                                        | 9838821                 | EXPEDITED (15-DAY)        |                             | OT                       | IE-FRI-1000052983             |                                  |                          | Female              | IRL                     |
| <a href="#">Preferred Term</a>                                                                     | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>      | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Autoimmune Hepatitis                                                                               | Escitalopram            |                           |                             | S                        |                               |                                  |                          | Forest              |                         |
| <a href="#">FDA Received Date</a>                                                                  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>    | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 23-Jan-2014                                                                                        | 9844395                 | EXPEDITED (15-DAY)        | Y                           | HO                       | 2014P1000227                  |                                  | 81 YR                    | Female              | ESP                     |
| <a href="#">Preferred Term</a>                                                                     | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>      | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Aphasia; Back Pain; Drug Interaction; Gamma-Glutamyltransferase Increased; Haemorrhage; Hemianopia | Escitalopram            |                           |                             | S                        |                               | 10 Mg; Qd;                       | 2 YR                     | Not Reported        |                         |
|                                                                                                    | Etoricoxib              |                           |                             | S                        |                               | 90 Mg; Qd;                       | 1 MTH                    | Not Reported        |                         |
|                                                                                                    | Acetamyphen/Tramadol    |                           |                             | S                        |                               | ;Tid;                            | 1 MTH                    | Not Reported        |                         |
|                                                                                                    | Tramadol                |                           |                             | S                        |                               | ; Qd;                            | 1 MTH                    | Not Reported        |                         |
|                                                                                                    | Deflazacort             |                           |                             | C                        |                               |                                  |                          | Not Reported        |                         |
|                                                                                                    | Salbutamol              |                           |                             | C                        |                               |                                  |                          | Not Reported        |                         |
|                                                                                                    | Montelukast             |                           |                             | C                        |                               |                                  |                          | Not Reported        |                         |
|                                                                                                    | Atorvastatin            |                           |                             | C                        |                               |                                  |                          | Not Reported        |                         |
|                                                                                                    | Omeprazole              |                           |                             | C                        |                               |                                  |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>    | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 23-Jan-2014                                                                                        | 9845339                 | DIRECT                    |                             | OT                       |                               |                                  | 33 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                                     | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>      | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Anxiety; Depression; Mental Disorder; Panic Attack; Product Substitution Issue                     | Escitalopram 10 Mg      |                           |                             | S                        | Oral                          | 1 Pill Once Daily Taken By Mouth |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>    | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 23-Jan-2014                                                                                        | 9845418                 | DIRECT                    |                             | DS                       |                               |                                  | 39 YR                    | Female              | USA                     |

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

| <u>Preferred Term</u>                                                                                                                                | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>   |                |
|------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|------------------------------------------|------------------------------------------|-----------------|--------------|----------------|
| Hypertension; Palpitations;<br>Product Quality Issue;<br>Product Substitution Issue                                                                  | Escitalopram              |                    |                    | S               | Oral                                     | 1 Tab Daily Once Daily<br>Taken By Mouth |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                             | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Jan-2014                                                                                                                                          | 9845946                   | DIRECT             |                    |                 |                                          |                                          | 39 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Depression;<br>Drug Ineffective; Insomnia;<br>Product Substitution Issue                                                                  | Escitalopram              |                    |                    | S               | Oral                                     |                                          |                 | Mylan        |                |
| <u>FDA Received Date</u>                                                                                                                             | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Jan-2014                                                                                                                                          | 9845965                   | DIRECT             |                    | OT              |                                          |                                          | 44 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective; Product<br>Substitution Issue                                                                                                      | Escitalopram              |                    |                    | S               | Oral                                     | 2 Once Daily Taken By<br>Mouth           |                 | Camber       |                |
| <u>FDA Received Date</u>                                                                                                                             | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Jan-2014                                                                                                                                          | 9530045                   | EXPEDITED (15-DAY) |                    | OT              |                                          | CA-FRI-1000048801                        |                 | Female       | CAN            |
| <u>Preferred Term</u>                                                                                                                                | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>   |                |
| Abortion Spontaneous;<br>Arthralgia; Blood Iron<br>Decreased; Lung<br>Infection; Melanocytic<br>Naevus; Pregnancy;<br>Rheumatoid Factor<br>Increased | Escitalopram              |                    |                    | S               |                                          | 10 Mg                                    |                 | Forest       |                |
|                                                                                                                                                      | Imodium                   |                    |                    | S               |                                          |                                          |                 | Not Reported |                |
|                                                                                                                                                      | Remicade                  |                    |                    | S               | Intravenous (not<br>otherwise specified) | 5.3571 Mg                                |                 | Not Reported |                |
|                                                                                                                                                      | Tecta                     |                    |                    | S               |                                          | 30 Mg                                    |                 | Not Reported |                |
|                                                                                                                                                      | Tylenol With Codeine No.3 |                    |                    | S               |                                          |                                          |                 | Not Reported |                |
|                                                                                                                                                      | Ventolin                  |                    |                    | S               |                                          |                                          | Not Reported    |              |                |
|                                                                                                                                                      | Multivitamin              |                    |                    | C               |                                          |                                          | Not Reported    |              |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                               | <u>Case #</u>                                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------|-----------------------------------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 24-Jan-2014                                            | 9840419                                             | EXPEDITED (15-DAY) |                    | DE              | US-PAR<br>PHARMACEUTICAL,<br>INC-2014SCPR008205 |                      | 55 YR           | Male         | USA            |
| <u>Preferred Term</u>                                  | <u>Product</u>                                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardio-Respiratory Arrest;<br>Completed Suicide; Death | Bupropion Hcl XI                                    |                    |                    | S               | Oral                                            | Unk, Unknown         |                 | Par          |                |
|                                                        | Clonazepam                                          |                    |                    | S               | Oral                                            | Unk, Unknown         |                 | Par          |                |
|                                                        | Citalopram                                          |                    |                    | S               | Oral                                            | Unk, Unknown         |                 | Not Reported |                |
|                                                        | Escitalopram                                        |                    |                    | S               | Oral                                            | Unk, Unknown         |                 | Not Reported |                |
|                                                        | Acetaminophen<br>W/Diphenhydramine<br>Hydrochloride |                    |                    | S               | Oral                                            | Unk, Unknown         |                 | Not Reported |                |
|                                                        | Tadalafil                                           |                    |                    | S               | Oral                                            | Unk, Unknown         |                 | Not Reported |                |
| <u>FDA Received Date</u>                               | <u>Case #</u>                                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Jan-2014                                            | 9840840                                             | EXPEDITED (15-DAY) |                    | DE              | US-PAR<br>PHARMACEUTICAL,<br>INC-2014SCPR008215 |                      | 47 YR           | Female       | USA            |
| <u>Preferred Term</u>                                  | <u>Product</u>                                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardio-Respiratory Arrest;<br>Completed Suicide; Death | Bupropion Hcl XI                                    |                    |                    | S               | Oral                                            | Unk, Unknown         |                 | Par          |                |
|                                                        | Alprazolam                                          |                    |                    | S               | Oral                                            | Unk, Unknown         |                 | Par          |                |
|                                                        | Amlodipine                                          |                    |                    | S               | Oral                                            | Unk, Unknown         |                 | Not Reported |                |
|                                                        | Carvedilol                                          |                    |                    | S               | Oral                                            | Unk, Unknown         |                 | Not Reported |                |
|                                                        | Acetaminophen/Hydrocodone                           |                    |                    | S               | Oral                                            | Unk, Unknown         |                 | Not Reported |                |
|                                                        | Citalopram                                          |                    |                    | S               | Oral                                            | Unk, Unknown         |                 | Not Reported |                |
|                                                        | Escitalopram                                        |                    |                    | S               | Oral                                            | Unk, Unknown         |                 | Not Reported |                |
| <u>FDA Received Date</u>                               | <u>Case #</u>                                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Jan-2014                                            | 9842346                                             | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000053015                               |                      | < 1 DAY         | Female       | USA            |
| <u>Preferred Term</u>                                  | <u>Product</u>                                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |



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

|                                                                                                                                                                                                                                                                            |         |   |                |        |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|---|----------------|--------|
| Atrial Septal Defect;<br>Congenital Pulmonary<br>Valve Atresia; Congenital<br>Tricuspid Valve Atresia;<br>Ebstein'S Anomaly;<br>Hypoplastic Right Heart<br>Syndrome; Palatal<br>Disorder; Pulmonary Valve<br>Stenosis; Speech<br>Disorder; Tricuspid Valve<br>Incompetence | Lexapro | S | Transplacental | Forest |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|---|----------------|--------|

| <u>FDA Received Date</u>                                                    | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 24-Jan-2014                                                                 | 9842842        | EXPEDITED (15-DAY) |                    | OT              | CA-FRI-1000053064    |                      | 53 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                                       | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Arrhythmia; Bradycardia;<br>Electrocardiogram Qt<br>Prolonged; Palpitations | Escitalopram   |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                                                             | Zoloft         |                    |                    | S               | Oral                 | 50 Mg                |                 | Not Reported |                |
|                                                                             | Calcium        |                    |                    | C               |                      | 1000 Mg              |                 | Not Reported |                |
|                                                                             | D-Tabs         |                    |                    | C               |                      | 10000 Iu Weekly      |                 | Not Reported |                |
|                                                                             | Estrogel       |                    |                    | C               |                      | 1 Df                 |                 | Not Reported |                |
|                                                                             | Olmetec        |                    |                    | C               |                      | 20 Mg                |                 | Not Reported |                |
|                                                                             | Prometrium     |                    |                    | C               |                      | 100 Mg               |                 | Not Reported |                |
|                                                                             | Restoril       |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 24-Jan-2014              | 9848038              | DIRECT           |                    |                 |                      |                      | 53 YR           | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Sexual Dysfunction       | Excitalopram Oxalate |                  |                    | S               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Jan-2014              | 9848073       | DIRECT           |                    | OT              |                      |                      | 50 YR      | Female     | USA            |

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

| <u>Preferred Term</u>                                                                                                                                                                                                                                            | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                | <u>Duration</u> | <u>Mfr</u>   |                |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------------------------------------------|-----------------|--------------|----------------|
| Inappropriate Schedule Of Product Administration;<br>Medication Error                                                                                                                                                                                            | Escitalopram 20mg              |                    |                    | S               | Oral                 | 60 Tablets, One Month,3 Refills 2 Pills Once Daily Taken By Mouth | 1 MTH           | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                         | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Jan-2014                                                                                                                                                                                                                                                      | 9849397                        | DIRECT             |                    | OT              |                      |                                                                   | 56 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                            | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                | <u>Duration</u> | <u>Mfr</u>   |                |
| Bone Loss; Condition Aggravated; Osteoporosis; Product Substitution Issue                                                                                                                                                                                        | Lexapro                        |                    |                    | S               | Oral                 |                                                                   |                 | Aurobindo    |                |
|                                                                                                                                                                                                                                                                  | Escitalopram                   |                    |                    | C               |                      |                                                                   |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                  | Vitamin D Nos                  |                    |                    | C               |                      |                                                                   |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                  | Fish Oil                       |                    |                    | C               |                      |                                                                   |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                  | Multi-Vitamin                  |                    |                    | C               |                      |                                                                   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                         | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Jan-2014                                                                                                                                                                                                                                                      | 9849496                        | EXPEDITED (15-DAY) | Y                  | OT              | 2014P1000211         |                                                                   | 42 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                            | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Behaviour;<br>Amnesia; Aphasia;<br>Contusion; Diplopia;<br>Dysgraphia; Headache;<br>Mental Status Changes;<br>Nausea; Night Sweats;<br>Product Quality Issue;<br>Product Substitution Issue;<br>Reaction To Excipient;<br>Sleep Terror;<br>Somnambulism | Escitalopram Tablets Usp 20 Mg |                    |                    | S               | Oral                 |                                                                   |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                  | Adderall                       |                    |                    | C               |                      |                                                                   |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                  | Clonazepam                     |                    |                    | C               |                      |                                                                   |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                  | Percocet                       |                    |                    | C               |                      |                                                                   |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                  | Soma                           |                    |                    | C               |                      |                                                                   |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                  | Fioricet                       |                    |                    | C               |                      |                                                                   |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                  |                                |                    |                    |                 |                      |                                                                   |                 |              |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                         | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Jan-2014                                                                                                                                                                                                                                                      | 9850805                        | EXPEDITED (15-DAY) | Y                  | DE              | 2014AP000584         |                                                                   | 93 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                            | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                | <u>Duration</u> | <u>Mfr</u>   |                |

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

|                   |                             |   |      |              |
|-------------------|-----------------------------|---|------|--------------|
| Completed Suicide | Amlodipine Besylate Tablets | S | Oral | Not Reported |
|                   | Escitalopram                | S | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Jan-2014              | 9240913       | EXPEDITED (15-DAY) | HO                 |                 | FR-FRI-1000044442    |                      | 17 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                  | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------|-----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Acute Generalised<br>Exanthematous<br>Pustulosis; Product Use<br>Issue | Escitalopram          |              |            | S           | Oral         |                    |                 | Forest       |
|                                                                        | Atarax                |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                        | Lasilix               |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                        | Candesartan Cilexetil |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                        | Victoza               |              |            | C           |              |                    |                 | Not Reported |
|                                                                        | Lantus                |              |            | C           |              |                    |                 | Not Reported |
|                                                                        | Glucophage            |              |            | C           |              |                    |                 | Not Reported |
|                                                                        | Novorapid             |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 27-Jan-2014              | 9845080       | EXPEDITED (15-DAY) | DE                 |                 | US-MALLINCKRODT-T201400827 |                      | 86 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Acetaminophen\Hydrocodone |              |            | S           | Oral         |                    |                 | Tyco         |
|                       | Bitartrate                |              |            |             |              |                    |                 |              |
|                       | Isosorbide Mononitrate    |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Amlodipine                |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Doxazosin                 |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Escitalopram              |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Warfarin                  |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Furosemide                |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Levothyroxine             |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                       | Potassium /00031402/      |              |            | S           | Oral         |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 27-Jan-2014              | 9845172       | EXPEDITED (15-DAY) |                    | HO, LT          | CH-MYLANLABS-2014S1001207 |                      | 31 YR      | Male       | CHE            |

| <u>Preferred Term</u>                                                                                                                                                                                    | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                          | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------|------------|-------------|---------------------------------------|--------------------|-----------------|--------------|
| Abdominal Pain; Drug Interaction; Dyspepsia; Electrocardiogram Qt Prolonged; Hypokalaemia; Hypomagnesaemia; Product Administration Error; Stress Cardiomyopathy; Torsade De Pointes; Withdrawal Syndrome | Methadone                |              |            | S           | Oral                                  | 50-60mg Daily      |                 | Mylan        |
|                                                                                                                                                                                                          | Escitalopram             |              |            | S           | Unknown                               |                    |                 | Not Reported |
|                                                                                                                                                                                                          | Ondansetron              |              |            | S           | Intravenous (not otherwise specified) |                    |                 | Not Reported |
|                                                                                                                                                                                                          | Esomeprazole             |              |            | C           | Intravenous (not otherwise specified) |                    |                 | Not Reported |
|                                                                                                                                                                                                          | Scopolamine Butylbromide |              |            | C           | Intravenous (not otherwise specified) |                    |                 | Not Reported |
|                                                                                                                                                                                                          | Dipyrone                 |              |            | C           | Intravenous (not otherwise specified) |                    |                 | Not Reported |
|                                                                                                                                                                                                          | Paracetamol              |              |            | C           | Intravenous (not otherwise specified) |                    |                 | Not Reported |
|                                                                                                                                                                                                          | Pethidine                |              |            | C           | Intravenous (not otherwise specified) |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 27-Jan-2014              | 9845751       | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2014022770 |                      |            | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Ineffective      | Efexor         |              |            | S           |              | Unk                |                 | Pfizer       |
|                       | Zoloft         |              |            | S           |              | Unk                |                 | Pfizer       |
|                       | Lexapro        |              |            | S           |              | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Jan-2014              | 9849018       | DIRECT           |                    | OT              |                      |                      | 45 YR      | Male       | USA            |

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

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| Eczema                                                         | Lexapro                        |                    |                    | S               | Oral                 |                      |                 |              | Not Reported   |
|----------------------------------------------------------------|--------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| <u>FDA Received Date</u>                                       | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Jan-2014                                                    | 9856708                        | EXPEDITED (15-DAY) | Y                  | HO              | E2B_7260692          |                      | 81 YR           | Female       | ESP            |
| <u>Preferred Term</u>                                          | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Pruritus; Rash Maculo-Papular                                  | Eutirox (Levothyroxine Sodium) |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                | Lexatin (Bromazepam)           |                    |                    | S               | Oral                 |                      | 7 MTH           | Not Reported |                |
|                                                                | Lorazepam (Lorazepam)          |                    |                    | S               | Oral                 |                      | 7 MTH           | Not Reported |                |
|                                                                | Escitalopram (Escitalopram)    |                    |                    | S               | Oral                 |                      | 7 MTH           | Not Reported |                |
|                                                                | Clopidogrel (Clopidogrel)      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                | Atorvastatin (Atorvastatin)    |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                | Zamene (Deflazacort)           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                | (Deflazacort)                  |                    |                    |                 |                      |                      |                 |              |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Jan-2014                                                    | 9643092                        | EXPEDITED (15-DAY) |                    | LT, OT          | DE-FRI-1000050479    |                      |                 | Male         | DEU            |
| <u>Preferred Term</u>                                          | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Electrocardiogram Qt Prolonged                 | Escitalopram                   |                    |                    | S               |                      |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Jan-2014                                                    | 9696331                        | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000051450    |                      | 31 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                          | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Bilirubin Increased; Drug-Induced Liver Injury; Jaundice | Escitalopram                   |                    |                    | S               |                      | 10 Mg                |                 | Forest       |                |
|                                                                | Escitalopram                   |                    |                    | S               |                      | 15 Mg                |                 | Forest       |                |
|                                                                | Lexomil                        |                    |                    | C               | Oral                 | 1 Df                 |                 | Not Reported |                |

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

|  |                        |   |      |       |              |
|--|------------------------|---|------|-------|--------------|
|  | Stilnox                | C | Oral | 1 Df  | Not Reported |
|  | Imovane                | C | Oral | 1 Df  | Not Reported |
|  | Aerius (Desloratadine) | C | Oral | 1 Df  | Not Reported |
|  | Omeprazole             | C | Oral | 10 Mg | Not Reported |
|  | Humalog                | C |      |       | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Jan-2014              | 9828436       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000052920    |                      | 88 YR      | Male       | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Haemorrhagic Stroke   | Escitalopram   |              |            | S           | Oral         | 1 Df               |                 | Forest       |
|                       | Kardegic       |              |            | S           | Oral         | 1 Df               |                 | Not Reported |
|                       | Plavix         |              |            | S           | Oral         | 1 Df               |                 | Not Reported |
|                       | Lasilix        |              |            | C           | Oral         | 1 Df               |                 | Not Reported |
|                       | Tahor          |              |            | C           | Oral         | 1 Df               |                 | Not Reported |
|                       | Zyloric        |              |            | C           | Oral         | 1 Df               |                 | Not Reported |
|                       | Risperdal      |              |            | C           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 28-Jan-2014              | 9848572       | EXPEDITED (15-DAY) |                    | HO, OT          | US-JNJFOC-20140109355 |                      | 81 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                 | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------------------------------------------------------|-----------------|--------------|
| Abnormal Loss Of Weight;<br>Adverse Event; Asthenia;<br>Blood Pressure Diastolic<br>Decreased; Fall; Feeling<br>Abnormal; Inadequate<br>Diet; Palpitations; Upper<br>Respiratory Tract<br>Infection; Urine Odour<br>Abnormal | Risperdal      |              |            | S           | Oral         |                                                                    |                 | Not Reported |
|                                                                                                                                                                                                                              | Risperdal      |              |            | S           | Oral         | 1/4 Tablet Daily Or One<br>Tablet Every Other Day<br>During Week 2 |                 | Not Reported |
|                                                                                                                                                                                                                              | Risperdal      |              |            | S           | Oral         | 1/2 Tablet                                                         |                 | Not Reported |
|                                                                                                                                                                                                                              | Levothyroxine  |              |            | S           | Oral         |                                                                    |                 | Not Reported |
|                                                                                                                                                                                                                              | Levothyroxine  |              |            | S           | Oral         |                                                                    |                 | Not Reported |
|                                                                                                                                                                                                                              | Ciprofloxacin  |              |            | S           | Oral         |                                                                    |                 | Not Reported |
|                                                                                                                                                                                                                              |                |              |            |             |              |                                                                    |                 |              |

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

|               |   |         |              |
|---------------|---|---------|--------------|
| Lexapro       | S | Oral    | Not Reported |
| Vitamin D3    | C | Unknown | Not Reported |
| Aspirin       | C | Oral    | Not Reported |
| Iron          | C | Oral    | Not Reported |
| Amiodarone    | C | Oral    | Not Reported |
| Multivitamins | C | Oral    | Not Reported |
| Atorvastatin  | C | Oral    | Not Reported |
| Aricept       | C | Oral    | Not Reported |
| Aricept       | C | Oral    | Not Reported |
| Coumadin      | C | Oral    | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>   | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|-----------------|------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 28-Jan-2014              | 9849759         | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2014024831 |                      | 54 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>  | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity    | Zoloft          |                  |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                          | Citalopram Hbr  |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                          | Codeine Sulfate |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                          | Macrobid        |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                          | Lexapro         |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                          | Wellbutrin Sr   |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 29-Jan-2014              | 9656674        | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000050591    |                      | 77 YR           | Male         | FRA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Neutropenia              | Escitalopram   |                    |                    | S               | Oral                 | 1 Df                 |                 | Forest       |                |
|                          | Ebixa          |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Aricept        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Risperdal      |                    |                    | C               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 29-Jan-2014              | 9852045       | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2013295775 |                      | 55 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Hypersensitivity | Enbrel                     |              |            | S           |              | Unk                |                 | Pfizer       |
|                       | Effexor Xr                 |              |            | S           |              | Unk                |                 | Pfizer       |
|                       | Effexor                    |              |            | S           |              | Unk                |                 | Pfizer       |
|                       | Orencia                    |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Cymbalta                   |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Simponi                    |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Prava (Pravastatin Sodium) |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Lexapro                    |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Rituxan                    |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Humira                     |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Savella                    |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Viibryd                    |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Wellbutrin Sr              |              |            | S           |              | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Jan-2014              | 9852914       | EXPEDITED (15-DAY) |                    | HO, LT          | CH-TEVA-458122ISR    |                      | 31 YR      | Male       | CHE            |

| <u>Preferred Term</u>                                                                                                                                                                                       | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                          | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------|------------|-------------|---------------------------------------|--------------------|-----------------|--------------|
| Abdominal Pain; Drug Interaction; Dyspepsia; Electrocardiogram Qt Prolonged; Generalised Tonic-Clonic Seizure; Product Administration Error; Stress Cardiomyopathy; Torsade De Pointes; Withdrawal Syndrome | Ondansetron              |              |            | S           | Intravenous (not otherwise specified) |                    |                 | Teva         |
|                                                                                                                                                                                                             | Methadone                |              |            | S           | Oral                                  | 50-60mg Daily      |                 | Not Reported |
|                                                                                                                                                                                                             | Escitalopram             |              |            | S           | Unknown                               |                    |                 | Not Reported |
|                                                                                                                                                                                                             | Esomeprazole             |              |            | C           | Intravenous (not otherwise specified) |                    |                 | Not Reported |
|                                                                                                                                                                                                             | Scopolamine Butylbromide |              |            | C           | Intravenous (not otherwise specified) |                    |                 | Not Reported |



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|             |   |                                       |              |
|-------------|---|---------------------------------------|--------------|
| Dipyrrone   | C | Intravenous (not otherwise specified) | Not Reported |
| Paracetamol | C | Intravenous (not otherwise specified) | Not Reported |
| Pethidine   | C | Intravenous (not otherwise specified) | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 29-Jan-2014              | 9853494                    | EXPEDITED (15-DAY) | LT                 |                 | CH-PERRIGO-14CH000577 |                      | 55 YR           | Male         | CHE            |
| <u>Preferred Term</u>    | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Torsade De Pointes       | Ibuprofen 200 Mg 604       |                    |                    | S               | Oral                  | 1200 Mg, Unknown     |                 | Perrigo      |                |
|                          | Acetaminophen 650mg Er 544 |                    |                    | S               | Oral                  | 2 G, Unknown         |                 | Perrigo      |                |
|                          | Methadone                  |                    |                    | S               | Unknown               | 80 Mg, Unknown       |                 | Not Reported |                |
|                          | Escitalopram               |                    |                    | S               | Unknown               | 30 Mg, Unknown       |                 | Not Reported |                |
|                          | Olanzapine                 |                    |                    | S               | Unknown               | 20 Mg, Unknown       |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                 | <u>Case #</u>                         | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------|---------------------------------------|------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|-----------------|----------------|
| 29-Jan-2014                                                                                                              | 9853696                               | NON-EXPEDITED    |                    |                 | US-GLAXOSMITHKLINE-A1007689A |                      | 72 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                                                                    | <u>Product</u>                        | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Depression; Drug Ineffective; Drug Interaction; Fatigue; Fatigue; Influenza Like Illness; Therapeutic Response Decreased | Wellbutrin                            |                  |                    | S               | Oral                         |                      |                 | Glaxosmithkline |                |
|                                                                                                                          | Paxil                                 |                  |                    | S               | Unknown                      |                      |                 | Glaxosmithkline |                |
|                                                                                                                          | Lamictal                              |                  |                    | S               | Oral                         | 25mg See Dosage Text |                 | Glaxosmithkline |                |
|                                                                                                                          | Lexapro                               |                  |                    | S               |                              |                      |                 | Not Reported    |                |
|                                                                                                                          | Simvastatin                           |                  |                    | C               |                              |                      |                 | Glaxosmithkline |                |
|                                                                                                                          | Iron Supplement                       |                  |                    | C               |                              |                      |                 | Not Reported    |                |
|                                                                                                                          | Unknown Drug                          |                  |                    | C               |                              |                      |                 | Glaxosmithkline |                |
|                                                                                                                          | Cal-Mag                               |                  |                    | C               |                              |                      |                 | Not Reported    |                |
|                                                                                                                          | Unknown Drug                          |                  |                    | C               |                              |                      |                 | Glaxosmithkline |                |
|                                                                                                                          | Vitamin D3                            |                  |                    | C               |                              |                      |                 | Glaxosmithkline |                |
|                                                                                                                          | Ester-C [Ascorbic Acid\Bioflavonoids] |                  |                    | C               |                              |                      |                 | Not Reported    |                |

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

|                                                                                                                                                                                |                                   | Methylfolate       |                    | C               |                                      |                                     |                 |                                 | Glaxosmithkline |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|--------------------|--------------------|-----------------|--------------------------------------|-------------------------------------|-----------------|---------------------------------|-----------------|
|                                                                                                                                                                                |                                   | Tocopherol         |                    | C               |                                      |                                     |                 |                                 | Glaxosmithkline |
|                                                                                                                                                                                |                                   | Unknown Drug       |                    | C               |                                      |                                     |                 |                                 | Glaxosmithkline |
|                                                                                                                                                                                |                                   | Melatonin          |                    | C               |                                      |                                     |                 |                                 | Not Reported    |
|                                                                                                                                                                                |                                   | Synthroid          |                    | C               |                                      |                                     |                 |                                 | Glaxosmithkline |
| <u>FDA Received Date</u>                                                                                                                                                       | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>                      | <u>Country</u>  |
| 29-Jan-2014                                                                                                                                                                    | 9853720                           | NON-EXPEDITED      |                    |                 | US-<br>GLAXOSMITHKLINE-<br>A1012959A |                                     |                 | Female                          | USA             |
| <u>Preferred Term</u>                                                                                                                                                          | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>                      |                 |
| Depressed Mood;<br>Hyperphagia                                                                                                                                                 | Wellbutrin<br>Lexapro             |                    |                    | S<br>S          |                                      |                                     |                 | Glaxosmithkline<br>Not Reported |                 |
| <u>FDA Received Date</u>                                                                                                                                                       | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>                      | <u>Country</u>  |
| 29-Jan-2014                                                                                                                                                                    | 9854042                           | EXPEDITED (15-DAY) |                    | DS, HO          | IE-FRI-1000053244                    |                                     | 66 YR           | Male                            | IRL             |
| <u>Preferred Term</u>                                                                                                                                                          | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>                      |                 |
| Schizophrenia                                                                                                                                                                  | Lexapro                           |                    |                    | S               | Oral                                 |                                     |                 | Forest                          |                 |
|                                                                                                                                                                                | Unspecified Sleep Apnoea<br>Drugs |                    |                    | C               |                                      |                                     |                 | Not Reported                    |                 |
| <u>FDA Received Date</u>                                                                                                                                                       | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>                      | <u>Country</u>  |
| 29-Jan-2014                                                                                                                                                                    | 9859103                           | EXPEDITED (15-DAY) | Y                  | OT              | AUR-APL-2014-00671                   |                                     | 50 YR           | Female                          | CAN             |
| <u>Preferred Term</u>                                                                                                                                                          | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>                      |                 |
| Bruxism; Disturbance In<br>Attention; Fear;<br>Hyperhidrosis; Initial<br>Insomnia; Irritability;<br>Myalgia; Palpitations;<br>Platelet Dysfunction;<br>Social Anxiety Disorder | Citalopram                        |                    |                    | S               |                                      | (20 Mg, 1 D), Unknown               |                 | Not Reported                    |                 |
|                                                                                                                                                                                | Escitalopram (Escitalopram)       |                    |                    | S               |                                      | (10 Mg, 1 D), Unknown               |                 | Not Reported                    |                 |
|                                                                                                                                                                                | Clomipramine (Clomipramine)       |                    |                    | S               |                                      | 50 Mg (25 Mg, 2 In 1 D),<br>Unknown |                 | Not Reported                    |                 |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                      | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 30-Jan-2014                                                                   | 7953042                     | EXPEDITED (15-DAY) |                    | HO, OT          | US-RANBAXY-2011US-44443  |                      | 62 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                         | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Long Qt Syndrome; Sinus Bradycardia; Ventricular Fibrillation | Nortriptyline Hydrochloride |                    |                    | S               | Unknown                  | 25 Mg, Daily         |                 | Ranbaxy      |                |
|                                                                               | Escitalopram                |                    |                    | S               | Unknown                  | 10 Mg, Daily         |                 | Not Reported |                |
|                                                                               | Ondansetron                 |                    |                    | S               | Unknown                  | Unk                  |                 | Ranbaxy      |                |
|                                                                               | Succinylcholine             |                    |                    | S               | Unknown                  | Unk                  |                 | Not Reported |                |
|                                                                               | Aspirin                     |                    |                    | C               | Unknown                  | Unk                  |                 | Not Reported |                |
|                                                                               | Heparin                     |                    |                    | C               | Subcutaneous             |                      |                 | Not Reported |                |
|                                                                               | Topiramate                  |                    |                    | C               | Unknown                  | Unk                  |                 | Not Reported |                |
|                                                                               | Atorvastatin                |                    |                    | C               | Unknown                  | 20 Mg, Daily         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                      | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Jan-2014                                                                   | 9631596                     | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2013297160 |                      | 74 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                         | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity                                                         | Enbrel                      |                    |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                                                                               | Zithromax                   |                    |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                                                                               | Remicade                    |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                                                                               | Lexapro                     |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                                                                               | Orencia                     |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                                                                               | Penicillamine               |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                                                                               | Cimzia                      |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                                                                               | Rituxan                     |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                                                                               | Ativan                      |                    |                    | C               |                          | Unk                  |                 | Not Reported |                |
|                                                                               | Wellbutrin                  |                    |                    | C               |                          | Unk                  |                 | Not Reported |                |
|                                                                               | Folic Acid                  |                    |                    | C               |                          | Unk                  |                 | Not Reported |                |
|                                                                               | Ambien                      |                    |                    | C               |                          | Unk                  |                 | Not Reported |                |

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

|                |   |     |              |
|----------------|---|-----|--------------|
| Protonix       | C | Unk | Not Reported |
| Tramadol       | C | Unk | Not Reported |
| Flexeril       | C | Unk | Not Reported |
| Flonase        | C | Unk | Not Reported |
| Vitamin D3     | C | Unk | Not Reported |
| Omega 3        | C | Unk | Not Reported |
| Baby Aspirin   | C | Unk | Not Reported |
| Calcium        | C | Unk | Not Reported |
| Tessalon Perle | C | Unk | Not Reported |

| <u>FDA Received Date</u>                               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 30-Jan-2014                                            | 9776258        | EXPEDITED (15-DAY) |                    | OT              | DE-FRI-1000052397    |                      |                 | Female       | DEU            |
| <u>Preferred Term</u>                                  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alopecia; Drug Withdrawal Syndrome; Erythema; Pruritus | Escitalopram   |                    |                    | S               |                      | 5 Or 10 Mg/Day       |                 | Forest       |                |
|                                                        | Escitalopram   |                    |                    | S               |                      | 1 Mg                 |                 | Forest       |                |
|                                                        | Escitalopram   |                    |                    | S               |                      | 5 Mg                 |                 | Not Reported |                |
|                                                        | Citalopram     |                    |                    | S               |                      | 20 Mg                |                 | Forest       |                |

| <u>FDA Received Date</u>                                          | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------|-----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 30-Jan-2014                                                       | 9776807         | EXPEDITED (15-DAY) |                    | LT              | FR-ROCHE-1320529     |                      | 36 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                             | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Circulatory Collapse; Coma; Disturbance In Attention; Hypothermia | Valium          |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                   | Stilnox         |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                   | Depakine        |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                   | Seroplex        |                    |                    | S               | Unknown              |                      |                 | Not Reported |                |
|                                                                   | Zyprexa         |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                   | Relpax          |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                   | Levomepromazine |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |

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| Tercian                                                      |                     |                    | S                  |                 | Oral                 |                               |                 | Not Reported |                |
|--------------------------------------------------------------|---------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------|-----------------|--------------|----------------|
| <u>FDA Received Date</u>                                     | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Jan-2014                                                  | 9836203             | EXPEDITED (15-DAY) |                    | OT              | PHHY2014BR004456     |                               |                 | Male         | BRA            |
| <u>Preferred Term</u>                                        | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Drug Dependence; Panic Disorder; Visual Impairment | Tofranil            |                    |                    | S               |                      | Unk Unk, Unk                  |                 | Not Reported |                |
|                                                              | Anafranil           |                    |                    | S               |                      | Unk Unk, Unk                  |                 | Not Reported |                |
|                                                              | Fluoxetine          |                    |                    | S               |                      | Unk Unk, Unk                  |                 | Novartis     |                |
|                                                              | Risperidone         |                    |                    | S               |                      | Unk Unk, Unk                  |                 | Not Reported |                |
|                                                              | Tranxilene          |                    |                    | S               |                      | Unk Unk, Unk                  |                 | Not Reported |                |
|                                                              | Lorax//Lorazepam    |                    |                    | S               |                      | Unk Unk, Unk                  |                 | Not Reported |                |
|                                                              | Escitalopram        |                    |                    | S               |                      | Unk Unk, Unk                  |                 | Not Reported |                |
|                                                              | Amitriptyline       |                    |                    | S               |                      | Unk Unk, Unk                  |                 | Not Reported |                |
|                                                              | Venlafaxine         |                    |                    | S               |                      | Unk Unk, Unk                  |                 | Not Reported |                |
|                                                              | Rivotril            |                    |                    | S               |                      | 2 Mg, Bid (Morning And Night) |                 | Not Reported |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Jan-2014                                                  | 9855362             | EXPEDITED (15-DAY) |                    | HO              | DE-FRI-1000053116    |                               |                 | Female       | DEU            |
| <u>Preferred Term</u>                                        | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated; Psoriasis                              | Escitalopram        |                    |                    | S               | Oral                 | 20 Mg                         |                 | Forest       |                |
|                                                              | Luaf41156           |                    |                    | S               | Oral                 | 1 Mg                          |                 | Not Reported |                |
|                                                              | Micardis            |                    |                    | C               | Oral                 | 40 Mg                         |                 | Not Reported |                |
|                                                              | Torsemide           |                    |                    | C               | Oral                 | 20 Mg                         |                 | Not Reported |                |
|                                                              | Methotrexate Sodium |                    |                    | C               | Oral                 | 15 Mg                         |                 | Not Reported |                |
|                                                              | Folic Acid          |                    |                    | C               | Oral                 | 5 Mg                          |                 | Not Reported |                |
|                                                              | Paracetamol         |                    |                    | C               | Oral                 | 1000 Mg                       |                 | Not Reported |                |

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| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 30-Jan-2014              | 9856959       | NON-EXPEDITED    |                    |                 | NL-JNJFOC-20140113128 |                      |            | Female     | NLD            |

| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Exposure During Pregnancy | Risperidone    |              |            | S           | Unknown      |                    |                 | Not Reported |
|                           | Risperidone    |              |            | S           | Unknown      |                    |                 | Not Reported |
|                           | Risperidone    |              |            | S           | Unknown      |                    |                 | Not Reported |
|                           | Risperidone    |              |            | S           | Unknown      |                    |                 | Not Reported |
|                           | Haloperidol    |              |            | S           | Unknown      |                    |                 | Not Reported |
|                           | Haloperidol    |              |            | S           | Unknown      |                    |                 | Not Reported |
|                           | Haloperidol    |              |            | S           | Unknown      |                    |                 | Not Reported |
|                           | Haloperidol    |              |            | S           | Unknown      |                    |                 | Not Reported |
|                           | Pipamperon     |              |            | S           | Unknown      |                    |                 | Not Reported |
|                           | Pipamperon     |              |            | S           | Unknown      |                    |                 | Not Reported |
|                           | Pipamperon     |              |            | S           | Unknown      |                    |                 | Not Reported |
|                           | Pipamperon     |              |            | S           | Unknown      |                    |                 | Not Reported |
|                           | Citalopram     |              |            | S           | Unknown      |                    |                 | Not Reported |
|                           | Citalopram     |              |            | S           | Unknown      |                    |                 | Not Reported |
|                           | Citalopram     |              |            | S           | Unknown      |                    |                 | Not Reported |
|                           | Citalopram     |              |            | S           | Unknown      |                    |                 | Not Reported |
|                           | Paroxetine     |              |            | S           | Unknown      |                    |                 | Not Reported |
|                           | Paroxetine     |              |            | S           | Unknown      |                    |                 | Not Reported |
|                           | Paroxetine     |              |            | S           | Unknown      |                    |                 | Not Reported |
|                           | Paroxetine     |              |            | S           | Unknown      |                    |                 | Not Reported |
|                           | Fluvoxamine    |              |            | S           | Unknown      |                    |                 | Not Reported |
|                           | Fluvoxamine    |              |            | S           | Unknown      |                    |                 | Not Reported |
|                           | Fluvoxamine    |              |            | S           | Unknown      |                    |                 | Not Reported |
|                           | Fluvoxamine    |              |            | S           | Unknown      |                    |                 | Not Reported |
|                           | Fluoxetine     |              |            | S           | Unknown      |                    |                 | Not Reported |

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

|               |   |         |              |
|---------------|---|---------|--------------|
| Fluoxetine    | S | Unknown | Not Reported |
| Fluoxetine    | S | Unknown | Not Reported |
| Fluoxetine    | S | Unknown | Not Reported |
| Escitalopram  | S | Unknown | Not Reported |
| Escitalopram  | S | Unknown | Not Reported |
| Escitalopram  | S | Unknown | Not Reported |
| Escitalopram  | S | Unknown | Not Reported |
| Sertraline    | S | Unknown | Not Reported |
| Sertraline    | S | Unknown | Not Reported |
| Sertraline    | S | Unknown | Not Reported |
| Sertraline    | S | Unknown | Not Reported |
| Venlafaxine   | S | Unknown | Not Reported |
| Venlafaxine   | S | Unknown | Not Reported |
| Venlafaxine   | S | Unknown | Not Reported |
| Venlafaxine   | S | Unknown | Not Reported |
| Mirtazapine   | S | Unknown | Not Reported |
| Mirtazapine   | S | Unknown | Not Reported |
| Mirtazapine   | S | Unknown | Not Reported |
| Mirtazapine   | S | Unknown | Not Reported |
| Clomipramine  | S | Unknown | Not Reported |
| Clomipramine  | S | Unknown | Not Reported |
| Clomipramine  | S | Unknown | Not Reported |
| Clomipramine  | S | Unknown | Not Reported |
| Amitriptyline | S | Unknown | Not Reported |
| Amitriptyline | S | Unknown | Not Reported |
| Amitriptyline | S | Unknown | Not Reported |
| Amitriptyline | S | Unknown | Not Reported |
| Bupropion     | S | Unknown | Not Reported |
| Bupropion     | S | Unknown | Not Reported |

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

|               |   |         |              |
|---------------|---|---------|--------------|
| Bupropion     | S | Unknown | Not Reported |
| Bupropion     | S | Unknown | Not Reported |
| Quetiapine    | S | Unknown | Not Reported |
| Quetiapine    | S | Unknown | Not Reported |
| Quetiapine    | S | Unknown | Not Reported |
| Quetiapine    | S | Unknown | Not Reported |
| Olanzapine    | S | Unknown | Not Reported |
| Olanzapine    | S | Unknown | Not Reported |
| Olanzapine    | S | Unknown | Not Reported |
| Olanzapine    | S | Unknown | Not Reported |
| Aripiprazole  | S | Unknown | Not Reported |
| Aripiprazole  | S | Unknown | Not Reported |
| Aripiprazole  | S | Unknown | Not Reported |
| Aripiprazole  | S | Unknown | Not Reported |
| Lithium       | S | Unknown | Not Reported |
| Lithium       | S | Unknown | Not Reported |
| Lithium       | S | Unknown | Not Reported |
| Lithium       | S | Unknown | Not Reported |
| Valproic Acid | S | Unknown | Not Reported |
| Valproic Acid | S | Unknown | Not Reported |
| Valproic Acid | S | Unknown | Not Reported |
| Valproic Acid | S | Unknown | Not Reported |
| Levothyroxine | C | Unknown | Not Reported |
| Biperiden     | C | Unknown | Not Reported |
| Insulin       | C | Unknown | Not Reported |
| Dexamethasone | C | Unknown | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Jan-2014              | 9857164       | EXPEDITED (15-DAY) | CA                 |                 | US-FRI-1000053173    |                      | < 1 DAY    | Male       | USA            |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                                        | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|----------------------------------------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Atrial Septal Defect;<br>Fallot'S Tetralogy;<br>Hypospadias; Pulmonary<br>Valve Incompetence | Lexapro                     |                    |                    | S               | Transplacental       |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                     | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-Jan-2014                                                                                  | 9688460                     | EXPEDITED (15-DAY) |                    | DE              | DE-FRI-1000051147    |                      | 29 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                                                        | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyperhidrosis; Sudden<br>Death; Weight Increased                                             | Escitalopram                |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                                                                              | Escitalopram                |                    |                    | S               |                      |                      |                 | Forest       |                |
|                                                                                              | Escitalopram Oral Solution  |                    |                    | S               | Oral                 | Slow Dosage Increase |                 | Forest       |                |
|                                                                                              | Escitalopram Oral Solution  |                    |                    | S               |                      |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                     | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-Jan-2014                                                                                  | 9727493                     | EXPEDITED (15-DAY) |                    | LT              | FR-FRI-1000051816    |                      | 49 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                        | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Coma; Hypokalaemia;<br>Hyponatraemia; Seizure                                                | Escitalopram                |                    |                    | S               | Oral                 | 1 Df                 |                 | Forest       |                |
|                                                                                              | Fludex (Indapamide)         |                    |                    | S               | Oral                 | 1 Df                 |                 | Not Reported |                |
|                                                                                              | Xeroquel                    |                    |                    | C               | Oral                 | 1 Df                 |                 | Not Reported |                |
|                                                                                              | Alprazolam                  |                    |                    | C               | Oral                 | 1 Df                 |                 | Not Reported |                |
|                                                                                              | Zolpidem                    |                    |                    | C               | Oral                 | 5 Mg                 |                 | Not Reported |                |
|                                                                                              | Vasten [Pravastatin Sodium] |                    |                    | C               | Oral                 | 1 Dr                 |                 | Not Reported |                |
|                                                                                              | Doliprane                   |                    |                    | C               | Oral                 | 6 Df                 |                 | Not Reported |                |
|                                                                                              | Domperidone                 |                    |                    | C               | Oral                 | 3 Df                 |                 | Not Reported |                |
|                                                                                              | Tarka                       |                    |                    | C               | Oral                 | 180 Mg /2 Mg Daily   |                 | Not Reported |                |
|                                                                                              | Inexium                     |                    |                    | C               | Oral                 | 2 Df                 |                 | Not Reported |                |
|                                                                                              | Levothyrox                  |                    |                    | C               | Oral                 | 1 Df                 |                 | Not Reported |                |
|                                                                                              | Ostram Vitamine D3          |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |

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

|                                                                                                                                    |   |      |      |              |
|------------------------------------------------------------------------------------------------------------------------------------|---|------|------|--------------|
| Transipeg (Polyethylene Glycol<br>3350\Potassium<br>Chloride\Sodium<br>Bicarbonate\Sodium<br>Chloride\Sodium Sulfate<br>Anhydrous) | C | Oral | 2 Df | Not Reported |
|------------------------------------------------------------------------------------------------------------------------------------|---|------|------|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-Jan-2014              | 9783378       | EXPEDITED (15-DAY) |                    | LT, OT          | FR-SA-2013SA130931   |                      | 36 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                   | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                   |
|-------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------------------------|
| Circulatory Collapse;<br>Coma; Disturbance In<br>Attention; Hypothermia | Tercian              |              |            | S           | Oral         |                    |                 | Not Reported                 |
|                                                                         | Levomepromazine      |              |            | S           | Oral         |                    |                 | Not Reported                 |
|                                                                         | Depakine             |              |            | S           | Oral         |                    |                 | Not Reported                 |
|                                                                         | Stilnox              |              |            | S           | Oral         |                    |                 | Not Reported                 |
|                                                                         | Valium               |              |            | S           | Oral         |                    |                 | Not Reported                 |
|                                                                         | Seroplex             |              |            | S           | Oral         |                    |                 | Not Reported                 |
|                                                                         | Zyprexa              |              |            | S           | Oral         |                    |                 | Not Reported                 |
|                                                                         | Relpax               |              |            | S           | Oral         |                    |                 | Not Reported                 |
|                                                                         | Ketum<br>Paracetamol |              |            | C<br>C      |              |                    |                 | Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 31-Jan-2014              | 9842258       | EXPEDITED (15-DAY) |                    | LT, OT          | FR-PFIZER INC-<br>2014020668 |                      | 36 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                                                                           | <u>Product</u>  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------|-----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Circulatory Collapse;<br>Coma; Disturbance In<br>Attention; Hypothermia;<br>Pneumonia Aspiration;<br>Toxicity To Various Agents | Relpax          |              |            | S           | Oral         | Unk                |                 | Pfizer       |
|                                                                                                                                 | Valium          |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                                                                                                                                 | Stilnox         |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                                                                                                                                 | Depakine        |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                                                                                                                                 | Tercian         |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                                                                                                                                 | Levomepromazine |              |            | S           | Oral         | Unk                |                 | Not Reported |

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

|             |   |      |              |
|-------------|---|------|--------------|
| Seroplex    | S | Unk  | Not Reported |
| Zyprexa     | S | Oral | Unk          |
| Ketum       | C | Unk  | Not Reported |
| Paracetamol | C | Unk  | Not Reported |
| Noctran     | C |      | Not Reported |
| Nordazepam  | C | Unk  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|---------------------------|--------------------|--------------------|-----------------|------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 31-Jan-2014              | 9858138                   | EXPEDITED (15-DAY) |                    | DE              | US-LUPIN<br>PHARMACEUTICALS<br>INC.-2014-00125 |                      | 86 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide        | Amlodipine                |                    |                    | S               | Oral                                           |                      |                 | Not Reported |                |
|                          | Escitalopram              |                    |                    | S               | Oral                                           |                      |                 | Not Reported |                |
|                          | Acetaminophen+Hydrocodone |                    |                    | S               | Oral                                           |                      |                 | Not Reported |                |
|                          | Isosorbide Mononitrate    |                    |                    | S               | Oral                                           |                      |                 | Not Reported |                |
|                          | Doxazosin                 |                    |                    | S               | Oral                                           |                      |                 | Not Reported |                |
|                          | Warfarin                  |                    |                    | S               | Oral                                           |                      |                 | Not Reported |                |
|                          | Furosemide                |                    |                    | S               | Oral                                           |                      |                 | Not Reported |                |
|                          | Levothyroxine             |                    |                    | S               | Oral                                           |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 31-Jan-2014              | 9858145        | EXPEDITED (15-DAY) |                    | DE, HO          | US-LUPIN<br>PHARMACEUTICALS<br>INC.-2014-00128 |                      | 31 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide        | Escitalopram   |                    |                    | S               | Oral                                           |                      |                 | Lupin        |                |
|                          | Meloxicam      |                    |                    | S               | Oral                                           |                      |                 | Not Reported |                |
|                          | Lamotrigine    |                    |                    | S               | Oral                                           |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| 31-Jan-2014                                                             | 9858729              | EXPEDITED (15-DAY) |                    | LT, OT          | FR-ABBVIE-14P-056-1196584-00 |                      | 36 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Circulatory Collapse;<br>Coma; Disturbance In<br>Attention; Hypothermia | Depakine             |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                                         | Tercian              |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                                         | Levomepromazine      |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                                         | Stilnox              |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                                         | Valium               |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                                         | Seroplex             |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                                         | Zyprexa              |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                                         | Relpax               |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                                         | Ketum                |                    |                    | C               |                              |                      |                 | Not Reported |                |
|                                                                         | Paracetamol          |                    |                    | C               |                              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-Jan-2014                                                             | 9858878              | EXPEDITED (15-DAY) |                    | OT              | ES-TEVA-437945ISR            |                      | 57 YR           | Female       | ESP            |
| <u>Preferred Term</u>                                                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyponatraemia                                                           | Venlafaxine          |                    |                    | S               | Unknown                      |                      |                 | Not Reported |                |
|                                                                         | Citalopram           |                    |                    | S               | Unknown                      |                      |                 | Not Reported |                |
|                                                                         | Escitalopram         |                    |                    | S               | Unknown                      |                      |                 | Not Reported |                |
|                                                                         | Olanzapine           |                    |                    | S               | Unknown                      |                      |                 | Teva         |                |
|                                                                         | Haloperidol          |                    |                    | S               | Unknown                      |                      |                 | Not Reported |                |
|                                                                         | Enalapril            |                    |                    | S               | Unknown                      |                      |                 | Not Reported |                |
|                                                                         | Unspecified Thiazide |                    |                    | S               |                              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-Jan-2014                                                             | 9859275              | EXPEDITED (15-DAY) |                    | OT              | NL-JNJFOC-20140113524        |                      |                 | Unknown      | NLD            |

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

| <u>Preferred Term</u>                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Apgar Score Low; Foetal Exposure During Pregnancy | Risperidone    |              |            | S           | Transplacental | Mother'S Dosing    |                 | Not Reported |
|                                                   | Haloperidol    |              |            | S           | Transplacental | Mother'S Dosing    |                 | Not Reported |
|                                                   | Pipamperon     |              |            | S           | Transplacental | Mother'S Dosing    |                 | Not Reported |
|                                                   | Citalopram     |              |            | S           | Transplacental | Mother'S Dosing    |                 | Not Reported |
|                                                   | Paroxetine     |              |            | S           | Transplacental | Mother'S Dosing    |                 | Not Reported |
|                                                   | Fluvoxamine    |              |            | S           | Transplacental | Mother'S Dosing    |                 | Not Reported |
|                                                   | Fluoxetine     |              |            | S           | Transplacental | Mother'S Dosing    |                 | Not Reported |
|                                                   | Escitalopram   |              |            | S           | Transplacental | Mother'S Dosing    |                 | Not Reported |
|                                                   | Sertraline     |              |            | S           | Transplacental | Mother'S Dosing    |                 | Not Reported |
|                                                   | Venlafaxine    |              |            | S           | Transplacental | Mother'S Dosing    |                 | Not Reported |
|                                                   | Mirtazapine    |              |            | S           | Transplacental | Mother'S Dosing    |                 | Not Reported |
|                                                   | Clomipramine   |              |            | S           | Transplacental | Mother'S Dosing    |                 | Not Reported |
|                                                   | Amitriptyline  |              |            | S           | Transplacental | Mother'S Dosing    |                 | Not Reported |
|                                                   | Bupropion      |              |            | S           | Transplacental | Mother'S Dosing    |                 | Not Reported |
|                                                   | Quetiapine     |              |            | S           | Transplacental | Mother'S Dosing    |                 | Not Reported |
|                                                   | Olanzapine     |              |            | S           | Transplacental | Mother'S Dosing    |                 | Not Reported |
|                                                   | Aripiprazole   |              |            | S           | Transplacental | Mother'S Dosing    |                 | Not Reported |
|                                                   | Lithium        |              |            | S           | Transplacental | Mother'S Dosing    |                 | Not Reported |
|                                                   | Valproic Acid  |              |            | S           | Transplacental | Mother'S Dosing    |                 | Not Reported |
|                                                   | Levothyroxine  |              |            | C           | Transplacental | Mother'S Dosing    |                 | Not Reported |
|                                                   | Biperiden      |              |            | C           | Transplacental | Mother'S Dosing    |                 | Not Reported |
|                                                   | Insulin        |              |            | C           | Transplacental | Mother'S Dosing    |                 | Not Reported |
|                                                   | Dexamethasone  |              |            | C           | Transplacental | Mother'S Dosing    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-Jan-2014              | 9859678       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000053329    |                      | 55 YR      | Female     | FRA            |

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

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

|                          |              |   |      |                           |              |
|--------------------------|--------------|---|------|---------------------------|--------------|
| Confusional State;       | Escitalopram | S | Oral | 1 Df                      | Forest       |
| Electrocardiogram Qt     | Escitalopram | S |      | Overdose Of 13 Tablets Of | Not Reported |
| Prolonged; Encephalitis; |              |   |      | 20 Mg                     |              |
| Extrapyramidal Disorder; | Teralithe    | S | Oral | 1 Df                      | Not Reported |
| Intentional Overdose     | Teralithe    | S |      | Overdose Of 6 Or 7        | Not Reported |
|                          |              |   |      | Tablets Of 250 Mg         |              |
|                          | Seresta      | S | Oral |                           | Not Reported |
|                          | Seresta      | S | Oral | Overdose Of An Unknown    | Not Reported |
|                          |              |   |      | Dose                      |              |
|                          | Havlane      | S | Oral | 1 Df                      | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-Jan-2014              | 9859705       | EXPEDITED (15-DAY) |                    | LT              | FR-FRI-1000053300    |                      | 36 YR      | Female     | FRA            |

| <u>Preferred Term</u>  | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Circulatory Collapse;  | Escitalopram        |              |            | S           |              |                    |                 | Forest       |
| Coma; Disturbance In   | Valium              |              |            | S           |              |                    |                 | Not Reported |
| Attention; Hypothermia | Stilnox             |              |            | S           |              |                    |                 | Not Reported |
|                        | Valproate De Sodium |              |            | S           |              |                    |                 | Not Reported |
|                        | Tercian             |              |            | S           |              |                    |                 | Not Reported |
|                        | Levomepromazine     |              |            | S           |              |                    |                 | Not Reported |
|                        | Zyprexa             |              |            | S           |              |                    |                 | Not Reported |
|                        | Relpax              |              |            | S           |              |                    |                 | Not Reported |
|                        | Noctran             |              |            | S           |              |                    |                 | Not Reported |
|                        | Ketum               |              |            | C           |              |                    |                 | Not Reported |
|                        | Paracetamol         |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-Jan-2014              | 9859721       | EXPEDITED (15-DAY) |                    | LT              | FR-FRI-1000053299    |                      | 81 YR      | Female     | FRA            |

| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |
|------------------------|----------------|--------------|------------|-------------|--------------|--------------------------|-----------------|--------------|
| Electrocardiogram Qt   | Escitalopram   |              |            | S           | Oral         |                          |                 | Forest       |
| Prolonged; Hypercapnic | Escitalopram   |              |            | S           | Oral         | Overdose With 24 Tablets |                 | Forest       |
| Coma; Overdose;        |                |              |            |             |              |                          |                 |              |
| Respiratory Arrest     | Victan         |              |            | S           | Oral         |                          |                 | Not Reported |

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

|  |             |   |      |                          |              |
|--|-------------|---|------|--------------------------|--------------|
|  | Victan      | S | Oral | Overdose With 30 Tablets | Not Reported |
|  | Valdoxan    | C |      |                          | Not Reported |
|  | Kardegic    | C |      |                          | Not Reported |
|  | Flecaine    | C |      |                          | Not Reported |
|  | Aldactazine | C |      |                          | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-Jan-2014              | 9860971       | DIRECT           |                    |                 |                      |                      | 53 YR      | Female     | USA            |

| <u>Preferred Term</u>                | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------|--------------------|--------------|------------|-------------|--------------|-----------------------------------|-----------------|--------------|
| Headache; Product Substitution Issue | Escitalopram 10 Mg |              |            | S           | Oral         | Q Daily Once Daily Taken By Mouth |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-Jan-2014              | 9867261       | EXPEDITED (15-DAY) | Y                  | DE              | 2014AP000499         |                      | 55 YR      | Male       | USA            |

| <u>Preferred Term</u>                        | <u>Product</u>                                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------|-----------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardio-Respiratory Arrest; Completed Suicide | Citalopram Hydrobromide Tablets               |              |            | S           | Oral         | ; Po               |                 | Not Reported |
|                                              | Escitalopram 20mg Generic                     |              |            | S           | Oral         | ; Po               |                 | Not Reported |
|                                              | Acetaminophen W/Diphenhydramine Hydrochloride |              |            | S           | Oral         | ; Po               |                 | Not Reported |
|                                              | Bupropion Hydrochloride Tablets               |              |            | S           | Oral         | ; Po               |                 | Not Reported |
|                                              | Clonazepam Tablets, Usp                       |              |            | S           | Oral         | ; Po               |                 | Not Reported |
|                                              | Tadalafil                                     |              |            | S           | Oral         | ; Po               |                 | Not Reported |
|                                              |                                               |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------------------|----------------------|------------|------------|----------------|
| 01-Feb-2014              | 9860176       | EXPEDITED (15-DAY) |                    | DE              | US-LUPIN PHARMACEUTICALS INC.-2014-00184 |                      | 47 YR      | Female     | USA            |

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

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                              |   |      |              |
|------------------------------|---|------|--------------|
| Escitalopram                 | S | Oral | Not Reported |
| Carvedilol                   | S | Oral | Not Reported |
| Citalopram                   | S | Oral | Not Reported |
| Alprazolam                   | S | Oral | Not Reported |
| Bupropion (Extended Release) | S | Oral | Not Reported |
| Acetaminophen/Hydrocodone    | S | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Feb-2014              | 9657648       | EXPEDITED (15-DAY) |                    | HO              | FR-SA-2013SA106956   |                      | 36 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abdominal Pain; Hepatic Enzyme Increased; Pancreatitis Acute; Vomiting | Stilnox        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                        | Stilnox        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                        | Seroplex       |              |            | S           | Oral         | Strength: 10 Mg    |                 | Not Reported |
|                                                                        | Seroplex       |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                        | Methadone      |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                        | Methadone      |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Feb-2014              | 9861807       | EXPEDITED (15-DAY) |                    | HO              | FR-ROCHE-1342576     |                      | 90 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hyponatraemia         | Rocephine      |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Rocephine      |              |            | S           |              |                    |                 | Not Reported |
|                       | Seroplex       |              |            | S           | Oral         | Coated-Film Tablet |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Feb-2014              | 9862826       | EXPEDITED (15-DAY) |                    | DE, OT          | CHPA2014US001719     |                      | 55 YR      | Male       | USA            |

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



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

|                                                 |                       |   |   |      |  |              |
|-------------------------------------------------|-----------------------|---|---|------|--|--------------|
| Cardio-Respiratory Arrest;<br>Completed Suicide | Acetam/Diphen Citrate | Y | S | Oral |  | Novartis     |
|                                                 | Citalopram            |   | S | Oral |  | Not Reported |
|                                                 | Escitalopram          |   | S | Oral |  | Not Reported |
|                                                 | Bupropion             |   | S | Oral |  | Not Reported |
|                                                 | Clonazepam            |   | S | Oral |  | Not Reported |
|                                                 | Tadalafil             |   | S | Oral |  | Not Reported |

| <u>FDA Received Date</u>                                                                                                                                                                                       | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|--------------------|--------------------|-----------------|-------------------------------------------------|--------------------------------|-----------------|--------------|----------------|
| 03-Feb-2014                                                                                                                                                                                                    | 9863160         | EXPEDITED (15-DAY) |                    | DE, HO          | US-PAR<br>PHARMACEUTICAL,<br>INC-2014SCPR008744 |                                | 55 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                          | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Arrhythmia; Bradycardia;<br>Cardio-Respiratory Arrest;<br>Completed Suicide; Death;<br>Hyperhidrosis;<br>Hyperthermia;<br>Hypotension; Muscle<br>Rigidity; Nystagmus;<br>Overdose; Pulmonary<br>Oedema; Tremor | Alprazolam      |                    |                    | S               |                                                 | Unk, Unknown, Ingst +<br>Aspir |                 | Par          |                |
|                                                                                                                                                                                                                | Vilazodone      |                    |                    | S               |                                                 | Unk, Unknown, Ingst+<br>Aspir  |                 | Not Reported |                |
|                                                                                                                                                                                                                | Salicylates Nos |                    |                    | S               |                                                 | Unk, Unknown, Ingst+<br>Aspir  |                 | Not Reported |                |
|                                                                                                                                                                                                                | Escitalopram    |                    |                    | S               |                                                 | Unk, Unknown, Ingst+<br>Aspir  |                 | Not Reported |                |
|                                                                                                                                                                                                                | Duloxetine      |                    |                    | S               |                                                 | Unk, Unknown, Ingst+<br>Aspir  |                 | Not Reported |                |

| <u>FDA Received Date</u>                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 03-Feb-2014                                            | 9863176              | EXPEDITED (15-DAY) |                    | DE              | US-PAR<br>PHARMACEUTICAL,<br>INC-2014SCPR008742 |                      | 45 YR           | Female       | USA            |
| <u>Preferred Term</u>                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardio-Respiratory Arrest;<br>Completed Suicide; Death | Alprazolam           |                    |                    | S               | Oral                                            | Unk, Unknown         |                 | Par          |                |
|                                                        | Zolpidem Tartrate Er |                    |                    | S               | Oral                                            | Unk, Unknown         |                 | Par          |                |
|                                                        | Escitalopram         |                    |                    | S               | Oral                                            | Unk, Unknown         |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|------------------------------|-----------------|--------------|----------------|
| 03-Feb-2014                                                   | 9865170        | EXPEDITED (15-DAY) |                    | OT              | PHHY2014IT011645     |                              |                 | Unknown      | ITA            |
| <u>Preferred Term</u>                                         | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Foetal Exposure During Pregnancy; Low Birth Weight Baby       | Escitalopram   |                    |                    | S               | Transplacental       | Maternal Dose: 10 Mg, Daily  |                 | Not Reported |                |
|                                                               | Alprazolam     |                    |                    | S               | Transplacental       | Maternal Dose: 0.25 Mg Daily |                 | Novartis     |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Feb-2014                                                   | 9869660        | DIRECT             |                    |                 |                      |                              | 44 YR           | Female       | USA            |
| <u>Preferred Term</u>                                         | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective; Product Substitution Issue                  | Escitalopram   |                    |                    | S               | Oral                 |                              |                 | Mylan        |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Feb-2014                                                   | 9880363        | EXPEDITED (15-DAY) | Y                  | DE              | ABR_01414_2014       |                              | 31 YR           | Female       | USA            |
| <u>Preferred Term</u>                                         | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Completed Suicide; Respiratory Arrest         | Lamotrigine    |                    |                    | S               | Oral                 |                              |                 | Not Reported |                |
|                                                               | Escitalopram   |                    |                    | S               | Oral                 |                              |                 | Not Reported |                |
|                                                               | Meloxicam      |                    |                    | S               | Oral                 |                              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Feb-2014                                                   | 9735120        | EXPEDITED (15-DAY) |                    | DE              | FR-FRI-1000051902    |                              | 40 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                         | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Labelled Drug-Drug Interaction Medication Error; Sudden Death | Escitalopram   |                    |                    | S               | Oral                 | 1 Df                         |                 | Forest       |                |
|                                                               | Methadone      |                    |                    | S               |                      | 1 Df                         |                 | Not Reported |                |

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|           |   |      |       |              |
|-----------|---|------|-------|--------------|
| Tercian   | C | Oral | 6 Df  | Not Reported |
| Valdoxan  | C | Oral | 1 Df  | Not Reported |
| Noctamide | C | Oral | 1 Df  | Not Reported |
| Xanax     | C | Oral | 6 Df  | Not Reported |
| Theralene | C | Oral | 50 Df | Not Reported |
| Neuleptil | C |      | 2 Df  | Not Reported |
| Efexor    | C |      | 1 Df  | Not Reported |
| Crestor   | C |      | 1 Df  | Not Reported |
| Inexium   | C |      | 1 Df  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 05-Feb-2014              | 9868972        | EXPEDITED (15-DAY) |                    | DE              | US-LUPIN<br>PHARMACEUTICALS<br>INC.-2014-00239 |                      | 93 YR           | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide        | Amlodipine     |                    |                    | S               | Oral                                           |                      |                 | Not Reported |                |
|                          | Escitalopram   |                    |                    | S               | Oral                                           |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|-----------------|--------------|----------------|
| 05-Feb-2014              | 9869240        | EXPEDITED (15-DAY) |                    | CA              | DE-ASTRAZENECA-<br>2014SE06138 |                      | 1 DAY           | Male         | DEU            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Haemangioma              | Seroquel       |                    |                    | S               | Transplacental                 |                      |                 | Zeneca       |                |
|                          | Ciprallex      |                    |                    | S               | Transplacental                 |                      |                 | Not Reported |                |
|                          | Medikinet      |                    |                    | S               | Transplacental                 |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 05-Feb-2014              | 9869941        | EXPEDITED (15-DAY) |                    | OT              | CA-FRI-1000053375    |                      | 58 YR           | Male       | CAN            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                               |                        |        |      |       |                        |
|-------------------------------|------------------------|--------|------|-------|------------------------|
| Hip Fracture;<br>Osteoporosis | Escitalopram<br>Forteo | S<br>C | Oral | 20 Mg | Forest<br>Not Reported |
|-------------------------------|------------------------|--------|------|-------|------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Feb-2014              | 9880642       | EXPEDITED (15-DAY) | Y                  | HO              | AUR-APL-2013-10922   |                      | 33 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                                                                                                                               | <u>Product</u>                  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|--------------|------------|-------------|--------------|----------------------------|-----------------|--------------|
| Agitation; Confusional State; Depressed Level Of Consciousness; Refusal Of Treatment By Patient; Self-Medication; Somnolence; Toxicity To Various Agents; Toxicologic Test Abnormal | Olanzapine (Olanzapine)         |              |            | S           | Oral         |                            |                 | Not Reported |
|                                                                                                                                                                                     | Lyrica (Pregabalin)             |              |            | S           | Oral         | 28 Df, Single 7.5 Mg, Oral |                 | Not Reported |
|                                                                                                                                                                                     | Lexomil (Bromazepam)            |              |            | S           | Oral         | Stopped                    |                 | Not Reported |
|                                                                                                                                                                                     | Seroplex (Escitalopram Oxalate) |              |            | S           | Oral         |                            |                 | Not Reported |
|                                                                                                                                                                                     |                                 |              |            |             | Oral         | 12 Df, Single 20 Mg, Oral  |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Feb-2014              | 9881535       | EXPEDITED (15-DAY) | Y                  | DE              | IMP_07344_2014       |                      | 45 YR      | Female     | USA            |

| <u>Preferred Term</u>                                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiac Arrest; Completed Suicide; Respiratory Arrest | Alprazolam     |              |            | S           |              |                    |                 | Not Reported |
|                                                       | Escitalopram   |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                       | Zolpidem       |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Feb-2014              | 9882075       | EXPEDITED (15-DAY) | Y                  | DE              | IMP_07445_2014       |                      | 55 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                          | <u>Product</u>  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------|-----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Arrhythmia; Atrial Flutter; Bradycardia; Cardio-Respiratory Arrest; Completed Suicide; Exposure Via Ingestion; | Alprazolam      |              |            | S           |              | (~100 Df Oral)     |                 | Not Reported |
|                                                                                                                | Vilazodone      |              |            | S           |              | (~21 Df Oral)      |                 | Not Reported |
|                                                                                                                | Salizylates Nos |              |            | S           |              | (Df Oral)          |                 | Not Reported |
|                                                                                                                | Escitalopram    |              |            | S           |              | (Df Oral)          |                 | Not Reported |

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

|                                |             |   |              |
|--------------------------------|-------------|---|--------------|
| Exposure Via Inhalation;       | Duloxetine  | S | Not Reported |
| Haematemesis;                  | Aripirazole | C | Not Reported |
| Hyperhidrosis;                 | Clonazepam  | C | Not Reported |
| Hyperthermia;                  |             |   |              |
| Hypotension; Intentional       |             |   |              |
| Overdose; Livedo               |             |   |              |
| Reticularis; Lung              |             |   |              |
| Infiltration; Muscle Rigidity; |             |   |              |
| Nystagmus; Pulmonary           |             |   |              |
| Oedema; Tremor;                |             |   |              |
| Unresponsive To Stimuli;       |             |   |              |
| Ventricular Tachycardia        |             |   |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Feb-2014              | 9883112       | EXPEDITED (15-DAY) | Y                  | DE              | IMP_07159_2014       |                      | 55 YR      | Male       | USA            |

| <u>Preferred Term</u>                           | <u>Product</u>                                      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------|-----------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiac Arrest; Completed<br>Suicide; Poisoning | Bupropion                                           |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                                 | Citalopram                                          |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                                 | Escitalopram                                        |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                                 | Acetaminophen<br>W/Diphenhydramine<br>Hydrochloride |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                                 | Clonazepam                                          |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                                 | Tadalafil                                           |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Feb-2014              | 9885768       | EXPEDITED (15-DAY) | Y                  | DE              | IMP_07169_2014       |                      | 47 YR      | Female     | USA            |

| <u>Preferred Term</u>                                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                        | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------|----------------|--------------|------------|-------------|--------------|-------------------------------------------|-----------------|--------------|
| Cardiac Arrest; Completed<br>Suicide; Respiratory Arrest | Bupropion      |              |            | S           |              | (Df Oral) Unknown Until<br>Not Continuing |                 | Not Reported |
|                                                          | Alprazolam     |              |            | S           |              | (Df Oral) Unknown Until<br>Not Continuing |                 | Not Reported |
|                                                          | Amlodipine     |              |            | S           |              | (Df Oral) Unknown Until                   |                 | Not Reported |

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

|                             |   |                                                             |              |
|-----------------------------|---|-------------------------------------------------------------|--------------|
| Carvediol                   | S | Not Continuing<br>(Df Oral) Unknown Until<br>Not Continuing | Not Reported |
| Acetaminophen W/Hydrocodone | S | (Df Oral) Unknown Until<br>Not Continuing                   | Not Reported |
| Citalopram                  | S | (Df Oral) Unknown Until<br>Not Continuing                   | Not Reported |
| Escitalopram                | S | (Df Oral) Unknown Until<br>Not Continuing                   | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Feb-2014              | 9615443       | EXPEDITED (15-DAY) |                    | OT              | DE-FRI-1000049927    |                      | 25 YR      | Female     | DEU            |

| <u>Preferred Term</u>                                               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Cyanosis; Extremity<br>Necrosis; Prescribed<br>Overdose; Vasculitis | Escitalopram   |              |            | S           | Oral         | 30 Mg              |                 | Forest     |
|                                                                     | Escitalopram   |              |            | S           |              |                    |                 | Forest     |
|                                                                     | Escitalopram   |              |            | S           | Oral         | 20 Mg              |                 | Forest     |
|                                                                     | Escitalopram   |              |            | S           | Oral         | 10 Mg              |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------------|----------------------|------------|------------|----------------|
| 06-Feb-2014              | 9704869       | EXPEDITED (15-DAY) |                    | HO              | BR-ABBVIE-13P-020-<br>1169600-00 |                      | 54 YR      | Female     | BRA            |

| <u>Preferred Term</u>                                                               | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------|-----------------------|--------------|------------|-------------|--------------|-------------------------|-----------------|--------------|
| Acute Myocardial<br>Infarction; Coronary Artery<br>Dissection; Pain In<br>Extremity | Humira                |              |            | S           | Subcutaneous |                         |                 | Not Reported |
|                                                                                     | Escitalopram          |              |            | S           | Oral         |                         |                 | Not Reported |
|                                                                                     | Pantoprazole          |              |            | C           | Oral         |                         |                 | Not Reported |
|                                                                                     | Clopidogrel Bisulfate |              |            | C           | Oral         | 1 Tablet After Lunch    |                 | Not Reported |
|                                                                                     | Aas                   |              |            | C           | Oral         | 1 Tablet After Lunch    |                 | Not Reported |
|                                                                                     | Atorvastatin          |              |            | C           | Oral         |                         |                 | Not Reported |
|                                                                                     | Atorvastatin          |              |            | C           | Oral         | 1 Tablet After Dinner   |                 | Not Reported |
|                                                                                     | Enalapril Maleate     |              |            | C           | Oral         | 1 Tablet In The Morning |                 | Not Reported |

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

|  |                           |   |       |  |                        |                                                                                |  |  |              |
|--|---------------------------|---|-------|--|------------------------|--------------------------------------------------------------------------------|--|--|--------------|
|  |                           |   |       |  | And 1 Tablet At Night. |                                                                                |  |  |              |
|  | Bromide Otilonio (Lonium) | C | Oral  |  |                        |                                                                                |  |  | Not Reported |
|  | Bromide Otilonio (Lonium) | C |       |  |                        |                                                                                |  |  | Not Reported |
|  | Dipyrone                  | C | Oral  |  |                        |                                                                                |  |  | Not Reported |
|  | Foraseq                   | C |       |  |                        | Form Of Administration:<br>Inhalant/Spray, Once A Day                          |  |  | Not Reported |
|  | Nasonex                   | C | Nasal |  |                        | Form Of Administration:<br>Inhalant/Spray 2 Puffs In Each Nostril, Twice A Day |  |  | Not Reported |
|  | Nasonex                   | C |       |  |                        |                                                                                |  |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 06-Feb-2014              | 9771156        | EXPEDITED (15-DAY) |                    | HO              | AU-FRI-1000052319    |                      |                 | Male       | AUS            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Partial Seizures         | Escitalopram   |                    |                    | S               |                      |                      |                 |            | Forest         |
|                          | Quetiapine     |                    |                    | S               |                      |                      |                 |            | Not Reported   |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|------------|----------------|
| 06-Feb-2014              | 9875861        | NON-EXPEDITED    |                    |                 | US-ACORDA-<br>ACO_35712_2013 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Dizziness                | Ampyra         |                  |                    | S               | Oral                         | 10 Mg, Q 12 Hrs      |                 |            | Acorda         |
|                          | Seroquel       |                  |                    | S               |                              | 25 Mg, Qd Hs         |                 |            | Not Reported   |
|                          | Wellbutrin XI  |                  |                    | S               |                              | 150 Mg, Qd           |                 |            | Not Reported   |
|                          | Lexapro        |                  |                    | S               |                              | 30 Mg, Qd            |                 |            | Not Reported   |
|                          | Provigil       |                  |                    | S               |                              | 100 Mg, Bid          |                 |            | Not Reported   |
|                          | Strattera      |                  |                    | C               |                              | 40 Mg, Qd            |                 |            | Not Reported   |
|                          | Baclofen       |                  |                    | C               |                              | 20 Mg, Tid           |                 |            | Not Reported   |
|                          | Toviaz         |                  |                    | C               |                              | 8 Mg, Qd Hs          |                 |            | Not Reported   |
|                          | Lisinopril     |                  |                    | C               |                              | 7.5 Unk, Qd          |                 |            | Not Reported   |

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

|             |   |           |              |
|-------------|---|-----------|--------------|
| Pravastatin | C | 20 Mg, Qd | Not Reported |
| Omeprazole  | C | 40 Mg, Qd | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Feb-2014              | 9877936       | EXPEDITED (15-DAY) | HO, LT             |                 | FR-FRI-1000053243    |                      | 53 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|---------------------------------------------|-----------------|--------------|
| Intentional Overdose;<br>Intentional Product<br>Misuse; Suicide Attempt | Escitalopram   |              |            | S           |              | 20 Mg                                       |                 | Forest       |
|                                                                         | Lysanxia       |              |            | C           | Oral         | 10 Mg                                       |                 | Not Reported |
|                                                                         | Lysanxia       |              |            | C           | Oral         | Overdose Of 80 Tablets Of<br>10 Mg (800 Mg) |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|------------|------------|----------------|
| 06-Feb-2014              | 9879282       | EXPEDITED (15-DAY) | HO                 |                 | CH-ASTRAZENECA-<br>2014SE07160 |                      | 61 YR      | Female     | CHE            |

| <u>Preferred Term</u>                                                                                       | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                             | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------|-------------------------------|--------------|------------|-------------|------------------------------------------|--------------------|-----------------|--------------|
| Application Site<br>Haemorrhage; Blood<br>Pressure Decreased; Drug<br>Interaction; Haemoglobin<br>Decreased | Brilique                      |              |            | S           | Oral                                     |                    |                 | Astrazeneca  |
|                                                                                                             | Klacid I.V.Infusionspraeparat |              |            | S           | Intravenous (not<br>otherwise specified) |                    |                 | Not Reported |
|                                                                                                             | Aspirin                       |              |            | S           | Oral                                     |                    |                 | Not Reported |
|                                                                                                             | Cipralext                     |              |            | S           | Oral                                     |                    |                 | Not Reported |
|                                                                                                             | Fragmin                       |              |            | S           | Subcutaneous                             |                    |                 | Not Reported |
|                                                                                                             | Sortis                        |              |            | C           |                                          |                    |                 | Not Reported |
|                                                                                                             | Seretide                      |              |            | C           |                                          |                    |                 | Not Reported |
|                                                                                                             | Ventolin                      |              |            | C           |                                          |                    |                 | Not Reported |
|                                                                                                             | Spiriva                       |              |            | C           |                                          |                    |                 | Not Reported |
|                                                                                                             | Lyrica                        |              |            | C           |                                          |                    |                 | Not Reported |
|                                                                                                             | Truxal                        |              |            | C           |                                          |                    |                 | Not Reported |
|                                                                                                             | Amaryl                        |              |            | C           |                                          |                    |                 | Not Reported |
|                                                                                                             | Tazobac                       |              |            | C           |                                          |                    |                 | Not Reported |
|                                                                                                             | Tamiflu                       |              |            | C           |                                          |                    |                 | Not Reported |



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

| <u>FDA Received Date</u>                                 | <u>Case #</u>                                                                                                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 06-Feb-2014                                              | 9879490                                                                                                             | EXPEDITED (15-DAY) |                    | OT              | DE-FRI-1000053965    |                      | 19 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                    | <u>Product</u>                                                                                                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Caesarean Section; Hellp Syndrome; Pre-Eclampsia         | Escitalopram                                                                                                        |                    |                    | S               | Oral                 | 20 Mg                |                 | Forest       |                |
|                                                          | Seroquel                                                                                                            |                    |                    | S               | Oral                 | 25 Mg                |                 | Not Reported |                |
|                                                          | Medikinet                                                                                                           |                    |                    | S               | Oral                 | 20 Mg                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                 | <u>Case #</u>                                                                                                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Feb-2014                                              | 9879609                                                                                                             | EXPEDITED (15-DAY) |                    | DE              | FR-FRI-1000054021    |                      | 87 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                    | <u>Product</u>                                                                                                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Subdural Haematoma                                       | Escitalopram                                                                                                        |                    |                    | S               | Oral                 |                      |                 | Forest       |                |
|                                                          | Plavix                                                                                                              |                    |                    | S               | Oral                 | 1 Df                 |                 | Not Reported |                |
|                                                          | Diamicron                                                                                                           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                          | Glucor                                                                                                              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                          | Ikorel                                                                                                              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                          | Pravastatin                                                                                                         |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                          | Transipeg (Polyethylene Glycol 3350\Potassium Chloride\Sodium Bicarbonate\Sodium Chloride\Sodium Sulfate Anhydrous) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                          | Triatec (Ramipril)                                                                                                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                          | Modopar                                                                                                             |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                          |                                                                                                                     |                    |                    |                 |                      |                      |                 |              |                |
| <u>FDA Received Date</u>                                 | <u>Case #</u>                                                                                                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Feb-2014                                              | 9879667                                                                                                             | EXPEDITED (15-DAY) |                    | CA              | DE-FRI-1000054006    |                      | < 1 DAY         | Male         | DEU            |
| <u>Preferred Term</u>                                    | <u>Product</u>                                                                                                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Foetal Exposure During Pregnancy; Haemangioma; Low Birth | Escitalopram                                                                                                        |                    |                    | S               | Transplacental       | 20 Mg                |                 | Forest       |                |
|                                                          | Seroquel                                                                                                            |                    |                    | S               | Transplacental       | 25 Mg                |                 | Not Reported |                |

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

|                                                                  |           |   |                |       |              |
|------------------------------------------------------------------|-----------|---|----------------|-------|--------------|
| Weight Baby; Neonatal<br>Respiratory Distress;<br>Premature Baby | Medikinet | S | Transplacental | 20 Mg | Not Reported |
|------------------------------------------------------------------|-----------|---|----------------|-------|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Feb-2014              | 9879742       | EXPEDITED (15-DAY) |                    | HO              | IT-TEVA-384276ISR    |                      | 56 YR      | Female     | ITA            |

| <u>Preferred Term</u>                                                 | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                                 | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------|---------------------|--------------|------------|-------------|--------------|------------------------------------------------------------------------------------|-----------------|--------------|
| Drug Abuse; Respiratory<br>Acidosis; Respiratory<br>Depression; Sopor | Paracetamol         |              |            | S           | Oral         | 28 Dosage Forms Daily;                                                             |                 | Not Reported |
|                                                                       | Venlafaxine         |              |            | S           | Oral         | 21 Dosage Forms Daily;                                                             |                 | Teva         |
|                                                                       | Lexotan             |              |            | S           | Oral         | 51 Dosage Forms Daily;                                                             |                 | Not Reported |
|                                                                       | Patrol 37.5mg/325mg |              |            | S           | Oral         | 4 Dosage Forms Daily; 1<br>Dosage Form = Tramadol<br>37.5mg + Paracetamol<br>325mg |                 | Not Reported |
|                                                                       | Moment              |              |            | S           | Oral         | 18 Dosage Forms Daily;                                                             |                 | Not Reported |
|                                                                       | Cipralext           |              |            | S           | Oral         | 18 Dosage Forms Daily;                                                             |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Feb-2014              | 9885576       | EXPEDITED (15-DAY) | Y                  | OT              | 2014HINLIT0093       |                      | 83 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|--------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hyperglycaemia        | Escitalopram                   |              |            | S           |              |                    | 3 DAY<br>15 DAY | Not Reported |
|                       | Glibenclamide                  |              |            | C           |              |                    |                 | Not Reported |
|                       | Enalapril + Hydrochlorotiazide |              |            | C           |              |                    |                 | Not Reported |
|                       | Doxazosin                      |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 07-Feb-2014              | 8889958       | NON-EXPEDITED    |                    |                 | US-PFIZER INC-<br>2012275999 |                      |            | Female     | USA            |

| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Drug Hypersensitivity; | Norvasc        |              |            | S           |              | Unk                |                 | Pfizer     |

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

|                             |          |   |      |               |              |
|-----------------------------|----------|---|------|---------------|--------------|
| Oedema; Peripheral Swelling | Lexapro  | S |      | Unk           | Not Reported |
|                             | Celebrex | C | Oral | 200 Mg, Daily | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 07-Feb-2014              | 9859811       | EXPEDITED (15-DAY) |                    | DE, OT          | NO-ABBVIE-14P-122-1195825-00 |                      | 41 YR      | Male       | NOR            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Antidepressant Drug Level; Aortic Thrombosis; Arterial Disorder; Arterial Thrombosis; Arterial Thrombosis; Cardiac Ventricular Thrombosis; Cardiovascular Disorder; Cerebral Artery Occlusion; Cerebral Artery Stenosis; Cerebral Haemorrhage; Cerebral Infarction; Cerebral Infarction; Cerebrovascular Disorder; Circulatory Collapse; Connective Tissue Disorder; Coronary Artery Occlusion; Drug Screen Positive; Emphysema; Infarction; Myocardial Infarction; Renal Artery Thrombosis | Norvir         |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Reyataz        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Truvada        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Escitalopram   |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Cannabis       |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Sarotex        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Neurontin      |              |            | C           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 07-Feb-2014              | 9881157       | EXPEDITED (15-DAY) |                    | DE              | US-MALLINCKRODT-T201400872 |                      | 47 YR      | Female     | USA            |

| <u>Preferred Term</u>                        | <u>Product</u>                       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------|--------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardio-Respiratory Arrest; Completed Suicide | Acetaminophen\Hydrocodone Bitartrate |              |            | S           | Oral         | Unk                |                 | Tyco         |
|                                              | Amlodipine                           |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                                              | Carvedilol                           |              |            | S           | Oral         | Unk                |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                  |   |      |     |              |
|------------------|---|------|-----|--------------|
| Bupropion Hcl Er | S | Oral | Unk | Not Reported |
| Citalopram       | S | Oral | Unk | Not Reported |
| Escitalopram     | S | Oral | Unk | Not Reported |
| Alprazolam       | S | Oral | Unk | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Feb-2014              | 9882116       | EXPEDITED (15-DAY) |                    | OT              | JP-FRI-1000053969    |                      | 20 YR      | Male       | JPN            |

| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Glucose Increased | Lexapro        |              |            | S           | Oral         |                    |                 | Forest       |
|                         | Abilify        |              |            | S           | Oral         |                    |                 | Not Reported |
|                         | Abilit         |              |            | C           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Feb-2014              | 9882673       | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000053339    |                      | 3 YR       | Male       | USA            |

| <u>Preferred Term</u>                                                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|------------|
| Arnold-Chiari Malformation; Congenital Anomaly; Spina Bifida; Talipes | Lexapro        |              |            | S           | Transplacental |                    |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Feb-2014              | 9884464       | DIRECT           |                    |                 |                      |                      | 54 YR      | Female     | USA            |

| <u>Preferred Term</u>                        | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------|--------------------|--------------|------------|-------------|--------------|------------------------|-----------------|--------------|
| Drug Ineffective; Product Substitution Issue | Escitalopram 10 Mg |              |            | S           | Oral         | 1 Pill Once Daily Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Feb-2014              | 9884860       | DIRECT           |                    | OT              |                      |                      |            | Female     | USA            |

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

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Depression                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Lexapro        |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Feb-2014                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 9888716        | EXPEDITED (15-DAY) | Y                  | DE              | SYM-2014-16251       |                      | 55 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Bicarbonate Decreased; Blood Chloride Increased; Blood Creatine Phosphokinase Increased; Blood Creatinine Increased; Blood Lactic Acid Abnormal; Blood Ph Decreased; Blood Potassium Increased; Blood Urea Increased; Bradycardia; Cardio-Respiratory Arrest; Completed Suicide; Electrocardiogram Qrs Complex Prolonged; Exposure Via Ingestion; Haematemesis; Hyperhidrosis; Hyperthermia; Hypotension; Intentional Overdose; Livedo Reticularis; Muscle Rigidity; Nystagmus; Oxygen Saturation Decreased; Poisoning; Pulmonary Oedema; Respiratory Rate Decreased; Tremor; | Salicylate     |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Escitalopram   |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Vilazodone     |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Alprazolam     |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Duloxetine     |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Unresponsive To Stimuli;  
Ventricular Tachycardia

| <u>FDA Received Date</u>         | <u>Case #</u>           | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------|-------------------------|------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 10-Feb-2014                      | 9886199                 | NON-EXPEDITED    |                    |                 | US-ENDO<br>PHARMACEUTICALS<br>INC.-PHEN20130002 |                      |                 | Male         | USA            |
| <u>Preferred Term</u>            | <u>Product</u>          | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| White Blood Cell Count Increased | Phentermine Hcl Tablets |                  |                    | S               | Oral                                            | Unknown              |                 | Not Reported |                |
|                                  | Lexapro                 |                  |                    | S               | Oral                                            |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                             | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|------------------------------------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 10-Feb-2014                                                                                          | 9890446        | DIRECT           |                    |                 |                      |                      | 51 YR           | Female     | USA            |
| <u>Preferred Term</u>                                                                                | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Anxiety; Atrial Fibrillation;<br>Palpitations; Product<br>Substitution Issue;<br>Withdrawal Syndrome | Escitalopram   |                  |                    | S               | Oral                 |                      |                 | Teva       |                |

| <u>FDA Received Date</u>                                     | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 10-Feb-2014                                                  | 9890974                       | EXPEDITED (15-DAY) | Y                  | OT              | ADR-2014-00215       |                      | 35 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                        | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alcohol Withdrawal<br>Syndrome; Blood<br>Pressure Increased; | Baclofen                      |                    |                    | S               |                      | 240 Mg/Day           |                 | Not Reported |                |
| Confusional State; Drug<br>Withdrawal Syndrome;              | Alcohol (Ethanol)             |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Hallucination, Visual;                                       | Alprazolam                    |                    |                    | S               |                      | 2mg/Day              |                 | Not Reported |                |
| Hepatocellular Injury;                                       | Escitalopram                  |                    |                    | S               |                      | 20mg/Day             |                 | Not Reported |                |
| Hyperhidrosis;                                               | Amitriptyline                 |                    |                    | S               |                      | 75mg/Day             |                 | Not Reported |                |
| Leukocytosis;                                                | Cannabis                      |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Neutrophilia; Sinus<br>Tachycardia; Tremor                   | Possible Other Benzodiazepine |                    |                    | S               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                      | <u>Case #</u>                                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------|-------------------------------------------------|--------------------|--------------------|-----------------|---------------------------------------|----------------------|-----------------|--------------|----------------|
| 10-Feb-2014                                   | 9891415                                         | EXPEDITED (15-DAY) | Y                  | OT              | 2014030472                            |                      | 61 YR           | Female       | CHE            |
| <u>Preferred Term</u>                         | <u>Product</u>                                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Acute Myocardial Infarction                   | Fragmin                                         |                    |                    | S               | Subcutaneous                          |                      |                 | Not Reported |                |
|                                               | Cipralex                                        |                    |                    | S               | Oral                                  |                      |                 | Not Reported |                |
|                                               | Klacid                                          |                    |                    | S               | Intravenous (not otherwise specified) |                      |                 | Not Reported |                |
|                                               | Seretide                                        |                    |                    | C               |                                       |                      |                 | Not Reported |                |
|                                               | Ventolin(Salbutamol)                            |                    |                    | C               |                                       |                      |                 | Not Reported |                |
|                                               | Spiriva                                         |                    |                    | C               |                                       |                      |                 | Not Reported |                |
|                                               | Lyrica(Pregabalin)                              |                    |                    | C               |                                       |                      |                 | Not Reported |                |
|                                               | Truxal(Chlorprothixene Hydrochloride)           |                    |                    | C               |                                       |                      |                 | Not Reported |                |
|                                               | Amaryl(Glimepiride)                             |                    |                    | C               |                                       |                      |                 | Not Reported |                |
|                                               | Tazobac(Piperacillin Sodium, Tazobactam Sodium) |                    |                    | C               |                                       |                      |                 | Not Reported |                |
|                                               | Tamiflu(Oseltamivir)                            |                    |                    | C               |                                       |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                      | <u>Case #</u>                                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Feb-2014                                   | 9348609                                         | EXPEDITED (15-DAY) |                    | HO              | US-SHIRE-ALL1-2013-03833              |                      | 34 YR           | Female       | USA            |
| <u>Preferred Term</u>                         | <u>Product</u>                                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Angina Pectoris; Dizziness; Pain In Extremity | Blinded 489 (Lisdexamfetamine Dimesylate)       |                    |                    | S               | Oral                                  | Unk, Unknown         |                 | Shire        |                |
|                                               | Blinded Escitalopram Oxalate                    |                    |                    | S               | Oral                                  | Unk, Unknown         |                 | Shire        |                |
|                                               | Blinded Placebo                                 |                    |                    | S               | Oral                                  | Unk, Unknown         |                 | Shire        |                |
|                                               | Blinded Venlafaxine Hydrochloride               |                    |                    | S               | Oral                                  | Unk, Unknown         |                 | Shire        |                |
|                                               | Escitalopram Oxalate                            |                    |                    | S               | Oral                                  | 10 Mg, Unknown       |                 | Unknown      |                |
|                                               | Mirena                                          |                    |                    | C               | Vaginal                               | Unk Unk, Unknown     |                 | Not Reported |                |
|                                               | Albuterol /00139501/                            |                    |                    | C               | Unknown                               | Unk Unk, Unknown     |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|------------------------------------------|----------------------|-----------------|--------------|----------------|
| 11-Feb-2014                                                                                    | 9741190        | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000051969                        |                      |                 | Female       | FRA            |
| <u>Preferred Term</u>                                                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Initial Insomnia;<br>Muscle Contracture; Off<br>Label Use                             | Escitalopram   |                    |                    | S               | Oral                                     | 10 Mg                |                 | Forest       |                |
|                                                                                                | Escitalopram   |                    |                    | S               |                                          |                      |                 | Forest       |                |
|                                                                                                | Escitalopram   |                    |                    | S               |                                          |                      |                 | Forest       |                |
|                                                                                                | Escitalopram   |                    |                    | S               |                                          |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Feb-2014                                                                                    | 9887664        | EXPEDITED (15-DAY) |                    | OT              | IT-MYLANLABS-<br>2013S1025458            |                      |                 | Unknown      | ITA            |
| <u>Preferred Term</u>                                                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Withdrawal<br>Syndrome Neonatal;<br>Foetal Exposure During<br>Pregnancy;<br>Hypoglycaemia | Escitalopram   |                    |                    | S               | Transplacental                           |                      |                 | Not Reported |                |
|                                                                                                | Paroxetine     |                    |                    | S               | Transplacental                           | 20-40mg/Day          |                 | Not Reported |                |
|                                                                                                | Clonazepam     |                    |                    | S               | Transplacental                           |                      |                 | Not Reported |                |
|                                                                                                | Lorazepam      |                    |                    | S               | Transplacental                           |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Feb-2014                                                                                    | 9888572        | EXPEDITED (15-DAY) |                    | HO              | CH-FRI-1000054059                        |                      |                 | Female       | CHE            |
| <u>Preferred Term</u>                                                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Application Site<br>Haemorrhage; Blood<br>Pressure Decreased;<br>Haemoglobin Decreased         | Escitalopram   |                    |                    | S               | Oral                                     | 10 Mg                |                 | Forest       |                |
|                                                                                                | Fragmin        |                    |                    | S               |                                          | 5000 Iu              |                 | Not Reported |                |
|                                                                                                | Brilique       |                    |                    | S               | Oral                                     |                      |                 | Not Reported |                |
|                                                                                                | Aspirin        |                    |                    | S               | Oral                                     |                      |                 | Not Reported |                |
|                                                                                                | Klacid         |                    |                    | S               | Intravenous (not<br>otherwise specified) |                      |                 | Not Reported |                |
|                                                                                                | Tazobac        |                    |                    | S               |                                          |                      |                 | Not Reported |                |
|                                                                                                | Amaryl         |                    |                    | S               |                                          |                      |                 | Not Reported |                |
|                                                                                                | Lyrica         |                    |                    | C               |                                          |                      |                 | Not Reported |                |



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|                           | Seretide       |                    |                    | C               |                              |                      |                 |              | Not Reported   |
|---------------------------|----------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
|                           | Ventolin       |                    |                    | C               |                              |                      |                 |              | Not Reported   |
|                           | Truxal         |                    |                    | C               |                              |                      |                 |              | Not Reported   |
|                           | Amaryl         |                    |                    | C               |                              |                      |                 |              | Not Reported   |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Feb-2014               | 9889133        | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000054115            |                      | 82 YR           | Female       | FRA            |
| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cerebral Haematoma;       | Escitalopram   |                    |                    | S               | Oral                         | 1 Df                 |                 | Forest       |                |
| Drug Interaction;         | Kardegic       |                    |                    | S               | Oral                         | 1 Df                 |                 | Not Reported |                |
| Headache                  |                |                    |                    |                 |                              |                      |                 |              |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Feb-2014               | 9889134        | EXPEDITED (15-DAY) |                    | OT              | SE-FRI-1000054117            |                      | 37 YR           | Female       | SWE            |
| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Optic Neuritis; Vision    | Escitalopram   |                    |                    | S               |                              |                      |                 | Forest       |                |
| Blurred                   |                |                    |                    |                 |                              |                      |                 |              |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Feb-2014               | 9889339        | EXPEDITED (15-DAY) |                    | CA, OT          | US-FRI-1000054042            |                      | < 1 DAY         | Male         | USA            |
| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Arnold-Chiari             | Lexapro        |                    |                    | S               | Transplacental               |                      |                 | Forest       |                |
| Malformation; Cerebral    |                |                    |                    |                 |                              |                      |                 |              |                |
| Dysgenesis; Cleft Lip And |                |                    |                    |                 |                              |                      |                 |              |                |
| Palate; Congenital        |                |                    |                    |                 |                              |                      |                 |              |                |
| Anomaly; Congenital       |                |                    |                    |                 |                              |                      |                 |              |                |
| Central Nervous System    |                |                    |                    |                 |                              |                      |                 |              |                |
| Anomaly; Hydrocephalus;   |                |                    |                    |                 |                              |                      |                 |              |                |
| Seizure                   |                |                    |                    |                 |                              |                      |                 |              |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Feb-2014               | 9889669        | NON-EXPEDITED      |                    |                 | US-PFIZER INC-<br>2014037604 |                      |                 | Female       | USA            |

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| <u>Preferred Term</u>                                                                                     | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|-----------------------------------------------------------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| Drug Hypersensitivity                                                                                     | Zoloft                        |                    |                    | S               |                            | Unk                  |                 | Pfizer       |                |
|                                                                                                           | Viibryd                       |                    |                    | S               |                            | Unk                  |                 | Not Reported |                |
|                                                                                                           | Wellbutrin                    |                    |                    | S               |                            | Unk                  |                 | Not Reported |                |
|                                                                                                           | Lexapro                       |                    |                    | S               |                            | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                  | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Feb-2014                                                                                               | 9904797                       | EXPEDITED (15-DAY) |                    | OT              | AUR-APL-2014-01264         |                      | 35 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                                                     | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Maternal Exposure During Pregnancy; No Therapeutic Response                                               | Escitalopram                  |                    |                    | S               |                            | 1 D                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                  | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Feb-2014                                                                                               | 9908450                       | EXPEDITED (15-DAY) |                    | DE              | AUR-APL-2014-00967         |                      | 31 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                     | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Completed Suicide; Exposure Via Ingestion; Respiratory Arrest; Toxicity To Various Agents | Lamotrigine (Lamotrigine)     |                    |                    | S               | Oral                       |                      |                 | Aurobindo    |                |
|                                                                                                           | Escitalopram (Escitalopram)   |                    |                    | S               |                            |                      |                 | Not Reported |                |
|                                                                                                           | Meloxicam (Meloxicam)         |                    |                    | S               |                            |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                  | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Feb-2014                                                                                               | 9068661                       | EXPEDITED (15-DAY) |                    | DE, HO, OT      | US-009507513-1301USA009711 |                      | 66 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                     | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardio-Respiratory Arrest; Completed Suicide; Toxicity To Various Agents                                  | Zocor                         |                    |                    | S               | Oral                       |                      |                 | Merck        |                |
|                                                                                                           | Methylphenidate Hydrochloride |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                                                                           | Acetaminophen                 |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                                                                           | Lithium                       |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |

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|                            |   |      |              |
|----------------------------|---|------|--------------|
| Escitalopram               | S | Oral | Not Reported |
| Aripiprazole               | S | Oral | Not Reported |
| Valacyclovir Hydrochloride | S | Oral | Not Reported |
| Propoxyphene               | S | Oral | Not Reported |
| Hydrocodone                | S | Oral | Not Reported |
| Oxycodone                  | S | Oral | Not Reported |
| Triazolam                  | S | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Feb-2014              | 9910175       | EXPEDITED (15-DAY) | CA, DE             |                 | 2014AP001191         |                      | 1 DAY      | Male       | USA            |

| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cleft Lip; Foetal Exposure | Paroxetine Hcl |              |            | S           |              |                    |                 | Not Reported |
| During Pregnancy; Hernia;  | Lexapro        |              |            | S           |              |                    |                 | Not Reported |
| Hydrocele; Maternal Drugs  |                |              |            |             |              |                    |                 |              |
| Affecting Foetus           |                |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Feb-2014              | 9913063       | EXPEDITED (15-DAY) | Y                  | HO              | 2014027812           |                      | 61 YR      | Female     | CHE            |

| <u>Preferred Term</u>        | <u>Product</u>               | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------|------------------------------|--------------|------------|-------------|--------------|---------------------|-----------------|--------------|
| Acute Myocardial             | Fragmin                      |              |            | S           | Subcutaneous |                     |                 | Not Reported |
| Infarction; Application Site | Brilique                     |              |            | S           | Oral         | 1 Df 1x Day Oral    |                 | Not Reported |
| Haemorrhage; Blood           | Aspirin                      |              |            | S           | Oral         | 1 Df 1x//Dayy, Oral |                 | Bayer        |
| Pressure Decreased;          | Cipraxel                     |              |            | S           | Oral         |                     |                 | Not Reported |
| Chronic Obstructive          | Ventolin(Slbutamol)          |              |            | C           |              |                     |                 | Not Reported |
| Pulmonary Disease; Drug      | Spirivia(Tiotropium Bromide) |              |            | C           |              |                     |                 | Not Reported |
| Interaction; Haemoglobin     | Lyrica(Pregabalin)           |              |            | C           |              |                     |                 | Not Reported |
| Decreased; Injection Site    | Truxal(Chlorprothixene       |              |            | C           |              |                     |                 | Not Reported |
| Pain; Pneumonia; Sepsis      | Hydrochloride)               |              |            |             |              |                     |                 |              |
|                              | Amaryl(Glimepiride)          |              |            | C           |              |                     |                 | Not Reported |
|                              | Tazobac(Piperacillin Sodium, |              |            | C           |              |                     |                 | Not Reported |
|                              | Tazobactam Sodium)           |              |            |             |              |                     |                 |              |
|                              | Tamiflu(Oseltamivir)         |              |            | C           |              |                     |                 | Not Reported |

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| Sortis(Atorvastatin)                                                                                                               |                                      |                    | C                  |                 |                          |                      | Not Reported    |              |                |
|------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| Seretide                                                                                                                           |                                      |                    | C                  |                 |                          |                      | Not Reported    |              |                |
| <u>FDA Received Date</u>                                                                                                           | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Feb-2014                                                                                                                        | 9913965                              | EXPEDITED (15-DAY) | Y                  | DE              | AUR-APL-2014-01215       |                      | 55 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                              | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Completed Suicide; Exposure Via Ingestion; Intentional Self-Injury; Respiratory Arrest; Toxicity To Various Agents | Citalopram (Citalopram)              |                    |                    | S               | Oral                     | Oral                 |                 | Not Reported |                |
|                                                                                                                                    | Escitalopram (Escitalopram)          |                    |                    | S               |                          | Unknown              |                 | Not Reported |                |
|                                                                                                                                    | Dozol                                |                    |                    | S               |                          | Unknown              |                 | Not Reported |                |
|                                                                                                                                    | Bupropion (Bupropion)                |                    |                    | S               |                          | Unknown              |                 | Not Reported |                |
|                                                                                                                                    | Clonazepam (Clonazepam) (Clonazepam) |                    |                    | S               |                          | Unknown              |                 | Not Reported |                |
|                                                                                                                                    | Tadalafil                            |                    |                    | S               |                          | Unknown              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                           | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Feb-2014                                                                                                                        | 9342556                              | EXPEDITED (15-DAY) |                    | OT              | AT-PFIZER INC-2013170797 |                      | 20 YR           | Male         | AUT            |
| <u>Preferred Term</u>                                                                                                              | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Fall; Loss Of Consciousness; Sleep Disorder                                                                             | Zeldox                               |                    |                    | S               |                          | 40 Mg, 1x/Day        |                 | Pfizer       |                |
|                                                                                                                                    | Zeldox                               |                    |                    | S               |                          | 60 Mg, 1x/Day        |                 | Pfizer       |                |
|                                                                                                                                    | Trittico Retard                      |                    |                    | S               |                          | 150 Mg, 1x/Day       |                 | Not Reported |                |
|                                                                                                                                    | Trittico Retard                      |                    |                    | S               |                          | 300 Mg, 1x/Day       |                 | Not Reported |                |
|                                                                                                                                    | Cipralelex                           |                    |                    | S               |                          | 10 Mg, 1x/Day        |                 | Not Reported |                |
|                                                                                                                                    | Cipralelex                           |                    |                    | S               |                          | 10 Mg, 1x/Day        |                 | Not Reported |                |
|                                                                                                                                    | Cipralelex                           |                    |                    | S               |                          | 20 Mg, Daily         |                 | Not Reported |                |
|                                                                                                                                    | Risperdal                            |                    |                    | C               |                          | 4 Mg, Daily          |                 | Not Reported |                |
|                                                                                                                                    | Risperdal                            |                    |                    | C               |                          | 3 Mg, Daily          |                 | Not Reported |                |
|                                                                                                                                    | Risperdal                            |                    |                    | C               |                          | 1 Mg, Daily          |                 | Not Reported |                |
|                                                                                                                                    | Dominal Forte                        |                    |                    | C               |                          | 80 Mg, Daily         |                 | Not Reported |                |
|                                                                                                                                    | Nicorette Inhaler                    |                    |                    | C               |                          | Unk Mg, 1x/Day       |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                           | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|--------------------|--------------------|-----------------|---------------------------------------------|----------------------|-----------------|------------------|----------------|
| 13-Feb-2014                                                                                                                                        | 9828461             | EXPEDITED (15-DAY) |                    | OT              | AU-FRI-1000052922                           |                      | 46 YR           | Female           | AUS            |
| <u>Preferred Term</u>                                                                                                                              | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |
| Diabetes Mellitus; Hepatic Function Abnormal; Hepatic Steatosis; Renal Impairment; Weight Increased                                                | Escitalopram        |                    |                    | S               | Oral                                        | 250 Mg               |                 | Forest           |                |
|                                                                                                                                                    | Clopine             |                    |                    | S               |                                             |                      |                 | Not Reported     |                |
|                                                                                                                                                    | Diazepam            |                    |                    | S               |                                             |                      |                 | Not Reported     |                |
|                                                                                                                                                    | Levetiracetam       |                    |                    | S               |                                             |                      |                 | Not Reported     |                |
|                                                                                                                                                    | Risperidone         |                    |                    | S               |                                             |                      |                 | Not Reported     |                |
| <u>FDA Received Date</u>                                                                                                                           | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 13-Feb-2014                                                                                                                                        | 9866805             | EXPEDITED (15-DAY) |                    | OT              | CH-009507513-1401CHE014395                  |                      | 43 YR           | Female           | CHE            |
| <u>Preferred Term</u>                                                                                                                              | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |
| Agitation; Intentional Overdose; Suicide Attempt                                                                                                   | Remeron             |                    |                    | S               | Oral                                        | 12 Df, Once          |                 | Merck            |                |
|                                                                                                                                                    | Ethanol             |                    |                    | S               | Oral                                        | Unk                  |                 | Not Reported     |                |
|                                                                                                                                                    | Escitalopram        |                    |                    | S               | Oral                                        | 5 Df, Once           |                 | Not Reported     |                |
|                                                                                                                                                    | Lorazepam           |                    |                    | S               | Oral                                        | 2 Mg, Unk            |                 | Not Reported     |                |
| <u>FDA Received Date</u>                                                                                                                           | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 13-Feb-2014                                                                                                                                        | 9883838             | EXPEDITED (15-DAY) |                    | HO, LT, OT      | FR-ELI_LILLY_AND_COMP<br>ANY-FR201401010987 |                      | 36 YR           | Female           | FRA            |
| <u>Preferred Term</u>                                                                                                                              | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |
| Circulatory Collapse; Coma; Disturbance In Attention; Drug Level Above Therapeutic; Hypothermia; Oxygen Saturation Decreased; Pneumonia Aspiration | Zyprexa             |                    |                    | S               | Oral                                        | 1 Df, Unknown        |                 | Eli Lilly And Co |                |
|                                                                                                                                                    | Valium /00017001/   |                    |                    | S               | Oral                                        | 1 Df, Unknown        |                 | Not Reported     |                |
|                                                                                                                                                    | Stilnox             |                    |                    | S               | Oral                                        | 1 Df, Unknown        |                 | Not Reported     |                |
|                                                                                                                                                    | Depakine /00228502/ |                    |                    | S               | Oral                                        | 1 Df, Unknown        |                 | Not Reported     |                |
|                                                                                                                                                    | Tercian /00759301/  |                    |                    | S               | Oral                                        | 1 Df, Unknown        |                 | Not Reported     |                |
|                                                                                                                                                    | Levomepromazine     |                    |                    | S               | Oral                                        | 1 Df, Unknown        |                 | Not Reported     |                |
|                                                                                                                                                    | Seroplex            |                    |                    | S               | Oral                                        | 1 Df, Unknown        |                 | Not Reported     |                |

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|             |   |         |               |              |
|-------------|---|---------|---------------|--------------|
| Relpax      | S | Oral    | 1 Df, Unknown | Not Reported |
| Ketum       | C | Unknown | 1 Df, Prn     | Not Reported |
| Paracetamol | C | Unknown | 1 Df, Prn     | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------------------------------------|----------------------|------------|------------|----------------|
| 13-Feb-2014              | 9893811       | EXPEDITED (15-DAY) |                    | OT              | BE-B.I.<br>PHARMACEUTICALS,I<br>NC./RIDGEFIELD-2014-<br>BI-05 |                      | 81 YR      | Male       | BEL            |

| <u>Preferred Term</u>                                                                                                                   | <u>Product</u>   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                         | <u>Duration</u> | <u>Mfr</u>           |
|-----------------------------------------------------------------------------------------------------------------------------------------|------------------|--------------|------------|-------------|--------------|--------------------------------------------|-----------------|----------------------|
| Altered State Of<br>Consciousness; Food<br>Interaction; Hallucination;<br>Hypertonia; Parkinsonism<br>Hyperpyrexia Syndrome;<br>Pyrexia | Pramipexole      |              |            | S           | Oral         | 2.1 Mg                                     |                 | Boehringer Ingelheim |
|                                                                                                                                         | Pramipexole      |              |            | S           |              | 1.05 Mg                                    |                 | Boehringer Ingelheim |
|                                                                                                                                         | Levodopa         |              |            | S           | Oral         | 250 Mg                                     |                 | Not Reported         |
|                                                                                                                                         | Levodopa         |              |            | S           |              | 750 Mg                                     |                 | Not Reported         |
|                                                                                                                                         | Venlafaxine      |              |            | S           | Oral         | 150 Mg                                     |                 | Not Reported         |
|                                                                                                                                         | Escitalopram     |              |            | S           | Oral         | 10 Mg                                      |                 | Not Reported         |
|                                                                                                                                         | Isosource Energy |              |            | S           |              | 20 MI/H (Protein Content:<br>6.1 G/100 MI) |                 | Not Reported         |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 13-Feb-2014              | 9893837       | EXPEDITED (15-DAY) |                    | HO              | CH-PFIZER INC-<br>2014035238 |                      | 76 YR      | Female     | CHE            |

| <u>Preferred Term</u>                                  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------|----------------|--------------|------------|-------------|--------------|---------------------------|-----------------|--------------|
| Drug Interaction;<br>Electrocardiogram Qt<br>Prolonged | Aromasin       |              |            | S           | Oral         | 25 Mg, 1x/Day             |                 | Pfizer       |
|                                                        | Cipraxel       |              |            | S           | Oral         | Unk                       |                 | Not Reported |
|                                                        | Procoralan     |              |            | S           | Oral         | Unk                       |                 | Not Reported |
|                                                        | Bactrim        |              |            | S           | Oral         | Unk                       |                 | Not Reported |
|                                                        | Beloc-Zok      |              |            | C           | Oral         | 25 Mg, 1x/Day             |                 | Not Reported |
|                                                        | Cosaar Plus    |              |            | C           | Oral         | 1 Df (50/12.5 Mg), 1x/Day |                 | Not Reported |
|                                                        | Aldactone      |              |            | C           | Oral         | 25 Mg, 1x/Day             |                 | Not Reported |
|                                                        | Prolia         |              |            | C           |              | Unk                       |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| Potassium                                                                                |                    |                    | C                  |                 |                      | Unk                    |                 |              | Not Reported   |  |
|------------------------------------------------------------------------------------------|--------------------|--------------------|--------------------|-----------------|----------------------|------------------------|-----------------|--------------|----------------|--|
| <u>FDA Received Date</u>                                                                 | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |  |
| 14-Feb-2014                                                                              | 9626159            | EXPEDITED (15-DAY) |                    | DE, HO, LT      | FR-UCBSA-100212      |                        | 58 YR           | Female       | FRA            |  |
| <u>Preferred Term</u>                                                                    | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |  |
| Death; Thrombocytopenia                                                                  | Keppra             |                    |                    | S               | Oral                 |                        |                 | Not Reported |                |  |
|                                                                                          | Seroplex           |                    |                    | S               | Oral                 |                        |                 | Not Reported |                |  |
|                                                                                          | Vfend              |                    |                    | S               | Oral                 |                        |                 | Not Reported |                |  |
|                                                                                          | Vfend              |                    |                    | S               | Oral                 |                        |                 | Not Reported |                |  |
|                                                                                          | Noxafil            |                    |                    | C               |                      |                        |                 | Not Reported |                |  |
|                                                                                          | Noxafil            |                    |                    | C               |                      |                        |                 | Not Reported |                |  |
|                                                                                          | Itraconazole       |                    |                    | C               |                      |                        |                 | Not Reported |                |  |
|                                                                                          | Itraconazole       |                    |                    | C               |                      |                        |                 | Not Reported |                |  |
|                                                                                          | Cyclosporine       |                    |                    | C               |                      |                        |                 | Not Reported |                |  |
|                                                                                          | Cellcept           |                    |                    | C               |                      |                        |                 | Not Reported |                |  |
|                                                                                          | Zophren            |                    |                    | C               |                      |                        |                 | Not Reported |                |  |
|                                                                                          | Amlor              |                    |                    | C               |                      |                        |                 | Not Reported |                |  |
|                                                                                          | Methylprednisolone |                    |                    | C               |                      |                        |                 | Not Reported |                |  |
|                                                                                          | Domperidone        |                    |                    | C               |                      |                        |                 | Not Reported |                |  |
|                                                                                          | Esomeprazole       |                    |                    | C               |                      |                        |                 | Not Reported |                |  |
|                                                                                          | Effexor            |                    |                    | C               |                      | Unknown Dose           |                 | Not Reported |                |  |
|                                                                                          | Vimpat             |                    |                    | C               |                      | Unknown Dose           |                 | Not Reported |                |  |
|                                                                                          | Urbanyl            |                    |                    | C               |                      | Unknown Dose           |                 | Not Reported |                |  |
|                                                                                          | Ogastoro           |                    |                    | C               |                      | Unknown Dose           |                 | Not Reported |                |  |
| <u>FDA Received Date</u>                                                                 | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |  |
| 14-Feb-2014                                                                              | 9769130            | EXPEDITED (15-DAY) | Y                  | HO              | AUR-APL-2013-10493   |                        | 86 YR           | Female       | ITA            |  |
| <u>Preferred Term</u>                                                                    | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |  |
| Bradycardia; Drug Abuse;<br>Intentional Overdose;<br>Psychomotor<br>Hyperactivity; Sopor | Bisoprolol         |                    |                    | S               | Oral                 | (3 Dosage Forms,Total) |                 | Not Reported |                |  |
|                                                                                          | Metformin          |                    |                    | S               | Oral                 | (1500 Mg,Total), Oral  |                 | Not Reported |                |  |
|                                                                                          | Tavor (Lorazepam)  |                    |                    | S               | Oral                 | (6 Dosage Forms,Total) |                 | Not Reported |                |  |

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

|                                   |   |      |                                  |              |
|-----------------------------------|---|------|----------------------------------|--------------|
| Cipralex                          | S | Oral | (3 Dosage Forms, Total)          | Not Reported |
| Diamicon                          | S | Oral | (3 Dosage Forms, Total),<br>Oral | Not Reported |
| Tachipirina                       | S | Oral | (3 Dosage Forms, Total)          | Not Reported |
| Serenase (Haloperidol)            | S | Oral | (2 Dosage Forms, Total)          | Not Reported |
| Coumadin (Warfarin Sodium)        | C |      |                                  | Not Reported |
| Dibase (Calecaliferol)            | C |      |                                  | Not Reported |
| Nexium (Esomeprazole)             | C |      |                                  | Not Reported |
| Magnesium                         |   |      |                                  |              |
| Isoptin (Verapamil Hydrochloride) | C |      |                                  | Not Reported |

| <u>FDA Received Date</u>                                                                                                  | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------|----------------------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|-----------------|--------------|----------------|
| 14-Feb-2014                                                                                                               | 9897831                    | EXPEDITED (15-DAY) |                    | OT              | DE-DRREDDYS-GER/GER/14/0038089 |                      | 25 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                                                                                     | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Exposure During Pregnancy; Premature Labour                                                                               | Lamotrigine                |                    |                    | S               | Oral                           | 150 [Mg/D ]          |                 | Not Reported |                |
|                                                                                                                           | Escitalopram               |                    |                    | S               | Oral                           | 20 [Mg/D ]           |                 | Not Reported |                |
|                                                                                                                           | Femibion Schwangerschaft 1 |                    |                    | C               | Oral                           | 0.8 [Mg/D ]          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                  | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Feb-2014                                                                                                               | 9897833                    | EXPEDITED (15-DAY) |                    | CA, OT          | DE-DRREDDYS-GER/GER/14/0038082 |                      | 1 DAY           | Male         | DEU            |
| <u>Preferred Term</u>                                                                                                     | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Foetal Exposure During Pregnancy; Hypospadias; Hypotonia; Motor Developmental Delay; Premature Baby; Small For Dates Baby | Lamotrigine                |                    |                    | S               | Transplacental                 |                      |                 | Not Reported |                |
|                                                                                                                           | Escitalopram               |                    |                    | S               | Transplacental                 | 20 [Mg/D ]           |                 | Not Reported |                |
|                                                                                                                           | Femibion Schwangerschaft 1 |                    |                    | C               | Transplacental                 | 0.8 [Mg/D ]          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                  | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Feb-2014                                                                                                               | 9898034                    | EXPEDITED (15-DAY) |                    | HO, OT          | CH-ASTRAZENECA-2014SE09132     |                      | 64 YR           | Female       | CHE            |



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

| <u>Preferred Term</u>                                                                                                                                                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                        | <u>Dosage Text</u>                                                       | <u>Duration</u>                                             | <u>Mfr</u>   |                |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|-----------------------------------------------------|--------------------------------------------------------------------------|-------------------------------------------------------------|--------------|----------------|
| Drug Interaction;<br>Electrocardiogram Qt<br>Prolonged;<br>Haematotoxicity;<br>Hypokalaemia; Renal<br>Failure; Toxicity To<br>Various Agents; Urinary<br>Tract Infection | Nexium         |                    |                    | S               | Oral                                                |                                                                          |                                                             | Astrazeneca  |                |
|                                                                                                                                                                          | Cipralext      |                    |                    | S               | Oral                                                |                                                                          |                                                             | Not Reported |                |
|                                                                                                                                                                          | Cipralext      |                    |                    | S               | Oral                                                |                                                                          |                                                             | Not Reported |                |
|                                                                                                                                                                          | Cipralext      |                    |                    | S               | Oral                                                |                                                                          |                                                             | Not Reported |                |
|                                                                                                                                                                          | Temgesic       |                    |                    | S               | Sublingual                                          |                                                                          |                                                             | Not Reported |                |
|                                                                                                                                                                          | Transtec       |                    |                    | S               | Transdermal                                         |                                                                          |                                                             | Not Reported |                |
|                                                                                                                                                                          | Afinitor       |                    |                    | S               | Oral                                                |                                                                          |                                                             | Not Reported |                |
|                                                                                                                                                                          | Afinitor       |                    |                    | S               | Oral                                                |                                                                          |                                                             | Not Reported |                |
|                                                                                                                                                                          | Afinitor       |                    |                    | S               | Oral                                                | After The 22-Jan-2014<br>10mg/Day And Every 2nd<br>Day+5 Mg/Day Addition |                                                             | Not Reported |                |
|                                                                                                                                                                          | Aromasin       |                    |                    | C               | Oral                                                |                                                                          |                                                             | Not Reported |                |
|                                                                                                                                                                          | Xgeva          |                    |                    | C               |                                                     | Per 2 Months                                                             |                                                             | Not Reported |                |
|                                                                                                                                                                          | Importal       |                    |                    | C               | Oral                                                |                                                                          |                                                             | Not Reported |                |
|                                                                                                                                                                          | Xanax          |                    |                    | C               | Oral                                                |                                                                          |                                                             | Not Reported |                |
|                                                                                                                                                                          | Seresta        |                    |                    | C               | Oral                                                |                                                                          |                                                             | Not Reported |                |
|                                                                                                                                                                          | Dafalgan       |                    |                    | C               | Oral                                                |                                                                          |                                                             | Not Reported |                |
|                                                                                                                                                                          | Irfen          |                    |                    | C               | Oral                                                |                                                                          |                                                             | Not Reported |                |
|                                                                                                                                                                          | Magnesium      |                    |                    | C               | Oral                                                |                                                                          |                                                             | Not Reported |                |
|                                                                                                                                                                          | Aranesp        |                    |                    | C               |                                                     |                                                                          | 3 Occasions (29-Aug-<br>2013, 26-Sep-2013, 28-<br>Nov-2013) |              | Not Reported   |
|                                                                                                                                                                          | Aranesp        |                    |                    | C               |                                                     |                                                                          | To 10 Mg 1 Per Day And 5<br>Mg Every Second Day             |              | Not Reported   |
| <u>FDA Received Date</u>                                                                                                                                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                | <u>503B Facility</u>                                                     | <u>Age</u>                                                  | <u>Sex</u>   | <u>Country</u> |
| 14-Feb-2014                                                                                                                                                              | 9898858        | EXPEDITED (15-DAY) |                    | OT              | CH-ROXANE<br>LABORATORIES, INC.-<br>2014-RO-00188RO |                                                                          | 56 YR                                                       | Male         | CHE            |
| <u>Preferred Term</u>                                                                                                                                                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                        | <u>Dosage Text</u>                                                       | <u>Duration</u>                                             | <u>Mfr</u>   |                |

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

|                                                    |                |   |        |              |
|----------------------------------------------------|----------------|---|--------|--------------|
| Electrocardiogram Qt Prolonged; Torsade De Pointes | Zidovudine     | S | 600 Mg | Roxane       |
|                                                    | Methadone      | S | 80 Mg  | Roxane       |
|                                                    | Escitalopram   | S | 30 Mg  | Not Reported |
|                                                    | Fluoxetine     | S | 20 Mg  | Not Reported |
|                                                    | Zuclopenthixol | S | 40 Mg  | Not Reported |
|                                                    | Atazanavir     | S | 400 Mg | Not Reported |
|                                                    | Lamivudine     | S | 300 Mg | Not Reported |
|                                                    | Ritonavir      | S | 200 Mg | Not Reported |

| <u>FDA Received Date</u>                             | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------|-----------------|--------------------|--------------------|-----------------|-----------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 14-Feb-2014                                          | 9898976         | EXPEDITED (15-DAY) |                    | DE, OT          | CH-ROXANE<br>LABORATORIES, INC.-<br>2014-RO-00192RO |                      | 55 YR           | Male         | CHE            |
| <u>Preferred Term</u>                                | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Electrocardiogram Qt Prolonged; Sudden Cardiac Death | Methadone       |                    |                    | S               |                                                     |                      |                 | Roxane       |                |
|                                                      | Zidovudine      |                    |                    | S               |                                                     | 600 Mg               |                 | Roxane       |                |
|                                                      | Escitalopram    |                    |                    | S               |                                                     | 30 Mg                |                 | Not Reported |                |
|                                                      | Atazanavir      |                    |                    | S               |                                                     | 400 Mg               |                 | Not Reported |                |
|                                                      | Levomepromazine |                    |                    | S               |                                                     | 50 Mg                |                 | Not Reported |                |
|                                                      | Lamivudine      |                    |                    | S               |                                                     | 300 Mg               |                 | Not Reported |                |

| <u>FDA Received Date</u>                                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 14-Feb-2014                                                | 9900075        | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000054151    |                      | < 1 DAY         | Female       | USA            |
| <u>Preferred Term</u>                                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aortic Stenosis; Bicuspid Aortic Valve; Congenital Anomaly | Lexapro        |                    |                    | S               |                      |                      |                 | Forest       |                |
|                                                            | Zoloft         |                    |                    | S               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Feb-2014              | 9913530       | EXPEDITED (15-DAY) | Y                  | DE              | AUR-APL-2014-01183   |                      | 47 YR      | Female     | USA            |

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

| <u>Preferred Term</u>                                                                                     | <u>Product</u>                                                                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|-----------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| Cardiac Arrest; Completed Suicide; Exposure Via Ingestion; Respiratory Arrest; Toxicity To Various Agents | Amlodipine                                                                       |                    |                    | S               | Oral                  | Oral                 |                 | Not Reported |                |
|                                                                                                           | Carvedilol (Carvedilol)                                                          |                    |                    | S               |                       | Unknown              |                 | Not Reported |                |
|                                                                                                           | Hydrocodone+Paracetamol(Vododin) (Unknown) (Paracetamol, Hydrocodone Bitartrate) |                    |                    | S               |                       | Unknown              |                 | Not Reported |                |
|                                                                                                           | Citalopram (Citalopram)                                                          |                    |                    | S               |                       | Unknown              |                 | Not Reported |                |
|                                                                                                           | Escitalopram (Escitalopram)                                                      |                    |                    | S               |                       | Unknown              |                 | Not Reported |                |
|                                                                                                           | Alprazolam (Alprazolam)                                                          |                    |                    | S               |                       | Unknown              |                 | Not Reported |                |
|                                                                                                           | Bupropion (Bupropion)                                                            |                    |                    | S               |                       | Unknown              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                  | <u>Case #</u>                                                                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Feb-2014                                                                                               | 9903000                                                                          | EXPEDITED (15-DAY) |                    | OT              | PHHY2014BR018176      |                      | 21 YR           | Female       | BRA            |
| <u>Preferred Term</u>                                                                                     | <u>Product</u>                                                                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Dizziness; Hallucination                                                                        | Oxcarbazepine                                                                    |                    |                    | S               |                       | 600 Mg, Bid          |                 | Novartis     |                |
|                                                                                                           | Sertraline                                                                       |                    |                    | S               |                       | 100 Mg, Bid          |                 | Not Reported |                |
|                                                                                                           | Lexapro                                                                          |                    |                    | S               |                       | 20 Mg, Qd            |                 | Not Reported |                |
|                                                                                                           | Lexapro                                                                          |                    |                    | S               |                       |                      |                 | Not Reported |                |
|                                                                                                           | Seroquel Xro                                                                     |                    |                    | S               |                       | 50 Mg, Qd            |                 | Not Reported |                |
|                                                                                                           | Seroquel Xro                                                                     |                    |                    | S               |                       |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                  | <u>Case #</u>                                                                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Feb-2014                                                                                               | 9350925                                                                          | EXPEDITED (15-DAY) |                    | OT              | AT-JNJFOC-20130604091 |                      | 20 YR           | Male         | AUT            |
| <u>Preferred Term</u>                                                                                     | <u>Product</u>                                                                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Circulatory Collapse; Dysphagia; Fall; Loss Of Consciousness; Myalgia                                     | Risperdal                                                                        |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                           | Risperdal                                                                        |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                           | Risperdal                                                                        |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                           | Cipralex                                                                         |                    |                    | S               | Unknown               |                      |                 | Not Reported |                |
|                                                                                                           | Cipralex                                                                         |                    |                    | S               | Unknown               |                      |                 | Not Reported |                |

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

|               |   |         |              |
|---------------|---|---------|--------------|
| Ciprallex     | S | Unknown | Not Reported |
| Dominal Forte | S | Unknown | Not Reported |
| Dominal Forte | S | Unknown | Not Reported |
| Dominal Forte | S | Unknown | Not Reported |
| Trittico      | S | Unknown | Not Reported |
| Trittico      | S | Unknown | Not Reported |
| Nicotine      | S | Unknown | Not Reported |
| Zeldox        | S | Unknown | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Feb-2014              | 9832944       | EXPEDITED (15-DAY) |                    | HO              | AU-FRI-1000052948    |                      | 36 YR      | Male       | AUS            |

| <u>Preferred Term</u>                                          | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------|--------------------------|--------------|------------|-------------|--------------|------------------------------|-----------------|--------------|
| Diarrhoea; Hypotension;<br>Seizure; Ventricular<br>Tachycardia | Escitalopram             |              |            | S           | Oral         | 10 Mg                        |                 | Forest       |
|                                                                | Warfarin Sodium          |              |            | S           | Oral         | 4 Mg                         |                 | Not Reported |
|                                                                | Amiodarone Hydrochloride |              |            | C           |              | 200 Mg                       |                 | Not Reported |
|                                                                | Carvedilol Hydrochloride |              |            | C           |              | 12.5 Mg                      |                 | Not Reported |
|                                                                | Furosemide               |              |            | C           |              | 80 Mg                        |                 | Not Reported |
|                                                                | Levetiracetam            |              |            | C           |              | 1000 Mg                      |                 | Not Reported |
|                                                                | Levetiracetam            |              |            | C           |              | 2000 Mg                      |                 | Not Reported |
|                                                                | Lisinopril               |              |            | C           |              | 10 Mg                        |                 | Not Reported |
|                                                                | Sodium Valproate         |              |            | C           |              | 1000 Mg Mane/500 Mg<br>Nocte |                 | Not Reported |
|                                                                | Thyroxine Sodium         |              |            | C           | Oral         | 50 Mcg                       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>        | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------------|----------------------|------------|------------|----------------|
| 18-Feb-2014              | 9873373       | EXPEDITED (15-DAY) |                    | HO, LT, OT      | CH-RANBAXY-2014RR-<br>77399 |                      | 31 YR      | Male       | CHE            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abdominal Pain Upper; | Ciprallex      |              |            | S           | Unknown      | Unk                |                 | Not Reported |

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

|                                                                                                                               |           |   |         |              |              |
|-------------------------------------------------------------------------------------------------------------------------------|-----------|---|---------|--------------|--------------|
| Drug Interaction;<br>Electrocardiogram Qt<br>Prolonged; Generalised<br>Tonic-Clonic Seizure;<br>Nausea; Torsade De<br>Pointes | Zofran    | S | Unknown | Unk          | Not Reported |
|                                                                                                                               | Methadone | S | Oral    | 50-60 Mg/Day | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 18-Feb-2014              | 9879489       | EXPEDITED (15-DAY) |                    | OT              | IT-PFIZER INC-<br>2014032942 |                      | 83 YR      | Female     | ITA            |

| <u>Preferred Term</u>                                                           | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Diabetes Mellitus<br>Inadequate Control; Drug<br>Interaction;<br>Hyperglycaemia | Escitalopram Oxalate |              |            | S           | Unknown      | 5 Mg, 1x/Day       |                 | Not Reported |
|                                                                                 | Escitalopram Oxalate |              |            | S           | Unknown      | 10 Mg, Daily       |                 | Not Reported |
|                                                                                 | Escitalopram Oxalate |              |            | S           | Unknown      | 10 Mg, Unk         |                 | Not Reported |
|                                                                                 | Glibenclamide        |              |            | S           | Unknown      | 7.5 Mg, 3x/Day     |                 | Not Reported |
|                                                                                 | Glibenclamide        |              |            | S           | Unknown      | 5 Mg, 3x/Day       |                 | Not Reported |
|                                                                                 | Glibenclamide        |              |            | S           | Unknown      | 2.5 Mg, 3x/Day     |                 | Not Reported |
|                                                                                 | Enap-HI              |              |            | C           | Unknown      | Unk                |                 | Not Reported |
|                                                                                 | Doxazosin            |              |            | C           | Unknown      | 2 Mg, 1x/Day       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Feb-2014              | 9903755       | EXPEDITED (15-DAY) |                    | CA, OT          | GXKR2014DE000894     |                      | 1 DAY      | Male       | DEU            |

| <u>Preferred Term</u>                                                                 | <u>Product</u>                          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------|-----------------------------------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Hypospadias; Motor<br>Developmental Delay;<br>Premature Baby; Small<br>For Dates Baby | Escitalopram                            |              |            | S           | Transplacental | 20 [Mg/D ]         |                 | Not Reported |
|                                                                                       | Lamotrigine                             |              |            | S           | Transplacental | 150 Mg/D           |                 | Novartis     |
|                                                                                       | Femibion [Minerals Nos;Vitamins<br>Nos] |              |            | C           | Transplacental | 0.8 [Mg/D ]        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Feb-2014              | 9907220       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000053967    |                      | 54 YR      | Female     | FRA            |

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

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

|                                                                                     |              |   |      |              |              |
|-------------------------------------------------------------------------------------|--------------|---|------|--------------|--------------|
| Agitation; Dizziness;<br>Hyperhidrosis; Insomnia;<br>Tremor; Withdrawal<br>Syndrome | Escitalopram | S | Oral | 1 Df         | Forest       |
|                                                                                     | Laroxyl      | C |      |              | Not Reported |
|                                                                                     | Lexomil      | C |      |              | Not Reported |
|                                                                                     | Actonel      | C |      | Not Reported |              |
|                                                                                     | Skenan       | C |      | 20 Mg        | Not Reported |
|                                                                                     | Prothiaden   | C |      |              | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Feb-2014              | 9907358       | EXPEDITED (15-DAY) |                    | HO              | CH-RB-063468-14      |                      | 64 YR      | Female     | CHE            |

| <u>Preferred Term</u>             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>        |
|-----------------------------------|----------------|--------------|------------|-------------|--------------|---------------------------|-----------------|-------------------|
| Electrocardiogram Qt<br>Prolonged | Temgesic       |              |            | S           | Sublingual   | 10 Mg/Daily + 5 Mg 1day/2 |                 | Reckitt Benckiser |
|                                   | Transtec       |              |            | S           | Transdermal  |                           |                 | Reckitt Benckiser |
|                                   | Afinitor       |              |            | S           | Oral         |                           |                 | Not Reported      |
|                                   | Afinitor       |              |            | S           | Oral         |                           |                 | Not Reported      |
|                                   | Afinitor       |              |            | S           | Oral         |                           |                 | Not Reported      |
|                                   | Nexium         |              |            | S           | Oral         |                           |                 | Not Reported      |
|                                   | Cipralex       |              |            | S           | Oral         |                           |                 | Not Reported      |
|                                   | Aromasin       |              |            | C           | Oral         | Dosing Details Unknown    |                 | Not Reported      |
|                                   | Xgeva          |              |            | C           | Oral         |                           |                 | Not Reported      |
|                                   | Importal       |              |            | C           | Oral         |                           |                 | Not Reported      |
|                                   | Xanax          |              |            | C           | Oral         |                           |                 | Not Reported      |
|                                   | Seresta        |              |            | C           | Oral         |                           |                 | Not Reported      |
|                                   | Dafalgan       |              |            | C           | Oral         |                           |                 | Not Reported      |
|                                   | Irfen          |              |            | C           | Oral         |                           |                 | Not Reported      |
|                                   | Magnesium      |              |            | C           | Oral         |                           |                 | Not Reported      |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Feb-2014              | 9995107       | NON-EXPEDITED    | Y                  | RI, OT          | 1000051657           |                      |            | Male       | USA            |

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

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

|                                                  |              |   |      |                                                         |       |              |
|--------------------------------------------------|--------------|---|------|---------------------------------------------------------|-------|--------------|
| Anxiety; Medication Error;<br>Serotonin Syndrome | Viibryd      | S |      | 7 D, 10 Mg (10 Mg, 1 In 1 D)<br>20 Mg (20 Mg, 1 In 1 D) | 7 DAY | Not Reported |
|                                                  | Viibryd      | S | Oral | 40 Mg (40 Mg, 1 In 1 D),<br>Oral                        | 7 DAY | Not Reported |
|                                                  | Escitalopram | S |      |                                                         |       | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Feb-2014              | 9997303       | NON-EXPEDITED    |                    | OT              | 1000051571           |                      | 31 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                   | <u>Product</u>                                                       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Disturbance In<br>Attention; Dizziness; Drug<br>Ineffective; Menstruation<br>Irregular; Nervousness;<br>Night Sweats; Off Label<br>Use; Tremor | Viibryd                                                              |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                         | Viibryd                                                              |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                         | Escitalopram (Escitalopram)                                          |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                         | Wellbutrin (Bupropion<br>Hydrochloride) (Bupropion<br>Hydrochloride) |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                         | Vitamin B12 (Vitamin B12)<br>(Vitamin B12)                           |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 19-Feb-2014              | 8564445       | EXPEDITED (15-DAY) |                    | HO, OT          | ES-PFIZER INC-<br>2012111563 |                      | 35 YR      | Male       | ESP            |

| <u>Preferred Term</u>                        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Thrombocytopenia;<br>Transaminases Increased | Lyricea        |              |            | S           | Oral         | 150 Mg, 1x/Day     |                 | Pfizer       |
|                                              | Escitalopram   |              |            | S           | Oral         | 10 Mg, 1x/Day      |                 | Not Reported |
|                                              | Clonazepam     |              |            | C           | Oral         | 1.5 Mg, 1x/Day     |                 | Not Reported |
|                                              | Fluoxetine     |              |            | C           |              | 20 Mg, 1x/Day      |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 19-Feb-2014              | 9779994       | EXPEDITED (15-DAY) |                    | HO              | IT-WATSON-2013-<br>22917 |                      | 86 YR      | Female     | ITA            |

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

| <u>Preferred Term</u>                                                                    | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>  | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u>        |
|------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|---------------|---------------------|-----------------|-------------------|
| Bradycardia; Drug Abuse;<br>Intentional Overdose;<br>Psychomotor<br>Hyperactivity; Sopor | Metformin (Unknown)  |              |            | S           | Oral          | 1500 Mg, Total      |                 | Watson            |
|                                                                                          | Metformin (Unknown)  |              |            | S           | Oral          | 500 Mg, Daily       |                 | Watson            |
|                                                                                          | Bisoprolol (Unknown) |              |            | S           | Oral          | 3 Df, Total         |                 | Actavis Elizabeth |
|                                                                                          | Tavor /00273201/     |              |            | S           | Oral          | 6 Df, Total         |                 | Not Reported      |
|                                                                                          | Cipralext            |              |            | S           | Oral          | 10 Mg, 3 Df, Total  |                 | Not Reported      |
|                                                                                          | Cipralext            |              |            | S           | Oral          | 10 Mg, Unk          |                 | Not Reported      |
|                                                                                          | Diamicron            |              |            | S           | Oral          | 30 Mg, 3 Df, Total  |                 | Not Reported      |
|                                                                                          | Diamicron            |              |            | S           | Oral          | 30 Df, Tid          |                 | Not Reported      |
|                                                                                          | Tachipirina          |              |            | S           | Oral          | 3 Df, Total         |                 | Not Reported      |
|                                                                                          | Serenase /00015301/  |              |            | S           | Oral          | 0.5 Mg, 2 Df, Total |                 | Not Reported      |
|                                                                                          | Coumadin /00014802/  |              |            | C           | Unknown       | 5 Mg, Unk           |                 | Not Reported      |
|                                                                                          | Dibase               |              |            | C           | Intramuscular | 100, 1 Vial/Month   |                 | Not Reported      |
|                                                                                          | Nexium /01479302/    |              |            | C           | Unknown       | Unk                 |                 | Not Reported      |
|                                                                                          | Isoptin /00014302/   |              |            | C           | Unknown       | 80 Mg, Unk          |                 | Not Reported      |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------------------------------------|----------------------|------------|------------|----------------|
| 19-Feb-2014              | 9908102       | EXPEDITED (15-DAY) |                    | OT              | GB-MACLEODS<br>PHARMACEUTICALS<br>US LTD-<br>MAC2014000894 |                      |            | Unknown    | GBR            |

| <u>Preferred Term</u>                                                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Depressed Mood;<br>Inhibitory Drug Interaction;<br>Suicidal Ideation | Escitalopram   |              |            | S           | Unknown      | Unk                |                 | Macleods     |
|                                                                      | Gliclazide     |              |            | S           | Oral         | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Feb-2014              | 9911639       | EXPEDITED (15-DAY) |                    | HO              | PHHY2014CH015289     |                      | 64 YR      | Female     | CHE            |

| <u>Preferred Term</u>             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Electrocardiogram Qt<br>Prolonged | Afinitor       |              |            | S           | Oral         | 10 Mg, Qd          |                 | Novartis   |



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

|                                |   |             |                                           |              |
|--------------------------------|---|-------------|-------------------------------------------|--------------|
| Afinitor                       | S |             | 5 Mg, Day                                 | Novartis     |
| Afinitor                       | S |             | 10 Mg 1 Per Day And 5 Mg Every Second Day | Novartis     |
| Cipralex                       | S | Oral        | 20 Mg, Qd                                 | Not Reported |
| Cipralex                       | S |             |                                           | Not Reported |
| Temgesic                       | S | Sublingual  | 0.2 Mg                                    | Not Reported |
| Transtec                       | S | Transdermal | 50 Ug, Qh                                 | Not Reported |
| Nexium//Esomeprazole Magnesium | S | Oral        | 40 Mg, Qd                                 | Not Reported |
| Xgeva                          | C | Unknown     |                                           | Not Reported |
| Aromasin                       | C | Oral        | 25 Mg, Qd                                 | Not Reported |
| Magnesium                      | C | Oral        | 5 Mmol, Qd                                | Not Reported |
| Importal                       | C | Oral        |                                           | Not Reported |
| Xanax                          | C | Oral        | 1 Mg, Bid                                 | Not Reported |
| Seresta                        | C | Oral        | 50 Mg, Qd                                 | Not Reported |
| Dafalgan                       | C | Oral        | 1 G                                       | Not Reported |
| Irfen                          | C | Oral        | 400 Mg                                    | Not Reported |
| Aranesp                        | C |             |                                           | Not Reported |
| Aranesp                        | C |             |                                           | Not Reported |
| Aranesp                        | C |             |                                           | Not Reported |
| Aranesp                        | C |             | 10 Mg, Qd                                 | Not Reported |
| Aranesp                        | C |             | 5 Mg,Every Second Day                     | Not Reported |
| Zyprexa                        | C | Oral        | 2.5 Mg, Qd                                | Not Reported |
| Zyprexa                        | C |             |                                           | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Feb-2014              | 9785666       | EXPEDITED (15-DAY) |                    | DE              | CA-FRI-1000052465    |                      |            | Female     | CAN            |

| <u>Preferred Term</u> | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>     | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-------------------|--------------|------------|-------------|------------------|--------------------|-----------------|--------------|
| Ovarian Cancer        | Escitalopram      |              |            | S           | Oral             | 20 Mg              |                 | Forest       |
|                       | Hydromorph Contin |              |            | C           | Oral             | 42 Mg              |                 | Not Reported |
|                       | Taxol             |              |            | C           | Intravenous (not |                    |                 | Not Reported |

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

otherwise specified)

| <u>FDA Received Date</u>                                                                      | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                                                                          | <u>Age</u>      | <u>Sex</u>        | <u>Country</u> |
|-----------------------------------------------------------------------------------------------|---------------------|--------------------|--------------------|-----------------|------------------------------|-----------------------------------------------------------------------------------------------|-----------------|-------------------|----------------|
| 20-Feb-2014                                                                                   | 9914059             | EXPEDITED (15-DAY) |                    | CA, OT          | DE-GLAXOSMITHKLINE-D0082874A |                                                                                               | < 1 DAY         | Male              | DEU            |
| <u>Preferred Term</u>                                                                         | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                                                                            | <u>Duration</u> | <u>Mfr</u>        |                |
| Hypospadias; Hypotonia; Motor Developmental Delay; Premature Baby; Small For Dates Baby       | Lamotrigine         |                    |                    | S               | Transplacental               | 150mg Per Day                                                                                 |                 | Glaxosmithkline   |                |
|                                                                                               | Escitalopram        |                    |                    | S               | Transplacental               | 20mg Per Day                                                                                  |                 | Glaxosmithkline   |                |
|                                                                                               | Vitamin With Folate |                    |                    | C               | Transplacental               | .8mg Per Day                                                                                  |                 | Not Reported      |                |
|                                                                                               | Iodine              |                    |                    | C               | Transplacental               |                                                                                               |                 | Glaxosmithkline   |                |
| <u>FDA Received Date</u>                                                                      | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                                                                          | <u>Age</u>      | <u>Sex</u>        | <u>Country</u> |
| 20-Feb-2014                                                                                   | 9914734             | EXPEDITED (15-DAY) |                    | HO              | NO-RB-063876-14              |                                                                                               | 50 YR           | Male              | NOR            |
| <u>Preferred Term</u>                                                                         | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                                                                            | <u>Duration</u> | <u>Mfr</u>        |                |
| Abdominal Pain Upper; Drug Abuse; Drug Diversion; Hospitalisation; Intentional Product Misuse | Subutex             |                    |                    | S               | Unknown                      | At The Time When The Questionnaire Was Completed, Patient Had Been On Subutex 1 Year 7 Months |                 | Reckitt Benckiser |                |
|                                                                                               | Cannabis            |                    |                    | S               | Respiratory (inhalation)     | Details Unknown                                                                               |                 | Not Reported      |                |
|                                                                                               | Ciprallex           |                    |                    | S               | Unknown                      | Dosing Details Unknown                                                                        |                 | Not Reported      |                |
|                                                                                               | Remeron             |                    |                    | S               | Unknown                      | Dosing Details Unknown                                                                        |                 | Not Reported      |                |
|                                                                                               | Rivotril            |                    |                    | S               | Unknown                      | Dosing Details Unknown                                                                        |                 | Not Reported      |                |
|                                                                                               | Benzodiazepine      |                    |                    | S               | Unknown                      | Takes On A Regular Basis. Specific Dosing Details Unknown.                                    |                 | Not Reported      |                |
| <u>FDA Received Date</u>                                                                      | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                                                                          | <u>Age</u>      | <u>Sex</u>        | <u>Country</u> |
| 20-Feb-2014                                                                                   | 9916288             | DIRECT             |                    | DS              |                              |                                                                                               | 29 YR           | Female            | USA            |

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

| <u>Preferred Term</u>                                                                                                                                   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|--------------|----------------|
| Anxiety; Asthenia;<br>Depression; Diarrhoea;<br>Drug Intolerance; Fatigue;<br>Headache; Migraine;<br>Nausea; Product<br>Substitution Issue;<br>Vomiting | Escitalopram             |                    |                    | S               |                                                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Feb-2014                                                                                                                                             | 8841664                  | EXPEDITED (15-DAY) |                    | LT              | CA-FRI-1000039397                               |                      | 51 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                                                                                                                   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Condition                                                                                                                                      | Escitalopram             |                    |                    | S               | Oral                                            | 10 Mg                |                 | Forest       |                |
| Aggravated; Panic Attack;                                                                                                                               | Calcium                  |                    |                    | C               |                                                 |                      |                 | Not Reported |                |
| Suicidal Ideation                                                                                                                                       | Omeprazole               |                    |                    | C               | Oral                                            | 30 Mg                |                 | Not Reported |                |
|                                                                                                                                                         | Vitamin D Nos            |                    |                    | C               |                                                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Feb-2014                                                                                                                                             | 9916807                  | EXPEDITED (15-DAY) |                    | DE, HO, OT      | US-<br>ELI_LILLY_AND_COMP<br>ANY-US201402005391 |                      | 55 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrial Flutter; Cardio-                                                                                                                                 | Duloxetine Hydrochloride |                    |                    | S               | Unknown                                         |                      |                 | Unknown      |                |
| Respiratory Arrest;                                                                                                                                     | Alprazolam               |                    |                    | S               | Unknown                                         | 50 Mg, Single        |                 | Not Reported |                |
| Completed Suicide;                                                                                                                                      | Salicylate Sodium        |                    |                    | S               | Unknown                                         |                      |                 | Not Reported |                |
| Haematemesis;                                                                                                                                           | Escitalopram             |                    |                    | S               | Unknown                                         |                      |                 | Not Reported |                |
| Hyperhidrosis;                                                                                                                                          | Clonazepam               |                    |                    | C               |                                                 |                      |                 | Not Reported |                |
| Hyperthermia; Intentional                                                                                                                               | Aripiprazole             |                    |                    | C               |                                                 |                      |                 | Not Reported |                |
| Overdose; Livedo                                                                                                                                        |                          |                    |                    |                 |                                                 |                      |                 |              |                |
| Reticularis; Muscle                                                                                                                                     |                          |                    |                    |                 |                                                 |                      |                 |              |                |
| Rigidity; Nystagmus;                                                                                                                                    |                          |                    |                    |                 |                                                 |                      |                 |              |                |
| Tremor; Unresponsive To                                                                                                                                 |                          |                    |                    |                 |                                                 |                      |                 |              |                |
| Stimuli                                                                                                                                                 |                          |                    |                    |                 |                                                 |                      |                 |              |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                         | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
|------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|----------------------------------------|-----------------|------------------------------|----------------|
| 21-Feb-2014                                                      | 9917574                | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000054453    |                                        | 83 YR           | Female                       | FRA            |
| <u>Preferred Term</u>                                            | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>                   |                |
| Disinhibition; Intentional Overdose; Suicide Attempt             | Escitalopram           |                    |                    | S               | Oral                 | 10 Mg                                  |                 | Forest                       |                |
|                                                                  | Escitalopram           |                    |                    | S               | Oral                 | Overdose With One Intake Of 140 Mg     |                 | Forest                       |                |
|                                                                  | Escitalopram Imovane   |                    |                    | S<br>C          | Oral                 | Overdose With One Intake Of 105 Mg     |                 | Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                         | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 21-Feb-2014                                                      | 9921844                | DIRECT             |                    | OT              |                      |                                        | 42 YR           | Male                         | USA            |
| <u>Preferred Term</u>                                            | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>                   |                |
| Amnesia                                                          | Lexapro                |                    |                    | S               | Oral                 | 10 Mg/1 Pill Once Daily Taken By Mouth | 5 YR            | Teva                         |                |
| <u>FDA Received Date</u>                                         | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 21-Feb-2014                                                      | 9921920                | DIRECT             |                    | OT              |                      |                                        | 43 YR           | Female                       | USA            |
| <u>Preferred Term</u>                                            | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>                   |                |
| Anxiety; Irritability; Product Substitution Issue                | Escitalopram           |                    |                    | S               | Oral                 | 1 Tab Once Daily                       |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                                         | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 21-Feb-2014                                                      | 9924827                | EXPEDITED (15-DAY) |                    | CA, DE          | 2014AP001344         |                                        |                 | Male                         | USA            |
| <u>Preferred Term</u>                                            | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>                   |                |
| Cleft Lip; Congenital Anomaly; Hernia; Hydrocele; Maternal Drugs | Paroxetine Hcl Tablets |                    |                    | S               |                      |                                        |                 | Not Reported                 |                |
|                                                                  | Lexapro                |                    |                    | S               |                      |                                        |                 | Not Reported                 |                |

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

Affecting Foetus; Multiple  
Injuries

| <u>FDA Received Date</u>                                                                                                 | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------|--------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 24-Feb-2014                                                                                                              | 9665219                        | EXPEDITED (15-DAY) |                    | OT              | DE-FRI-1000050702    |                      | 78 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                                                                                    | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Colitis Ulcerative;<br>Intestinal Haemorrhage                                                                            | Escitalopram Oral Solution     |                    |                    | S               | Oral                 | 15 Mg                |                 | Forest       |                |
|                                                                                                                          | Lyrica                         |                    |                    | S               | Oral                 | 25 Mg                |                 | Not Reported |                |
|                                                                                                                          | Lyrica                         |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                          | Vasomotal                      |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                 | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Feb-2014                                                                                                              | 9922332                        | DIRECT             |                    | OT              |                      |                      | 52 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                    | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Disease Recurrence;<br>Headache; Panic Attack;<br>Product Substitution Issue;<br>Therapeutic Product Effect<br>Decreased | Escitalopram                   |                    |                    | S               | Oral                 | 1 Pill Once Daily    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                 | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Feb-2014                                                                                                              | 9925633                        | EXPEDITED (15-DAY) | Y                  | DE              | NL01PV14.35210       |                      | 45 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                    | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Completed<br>Suicide; Exposure Via<br>Ingestion; Respiratory<br>Arrest                                   | Zolpidem Tablets               |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                          | Escitalopram Tablets Usp 20 Mg |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                          | Alprazolam (Alprazolam)        |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                 | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Feb-2014                                                                                                              | 8838666                        | EXPEDITED (15-DAY) |                    | OT              | CA-FRI-1000039400    |                      | 31 YR           | Male         | CAN            |

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

| <a href="#">Preferred Term</a>    | <a href="#">Product</a>   | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
|-----------------------------------|---------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Serotonin Syndrome                | Escitalopram              |                           |                             | S                        | Oral                          |                               |                          | Forest              |                         |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>    | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 25-Feb-2014                       | 8842414                   | EXPEDITED (15-DAY)        |                             | OT                       | CA-FRI-1000039404             |                               |                          | Female              | CAN                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a>   | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Abdominal Discomfort;             | Escitalopram              |                           |                             | S                        | Oral                          | 0.5 Mg                        |                          | Forest              |                         |
| Abnormal Sensation In             | Diclofenac                |                           |                             | S                        |                               |                               | Not Reported             |                     |                         |
| Eye; Drug Interaction;            | Gilenya                   |                           |                             | S                        |                               |                               | Not Reported             |                     |                         |
| Dyspnoea; Eye Swelling;           | Amitriptyline             |                           |                             | C                        |                               |                               | Not Reported             |                     |                         |
| Fatigue; Headache;                | Baclofen                  |                           |                             | C                        |                               |                               | Not Reported             |                     |                         |
| Lymphocyte Count                  | Clonazepam                |                           |                             | C                        |                               |                               | Not Reported             |                     |                         |
| Decreased; Multiple               | Gabapentin                |                           |                             | C                        |                               |                               | Not Reported             |                     |                         |
| Sclerosis Relapse;                | Nexium                    |                           |                             | C                        |                               |                               | Not Reported             |                     |                         |
| Muscular Weakness;                | Tylenol Extra-Strength Ez |                           |                             | C                        |                               |                               | Not Reported             |                     |                         |
| Nausea; Neutropenia;              | Vesicare                  |                           |                             | C                        |                               |                               | Not Reported             |                     |                         |
| Pyrexia; Vision Blurred;          | Water Pills               |                           |                             | C                        | Not Reported                  |                               |                          |                     |                         |
| White Blood Cell Count            |                           |                           |                             |                          |                               |                               |                          | Not Reported        |                         |
| Decreased                         |                           |                           |                             |                          |                               |                               |                          |                     |                         |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>    | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 25-Feb-2014                       | 9921285                   | EXPEDITED (15-DAY)        |                             | HO                       | PHHY2014FR021234              |                               |                          | Unknown             | FRA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a>   | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Hyponatraemia; Seizure            | Tegretol                  |                           |                             | S                        | Oral                          | 0.5 Df, Daily                 |                          | Novartis            |                         |
|                                   | Inexium//Esomeprazole     |                           |                             | S                        |                               | Unk Ukn, Unk                  |                          | Not Reported        |                         |
|                                   | Magnesium                 |                           |                             |                          |                               |                               |                          |                     |                         |
|                                   | Seroplex                  |                           |                             | S                        |                               | Unk                           |                          | Not Reported        |                         |
|                                   | Co-Aprovel                |                           |                             | S                        |                               | Unk Ukn, Unk                  |                          | Not Reported        |                         |
|                                   | Keppra                    |                           |                             | C                        |                               | Unk Ukn, Unk                  |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>    | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 25-Feb-2014                       | 9921334                   | EXPEDITED (15-DAY)        |                             | HO                       | FR-ASTRAZENECA-2014SE11885    |                               | 70 YR                    | Female              | FRA                     |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                                       | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------------------------------------------------|----------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Hyponatraemia; Seizure                                                                      | Inexium                    |                    |                    | S               | Oral                 |                      |                 | Astrazeneca  |                |
|                                                                                             | Tegretol Sr                |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                             | Seroplex                   |                    |                    | S               | Unknown              |                      |                 | Not Reported |                |
|                                                                                             | Coaprovel                  |                    |                    | S               | Unknown              |                      |                 | Not Reported |                |
|                                                                                             | Keppra                     |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                    | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Feb-2014                                                                                 | 9922822                    | EXPEDITED (15-DAY) |                    | CA, OT          | DE-TEVA-462455GER    |                      | 1 DAY           | Male         | DEU            |
| <u>Preferred Term</u>                                                                       | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypospadias; Motor Developmental Delay; Premature Baby; Small For Dates Baby                | Escitalopram               |                    |                    | S               | Transplacental       |                      |                 | Ivax         |                |
|                                                                                             | Lamotrigine                |                    |                    | S               | Transplacental       |                      |                 | Teva         |                |
|                                                                                             | Femibion Schwangerschaft 1 |                    |                    | C               | Transplacental       |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                    | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Feb-2014                                                                                 | 9925260                    | DIRECT             |                    | OT              |                      |                      |                 | Male         | USA            |
| <u>Preferred Term</u>                                                                       | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Product Substitution Issue; Therapeutic Response Decreased                                  | Escitalopram               |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                    | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Feb-2014                                                                                 | 9290960                    | EXPEDITED (15-DAY) | Y                  | HO, OT          | 2013AP004963         |                      | 32 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                                       | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Abuse; Face Injury; Fall; Lethargy; Mydriasis; Nasal Injury; Sedation; Speech Disorder | Venlafaxine Hydrochloride  |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                             | Sertraline Hydrochloride   |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                             | Delorazepam (Delorazepam)  |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                             | Bromazepam (Bromazepam)    |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                             | Escitalopram Oxalate       |                    |                    | S               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

(Escitalopram Oxalate)

| <u>FDA Received Date</u>           | <u>Case #</u>                                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------|------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 26-Feb-2014                        | 9819275                                              | EXPEDITED (15-DAY) |                    | LT, OT          | JP-FRI-1000052779    |                      | 14 YR           | Female       | JPN            |
| <u>Preferred Term</u>              | <u>Product</u>                                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Activation Syndrome; Off Label Use | Lexapro                                              |                    |                    | S               | Oral                 | 2.5 Mg               |                 | Forest       |                |
|                                    | Lexapro                                              |                    |                    | S               | Oral                 | 5 Mg                 |                 | Forest       |                |
|                                    | Gasmotin                                             |                    |                    | C               | Oral                 | 15 Mg                |                 | Not Reported |                |
|                                    | Tsumura Shokenchuto Extract Granules For Ethical Use |                    |                    | C               | Oral                 | 5g                   |                 | Not Reported |                |
|                                    | Tsumura Shokenchuto Extract Granules For Ethical Use |                    |                    | C               | Oral                 | 2.5 G                |                 | Not Reported |                |
|                                    | Tsumura Shokenchuto Extract Granules For Ethical Use |                    |                    | C               | Oral                 | 10g                  |                 | Not Reported |                |
|                                    | Tsumura Shokenchuto Extract Granules For Ethical Use |                    |                    | C               | Oral                 | 10g                  |                 | Not Reported |                |
|                                    | Lamictal                                             |                    |                    | C               | Oral                 | 2 Mg                 |                 | Not Reported |                |
| <u>FDA Received Date</u>           | <u>Case #</u>                                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Feb-2014                        | 9925329                                              | EXPEDITED (15-DAY) |                    | HO              | FR-SA-2014SA020616   |                      | 70 YR           | Female       | FRA            |
| <u>Preferred Term</u>              | <u>Product</u>                                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyponatraemia; Seizure             | Coaprovel                                            |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                    | Tegretol                                             |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                    | Inexium                                              |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                    | Seroplex                                             |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                    | Keppra                                               |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>           | <u>Case #</u>                                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Feb-2014                        | 9925743                                              | EXPEDITED (15-DAY) |                    | CA, DE          | US-FRI-1000054610    |                      | < 1 DAY         | Female       | USA            |
| <u>Preferred Term</u>              | <u>Product</u>                                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                                                 |         |   |                |        |
|---------------------------------------------------------------------------------|---------|---|----------------|--------|
| Atrial Septal Defect;<br>Patent Ductus Arteriosus;<br>Ventricular Septal Defect | Lexapro | S | Transplacental | Forest |
|---------------------------------------------------------------------------------|---------|---|----------------|--------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Feb-2014              | 9926119       | EXPEDITED (15-DAY) | CA, OT             |                 | DE-FRI-1000054597    |                      | < 1 DAY    | Male       | DEU            |

| <u>Preferred Term</u>                                                                                                                            | <u>Product</u>                       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Foetal Exposure During Pregnancy; Hypospadias; Hypotonia; Low Birth Weight Baby; Motor Developmental Delay; Premature Baby; Small For Dates Baby | Escitalopram                         |              |            | S           | Transplacental | 20 Mg              |                 | Forest       |
|                                                                                                                                                  | Lamotrigin                           |              |            | S           | Transplacental | 150 Mg             |                 | Not Reported |
|                                                                                                                                                  | Femibion [Minerals Nos;Vitamins Nos] |              |            | C           | Transplacental | 0.8 Mg             |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Feb-2014              | 9926137       | EXPEDITED (15-DAY) | HO                 |                 | FR-FRI-1000054621    |                      | 70 YR      | Female     | FRA            |

| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hyponatraemia; Seizure | Escitalopram   |              |            | S           | Oral         | 200 Mg             |                 | Forest       |
|                        | Tegretol Lp    |              |            | S           |              |                    |                 | Not Reported |
|                        | Inexium        |              |            | S           |              |                    |                 | Not Reported |
|                        | Coaprovel      |              |            | S           |              |                    |                 | Not Reported |
|                        | Keppra         |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 26-Feb-2014              | 9926165       | EXPEDITED (15-DAY) | CA, OT             |                 | DE-MYLANLABS-2014S1003292 |                      | 1 DAY      | Male       | DEU            |

| <u>Preferred Term</u>                                                                                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|----------------------|-----------------|--------------|
| Exposure During Pregnancy; Hypospadias; Motor Developmental Delay; Premature Baby; Small For Dates Baby | Lamotrigin     |              |            | S           | Transplacental | 150 [Mg/D ]          |                 | Mylan        |
|                                                                                                         | Escitalopram   |              |            | S           | Transplacental | 20 [Mg/D ]           |                 | Not Reported |
|                                                                                                         | Folic Acid     |              |            | C           | Transplacental | 0.8 [Mg/D ] Femibion |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 26-Feb-2014                                                                                                                                           | 9928173        | DIRECT             |                    | OT              |                      |                      | 51 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Insomnia;<br>Night Sweats; Weight<br>Increased                                                                                            | Escitalopram   |                    |                    | S               |                      | 1 Pill At Bedtime    |                 | Camber       |                |
| <u>FDA Received Date</u>                                                                                                                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Feb-2014                                                                                                                                           | 9931904        | EXPEDITED (15-DAY) | Y                  | HO              | IMP_07475_2014       |                      | 29 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Areflexia; Brain Injury; Dry<br>Skin; Gastrointestinal<br>Sounds Abnormal;<br>Hypotension; Overdose;<br>Pulseless Electrical<br>Activity; Pupil Fixed | Bupropion      |                    |                    | S               |                      | (Df)                 |                 | Not Reported |                |
|                                                                                                                                                       | Quetiapine     |                    |                    | C               |                      | (Df)                 |                 | Not Reported |                |
|                                                                                                                                                       | Desvenlafaxine |                    |                    | S               |                      | (Df)                 |                 | Not Reported |                |
|                                                                                                                                                       | Escitalopram   |                    |                    | S               |                      | (Df)                 |                 | Not Reported |                |
|                                                                                                                                                       | Ibuprofen      |                    |                    | S               |                      | (Df)                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Feb-2014                                                                                                                                           | 9662179        | EXPEDITED (15-DAY) |                    | OT              | PHHY2013US118929     |                      | 23 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective; Drug<br>Intolerance; Paternal<br>Exposure Timing<br>Unspecified; Suicidal<br>Ideation; Therapeutic<br>Response Decreased            | Fluoxetine     |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                       | Citalopram     |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                       | Escitalopram   |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                       | Sertraline     |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                       | Bupropion      |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                       | Olanzapine     |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                       | Amitriptyline  |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                       | Valproic Acid  |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                       | Venlafaxine    |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                       | Risperidone    |                    |                    | S               |                      |                      |                 | Novartis     |                |
|                                                                                                                                                       | Zolpidem       |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                       | Quetiapine     |                    |                    | S               |                      |                      |                 | Not Reported |                |

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

|  |                 |   |  |  |  |  |  |  |              |
|--|-----------------|---|--|--|--|--|--|--|--------------|
|  | Diphenhydramine | S |  |  |  |  |  |  | Not Reported |
|  | Trazodone       | S |  |  |  |  |  |  | Not Reported |
|  | Prazosin        | S |  |  |  |  |  |  | Not Reported |
|  | Eszopiclone     | S |  |  |  |  |  |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Feb-2014              | 9853919       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000053219    |                      | 50 YR      | Female     | FRA            |

| <u>Preferred Term</u>                               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction;<br>Dysarthria; Speech<br>Disorder | Escitalopram   |              |            | S           | Oral         | 1 Df               |                 | Forest       |
|                                                     | Abilify        |              |            | S           | Oral         | 1 Df               |                 | Not Reported |
|                                                     | Valium         |              |            | C           |              | 1 Df               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------|----------------------|------------|------------|----------------|
| 27-Feb-2014              | 9931101       | EXPEDITED (15-DAY) |                    | HO              | NO-MERCK-1402NOR011979 |                      | 50 YR      | Male       | NOR            |

| <u>Preferred Term</u>                                                                                  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                | <u>Dosage Text</u>                                                                                        | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|-----------------------------|-----------------------------------------------------------------------------------------------------------|-----------------|--------------|
| Abdominal Pain Upper;<br>Drug Abuse; Drug<br>Diversion; Hospitalisation;<br>Intentional Product Misuse | Remeron        |              |            | S           | Unknown                     | Dosing Details Unknown                                                                                    |                 | Merck        |
|                                                                                                        | Subutex        |              |            | S           | Unknown                     | At The Time When The<br>Questionnaire Was<br>Completed, Patient Had<br>Been On Subutex 1 Year 7<br>Months |                 | Not Reported |
|                                                                                                        | Hemp           |              |            | S           | Respiratory<br>(inhalation) | Details Unknown                                                                                           |                 | Not Reported |
|                                                                                                        | Cipralext      |              |            | S           | Unknown                     | Dosing Details Unknown                                                                                    |                 | Not Reported |
|                                                                                                        | Rivotril       |              |            | S           | Unknown                     | Dosing Details Unknown                                                                                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Feb-2014              | 9931756       | DIRECT           |                    | DS              |                      |                      | 22 YR      | Male       | USA            |

| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Disturbance In | Escitalopram   |              |            | S           | Oral         |                    |                 | Not Reported |

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

Attention; Dizziness;  
Emotional Disorder;  
Hypertension; Memory  
Impairment; Nausea;  
Tachycardia; Therapy  
Cessation; Withdrawal  
Syndrome

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Feb-2014              | 9677807       | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000050878    |                      |            | Female     | FRA            |

| <u>Preferred Term</u>              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Gestational Diabetes;<br>Pregnancy | Escitalopram   |              |            | S           |              | 20 Mg              |                 | Forest       |
|                                    | Abilify        |              |            | S           |              | 10 Mg              |                 | Not Reported |
|                                    | Seresta        |              |            | S           |              | 50 Mg              |                 | Not Reported |
|                                    | Tercian        |              |            | S           |              | 12.5 Mg            |                 | Not Reported |
|                                    | Folic Acid     |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Feb-2014              | 9677837       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000050879    |                      | < 1 DAY    | Male       | FRA            |

| <u>Preferred Term</u>                                                                                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Drug Withdrawal<br>Syndrome Neonatal;<br>Foetal Exposure During<br>Pregnancy; Neonatal<br>Hypoxia; Tremor | Escitalopram   |              |            | S           | Transplacental | 20 Mg              |                 | Forest       |
|                                                                                                           | Abilify        |              |            | S           | Transplacental | 10 Mg              |                 | Not Reported |
|                                                                                                           | Seresta        |              |            | S           | Transplacental | 50 Mg              |                 | Not Reported |
|                                                                                                           | Tercian        |              |            | S           | Transplacental | 12.5 Mg            |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------------------------------------|----------------------|------------|------------|----------------|
| 28-Feb-2014              | 9846811       | EXPEDITED (15-DAY) |                    | DE, HO          | IE-B.I.<br>PHARMACEUTICALS,I<br>NC./RIDGEFIELD-2014-<br>BI-03 |                      | 83 YR      | Female     | IRL            |

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

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

|                           |                 |   |         |           |                      |
|---------------------------|-----------------|---|---------|-----------|----------------------|
| Acute Kidney Injury;      | Pradaxa         | S | Oral    | 220 Mg    | Boehringer Ingelheim |
| Anaemia; Blood Creatinine | Afinitor        | S | Oral    |           | Not Reported         |
| Increased; Diarrhoea;     | Escitalopram    | S | Unknown | 10 Mg     | Not Reported         |
| Gastritis Haemorrhagic;   | Lorazepam       | C | Unknown |           | Not Reported         |
| Gastrointestinal          | Lansoprazole    | C | Unknown | 30 Mg     | Not Reported         |
| Haemorrhage;              | Perindopril     | C | Unknown |           | Not Reported         |
| Hypotension; Vomiting     | Atorvastatin    | C | Unknown | 10 Mg     | Not Reported         |
|                           | Lercanidipine   | C | Unknown | 10 Mg     | Not Reported         |
|                           | Zolpidem        | C | Unknown | 5 Mg      | Not Reported         |
|                           | Oxycontin       | C | Unknown | 20 Mg     | Not Reported         |
|                           | Aromasin        | C | Unknown | 25 Mg     | Not Reported         |
|                           | Zoledronic Acid | C | Unknown | 0.0329 Mg | Not Reported         |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Feb-2014              | 9849216       | EXPEDITED (15-DAY) |                    | OT              | US-FRI-1000053073    |                      | 64 YR      | Male       | USA            |

| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Bundle Branch Block Left | Lexapro        |              |            | S           | Oral         | 10 Mg              |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Feb-2014              | 9852292       | EXPEDITED (15-DAY) |                    | OT              | AUR-APL-2014-00467   |                      |            | Female     | USA            |

| <u>Preferred Term</u>    | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Back Pain; Dyspnoea;     | Escitalopram        |              |            | S           |              |                    |                 | Not Reported |
| Generalised Tonic-Clonic | Depakote (Valproate |              |            | C           |              |                    |                 | Not Reported |
| Seizure; Hallucination,  | Semisodium)         |              |            |             |              |                    |                 |              |
| Auditory; Hallucination, |                     |              |            |             |              |                    |                 |              |
| Visual; Muscle Rigidity; |                     |              |            |             |              |                    |                 |              |
| Muscle Spasms            |                     |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Feb-2014              | 9892037       | EXPEDITED (15-DAY) |                    | OT              | IT-PFIZER INC-       |                      |            | Unknown    | ITA            |

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

2014038897

| <u>Preferred Term</u>                                           | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------|----------------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Low Birth Weight Baby;<br>Maternal Exposure During<br>Pregnancy | Escitalopram Oxalate |              |            | S           | Transplacental | 10 Mg, Daily       |                 | Not Reported |
|                                                                 | Alprazolam           |              |            | S           | Transplacental | 0.25 Mg, Daily     |                 | Pfizer       |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Feb-2014              | 9907139       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000054204    |                      | 40 YR      | Male       | FRA            |

| <u>Preferred Term</u>             | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------|------------------------|--------------|------------|-------------|--------------|------------------------|-----------------|--------------|
| Loss Of Consciousness;<br>Malaise | Escitalopram           |              |            | S           | Oral         | 1 Df                   |                 | Forest       |
|                                   | Oxycontin Lp           |              |            | S           | Oral         | 12 Df                  |                 | Not Reported |
|                                   | Oxynorm                |              |            | S           | Oral         | Up To 8 Capsules Daily |                 | Not Reported |
|                                   | Depamide               |              |            | S           | Oral         | 4 Df                   |                 | Not Reported |
|                                   | Lyrica                 |              |            | S           | Oral         | 2 Df                   |                 | Not Reported |
|                                   | Esomeprazole           |              |            | C           | Oral         | 20 Mg                  |                 | Not Reported |
|                                   | Gutron                 |              |            | C           | Oral         | 2 Df                   |                 | Not Reported |
|                                   | Aerius (Desloratadine) |              |            | C           | Oral         | 1 Df                   |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Feb-2014              | 9928442       | EXPEDITED (15-DAY) | Y                  | CA, OT          | AUR-APL-2014-01910   |                      | 1 DAY      | Male       | DEU            |

| <u>Preferred Term</u>                                                                                                                    | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Foetal Exposure During<br>Pregnancy; Hypospadias;<br>Hypotonia; Motor<br>Developmental Delay;<br>Premature Baby; Small<br>For Dates Baby | Escitalopram              |              |            | S           | Transplacental |                    |                 | Not Reported |
|                                                                                                                                          | Lamotrigine (Lamotrigine) |              |            | S           | Transplacental |                    |                 | Not Reported |

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

| <u>FDA Received Date</u>                                                              | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 28-Feb-2014                                                                           | 9934161                   | EXPEDITED (15-DAY) |                    | OT              | US-SA-2014SA024126   |                      | 76 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                 | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrial Fibrillation; Renal Disorder; Stress; Wrong Technique In Product Usage Process | Multaq                    |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                       | Lexapro                   |                    |                    | S               | Unknown              |                      |                 | Not Reported |                |
|                                                                                       | Lexapro                   |                    |                    | S               | Unknown              |                      |                 | Not Reported |                |
|                                                                                       | Coenzyme Q10              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                       | Tryptophan, L-            |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                       | Aminogran Food Supplement |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                       | Curcumen                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                       | Acetylcysteine            |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                       | Alpha Lipoic Acid         |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                       | Vitamin C                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                       | Melatonin                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                       | Fish Oil                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                              | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Feb-2014                                                                           | 9934527                   | EXPEDITED (15-DAY) |                    | OT              | JP-FRI-1000053970    |                      | 70 YR           | Male         | JPN            |
| <u>Preferred Term</u>                                                                 | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Electrocardiogram Qt Prolonged; Ventricular Extrasystoles                             | Lexapro                   |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                                                                       | Lexapro                   |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                                                                       | Lexapro                   |                    |                    | S               | Oral                 | 20 Mg                |                 | Forest       |                |
|                                                                                       | Lexapro                   |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                                                                       | Amaryl                    |                    |                    | C               | Oral                 | 0.5 Mg               |                 | Not Reported |                |
|                                                                                       | Actos                     |                    |                    | C               | Oral                 | 30 Mg                |                 | Not Reported |                |
|                                                                                       | Nesina                    |                    |                    | C               | Oral                 | 25 Mg                |                 | Not Reported |                |
|                                                                                       | Nu-Lotan                  |                    |                    | C               | Oral                 | 50 Mg                |                 | Not Reported |                |
|                                                                                       | Reflex                    |                    |                    | C               | Oral                 | 15 Mg                |                 | Not Reported |                |
|                                                                                       | Reflex                    |                    |                    | C               | Oral                 | 30 Mg                |                 | Not Reported |                |
|                                                                                       | Myslee                    |                    |                    | C               | Oral                 | 10 Mg                |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| Myslee                                         |                |                    | C                  | Oral            | 5 Mg                 |                                                      |                 | Not Reported |                |
|------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|------------------------------------------------------|-----------------|--------------|----------------|
| <u>FDA Received Date</u>                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Feb-2014                                    | 9935288        | EXPEDITED (15-DAY) |                    | HO, LT          | FR-FRI-1000054676    |                                                      | 36 YR           | Female       | FRA            |
| <u>Preferred Term</u>                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Coma; Intentional Overdose                     | Escitalopram   |                    |                    | S               | Oral                 | 10 Mg                                                |                 | Forest       |                |
|                                                | Escitalopram   |                    |                    | S               | Oral                 | Overdose Of One Intake Of 7 Tablets (I.E. 70 Mg)     |                 | Not Reported |                |
|                                                | Baclofene      |                    |                    | S               | Oral                 | 40 Mg                                                |                 | Not Reported |                |
|                                                | Baclofene      |                    |                    | S               | Oral                 | Overdose Of One Intake Of 8 Boxes (Unknown Strength) |                 | Not Reported |                |
|                                                | Chlormadinone  |                    |                    | C               |                      | 1 Df                                                 |                 | Not Reported |                |
|                                                | Chlormadinone  |                    |                    | C               |                      | Overdose Of One Intake Of 9 Tablets                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Feb-2014                                    | 9935488        | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000054678    |                                                      |                 | Male         | FRA            |
| <u>Preferred Term</u>                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Haematoma; Red Blood Cell Count Decreased      | Escitalopram   |                    |                    | S               | Oral                 |                                                      |                 | Forest       |                |
|                                                | Kardegic       |                    |                    | S               | Oral                 |                                                      |                 | Not Reported |                |
|                                                | Calcite        |                    |                    | S               |                      |                                                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Feb-2014                                    | 9935609        | EXPEDITED (15-DAY) |                    | OT              | PHHY2014IT023596     |                                                      | 36 YR           | Male         | ITA            |
| <u>Preferred Term</u>                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Seizure; Therapeutic Product Effect Incomplete | Ribavirin      |                    |                    | S               |                      | 1000 Mg, Per Day                                     |                 | Novartis     |                |
|                                                | Escitalopram   |                    |                    | S               |                      | 10 Mg, Per Day                                       |                 | Not Reported |                |



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

|                       |   |                |              |
|-----------------------|---|----------------|--------------|
| Telaprevir            | S | 750 Mg, Tid    | Not Reported |
| Peginterferon Alfa-2a | S | 180 Ug, Weekly | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Mar-2014              | 9474202       | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000048053    |                      | 57 YR      | Female     | FRA            |

| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction;      | Escitalopram   |              |            | S           | Oral         |                    |                 | Forest       |
| Spontaneous Haematoma; | Inipomp        |              |            | S           | Oral         |                    |                 | Not Reported |
| Thrombocytopenia       |                |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Mar-2014              | 9847362       | EXPEDITED (15-DAY) |                    | OT              | JP-FRI-1000053113    |                      | 55 YR      | Male       | JPN            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Activation Syndrome   | Lexapro        |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                       | Lexapro        |              |            | S           | Oral         | 20 Mg              |                 | Forest       |
|                       | Lexapro        |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                       | Paxil          |              |            | C           | Oral         | 10 Mg              |                 | Not Reported |
|                       | Paxil          |              |            | C           | Oral         | 40 Mg              |                 | Not Reported |
|                       | Paxil          |              |            | C           | Oral         | 20 Mg              |                 | Not Reported |
|                       | Paxil          |              |            | C           | Oral         | 10 Mg              |                 | Not Reported |
|                       | Anafranil      |              |            | C           | Oral         | 60 Mg              |                 | Not Reported |
|                       | Anafranil      |              |            | C           | Oral         | 30 Mg              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 03-Mar-2014              | 9938631       | EXPEDITED (15-DAY) |                    | OT              | IT-JNJFOC-20140212451 |                      | 45 YR      | Male       | ITA            |

| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Intentional Overdose;    | Risperdal      |              |            | S           | Oral         | 4 Tablets          |                 | Not Reported |
| Intentional Self-Injury; | Ciprallex      |              |            | S           | Oral         |                    |                 | Not Reported |
| Sluggishness             |                |              |            |             |              |                    |                 |              |

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

|                   |   |      |              |
|-------------------|---|------|--------------|
| Valium            | S | Oral | Not Reported |
| Tavor (Lorazepam) | S | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 03-Mar-2014              | 9938841       | NON-EXPEDITED    |                    |                 | US-ABBVIE-12P-163-0952017-00 |                      | 68 YR      | Female     | USA            |

| <u>Preferred Term</u>    | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>             | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|------------------------|--------------|------------|-------------|--------------------------|--------------------|-----------------|--------------|
| Fall; Injection Site     | Humira                 |              |            | S           | Subcutaneous             |                    |                 | Not Reported |
| Erythema; Injection Site | Sinemet                |              |            | S           |                          | 25/100 Mg          |                 | Not Reported |
| Erythema; Injection Site | Lexapro                |              |            | S           |                          |                    |                 | Not Reported |
| Pain; Injection Site     | Proair                 |              |            | C           | Respiratory (inhalation) |                    |                 | Not Reported |
| Pruritus; Muscular       |                        |              |            |             |                          |                    |                 |              |
| Weakness; Pain; Pain;    |                        |              |            |             |                          |                    |                 |              |
| Pain In Extremity;       | Flovent                |              |            | C           |                          |                    |                 | Not Reported |
| Parkinsonism; Rash       | Tylenol Extra Strength |              |            | C           |                          |                    |                 | Not Reported |
| Papular; Rash Papular;   | Calcium Nasal Spray    |              |            | C           |                          | Daily              |                 | Not Reported |
| Rash Papular;            | Lasix                  |              |            | C           |                          | Daily              |                 | Not Reported |
| Rheumatoid Arthritis;    | Levothyroxin           |              |            | C           |                          | Daily              |                 | Not Reported |
| Rheumatoid Arthritis     |                        |              |            |             |                          |                    |                 |              |
|                          | Metoprolol             |              |            | C           |                          |                    |                 | Not Reported |
|                          | Estropiate             |              |            | C           |                          | Daily              |                 | Not Reported |
|                          | Klonopin               |              |            | C           |                          |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Mar-2014              | 9940749       | EXPEDITED (15-DAY) |                    | DE, HO          | PHHY2014IE010058     |                      |            | Female     | IRL            |

| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Acute Kidney Injury;      | Afinitor       |              |            | S           | Oral         | 10 Mg, Qd          |                 | Novartis     |
| Anaemia; Blood Creatinine | Escitalopram   |              |            | S           |              | 10 Mg              |                 | Not Reported |
| Increased; Diarrhoea;     | Pradaxa        |              |            | S           |              | 110 Mg, Bid        |                 | Not Reported |
| Gastritis Haemorrhagic;   | Lorazepam      |              |            | C           |              | 0.5 Mg, Daily      |                 | Not Reported |
| Gastrointestinal          | Lansoprazole   |              |            | C           |              | 30 Mg, Daily       |                 | Not Reported |
| Haemorrhage;              |                |              |            |             |              |                    |                 |              |
| Hypotension; Vomiting     | Perindopril    |              |            | C           |              |                    |                 | Not Reported |
|                           | Atorvastatin   |              |            | C           |              | 10 Mg              |                 | Not Reported |

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

|                 |   |            |              |
|-----------------|---|------------|--------------|
| Lercanidipine   | C | 10 Mg      | Not Reported |
| Zolpidem        | C | 5 Mg       | Not Reported |
| Oxycontin       | C | 2 Df, Qd   | Not Reported |
| Aromasin        | C | 25 Mg      | Not Reported |
| Zoledronic Acid | C | 3 Mg, Q3mo | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 03-Mar-2014              | 9942340       | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2014059235 |                      | 59 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Hypersensitivity | Effexor Xr     |              |            | S           |              | Unk                |                 | Pfizer       |
|                       | Effexor        |              |            | S           |              | Unk                |                 | Pfizer       |
|                       | Wellbutrin     |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Abilify        |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Lexapro        |              |            | S           |              | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Mar-2014              | 9942377       | EXPEDITED (15-DAY) |                    | CA, OT          | DE-WATSON-2014-03195 |                      | 1 DAY      | Male       | DEU            |

| <u>Preferred Term</u>                                                                                          | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------|------------------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Foetal Exposure During Pregnancy; Hypospadias; Motor Developmental Delay; Premature Baby; Small For Dates Baby | Escitalopram (Unknown) |              |            | S           | Transplacental | 20 Mg, Daily       |                 | Not Reported |
|                                                                                                                | Lamotrigine (Unknown)  |              |            | S           | Transplacental | 150 Mg, Daily      |                 | Watson       |
|                                                                                                                | Folic Acid             |              |            | C           | Transplacental | 0.8 Mg, Daily      |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Mar-2014              | 9943964       | EXPEDITED (15-DAY) |                    | HO              | CH-FRI-1000054766    |                      | 73 YR      | Female     | CHE            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Essential Tremor      | Escitalopram   |              |            | S           | Oral         | 15 Mg              |                 | Forest     |

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

|                     |   |      |         |              |
|---------------------|---|------|---------|--------------|
| Risperdal           | S | Oral | 1 Mg    | Not Reported |
| Temesta (Lorazepam) | S | Oral | 1.5 Mg  | Not Reported |
| Depakine Chrono     | C | Oral | 1200 Mg | Not Reported |
| Rivotril            | C | Oral | 0.5 Mg  | Not Reported |
| Imovane             | C | Oral | 7.5 Mg  | Not Reported |
| Inderal             | C | Oral | 80 Mg   | Not Reported |
| Arimidex            | C | Oral | 1 Mg    | Not Reported |
| Mysoline            | C | Oral | 125 Mg  | Not Reported |
| Mysoline            | C | Oral | 250 Mg  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|-------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 03-Mar-2014              | 9944022           | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000054765    |                      | 52 YR           | Female       | FRA            |
| <u>Preferred Term</u>    | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Headache; Photopsia      | Escitalopram      |                    |                    | S               | Oral                 | 1 Df                 |                 | Forest       |                |
|                          | Prazepam Biogaran |                    |                    | S               | Oral                 | 1 To 3 Tablets Daily |                 | Not Reported |                |
|                          | Levothyrox        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Travatan          |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                            | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|--------------------------------------------|-----------------|--------------|----------------|
| 04-Mar-2014                                                         | 6950747        | NON-EXPEDITED    | Y                  | HO, OT          | RB-2644-2008         |                                            | 6 DAY           | Female       | USA            |
| <u>Preferred Term</u>                                               | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy | Suboxone 8 Mg  |                  |                    | S               | Transplacental       | 32 Mg Transplacental                       |                 | Not Reported |                |
|                                                                     | Subutex        |                  |                    | S               | Transplacental       | 10 Mg Transplacental, 12 Mg Transplacental |                 | Not Reported |                |
|                                                                     |                |                  |                    |                 | Transplacental       | 10 Mg Transplacental, 12 Mg Transplacental |                 |              |                |
|                                                                     | Lexapro        |                  |                    | S               | Transplacental       |                                            |                 | Not Reported |                |
|                                                                     | Clonazepam     |                  |                    | S               | Transplacental       |                                            |                 | Not Reported |                |
|                                                                     |                |                  |                    |                 | Transplacental       |                                            |                 |              |                |

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|                                                                                                                |                      |                    |                    |                 |                                                  |                      |                 |              |                |
|----------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|--------------------------------------------------|----------------------|-----------------|--------------|----------------|
| Alcohol                                                                                                        |                      |                    | S                  | Transplacental  | Maternal Use In Early Pregnancy                  |                      |                 | Not Reported |                |
| Nicotine (None)                                                                                                |                      |                    | S                  | Transplacental  |                                                  |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Mar-2014                                                                                                    | 9948728              | EXPEDITED (15-DAY) |                    | CA, OT          | DE-LUPIN<br>PHARMACEUTICALS<br>INC.-E2B_00001725 |                      | 1 DAY           | Male         | DEU            |
| <u>Preferred Term</u>                                                                                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                     | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Foetal Exposure During Pregnancy; Hypospadias; Motor Developmental Delay; Premature Baby; Small For Dates Baby | Lamotrigin           |                    |                    | S               | Transplacental                                   |                      |                 | Not Reported |                |
|                                                                                                                | Escitalopram         |                    |                    | S               | Transplacental                                   |                      |                 | Not Reported |                |
|                                                                                                                | Femibion Pregnancy 1 |                    |                    | C               | Transplacental                                   |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Mar-2014                                                                                                    | 8655007              | EXPEDITED (15-DAY) |                    | HO, LT          | PHHO2012DE009669                                 |                      | 29 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                                                                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                     | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Multiple Sclerosis Relapse; Organic Brain Syndrome; Personality Change                                         | Risperidone          |                    |                    | S               |                                                  | Unk                  |                 | Novartis     |                |
|                                                                                                                | Fty 720              |                    |                    | S               | Oral                                             | 1 Df, 16 Wk Ws + Fty |                 | Not Reported |                |
|                                                                                                                | Tysabri              |                    |                    | S               | Intravenous drip                                 | Unk                  |                 | Not Reported |                |
|                                                                                                                | Opi Pramol           |                    |                    | S               |                                                  |                      |                 | Not Reported |                |
|                                                                                                                | Ciprallex            |                    |                    | S               |                                                  |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Mar-2014                                                                                                    | 9788701              | EXPEDITED (15-DAY) |                    | HO              | JP-FRI-1000052524                                |                      | 77 YR           | Female       | JPN            |
| <u>Preferred Term</u>                                                                                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                     | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Seizure                                                                                                        | Lexapro              |                    |                    | S               | Oral                                             |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Mar-2014                                                                                                    | 9917245              | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000054454                                |                      | 83 YR           | Female       | FRA            |

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| <u>Preferred Term</u>                           | <u>Product</u>                                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------------------|---------------------------------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| Hypochloraemia;<br>Hyponatraemia                | Escitalopram                                      |                    |                    | S               | Oral                     | 10 Mg                |                 | Forest       |                |
|                                                 | Imovane                                           |                    |                    | C               | Oral                     |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                        | <u>Case #</u>                                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Mar-2014                                     | 9961593                                           | EXPEDITED (15-DAY) |                    | DE              | US-FRI-1000054885        |                      | 55 YR           | Male         | USA            |
| <u>Preferred Term</u>                           | <u>Product</u>                                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardio-Respiratory Arrest;<br>Completed Suicide | Citalopram                                        |                    |                    | S               |                          |                      |                 | Forest       |                |
|                                                 | Escitalopram                                      |                    |                    | S               |                          |                      |                 | Forest       |                |
|                                                 | Acetaminophen/Diphenhydramine                     |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                                 | Bupropion                                         |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                                 | Clonazepam                                        |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                                 | Tadalafil                                         |                    |                    | S               |                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                        | <u>Case #</u>                                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Mar-2014                                     | 9963940                                           | EXPEDITED (15-DAY) |                    | HO              | BE-PFIZER INC-2014059986 |                      |                 | Unknown      | BEL            |
| <u>Preferred Term</u>                           | <u>Product</u>                                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Ataxia; Dizziness; Drug Interaction             | Pantomed (Pantoprazole Sodium)                    |                    |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                                                 | Abilify                                           |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                                                 | Siprallexa                                        |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                        | <u>Case #</u>                                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Mar-2014                                     | 9964250                                           | EXPEDITED (15-DAY) |                    | DE              | US-BANPHARM-20142299     |                      | 55 YR           | Male         | USA            |
| <u>Preferred Term</u>                           | <u>Product</u>                                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Death                        | Diphenhydramine And Acetaminophen Unknown Product |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                                                 | Citalopram                                        |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                                 | Escitalopram                                      |                    |                    | S               |                          |                      |                 | Not Reported |                |

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|                                                                                                                                        |                           |                    |                    |                 |                      |                                     |                 |              |                |
|----------------------------------------------------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------------|-----------------|--------------|----------------|
| Bupropion                                                                                                                              |                           |                    | S                  |                 |                      | Not Reported                        |                 |              |                |
| <u>FDA Received Date</u>                                                                                                               | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Mar-2014                                                                                                                            | 9964933                   | EXPEDITED (15-DAY) |                    | OT              | PHHY2014US021139     |                                     | 70 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                  | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Implant Site Pain; Muscle Spasms; Muscle Tightness; Musculoskeletal Stiffness; Therapeutic Response Decreased; Urinary Tract Infection | Baclofen Intrathecal      |                    |                    | S               | Intrathecal          | 357.4 Ug/Day                        |                 | Not Reported |                |
|                                                                                                                                        | Baclofen                  |                    |                    | S               | Oral                 | 10 Mg, Bid                          |                 | Not Reported |                |
|                                                                                                                                        | Simvastatin               |                    |                    | S               |                      | Unk Ukn, Unk                        |                 | Novartis     |                |
|                                                                                                                                        | Duragesic                 |                    |                    | S               |                      | 150 Ug/Hr, (1 Patch Every 48 Hours) |                 | Not Reported |                |
|                                                                                                                                        | Klonopin                  |                    |                    | S               |                      | 0.5 Df, Bid (1 Mg)                  |                 | Not Reported |                |
|                                                                                                                                        | Levoxyl                   |                    |                    | S               |                      | 200 Ug, Unk                         |                 | Not Reported |                |
|                                                                                                                                        | Lexapro                   |                    |                    | S               |                      | Unk Ukn, Unk                        |                 | Not Reported |                |
|                                                                                                                                        | Macrobid                  |                    |                    | S               |                      | Unk Ukn, Unk                        |                 | Not Reported |                |
|                                                                                                                                        | Neurontin                 |                    |                    | S               |                      | Unk Ukn, Unk                        |                 | Not Reported |                |
|                                                                                                                                        | Oxycodone                 |                    |                    | S               |                      | 10/325                              |                 | Not Reported |                |
|                                                                                                                                        | Pepcid                    |                    |                    | S               |                      | Unk Ukn, Unk                        |                 | Not Reported |                |
|                                                                                                                                        | Probiotics                |                    |                    | S               |                      | Unk Ukn, Unk                        |                 | Not Reported |                |
|                                                                                                                                        | Skelaxin                  |                    |                    | S               |                      | Unk Ukn, Unk                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                               | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Mar-2014                                                                                                                            | 9967054                   | EXPEDITED (15-DAY) |                    | DE              | US-FRI-1000054855    |                                     | 86 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                  | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Completed Suicide; Respiratory Arrest                                                                                  | Escitalopram              |                    |                    | S               |                      |                                     |                 | Forest       |                |
|                                                                                                                                        | Levothroid                |                    |                    | S               |                      |                                     |                 | Forest       |                |
|                                                                                                                                        | Acetaminophen/Hydrocodone |                    |                    | S               |                      |                                     |                 | Not Reported |                |
|                                                                                                                                        | Isosorbide Mononitrate    |                    |                    | S               |                      |                                     |                 | Not Reported |                |
|                                                                                                                                        | Amlodipine                |                    |                    | S               |                      |                                     |                 | Not Reported |                |
|                                                                                                                                        | Doxazosin                 |                    |                    | S               |                      |                                     |                 | Not Reported |                |
|                                                                                                                                        | Warfarin                  |                    |                    | S               |                      |                                     |                 | Not Reported |                |
|                                                                                                                                        | Furosemide                |                    |                    | S               |                      |                                     |                 | Not Reported |                |

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|                                                                       |                |                    |                    |                 |                      |                      |                 |              |                |
|-----------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Potassium                                                             |                |                    | S                  |                 |                      | Not Reported         |                 |              |                |
| <u>FDA Received Date</u>                                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Mar-2014                                                           | 9967080        | EXPEDITED (15-DAY) |                    | DE              | US-FRI-1000054875    |                      | 45 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardio-Respiratory Arrest;<br>Completed Suicide                       | Escitalopram   |                    |                    | S               |                      |                      |                 | Forest       |                |
|                                                                       | Alprazolam     |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                       | Zolpidem       |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Mar-2014                                                           | 9967132        | EXPEDITED (15-DAY) |                    | DE              | US-FRI-1000054857    |                      | 31 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardio-Respiratory Arrest;<br>Completed Suicide                       | Escitalopram   |                    |                    | S               |                      |                      |                 | Forest       |                |
|                                                                       | Lamotrigine    |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                       | Meloxicam      |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Mar-2014                                                           | 9971279        | DIRECT             |                    |                 |                      |                      | 35 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Eyelid Ptosis; Peripheral Swelling; Swelling Face; Swelling Of Eyelid | Escitalopram   |                    |                    | S               | Oral                 |                      |                 | Accord       |                |
| <u>FDA Received Date</u>                                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Mar-2014                                                           | 9971321        | DIRECT             |                    | DS              |                      |                      | 48 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Neoplasm Malignant;<br>Pain; Peyronie'S Disease                       | Celexa         |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                       | Lexapro        |                    |                    | S               |                      |                      |                 | Not Reported |                |



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| <u>FDA Received Date</u>                                                                                  | <u>Case #</u>                                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------|-----------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|-----------------------|-----------------|--------------|----------------|
| 06-Mar-2014                                                                                               | 9904246                                                   | EXPEDITED (15-DAY) | Y                  | OT              | AUR-APL-2014-01467   |                       |                 | Unknown      | ITA            |
| <u>Preferred Term</u>                                                                                     | <u>Product</u>                                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Withdrawal Syndrome Neonatal; Low Birth Weight Baby; Maternal Drugs Affecting Foetus; Premature Baby | Escitalopram                                              |                    |                    | S               | Transplacental       |                       | 1 DAY           | Not Reported |                |
|                                                                                                           | Alprazolam                                                |                    |                    | S               | Transplacental       |                       | 1 DAY           | Not Reported |                |
| <u>FDA Received Date</u>                                                                                  | <u>Case #</u>                                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Mar-2014                                                                                               | 9926089                                                   | EXPEDITED (15-DAY) |                    | HO              | JP-FRI-1000054556    |                       | 51 YR           | Male         | JPN            |
| <u>Preferred Term</u>                                                                                     | <u>Product</u>                                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Deep Vein Thrombosis                                                                                      | Escitalopram                                              |                    |                    | S               | Oral                 | 10 Mg                 |                 | Forest       |                |
|                                                                                                           | Escitalopram                                              |                    |                    | S               | Oral                 | 20 Mg                 |                 | Forest       |                |
|                                                                                                           | Gaster                                                    |                    |                    | C               | Oral                 | 20 Mg                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                  | <u>Case #</u>                                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Mar-2014                                                                                               | 9969761                                                   | EXPEDITED (15-DAY) |                    | HO              | IT-TEVA-465961ISR    |                       | 61 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                                                     | <u>Product</u>                                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Abuse; Mydriasis; Sopor; Unresponsive To Stimuli                                                     | Alprazolam                                                |                    |                    | S               | Oral                 | 1 Dosage Forms Daily; |                 | Teva         |                |
|                                                                                                           | Ciprallex - Comprese Rivestite Con Film - H. Lundbeck A/S |                    |                    | S               | Oral                 | 80 Milligram Daily;   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                  | <u>Case #</u>                                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Mar-2014                                                                                               | 9970039                                                   | EXPEDITED (15-DAY) |                    | OT              | DE-TEVA-464641GER    |                       | 40 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                                                                     | <u>Product</u>                                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Abortion Spontaneous                                                                                      | Isotretinoin                                              |                    |                    | S               | Oral                 |                       |                 | Barr         |                |

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|                 |   |               |                                        |              |
|-----------------|---|---------------|----------------------------------------|--------------|
| Cipralex        | S | Oral          | 10 Milligram Daily;<br>Probably Longer | Not Reported |
| Cymbalta        | C | Oral          |                                        | Not Reported |
| Grippeimpfstoff | C | Intramuscular |                                        | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 06-Mar-2014              | 9971017       | NON-EXPEDITED    |                    |                 | US-ABBVIE-13P-163-1153315-00 |                      | 47 YR      | Male       | USA            |

| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|----------------|--------------|------------|-------------|--------------|---------------------|-----------------|--------------|
| Chromaturia; Discomfort;   | Humira         |              |            | S           | Subcutaneous | Loading Dose X 1    |                 | Not Reported |
| Dizziness; Gastric         | Lexapro        |              |            | S           | Oral         | 20 Milligrams Daily |                 | Not Reported |
| Dilatation; Gastric        | Balsalazide    |              |            | C           | Oral         |                     |                 | Not Reported |
| Dilatation;                | Morphine       |              |            | C           | Oral         |                     |                 | Not Reported |
| Haematospermia;            | Imuran         |              |            | C           | Oral         | Three Tablets Daily |                 | Not Reported |
| Haematuria; Injection Site | Vitamin C      |              |            | C           | Oral         |                     |                 | Not Reported |
| Erythema; Injection Site   | Iron           |              |            | C           | Oral         |                     |                 | Not Reported |
| Haemorrhage; Injection     | Zofran         |              |            | C           | Oral         |                     |                 | Not Reported |
| Site Pain; Lacrimation     | Kcl            |              |            | C           | Oral         | Liquid, Twice A Day |                 | Not Reported |
| Increased; Malaise;        | Marijuana      |              |            | C           |              |                     |                 | Not Reported |
| Malaise                    |                |              |            |             |              |                     |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Mar-2014              | 9975744       | EXPEDITED (15-DAY) |                    | DE              | US-FRI-1000054884    |                      | 55 YR      | Male       | USA            |

| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardio-Respiratory Arrest; | Vilazodone     |              |            | S           |              |                    |                 | Forest       |
| Completed Suicide;         | Escitalopram   |              |            | S           |              |                    |                 | Forest       |
| Overdose                   | Alprazolam     |              |            | S           |              |                    |                 | Not Reported |
|                            | Salicylate     |              |            | S           |              |                    |                 | Not Reported |
|                            | Duloxetine     |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Mar-2014              | 9976059       | EXPEDITED (15-DAY) |                    | CA, OT          | US-FRI-1000054760    |                      |            | Male       | USA            |

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

| <u>Preferred Term</u>                                                                                                                                             | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|----------------------|----------------------------------|-----------------|--------------|----------------|
| Autism Spectrum Disorder; Congenital Torticollis; Hydrocephalus; Speech Disorder Developmental                                                                    | Lexapro                   |                    |                    | S               | Transplacental       |                                  |                 | Forest       |                |
|                                                                                                                                                                   | Lexapro                   |                    |                    | S               |                      |                                  |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                                                          | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Mar-2014                                                                                                                                                       | 9978283                   | EXPEDITED (15-DAY) |                    | DE              | US-FRI-1000054898    |                                  | 47 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                             | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardio-Respiratory Arrest; Completed Suicide                                                                                                                      | Citalopram                |                    |                    | S               |                      |                                  |                 | Forest       |                |
|                                                                                                                                                                   | Escitalopram              |                    |                    | S               |                      |                                  |                 | Forest       |                |
|                                                                                                                                                                   | Amlodipine                |                    |                    | S               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                                   | Carvedilol                |                    |                    | S               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                                   | Bupropion                 |                    |                    | S               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                                   | Acetaminophen/Hydrocodone |                    |                    | S               |                      |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                          | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Mar-2014                                                                                                                                                       | 9980874                   | DIRECT             |                    |                 |                      |                                  | 18 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                             | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Distension; Abdominal Pain; Anxiety; Constipation; Dyspepsia; Educational Problem; Gastrooesophageal Reflux Disease; Nausea; Product Substitution Issue | Escitalopram              |                    |                    | S               | Oral                 | 1 Pill Once Daily Taken By Mouth |                 | Mylan        |                |
| <u>FDA Received Date</u>                                                                                                                                          | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Mar-2014                                                                                                                                                       | 9980934                   | DIRECT             |                    | OT              |                      |                                  | 40 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                             | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Anxiety; Depressed Mood; Drug                                                                                                                         | Escitalopram 10 Mg        |                    |                    | S               | Oral                 | 1 Tablet Once Daily Taken        |                 | Aurobindo    |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Ineffective; Paradoxical  
Drug Reaction; Product  
Substitution Issue; Stress

By Mouth

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 07-Mar-2014                       | 9980431                 | EXPEDITED (15-DAY)        |                             | OT                       | DE-RANBAXY-2014R1-78638       |                               | 37 YR                    | Female              | DEU                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Abortion Spontaneous              | Isotretinoin            |                           |                             | S                        | Oral                          | 10 Mg, 2/Week                 |                          | Ranbaxy             |                         |
|                                   | Cipralex                |                           |                             | S                        | Oral                          | 10 Mg, Qd                     |                          | Not Reported        |                         |
|                                   | Cymbalta                |                           |                             | C                        | Oral                          | Unk                           |                          | Not Reported        |                         |
|                                   | Gippeimpfstoff          |                           |                             | C                        | Intramuscular                 | Unk                           |                          | Not Reported        |                         |

| <a href="#">FDA Received Date</a>     | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|---------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 07-Mar-2014                           | 9984712                 | EXPEDITED (15-DAY)        |                             | CA                       | US-FRI-1000054994             |                               | < 1 DAY                  | Male                | USA                     |
| <a href="#">Preferred Term</a>        | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Cleft Lip; Congenital Anomaly; Hernia | Lexapro                 |                           |                             | S                        | Transplacental                |                               |                          | Forest              |                         |
| Congenital; Hydrocele                 | Paxil                   |                           |                             | S                        | Transplacental                |                               |                          | Not Reported        |                         |

| <a href="#">FDA Received Date</a>               | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 07-Mar-2014                                     | 9985108                 | NON-EXPEDITED             |                             |                          | US-ABBVIE-13P-163-1184626-00  |                               | 32 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Anxiety; Dry Mouth; Insomnia; Pain In Extremity | Humira                  |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
|                                                 | Lexapro                 |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
|                                                 | Lexapro                 |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 07-Mar-2014                       | 9994859                 | DIRECT                    |                             | DS, HO, LT               |                               |                               | 34 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                      |              |   |      |                                  |        |
|------------------------------------------------------|--------------|---|------|----------------------------------|--------|
| Depression; Generalised Tonic-Clonic Seizure; Stress | Escitalopram | S | Oral | 1 Pill Once Daily Taken By Mouth | Camber |
|------------------------------------------------------|--------------|---|------|----------------------------------|--------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Mar-2014              | 9995779       | EXPEDITED (15-DAY) |                    | OT              | BR-TORRENT-00001947  |                      | 61 YR      | Female     | BRA            |

| <u>Preferred Term</u>                                                                                                                                                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Pressure Decreased; Crying; Drug Ineffective; Fatigue; Fatigue; Malaise; Product Quality Issue; Product Substitution Issue; Productive Cough; Somnolence; Suicidal Ideation | Espran         |              |            | S           | Oral         | Once Daily/Oral    |                 | Not Reported |
|                                                                                                                                                                                   | Atorvastatin   |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                   | Aas Infantil   |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                   | Olcadil        |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                   | Atenolol       |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                   | Losartan       |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                   | Benlcaranlo    |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 10-Mar-2014              | 9562106       | EXPEDITED (15-DAY) |                    | HO, OT          | JP-009507513-1309JPN010149 |                      | 78 YR      | Female     | JPN            |

| <u>Preferred Term</u>                        | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                        | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------|--------------------------|--------------|------------|-------------|--------------|-------------------------------------------|-----------------|--------------|
| Inappropriate Antidiuretic Hormone Secretion | Reflex                   |              |            | S           | Oral         | 3.75 Mg, Divided Dose, Frequency: Unknown |                 | Merck        |
|                                              | Reflex                   |              |            | S           | Oral         | 7.5 Mg, Divided Dose, Frequency: Unknown  |                 | Merck        |
|                                              | Reflex                   |              |            | S           | Oral         | 15 Mg, Divided Dose, Frequency: Unknown   |                 | Merck        |
|                                              | Escitalopram Oxalate     |              |            | S           | Oral         | 20 Mg, Divided Dose, Frequency: Unknown   |                 | Not Reported |
|                                              | Escitalopram Oxalate     |              |            | S           | Oral         | 15 Mg, Divided Dose, Frequency: Unknown   |                 | Not Reported |
|                                              | Escitalopram Oxalate     |              |            | S           | Oral         | 10 Mg, Divided Dose, Frequency: Unknown   |                 | Not Reported |
|                                              | Duloxetine Hydrochloride |              |            | S           | Oral         | 20 Mg, Divided Dose,                      |                 | Not Reported |

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

|                          |   |      |                                                                  |              |
|--------------------------|---|------|------------------------------------------------------------------|--------------|
| Duloxetine Hydrochloride | S | Oral | Frequency: Unknown<br>40 Mg, Divided Dose,<br>Frequency: Unknown | Not Reported |
| Zolpidem Tartrate        | C | Oral | Daily Dose 10 Mg                                                 | Not Reported |
| Sulpiride                | C | Oral | 50 Mg, Divided Dose,<br>Frequency: Unknown                       | Not Reported |
| Amoxapine                | C | Oral | 10 Mg, Divided Dose,<br>Frequency: Unknown                       | Not Reported |
| Brotizolam               | C | Oral | Daily Dose 0.25 Mg                                               | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 10-Mar-2014              | 9859513       | EXPEDITED (15-DAY) |                    | HO              | FR-PFIZER INC-<br>2014026592 |                      | 49 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                     | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|------------------------------------------------------------------------|-----------------|--------------|
| Agitation; Confusional<br>State; Delirium;<br>Hallucination, Visual | Xanax          |              |            | S           |              | Unk                                                                    |                 | Pfizer       |
|                                                                     | Keppra         |              |            | S           |              | 1 G, Daily                                                             |                 | Not Reported |
|                                                                     | Keppra         |              |            | S           |              | 1 G, 2x/Day In The<br>Morning And In The<br>Evening                    |                 | Not Reported |
|                                                                     | Keppra         |              |            | S           |              | 1.5 G, Daily                                                           |                 | Not Reported |
|                                                                     | Keppra         |              |            | S           |              | 1 G, Daily                                                             |                 | Not Reported |
|                                                                     | Keppra         |              |            | S           |              | 500 Mg, Daily                                                          |                 | Not Reported |
|                                                                     | Keppra         |              |            | S           |              | Unk                                                                    |                 | Not Reported |
|                                                                     | Seroplex       |              |            | S           |              | Unk                                                                    |                 | Not Reported |
|                                                                     | Tranxene       |              |            | S           |              | Unk                                                                    |                 | Not Reported |
|                                                                     | Prodilantin    |              |            | C           |              | Unk                                                                    |                 | Not Reported |
|                                                                     | Urbanyl        |              |            | C           |              | Unk                                                                    |                 | Not Reported |
|                                                                     | Urbanyl        |              |            | C           |              | 10 Unk, 3x/Day, 1 In The<br>Morning, 1 At Noon And 2<br>In The Evening |                 | Not Reported |
|                                                                     | Temerit        |              |            | C           |              | 2.5 In The Morning And<br>2.5 In The Evening                           |                 | Not Reported |

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

| Loxen Lp                                                                                                                         |                                      | C                  |                    | 50 Unk, 1x/Day In The Morning |                      | Not Reported           |                 |              |                |
|----------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|--------------------|--------------------|-------------------------------|----------------------|------------------------|-----------------|--------------|----------------|
| Diffu-K                                                                                                                          |                                      | C                  |                    | Unk                           |                      | Not Reported           |                 |              |                |
| <u>FDA Received Date</u>                                                                                                         | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>               | <u>Mfr Control #</u> | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Mar-2014                                                                                                                      | 9991759                              | EXPEDITED (15-DAY) |                    | HO                            | NO-FRI-1000060417    |                        | 50 YR           | Male         | NOR            |
| <u>Preferred Term</u>                                                                                                            | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                   | <u>Route</u>         | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain Upper; Drug Abuse; Drug Diversion; Hospitalisation; Intentional Product Misuse                                    | Escitalopram                         |                    |                    | S                             |                      | Dosing Details Unknown |                 | Forest       |                |
|                                                                                                                                  | Remeron                              |                    |                    | S                             |                      | Dosing Details Unknown |                 | Not Reported |                |
|                                                                                                                                  | Rivotril                             |                    |                    | S                             |                      | Dosing Details Unknown |                 | Not Reported |                |
|                                                                                                                                  | Cannabis                             |                    |                    | S                             |                      | Details Unknown        |                 | Not Reported |                |
|                                                                                                                                  | Subutex                              |                    |                    | S                             |                      |                        |                 | Not Reported |                |
|                                                                                                                                  | Benzodiazepine                       |                    |                    | S                             |                      |                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                         | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>               | <u>Mfr Control #</u> | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Mar-2014                                                                                                                      | 9904804                              | EXPEDITED (15-DAY) | Y                  | OT                            | AUR-APL-2014-01433   |                        |                 | Unknown      | ITA            |
| <u>Preferred Term</u>                                                                                                            | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                   | <u>Route</u>         | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Exposure During Pregnancy; Hypoglycaemia; Hyporeflexia; Hypotonia; Lethargy; Therapy Non-Responder; Withdrawal Syndrome | Escitalopram (Escitalopram)          |                    |                    | S                             | Transplacental       |                        |                 | Not Reported |                |
|                                                                                                                                  | Lorazepam (Lorazepam)                |                    |                    | S                             | Transplacental       |                        |                 | Not Reported |                |
|                                                                                                                                  | Paroxetine                           |                    |                    | S                             | Transplacental       |                        |                 | Not Reported |                |
|                                                                                                                                  | Clonazepam (Clonazepam) (Clonazepam) |                    |                    | S                             | Transplacental       |                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                         | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>               | <u>Mfr Control #</u> | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Mar-2014                                                                                                                      | 9958838                              | EXPEDITED (15-DAY) | Y                  | OT                            | KAD201402-000272     |                        | 36 YR           | Male         | ITA            |
| <u>Preferred Term</u>                                                                                                            | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                   | <u>Route</u>         | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Seizure                                                                                                                          | Ribavirin (Ribavirin)                |                    |                    | S                             |                      |                        |                 | Not Reported |                |
|                                                                                                                                  | Peginterferon Alfa-2a                |                    |                    | S                             |                      | 180 Microg Weekly      |                 | Not Reported |                |

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

|                             |   |                            |              |
|-----------------------------|---|----------------------------|--------------|
| Telaprevir (Telaprevir)     | S | 750 Mg Three Times Per Day | Not Reported |
| Escitalopram (Escitalopram) | S | 10mg/Day                   | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Mar-2014              | 9996243       | EXPEDITED (15-DAY) | HO                 |                 | IT-FRI-1000060438    |                      | 61 YR      | Female     | ITA            |

| <u>Preferred Term</u>                                                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|------------------------------|-----------------|--------------|
| Drug Abuse; Intentional Overdose; Mydriasis; Sopor; Unresponsive To Stimuli | Escitalopram   |              |            | S           | Oral         |                              |                 | Forest       |
|                                                                             | Escitalopram   |              |            | S           | Oral         | Overdose: 80 Mg In One Dose  |                 | Forest       |
|                                                                             | Escitalopram   |              |            | S           | Oral         |                              |                 | Forest       |
|                                                                             | Alprazolam     |              |            | S           | Oral         |                              |                 | Not Reported |
|                                                                             | Alprazolam     |              |            | S           | Oral         | Overdose: One Bottle At Once |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 11-Mar-2014              | 9996399       | EXPEDITED (15-DAY) |                    | OT              | FR-GLAXOSMITHKLINE-B0974540A |                      |            | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Thrombocytopenia      | Votrient       |              |            | S           | Unknown      | 600mg Per Day      |                 | Glaxosmithkline |
|                       | Propranolol    |              |            | S           | Unknown      |                    |                 | Not Reported    |
|                       | Seroplex       |              |            | S           | Unknown      |                    |                 | Not Reported    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Mar-2014              | 9998955       | DIRECT           |                    | OT              |                      |                      | 34 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                         | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Condition Aggravated; Depression; Drug Ineffective; Loss Of Personal Independence In | Escitalopram Oxalate |              |            | S           |              |                    |                 | Not Reported |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| Daily Activities                                                                                     |                |                    |                    |                 |                              |                      |                 |              |                |
|------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| <u>FDA Received Date</u>                                                                             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Mar-2014                                                                                          | 9999607        | DIRECT             |                    |                 |                              |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Frustration<br>Tolerance Decreased;<br>Insomnia; Nervousness;<br>Product Substitution Issue | Escitalopram   |                    |                    | S               |                              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Mar-2014                                                                                          | 9733772        | EXPEDITED (15-DAY) |                    | HO              | IT-FRI-1000051937            |                      | 34 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                                                | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Sopor                                                                                                | Escitalopram   |                    |                    | S               | Oral                         |                      |                 | Forest       |                |
|                                                                                                      | Delorazepam    |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                                                                      | Ribavirin      |                    |                    | C               |                              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Mar-2014                                                                                          | 9999156        | EXPEDITED (15-DAY) |                    | OT              | CH-009507513-1403CHE001942   |                      | 30 YR           | Male         | CHE            |
| <u>Preferred Term</u>                                                                                | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Overdose;<br>Poisoning; Sopor; Suicide Attempt                                           | Remeron        |                    |                    | S               | Oral                         | Dose 1050 Mg, Once   |                 | Merck        |                |
|                                                                                                      | Escitalopram   |                    |                    | S               | Oral                         | Dose 410 Mg, Once    |                 | Not Reported |                |
|                                                                                                      | Aspirin        |                    |                    | S               | Oral                         | Dose 2800 Mg, Once   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Mar-2014                                                                                          | 10003687       | NON-EXPEDITED      |                    |                 | US-ABBVIE-13P-163-1084327-00 |                      | 51 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Fatigue; Somnolence;                                                                                 | Depakote       |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |

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

|         |              |   |      |  |              |
|---------|--------------|---|------|--|--------------|
| Trismus | Depakote     | S |      |  | Not Reported |
|         | Depakote     | S |      |  | Not Reported |
|         | Lexapro      | S | Oral |  | Not Reported |
|         | Lexapro      | S | Oral |  | Not Reported |
|         | Lexapro      | S | Oral |  | Not Reported |
|         | Lexapro      | S | Oral |  | Not Reported |
|         | Seroquel     | S | Oral |  | Not Reported |
|         | Seroquel     | S | Oral |  | Not Reported |
|         | Seroquel     | S | Oral |  | Not Reported |
|         | Synthroid    | C | Oral |  | Not Reported |
|         | Clomipramine | C |      |  | Not Reported |
|         | Metoprolol   | C |      |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 12-Mar-2014              | 10003756      | NON-EXPEDITED    |                    |                 | US-ABBVIE-13P-163-1070735-00 |                      | 43 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                   | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                        | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------|-----------------------------|--------------|------------|-------------|--------------|-----------------------------------------------------------|-----------------|--------------|
| Crying; Depression; Drug Ineffective; Loss Of Personal Independence In Daily Activities | Depakote                    |              |            | S           |              |                                                           |                 | Not Reported |
|                                                                                         | Lithium                     |              |            | S           |              |                                                           |                 | Not Reported |
|                                                                                         | Lexapro Film-Coated Tablets |              |            | S           |              |                                                           |                 | Not Reported |
|                                                                                         | Luvox                       |              |            | S           |              |                                                           |                 | Not Reported |
|                                                                                         | Pristiq                     |              |            | S           | Oral         |                                                           |                 | Not Reported |
|                                                                                         | Pristiq                     |              |            | S           | Oral         |                                                           |                 | Not Reported |
|                                                                                         | Pristiq                     |              |            | S           |              |                                                           |                 | Not Reported |
|                                                                                         | Pristiq                     |              |            | S           |              |                                                           |                 | Not Reported |
|                                                                                         |                             |              |            |             |              | 100mg In Morning, 50 Mg In The Afternoon, 100 Mg At Night |                 |              |
|                                                                                         | Zoloft                      |              |            | S           |              |                                                           |                 | Not Reported |
|                                                                                         | Prozac                      |              |            | S           |              |                                                           |                 | Not Reported |
|                                                                                         | Lamictal                    |              |            | S           |              |                                                           |                 | Not Reported |
|                                                                                         | Paxil                       |              |            | S           |              |                                                           |                 | Not Reported |
|                                                                                         | Valium                      |              |            | S           |              |                                                           |                 | Not Reported |
|                                                                                         | Klonopin                    |              |            | S           |              |                                                           |                 | Not Reported |
|                                                                                         | Topamax                     |              |            | S           |              |                                                           |                 | Not Reported |
|                                                                                         | Abilify                     |              |            | S           |              | 10 Mg Daily                                               |                 | Not Reported |

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

|  |                        |   |  |  |             |  |  |              |
|--|------------------------|---|--|--|-------------|--|--|--------------|
|  | Wellbutrin             | S |  |  |             |  |  | Not Reported |
|  | Celexa                 | S |  |  |             |  |  | Not Reported |
|  | Cymbalta               | S |  |  |             |  |  | Not Reported |
|  | Anafranil              | S |  |  |             |  |  | Not Reported |
|  | Imipramine             | S |  |  |             |  |  | Not Reported |
|  | Tegretol               | S |  |  |             |  |  | Not Reported |
|  | Seroquel               | S |  |  |             |  |  | Not Reported |
|  | Seroquel Xr            | C |  |  | 250mg Daily |  |  | Not Reported |
|  | Xanax                  | C |  |  |             |  |  | Not Reported |
|  | Adderall               | C |  |  |             |  |  | Not Reported |
|  | Unspecified Medication | C |  |  |             |  |  | Not Reported |

| <u>FDA Received Date</u>                              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 12-Mar-2014                                           | 10004678             | EXPEDITED (15-DAY) |                    | HO              | IT-ACTAVIS-2014-04311 |                      | 61 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Abuse; Mydriasis; Sopor; Unresponsive To Stimuli | Alprazolam (Unknown) |                    |                    | S               | Oral                  | 1 Df, Total          |                 | Watson       |                |
|                                                       | Cipraxex             |                    |                    | S               | Oral                  | 80 Mg, Total         |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                                                                                                                             | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                     | <u>Age</u>      | <u>Sex</u>        | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|--------------------|--------------------|-----------------|----------------------|------------------------------------------|-----------------|-------------------|----------------|
| 12-Mar-2014                                                                                                                                                                                                                                          | 10005385              | EXPEDITED (15-DAY) |                    | OT              | US-RB-064444-14      |                                          | 24 YR           | Female            | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>        |                |
| Depressed Mood; Depression; Drug Withdrawal Syndrome; Foetal Growth Restriction; Heart Rate Increased; Intentional Underdose; Lethargy; Maternal Exposure During Pregnancy; Nausea; Premature Delivery; Product Preparation Issue; Seizure; Vomiting | Buprenorphine Generic |                    |                    | S               | Sublingual           |                                          |                 | Reckitt Benckiser |                |
|                                                                                                                                                                                                                                                      | Suboxone Film         |                    |                    | S               | Sublingual           | Suboxone Film                            |                 | Reckitt Benckiser |                |
|                                                                                                                                                                                                                                                      | Suboxone Film         |                    |                    | S               | Sublingual           | Suboxone Film; Self Tapering And Cutting |                 | Reckitt Benckiser |                |
|                                                                                                                                                                                                                                                      | Suboxone Film         |                    |                    | S               | Sublingual           | Suboxone Film; Took One Piece Of Film    |                 | Reckitt Benckiser |                |
|                                                                                                                                                                                                                                                      | Wellbutrin            |                    |                    | S               | Oral                 | Dosing Details Unknown                   |                 | Not Reported      |                |
|                                                                                                                                                                                                                                                      | Lexapro               |                    |                    | S               | Oral                 |                                          |                 | Not Reported      |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Mar-2014              | 10018373      | EXPEDITED (15-DAY) | Y                  | HO, OT          | IMP_07498_2014       |                      | 62 YR      | Male       | CHN            |

| <u>Preferred Term</u>                                                                                                                                                                                               | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                              | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|--------------|------------|-------------|--------------|-----------------------------------------------------------------|-----------------|--------------|
| Abdominal Discomfort;<br>Agitation; Confusional<br>State; Constipation;<br>Delirium; Disorientation;<br>Drug Interaction; Dry<br>Mouth; Dry Skin;<br>Hallucination, Auditory;<br>Hallucination, Visual;<br>Insomnia | Bupropion                   |              |            | S           |              | Day, Titration Up<br>Performed),<br>Mg/Day<br>Mg/Day            |                 | Not Reported |
|                                                                                                                                                                                                                     | Quetiapine (Quetiapine)     |              |            | S           |              | Mg/D, Added On Day 8,<br>Titration Up Performed<br>Mg/D, Day 10 |                 | Not Reported |
|                                                                                                                                                                                                                     | Risperidone (Risperidone)   |              |            | S           |              | Mg/Day, Titration Up<br>Performed<br>Mg/Day<br>Mg/Day           |                 | Not Reported |
|                                                                                                                                                                                                                     | Lamotrigine (Lamotrigine)   |              |            | S           |              | Mg/Day, Titration Up<br>Performed<br>Mg/Day                     |                 | Not Reported |
|                                                                                                                                                                                                                     | Escitalopram (Escitalopram) |              |            | S           |              | Mg/Day                                                          |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Mar-2014              | 9820498       | EXPEDITED (15-DAY) |                    | HO              | HU-FRI-1000052875    |                      | 36 YR      | Female     | HUN            |

| <u>Preferred Term</u>                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Endometrial Hyperplasia;<br>Metrorrhagia | Escitalopram   |              |            | S           | Oral         | 5 Mg               |                 | Forest       |
|                                          | Escitalopram   |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                          | Frontin        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Mar-2014              | 9851026       | EXPEDITED (15-DAY) |                    | LT              | FR-FRI-1000053148    |                      | 47 YR      | Female     | FRA            |

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

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

|                                                                  |              |   |      |                                         |              |
|------------------------------------------------------------------|--------------|---|------|-----------------------------------------|--------------|
| Coma; Electrocardiogram<br>Qt Prolonged; Intentional<br>Overdose | Escitalopram | S | Oral | Overdose Of 1 Intake Of<br>Unknown Dose | Forest       |
|                                                                  | Tercian      | S |      | Overdose Of 1 Intake Of<br>Unknown Dose | Not Reported |
|                                                                  | Seresta      | S |      | Overdose Of 1 Intake Of<br>Unknown Dose | Not Reported |
|                                                                  | Stilnox      | S |      | Overdose Of 1 Intake Of<br>Unknown Dose | Not Reported |
|                                                                  | Alcohol      | S |      | Overdose Of 2 Bottles Of<br>Wine        | Not Reported |

| <u>FDA Received Date</u>                                                                 | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| 13-Mar-2014                                                                              | 9914139              | EXPEDITED (15-DAY) |                    | CA, HO          | NL-PFIZER INC-<br>2014045751 |                      |                 | Male         | NLD            |
| <u>Preferred Term</u>                                                                    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Coarctation Of The Aorta;<br>Foetal Exposure During<br>Pregnancy; Respiratory<br>Failure | Sertraline           |                    |                    | S               | Transplacental               | 50 Mg, 1x/Day        |                 | Pfizer       |                |
|                                                                                          | Escitalopram Oxalate |                    |                    | S               | Transplacental               | 10 Mg, 1x/Day        |                 | Not Reported |                |
|                                                                                          | Folic Acid           |                    |                    | C               | Transplacental               | Unk                  |                 | Not Reported |                |

| <u>FDA Received Date</u>                          | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 13-Mar-2014                                       | 10006459       | EXPEDITED (15-DAY) |                    | OT              | DE-FRI-1000064604    |                      | 28 YR           | Female       | DEU            |
| <u>Preferred Term</u>                             | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Haemorrhage In<br>Pregnancy; Nausea;<br>Pregnancy | Escitalopram   |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                                   | Amisulprid     |                    |                    | S               | Oral                 | 50 Mg                |                 | Not Reported |                |
|                                                   | Mutagrip       |                    |                    | C               | Intramuscular        |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 13-Mar-2014              | 10006478       | EXPEDITED (15-DAY) |                    | CA              | DE-FRI-1000064605    |                      | < 1 DAY         | Female     | DEU            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

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

|                                                                               |              |   |                |                                       |              |
|-------------------------------------------------------------------------------|--------------|---|----------------|---------------------------------------|--------------|
| Congenital Aural Fistula;<br>Foetal Exposure During<br>Pregnancy; Haemangioma | Escitalopram | S | Transplacental | 10 Mg                                 | Forest       |
|                                                                               | Amisulprid   | S | Transplacental | 50 Mg                                 | Not Reported |
|                                                                               | Mutagrip     | C | Transplacental |                                       | Not Reported |
|                                                                               | Omeprazole   | C | Transplacental | Only A Few Days In Third<br>Trimester | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Mar-2014              | 10007303      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000060525    |                      | 89 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Off Label Use; Partial<br>Seizures With Secondary<br>Generalisation | Escitalopram   |              |            | S           | Oral         | 15 Mg              |                 | Forest       |
|                                                                     | Zoloft         |              |            | S           | Oral         | 50 Mg              |                 | Not Reported |
|                                                                     | Alprazolam     |              |            | C           |              |                    |                 | Not Reported |
|                                                                     | Procoralan     |              |            | C           |              |                    |                 | Not Reported |
|                                                                     | Tahor          |              |            | C           |              |                    |                 | Not Reported |
|                                                                     | Doliprane      |              |            | C           |              |                    |                 | Not Reported |
|                                                                     | Forlax         |              |            | C           |              |                    |                 | Not Reported |
|                                                                     | Eductyl        |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|------------|------------|----------------|
| 13-Mar-2014              | 10007365      | EXPEDITED (15-DAY) |                    | LT              | US-ASTRAZENECA-<br>2011SE65282 |                      | 48 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Pressure Systolic<br>Decreased; Coma Scale<br>Abnormal; Heart Rate<br>Decreased; Metabolic<br>Acidosis; Overdose | Propranolol    |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                        | Quetiapine     |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                        | Escitalopram   |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                        | Atorvastatin   |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                        | Clonidine      |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                        | Lorazepam      |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Mar-2014              | 10008516      | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000064616    |                      |            | Male       | FRA            |

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

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                                                                                    |                         |                    |                    |                 |                      |                      |                 |              |                |
|--------------------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Hepatocellular Injury                                                                                              |                         | Escitalopram       |                    | S               |                      |                      |                 | Forest       |                |
|                                                                                                                    |                         | Imovane            |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                           | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Mar-2014                                                                                                        | 10008860                | EXPEDITED (15-DAY) |                    | HO              | PHHY2014BE028151     |                      | 81 YR           | Male         | BEL            |
| <u>Preferred Term</u>                                                                                              | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Altered State Of Consciousness; Drug Withdrawal Syndrome; Hyperthermia; Hypertonia; Neuroleptic Malignant Syndrome | Pramipexole             |                    |                    | S               |                      | 2.1 Mg Daily         |                 | Not Reported |                |
|                                                                                                                    | Pramipexole             |                    |                    | S               |                      | 0.350 Mg, Tid        |                 | Not Reported |                |
|                                                                                                                    | Venlafaxine             |                    |                    | S               |                      | 150 Mg               |                 | Novartis     |                |
|                                                                                                                    | Escitalopram            |                    |                    | S               |                      | 10 Mg                |                 | Not Reported |                |
|                                                                                                                    | Levodopa                |                    |                    | S               |                      | 250 Mg Daily         |                 | Not Reported |                |
|                                                                                                                    | Levodopa                |                    |                    | S               |                      | 125 Mg, Q4h          |                 | Not Reported |                |
|                                                                                                                    | Levodopa                |                    |                    | S               |                      | 125 Mg, Qid          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                           | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Mar-2014                                                                                                        | 10017237                | DIRECT             |                    | OT              |                      |                      | 26 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                              | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Condition Aggravated; Depression; Product Substitution Issue                                              | Escitalopram            |                    |                    | S               | Oral                 |                      |                 | Teva         |                |
| <u>FDA Received Date</u>                                                                                           | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Mar-2014                                                                                                        | 10021298                | EXPEDITED (15-DAY) | Y                  | OT              | 2014HINLIT0192       |                      | 36 YR           | Male         | ITA            |
| <u>Preferred Term</u>                                                                                              | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Seizure                                                                                          | Escitalopram            |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                    | Telaprevir (Telaprevir) |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                    | Peginterferon +2a       |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                    | Ribavirin (Ribavirin)   |                    |                    | S               |                      |                      |                 | Not Reported |                |

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

| <u>FDA Received Date</u>                                                                                                                                                                                                 | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|--------------------|--------------------|-----------------|----------------------|------------------------------------------|-----------------|--------------|----------------|
| 14-Mar-2014                                                                                                                                                                                                              | 10011522          | EXPEDITED (15-DAY) |                    | LT              | FR-SA-2014SA008103   |                                          |                 | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                                                    | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>   |                |
| Coma; Electrocardiogram<br>Qt Prolonged; Intentional<br>Overdose                                                                                                                                                         | Stilnox           |                    |                    | S               | Oral                 |                                          |                 | Not Reported |                |
|                                                                                                                                                                                                                          | Tercian           |                    |                    | S               | Oral                 |                                          |                 | Not Reported |                |
|                                                                                                                                                                                                                          | Seroplex          |                    |                    | S               | Oral                 |                                          |                 | Not Reported |                |
|                                                                                                                                                                                                                          | Seresta           |                    |                    | S               | Oral                 |                                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                 | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Mar-2014                                                                                                                                                                                                              | 10012953          | EXPEDITED (15-DAY) |                    | OT              | IT-FRI-1000064618    |                                          | 45 YR           | Male         | ITA            |
| <u>Preferred Term</u>                                                                                                                                                                                                    | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Overdose;<br>Intentional Self-Injury;<br>Somnolence                                                                                                                                                          | Escitalopram      |                    |                    | S               | Oral                 | 3 Tablets Of CipraleX 5 Mg               |                 | Forest       |                |
|                                                                                                                                                                                                                          | Risperdal         |                    |                    | S               | Oral                 | 4 Tablets Of Risperdal<br>2mg            |                 | Not Reported |                |
|                                                                                                                                                                                                                          | Tavor (Lorazepam) |                    |                    | S               |                      | 4 Tablets Of Tavor                       |                 | Not Reported |                |
|                                                                                                                                                                                                                          | Valium            |                    |                    | S               |                      | 25 Drops Of Valium 0.5%                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                 | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Mar-2014                                                                                                                                                                                                              | 10018755          | DIRECT             |                    | DS              |                      |                                          | 52 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                    | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>   |                |
| Anhedonia; Depressed<br>Mood; Depression; Drug<br>Ineffective; Drug<br>Withdrawal Syndrome;<br>Impaired Work Ability;<br>Irritability; Movement<br>Disorder; Product<br>Substitution Issue; Quality<br>Of Life Decreased | Escitalopram      |                    |                    | S               | Oral                 | 1 1/2 Pills Once Daily<br>Taken By Mouth |                 | Aurobindo    |                |



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

| <u>FDA Received Date</u>                                                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|------------------------------|--------------------------------------|-----------------|--------------|----------------|
| 17-Mar-2014                                                                           | 10016077       | EXPEDITED (15-DAY) |                    | HO              | BE-TEVA-468753ISR            |                                      | 81 YR           | Male         | BEL            |
| <u>Preferred Term</u>                                                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Food Interaction;<br>Neuroleptic Malignant<br>Syndrome; Withdrawal<br>Syndrome        | Venlafaxine    |                    |                    | S               | Oral                         | 150 Milligram Daily;                 |                 | Teva         |                |
|                                                                                       | Levodopa       |                    |                    | S               | Oral                         | 250 Milligram Daily;                 |                 | Not Reported |                |
|                                                                                       | Levodopa       |                    |                    | S               | Other                        |                                      |                 | Not Reported |                |
|                                                                                       | Pramipexole    |                    |                    | S               | Oral                         | 2.1 Milligram Daily;                 |                 | Not Reported |                |
|                                                                                       | Pramipexole    |                    |                    | S               | Other                        |                                      |                 | Not Reported |                |
|                                                                                       | Escitalopram   |                    |                    | S               | Oral                         | 10 Milligram Daily;                  |                 | Not Reported |                |
|                                                                                       | Cefuroxime     |                    |                    | C               | Unknown                      |                                      |                 | Not Reported |                |
|                                                                                       | Metronidazole  |                    |                    | C               | Unknown                      |                                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Mar-2014                                                                           | 7271875        | EXPEDITED (15-DAY) |                    | OT              | PHHY2010MX04920              |                                      | 80 YR           | Male         | MEX            |
| <u>Preferred Term</u>                                                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bone Contusion;<br>Dyspnoea; Embolism; Fall;<br>Groin Pain;<br>Haemarthrosis; Vertigo | Exelon Patch   |                    |                    | S               | Transdermal                  | 1 Df, Qd, 1 Patch (5 Cm2)<br>Per Day |                 | Novartis     |                |
|                                                                                       | Stalevo        |                    |                    | S               |                              | Unk Ukn, Unk                         |                 | Not Reported |                |
|                                                                                       | Lexapro        |                    |                    | S               |                              | Unk Ukn, Unk                         |                 | Not Reported |                |
|                                                                                       | Norvas         |                    |                    | C               |                              | Unk Ukn, Unk                         |                 | Not Reported |                |
|                                                                                       | Spiriva        |                    |                    | C               |                              | Unk Ukn, Unk                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Mar-2014                                                                           | 10016542       | EXPEDITED (15-DAY) |                    | OT              | AT-PFIZER INC-<br>2014074686 |                                      | 48 YR           | Male         | AUT            |
| <u>Preferred Term</u>                                                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Cholesterol<br>Increased; Blood Prolactin                                       | Lyrica         |                    |                    | S               |                              | 125 Mg, 1x/Day                       |                 | Pfizer       |                |

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

|                          |                    |   |      |                            |              |
|--------------------------|--------------------|---|------|----------------------------|--------------|
| Increased; Blood         | Lyrice             | S |      | 300 Mg, 1x/Day             | Pfizer       |
| Triglycerides Increased; | Lyrice             | S |      | 375 Mg, 1x/Day             | Pfizer       |
| Body Mass Index          | Lyrice             | S |      | 450 Mg, 1x/Day             | Pfizer       |
| Increased; Weight        | Doxazosin Mesilate | S |      | 4 Mg, 1x/Day               | Pfizer       |
| Increased                | Doxazosin Mesilate | S |      | 8 Mg, 1x/Day               | Pfizer       |
|                          | Mirtabene          | S |      | 45 Mg, 1x/Day              | Not Reported |
|                          | Mirtabene          | S |      | 90 Mg, 1x/Day              | Not Reported |
|                          | Mirtabene          | S |      | 60 Mg, 1x/Day              | Not Reported |
|                          | Mirtabene          | S |      | 30 Mg, 1x/Day              | Not Reported |
|                          | CipraleX           | S |      | 5 Mg, 1x/Day               | Not Reported |
|                          | CipraleX           | S |      | 10 Mg, 1x/Day              | Not Reported |
|                          | CipraleX           | S |      | 20 Mg, 1x/Day              | Not Reported |
|                          | CipraleX           | S |      | 30 Mg, 1x/Day              | Not Reported |
|                          | Risperdal          | S | Oral | 1 Mg, 1x/Day               | Not Reported |
|                          | Risperdal          | S | Oral | 2 Mg, 1x/Day               | Not Reported |
|                          | Sertraline         | C |      | 150 Mg, 1x/Day             | Not Reported |
|                          | Sertraline         | C |      | 100 Mg, 1x/Day             | Not Reported |
|                          | Lamictal           | C |      | 50 Mg, 1x/Day              | Not Reported |
|                          | Lamictal           | C |      | 75 Mg, 1x/Day              | Not Reported |
|                          | Lamictal           | C |      | 100 Mg, 1x/Day             | Not Reported |
|                          | Lamictal           | C |      | 200 Mg, 1x/Day             | Not Reported |
|                          | Rivotril           | C |      | 1.5 Mg, 1x/Day             | Not Reported |
|                          | Exforge            | C |      | 1 Df, 1x/Day, 10 To 160 Mg | Not Reported |
|                          | Exforge            | C |      | 1 Df, 1x/Day, 5 To 160 Mg  | Not Reported |
|                          | Folsan             | C |      | 10 Mg, 1x/Day              | Not Reported |
|                          | Folsan             | C |      | 5 Mg, 1x/Day               | Not Reported |
|                          | Fungoral           | C |      | 3, Three Times A Week      | Not Reported |
|                          | Fungoral           | S |      | 1 Unk, 1x/Day              | Not Reported |

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

|                         |   |               |              |
|-------------------------|---|---------------|--------------|
| Ebrantil                | C | 60 Mg, 1x/Day | Not Reported |
| Nebivolol Hydrochloride | C | 10 Mg, 1x/Day | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Mar-2014              | 10019952      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000064656    |                      | 49 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                    | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Depressed Level Of Consciousness; Hepatic Encephalopathy | Escitalopram        |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                                          | Temesta (Lorazepam) |              |            | S           | Oral         | 1 Df               |                 | Not Reported |
|                                                          | Lexomil Roche       |              |            | S           | Oral         | 1 Df               |                 | Not Reported |
|                                                          | Avlocardyl          |              |            | C           | Oral         | 160 Mg             |                 | Not Reported |
|                                                          | Lantus              |              |            | C           |              | 15 lu              |                 | Not Reported |
|                                                          | Humalog             |              |            | C           |              | 6 Df               |                 | Not Reported |
|                                                          | Sectral             |              |            | C           |              | 400 Mg             |                 | Not Reported |
|                                                          | Esidrex             |              |            | C           | Oral         | 12.5 Mg            |                 | Not Reported |
|                                                          | Kardegic            |              |            | C           | Oral         | 75 Mg              |                 | Not Reported |
|                                                          | Creon               |              |            | C           |              | 3 Df               |                 | Not Reported |
|                                                          | Inexium             |              |            | C           | Oral         | 20 Mg              |                 | Not Reported |
|                                                          | Speciafoldine       |              |            | C           | Oral         | 5 Mg               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Mar-2014              | 10020941      | DIRECT           |                    | OT              |                      |                      | 37 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Anxiety; Depressed Mood; Drug Ineffective; Irritability; Product Substitution Issue | Escitalopram   |              |            | S           | Oral         | 1                  |                 | Teva       |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Mar-2014              | 10021066      | DIRECT           |                    | OT              |                      |                      | 35 YR      | Female     | USA            |

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

| <u>Preferred Term</u>                                                                                                                 | <u>Product</u>                                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------------------|-----------------|--------------|----------------|
| Abdominal Discomfort; Diarrhoea; Gastrointestinal Disorder; Product Substitution Issue                                                | Escitalopram                                     |                    |                    | S               | Oral                 | 1 Pill Once Daily Taken By Mouth |                 | Lupin        |                |
| <u>FDA Received Date</u>                                                                                                              | <u>Case #</u>                                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Mar-2014                                                                                                                           | 10021124                                         | DIRECT             |                    | DS              |                      |                                  | 40 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                 | <u>Product</u>                                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Diarrhoea; Ear Pain; Hot Flush; Insomnia; Tinnitus; Vitreous Floaters                                                        | Lexapro Generic 10mg                             |                    |                    | S               | Oral                 | 1 Tab                            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                              | <u>Case #</u>                                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Mar-2014                                                                                                                           | 10021153                                         | DIRECT             |                    | LT              |                      |                                  | 24 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                 | <u>Product</u>                                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Drug Dependence; Gait Disturbance; Malaise; Suicidal Ideation; Thinking Abnormal                                           | Lexapro                                          |                    |                    | S               | Oral                 | 1 Tab                            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                              | <u>Case #</u>                                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Mar-2014                                                                                                                           | 10025599                                         | EXPEDITED (15-DAY) | Y                  | HO              | AUR-APL-2014-02932   |                                  | 21 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                 | <u>Product</u>                                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Anhedonia; Depressed Mood; Disturbance In Attention; Drug Ineffective; Fatigue; Feeling Guilty; Poor Quality Sleep; Suicidal Ideation | Escitalopram (Escitalopram)                      |                    |                    | S               |                      |                                  | 1460 DAY        | Aurobindo    |                |
|                                                                                                                                       | Oxycodone + Paracetamol (Paracetamol, Oxycodone) |                    |                    | S               |                      | 1 Dosage Form 4 In 1 D           |                 | Not Reported |                |
|                                                                                                                                       | Cyclobenzaprine (Cyclobenzaprine)                |                    |                    | S               |                      | 10 Mg 3 In 1 D                   | 1095 DAY        | Not Reported |                |
|                                                                                                                                       | Celecoxib (Celecoxib)                            |                    |                    | S               |                      | 200 Mg 2 In 1 D                  |                 | Not Reported |                |

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Diazepam (Diazepam)

S

1460 DAY

Not Reported

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Mar-2014              | 9889047       | EXPEDITED (15-DAY) |                    | HO, OT          | FR-UCBSA-111596      |                      | 49 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                         | <u>Product</u>                    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------|-----------------------------------|--------------|------------|-------------|--------------|--------------------------------------|-----------------|--------------|
| Agitation; Confusional State; Delirium; Disorientation; Hallucination, Visual | Keppra                            |              |            | S           | Oral         |                                      |                 | Not Reported |
|                                                                               | Keppra                            |              |            | S           | Oral         |                                      |                 | Not Reported |
|                                                                               | Keppra                            |              |            | S           | Oral         |                                      |                 | Not Reported |
|                                                                               | Keppra                            |              |            | S           | Oral         |                                      |                 | Not Reported |
|                                                                               | Keppra                            |              |            | S           | Oral         |                                      |                 | Not Reported |
|                                                                               | Keppra                            |              |            | S           | Oral         |                                      |                 | Not Reported |
|                                                                               | Xanan                             |              |            | S           | Oral         | Benzodiazepines Doses Were Increased |                 | Not Reported |
|                                                                               | Xanan                             |              |            | S           | Oral         |                                      |                 | Not Reported |
|                                                                               | Seroplex                          |              |            | S           | Oral         |                                      |                 | Not Reported |
|                                                                               | Tranxene                          |              |            | S           | Oral         | Benzodiazepines Doses Were Increased |                 | Not Reported |
|                                                                               | Tranxene                          |              |            | S           | Oral         |                                      |                 | Not Reported |
|                                                                               | Temerit                           |              |            | C           |              | 5 Mg                                 |                 | Not Reported |
|                                                                               | Loxen (Nicardipine Hydrochloride) |              |            | C           |              | 50 Mg                                |                 | Not Reported |
|                                                                               | Diffu-K                           |              |            | C           |              |                                      |                 | Not Reported |
| Prodilantin                                                                   |                                   |              | C          |             |              |                                      | Not Reported    |              |
| Urbanyl                                                                       |                                   |              | C          |             |              |                                      | Not Reported    |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Mar-2014              | 9996315       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000060416    |                      | 56 YR      | Female     | FRA            |

| <u>Preferred Term</u>                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Cerebrovascular Accident; Confusional State | Escitalopram   |              |            | S           | Oral         |                    |                 | Forest     |
|                                             | Escitalopram   |              |            | S           | Oral         | 10 Mg              |                 | Forest     |

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|                                                        |                |                    |                    |                 |                           |                      |                 |              |                |
|--------------------------------------------------------|----------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
| Lysanxia                                               |                |                    | S                  | Oral            | 10 Mg                     |                      | Not Reported    |              |                |
| <u>FDA Received Date</u>                               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Mar-2014                                            | 10004632       | EXPEDITED (15-DAY) |                    | OT              | CA-FRI-1000060440         |                      | 28 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Nephrolithiasis                                        | Escitalopram   |                    |                    | S               | Oral                      | 20 Mg                |                 | Forest       |                |
|                                                        | Wellbutrin Sr  |                    |                    | C               | Oral                      | 100 Mg               |                 | Not Reported |                |
| <u>FDA Received Date</u>                               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Mar-2014                                            | 10021318       | EXPEDITED (15-DAY) |                    | HO              | BE-MYLANLABS-2014S1005179 |                      | 81 YR           | Male         | BEL            |
| <u>Preferred Term</u>                                  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Food Interaction;<br>Neuroleptic Malignant<br>Syndrome | Levodopa       |                    |                    | S               | Oral                      | 250 Mg/Day           |                 | Not Reported |                |
|                                                        | Levodopa       |                    |                    | S               | Other                     |                      |                 | Not Reported |                |
|                                                        | Pramipexole    |                    |                    | S               | Oral                      | 2.1 Mg/Day           |                 | Not Reported |                |
|                                                        | Pramipexole    |                    |                    | S               | Other                     |                      |                 | Not Reported |                |
|                                                        | Venlafaxine    |                    |                    | S               | Oral                      | 150 Mg/Day           |                 | Not Reported |                |
|                                                        | Escitalopram   |                    |                    | S               | Oral                      | 10 Mg/Day            |                 | Not Reported |                |
|                                                        | Cefuroxime     |                    |                    | C               | Unknown                   |                      |                 | Not Reported |                |
|                                                        | Metronidazole  |                    |                    | C               | Unknown                   |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Mar-2014                                            | 10021399       | EXPEDITED (15-DAY) |                    | OT              | DE-FRI-1000054626         |                      |                 | Male         | DEU            |
| <u>Preferred Term</u>                                  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Intraocular Pressure<br>Increased                      | Escitalopram   |                    |                    | S               | Oral                      | 10 Mg                |                 | Forest       |                |
| <u>FDA Received Date</u>                               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Mar-2014                                            | 10021428       | EXPEDITED (15-DAY) |                    | OT              | CH-FRI-1000064778         |                      |                 | Female       | CHE            |

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| <u>Preferred Term</u>                                       | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                                   | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------------------------------|-----------------------|--------------------|--------------------|-----------------|--------------------------|------------------------------------------------------|-----------------|--------------|----------------|
| Foetal Exposure During Pregnancy; Foetal Growth Restriction | Escitalopram          |                    |                    | S               | Transplacental           | 20 Mg                                                |                 | Forest       |                |
|                                                             | Escitalopram          |                    |                    | S               | Transplacental           | 10 Mg                                                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                    | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Mar-2014                                                 | 10021450              | EXPEDITED (15-DAY) |                    | OT              | CA-FRI-1000064767        |                                                      | 46 YR           | Male         | CAN            |
| <u>Preferred Term</u>                                       | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Insomnia; Stress; Suicidal Ideation                         | Escitalopram          |                    |                    | S               | Oral                     | 10 Mg                                                |                 | Forest       |                |
|                                                             | Escitalopram          |                    |                    | S               | Oral                     | 20 Mg                                                |                 | Forest       |                |
|                                                             | Escitalopram          |                    |                    | S               | Oral                     | 10 Mg                                                |                 | Not Reported |                |
|                                                             | Sleeping Aid Drug Nos |                    |                    | C               |                          | Daily Dose Not Reported.                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                    | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Mar-2014                                                 | 10022678              | EXPEDITED (15-DAY) |                    | OT              | ES-PFIZER INC-2014074185 |                                                      | 40 YR           | Female       | ESP            |
| <u>Preferred Term</u>                                       | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Diarrhoea; Dizziness; Drug Interaction; Fall; Vertigo       | Champix               |                    |                    | S               | Oral                     | 0.5 Mg, 2x/Day (In The Morning And In The Afternoon) |                 | Pfizer       |                |
|                                                             | Escitalopram Oxalate  |                    |                    | S               |                          | 20 Mg, Unk                                           |                 | Not Reported |                |
|                                                             | Escitalopram Oxalate  |                    |                    | S               |                          | 10 Mg, Unk                                           |                 | Not Reported |                |
|                                                             | Diazepam              |                    |                    | C               |                          | At Nights                                            |                 | Not Reported |                |
|                                                             | Halcion               |                    |                    | C               |                          |                                                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                    | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Mar-2014                                                 | 10024607              | DIRECT             | Y                  | OT              |                          |                                                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                       | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Musculoskeletal Pain; Nausea                                | Lexapro               |                    |                    | S               |                          |                                                      |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                       | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------------|-----------------|--------------|----------------|
| 20-Mar-2014                                                    | 9856406                 | EXPEDITED (15-DAY) |                    | HO, LT          | JP-FRI-1000053218    |                                     | 58 YR           | Male         | JPN            |
| <u>Preferred Term</u>                                          | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Pancytopenia                                                   | Lexapro                 |                    |                    | S               | Oral                 | 10 Mg                               |                 | Forest       |                |
|                                                                | U-Pan                   |                    |                    | S               | Oral                 | 3 Mg                                |                 | Not Reported |                |
|                                                                | Depromel                |                    |                    | S               | Oral                 | 150 Mg                              |                 | Not Reported |                |
|                                                                | Foliamin                |                    |                    | S               | Oral                 | 15 Mg                               |                 | Not Reported |                |
|                                                                | Invega                  |                    |                    | S               | Oral                 | 6 Mg                                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Mar-2014                                                    | 9963949                 | EXPEDITED (15-DAY) |                    | HO              | JP-FRI-1000060237    |                                     | 83 YR           | Female       | JPN            |
| <u>Preferred Term</u>                                          | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Altered State Of Consciousness                                 | Lexapro                 |                    |                    | S               | Oral                 | 10 Mg                               |                 | Forest       |                |
|                                                                | Aricept                 |                    |                    | S               | Oral                 | 3 Mg                                |                 | Not Reported |                |
|                                                                | Aricept                 |                    |                    | S               | Oral                 | 5 Mg                                |                 | Not Reported |                |
|                                                                | Lotriga                 |                    |                    | C               | Oral                 | 2 Gram                              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Mar-2014                                                    | 10021254                | EXPEDITED (15-DAY) | Y                  | OT              | AUR-APL-2014-02581   |                                     | 36 YR           | Male         | USA            |
| <u>Preferred Term</u>                                          | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;<br>Electroencephalogram<br>Abnormal; Seizure | Escitalopram            |                    |                    | S               |                      |                                     |                 | Not Reported |                |
|                                                                | Telaprevir (Telaprevir) |                    |                    | S               |                      | 2250 Mg (750 Mg, 3 In 1 D), Unknown |                 | Not Reported |                |
|                                                                | Peginterferon Alfa-2a   |                    |                    | S               |                      |                                     |                 | Not Reported |                |
|                                                                | Ribavirin (Ribavirin)   |                    |                    | S               |                      | 1000 Mg, 1 In 1 Day.                |                 | Not Reported |                |



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| <u>FDA Received Date</u>                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 20-Mar-2014                                                         | 10023997       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000064771    |                      | 87 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State;<br>Hallucinations, Mixed;<br>Withdrawal Syndrome | Escitalopram   |                    |                    | S               | Oral                 | 5 Mg                 |                 | Forest       |                |
|                                                                     | Escitalopram   |                    |                    | S               | Oral                 | 2.5 Mg               |                 | Forest       |                |
|                                                                     | Tercian        |                    |                    | S               | Oral                 | 0.5 Df               |                 | Not Reported |                |
|                                                                     | Bisoc          |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                     | Furosemide     |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                     | Trivastal      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                     | Zopiclone      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                     | Micardis       |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                   | <u>Case #</u>       | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------|---------------------|------------------|--------------------|-----------------|------------------------------|-------------------------------|-----------------|--------------|----------------|
| 20-Mar-2014                                | 10025403            | NON-EXPEDITED    |                    |                 | US-PFIZER INC-<br>2014072456 |                               |                 | Female       | USA            |
| <u>Preferred Term</u>                      | <u>Product</u>      | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity;<br>Drug Intolerance | Zoloft              |                  |                    | S               |                              | 50 Mg, Unk                    |                 | Pfizer       |                |
|                                            | Protonix            |                  |                    | S               |                              | 40 Mg, Unk                    |                 | Pfizer       |                |
|                                            | Metronidazole       |                  |                    | S               |                              | 750 Mg (250mg+ 500mg),<br>Unk |                 | Pfizer       |                |
|                                            | Cefuroxime Axetil   |                  |                    | S               |                              | 500 Mg, Unk                   |                 | Not Reported |                |
|                                            | Celebrex            |                  |                    | S               |                              | 100 Mg, Unk                   |                 | Pfizer       |                |
|                                            | Detrol La           |                  |                    | S               |                              | 4 Mg, Unk                     |                 | Pfizer       |                |
|                                            | Benzonatate         |                  |                    | S               |                              | 200 Mg, Unk                   |                 | Pfizer       |                |
|                                            | Nadolol             |                  |                    | S               |                              | 20 Mg, Unk                    |                 | Pfizer       |                |
|                                            | Erythromycin        |                  |                    | S               |                              | Unk                           |                 | Pfizer       |                |
|                                            | Hydrochlorothiazide |                  |                    | S               |                              | 25 Mg, Unk                    |                 | Unknown      |                |
|                                            | Effexor Xr          |                  |                    | S               |                              | 75 Mg, Unk                    |                 | Pfizer       |                |
|                                            | Requip              |                  |                    | S               |                              | 1 Mg, Unk                     |                 | Not Reported |                |
|                                            | Amitrip-Cdp         |                  |                    | S               |                              | 12.5-5, Unk                   |                 | Not Reported |                |

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|                                              |   |               |              |
|----------------------------------------------|---|---------------|--------------|
| Micardis                                     | S | 80 Mg, Unk    | Not Reported |
| Micardis Hct                                 | S | 80 Mg, Unk    | Not Reported |
| Maxalt-Mlt                                   | S | 10 Mg, Unk    | Not Reported |
| Topamax                                      | S | 25 Mg, Unk    | Not Reported |
| Amitriptyline                                | S | 25 Mg, Unk    | Not Reported |
| Vioxx                                        | S | 25 Mg, Unk    | Not Reported |
| Darvocet                                     | S | 100 Mg, Unk   | Not Reported |
| Lexapro                                      | S | Unk           | Not Reported |
| Wellbutrin Sr                                | S | 150 Mg, Unk   | Not Reported |
| Chlorthalidone                               | S | 50 Mg, Unk    | Not Reported |
| Sucralfate                                   | S | 1 G, Unk      | Not Reported |
| Guaifenex La                                 | S | 600 Mg, Unk   | Not Reported |
| Naproxen Sodium                              | S | 500 Mg, Unk   | Not Reported |
| Ultrase                                      | S | 37.5 Mg, Unk  | Not Reported |
| Cyclobenzaprine Hcl                          | S | Unk           | Not Reported |
| Hyoscyamine                                  | S | 0.375 Mg, Unk | Not Reported |
| Flumadine                                    | S | 100 Mg, Unk   | Not Reported |
| Allegra                                      | S | 180 Mg, Unk   | Not Reported |
| Prilosec                                     | S | Unk           | Not Reported |
| Guaifenesin\Pseudoephedrine<br>Hydrochloride | S | Unk           | Not Reported |
| Bupropion Hcl                                | S | 100 Mg, Unk   | Not Reported |
| Cephalexin                                   | S | 500 Mg, Unk   | Not Reported |
| Levaquin                                     | S | 500 Mg, Unk   | Not Reported |
| Paxil                                        | S | Unk           | Not Reported |
| Baclofen                                     | S | Unk           | Not Reported |
| Citalopram Hydrobromide                      | S | Unk           | Not Reported |
| Carvedilol                                   | S | 6.25 Mg, Unk  | Not Reported |
| Antara                                       | S | 130 Mg, Unk   | Not Reported |
| Guaifen-Pse                                  | S | 600 Mg, Unk   | Not Reported |

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

|              |   |             |              |
|--------------|---|-------------|--------------|
| Flexeril     | S | 5 Mg, Unk   | Not Reported |
| Biaxin       | S | Unk         | Not Reported |
| Carisoprodol | S | 350 Mg, Unk | Not Reported |
| Tekturna     | S | Unk         | Not Reported |
| Buspar       | S | Unk         | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Mar-2014              | 10026118      | EXPEDITED (15-DAY) | OT                 |                 | AT-TEVA-468026ISR    |                      | 48 YR      | Male       | AUT            |

| <u>Preferred Term</u> | <u>Product</u>                                        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                   | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-------------------------------------------------------|--------------|------------|-------------|--------------|------------------------------------------------------|-----------------|--------------|
| Thrombophlebitis      | Mirtabene Filmdabletten<br>Ratiopharm , 30 Mg, 45 Mg. |              |            | S           | Unknown      | Dosage Form: Unspecified                             |                 | Teva         |
|                       | Mirtabene Filmdabletten<br>Ratiopharm , 30 Mg, 45 Mg. |              |            | S           |              | Dosage Form: Unspecified                             |                 | Teva         |
|                       | Mirtabene Filmdabletten<br>Ratiopharm , 30 Mg, 45 Mg. |              |            | S           | Unknown      | Dosage Form: Unspecified                             |                 | Teva         |
|                       | Mirtabene Filmdabletten<br>Ratiopharm , 30 Mg, 45 Mg. |              |            | S           | Unknown      | Dosage Form:<br>Unspecified, Started Since<br>Months |                 | Teva         |
|                       |                                                       |              |            |             |              |                                                      |                 |              |
|                       | CipraleX                                              |              |            | S           | Unknown      | Dosage Form: Unspecified                             |                 | Not Reported |
|                       | CipraleX                                              |              |            | S           | Unknown      | Dosage Form: Unspecified                             |                 | Not Reported |
|                       | CipraleX                                              |              |            | S           | Unknown      | Dosage Form: Unspecified                             |                 | Not Reported |
|                       | CipraleX                                              |              |            | S           | Unknown      | Dosage Form: Unspecified                             |                 | Not Reported |
|                       | Risperdal                                             |              |            | S           | Oral         | Dosage Form: Unspecified                             |                 | Not Reported |
|                       | Risperdal                                             |              |            | S           | Oral         | Dosage Form: Unspecified                             |                 | Not Reported |
|                       | Lyrice                                                |              |            | C           | Unknown      | Dosage Form: Unspecified                             |                 | Not Reported |
|                       | Lyrice                                                |              |            | C           | Unknown      | Dosage Form: Unspecified                             |                 | Not Reported |
|                       | Lyrice                                                |              |            | C           | Unknown      | Dosage Form: Unspecified                             |                 | Not Reported |
|                       | Lyrice                                                |              |            | C           | Unknown      | Dosage Form: Unspecified                             |                 | Not Reported |
|                       | Sertraline                                            |              |            | C           | Unknown      | Dosage Form: Unspecified                             |                 | Not Reported |
|                       | Sertraline                                            |              |            | C           | Unknown      | Dosaeg Form: Unspecified                             |                 | Not Reported |
|                       | Lamictal                                              |              |            | C           | Unknown      | Dosage Form: Unspecified                             |                 | Not Reported |

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

|           |   |         |                                                 |              |
|-----------|---|---------|-------------------------------------------------|--------------|
| Lamictal  | C | Unknown | Dosage Form: Unspecified                        | Not Reported |
| Lamictal  | C | Unknown | Dosage Form: Unspecified                        | Not Reported |
| Lamictal  | C | Unknown | Dosage Form: Unspecified                        | Not Reported |
| Rivotril  | C |         |                                                 | Not Reported |
| Doxazosin | C | Unknown | Dosage Form: Unspecified                        | Not Reported |
| Doxazosin | C | Unknown | Dosage Form: Unspecified                        | Not Reported |
| Folsan    | C | Unknown | Dosage Form: Unspecified                        | Not Reported |
| Folsan    | C | Unknown | Dosage Form: Unspecified, Started Since Months  | Not Reported |
| Exforge   | C | Unknown | Dosage Form: Unspecified, 10/160mg              | Not Reported |
| Exforge   | C | Unknown | Dosage Form: Unspecified, 5/160 Mg Since Months | Not Reported |
| Fungoral  | C | Unknown |                                                 | Not Reported |
| Fungoral  | C | Unknown |                                                 | Not Reported |
| Ebrantil  | C | Unknown | Dosage Form: Unspecified, Started Since Months  | Not Reported |
| Nomexor   | C | Unknown | Dosage Form: Unspecified, Started Since Months  | Not Reported |

|                          |               |                  |                    |                 |                      |                      |            |            |                |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
| 20-Mar-2014              | 10029633      | DIRECT           | Y                  | OT              |                      |                      | 43 YR      | Female     | USA            |

|                                      |                |              |            |             |              |                    |                 |            |
|--------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| <u>Preferred Term</u>                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
| Therapeutic Product Effect Decreased | Escitalopram   |              |            | S           | Oral         |                    |                 | Camber     |

|                          |               |                    |                    |                 |                      |                      |            |            |                |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
| 20-Mar-2014              | 10032422      | EXPEDITED (15-DAY) | Y                  | HO              | 2014AP001856         |                      | 81 YR      | Male       | BEL            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                        | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                           | <u>Duration</u> | <u>Mfr</u>       |                |
|--------------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------------------------------|-----------------|------------------|----------------|
| Food Interaction;<br>Neuroleptic Malignant<br>Syndrome       | Venlafaxine (Venlafaxine)     |                    |                    | S               | Oral                                            | 150 Mg; Unknown; Po; Qd                      |                 | Not Reported     |                |
|                                                              | Escitalopram (Escitalopram)   |                    |                    | S               | Oral                                            | 10 Mg; Unknown; Po; Qd                       |                 | Not Reported     |                |
|                                                              | Levodopa                      |                    |                    | S               | Oral<br>Oral                                    | 250 Mg; Unknown; Po; Qd<br>125 Mg; Po; Q4h   |                 | Not Reported     |                |
|                                                              | Pramipexole (Pramipexole)     |                    |                    | S               |                                                 | 2.1 Mg; Unknown; Qd<br>0.35 Mg; Unknown; Tid |                 | Not Reported     |                |
|                                                              | Cefuroxime (Cefuroxime)       |                    |                    | C               |                                                 |                                              |                 | Not Reported     |                |
|                                                              | Metronidazole (Metronidazole) |                    |                    | C               |                                                 |                                              |                 | Not Reported     |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                         | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 21-Mar-2014                                                  | 9893707                       | EXPEDITED (15-DAY) |                    | HO              | CA-FRI-1000054195                               |                                              | 49 YR           | Female           | CAN            |
| <u>Preferred Term</u>                                        | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                           | <u>Duration</u> | <u>Mfr</u>       |                |
| Chest Pain; Feeling Cold;<br>Palpitations; Vision<br>Blurred | Escitalopram                  |                    |                    | S               | Oral                                            | 20 Mg                                        |                 | Forest           |                |
|                                                              | Ativan                        |                    |                    | C               | Oral                                            | 0.5 Mg                                       |                 | Not Reported     |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                         | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 24-Mar-2014                                                  | 8960874                       | EXPEDITED (15-DAY) |                    | OT              | JP-<br>ELI_LILLY_AND_COMP<br>ANY-JP201211003156 |                                              | 65 YR           | Male             | JPN            |
| <u>Preferred Term</u>                                        | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                           | <u>Duration</u> | <u>Mfr</u>       |                |
| Rapid Eye Movements<br>Sleep Abnormal; Sleep<br>Talking      | Cymbalta                      |                    |                    | S               | Oral                                            | 20 Mg, Qd                                    |                 | Eli Lilly And Co |                |
|                                                              | Remeron                       |                    |                    | S               | Oral                                            | 15 Mg, Qd                                    |                 | Not Reported     |                |
|                                                              | Remeron                       |                    |                    | S               | Oral                                            | 25 Mg, Unk                                   |                 | Not Reported     |                |
|                                                              | Lexapro                       |                    |                    | S               | Oral                                            | 5 Mg, Qd                                     |                 | Not Reported     |                |
|                                                              | Reslin                        |                    |                    | S               | Oral                                            | 12.5 Mg, Qd                                  |                 | Not Reported     |                |
|                                                              | Rohypnol                      |                    |                    | C               | Oral                                            | 2 Mg, Qd                                     |                 | Not Reported     |                |
|                                                              | Lexotan                       |                    |                    | C               | Oral                                            | 2 Mg, Qd                                     |                 | Not Reported     |                |
|                                                              | Yokukan-San                   |                    |                    | C               | Oral                                            | 5 G, Unk                                     |                 | Not Reported     |                |
|                                                              | Yokukan-San                   |                    |                    | C               | Oral                                            | Unk                                          |                 | Not Reported     |                |

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

|                                                                                         |                         |                    |                    |                 |                              |                      |                 |              |                |
|-----------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| Yokukan-San                                                                             |                         |                    | C                  | Oral            | Unk                          | Not Reported         |                 |              |                |
| <u>FDA Received Date</u>                                                                | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Mar-2014                                                                             | 9934417                 | EXPEDITED (15-DAY) | CA                 |                 | NL-FRI-1000054749            |                      | < 1 DAY         | Male         | NLD            |
| <u>Preferred Term</u>                                                                   | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Coarctation Of The Aorta                                                                | Lexapro                 |                    |                    | S               | Transplacental               |                      |                 | Forest       |                |
|                                                                                         | Sertraline              |                    |                    | S               | Transplacental               |                      |                 | Not Reported |                |
|                                                                                         | Folic Acid              |                    |                    | C               | Transplacental               |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Mar-2014                                                                             | 9959102                 | EXPEDITED (15-DAY) | Y                  | CA, HO          | AUR-APL-2014-02025           |                      | < 1 DAY         | Male         | NLD            |
| <u>Preferred Term</u>                                                                   | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Coarctation Of The Aorta;<br>Maternal Drugs Affecting<br>Foetus; Respiratory<br>Failure | Sertraline              |                    |                    | S               | Transplacental               |                      |                 | Not Reported |                |
|                                                                                         | Escitalopram            |                    |                    | S               | Transplacental               |                      |                 | Not Reported |                |
|                                                                                         | Folic Acid (Folic Acid) |                    |                    | C               |                              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Mar-2014                                                                             | 10031673                | NON-EXPEDITED      |                    |                 | US-PFIZER INC-<br>2014083631 |                      | 69 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                   | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Flushing;<br>Insomnia                                                         | Escitalopram Oxalate    |                    |                    | S               |                              | Unk                  |                 | Not Reported |                |
|                                                                                         | Lyrica                  |                    |                    | S               |                              | 50 Mg, 3x/Day        |                 | Pfizer       |                |
|                                                                                         | Metoprolol              |                    |                    | C               |                              | 50 Mg, 2x/Day        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Mar-2014                                                                             | 10032848                | EXPEDITED (15-DAY) |                    | OT              | AT-WATSON-2014-<br>05102     |                      | 48 YR           | Male         | AUT            |
| <u>Preferred Term</u>                                                                   | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

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

|                  |                     |   |         |                        |              |
|------------------|---------------------|---|---------|------------------------|--------------|
| Weight Increased | Doxazosin (Unknown) | S | Unknown | 4 Mg, Daily            | Watson       |
|                  | Doxazosin (Unknown) | S | Unknown | 8 Mg, Daily            | Watson       |
|                  | Lyrica              | S | Unknown | 125 Mg, Daily          | Not Reported |
|                  | Lyrica              | S | Unknown | 300 Mg, Daily          | Not Reported |
|                  | Lyrica              | S | Unknown | 375 Mg, Daily          | Not Reported |
|                  | Lyrica              | S | Unknown | 450 Mg, Daily          | Not Reported |
|                  | Mirtabene           | S | Unknown | 90 Mg, Daily           | Not Reported |
|                  | Mirtabene           | S | Unknown | 60 Mg, Daily           | Not Reported |
|                  | Mirtabene           | S | Unknown | 30 Mg, Daily           | Not Reported |
|                  | Mirtabene           | S | Unknown | 45 Mg, Daily           | Not Reported |
|                  | Cipralext           | S | Unknown | 5 Mg, Daily            | Not Reported |
|                  | Cipralext           | S | Unknown | 10 Mg, Daily           | Not Reported |
|                  | Cipralext           | S | Unknown | 20 Mg, Daily           | Not Reported |
|                  | Cipralext           | S | Unknown | 30 Mg, Daily           | Not Reported |
|                  | Risperdal           | S | Oral    | 1 Mg, Daily            | Not Reported |
|                  | Risperdal           | S | Oral    | 2 Mg, Daily            | Not Reported |
|                  | Sertraline          | C | Unknown | 150 Mg, Daily          | Not Reported |
|                  | Sertraline          | C | Unknown | 100 Mg, Daily          | Not Reported |
|                  | Lamictal            | C | Unknown | 50 Mg, Daily           | Not Reported |
|                  | Lamictal            | C | Unknown | 75 Mg, Daily           | Not Reported |
|                  | Lamictal            | C | Unknown | 100 Mg, Daily          | Not Reported |
|                  | Lamictal            | C | Unknown | 200 Mg, Daily          | Not Reported |
|                  | Rivotril            | C | Unknown | 1.5 Mg, Daily          | Not Reported |
|                  | Exforge             | C | Unknown | 10/160 Mg, Daily       | Not Reported |
|                  | Exforge             | C | Unknown | 5/160 Mg, Daily        | Not Reported |
|                  | Folsan              | C | Unknown | 5 Mg, Daily            | Not Reported |
|                  | Folsan              | C | Unknown | 10 Mg, Daily           | Not Reported |
|                  | Fungoral            | C | Topical | 1 Df, 3/Week [Shampoo] | Not Reported |
|                  | Fungoral            | C | Topical | 1 Df, 3/Week [Cream]   | Not Reported |

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

|                     |   |         |              |              |
|---------------------|---|---------|--------------|--------------|
| Ebrantil /00631801/ | C | Unknown | 60 Mg, Daily | Not Reported |
| Nomexor             | C | Unknown | 10 Mg, Daily | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Mar-2014              | 10034481      | DIRECT           |                    | OT              |                      |                      | 52 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------|-------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Loss Of Personal Independence In Daily Activities; Neuropathy Peripheral; Product Substitution Issue | Escitalopram 20mg |              |            | S           | Oral         | I Pill             |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 25-Mar-2014              | 9844465       | EXPEDITED (15-DAY) |                    | HO              | CA-SHIRE-ALL1-2014-00472 |                      | 59 YR      | Female     | CAN            |

| <u>Preferred Term</u> | <u>Product</u>                    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|-----------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Suicidal Ideation     | 489 (Lisdexamfetamine Dimesylate) |              |            | S           | Oral         | 30 Mg, 1x/Day:Qd   |                 | Shire      |
|                       | Escitalopram Oxalate              |              |            | S           | Oral         | Unk, Unknown       |                 | Unknown    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 25-Mar-2014              | 9912465       | EXPEDITED (15-DAY) |                    | OT              | MX-ORION CORPORATION ORION PHARMA-ENTC2014-0068 |                      | 80 YR      | Male       | MEX            |

| <u>Preferred Term</u>                                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Dyspnoea; Embolism; Fall; Groin Pain; Traumatic Haemorrhage | Stalevo        |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                             | Exelon         |              |            | S           | Transdermal  | 1 Patch (5 Cm2)    |                 | Not Reported |
|                                                             | Lexapro        |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                             | Norvas         |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                             | Spiriva        |              |            | C           | Unknown      |                    |                 | Not Reported |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Mar-2014              | 10034321      | EXPEDITED (15-DAY) | Y                  | DE              | US-ROCHE-1370652     |                      | 55 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                | <u>Product</u>                              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------|---------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiac Arrest;<br>Respiratory Arrest;<br>Toxicity To Various Agents | Clonazepam                                  |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                      | Clonazepam                                  |              |            | S           | Oral         | Overdose           |                 | Not Reported |
|                                                                      | Citalopram                                  |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                      | Citalopram                                  |              |            | S           | Oral         | Overdose           |                 | Not Reported |
|                                                                      | Escitalopram                                |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                      | Escitalopram                                |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                      | Acetaminophen/Diphenhydramine Hydrochloride |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                      | Acetaminophen/Diphenhydramine Hydrochloride |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                      | Bupropion                                   |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                      | Bupropion                                   |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                      | Tadalafil                                   |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                      | Tadalafil                                   |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Mar-2014              | 10035025      | EXPEDITED (15-DAY) |                    | DS, HO          | NL-FRI-1000065727    |                      | 56 YR      | Male       | NLD            |

| <u>Preferred Term</u>                                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|----------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Drug Withdrawal Syndrome; Pulmonary Embolism; Thrombosis | Lexapro        |              |            | S           | Oral         |                    |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 25-Mar-2014              | 10035657      | EXPEDITED (15-DAY) |                    | HO              | FR-ASTRAZENECA-2014SE19514 |                      | 85 YR      | Female     | FRA            |

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

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

|                                                                                         |          |   |      |              |
|-----------------------------------------------------------------------------------------|----------|---|------|--------------|
| Dermatitis Bullous; Fall;<br>General Physical Health<br>Deterioration;<br>Hyponatraemia | Inexium  | S | Oral | Astrazeneca  |
|                                                                                         | Seroplex | S | Oral | Not Reported |

| <u>FDA Received Date</u>                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 25-Mar-2014                                           | 10036334       | EXPEDITED (15-DAY) |                    | DS, HO          | FI-FRI-1000065728    |                      | 15 YR           | Female       | FIN            |
| <u>Preferred Term</u>                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Intentional<br>Self-Injury; Off Label Use | Escitalopram   |                    |                    | S               | Oral                 |                      |                 | Forest       |                |
|                                                       | Mirtazapine    |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                  | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 25-Mar-2014                               | 10036335               | EXPEDITED (15-DAY) |                    | OT              | JP-FRI-1000065766    |                      | 34 YR           | Male         | JPN            |
| <u>Preferred Term</u>                     | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Activation Syndrome;<br>Suicidal Ideation | Lexapro                |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                           | Zolpidem Tartrate      |                    |                    | C               | Oral                 | 5 Mg                 |                 | Not Reported |                |
|                                           | Sorentmin (Brotizolam) |                    |                    | C               | Oral                 | 0.25 Mg              |                 | Not Reported |                |

| <u>FDA Received Date</u>                               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|-----------------------------------------------|-----------------|--------------|----------------|
| 25-Mar-2014                                            | 10036336       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000065767    |                                               | 94 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;<br>Epistaxis; Traumatic<br>Haematoma | Escitalopram   |                    |                    | S               | Oral                 | 10 Mg                                         |                 | Forest       |                |
|                                                        | Kardegic       |                    |                    | S               | Oral                 | 75 Mg                                         |                 | Not Reported |                |
|                                                        | Kardegic       |                    |                    | S               | Oral                 | 75 Mg                                         |                 | Not Reported |                |
|                                                        | Hydrea         |                    |                    | C               | Oral                 | 1 Capsule At Day 1 And 2<br>Capsules At Day 2 |                 | Not Reported |                |
|                                                        | Pariet         |                    |                    | C               | Oral                 | 10 Mg                                         |                 | Not Reported |                |
|                                                        | Lysanxia       |                    |                    | C               | Oral                 |                                               |                 | Not Reported |                |

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

|                                                                                         |                |                    |                    |                 |                      |                                        |                    |            |                |  |
|-----------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------------------------|--------------------|------------|----------------|--|
| Doliprane                                                                               |                |                    | C                  |                 | Oral                 |                                        | 1 To 3 Grams Daily |            | Not Reported   |  |
| <u>FDA Received Date</u>                                                                | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                   | <u>Age</u>         | <u>Sex</u> | <u>Country</u> |  |
| 25-Mar-2014                                                                             | 10037339       | DIRECT             |                    | DS              |                      |                                        | 42 YR              | Female     | USA            |  |
| <u>Preferred Term</u>                                                                   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                     | <u>Duration</u>    | <u>Mfr</u> |                |  |
| Product Substitution Issue; Suicidal Ideation                                           | Lexapro        |                    |                    | S               | Oral                 | Once A Day, Once Daily, Taken By Mouth |                    |            | Not Reported   |  |
| <u>FDA Received Date</u>                                                                | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                   | <u>Age</u>         | <u>Sex</u> | <u>Country</u> |  |
| 26-Mar-2014                                                                             | 10032137       | EXPEDITED (15-DAY) |                    | OT              | PHHY2014IT033223     |                                        | 32 YR              | Female     | ITA            |  |
| <u>Preferred Term</u>                                                                   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                     | <u>Duration</u>    | <u>Mfr</u> |                |  |
| Abortion Spontaneous; Maternal Exposure During Pregnancy                                | Fty 720        |                    |                    | S               | Oral                 |                                        |                    |            | Not Reported   |  |
|                                                                                         | Carbamazepine  |                    |                    | S               | Oral                 | 800 Mg, Daily                          |                    |            | Novartis       |  |
|                                                                                         | Escitalopram   |                    |                    | S               | Oral                 | 10 Mg, Daily                           |                    |            | Not Reported   |  |
|                                                                                         | Natalizumab    |                    |                    | S               |                      | 300 Mg, Daily                          |                    |            | Not Reported   |  |
| <u>FDA Received Date</u>                                                                | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                   | <u>Age</u>         | <u>Sex</u> | <u>Country</u> |  |
| 26-Mar-2014                                                                             | 10038072       | EXPEDITED (15-DAY) |                    | CA              | FR-FRI-1000065838    |                                        | < 1 DAY            | Male       | FRA            |  |
| <u>Preferred Term</u>                                                                   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                     | <u>Duration</u>    | <u>Mfr</u> |                |  |
| Congenital Arterial Malformation; Exposure During Pregnancy; Urinary Tract Malformation | Escitalopram   |                    |                    | S               | Transplacental       | 10 Mg                                  |                    |            | Forest         |  |
|                                                                                         | Escitalopram   |                    |                    | S               | Transplacental       | 5 Mg                                   |                    |            | Not Reported   |  |
| <u>FDA Received Date</u>                                                                | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                   | <u>Age</u>         | <u>Sex</u> | <u>Country</u> |  |
| 26-Mar-2014                                                                             | 10044284       | EXPEDITED (15-DAY) | Y                  | DE              | AUR-APL-2014-03477   |                                        | 93 YR              | Male       | USA            |  |
| <u>Preferred Term</u>                                                                   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                     | <u>Duration</u>    | <u>Mfr</u> |                |  |
| Completed Suicide;                                                                      | Amlodipine     |                    |                    | S               | Oral                 |                                        |                    |            | Not Reported   |  |

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

|                                                       |              |   |              |
|-------------------------------------------------------|--------------|---|--------------|
| Exposure Via Ingestion;<br>Toxicity To Various Agents | Escitalopram | S | Not Reported |
|-------------------------------------------------------|--------------|---|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Mar-2014              | 10044438      | EXPEDITED (15-DAY) | Y                  | HO, LT          | 2014/017             |                      | 81 YR      | Male       | BEL            |

| <u>Preferred Term</u>           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------|----------------|--------------|------------|-------------|--------------|-----------------------|-----------------|--------------|
| Altered State Of Consciousness; | Venlafaxine    |              |            | S           |              | 150 Mg/Day, Unk & Unk |                 | Not Reported |
| Appendicitis Perforated;        | Escitalopram   |              |            | S           |              | 10 Mg/Day, Unk & Unk  |                 | Not Reported |
| Hallucination;                  |                |              |            |             |              |                       |                 |              |
| Hyperreflexia; Hypertonia;      |                |              |            |             |              |                       |                 |              |
| Ileus; Myoclonus;               |                |              |            |             |              |                       |                 |              |
| Peritonitis; Pneumonia;         |                |              |            |             |              |                       |                 |              |
| Pyrexia                         |                |              |            |             |              |                       |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Mar-2014              | 10044757      | EXPEDITED (15-DAY) |                    | OT              | AUR-APL-2014-03752   |                      | 40 YR      | Female     | ESP            |

| <u>Preferred Term</u>                                               | <u>Product</u>                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------|--------------------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Diarrhoea; Dizziness;                                               | Escitalopram (Escitalopram)    |              |            | S           |              | (20 Mg), Unknown              |                 | Not Reported |
| Drug Interaction;                                                   |                                |              |            |             |              | (10 Mg), Unknown              |                 |              |
| Dysstasia; Impaired Driving Ability; Impaired Work Ability; Vertigo | Champix (Varenicline Tartrate) |              |            | S           | Oral         | 1 Mg (0.5 Mg, 2 In 1 D), Oral |                 | Not Reported |
|                                                                     | Halcion (Triazolam)            |              |            | C           |              |                               |                 | Not Reported |
|                                                                     | Diazepam (Diazepam)            |              |            | C           |              |                               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                 | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------------------------------|----------------------|------------|------------|----------------|
| 27-Mar-2014              | 10040320      | EXPEDITED (15-DAY) |                    | HO, LT          | CA-B.I. PHARMACEUTICALS, I NC./RIDGEFIELD-2014-BI-13 |                      | 48 YR      | Female     | CAN            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>           |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------|
| Overdose              | Clonidine      |              |            | S           | Oral         | 2.8 Mg             |                 | Boehringer Ingelheim |
|                       | Propranolol    |              |            | S           | Oral         | 1120 Mg            |                 | Not Reported         |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|              |   |      |         |              |
|--------------|---|------|---------|--------------|
| Escitalopram | S | Oral | 400 Mg  | Not Reported |
| Lorazepam    | S | Oral | 28 Mg   | Not Reported |
| Atorvastatin | S | Oral | 560 Mg  | Not Reported |
| Quetiapine   | S | Oral | 5600 Mg | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Mar-2014              | 10041052      | EXPEDITED (15-DAY) |                    | HO              | FR-SA-2014SA034137   |                      | 62 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|-----------------------|-----------------|--------------|
| Meningorrhagia        | Plavix         |              |            | S           | Oral         |                       |                 | Not Reported |
|                       | Seroplex       |              |            | S           | Oral         | Strength:10 Mg Scored |                 | Not Reported |
|                       | Stagid         |              |            | C           |              |                       |                 | Not Reported |
|                       | Tahor          |              |            | C           |              |                       |                 | Not Reported |
|                       | Diamicron      |              |            | C           |              |                       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Mar-2014              | 10041156      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000065850    |                      | 62 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Meningorrhagia        | Escitalopram   |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                       | Plavix         |              |            | S           | Oral         | 75 Mg              |                 | Not Reported |
|                       | Stagid         |              |            | C           |              |                    |                 | Not Reported |
|                       | Tahor          |              |            | C           |              |                    |                 | Not Reported |
|                       | Diamicron      |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Mar-2014              | 10048587      | EXPEDITED (15-DAY) | Y                  | DE, HO, OT      | AUR-APL-2014-03842   |                      | 55 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                      | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------|-----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Atrial Flutter; Blood Chloride Decreased; Blood Potassium Decreased; Blood | Alprazolam (Alprazolam)     |              |            | S           |              |                    |                 | Not Reported |
|                                                                            | Escitalopram (Escitalopram) |              |            | S           |              |                    |                 | Not Reported |
|                                                                            | Duloxetine (Duloxetine)     |              |            | S           |              |                    |                 | Not Reported |
|                                                                            | (Duloxetine)                |              |            |             |              |                    |                 |              |

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

|                                                                                                                                                                                                                                                                                                                                          |            |   |                                     |              |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|---|-------------------------------------|--------------|
| Pressure Decreased;<br>Cardio-Respiratory Arrest;<br>Completed Suicide;<br>Haematemesis; Heart<br>Rate Decreased;<br>Hyperhidrosis; Muscle<br>Rigidity; Nystagmus;<br>Overdose; Oxygen<br>Saturation Decreased;<br>Pulmonary Oedema;<br>Respiratory Rate<br>Decreased; Toxicity To<br>Various Agents; Tremor;<br>Unresponsive To Stimuli | Vilazodone | S | Oral<br>Respiratory<br>(inhalation) | Not Reported |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|---|-------------------------------------|--------------|

| <u>FDA Received Date</u> | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|-----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 28-Mar-2014              | 9353713         | EXPEDITED (15-DAY) |                    | DS              | FR-FRI-1000045959    |                      | 87 YR           | Male         | FRA            |
| <u>Preferred Term</u>    | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Metabolic Encephalopathy | Escitalopram    |                    |                    | S               | Oral                 |                      |                 | Forest       |                |
|                          | Keal            |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                          | Inexium         |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                          | Seretide Diskus |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Spiriva         |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Procoralan      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Amlor           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Gaviscon        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Tahor           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Kardegic        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Tardyferon      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Motilium        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Kaleorid        |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 28-Mar-2014              | 9595418        | EXPEDITED (15-DAY) |                    | DS              | 2013-US-001380       |                      | 55 YR           | Female     | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

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

| Disability                                                                  | Xyrem                                                 | S                  | Oral               |                 |                      |                      |                 |            | Not Reported   |
|-----------------------------------------------------------------------------|-------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
|                                                                             |                                                       |                    | Oral               |                 |                      | 3 G, Bid, Po         |                 |            |                |
|                                                                             |                                                       |                    | Oral               |                 |                      |                      |                 |            |                |
|                                                                             | Klonopin (Clonazepam)                                 | C                  |                    |                 |                      |                      |                 |            | Not Reported   |
|                                                                             | (Tablets)                                             |                    |                    |                 |                      |                      |                 |            |                |
|                                                                             | Wellbutrin                                            | C                  |                    |                 |                      |                      |                 |            | Not Reported   |
|                                                                             | Lexapro (Escitalopram Oxalate)                        | S                  |                    |                 |                      |                      |                 |            | Not Reported   |
|                                                                             | Adderall                                              | C                  |                    |                 |                      |                      |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                                    | <u>Case #</u>                                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 28-Mar-2014                                                                 | 10046877                                              | DIRECT             |                    | HO              |                      |                      | 19 YR           | Male       | USA            |
| <u>Preferred Term</u>                                                       | <u>Product</u>                                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Feeling Abnormal;<br>Paraesthesia; Seizure                                  | Lexapro                                               |                    |                    | S               | Oral                 |                      |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                                    | <u>Case #</u>                                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 28-Mar-2014                                                                 | 10047676                                              | DIRECT             |                    | OT              |                      |                      | 34 YR           | Female     | USA            |
| <u>Preferred Term</u>                                                       | <u>Product</u>                                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective; Product<br>Substitution Issue                             | Escitalopram 10 Mg                                    |                    |                    | S               | Oral                 |                      | 6 MTH           |            | Not Reported   |
| <u>FDA Received Date</u>                                                    | <u>Case #</u>                                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 28-Mar-2014                                                                 | 10050385                                              | EXPEDITED (15-DAY) | Y                  | DE              | AUR-APL-2014-03693   |                      | 86 YR           | Female     | USA            |
| <u>Preferred Term</u>                                                       | <u>Product</u>                                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Completed Suicide;<br>Exposure Via Ingestion;<br>Toxicity To Various Agents | Hydrocodone+Paracetamol<br>(Paracetamol, Hydrocodone) |                    |                    | S               | Oral                 |                      |                 |            | Not Reported   |
|                                                                             | Amlodipine (Amlodipine)                               |                    |                    | S               |                      |                      |                 |            | Not Reported   |
|                                                                             | Escitalopram (Escitalopram)                           |                    |                    | S               |                      |                      |                 |            | Not Reported   |
|                                                                             | Isosorbide Mononitrate                                |                    |                    | S               |                      |                      |                 |            | Not Reported   |
|                                                                             | Doxazocin                                             |                    |                    | S               |                      |                      |                 |            | Not Reported   |
|                                                                             | Warfarin (Warfarin)                                   |                    |                    | S               |                      |                      |                 |            | Not Reported   |
|                                                                             | Furosemide (Furosemide)                               |                    |                    | S               |                      |                      |                 |            | Not Reported   |
|                                                                             | Levothyroxine (Levothyroxine)                         |                    |                    | S               |                      |                      |                 |            | Not Reported   |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                                  | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 31-Mar-2014                                                                                                                                                                                                               | 9789616                   | EXPEDITED (15-DAY) |                    | LT              | FR-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>19932425 |                      | 20 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                                                     | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State; Liver<br>Injury; Mydriasis;<br>Rhabdomyolysis                                                                                                                                                          | Abilify                   |                    |                    | S               |                                                 |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                           | Paracetamol               |                    |                    | S               |                                                 |                      |                 | Cadence      |                |
|                                                                                                                                                                                                                           | Zolpidem                  |                    |                    | S               |                                                 |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                           | Paroxetine                |                    |                    | S               |                                                 |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                           | Hept-A-Myl                |                    |                    | S               |                                                 |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                           | Cymbalta                  |                    |                    | S               |                                                 |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                           | Lamotrigine               |                    |                    | S               |                                                 |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                           | Escitalopram              |                    |                    | S               |                                                 |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                           | Agomelatine               |                    |                    | S               |                                                 |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                           | Avlocardyl                |                    |                    | S               |                                                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                  | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-Mar-2014                                                                                                                                                                                                               | 10051578                  | EXPEDITED (15-DAY) | Y                  | DE, HO          | 2014P1002449                                    |                      | 45 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                     | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cerebral Vasoconstriction;<br>International Normalised<br>Ratio Increased;<br>Ischaemic Cerebral<br>Infarction; Posterior<br>Reversible<br>Encephalopathy<br>Syndrome; Serotonin<br>Syndrome; Subarachnoid<br>Haemorrhage | Escitalopram              |                    |                    | S               |                                                 |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                           | Hydromorphone             |                    |                    | S               |                                                 |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                           | Dihydroergotamine         |                    |                    | S               | Intravenous (not<br>otherwise specified)        |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                           | Hydrocodone               |                    |                    | S               |                                                 |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                           | Tetrahydrocannabinol      |                    |                    | S               |                                                 |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                           | Unspecified Anticoagulant |                    |                    | C               |                                                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                  | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Apr-2014                                                                                                                                                                                                               | 9614700                   | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000049925                               |                      | 85 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                                                     | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Haematoma; Haemoglobin                                                                                                                                                                                                    | Escitalopram              |                    |                    | S               | Oral                                            | 1 Df                 |                 | Forest       |                |



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

|           |                        |   |      |                       |              |
|-----------|------------------------|---|------|-----------------------|--------------|
| Decreased | Previscan (Fluindione) | S | Oral | 15 Mg Daily D1 And D2 | Not Reported |
|           | Previscan (Fluindione) | S |      | 20 Mg Daily On D3     | Not Reported |
|           | Furosemide             | C |      | 1 Df                  | Not Reported |
|           | Cynomel                | C |      | 1 Df                  | Not Reported |
|           | Sotalol                | C |      | 2 Df                  | Not Reported |
|           | Amlodipine             | C |      | 2 Df                  | Not Reported |
|           | Spironolactone         | C |      | 1 Df                  | Not Reported |
|           | Neo-Mercazole          | C |      | 1 Df                  | Not Reported |
|           | Levothyrox             | C |      | 150 Mcg               | Not Reported |

| <u>FDA Received Date</u>                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|--------------------------|-----------------|--------------|----------------|
| 01-Apr-2014                                           | 9645438        | EXPEDITED (15-DAY) |                    | HO, OT          | CA-FRI-1000050331    |                          | 53 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Extrapyramidal Disorder;<br>Large Intestine Operation | Escitalopram   |                    |                    | S               | Oral                 | 20 Mg                    |                 | Forest       |                |
|                                                       | Zeldox         |                    |                    | S               | Oral                 | 40 Mg                    |                 | Not Reported |                |
|                                                       | Zeldox         |                    |                    | S               | Oral                 | 160 Mg                   |                 | Not Reported |                |
|                                                       | Clonazepam     |                    |                    | C               | Oral                 | 1 Mg                     |                 | Not Reported |                |
|                                                       | Cogentin       |                    |                    | C               |                      | Daily Dose Not Reported. |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 01-Apr-2014                                                                               | 9785835        | EXPEDITED (15-DAY) |                    | HO, LT          | FR-SA-2013SA132873   |                      | 20 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State;<br>Intentional Overdose;<br>Liver Injury; Mydriasis;<br>Rhabdomyolysis | Zolpidem       |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                           | Paroxetine     |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                           | Hept A Myl     |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                           | Escitalopram   |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                           | Paracetamol    |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                           | Abilify        |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |

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

|             |   |      |              |
|-------------|---|------|--------------|
| Cymbalta    | S | Oral | Not Reported |
| Lamotrigine | S | Oral | Not Reported |
| Agomelatine | S | Oral | Not Reported |
| Avlocardyl  | S | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 01-Apr-2014              | 9814292       | EXPEDITED (15-DAY) |                    | LT              | FR-<br>ELI_LILLY_AND_COMP<br>ANY-FR201401002011 |                      | 20 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                                                    | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>       |
|----------------------------------------------------------------------------------------------------------|-----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------------|
| Confusional State; Drug Interaction; Liver Injury; Mydriasis; Rhabdomyolysis; Toxicity To Various Agents | Cymbalta              |              |            | S           | Oral         | 1 Df, Unknown      |                 | Eli Lilly And Co |
|                                                                                                          | Zolpidem              |              |            | S           | Oral         | 1 Df, Unknown      |                 | Not Reported     |
|                                                                                                          | Paroxetine            |              |            | S           | Oral         | 1 Df, Unknown      |                 | Not Reported     |
|                                                                                                          | Heptamyl              |              |            | S           | Oral         | 1 Df, Unknown      |                 | Not Reported     |
|                                                                                                          | Abilify               |              |            | S           | Oral         | 1 Df, Unknown      |                 | Not Reported     |
|                                                                                                          | Lamotrigine           |              |            | S           | Oral         | 1 Df, Unknown      |                 | Not Reported     |
|                                                                                                          | Escitalopram          |              |            | S           | Oral         | 1 Df, Unknown      |                 | Not Reported     |
|                                                                                                          | Agomelatine           |              |            | S           | Oral         | 1 Df, Unknown      |                 | Not Reported     |
|                                                                                                          | Avlocardyl /00030001/ |              |            | S           | Oral         | 1 Df, Unknown      |                 | Not Reported     |
|                                                                                                          | Paracetamol           |              |            | S           | Oral         | 1 Df, Unknown      |                 | Not Reported     |
|                                                                                                          |                       |              |            |             |              |                    |                 |                  |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 01-Apr-2014              | 9992616       | NON-EXPEDITED    |                    |                 | US-PFIZER INC-<br>2014067494 |                      | 66 YR      | Female     | USA            |

| <u>Preferred Term</u>                                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Hypersensitivity; Dyskinesia; Tardive Dyskinesia | Gabapentin     |              |            | S           |              | Unk                |                 | Pfizer       |
|                                                       | Neurontin      |              |            | S           | Oral         | 900 Mg, Unk        |                 | Pfizer       |
|                                                       | Lexapro        |              |            | S           |              | Unk                |                 | Not Reported |
|                                                       | Cymbalta       |              |            | S           |              | Unk                |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|---------------------------------------------|-----------------|--------------|----------------|
| 01-Apr-2014                                                                               | 10051231             | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000049998    |                                             | 45 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Electrocardiogram Qt Prolonged; Labelled Drug-Drug Interaction Medication Error; Overdose | Escitalopram         |                    |                    | S               | Oral                 | 30 Mg                                       |                 | Forest       |                |
|                                                                                           | Escitalopram         |                    |                    | S               |                      |                                             |                 | Forest       |                |
|                                                                                           | Tercian              |                    |                    | S               | Oral                 | 50 Mg                                       |                 | Not Reported |                |
|                                                                                           | Teralithe            |                    |                    | C               | Oral                 | 1400 Mg                                     |                 | Not Reported |                |
|                                                                                           | Zopiclone            |                    |                    | C               | Oral                 | 7.5 Mg                                      |                 | Not Reported |                |
|                                                                                           | Temerit              |                    |                    | C               | Oral                 | 5 Mg                                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Apr-2014                                                                               | 10051376             | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000066023    |                                             | 23 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Epilepsy                                                                                  | Escitalopram         |                    |                    | S               | Oral                 | 10 Mg                                       |                 | Forest       |                |
|                                                                                           | Xeroquel             |                    |                    | S               | Oral                 | 50 Mg                                       |                 | Not Reported |                |
|                                                                                           | Xeroquel             |                    |                    | S               | Oral                 | 100 Mg                                      |                 | Not Reported |                |
|                                                                                           | Xeroquel             |                    |                    | S               | Oral                 | 50 Mg                                       |                 | Not Reported |                |
|                                                                                           | Depamide             |                    |                    | C               |                      |                                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Apr-2014                                                                               | 10052120             | DIRECT             | Y                  | OT              |                      |                                             | 52 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Discomfort; Product Substitution Issue; Therapeutic Product Effect Decreased    | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg Once Daily, 10 Mg By Mouth Once Daily |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                           | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------|----------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|-----------------|--------------|----------------|
| 02-Apr-2014                                        | 9550659        | NON-EXPEDITED      |                    |                 | US-SANOFI-AVENTIS-2013SA043992 |                      | 72 YR           | Female       | USA            |
| <u>Preferred Term</u>                              | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Asthenia; Blood Pressure Fluctuation;     | Aubagio        |                    |                    | S               | Oral                           |                      |                 | Not Reported |                |
| Blood Pressure Increased;                          | Aubagio        |                    |                    | S               | Oral                           |                      |                 | Not Reported |                |
| Fatigue; Gait Disturbance;                         | Aubagio        |                    |                    | S               | Oral                           |                      |                 | Not Reported |                |
| Heart Rate Increased; Nausea; Paraesthesia; Tremor | Lexapro        |                    |                    | S               |                                |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                           | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Apr-2014                                        | 10018159       | EXPEDITED (15-DAY) |                    | OT              | US-FRI-1000064678              |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                              | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Colon Cancer; Drug Ineffective                     | Lexapro        |                    |                    | S               | Oral                           | 20mg                 |                 | Forest       |                |
|                                                    | Temazepam      |                    |                    | C               |                                | 7.5mg                |                 | Not Reported |                |
|                                                    | Vitamins Nos   |                    |                    | C               |                                | Daily                |                 | Not Reported |                |
| <u>FDA Received Date</u>                           | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Apr-2014                                        | 10041155       | EXPEDITED (15-DAY) |                    | OT              | DE-FRI-1000065729              |                      | 66 YR           | Female       | DEU            |
| <u>Preferred Term</u>                              | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aortitis                                           | Escitalopram   |                    |                    | S               |                                | 10 Mg                |                 | Forest       |                |
| <u>FDA Received Date</u>                           | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Apr-2014                                        | 10054496       | EXPEDITED (15-DAY) |                    | HO, OT          | BR-FRI-1000066085              |                      | 62 YR           | Female       | BRA            |
| <u>Preferred Term</u>                              | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Pressure Fluctuation; Bradycardia;           | Lexapro        |                    |                    | S               | Oral                           | 5 Mg                 |                 | Forest       |                |

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

|              |           |   |      |        |              |
|--------------|-----------|---|------|--------|--------------|
| Hyperthermia | Lexapro   | S | Oral | 10 Mg  | Forest       |
|              | Synthroid | C | Oral | 75 Mcg | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 03-Apr-2014              | 8260674       | NON-EXPEDITED    |                    | CA, HO, OT      | US-JNJFOC-20111109043 |                      | < 1 DAY    | Female     | USA            |

| <u>Preferred Term</u>      | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|-------------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Apgar Score Low;           | Topamax           |              |            | S           | Transplacental |                    |                 | Not Reported |
| Asthma-Chronic             | Clindamycin       |              |            | S           | Transplacental |                    |                 | Not Reported |
| Obstructive Pulmonary      | Terbutaline       |              |            | S           | Transplacental |                    |                 | Not Reported |
| Disease Overlap            | Prometrium        |              |            | S           | Transplacental |                    |                 | Not Reported |
| Syndrome; Attention        | Lexapro           |              |            | S           | Transplacental |                    |                 | Not Reported |
| Deficit/Hyperactivity      | Lithium Carbonate |              |            | S           | Transplacental |                    |                 | Not Reported |
| Disorder; Behaviour        | Zithromax         |              |            | S           | Transplacental |                    |                 | Not Reported |
| Disorder;                  | Betamethasone     |              |            | S           | Transplacental |                    |                 | Not Reported |
| Bronchopulmonary           | Nifedipine        |              |            | S           | Transplacental |                    |                 | Not Reported |
| Dysplasia; Cleft Lip And   | Ampicillin        |              |            | S           | Transplacental |                    |                 | Not Reported |
| Palate; Congenital Central |                   |              |            |             |                |                    |                 |              |
| Nervous System Anomaly;    |                   |              |            |             |                |                    |                 |              |
| Developmental Delay;       |                   |              |            |             |                |                    |                 |              |
| Emotional Disorder;        |                   |              |            |             |                |                    |                 |              |
| Enlarged Clitoris;         |                   |              |            |             |                |                    |                 |              |
| Gastroesophageal Reflux    |                   |              |            |             |                |                    |                 |              |
| Disease; Intraventricular  |                   |              |            |             |                |                    |                 |              |
| Haemorrhage Neonatal;      |                   |              |            |             |                |                    |                 |              |
| Lung Disorder;             |                   |              |            |             |                |                    |                 |              |
| Malocclusion; Meningitis   |                   |              |            |             |                |                    |                 |              |
| Neonatal; Nasal Septum     |                   |              |            |             |                |                    |                 |              |
| Deviation; Patent Ductus   |                   |              |            |             |                |                    |                 |              |
| Arteriosus;                |                   |              |            |             |                |                    |                 |              |
| Pharyngotonsillitis;       |                   |              |            |             |                |                    |                 |              |
| Premature Baby;            |                   |              |            |             |                |                    |                 |              |
| Retinopathy Of             |                   |              |            |             |                |                    |                 |              |
| Prematurity; Sepsis; Sleep |                   |              |            |             |                |                    |                 |              |
| Apnoea Syndrome;           |                   |              |            |             |                |                    |                 |              |
| Strabismus                 |                   |              |            |             |                |                    |                 |              |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 03-Apr-2014              | 9894472       | EXPEDITED (15-DAY) |                    | CA, OT          | US-PFIZER INC-2014039954 |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Atrial Septal Defect;<br>Bicuspid Aortic Valve;<br>Congenital Aortic Stenosis; Maternal Exposure During Pregnancy; Ventricular Dysfunction | Zoloft         |              |            | S           | Transplacental | Unk                |                 | Pfizer       |
|                                                                                                                                            | Sertraline Hcl |              |            | S           | Transplacental | Unk                |                 | Pfizer       |
|                                                                                                                                            | Lexapro        |              |            | S           | Transplacental | Unk                |                 | Not Reported |
|                                                                                                                                            | Bupropion      |              |            | C           | Transplacental | Unk                |                 | Not Reported |
|                                                                                                                                            | Trazodone      |              |            | C           | Transplacental | Unk                |                 | Not Reported |
|                                                                                                                                            | Nuvaring       |              |            | C           | Transplacental | Unk                |                 | Not Reported |
|                                                                                                                                            | Albuterol      |              |            | C           | Transplacental | Unk                |                 | Not Reported |
|                                                                                                                                            | Acetaminophen  |              |            | C           | Transplacental | Unk                |                 | Not Reported |
|                                                                                                                                            | Hydroxyzine    |              |            | C           | Transplacental | Unk                |                 | Not Reported |
|                                                                                                                                            | Natelle        |              |            | C           | Transplacental | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Apr-2014              | 10060468      | EXPEDITED (15-DAY) |                    | HO              | FR-SA-2014SA039866   |                      | 75 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Pancreatitis Acute    | Zopiclone      |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Kardegic       |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Omeprazole     |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Lantus         |              |            | S           | Subcutaneous | Dose:15 Unit(S)    |                 | Not Reported |
|                       | Doliprane      |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Victoza        |              |            | S           | Subcutaneous |                    |                 | Not Reported |
|                       | Celebrex       |              |            | S           | Oral         | Frequency - 2 Days |                 | Not Reported |
|                       | Crestor        |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Athymil        |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Amlor          |              |            | S           | Oral         |                    |                 | Not Reported |

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

|                             |   |      |                    |              |
|-----------------------------|---|------|--------------------|--------------|
| Renitec [Enalapril Maleate] | S | Oral |                    | Not Reported |
| Diamicon                    | S | Oral |                    | Not Reported |
| Glucophage                  | S | Oral | Frequency - 2 Days | Not Reported |
| Seroplex                    | S | Oral |                    | Not Reported |
| Ceris                       | S | Oral |                    | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 04-Apr-2014              | 10060893      | EXPEDITED (15-DAY) | HO                 |                 | FR-ALLERGAN-1406766US |                      | 75 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Pancreatitis Acute    | Trospium Chloride Unk |              |            | S           | Oral         | 20 Mg, Unk         |                 | Indevus      |
|                       | Lantus                |              |            | S           | Subcutaneous | 15 Units, Unk      |                 | Not Reported |
|                       | Doliprane             |              |            | S           | Oral         | 500 Mg, Prn        |                 | Not Reported |
|                       | Celebrex              |              |            | S           | Oral         | 200 Mg, Qod        |                 | Not Reported |
|                       | Crestor               |              |            | S           | Oral         | 10 Mg, Unk         |                 | Not Reported |
|                       | Athymil               |              |            | S           | Oral         | 10 Mg, Unk         |                 | Not Reported |
|                       | Amlor                 |              |            | S           | Oral         | 5 Mg, Unk          |                 | Not Reported |
|                       | Renitec /00574902/    |              |            | S           | Oral         | 10 Mg, Unk         |                 | Not Reported |
|                       | Diamicon              |              |            | S           | Oral         | 30 Mg, Unk         |                 | Not Reported |
|                       | Glucophage            |              |            | S           | Oral         | 8850 Mg, Unk       |                 | Not Reported |
|                       | Seroplex              |              |            | S           | Oral         | 10 Mg, Unk         |                 | Not Reported |
|                       | Zopiclone             |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                       | Kardegic              |              |            | S           | Oral         | 75 Mg, Unk         |                 | Not Reported |
|                       | Omeprazole            |              |            | S           |              | 20 Mg, Unk         |                 | Not Reported |
|                       | Victoza               |              |            | C           | Subcutaneous | 1.8 Mg, Qd         |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------|----------------------|------------|------------|----------------|
| 07-Apr-2014              | 9412441       | EXPEDITED (15-DAY) | HO, OT             |                 | CA-MERCK-1307CAN011138 |                      | 50 YR      | Female     | CAN            |

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

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                           |           |   |      |              |              |
|---------------------------|-----------|---|------|--------------|--------------|
| Angle Closure Glaucoma;   | Saphris   | S | Oral | 1.25 Mg, Unk | Merck        |
| Inappropriate Schedule Of | Ciprallex | S | Oral | 5 Mg, Unk    | Not Reported |
| Product Administration;   |           |   |      |              |              |
| Underdose                 |           |   |      |              |              |

| <u>FDA Received Date</u>                                      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 07-Apr-2014                                                   | 9656456        | EXPEDITED (15-DAY) |                    | HO              | CA-FRI-1000050614    |                      | 57 YR           | Female     | CAN            |
| <u>Preferred Term</u>                                         | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Dizziness; Heart Rate Increased; Heart Rate Irregular; Nausea | Escitalopram   |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest     |                |

| <u>FDA Received Date</u>                                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 07-Apr-2014                                                              | 9656495        | EXPEDITED (15-DAY) |                    | HO, OT          | CA-FRI-1000050619    |                      | 41 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Electrocardiogram Qt Prolonged; Fibula Fracture; Syncope; Tibia Fracture | Escitalopram   |                    |                    | S               | Oral                 | 20 Mg                |                 | Forest       |                |
|                                                                          | Escitalopram   |                    |                    | S               |                      |                      |                 | Forest       |                |
|                                                                          | Seroquel       |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                          | Seroquel       |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 07-Apr-2014                                                                            | 9656649        | EXPEDITED (15-DAY) |                    | DE              | CA-FRI-1000050617    |                      | 48 YR           | Male         | CAN            |
| <u>Preferred Term</u>                                                                  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Completed Suicide; Panic Attack; Product Dose Omission; Suicidal Behaviour | Escitalopram   |                    |                    | S               |                      | 10 Mg                |                 | Forest       |                |
|                                                                                        | Trazodone      |                    |                    | C               |                      | 50 Mg                |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Apr-2014              | 9656650       | EXPEDITED (15-DAY) |                    | OT              | CA-FRI-1000050612    |                      |            | Female     | CAN            |



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

| <a href="#">Preferred Term</a>                                                                                                                                                                                                      | <a href="#">Product</a>    | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Bladder Pain; Depressed Mood; Disturbance In Sexual Arousal; Hypertonic Bladder; Insomnia; Muscle Spasms; Paraesthesia; Product Use In Unapproved Indication; Restless Legs Syndrome; Urethral Pain; Vulvovaginal Burning Sensation | Escitalopram               |                           |                             | S                        | Oral                          | 2.5 Mg                        |                          | Forest              |                         |
| <a href="#">FDA Received Date</a>                                                                                                                                                                                                   | <a href="#">Case #</a>     | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 07-Apr-2014                                                                                                                                                                                                                         | 10041153                   | EXPEDITED (15-DAY)        |                             | HO                       | NO-FRI-1000065848             |                               | 78 YR                    | Female              | NOR                     |
| <a href="#">Preferred Term</a>                                                                                                                                                                                                      | <a href="#">Product</a>    | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Delirium; Dizziness; Executive Dysfunction; Syncope                                                                                                                                                                                 | Escitalopram               |                           |                             | S                        | Oral                          | 20 Mg                         |                          | Forest              |                         |
|                                                                                                                                                                                                                                     | Escitalopram               |                           |                             | S                        | Oral                          | 10 Mg                         |                          | Not Reported        |                         |
|                                                                                                                                                                                                                                     | Zyprexa                    |                           |                             | S                        | Oral                          | 20 Mg                         |                          | Not Reported        |                         |
|                                                                                                                                                                                                                                     | Norspan                    |                           |                             | C                        |                               | 240 Mcg                       |                          | Not Reported        |                         |
|                                                                                                                                                                                                                                     | Vallergan                  |                           |                             | C                        | Oral                          | 30 Mg                         |                          | Not Reported        |                         |
|                                                                                                                                                                                                                                     | Zopiclone Actavis          |                           |                             | C                        | Oral                          |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                                                                                                                                   | <a href="#">Case #</a>     | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 07-Apr-2014                                                                                                                                                                                                                         | 10062568                   | EXPEDITED (15-DAY)        |                             | HO                       | IT-FRI-1000066196             |                               | 78 YR                    | Female              | ITA                     |
| <a href="#">Preferred Term</a>                                                                                                                                                                                                      | <a href="#">Product</a>    | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Accidental Overdose; Haemolysis                                                                                                                                                                                                     | Escitalopram Oral Solution |                           |                             | S                        | Oral                          | Overdose: Cipralext 30 Drops  |                          | Forest              |                         |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                      | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------|--------------------------------|--------------------|--------------------|-----------------|----------------------|--------------------------------------|-----------------|--------------|----------------|
| 07-Apr-2014                                                                                                   | 10063235                       | EXPEDITED (15-DAY) |                    | OT              | CA-FRI-1000066178    |                                      | 57 YR           | Male         | CAN            |
| <u>Preferred Term</u>                                                                                         | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Accidental Overdose;<br>Aggression; Anger; Binge<br>Drinking; Feeling<br>Abnormal; Insomnia; Legal<br>Problem | Escitalopram                   |                    |                    | S               | Oral                 | 10 Mg                                |                 | Forest       |                |
|                                                                                                               | Escitalopram                   |                    |                    | S               | Oral                 | 20 Mg                                |                 | Not Reported |                |
|                                                                                                               | Escitalopram                   |                    |                    | S               | Oral                 | Overdose: Escitalopram<br>40 Mg Once |                 | Not Reported |                |
|                                                                                                               | Blood Pressure Pills Nos       |                    |                    | C               |                      | Daily Dose Not Reported              |                 | Not Reported |                |
|                                                                                                               | Prostate Cancer Medication Nos |                    |                    | C               |                      | Daily Dose Not Reported              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                      | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Apr-2014                                                                                                   | 10063444                       | EXPEDITED (15-DAY) |                    | OT              | US-FRI-1000066082    |                                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                         | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Behaviour;<br>Aggression; Dissociative<br>Disorder; Feeling<br>Abnormal; Physical<br>Assault         | Lexapro                        |                    |                    | S               |                      |                                      |                 | Forest       |                |
|                                                                                                               | Lexapro                        |                    |                    | S               |                      |                                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                      | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Apr-2014                                                                                                   | 10063486                       | EXPEDITED (15-DAY) |                    | DE              | FR-FRI-1000066199    |                                      | 70 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                         | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Subdural Haematoma                                                                                            | Escitalopram                   |                    |                    | S               | Oral                 | 20 Mg                                |                 | Forest       |                |
|                                                                                                               | Duoplavin                      |                    |                    | S               | Oral                 | 1 Df                                 |                 | Not Reported |                |
|                                                                                                               | Coversyl                       |                    |                    | C               |                      |                                      |                 | Not Reported |                |
|                                                                                                               | Doliprane                      |                    |                    | C               |                      |                                      |                 | Not Reported |                |
|                                                                                                               | Eupantol                       |                    |                    | C               |                      |                                      |                 | Not Reported |                |
|                                                                                                               | Crestor                        |                    |                    | C               |                      |                                      |                 | Not Reported |                |
|                                                                                                               | Exelon                         |                    |                    | C               |                      |                                      |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|--------------------------------------------------|-----------------|--------------|----------------|
| 07-Apr-2014                                                             | 10063724       | EXPEDITED (15-DAY) |                    | HO, LT          | PHHY2014ES040668     |                                                  | 77 YR           | Female       | ESP            |
| <u>Preferred Term</u>                                                   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                               | <u>Duration</u> | <u>Mfr</u>   |                |
| Craniocerebral Injury;<br>Hyponatraemia;<br>Subarachnoid<br>Haemorrhage | Exforge        |                    |                    | S               | Oral                 | Unk Unk, Unk                                     |                 | Novartis     |                |
|                                                                         | Heipram        |                    |                    | S               | Oral                 | Unk Unk, Unk                                     |                 | Not Reported |                |
|                                                                         | Adiro          |                    |                    | C               | Oral                 | 100 Mg, Unk                                      |                 | Not Reported |                |
|                                                                         | Inegy          |                    |                    | C               | Oral                 | 1 Df (10 Mg Ezet/ 20 Mg Simv), Qd                |                 | Not Reported |                |
|                                                                         | Orfidal        |                    |                    | C               | Oral                 | 1 Mg, Qd                                         |                 | Not Reported |                |
|                                                                         | Sevikar Hct    |                    |                    | C               | Oral                 | 1 Df (5 Mg Amlol/ 12.5 Mg Hydr/ 40 Mg Olme), Unk |                 | Not Reported |                |
|                                                                         | Uniket Retard  |                    |                    | C               |                      | 50 Mg, Unk                                       |                 | Not Reported |                |
|                                                                         | Vesicare       |                    |                    | C               | Oral                 | 5 Mg, Unk                                        |                 | Not Reported |                |
|                                                                         | Diuretics      |                    |                    | C               |                      | Unk Unk, Unk                                     |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 07-Apr-2014                                                                                                                                                                                                                                                                               | 10067451       | EXPEDITED (15-DAY) | Y                  | HO              | 2014P1002744         |                      | 48 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Bicarbonate<br>Decreased; Blood Glucose<br>Increased; Blood Lactic<br>Acid Increased; Blood Ph<br>Decreased; Blood<br>Pressure Systolic<br>Decreased; Coma Scale<br>Abnormal; Incorrect Dose<br>Administered; Po2<br>Decreased; Toxicity To<br>Various Agents; Treatment<br>Failure | Clonidine      |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                           | Propanolol     |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                           | Escitalopram   |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                           | Lorazepam      |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                           | Atorvastatin   |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                           | Quetiapine     |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                          | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------|--------------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| 08-Apr-2014                                                                                                                       | 9612065            | NON-EXPEDITED      |                    | OT              | US-ASTELLAS-2013US009182   |                      | 87 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                             | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Constipation; Discomfort; Drug Ineffective; Drug Interaction; Inappropriate Schedule Of Product Administration; Urinary Retention | Myrbetriq          |                    |                    | S               | Oral                       | 50 Mg, Unknown/D     |                 | Astellas     |                |
|                                                                                                                                   | Myrbetriq          |                    |                    | S               | Oral                       | 50 Mg, Uid/Qd        |                 | Astellas     |                |
|                                                                                                                                   | Myrbetriq          |                    |                    | S               | Unknown                    | 25 Mg, Unknown/D     |                 | Astellas     |                |
|                                                                                                                                   | Myrbetriq          |                    |                    | S               | Oral                       | Evry Other Day       |                 | Astellas     |                |
|                                                                                                                                   | Nexium /01479302/  |                    |                    | S               | Unknown                    | Unk                  |                 | Not Reported |                |
|                                                                                                                                   | Humalog            |                    |                    | S               | Unknown                    | Unk                  |                 | Not Reported |                |
|                                                                                                                                   | Lantus             |                    |                    | S               | Unknown                    | Unk                  |                 | Not Reported |                |
|                                                                                                                                   | Tiazac /00489702/  |                    |                    | S               | Unknown                    | Unk                  |                 | Not Reported |                |
|                                                                                                                                   | Losartan           |                    |                    | S               | Unknown                    | Unk                  |                 | Not Reported |                |
|                                                                                                                                   | Lexapro            |                    |                    | S               | Unknown                    | Unk                  |                 | Not Reported |                |
|                                                                                                                                   | Buspar             |                    |                    | S               | Unknown                    | Unk                  |                 | Not Reported |                |
|                                                                                                                                   | Miralax /00754501/ |                    |                    | C               | Unknown                    | Unk                  |                 | Not Reported |                |
|                                                                                                                                   | Linaclotide        |                    |                    | C               | Unknown                    | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                          | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Apr-2014                                                                                                                       | 9657922            | EXPEDITED (15-DAY) |                    | HO              | CA-FRI-1000050623          |                      | 18 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                                                                                             | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypersomnia; Suicidal Behaviour; Suicidal Ideation                                                                                | Escitalopram       |                    |                    | S               | Oral                       | 20 Mg                |                 | Forest       |                |
|                                                                                                                                   | Escitalopram       |                    |                    | S               | Oral                       | 10 Mg                |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                          | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Apr-2014                                                                                                                       | 10064696           | EXPEDITED (15-DAY) |                    | HO              | FR-ASTRAZENECA-2014SE23410 |                      | 75 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                             | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

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

|                    |                             |   |              |              |
|--------------------|-----------------------------|---|--------------|--------------|
| Pancreatitis Acute | Omeprazole                  | S | Oral         | Not Reported |
|                    | Crestor                     | S | Oral         | Not Reported |
|                    | Glucophage                  | S | Oral         | Not Reported |
|                    | Doliprane                   | S | Oral         | Not Reported |
|                    | Victoza                     | S | Subcutaneous | Not Reported |
|                    | Celebrex                    | S | Oral         | Not Reported |
|                    | Athymil                     | S | Oral         | Not Reported |
|                    | Amlor                       | S | Oral         | Not Reported |
|                    | Renitec [Enalapril Maleate] | S | Oral         | Not Reported |
|                    | Diamicron                   | S | Oral         | Not Reported |
|                    | Seroplex                    | S | Oral         | Not Reported |
|                    | Zopiclone                   | S | Oral         | Not Reported |
|                    | Kardegic                    | S | Oral         | Not Reported |
|                    | Ceris                       | S | Oral         | Not Reported |
|                    | Lantus                      | S | Subcutaneous | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------|----------------------|------------|------------|----------------|
| 08-Apr-2014              | 10065545      | EXPEDITED (15-DAY) |                    | HO, LT          | ES-DSJP-DSE-2014-103973 |                      |            | Unknown    | ESP            |

| <u>Preferred Term</u>                                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Head Injury;<br>Hyponatraemia;<br>Subarachnoid<br>Haemorrhage | Sevikar Hct    |              |            | S           | Oral         | 1 Df, Qd           |                 | Not Reported |
|                                                               | Heipram        |              |            | S           | Oral         | 1-0-0              |                 | Not Reported |
|                                                               | Exforge        |              |            | S           | Oral         | 1 Df, Qd           |                 | Not Reported |
|                                                               | Uniket         |              |            | C           | Oral         | 50 Mg, Qd          |                 | Not Reported |
|                                                               | Inegy          |              |            | C           | Oral         | 10/20 Mg, Qd       |                 | Not Reported |
|                                                               | Orfidal        |              |            | C           | Oral         | 1-0-0              |                 | Not Reported |
|                                                               | Vesicare       |              |            | C           | Oral         | 5 Mg, Qd           |                 | Not Reported |
|                                                               | Adiro          |              |            | C           | Oral         | 100 Mg, Qd         |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                           | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 08-Apr-2014                                                                                                                                                                        | 10066756        | EXPEDITED (15-DAY) |                    | OT              | PHHY2014TW037744     |                      | 43 YR           | Male         | TWN            |
| <u>Preferred Term</u>                                                                                                                                                              | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated;<br>Erythema; Obsessive-<br>Compulsive Disorder;<br>Photosensitivity Reaction;<br>Skin Hyperpigmentation;<br>Sunburn; Therapeutic<br>Product Cross-Reactivity | Escitalopram    |                    |                    | S               |                      | 20-30 Mg             |                 | Not Reported |                |
|                                                                                                                                                                                    | Fluvoxamine     |                    |                    | S               |                      | 100-150 Mg           |                 | Novartis     |                |
|                                                                                                                                                                                    | Fluoxetine      |                    |                    | S               |                      | 40-60 Mg Per Day     |                 | Not Reported |                |
|                                                                                                                                                                                    | Clonazepam      |                    |                    | C               |                      | 1 Mg                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                           | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Apr-2014                                                                                                                                                                        | 9656603         | EXPEDITED (15-DAY) |                    | OT              | CA-FRI-1000050622    |                      | 31 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                                                                                                                                              | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Withdrawal Syndrome                                                                                                                                                                | Escitalopram    |                    |                    | S               | Oral                 | 20 Mg                |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                                                                           | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Apr-2014                                                                                                                                                                        | 9661104         | EXPEDITED (15-DAY) |                    | HO, OT          | CA-FRI-1000050683    |                      |                 | Male         | CAN            |
| <u>Preferred Term</u>                                                                                                                                                              | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Withdrawal<br>Syndrome Neonatal;<br>Exposure Via Breast Milk;<br>Foetal Exposure During<br>Pregnancy; Hyperthermia                                                            | Escitalopram    |                    |                    | S               | Transplacental       |                      |                 | Forest       |                |
|                                                                                                                                                                                    | Corticosteroids |                    |                    | S               | Transplacental       |                      |                 | Not Reported |                |
|                                                                                                                                                                                    | Nicotine        |                    |                    | S               | Transplacental       |                      |                 | Not Reported |                |
|                                                                                                                                                                                    | Suboxone        |                    |                    | S               | Transplacental       | 2 Mg                 |                 | Not Reported |                |
|                                                                                                                                                                                    | Subutex         |                    |                    | S               | Transplacental       | 1 Df                 |                 | Not Reported |                |
|                                                                                                                                                                                    | Subutex         |                    |                    | S               | Transmammary         | 1 Df                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                           | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Apr-2014                                                                                                                                                                        | 9980812         | EXPEDITED (15-DAY) |                    | HO              | NO-ROCHE-1355597     |                      | 50 YR           | Male         | NOR            |

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

| <u>Preferred Term</u>                                                                                  | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                                                                        | <u>Duration</u> | <u>Mfr</u>   |                |
|--------------------------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|-----------------------------------------------------------------------------------------------------------|-----------------|--------------|----------------|
| Abdominal Pain Upper;<br>Drug Abuse; Drug<br>Diversion; Hospitalisation;<br>Intentional Product Misuse | Clonazepam             |                    |                    | S               | Unknown                                         | Dosing Details Unknown                                                                                    |                 | Not Reported |                |
|                                                                                                        | Subutex                |                    |                    | S               | Unknown                                         | At The Time When The<br>Questionnaire Was<br>Completed, Patient Had<br>Been On Subutex 1 Year 7<br>Months |                 | Not Reported |                |
|                                                                                                        | Remeron                |                    |                    | S               | Unknown                                         | Dosing Details Unknown                                                                                    |                 | Not Reported |                |
|                                                                                                        | Cannabis               |                    |                    | S               | Respiratory<br>(inhalation)                     | Details Unknown                                                                                           |                 | Not Reported |                |
|                                                                                                        | Cipralext              |                    |                    | S               | Unknown                                         | Dosing Details Unknown                                                                                    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                               | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                                                                                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Apr-2014                                                                                            | 10068044               | EXPEDITED (15-DAY) |                    | HO              | US-FRI-1000066235                               |                                                                                                           | 47 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                  | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                                                                        | <u>Duration</u> | <u>Mfr</u>   |                |
| Tendon Rupture                                                                                         | Escitalopram           |                    |                    | S               | Oral                                            |                                                                                                           |                 | Forest       |                |
|                                                                                                        | Escitalopram           |                    |                    | S               | Oral                                            | 20 Mg                                                                                                     |                 | Forest       |                |
|                                                                                                        | Luaf41156              |                    |                    | S               | Oral                                            | Unk                                                                                                       |                 | Not Reported |                |
|                                                                                                        | Blinded-Placebo        |                    |                    | S               | Oral                                            |                                                                                                           |                 | Not Reported |                |
|                                                                                                        | Blinded Serequel Xr    |                    |                    | S               | Oral                                            | Unk                                                                                                       |                 | Not Reported |                |
|                                                                                                        | Prazosin Hydrochloride |                    |                    | C               | Oral                                            | 6 Mg Milligram(S), Qpm                                                                                    |                 | Not Reported |                |
|                                                                                                        | Loratadine             |                    |                    | C               | Oral                                            | 10 Mg Milligram(S), Prn                                                                                   |                 | Not Reported |                |
|                                                                                                        | Flunisolide Acetate    |                    |                    | C               |                                                 | 0.025 % Percent, Unk                                                                                      |                 | Not Reported |                |
|                                                                                                        | Lisinopril/Hctz        |                    |                    | C               | Oral                                            | 20/25 Mg Milligram(S), Qd                                                                                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                               | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                                                                                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Apr-2014                                                                                            | 10068546               | EXPEDITED (15-DAY) |                    | HO              | FR-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>20608998 |                                                                                                           | 75 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                  | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                                                                        | <u>Duration</u> | <u>Mfr</u>   |                |

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

|                    |                             |   |              |                      |
|--------------------|-----------------------------|---|--------------|----------------------|
| Pancreatitis Acute | Glucophage                  | S | Oral         | Bristol Myers Squibb |
|                    | Victoza                     | S | Subcutaneous | Not Reported         |
|                    | Celebrex                    | S | Oral         | Not Reported         |
|                    | Crestor                     | S | Oral         | Not Reported         |
|                    | Athymil                     | S | Oral         | Not Reported         |
|                    | Amlor                       | S | Oral         | Not Reported         |
|                    | Renitec [Enalapril Maleate] | S | Oral         | Not Reported         |
|                    | Diamicron                   | S | Oral         | Not Reported         |
|                    | Seroplex                    | S | Oral         | Not Reported         |
|                    | Zopiclone                   | S | Oral         | Not Reported         |
|                    | Kardegic                    | S | Oral         | Not Reported         |
|                    | Omeprazole                  | S | Oral         | Not Reported         |
|                    | Ceris                       | S | Oral         | Not Reported         |
|                    | Lantus                      | S | Subcutaneous | Not Reported         |
|                    | Doliprane                   | S | Oral         | Cadence              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Apr-2014              | 10068940      | EXPEDITED (15-DAY) |                    | HO              | CA-FRI-1000066340    |                      | 48 YR      | Female     | CAN            |

| <u>Preferred Term</u>                                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Pressure Systolic Decreased; Coma Scale Abnormal; Overdose | Escitalopram   |              |            | S           |              | Overdose 400 Mg    |                 | Forest       |
|                                                                  | Clonidine      |              |            | S           |              | Overdose 2.8 Mg    |                 | Not Reported |
|                                                                  | Propranolol    |              |            | S           |              | Overdose 1120 Mg   |                 | Not Reported |
|                                                                  | Lorazepam      |              |            | S           |              | Overdose 28 Mg     |                 | Not Reported |
|                                                                  | Atorvastatin   |              |            | S           |              | Overdose 560 Mg    |                 | Not Reported |
|                                                                  | Quetiapine     |              |            | S           |              | Overdose 5600 Mg   |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Apr-2014              | 10085113      | NON-EXPEDITED    | Y                  | DE, HO          | 2014-00700           |                      | 45 YR      | Female     | USA            |



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

| <u>Preferred Term</u>                                                | <u>Product</u>         | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|----------------------------------------------------------------------|------------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Completed Suicide                                                    | Escitalopram (Unknown) |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                      | Zolpidem (Unknown)     |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                      | Alprazolam (Unknown)   |                  |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                             | <u>Case #</u>          | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Apr-2014                                                          | 10085115               | NON-EXPEDITED    | Y                  | DE, HO          | 2014-00717           |                      | 55 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                | <u>Product</u>         | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                                    | Escitalopram           |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                      | Duloxetine             |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                      | Alprazolam             |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                      | Vilazodone             |                  |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                             | <u>Case #</u>          | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Apr-2014                                                          | 10085121               | NON-EXPEDITED    | Y                  | DE, HO          | 2014-00718           |                      | 55 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                | <u>Product</u>         | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                                    | Escitalopram (Unknown) |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                      | Citalopram (Unknown)   |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                      | (Citalopram)           |                  |                    |                 |                      |                      |                 |              |                |
|                                                                      | Bupropion (Unknown)    |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                      | Clonazepam (Unknown)   |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                      | Tadalafil (Unknown)    |                  |                    | S               |                      |                      |                 | Not Reported |                |
| Acetaminophen +<br>Diphenhydramine (Unknown)                         |                        |                  | S                  |                 |                      |                      | Not Reported    |              |                |
| <u>FDA Received Date</u>                                             | <u>Case #</u>          | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Apr-2014                                                          | 10085130               | NON-EXPEDITED    |                    | OT              | E2B_00001718         |                      | 54 YR           | Male         | GBR            |
| <u>Preferred Term</u>                                                | <u>Product</u>         | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depressed Mood;<br>Inhibitory Drug Interaction;<br>Suicidal Ideation | Escitalopram (Unknown) |                  |                    | S               |                      | 10-20mg Daily        | 1 DAY           | Not Reported |                |
|                                                                      | Gliclazide (Unknown)   |                  |                    | S               | Oral                 |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Apr-2014              | 9326083       | EXPEDITED (15-DAY) |                    | OT              | JP-FRI-1000045596    |                      | 68 YR      | Female     | JPN            |

| <u>Preferred Term</u>                                                                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction;<br>Supraventricular<br>Extrasystoles; Ventricular<br>Extrasystoles | Lexapro        |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                                                                      | Takepron       |              |            | S           | Oral         | 15 Mg              |                 | Not Reported |
|                                                                                      | Paxil          |              |            | S           | Oral         | 40 Mg              |                 | Not Reported |
|                                                                                      | Predonine      |              |            | S           | Oral         | 20 Mg              |                 | Not Reported |
|                                                                                      | Predonine      |              |            | S           | Oral         | 15 Mg              |                 | Not Reported |
|                                                                                      | Prednisolone   |              |            | S           | Oral         | 3 Mg               |                 | Not Reported |
|                                                                                      | Risperdal      |              |            | C           | Oral         | 2 Mg               |                 | Not Reported |
|                                                                                      | Singulair      |              |            | C           | Oral         | 10 Mg              |                 | Not Reported |
|                                                                                      | Maglax         |              |            | C           | Oral         | 990 Mg             |                 | Not Reported |
|                                                                                      | Apidra         |              |            | C           | Subcutaneous | 24 Ut              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Apr-2014              | 10062891      | EXPEDITED (15-DAY) |                    | OT              | CH-FRI-1000066177    |                      | 36 YR      | Female     | CHE            |

| <u>Preferred Term</u>              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Erythema Nodosum; Off<br>Label Use | Escitalopram   |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                    | Tysabri        |              |            | S           | Other        | 10 Mg              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 10-Apr-2014              | 10070561      | EXPEDITED (15-DAY) |                    | HO, OT          | FR-PFIZER INC-<br>2014097539 |                      | 32 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                                                                                 | <u>Product</u>  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------|-----------------|--------------|------------|-------------|--------------|----------------------------|-----------------|--------------|
| Coma; Heart Rate<br>Increased; Hypertension;<br>Intentional Overdose;<br>Pneumonia Aspiration;<br>Respiratory Failure | Xanax           |              |            | S           | Oral         | 0.50 Mg, Unk               |                 | Pfizer       |
|                                                                                                                       | Methadone Ap-Hp |              |            | S           | Oral         | 3 Tablets Of 20 Mg, Single |                 | Not Reported |
|                                                                                                                       | Seroplex        |              |            | S           | Oral         | 11 Df, Single              |                 | Not Reported |

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

| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                          | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                        | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|-------------------------------------------------------------|-----------------|------------|----------------|
| 10-Apr-2014                                                                                                                                                                                                                                                                                                       | 10070906       | EXPEDITED (15-DAY) |                    | CA, DE          | US-FRI-1000066206    |                                                             |                 | Female     | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                             | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                          | <u>Duration</u> | <u>Mfr</u> |                |
| Cardiac Failure; Foetal Cardiac Disorder; Hypoplastic Left Heart Syndrome; Ventricular Fibrillation                                                                                                                                                                                                               | Lexapro        |                    |                    | S               |                      |                                                             |                 | Forest     |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                          | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                        | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 10-Apr-2014                                                                                                                                                                                                                                                                                                       | 10071061       | EXPEDITED (15-DAY) |                    | OT              | CH-FRI-1000066208    |                                                             |                 | Male       | CHE            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                             | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                          | <u>Duration</u> | <u>Mfr</u> |                |
| Alcohol Interaction; Loss Of Consciousness                                                                                                                                                                                                                                                                        | Escitalopram   |                    |                    | S               |                      |                                                             |                 | Forest     |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                          | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                        | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 10-Apr-2014                                                                                                                                                                                                                                                                                                       | 10072145       | DIRECT             |                    | DS, OT          |                      |                                                             | 20 YR           | Female     | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                             | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                          | <u>Duration</u> | <u>Mfr</u> |                |
| Anhedonia; Anorgasmia; Bulimia Nervosa; Condition Aggravated; Frustration Tolerance Decreased; Hypoaesthesia; Impaired Work Ability; Insomnia; Intentional Self-Injury; Orgasm Abnormal; Post-Traumatic Stress Disorder; Quality Of Life Decreased; Self-Injurious Ideation; Sexual Dysfunction; Vaginal Disorder | Lexapro        |                    |                    | S               | Oral                 | 1 Pill Once Daily Taken By Mouth A Few Months (3-6 At Most) |                 | Forest     |                |

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

| <u>FDA Received Date</u>                                                                                                                        | <u>Case #</u>                                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                                                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|-----------------------------------------------------------------------------------------------------------------------|-----------------|--------------|----------------|
| 10-Apr-2014                                                                                                                                     | 10072195                                             | DIRECT             |                    | DS              |                      |                                                                                                                       | 18 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                           | <u>Product</u>                                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                                                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Colitis Ulcerative; Crohn'S Disease; Gastritis; Helicobacter Gastritis; Mouth Ulceration; Weight Decreased                                      | Escitalopram                                         |                    |                    | S               | Oral                 | 1 Tablet, Once Daily Taken By Mouth                                                                                   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                        | <u>Case #</u>                                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                                                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Apr-2014                                                                                                                                     | 9875755                                              | EXPEDITED (15-DAY) | Y                  | OT              | AUR-APL-2014-01098   |                                                                                                                       | 83 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                                                                                           | <u>Product</u>                                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                                                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Depressed Mood; Depression; Diabetes Mellitus Inadequate Control; Drug Interaction; Glycosylated Haemoglobin Abnormal; Hyperglycaemia; Insomnia | Escitalopram                                         |                    |                    | S               |                      | 5 Mg, 1 In 1 D<br>1 D                                                                                                 | 3 DAY           | Not Reported |                |
|                                                                                                                                                 | Glibenclamide                                        |                    |                    | S               |                      | 22.5 Mg (7.5 Mg, 3 In 1 D),<br>Unknown<br>15 Mg (5 Mg, 3 In 1 D),<br>Unknown<br>7.5 Mg (2.5 Mg, 3 In 1 D),<br>Unknown |                 | Not Reported |                |
|                                                                                                                                                 | Enalapril W/Hydrochlorothiazide (Enap -HI/06436201/) |                    |                    | C               |                      |                                                                                                                       |                 | Not Reported |                |
|                                                                                                                                                 | Doxazosin (Doxazosin)                                |                    |                    | C               |                      |                                                                                                                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                        | <u>Case #</u>                                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                                                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Apr-2014                                                                                                                                     | 10041158                                             | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000065851    |                                                                                                                       | 49 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                           | <u>Product</u>                                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                                                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Withdrawal Syndrome                                                                                                                             | Escitalopram                                         |                    |                    | S               |                      | 20 Mg                                                                                                                 |                 | Forest       |                |
|                                                                                                                                                 | Escitalopram                                         |                    |                    | S               |                      |                                                                                                                       |                 | Forest       |                |
|                                                                                                                                                 | Lexomil                                              |                    |                    | C               |                      | 0.5 Df                                                                                                                |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                            | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------|------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 11-Apr-2014                                         | 10072697               | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2014100824 |                      |                 | Male         | USA            |
| <u>Preferred Term</u>                               | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Amnesia; Disturbance In Attention; Drug Ineffective | Pristiq                |                    |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                                                     | Effexor Xr             |                    |                    | S               |                          | 75 Mg, Unk           |                 | Pfizer       |                |
|                                                     | Lexapro                |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                                                     | Wellbutrin             |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                                                     | Xalatan                |                    |                    | C               |                          | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                            | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Apr-2014                                         | 10072802               | EXPEDITED (15-DAY) |                    | HO              | FR-SA-2014SA040407       |                      | 88 YR           | Female       | FRA            |
| <u>Preferred Term</u>                               | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Oedema Peripheral                                   | Endotelon              |                    | Y                  | S               | Oral                     | Dose:2 Unit(S)       |                 | Not Reported |                |
|                                                     | Rilmenidine            |                    |                    | S               | Oral                     | Dose:1 Unit(S)       |                 | Not Reported |                |
|                                                     | Lasilix                |                    |                    | S               | Oral                     | Dose:1 Unit(S)       |                 | Not Reported |                |
|                                                     | Sifrol                 |                    |                    | S               | Oral                     | Dose:1 Unit(S)       |                 | Not Reported |                |
|                                                     | Seroplex               |                    |                    | S               | Oral                     | Dose:1 Unit(S)       |                 | Not Reported |                |
|                                                     | Previscan (Fluindione) |                    |                    | C               | Oral                     |                      |                 | Not Reported |                |
|                                                     | Metformin              |                    |                    | C               | Oral                     |                      |                 | Not Reported |                |
|                                                     | Atenolol               |                    |                    | C               | Oral                     |                      |                 | Not Reported |                |
|                                                     | Zopiclone              |                    |                    | C               | Oral                     |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                            | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Apr-2014                                         | 10073589               | EXPEDITED (15-DAY) |                    | OT              | CH-FRI-1000066374        |                      |                 | Female       | CHE            |
| <u>Preferred Term</u>                               | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Anxiety; Blood Pressure Increased; Body  | Escitalopram           |                    |                    | S               | Oral                     | 5 Mg                 |                 | Forest       |                |

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

|                                                                                                                                                                                                                                                                                                                                                                                       |                             |             |                      |      |                                              |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|-------------|----------------------|------|----------------------------------------------|
| Temperature Increased;<br>Diarrhoea; Dizziness;<br>Dysphoria; Dysstasia;<br>Fatigue; Gait Disturbance;<br>Headache; Heart Rate<br>Increased; Hyperhidrosis;<br>Hyperventilation; Impaired<br>Work Ability; Insomnia;<br>Listless; Nausea;<br>Palpitations; Refusal Of<br>Treatment By Patient;<br>Serotonin Syndrome;<br>Tachycardia; Tremor;<br>Unresponsive To Stimuli;<br>Vomiting | Concor<br>Climen<br>Halcion | C<br>C<br>C | Oral<br>Oral<br>Oral | 5 Mg | Not Reported<br>Not Reported<br>Not Reported |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|-------------|----------------------|------|----------------------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Apr-2014              | 10073602      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000066334    |                      | 75 YR      | Female     | FRA            |

| <u>Preferred Term</u>  | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                             | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------|-------------------------------|--------------|------------|-------------|------------------------------------------|--------------------|-----------------|--------------|
| Coma; Drug Interaction | Escitalopram                  |              |            | S           | Oral                                     |                    |                 | Forest       |
|                        | Tercian                       |              |            | S           | Intravenous (not<br>otherwise specified) | 50 Mg/5 MI Daily   |                 | Not Reported |
|                        | Tercian                       |              |            | S           | Oral                                     | 2 Df               |                 | Not Reported |
|                        | Noctamide                     |              |            | S           | Oral                                     | 1 Df               |                 | Not Reported |
|                        | Valium                        |              |            | S           | Intravenous (not<br>otherwise specified) | 10 Mg/2 MI         |                 | Not Reported |
|                        | Anafranil                     |              |            | S           | Oral                                     | 1 Df               |                 | Not Reported |
|                        | Seresta                       |              |            | S           | Oral                                     | 30 Df              |                 | Not Reported |
|                        | Seresta                       |              |            | S           | Oral                                     | 100 Mg             |                 | Not Reported |
|                        | Mianserine                    |              |            | S           | Oral                                     | 1 Df               |                 | Not Reported |
|                        | Mianserine                    |              |            | S           | Oral                                     | 2 Df               |                 | Not Reported |
|                        | Lescol                        |              |            | C           |                                          |                    |                 | Not Reported |
|                        | Hydrochlorothiazide/Valsartan |              |            | C           |                                          | 80/12.5 Mg         |                 | Not Reported |
|                        | Lamaline                      |              |            | C           | Oral                                     | 1 Df               |                 | Not Reported |

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

(Acetaminophen\Caffeine\Opium  
)

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Apr-2014              | 10073604      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000066335    |                      | 16 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Conversion Disorder;<br>Product Use In<br>Unapproved Indication | Escitalopram   |              |            | S           | Oral         |                    |                 | Forest       |
|                                                                 | Escitalopram   |              |            | S           |              |                    |                 | Forest       |
|                                                                 | Escitalopram   |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                                                 | Escitalopram   |              |            | S           |              |                    |                 | Forest       |
|                                                                 | Alprazolam     |              |            | C           |              | 0.25 Mg            |                 | Not Reported |
|                                                                 | Alprazolam     |              |            | C           |              | 0.75 Mg            |                 | Not Reported |
|                                                                 | Alprazolam     |              |            | C           |              | 0.5 Mg             |                 | Not Reported |
|                                                                 | Alprazolam     |              |            | C           |              | 0.25 Mg            |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Apr-2014              | 10075405      | DIRECT           |                    | OT              |                      |                      | 49 YR      | Female     | USA            |

| <u>Preferred Term</u>                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Drug Withdrawal<br>Syndrome; Hyperhidrosis | Escitalopram   |              |            | S           | Oral         |                    | 1 MTH           | Cadista    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Apr-2014              | 10076549      | DIRECT           |                    | OT              |                      |                      | 56 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u> |
|-------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|------------|
| Abdominal Pain Upper;<br>Anxiety; Diarrhoea;<br>Feeling Abnormal;<br>Insomnia | Escitalopram   |              |            | S           | Oral         | 1, Once Daily, Taken By<br>Mouth |                 | Walmart    |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>            | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------|-----------------|--------------------|--------------------|-----------------|---------------------------------------|------------------------------------|-----------------|--------------|----------------|
| 11-Apr-2014                         | 10076559        | DIRECT             |                    | OT              |                                       |                                    | 16 YR           | Female       | USA            |
| <u>Preferred Term</u>               | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Mania; Product Substitution Issue   | Escitalopram    |                    |                    | S               | Oral                                  | 1 Pill, Once Daily, Taken By Mouth |                 | Forest       |                |
| <u>FDA Received Date</u>            | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Apr-2014                         | 8052948         | EXPEDITED (15-DAY) |                    | OT              | US-SANOFI-AVENTIS-2011SA046917        |                                    | 45 YR           | Male         | USA            |
| <u>Preferred Term</u>               | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Amnesia; Anger; Homicide | Zolpidem        |                    |                    | S               | Oral                                  |                                    |                 | Not Reported |                |
|                                     | Citalopram      |                    |                    | S               | Unknown                               |                                    |                 | Not Reported |                |
|                                     | Diphenhydramine |                    |                    | S               | Unknown                               |                                    |                 | Not Reported |                |
|                                     | Acetone         |                    |                    | S               | Unknown                               |                                    |                 | Not Reported |                |
|                                     | Caffeine        |                    |                    | S               | Unknown                               |                                    |                 | Not Reported |                |
|                                     | Lexapro         |                    |                    | S               | Unknown                               |                                    |                 | Not Reported |                |
|                                     | Xanax           |                    |                    | S               | Unknown                               |                                    |                 | Not Reported |                |
| <u>FDA Received Date</u>            | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Apr-2014                         | 10075095        | EXPEDITED (15-DAY) |                    | HO              | FR-ROCHE-1376533                      |                                    | 75 YR           | Female       | FRA            |
| <u>Preferred Term</u>               | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Coma; Drug Interaction              | Valium          |                    |                    | S               | Intravenous (not otherwise specified) |                                    |                 | Not Reported |                |
|                                     | Tercian         |                    |                    | S               | Intravenous (not otherwise specified) | 50mg/5ml                           |                 | Not Reported |                |
|                                     | Tercian         |                    |                    | S               | Oral                                  | 25mg                               |                 | Not Reported |                |
|                                     | Noctamide       |                    |                    | S               | Oral                                  | 2 Mg                               |                 | Not Reported |                |
|                                     | Anafranil       |                    |                    | S               | Oral                                  | 75mg                               |                 | Not Reported |                |



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

|                               |   |         |           |              |
|-------------------------------|---|---------|-----------|--------------|
| Seresta                       | S | Oral    | 50mg      | Not Reported |
| Mianserine                    | S | Oral    |           | Not Reported |
| Seroplex                      | S | Oral    |           | Not Reported |
| Lescol                        | C | Unknown |           | Not Reported |
| Hydrochlorothiazide/Valsartan | C | Unknown | 80/12.5mg | Not Reported |
| Xeroquel                      | C | Unknown |           | Not Reported |

| <u>FDA Received Date</u>                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|----------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 14-Apr-2014                                                    | 10075628       | EXPEDITED (15-DAY) |                    | OT              | IT-MYLANLABS-2014S1007973 |                      |                 | Unknown    | ITA            |
| <u>Preferred Term</u>                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Congenital Nose Malformation; Foetal Exposure During Pregnancy | Escitalopram   |                    |                    | S               | Transplacental            | 20 Mg/Day            |                 | Mylan      |                |

| <u>FDA Received Date</u>                                             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|----------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 14-Apr-2014                                                          | 10075634       | EXPEDITED (15-DAY) |                    | OT              | IT-MYLANLABS-2014S1007974 |                      |                 | Unknown    | ITA            |
| <u>Preferred Term</u>                                                | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Foetal Exposure During Pregnancy; Necrotising Enterocolitis Neonatal | Escitalopram   |                    |                    | S               | Transplacental            | 20 Mg/Day            |                 | Mylan      |                |

| <u>FDA Received Date</u>                                                                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|--------------------------|-----------------|--------------|----------------|
| 14-Apr-2014                                                                               | 10075958       | EXPEDITED (15-DAY) |                    | HO, LT          | FR-FRI-1000066377    |                          | 41 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Acute Respiratory Failure; Altered State Of Consciousness; Overdose; Pneumonia Aspiration | Escitalopram   |                    |                    | S               | Oral                 | Unknown Dose             |                 | Forest       |                |
|                                                                                           | Alprazolam     |                    |                    | S               | Oral                 | Overdose (Unknown Dose)  |                 | Not Reported |                |
|                                                                                           | Alcohol        |                    |                    | S               |                      | Overdose Of Unknown Dose |                 | Not Reported |                |

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

| <u>FDA Received Date</u>                                                    | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| 14-Apr-2014                                                                 | 10077311               | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000066463          |                      | 83 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                       | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cognitive Disorder; Drug Interaction; Hyponatraemia                         | Escitalopram           |                    |                    | S               | Oral                       | 5 Mg                 |                 | Forest       |                |
|                                                                             | Bipreterax             |                    |                    | S               | Oral                       | 5mg/ 1.25 Mg         |                 | Not Reported |                |
|                                                                             | Sectral                |                    |                    | C               | Oral                       | 100 Mg               |                 | Not Reported |                |
|                                                                             | Previscan (Fluindione) |                    |                    | C               | Oral                       | 25 Mg                |                 | Not Reported |                |
|                                                                             | Levothyrox             |                    |                    | C               | Oral                       | 125 Mcg              |                 | Not Reported |                |
|                                                                             | Exelon                 |                    |                    | C               | Transdermal                |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                    | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Apr-2014                                                                 | 10077612               | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000066379          |                      | 47 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                       | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Gamma-Glutamyltransferase Increased; Off Label Use; Transaminases Increased | Escitalopram           |                    |                    | S               | Oral                       |                      |                 | Forest       |                |
|                                                                             | Xeroquel               |                    |                    | S               | Oral                       | 300 Mg               |                 | Not Reported |                |
|                                                                             | Noctamide              |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                    | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Apr-2014                                                                 | 9818173                | EXPEDITED (15-DAY) |                    | HO              | FR-ASTRAZENECA-2014SE01550 |                      | 50 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                       | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Erythema Multiforme; Stevens-Johnson Syndrome; Toxic Skin Eruption          | Esomeprazole           |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                                             | Crestor                |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                                             | Seroplex               |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                                             | Primperan              |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                                             | Lyrica                 |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                                             | Oxynorm                |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |

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

|             |   |              |
|-------------|---|--------------|
| Kardegic    | C | Not Reported |
| Plavix      | C | Not Reported |
| Lovenox     | C | Not Reported |
| Metoprolol  | C | Not Reported |
| Insuline    | C | Not Reported |
| Hexaspray   | C | Not Reported |
| Hydroxyzine | C | Not Reported |
| Solumedrol  | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Apr-2014              | 10080114      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000066503    |                      | 32 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                | <u>Product</u>  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------|-----------------|--------------|------------|-------------|--------------|----------------------|-----------------|--------------|
| Coma; Intentional Overdose; Product Dispensing Error | Escitalopram    |              |            | S           | Oral         |                      |                 | Forest       |
|                                                      | Escitalopram    |              |            | S           | Oral         | Overdose: 11 Tablets |                 | Not Reported |
|                                                      | Methadone Ap Hp |              |            | S           | Oral         |                      |                 | Not Reported |
|                                                      | Methadone Ap Hp |              |            | S           | Oral         | Overdose: 3 Df       |                 | Not Reported |
|                                                      | Xanax           |              |            | S           | Oral         |                      |                 | Not Reported |
|                                                      | Xanax           |              |            | S           | Oral         | Overdose: Unknown    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Apr-2014              | 10081989      | DIRECT           | Y                  |                 |                      |                      | 58 YR      | Female     | USA            |

| <u>Preferred Term</u>                                      | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Product Substitution Issue; Therapeutic Response Decreased | Lexapro Generic 10mg |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Apr-2014              | 10173072      | NON-EXPEDITED    | Y                  | OT              | ALL1-2013-06454      |                      | 24 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u>                                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-----------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Seizure               | Vyvanse (Lisdexamfetamine Dimesylate) Capsule |              |            | S           | Oral         |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                                                                                      | Remeron                            |                    |                    | S               |                      |                                            |                 |              | Not Reported   |
|----------------------------------------------------------------------------------------------------------------------|------------------------------------|--------------------|--------------------|-----------------|----------------------|--------------------------------------------|-----------------|--------------|----------------|
|                                                                                                                      | Lexapro (Escitalopram Oxalate)     |                    |                    | S               |                      |                                            |                 |              | Not Reported   |
| <u>FDA Received Date</u>                                                                                             | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Apr-2014                                                                                                          | 10082250                           | EXPEDITED (15-DAY) |                    | HO              | PHHY2014FR044745     |                                            | 77 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Bradycardia;<br>Electrocardiogram Qt<br>Prolonged; Fall;<br>Hypokalaemia; Malaise                                    | Rasilez Hct                        |                    |                    | S               | Oral                 | 1 Df, Daily (Alis 300 Mg,<br>Hctz 12.5 Mg) |                 | Novartis     |                |
|                                                                                                                      | Domperidone                        |                    |                    | S               | Oral                 | Unk Unk, Prn                               |                 | Not Reported |                |
|                                                                                                                      | Cordarone                          |                    |                    | S               | Oral                 | 1 Df, Daily (200 Mg)                       |                 | Not Reported |                |
|                                                                                                                      | Seroplex                           |                    |                    | S               | Oral                 | 1 Df, Daily (10 Mg)                        |                 | Not Reported |                |
|                                                                                                                      | Xarelto                            |                    |                    | C               |                      | 15 Mg, Unk                                 |                 | Not Reported |                |
|                                                                                                                      | Levothyrox                         |                    |                    | C               |                      | Unk Unk, Unk                               |                 | Not Reported |                |
|                                                                                                                      | Modopar                            |                    |                    | C               |                      | Unk Unk, Unk                               |                 | Not Reported |                |
|                                                                                                                      | Inexium//Esomeprazole<br>Magnesium |                    |                    | C               |                      | 40 Mg, Unk                                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                             | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Apr-2014                                                                                                          | 8961684                            | EXPEDITED (15-DAY) |                    | HO              | JP-FRI-1000040992    |                                            | 41 YR           | Male         | JPN            |
| <u>Preferred Term</u>                                                                                                | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;<br>Electrocardiogram Qt<br>Prolonged; Listless;<br>Torsade De Pointes;<br>Ventricular Fibrillation | Lexapro                            |                    |                    | S               | Oral                 | 10 Mg                                      |                 | Forest       |                |
|                                                                                                                      | Lexapro                            |                    |                    | S               | Oral                 | 10 Mg                                      |                 | Forest       |                |
|                                                                                                                      | Takepron                           |                    |                    | S               | Oral                 | 15 Mg                                      |                 | Not Reported |                |
|                                                                                                                      | Lamictal                           |                    |                    | C               | Oral                 | 100 Mg                                     |                 | Not Reported |                |
|                                                                                                                      | Landsen                            |                    |                    | C               | Oral                 | 0.5 Mg                                     |                 | Not Reported |                |
|                                                                                                                      | Rivotril                           |                    |                    | C               | Oral                 | 0.5 Mg                                     |                 | Not Reported |                |
|                                                                                                                      | Plavix                             |                    |                    | C               | Oral                 | 75 Mg                                      |                 | Not Reported |                |
|                                                                                                                      | Bayaspirin                         |                    |                    | C               | Oral                 | 100 Mg                                     |                 | Not Reported |                |
|                                                                                                                      | Crestor                            |                    |                    | C               | Oral                 | 2.5 Mg                                     |                 | Not Reported |                |

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|                 |   |                  |        |              |
|-----------------|---|------------------|--------|--------------|
| Nicorandis      | C | Oral             | 15 Mg  | Not Reported |
| Magnesium Oxide | C | Oral             | 1.5 G  | Not Reported |
| Solita-T No.1   | C | Intravenous drip | 500 MI | Not Reported |
| Heparin Sodium  | C | Intravenous drip | 12 Ku  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Apr-2014              | 10084580      | EXPEDITED (15-DAY) |                    | OT              | US-FRI-1000066405    |                      | 19 YR      | Male       | USA            |

| <u>Preferred Term</u>                                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hepatic Enzyme Increased; Hepatic Mass; Hepatic Steatosis | Lexapro        |              |            | S           | Oral         | 20 Mg              |                 | Forest       |
|                                                           | Cymbalta       |              |            | C           | Oral         | 60 Mg              |                 | Not Reported |
|                                                           | Latuda         |              |            | C           | Oral         | 40 Mg              |                 | Not Reported |
|                                                           | Topiramate     |              |            | C           | Oral         | 50 Mg              |                 | Not Reported |
|                                                           | Quetiapine     |              |            | C           | Oral         | 50 Mg              |                 | Not Reported |
|                                                           | Benzotropine   |              |            | C           | Oral         | 1 Mg               |                 | Not Reported |
|                                                           | Vitamin D3     |              |            | C           |              |                    |                 | Not Reported |
|                                                           | Skelaxin       |              |            | C           | Oral         | 100 Mg             |                 | Not Reported |
|                                                           | Astepro        |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Apr-2014              | 10089833      | EXPEDITED (15-DAY) | Y                  | HO, OT          | NSR_01541_2014       |                      | 48 YR      | Female     | CAN            |

| <u>Preferred Term</u>                                                                                               | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------|-----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Glucose Increased; Blood Pressure Systolic Decreased; Overdose; Toxicity To Various Agents; Treatment Failure | Propranolol (Propranolol)   |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                     | Clonidine (Clonidine)       |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                     | Escitalopram (Escitalopram) |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                     | Lorazepam (Lorazepam)       |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                     | Atorvastatin (Atorvastatin) |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                     | Quetiapine (Quetiapine)     |              |            | S           | Oral         |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                    | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                                                                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|------------------------------------------------------------------------------------------|-----------------|--------------|----------------|
| 18-Apr-2014                                                                                 | 9760468                 | EXPEDITED (15-DAY) |                    | DE, OT          | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>19885235 |                                                                                          | 19 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                       | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                                                       | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Depression; Diplopia;<br>Disturbance In Attention;<br>Insomnia; Mania | Abilify                 |                    |                    | S               | Oral                                            | 1/2 Tab. 12feb2013: 1mg.<br>14feb2013: 2mg.<br>26feb2013: 5mg.<br>04mar2013: 5mg 1/2 Tab |                 | Not Reported |                |
|                                                                                             | Lexapro                 |                    |                    | S               |                                                 |                                                                                          |                 | Not Reported |                |
|                                                                                             | Topamax                 |                    |                    | C               |                                                 |                                                                                          |                 | Not Reported |                |
|                                                                                             | Risperdal               |                    |                    | C               |                                                 |                                                                                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                    | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                                                                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Apr-2014                                                                                 | 9964120                 | EXPEDITED (15-DAY) |                    | HO, OT          | PHHY2014BR026048                                |                                                                                          | 86 YR           | Female       | BRA            |
| <u>Preferred Term</u>                                                                       | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                                                       | <u>Duration</u> | <u>Mfr</u>   |                |
| Aphonia; Drug Ineffective;<br>Pneumonia; Urinary Tract<br>Infection                         | Exelon Patch            |                    |                    | S               | Transdermal                                     | 1 Df, Daily                                                                              |                 | Novartis     |                |
|                                                                                             | Fluoxetine              |                    |                    | S               |                                                 | 1 Df, Daily                                                                              |                 | Not Reported |                |
|                                                                                             | Lexapro                 |                    |                    | S               |                                                 | 10 Drops                                                                                 |                 | Not Reported |                |
|                                                                                             | Pantocal                |                    |                    | C               |                                                 | Once A Day                                                                               |                 | Not Reported |                |
|                                                                                             | Verapamil Hydrochloride |                    |                    | C               |                                                 | Once A Day                                                                               |                 | Not Reported |                |
|                                                                                             | Vitamiin C              |                    |                    | C               |                                                 | Once A Day                                                                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                    | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                                                                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Apr-2014                                                                                 | 10086542                | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000066608                               |                                                                                          | 86 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                       | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                                                       | <u>Duration</u> | <u>Mfr</u>   |                |
| Cerebral Haematoma                                                                          | Escitalopram            |                    |                    | S               | Oral                                            |                                                                                          |                 | Forest       |                |
|                                                                                             | Previscan (Fluindione)  |                    |                    | S               | Oral                                            |                                                                                          |                 | Not Reported |                |
|                                                                                             | Sectral                 |                    |                    | C               |                                                 |                                                                                          |                 | Not Reported |                |
|                                                                                             | Esomeprazole            |                    |                    | C               |                                                 |                                                                                          |                 | Not Reported |                |

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

|                                                                                             | Melaxose       |                  |                    | C               |                              |                      |                 |              | Not Reported   |
|---------------------------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
|                                                                                             | Ketum          |                  |                    | C               |                              |                      |                 |              | Not Reported   |
|                                                                                             | Lexomil        |                  |                    | C               |                              |                      |                 |              | Not Reported   |
| <u>FDA Received Date</u>                                                                    | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Apr-2014                                                                                 | 10089040       | DIRECT           |                    | OT              |                              |                      | 71 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                       | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Contusion; Diarrhoea;<br>Disorientation; Dizziness;<br>Fall; Headache; Nausea;<br>Nightmare | Lexapro        |                  |                    | S               | Oral                         | 1 Pill               | 1 DAY           | Not Reported |                |
|                                                                                             | Prazosin       |                  |                    | C               |                              |                      |                 | Not Reported |                |
|                                                                                             | Aspirin        |                  |                    | C               |                              |                      |                 | Not Reported |                |
|                                                                                             | Zocor          |                  |                    | C               |                              |                      |                 | Not Reported |                |
|                                                                                             | Multi-Vitamin  |                  |                    | C               |                              |                      |                 | Not Reported |                |
|                                                                                             | Vitamin D3     |                  |                    | C               |                              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                    | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Apr-2014                                                                                 | 10089107       | DIRECT           |                    | OT              |                              |                      | 26 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                       | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Product Counterfeit;<br>Seizure                                                             | Lexapro        |                  |                    | S               | Oral                         | 1                    |                 | Apotex       |                |
| <u>FDA Received Date</u>                                                                    | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Apr-2014                                                                                 | 10089498       | DIRECT           |                    | OT              |                              |                      | 53 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                       | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated;<br>Product Substitution Issue                                         | Lexapro        |                  |                    | S               | Oral                         |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                    | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Apr-2014                                                                                 | 9978173        | NON-EXPEDITED    |                    | OT              | US-PFIZER INC-<br>2014065074 |                      | 84 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                       | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity;                                                                      | Zoloft         |                  |                    | S               |                              | Unk                  |                 | Pfizer       |                |

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|                   |          |   |     |              |
|-------------------|----------|---|-----|--------------|
| Urinary Retention | Lexapro  | S | Unk | Not Reported |
|                   | Requip   | S | Unk | Not Reported |
|                   | Cymbalta | S | Unk | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Apr-2014              | 10080456      | EXPEDITED (15-DAY) |                    | OT              | CA-ROCHE-1369728     |                      | 58 YR      | Male       | CAN            |

| <u>Preferred Term</u>                                                                                                          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                             | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|------------------------------------------|--------------------|-----------------|--------------|
| Abdominal Pain;<br>Accidental Overdose;<br>Asthenia; Dizziness;<br>Dyspnoea; Faeces Soft;<br>Malignant Neoplasm<br>Progression | Avastin        |              |            | S           | Intravenous (not<br>otherwise specified) |                    |                 | Not Reported |
|                                                                                                                                | Avastin        |              |            | S           | Intravenous (not<br>otherwise specified) |                    |                 | Not Reported |
|                                                                                                                                | Crestor        |              |            | S           | Unknown                                  |                    |                 | Not Reported |
|                                                                                                                                | Frisium        |              |            | S           | Unknown                                  |                    |                 | Not Reported |
|                                                                                                                                | Trazodone      |              |            | S           | Unknown                                  |                    |                 | Not Reported |
|                                                                                                                                | Cipralex       |              |            | S           | Unknown                                  |                    |                 | Not Reported |
|                                                                                                                                | Avodart        |              |            | C           | Unknown                                  |                    |                 | Not Reported |
|                                                                                                                                | Keppra         |              |            | C           |                                          |                    |                 | Not Reported |
|                                                                                                                                | Pantoprazole   |              |            | C           |                                          |                    |                 | Not Reported |
|                                                                                                                                | Decadron       |              |            | C           |                                          |                    |                 | Not Reported |
|                                                                                                                                | Docusate       |              |            | C           |                                          |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Apr-2014              | 10090593      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000066612    |                      | 61 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Coma                  | Escitalopram   |              |            | S           |              |                    |                 | Forest       |
|                       | Lexomil Roche  |              |            | S           | Oral         | 6 Mg               |                 | Not Reported |
|                       | Stablon        |              |            | S           |              |                    |                 | Not Reported |
|                       | Euphytose      |              |            | S           |              |                    |                 | Not Reported |



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

| <a href="#">FDA Received Date</a>                                                                                                               | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>     | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-----------------------------------|--------------------------|---------------------|-------------------------|
| 21-Apr-2014                                                                                                                                     | 10094453                | DIRECT                    |                             |                          |                               |                                   | 37 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                                                                                  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>       | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Therapeutic Response Unexpected                                                                                                                 | Lexapro Generic 10mg    |                           |                             | S                        | Oral                          | 10 Mg, At Bedtime, Taken By Mouth |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                                               | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>     | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 21-Apr-2014                                                                                                                                     | 10098443                | EXPEDITED (15-DAY)        | Y                           | OT                       | 2014HINLIT0363                |                                   |                          | Unknown             | ITA                     |
| <a href="#">Preferred Term</a>                                                                                                                  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>       | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Necrotising Colitis                                                                                                                             | Escitalopram            |                           |                             | S                        | Transplacental                |                                   |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                                               | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>     | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 21-Apr-2014                                                                                                                                     | 10098463                | EXPEDITED (15-DAY)        | Y                           | CA, OT                   | 2014HINLIT0364                |                                   |                          | Unknown             | ITA                     |
| <a href="#">Preferred Term</a>                                                                                                                  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>       | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Congenital Nose Malformation; Maternal Drugs Affecting Foetus                                                                                   | Escitalopram            |                           |                             | S                        | Transplacental                |                                   |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                                               | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>     | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 22-Apr-2014                                                                                                                                     | 9689535                 | EXPEDITED (15-DAY)        |                             | OT                       | PHHY2013IT128638              |                                   |                          | Unknown             | ITA                     |
| <a href="#">Preferred Term</a>                                                                                                                  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>       | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Hypoglycaemia; Hyporeflexia; Hypotonia; Lethargy; Slow Response To Stimuli | Paroxetine              |                           |                             | S                        | Transplacental                | Maternal Dose: 20-40 Mg Daily     |                          | Novartis            |                         |
|                                                                                                                                                 | Clonazepam              |                           |                             | S                        | Transplacental                | Maternal Dose: 0.5 Mg Daily       |                          | Not Reported        |                         |
|                                                                                                                                                 | Escitalopram            |                           |                             | S                        | Transplacental                | Maternal Dose: 10 Mg Daily        |                          | Not Reported        |                         |

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|                                                                                   |                   |                    |                    |                 |                          |                               |                           |              |                |
|-----------------------------------------------------------------------------------|-------------------|--------------------|--------------------|-----------------|--------------------------|-------------------------------|---------------------------|--------------|----------------|
| Lorazepam                                                                         |                   |                    | S                  |                 | Transplacental           |                               | Maternal Dose: 1 Mg Daily |              | Not Reported   |
| <u>FDA Received Date</u>                                                          | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>          | <u>Age</u>                | <u>Sex</u>   | <u>Country</u> |
| 22-Apr-2014                                                                       | 9907251           | EXPEDITED (15-DAY) |                    | HO              | IT-FRI-1000054291        |                               | 34 YR                     | Female       | ITA            |
| <u>Preferred Term</u>                                                             | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>            | <u>Duration</u>           | <u>Mfr</u>   |                |
| Drug Abuse; Nausea; Overdose; Sopor                                               | Escitalopram      |                    |                    | S               | Oral                     | Overdose: 280 Mg              |                           | Forest       |                |
|                                                                                   | Valeriana Alfa    |                    |                    | S               | Oral                     | Overdose: 3000 Mg             |                           | Not Reported |                |
| <u>FDA Received Date</u>                                                          | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>          | <u>Age</u>                | <u>Sex</u>   | <u>Country</u> |
| 22-Apr-2014                                                                       | 10094049          | EXPEDITED (15-DAY) |                    | HO              | FR-PFIZER INC-2014110315 |                               | 77 YR                     | Female       | FRA            |
| <u>Preferred Term</u>                                                             | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>            | <u>Duration</u>           | <u>Mfr</u>   |                |
| Bradycardia; Electrocardiogram Qt Prolonged; Fall; Hypokalaemia; Malaise; Vertigo | Cordarone         |                    |                    | S               | Oral                     | 200 Mg (1 Tablet), Once Daily |                           | Pfizer       |                |
|                                                                                   | Domperidone       |                    |                    | S               | Oral                     | Unk, As Needed                |                           | Not Reported |                |
|                                                                                   | Seroplex          |                    |                    | S               | Oral                     | 1 Df, Once Daily              |                           | Not Reported |                |
|                                                                                   | Rasilez Hct       |                    |                    | S               | Oral                     | 1 Df, Once Daily              |                           | Not Reported |                |
|                                                                                   | Xarelto           |                    |                    | C               |                          |                               |                           | Not Reported |                |
|                                                                                   | Levothyrox        |                    |                    | C               |                          |                               |                           | Not Reported |                |
|                                                                                   | Modopar           |                    |                    | C               |                          |                               |                           | Not Reported |                |
|                                                                                   | Inexium           |                    |                    | C               |                          |                               |                           | Not Reported |                |
|                                                                                   | Vit K Antagonists |                    |                    | C               |                          |                               |                           | Not Reported |                |
| <u>FDA Received Date</u>                                                          | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>          | <u>Age</u>                | <u>Sex</u>   | <u>Country</u> |
| 22-Apr-2014                                                                       | 10094624          | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2014110073 |                               |                           | Female       | USA            |
| <u>Preferred Term</u>                                                             | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>            | <u>Duration</u>           | <u>Mfr</u>   |                |
| Drug Hypersensitivity                                                             | Lyrica            |                    |                    | S               |                          | Unk                           |                           | Pfizer       |                |
|                                                                                   | Neurontin         |                    |                    | S               |                          | Unk                           |                           | Pfizer       |                |
|                                                                                   | Relpax            |                    |                    | S               |                          | Unk                           |                           | Pfizer       |                |
|                                                                                   | Diclofenac Sodium |                    |                    | S               |                          | Unk                           |                           | Pfizer       |                |

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|  |           |   |     |              |
|--|-----------|---|-----|--------------|
|  | Celexa    | S | Unk | Not Reported |
|  | Imitrex   | S | Unk | Not Reported |
|  | Keppra    | S | Unk | Not Reported |
|  | Lexapro   | S | Unk | Not Reported |
|  | Reglan    | S | Unk | Not Reported |
|  | Restoril  | S | Unk | Not Reported |
|  | Synthroid | S | Unk | Not Reported |

| <u>FDA Received Date</u>    | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 22-Apr-2014                 | 10094856       | EXPEDITED (15-DAY) |                    | DS              | US-FRI-1000066625    |                      |                 | Male         | USA            |
| <u>Preferred Term</u>       | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Jaundice; Learning Disorder | Lexapro        |                    |                    | S               | Transplacental       |                      |                 | Forest       |                |
|                             | Lovenox        |                    |                    | C               | Transplacental       |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 22-Apr-2014                                                                                               | 10096705       | EXPEDITED (15-DAY) |                    | OT              | PHHY2014IT042289     |                      | 37 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                                                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Disease Recurrence; Generalised Anxiety Disorder; Maternal Exposure During Pregnancy; Prolonged Pregnancy | Escitalopram   |                    |                    | S               |                      | 20 Mg, Unk           |                 | Not Reported |                |
|                                                                                                           | Alprazolam     |                    |                    | S               |                      | 1.25 Mg, Unk         |                 | Novartis     |                |

| <u>FDA Received Date</u>                                | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|--------------------------|-----------------|--------------|----------------|
| 22-Apr-2014                                             | 10096714       | EXPEDITED (15-DAY) |                    | CA              | PHHY2014IT042322     |                          |                 | Unknown      | ITA            |
| <u>Preferred Term</u>                                   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Foetal Exposure During Pregnancy; Low Birth Weight Baby | Escitalopram   |                    |                    | S               | Transplacental       | Maternal Dose: 10 Mg/Day |                 | Not Reported |                |
|                                                         | Alprazolam     |                    |                    | S               |                      | Maternal Dose: 0.25      |                 | Novartis     |                |

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| Mg/Kg                                                                                                                |                       |                    |                    |                 |                      |                                            |                 |              |                |
|----------------------------------------------------------------------------------------------------------------------|-----------------------|--------------------|--------------------|-----------------|----------------------|--------------------------------------------|-----------------|--------------|----------------|
| <u>FDA Received Date</u>                                                                                             | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Apr-2014                                                                                                          | 10097122              | EXPEDITED (15-DAY) |                    | OT              | CA-FRI-1000066736    |                                            | 23 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                                                                                | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Alopecia Totalis; Self Esteem Decreased                                                                              | Escitalopram          |                    |                    | S               | Oral                 | 20 Mg                                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                             | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Apr-2014                                                                                                          | 10098603              | DIRECT             | Y                  |                 |                      |                                            | 17 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Anxiety; Depression; Irritability; Product Substitution Issue                                             | Escitalopram          |                    |                    | S               | Oral                 |                                            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                             | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Apr-2014                                                                                                          | 10099926              | DIRECT             |                    |                 |                      |                                            | 35 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Drug Withdrawal Syndrome; Impaired Work Ability; Nausea; Tremor; Wrong Technique In Product Usage Process | Lexapro               |                    |                    | S               | Oral                 | 10mg At Bedtime Taken By Mouth             | 3 YR            | Not Reported |                |
| <u>FDA Received Date</u>                                                                                             | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Apr-2014                                                                                                          | 10101644              | EXPEDITED (15-DAY) | Y                  | HO              | IMP_07560_2014       |                                            | 48 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                                                                                | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Glucose Increased; Blood Ph Decreased;                                                                         | Clonidine (Clonidine) |                    |                    | S               |                      | (2.8 Mg, Once [Not The Prescribed Amount]) | 1 DAY           | Not Reported |                |

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|                                                                                              |                                                          |   |                                             |       |              |
|----------------------------------------------------------------------------------------------|----------------------------------------------------------|---|---------------------------------------------|-------|--------------|
| Blood Pressure Systolic Decreased; Coma Scale Abnormal; Overdose; Toxicity To Various Agents | Propranolol (Propranolol)                                | S | (1120 Mg, Once [Not The Prescribed Amount]) | 1 DAY | Not Reported |
|                                                                                              | Escitalopram (Escitalopram)                              | S | (400 Mg, Once [Not The Prescribed Amount])  | 1 DAY | Not Reported |
|                                                                                              | Lorazepam (Lorazepam)                                    | S | 928 Mg, Once [Not The Prescribed Amount])   | 1 DAY | Not Reported |
|                                                                                              | Atorvastatine /01326101/ (Atorvastatine) (Not Specified) | S | (560 Mg, Once [Not The Prescribed Amount])  | 1 DAY | Not Reported |
|                                                                                              | Quetiapine (Quetiapine)                                  | S | (5600 Mg, Once [Not The Prescribed Amount]) | 1 DAY | Not Reported |

| <u>FDA Received Date</u>                                    | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 23-Apr-2014                                                 | 9748558        | EXPEDITED (15-DAY) |                    | OT              | CH-FRI-1000052184    |                      | 1 DAY           | Female       | CHE            |
| <u>Preferred Term</u>                                       | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Foetal Exposure During Pregnancy; Foetal Growth Restriction | Escitalopram   |                    |                    | S               | Transplacental       | 5 Mg                 |                 | Forest       |                |
|                                                             | Escitalopram   |                    |                    | S               | Oral                 | 10 Mg                |                 | Not Reported |                |
|                                                             | Abilify        |                    |                    | S               | Transplacental       | 10 Mg                |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u>                         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|-------------------------|----------------------------------------------|-----------------|--------------|----------------|
| 23-Apr-2014                                                                                                                                      | 9903768        | EXPEDITED (15-DAY) |                    | OT              | IT-RANBAXY-2013RR-75219 |                                              |                 | Unknown      | ITA            |
| <u>Preferred Term</u>                                                                                                                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>                           | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Hypoglycaemia; Hyporeflexia; Hyporesponsive To Stimuli; Hypotonia; Lethargy | Cipralex       |                    |                    | S               | Transplacental          | 10 Mg/Day, During 0-16 Gestational Weeks     |                 | Not Reported |                |
|                                                                                                                                                  | Sereupin       |                    |                    | S               | Transplacental          | 20-40 Mg/Day, During 16-38 Gestational Weeks |                 | Not Reported |                |
|                                                                                                                                                  | Rivotril       |                    |                    | S               | Transplacental          | 0.5 Mg/Day, During 0-11 Gestational Weeks    |                 | Not Reported |                |
|                                                                                                                                                  | Lorazepam      |                    |                    | S               | Transplacental          | 1 Mg/Day, During 12-38 Gestational Weeks     |                 | Ranbaxy      |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>             | <u>Case #</u>    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------|------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| 23-Apr-2014                          | 10016464         | NON-EXPEDITED      |                    | OT              | CH-FRI-1000052183            |                      | 33 YR           | Female       | CHE            |
| <u>Preferred Term</u>                | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Oligohydramnios;<br>Pregnancy        | Escitalopram     |                    |                    | S               | Oral                         | 5 Mg                 |                 | Forest       |                |
|                                      | Escitalopram     |                    |                    | S               | Oral                         | 10 Mg                |                 | Not Reported |                |
|                                      | Abilify          |                    |                    | S               | Oral                         | 10 Mg                |                 | Not Reported |                |
| <u>FDA Received Date</u>             | <u>Case #</u>    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Apr-2014                          | 10098482         | NON-EXPEDITED      |                    |                 | US-PFIZER INC-<br>2014111166 |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity                | Geodon           |                    |                    | S               |                              | Unk                  |                 | Pfizer       |                |
|                                      | Morphine Sulfate |                    |                    | S               |                              | Unk                  |                 | Pfizer       |                |
|                                      | Creon            |                    |                    | S               |                              | Unk                  |                 | Not Reported |                |
|                                      | Seroquel         |                    |                    | S               |                              | Unk                  |                 | Not Reported |                |
|                                      | Tegretol         |                    |                    | S               |                              | Unk                  |                 | Not Reported |                |
|                                      | Abilify          |                    |                    | S               |                              | Unk                  |                 | Not Reported |                |
|                                      | Lexapro          |                    |                    | S               |                              | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>             | <u>Case #</u>    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Apr-2014                          | 10041915         | EXPEDITED (15-DAY) |                    | DE              | US-FRI-1000065785            |                      | 60 YR           | Male         | USA            |
| <u>Preferred Term</u>                | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Gun<br>Shot Wound | Viibryd          |                    |                    | S               | Oral                         | 10 Mg                |                 | Forest       |                |
|                                      | Viibryd          |                    |                    | S               | Oral                         | 20 Mg                |                 | Forest       |                |
|                                      | Viibryd          |                    |                    | S               | Oral                         | 40 Mg                |                 | Not Reported |                |
|                                      | Lexapro          |                    |                    | S               |                              | 10 Mg                |                 | Forest       |                |
|                                      | Seroquel Xr      |                    |                    | C               |                              | 50 Mg Qhs            |                 | Not Reported |                |

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|          |   |              |              |
|----------|---|--------------|--------------|
| Xanax    | C | 0.5 Mg       | Not Reported |
| Crestor  | C |              | Not Reported |
| Seroquel | C | 50 Mg Qhs    | Not Reported |
| Seroquel | C | 100 Mg Qhs   | Not Reported |
| Ambien   | C | 12.5 Mg      | Not Reported |
| Ambien   | C | 12.5 Mg      | Not Reported |
| Halcion  | C | 0.25 Mg Qhs  | Not Reported |
| Xanax Xr | C | 3 Mg         | Not Reported |
| Zyprexa  | C | 10 Mg        | Not Reported |
| Silenor  | C | 1 Tablet Qhs | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Apr-2014              | 10101988      | EXPEDITED (15-DAY) |                    | HO, LT          | FR-FRI-1000066767    |                      | 63 YR      | Male       | FRA            |

| <u>Preferred Term</u>                             | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anaemia; Gastrointestinal<br>Haemorrhage; Melaena | Escitalopram        |              |            | S           | Oral         | 1 Df               |                 | Forest       |
|                                                   | Coumadine           |              |            | S           | Oral         | 1.5 Df             |                 | Not Reported |
|                                                   | Lasilix             |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                   | Perindopril         |              |            | C           |              |                    |                 | Not Reported |
|                                                   | Bisoprolol Fumarate |              |            | C           |              |                    |                 | Not Reported |
|                                                   | Foradil             |              |            | C           |              |                    |                 | Not Reported |
|                                                   | Tardyferon          |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Apr-2014              | 10103707      | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000066768    |                      | 55 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Creatine<br>Phosphokinase Increased;<br>Myalgia; Overdose | Escitalopram   |              |            | S           | Oral         | 20 Mg              |                 | Forest       |
|                                                                 | Escitalopram   |              |            | S           | Oral         | 40 Mg              |                 | Forest       |
|                                                                 | Escitalopram   |              |            | S           | Oral         | 60 Mg              |                 | Not Reported |
|                                                                 | Levothyrox     |              |            | C           | Oral         | 0.5 Df             |                 | Not Reported |

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|                                                                                              |                                |                    |                    |                 |                          |                                 |                 |            |                                        |  |
|----------------------------------------------------------------------------------------------|--------------------------------|--------------------|--------------------|-----------------|--------------------------|---------------------------------|-----------------|------------|----------------------------------------|--|
| Tranxene                                                                                     |                                |                    | C                  |                 |                          | 10 To 15 Mg                     |                 |            | Not Reported                           |  |
| <u>FDA Received Date</u>                                                                     | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u> | <u>Country</u>                         |  |
| 24-Apr-2014                                                                                  | 10111066                       | DIRECT             | Y                  |                 |                          |                                 | 31 YR           | Female     | USA                                    |  |
| <u>Preferred Term</u>                                                                        | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u> |                                        |  |
| Anxiety; Condition Aggravated; Depression; Drug Ineffective                                  | Escitalopram                   |                    |                    | S               | Oral                     | 1 Tab                           |                 |            | Not Reported                           |  |
| <u>FDA Received Date</u>                                                                     | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u> | <u>Country</u>                         |  |
| 24-Apr-2014                                                                                  | 10128999                       | DIRECT             | Y                  |                 |                          |                                 | 31 YR           | Female     | USA                                    |  |
| <u>Preferred Term</u>                                                                        | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u> |                                        |  |
| Depression; Drug Ineffective; Product Substitution Issue                                     | Escitalopram                   |                    |                    | S               | Oral                     | 1 Tab                           |                 |            | Not Reported                           |  |
| <u>FDA Received Date</u>                                                                     | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u> | <u>Country</u>                         |  |
| 25-Apr-2014                                                                                  | 9935070                        | EXPEDITED (15-DAY) |                    | HO              | IT-PFIZER INC-2014058009 |                                 | 61 YR           | Female     | ITA                                    |  |
| <u>Preferred Term</u>                                                                        | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u> |                                        |  |
| Drug Abuse; Mydriasis; Sopor; Unresponsive To Stimuli                                        | Alprazolam<br>Ciprallex        |                    |                    | S<br>S          | Oral<br>Oral             | 1 Df, Single<br>80 Mg, Unk      |                 |            | Pfizer<br>Not Reported                 |  |
| <u>FDA Received Date</u>                                                                     | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u> | <u>Country</u>                         |  |
| 25-Apr-2014                                                                                  | 10119316                       | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2014110807 |                                 | 47 YR           | Female     | USA                                    |  |
| <u>Preferred Term</u>                                                                        | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u> |                                        |  |
| Asthenia; Diarrhoea; Hypervigilance; Immune System Disorder; Malaise; Nausea; Off Label Use; | Celebrex<br>Lexapro<br>Omega-3 |                    |                    | S<br>S<br>C     | <br>Oral                 | Unk<br>10 Mg, (1 In 1 D)<br>Unk |                 |            | Pfizer<br>Not Reported<br>Not Reported |  |



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Vertigo; Vomiting

| <u>FDA Received Date</u>                                                                        | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>                      | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|-------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|------------------------------------------|-------------------------------------------|-----------------|----------------------|----------------|
| 25-Apr-2014                                                                                     | 10130316                | DIRECT             |                    | DS, LT, OT      |                                          |                                           | 13 YR           | Female               | USA            |
| <u>Preferred Term</u>                                                                           | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>                        | <u>Duration</u> | <u>Mfr</u>           |                |
| Attention Deficit/Hyperactivity Disorder; Dental Caries; Educational Problem; Gingival Disorder | Lexapro                 |                    |                    | S               |                                          | 20mgs Daily, Once Daily, Taken With Water |                 | Forest               |                |
| <u>FDA Received Date</u>                                                                        | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>                      | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 28-Apr-2014                                                                                     | 10016313                | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2014075488                 |                                           |                 | Female               | USA            |
| <u>Preferred Term</u>                                                                           | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>                        | <u>Duration</u> | <u>Mfr</u>           |                |
| Drug Hypersensitivity                                                                           | Zoloft                  |                    |                    | S               | Oral                                     | Unk                                       |                 | Pfizer               |                |
|                                                                                                 | Reglan                  |                    |                    | S               | Oral                                     | Unk                                       |                 | Not Reported         |                |
|                                                                                                 | Lexapro                 |                    |                    | S               | Oral                                     | Unk                                       |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                                        | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>                      | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 28-Apr-2014                                                                                     | 10128419                | EXPEDITED (15-DAY) |                    | HO, LT          | FR-BRISTOL-MYERS SQUIBB COMPANY-20654596 |                                           | 63 YR           | Male                 | FRA            |
| <u>Preferred Term</u>                                                                           | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>                        | <u>Duration</u> | <u>Mfr</u>           |                |
| Acute Kidney Injury; Anaemia; Gastrointestinal Haemorrhage                                      | Coumadin Tabs 2 Mg      |                    |                    | S               | Oral                                     | 1 Df:1.5 Tablet Unit Nos                  |                 | Bristol Myers Squibb |                |
|                                                                                                 | Seroplex                |                    |                    | S               | Oral                                     | Scored Film-Coated Tablet                 |                 | Not Reported         |                |
|                                                                                                 | Lasilix                 |                    |                    | C               |                                          | Scored Tablet                             |                 | Not Reported         |                |
|                                                                                                 | Perindopril             |                    |                    | C               |                                          |                                           |                 | Not Reported         |                |
|                                                                                                 | Bisoprolol Hemifumarate |                    |                    | C               |                                          |                                           |                 | Not Reported         |                |
|                                                                                                 | Foradil                 |                    |                    | C               |                                          |                                           |                 | Not Reported         |                |
|                                                                                                 | Tardyferon              |                    |                    | C               |                                          |                                           |                 | Not Reported         |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 28-Apr-2014                                                                                                    | 10130063       | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2014112297 |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity                                                                                          | Doxepin Hcl    |                    |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                                                                                                                | Zoloft         |                    |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                                                                                                                | Lexapro        |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Apr-2014                                                                                                    | 10137423       | DIRECT             |                    |                 |                          |                      | 41 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Disease Recurrence; Product Substitution Issue                                                        | Escitalopram   |                    |                    | S               | Oral                     |                      |                 | Accord       |                |
| <u>FDA Received Date</u>                                                                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Apr-2014                                                                                                    | 10138710       | EXPEDITED (15-DAY) |                    | HO, LT          | IT-FRI-1000066854        |                      | 45 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Overdose; Loss Of Consciousness; Respiratory Arrest                                                | Escitalopram   |                    |                    | S               | Oral                     | Overdose: 480 Mg     |                 | Forest       |                |
|                                                                                                                | Furosemide     |                    |                    | S               | Oral                     | Overdose: 750 Mg     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Apr-2014                                                                                                    | 10140139       | EXPEDITED (15-DAY) |                    | HO, LT, OT      | FR-PFIZER INC-2014113357 |                      | 85 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardio-Respiratory Arrest; Electrocardiogram Qt Prolonged; Fall; Hypokalaemia; Torsade De Pointes; Ventricular | Xanax          |                    |                    | S               | Oral                     | 0.5 Mg, 1x/Day       |                 | Pfizer       |                |
|                                                                                                                | Seroplex       |                    |                    | S               | Oral                     | 10 Mg, 1x/Day        |                 | Not Reported |                |
|                                                                                                                | Plavix         |                    |                    | C               |                          | Unk                  |                 | Not Reported |                |

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

|              |                      |   |     |              |
|--------------|----------------------|---|-----|--------------|
| Fibrillation | Stagid               | C | Unk | Not Reported |
|              | Pritor (Telmisartan) | C | Unk | Not Reported |
|              | Aricept              | C | Unk | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Apr-2014              | 10062252      | EXPEDITED (15-DAY) |                    | LT              | JP-FRI-1000066194    |                      | 52 YR      | Female     | JPN            |

| <u>Preferred Term</u>                                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Aggression; Altered State<br>Of Consciousness;<br>Suicide Attempt | Lexapro        |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                                                   | Limas          |              |            | C           | Oral         | 300 Mg             |                 | Not Reported |
|                                                                   | Solanax        |              |            | C           | Oral         | 1.2 Mg             |                 | Not Reported |
|                                                                   | Etizolam       |              |            | C           | Oral         | 1 Mg               |                 | Not Reported |
|                                                                   | Brotizolam Od  |              |            | C           | Oral         | 0.25 Mg            |                 | Not Reported |
|                                                                   | Flunitrazepam  |              |            | C           | Oral         | 2 Mg               |                 | Not Reported |
|                                                                   | Phenobal       |              |            | C           | Oral         | 30 Mg              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Apr-2014              | 10143378      | EXPEDITED (15-DAY) |                    | HO, OT          | CA-FRI-1000066881    |                      | 197 DAY    | Female     | CAN            |

| <u>Preferred Term</u>                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction; Tonic<br>Convulsion; Vomiting | Escitalopram   |              |            | S           | Transmammary | 10 Mg              |                 | Forest       |
|                                                 | Bupropion XI   |              |            | S           | Transmammary | 150 Mg             |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>        | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------------|----------------------|------------|------------|----------------|
| 30-Apr-2014              | 10143443      | EXPEDITED (15-DAY) |                    | HO, LT, OT      | JP-TAKEDA-<br>THQ2012A11181 |                      | 41 YR      | Male       | JPN            |

| <u>Preferred Term</u>                                                        | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Apathy; Drug Interaction;<br>Torsade De Pointes;<br>Ventricular Fibrillation | Takepron Od Tablets 15 |              |            | S           | Oral         | 15 Mg, Qd          |                 | Takeda       |
|                                                                              | Lexapro                |              |            | S           | Oral         | 10 Mg, Qd          |                 | Not Reported |
|                                                                              | Lexapro                |              |            | S           | Oral         | 10 Mg, Qd          |                 | Not Reported |

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

|                       |   |                  |             |              |
|-----------------------|---|------------------|-------------|--------------|
| Lamictal              | C | Oral             | 50 Mg, Bid  | Not Reported |
| Landsen               | C | Oral             | 0.5 Mg, Qd  | Not Reported |
| Rivotril              | C | Oral             | 0.5 Mg, Qd  | Not Reported |
| Plavix                | C | Oral             | 75 Mg, Qd   | Not Reported |
| Bayaspirin            | C | Oral             | 100 Mg, Qd  | Not Reported |
| Crestor               | C | Oral             | 2.5 Mg, Qd  | Not Reported |
| Nicorandis            | C | Oral             | 5 Mg, Tid   | Not Reported |
| Magnesium Oxide       | C |                  | 0.5 Mg, Tid | Not Reported |
| Solita                | C | Intravenous drip | 500 MI, Unk | Not Reported |
| Heparin Sodium        | C | Intravenous drip | 12 Kiu, Unk | Not Reported |
| Acetylsalicylic Acid  | C | Oral             | Unk         | Not Reported |
| Clopidogrel Bisulfate | C | Oral             | Unk         | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 30-Apr-2014              | 10144057      | EXPEDITED (15-DAY) |                    | DE, LT          | FR-PFIZER INC-2014115848 |                      | 45 YR      | Male       | FRA            |

| <u>Preferred Term</u> | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-------------------|--------------|------------|-------------|--------------|--------------------------|-----------------|--------------|
| Coma; Snoring         | Lyrica            |              |            | S           | Oral         | 300 Mg, Unk              |                 | Pfizer       |
|                       | Durogesic         |              |            | S           | Transdermal  | 100 Ug Once Every 3 Days |                 | Not Reported |
|                       | Oxynorm           |              |            | S           | Oral         | 10mg To 30mg Daily       |                 | Not Reported |
|                       | Topalgic (France) |              |            | S           | Oral         | 1 To 3 Df Daily          |                 | Not Reported |
|                       | Tercian           |              |            | S           |              | 50 Gtt, 1x/Day           |                 | Not Reported |
|                       | Imovane           |              |            | S           | Oral         | 7.5 Mg, 1x/Day           |                 | Not Reported |
|                       | Seroplex          |              |            | S           | Oral         | 15 Mg, 1x/Day            |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Apr-2014              | 10144078      | EXPEDITED (15-DAY) |                    | OT              | AT-FRI-1000066855    |                      | 38 YR      | Female     | AUT            |

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

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

|                                          |                         |                           |                             |                          |                               |                               |                             |                          |                         |
|------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|-----------------------------|--------------------------|-------------------------|
| Focal Dyscognitive Seizures              | Escitalopram            |                           | S                           |                          |                               | 10 Mg                         |                             | Forest                   |                         |
| <a href="#">FDA Received Date</a>        | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>         | <a href="#">Sex</a>      | <a href="#">Country</a> |
| 30-Apr-2014                              | 10144201                | EXPEDITED (15-DAY)        |                             | OT                       | AT-FRI-1000066867             |                               | 53 YR                       | Male                     | AUT                     |
| <a href="#">Preferred Term</a>           | <a href="#">Product</a> |                           | <a href="#">Comp.</a>       | <a href="#">OTC</a>      | <a href="#">Role</a>          | <a href="#">Route</a>         | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a>     |
| Focal Dyscognitive Seizures              | Escitalopram            |                           |                             | S                        |                               |                               | 10 Mg                       |                          | Forest                  |
| <a href="#">FDA Received Date</a>        | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>         | <a href="#">Sex</a>      | <a href="#">Country</a> |
| 30-Apr-2014                              | 10144203                | EXPEDITED (15-DAY)        |                             | OT                       | AT-FRI-1000066868             |                               | 25 YR                       | Male                     | AUT                     |
| <a href="#">Preferred Term</a>           | <a href="#">Product</a> |                           | <a href="#">Comp.</a>       | <a href="#">OTC</a>      | <a href="#">Role</a>          | <a href="#">Route</a>         | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a>     |
| Generalised Tonic-Clonic Seizure         | Escitalopram            |                           |                             | S                        |                               |                               | 10 Mg                       |                          | Forest                  |
| <a href="#">FDA Received Date</a>        | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>         | <a href="#">Sex</a>      | <a href="#">Country</a> |
| 30-Apr-2014                              | 10144290                | EXPEDITED (15-DAY)        |                             | DE                       | FR-FRI-1000066922             |                               |                             | Male                     | FRA                     |
| <a href="#">Preferred Term</a>           | <a href="#">Product</a> |                           | <a href="#">Comp.</a>       | <a href="#">OTC</a>      | <a href="#">Role</a>          | <a href="#">Route</a>         | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a>     |
| Completed Suicide; Mood Altered          | Escitalopram            |                           |                             | S                        |                               |                               |                             |                          | Forest                  |
| <a href="#">FDA Received Date</a>        | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>         | <a href="#">Sex</a>      | <a href="#">Country</a> |
| 01-May-2014                              | 10090594                | EXPEDITED (15-DAY)        |                             | HO                       | FR-FRI-1000066609             |                               | 79 YR                       | Male                     | FRA                     |
| <a href="#">Preferred Term</a>           | <a href="#">Product</a> |                           | <a href="#">Comp.</a>       | <a href="#">OTC</a>      | <a href="#">Role</a>          | <a href="#">Route</a>         | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a>     |
| Medication Error; Off Label Use; Seizure | Escitalopram            |                           |                             | S                        | Oral                          |                               | 10 Mg                       |                          | Forest                  |
|                                          | Escitalopram            |                           |                             | S                        | Oral                          |                               | 15 Mg                       |                          | Forest                  |
|                                          | Escitalopram            |                           |                             | S                        | Oral                          |                               | Dose Reduced (Nos)          |                          | Forest                  |
|                                          | Temerit                 |                           |                             | C                        |                               |                               | 5 Mg                        |                          | Not Reported            |

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

|  |            |   |           |              |
|--|------------|---|-----------|--------------|
|  | Hemigoxine | C | 0.0625 Mg | Not Reported |
|  | Xarelto    | C | 15 Mg     | Not Reported |
|  | Kardegic   | C | 75 Mg     | Not Reported |
|  | Galvus     | C | 50 Mg     | Not Reported |
|  | Lasilix    | C | 40 Mg     | Not Reported |
|  | Zyloric    | C | 50 Mg     | Not Reported |
|  | Inexium    | C | 20 Mg     | Not Reported |
|  | Calcium    | C | 500 Mg    | Not Reported |
|  | Lansoyl    | C |           | Not Reported |
|  | Eductyl    | C |           | Not Reported |
|  | Tobradex   | C |           | Not Reported |
|  | Ocufen     | C |           | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-May-2014              | 10146772      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000066942    |                      | 4 DAY      | Female     | FRA            |

| <u>Preferred Term</u>                                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Foetal Exposure During Pregnancy; Nervousness; Tremor | Escitalopram   |              |            | S           | Transplacental | 15 Mg              |                 | Forest       |
|                                                       | Escitalopram   |              |            | S           | Transplacental | 20 Mg              |                 | Not Reported |
|                                                       | Lexomil Roche  |              |            | S           | Transplacental |                    |                 | Not Reported |
|                                                       | Ritaline       |              |            | C           | Transplacental | 60 Mg              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 02-May-2014              | 9786820       | EXPEDITED (15-DAY) |                    | LT              | IT-ABBVIE-13P-083-1183602-00 |                      | 38 YR      | Male       | ITA            |

| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Coma; Drug Interaction | Depakin        |              |            | S           | Oral         |                    |                 | Not Reported |
|                        | Tranquirit     |              |            | S           | Oral         | Solution           |                 | Not Reported |
|                        | Paliperidone   |              |            | S           | Oral         | Extended Release   |                 | Not Reported |
|                        | Venlafaxine    |              |            | S           | Oral         |                    |                 | Not Reported |
|                        | Akineton       |              |            | S           | Oral         | Extended Release   |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|  |           |   |      |  |  |  |  |              |
|--|-----------|---|------|--|--|--|--|--------------|
|  | Cipralex  | S | Oral |  |  |  |  | Not Reported |
|  | Lorazepam | C |      |  |  |  |  | Not Reported |
|  | Alcohol   | C |      |  |  |  |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-May-2014              | 9838827       | EXPEDITED (15-DAY) |                    | HO, OT          | SE-FRI-1000052984    |                      | 59 YR      | Male       | SWE            |

| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Arrhythmia; Tachycardia | Escitalopram   |              |            | S           | Oral         | 5 Mg               |                 | Forest       |
|                         | Trombyl        |              |            | C           |              | 75 Mg              |                 | Not Reported |
|                         | Plavix         |              |            | C           |              | 75 Mg              |                 | Not Reported |
|                         | Atacand        |              |            | C           |              | 8 Mg               |                 | Not Reported |
|                         | Bisoprolol     |              |            | C           |              | 10 Mg              |                 | Not Reported |
|                         | Spironolakton  |              |            | C           |              | 25 Mg              |                 | Not Reported |
|                         | Simvastatin    |              |            | C           |              | 20 Mg              |                 | Not Reported |
|                         | Mirtazapin     |              |            | C           |              | 30 Mg              |                 | Not Reported |
|                         | Oxascand       |              |            | C           |              |                    |                 | Not Reported |
|                         | Cordarone      |              |            | C           |              |                    |                 | Not Reported |
|                         | Metoprolol     |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 02-May-2014              | 10149609      | NON-EXPEDITED    |                    | OT              | US-PFIZER INC-2014118074 |                      |            | Unknown    | USA            |

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

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-May-2014              | 10150001      | EXPEDITED (15-DAY) |                    | HO              | TR-FRI-1000066926    |                      |            | Male       | TUR            |

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

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

|                                                          |              |   |      |       |              |
|----------------------------------------------------------|--------------|---|------|-------|--------------|
| Abdominal Pain;<br>Diarrhoea; Gastrointestinal<br>Oedema | Escitalopram | S | Oral | 10 Mg | Forest       |
|                                                          | Norvasc      | C | Oral |       | Not Reported |
|                                                          | Co-Diovan    | C | Oral |       | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-May-2014              | 10151064      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000066974    |                      | 44 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Pleural Effusion      | Escitalopram   |              |            | S           |              | 10 Mg              |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-May-2014              | 10151074      | EXPEDITED (15-DAY) |                    | DE              | FR-FRI-1000067037    |                      | 79 YR      | Male       | FRA            |

| <u>Preferred Term</u>                   | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Coma; Haematoma;<br>Haemorrhagic Stroke | Escitalopram           |              |            | S           | Oral         | 1 Df               |                 | Forest       |
|                                         | Previscan (Fluindione) |              |            | S           | Oral         | 15 Mg              |                 | Not Reported |
|                                         | Previscan (Fluindione) |              |            | S           | Oral         | 10 Mg              |                 | Not Reported |
|                                         | Kardegic               |              |            | S           | Oral         | 1 Df               |                 | Not Reported |
|                                         | Cordarone              |              |            | C           | Oral         | 200 Mg             |                 | Not Reported |
|                                         | Tahor                  |              |            | C           | Oral         | 10 Mg              |                 | Not Reported |
|                                         | Stagid                 |              |            | C           | Oral         | 280 Mg             |                 | Not Reported |
|                                         | Diamicron              |              |            | C           | Oral         | 60 Mg              |                 | Not Reported |
|                                         | Pariet                 |              |            | C           | Oral         | 20 Mg              |                 | Not Reported |
|                                         | Permixon               |              |            | C           | Oral         | 160 Mg             |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-May-2014              | 10152306      | DIRECT           |                    | HO              |                      |                      | 48 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Agitation; Delusion;  | Lexapro        |              |            | S           | Oral         | 1 Pill             |                 | Forest     |



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

Feeling Abnormal;  
Myocardial Infarction;  
Nightmare; Panic Attack;  
Paranoia; Restlessness;  
Serotonin Syndrome

| <u>FDA Received Date</u>                                                                                                             | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                       | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|--------------------|--------------------|-----------------|------------------------------------------------------------|-------------------------------------|-----------------|--------------|----------------|
| 03-May-2014                                                                                                                          | 10151493                             | EXPEDITED (15-DAY) |                    | OT              | IT-ACCORD-023421                                           |                                     | 54 YR           | Male         | ITA            |
| <u>Preferred Term</u>                                                                                                                | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                               | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Akathisia; Anxiety;<br>Bruxism; Hypomania                                                                                            | Escitalopram                         |                    |                    | S               |                                                            | Started Drug With<br>5mg/Day Dose   |                 | Accord       |                |
|                                                                                                                                      | Valproate                            |                    |                    | S               |                                                            | 750 Mg/Day Dose Drug<br>Was Started |                 | Not Reported |                |
|                                                                                                                                      | Lithium                              |                    |                    | S               |                                                            |                                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                             | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                       | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-May-2014                                                                                                                          | 10151495                             | EXPEDITED (15-DAY) |                    | HO              | CA-MACLEODS<br>PHARMACEUTICALS<br>US LTD-<br>MAC2014001052 |                                     |                 | Unknown      | CAN            |
| <u>Preferred Term</u>                                                                                                                | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                               | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Tonic<br>Convulsion; Vomiting                                                                                      | Escitalopram Oxalate                 |                    |                    | S               | Oral                                                       | Unk                                 |                 | Macleods     |                |
|                                                                                                                                      | Bupropion XI                         |                    |                    | S               | Oral                                                       | Unk                                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                             | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                       | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-May-2014                                                                                                                          | 10151836                             | EXPEDITED (15-DAY) |                    | HO, OT          | CA-ACCORD-023455                                           |                                     | 212 DAY         | Female       | CAN            |
| <u>Preferred Term</u>                                                                                                                | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                               | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Cyanosis; Drug<br>Interaction; Exposure Via<br>Breast Milk; Hypertonia;<br>Seizure Like Phenomena;<br>Sleep Disorder;<br>Somnolence; | Bupropion/Bupropion<br>Hydrochloride |                    |                    | S               | Transmammary                                               |                                     |                 | Not Reported |                |
|                                                                                                                                      | Escitalopram                         |                    |                    | S               | Transmammary                                               |                                     |                 | Accord       |                |

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

Unresponsive To Stimuli;  
Vomiting

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-May-2014              | 10152476      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000066977    |                      | 87 YR      | Female     | FRA            |

| <u>Preferred Term</u>            | <u>Product</u>   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------|------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Generalised Tonic-Clonic Seizure | Escitalopram     |              |            | S           | Oral         | 20 Mg              |                 | Forest       |
|                                  | Olanzapine Mylan |              |            | S           |              | 15 Mg              |                 | Not Reported |
|                                  | Diffu K          |              |            | C           |              |                    |                 | Not Reported |
|                                  | Keppra           |              |            | C           |              |                    |                 | Not Reported |
|                                  | Lasilix          |              |            | C           |              |                    |                 | Not Reported |
|                                  | Inexium          |              |            | C           |              |                    |                 | Not Reported |
|                                  | Levothyrox       |              |            | C           |              |                    |                 | Not Reported |
|                                  | Kardegic         |              |            | C           |              |                    |                 | Not Reported |
|                                  | Bisoprolol       |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-May-2014              | 10155214      | DIRECT           |                    |                 |                      |                      | 47 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Amnesia               | Lexapro 5 Mg   |              |            | S           | Oral         |                    | 6 MTH           | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 06-May-2014              | 9323974       | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2013166796 |                      | 60 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Back Disorder; Crying;<br>Drug Ineffective; Fatigue;<br>Feeling Abnormal; Hot<br>Flush; Night Sweats | Pristiq        |              |            | S           |              | 50 Mg, Daily       |                 | Pfizer       |
|                                                                                                      | Pristiq        |              |            | S           |              | 100 Mg, Daily      |                 | Pfizer       |
|                                                                                                      | Effexor Xr     |              |            | S           |              | Unk                |                 | Pfizer       |
|                                                                                                      | Wellbutrin     |              |            | S           |              | Unk                |                 | Not Reported |
|                                                                                                      | Lexapro        |              |            | S           |              | Unk                |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                          | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------|-----------------------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 06-May-2014                                                                       | 9511374                           | NON-EXPEDITED      |                    | LT              | IT-JNJFOC-20130902231 |                      | 38 YR           | Male         | ITA            |
| <u>Preferred Term</u>                                                             | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bradypnoea; Coma; Drug Interaction; Intentional Overdose; Intentional Self-Injury | Invega                            |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                   | Lorazepam                         |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                   | Depakin                           |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                   | Tranquirit                        |                    |                    | S               | Oral                  | 0.5%                 |                 | Not Reported |                |
|                                                                                   | Venlafaxine                       |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                   | Akineton                          |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                   | Cipralext                         |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                   | Ethanol                           |                    |                    | S               | Unknown               |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                          | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-May-2014                                                                       | 9983355                           | EXPEDITED (15-DAY) |                    | HO              | US-SHIRE-US201400224  |                      | 46 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                             | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Suicidal Ideation                                                                 | 489 (Lisdexamfetamine Dimesylate) |                    |                    | S               | Oral                  | 70 Mg, 1x/Day:Qd     |                 | Shire        |                |
|                                                                                   | 489 (Lisdexamfetamine Dimesylate) |                    |                    | S               | Oral                  | Unk, Unknown         |                 | Shire        |                |
|                                                                                   | Escitalopram Oxalate              |                    |                    | S               | Oral                  | 20 Mg, 1x/Day:Qd     |                 | Not Reported |                |
|                                                                                   | Escitalopram Oxalate              |                    |                    | S               |                       | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                          | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-May-2014                                                                       | 10155023                          | EXPEDITED (15-DAY) |                    | HO              | JP-FRI-1000067064     |                      | 50 YR           | Male         | JPN            |
| <u>Preferred Term</u>                                                             | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrioventricular Block Complete                                                   | Lexapro                           |                    |                    | S               | Oral                  | 10 Mg                |                 | Forest       |                |
|                                                                                   | Dogmatyl                          |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |

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

| Meilax                                           |                      |                    | C                  |                 | Oral                 |                              |                 | Not Reported |                |
|--------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|------------------------------|-----------------|--------------|----------------|
| <u>FDA Received Date</u>                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-May-2014                                      | 10155084             | EXPEDITED (15-DAY) |                    | DE, LT          | FR-FRI-1000067065    |                              | 45 YR           | Male         | FRA            |
| <u>Preferred Term</u>                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Coma                                             | Escitalopram         |                    |                    | S               | Oral                 | 15 Mg                        |                 | Forest       |                |
|                                                  | Durogesic            |                    |                    | S               | Transdermal          | 33.3333 Mcg                  |                 | Not Reported |                |
|                                                  | Oxynorm              |                    |                    | S               | Oral                 | 1 To 3 Capsules Daily        |                 | Not Reported |                |
|                                                  | Topalgic (France)    |                    |                    | S               | Oral                 | 1 To 3 Capsules Daily        |                 | Not Reported |                |
|                                                  | Imovane              |                    |                    | S               | Oral                 | 7.5 Mg                       |                 | Not Reported |                |
|                                                  | Lyrica               |                    |                    | S               | Oral                 |                              |                 | Not Reported |                |
|                                                  | Tercian              |                    |                    | S               | Oral                 | 50 Mg                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-May-2014                                      | 10155913             | EXPEDITED (15-DAY) |                    | HO              | PHHY2014FR053072     |                              | 84 YR           | Female       | FRA            |
| <u>Preferred Term</u>                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Behaviour Disorder; Confusional State | Stalevo              |                    |                    | S               | Oral                 | 3 Df (100/25/200 Mg), Daily  |                 | Not Reported |                |
|                                                  | Stalevo              |                    |                    | S               | Oral                 | 3 Df (50/12.5/200 Mg), Daily |                 | Not Reported |                |
|                                                  | Tramadol             |                    |                    | S               | Oral                 | 50 Mg, Bid                   |                 | Novartis     |                |
|                                                  | Seroplex             |                    |                    | S               | Oral                 | 20 Mg, Daily                 |                 | Not Reported |                |
|                                                  | Seroplex             |                    |                    | S               | Oral                 | 10 Mg, Daily                 |                 | Not Reported |                |
|                                                  | Seroplex             |                    |                    | S               | Oral                 | 05 Mg, Daily                 |                 | Not Reported |                |
|                                                  | Calcidose Vitamine D |                    |                    | C               |                      | 1 Df (500 Mg/400 Iu), Bid    |                 | Not Reported |                |
|                                                  | Mopral               |                    |                    | C               |                      | 20 Mg, Qd                    |                 | Not Reported |                |
|                                                  | Imovane              |                    |                    | C               |                      | Unk Unk, Unk                 |                 | Not Reported |                |
|                                                  | Kardegic             |                    |                    | C               |                      | 160 Mg, Daily                |                 | Not Reported |                |

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

|                                                                                                                       | Levothyrox                  | C                  |                    | 50 Ug, Qd            |                      | Not Reported         |                 |              |                |
|-----------------------------------------------------------------------------------------------------------------------|-----------------------------|--------------------|--------------------|----------------------|----------------------|----------------------|-----------------|--------------|----------------|
|                                                                                                                       | Seresta                     | C                  |                    | 10 Mg, Bid           |                      | Not Reported         |                 |              |                |
|                                                                                                                       | Paracetamol                 | C                  |                    | 2 Df, Q8h, If Needed |                      | Not Reported         |                 |              |                |
| <u>FDA Received Date</u>                                                                                              | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>      | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-May-2014                                                                                                           | 10157087                    | DIRECT             | Y                  | OT                   |                      |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                 | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>          | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Panic Attack                                                                                                          | Escitalopram 20mg           |                    |                    | S                    | Oral                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                              | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>      | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-May-2014                                                                                                           | 10159222                    | EXPEDITED (15-DAY) | Y                  | HO                   | 2014HINLIT0418       |                      | 195 DAY         | Female       | CAN            |
| <u>Preferred Term</u>                                                                                                 | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>          | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cyanosis; Exposure Via Breast Milk; Hypertonia; Maternal Drugs Affecting Foetus; Sleep Disorder; Somnolence; Vomiting | Escitalopram (Escitalopram) |                    |                    | S                    | Transmammary         | 10 Mg/Day            |                 | Not Reported |                |
|                                                                                                                       | Unknown                     |                    |                    |                      |                      |                      |                 |              |                |
|                                                                                                                       | Bupropion XI (Bupropion)    |                    |                    | S                    | Transmammary         | 150 Mg/Day           |                 | Not Reported |                |
|                                                                                                                       | Unknown                     |                    |                    |                      |                      |                      |                 |              |                |
| <u>FDA Received Date</u>                                                                                              | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>      | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-May-2014                                                                                                           | 10159886                    | EXPEDITED (15-DAY) | Y                  | OT                   | 2014HINLIT0414       |                      | 54 YR           | Male         | ITA            |
| <u>Preferred Term</u>                                                                                                 | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>          | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Akathisia; Anger;                                                                                                     | Escitalopram                |                    |                    | S                    |                      |                      |                 | Not Reported |                |
| Anhedonia; Anxiety;                                                                                                   | Valproate (Valproate)       |                    |                    | C                    |                      |                      |                 | Not Reported |                |
| Apathy; Bruxism;                                                                                                      | Amisulpride (Amisulpride)   |                    |                    | C                    |                      |                      |                 | Not Reported |                |
| Hypomania; Irritability;                                                                                              | Lithium (Lithium)           |                    |                    | C                    |                      |                      |                 | Not Reported |                |
| Middle Insomnia; Muscle Tightness; Nervousness;                                                                       |                             |                    |                    |                      |                      |                      |                 |              |                |
| Nervousness; Tongue Biting; Tremor                                                                                    |                             |                    |                    |                      |                      |                      |                 |              |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                             | <u>Case #</u>                                                                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| 06-May-2014                                                                                          | 10159916                                                                           | EXPEDITED (15-DAY) | Y                  | OT              | 2014HINLIT0416               |                      | 44 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                                                | <u>Product</u>                                                                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bruxism; Depression;<br>Dysphoria; Irritability;<br>Migraine; Nervousness;<br>Therapy Change; Tremor | Escitalopram                                                                       |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                                                                                                      | Valproate (Valproate)                                                              |                    |                    | C               |                              |                      |                 | Not Reported |                |
|                                                                                                      | Amisulpride (Amisulpride)                                                          |                    |                    | C               |                              |                      |                 | Not Reported |                |
|                                                                                                      | Lithium (Lithium)                                                                  |                    |                    | C               |                              |                      |                 | Not Reported |                |
|                                                                                                      | Indomethacin+Caffeine+Prochlorperazine<br>(Indomethacin+Caffeine+Prochlorperazine) |                    |                    | C               |                              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                             | <u>Case #</u>                                                                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-May-2014                                                                                          | 10156240                                                                           | EXPEDITED (15-DAY) |                    | HO              | FR-ABBVIE-14K-056-1233693-00 |                      | 66 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                | <u>Product</u>                                                                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Coma; Overdose                                                                                       | Depakote                                                                           |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                                                                      | Depakote                                                                           |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                                                                      | Alprazolam                                                                         |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                                                                      | Alprazolam                                                                         |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                                                                      | Cyamemazine                                                                        |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                                                                      | Cyamemazine                                                                        |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                                                                      | Risperdal                                                                          |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                                                                      | Risperdal                                                                          |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                                                                      | Seroplex                                                                           |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                                                                      | Seroplex                                                                           |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                                                                      | Lepticur                                                                           |                    |                    | C               |                              |                      |                 | Not Reported |                |
|                                                                                                      | Mirtazapine                                                                        |                    |                    | C               |                              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                             | <u>Case #</u>                                                                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-May-2014                                                                                          | 10157104                                                                           | EXPEDITED (15-DAY) |                    | HO              | FR-SA-2014SA058636           |                      | 86 YR           | Male         | FRA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u> | <u>Product</u>                     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                      | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|------------------------------------|--------------|------------|-------------|--------------|---------------------------------------------------------|-----------------|--------------|
| Urinary Retention     | Nozinan                            |              |            | S           | Oral         | Daily Dose: 5 Drops Daily                               |                 | Not Reported |
|                       | Plavix                             |              |            | S           | Oral         |                                                         |                 | Not Reported |
|                       | Zolpidem                           |              |            | S           | Oral         | Dose:1 Unit(S)                                          |                 | Not Reported |
|                       | Theralene                          |              |            | S           | Oral         | Daily Dose: 10 Drops Per Day                            |                 | Not Reported |
|                       | Seroplex                           |              |            | S           | Oral         |                                                         |                 | Not Reported |
|                       | Levothyrox                         |              |            | S           | Oral         |                                                         |                 | Not Reported |
|                       | Pariet                             |              |            | S           | Oral         | Form - Gastrotab                                        |                 | Not Reported |
|                       | Seresta                            |              |            | S           | Oral         | Daily Dose 10 Mg Morning / 10 Mg Midday / 25 Mg Evening |                 | Not Reported |
|                       | Loxen (Niacardipine Hydrochloride) |              |            | S           | Oral         |                                                         |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 07-May-2014              | 10157238      | EXPEDITED (15-DAY) |                    | DE, LT          | FR-JNJFOC-20140417838 |                      | 45 YR      | Male       | FRA            |

| <u>Preferred Term</u> | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Coma                  | Durogesic         |              |            | S           | Transdermal  |                    |                 | Not Reported |
|                       | Oxynorm           |              |            | S           | Oral         | 1-3 Capsules A Day |                 | Not Reported |
|                       | Imovane           |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Lyrica            |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Tercian           |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Seroplex          |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Topalgic (France) |              |            | S           | Oral         | 1-3 Capsules       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|------------|------------|----------------|
| 07-May-2014              | 10158139      | EXPEDITED (15-DAY) |                    | HO              | FR-EISAI INC-E3810-07077-SPO-FR |                      | 86 YR      | Male       | FRA            |

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

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

|                   |                                   |   |      |                |              |
|-------------------|-----------------------------------|---|------|----------------|--------------|
| Urinary Retention | Pariet                            | S | Oral |                | Not Reported |
|                   | Nozinan                           | S | Oral | 5 Gtt          | Not Reported |
|                   | Theralene                         | S | Oral | 10 Gtt         | Not Reported |
|                   | Seroplex                          | S | Oral |                | Not Reported |
|                   | Levothyrox                        | S | Oral | 50 Ug          | Not Reported |
|                   | Plavix                            | S | Oral |                | Not Reported |
|                   | Seresta                           | S | Oral | 45 Mg In 1 Day | Not Reported |
|                   | Zolpidem                          | S | Oral | 1 Dose(S)      | Not Reported |
|                   | Loxen (Nicardipine Hydrochloride) | S | Oral |                | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-May-2014              | 9788707       | EXPEDITED (15-DAY) | LT                 |                 | JP-FRI-1000052527    |                      | 38 YR      | Female     | JPN            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hepatic Failure       | Lexapro        |              |            | S           | Oral         | 5 Mg               |                 | Forest       |
|                       | Meilax         |              |            | C           | Oral         | 4 Mg               |                 | Not Reported |
|                       | Depromel       |              |            | C           | Oral         | 150 Mg             |                 | Not Reported |
|                       | Seroquel       |              |            | C           | Oral         | 50 Mg              |                 | Not Reported |
|                       | Goodmin        |              |            | C           | Oral         | 0.5 Mg             |                 | Not Reported |
|                       | Lexotan        |              |            | C           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-May-2014              | 10079095      | EXPEDITED (15-DAY) | OT                 |                 | PHEH2014US007142     |                      | 43 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|------------------------|-----------------|--------------|
| Drug Interaction; Nasal Congestion; Rhinorrhoea; Sinusitis; Sleep Apnoea Syndrome; Snoring | Tasigna        |              |            | S           | Oral         | 400 Mg, Bid            |                 | Novartis     |
|                                                                                            | Tasigna        |              |            | S           | Oral         | 300 Mg, Unk            |                 | Novartis     |
|                                                                                            | Morphine       |              |            | S           |              | 15 Mg, Bid For 07 Days |                 | Not Reported |
|                                                                                            | Lexapro        |              |            | S           | Oral         | 20 Mg, Unk             |                 | Not Reported |



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

|             |   |      |             |              |
|-------------|---|------|-------------|--------------|
| Oxycodone   | C | Oral | 5 Mg, Q4h   | Not Reported |
| Mirtazapine | C | Oral | 15 Mg, Unk  | Not Reported |
| Neurontin   | C | Oral | 400 Mg, Tid | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------------------------------------|----------------------|------------|------------|----------------|
| 08-May-2014              | 10160249      | EXPEDITED (15-DAY) |                    | OT              | CA-B.I.<br>PHARMACEUTICALS,I<br>NC./RIDGEFIELD-2014-<br>BI-20 |                      | 93 YR      | Male       | CAN            |

| <u>Preferred Term</u>       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>           |
|-----------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------|
| Anhedonia; Asthenia;        | Telmisartan    |              |            | S           | Unknown      | 80 Mg              |                 | Boehringer Ingelheim |
| Balance Disorder;           | Telmisartan    |              |            | S           |              |                    |                 | Boehringer Ingelheim |
| Decreased Appetite;         | Pantoprazole   |              |            | S           | Unknown      | 80 Mg              |                 | Not Reported         |
| Depressed Mood;             | Prednisone     |              |            | S           | Unknown      | 10 Mg              |                 | Not Reported         |
| Diarrhoea; Dizziness; Fall; | Metoprolol     |              |            | S           | Unknown      | 50 Mg              |                 | Not Reported         |
| Fatigue; Hyponatraemia;     | Metoprolol     |              |            | S           |              |                    |                 | Not Reported         |
| Hypotension; Orthostatic    | Escitalopram   |              |            | S           | Unknown      | 10 Mg              |                 | Not Reported         |
| Hypotension;                | Lorazepam      |              |            | S           | Unknown      | 1 Mg               |                 | Not Reported         |
| Osteoporosis; Skin          | Tamsulosine    |              |            | C           | Unknown      | 0.4 Mg             |                 | Not Reported         |
| Laceration; Somnolence;     | Loperamide     |              |            | C           | Unknown      | 1 Mg               |                 | Not Reported         |
| Vitamin B12 Deficiency;     |                |              |            |             |              |                    |                 |                      |
| Vitamin D Deficiency;       |                |              |            |             |              |                    |                 |                      |
| Weight Decreased            |                |              |            |             |              |                    |                 |                      |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-May-2014              | 9627504       | EXPEDITED (15-DAY) |                    | OT              | IE-FRI-1000049997    |                      | 50 YR      | Male       | IRL            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Withdrawal Syndrome   | Lexapro        |              |            | S           | Oral         | 20 Mg              |                 | Forest       |
|                       | Lexapro        |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                       | Lexapro        |              |            | S           | Oral         | 5 Mg               |                 | Forest       |
|                       | Lexapro        |              |            | S           | Oral         |                    |                 | Forest       |
|                       | Lithium        |              |            | C           |              |                    |                 | Not Reported |
|                       | Seroquel Xr    |              |            | C           |              |                    |                 | Not Reported |
|                       | Crestor        |              |            | C           |              |                    |                 | Not Reported |

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

|                                                                               |                                                                                    |                    |                    |                 |                      |                                |                 |              |                |
|-------------------------------------------------------------------------------|------------------------------------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|--------------------------------|-----------------|--------------|----------------|
| Tritace                                                                       |                                                                                    | C                  |                    | Not Reported    |                      | Not Reported                   |                 |              |                |
| Aspirin                                                                       |                                                                                    | C                  |                    |                 |                      |                                |                 |              |                |
| <u>FDA Received Date</u>                                                      | <u>Case #</u>                                                                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-May-2014                                                                   | 10163676                                                                           | EXPEDITED (15-DAY) |                    | CA, OT          | DE-FRI-1000067099    |                                | 1 DAY           | Female       | DEU            |
| <u>Preferred Term</u>                                                         | <u>Product</u>                                                                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Cleft Lip; Foetal Exposure During Pregnancy; Small For Dates Baby; Syndactyly | Escitalopram Oral Solution                                                         |                    |                    | S               | Transplacental       | 6 Mg                           |                 | Forest       |                |
|                                                                               | Escitalopram Oral Solution                                                         |                    |                    | S               | Transplacental       | 3 Mg                           |                 | Not Reported |                |
|                                                                               | L-Thyroxin                                                                         |                    |                    | C               | Transplacental       | 100 Mcg                        |                 | Not Reported |                |
|                                                                               | Folsaeure                                                                          |                    |                    | C               | Transplacental       |                                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                      | <u>Case #</u>                                                                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-May-2014                                                                   | 10167516                                                                           | DIRECT             | Y                  | OT              |                      |                                | 44 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                         | <u>Product</u>                                                                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Headache; Product Substitution Issue                                          | Escitalopram                                                                       |                    |                    | S               | Oral                 | Had Used Brand Lexapro In Past |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                      | <u>Case #</u>                                                                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-May-2014                                                                   | 10168724                                                                           | EXPEDITED (15-DAY) | Y                  | HO              | 7290115              |                                | 86 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                         | <u>Product</u>                                                                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Urinary Retention                                                             | Levothyrox (Levothyroxine Sodium) (50 Microgram, Tablet)                           |                    |                    | S               | Oral                 |                                |                 | Not Reported |                |
|                                                                               | Nozinan /00038601/ (Levomepromazine) (4 Percent, Oral Solution)                    |                    |                    | S               | Oral                 |                                |                 | Not Reported |                |
|                                                                               | (Levomepromazine)                                                                  |                    |                    |                 |                      |                                |                 |              |                |
|                                                                               | Theralene (Alimemazine Tartrate) (4 Percent, Oral Solution) (Alimemazine Tartrate) |                    |                    | S               | Oral                 |                                |                 | Not Reported |                |
|                                                                               | Seroplex (Escitalopram Oxalate)                                                    |                    |                    | S               | Oral                 |                                |                 | Not Reported |                |

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

|                                                                                                                                                  |   |      |                                              |              |
|--------------------------------------------------------------------------------------------------------------------------------------------------|---|------|----------------------------------------------|--------------|
| (20 Mg, Film-Coated Tablet)<br>(Escitalopram Oxalate)<br>Pariet (Rabeprazole Sodium) (20<br>Mg, Gastro-Resistant Tablet)<br>(Rabeprazole Sodium) | S | Oral |                                              | Not Reported |
| Plavix /01220701/ (Clopidogrel)<br>(75 Mg, Film-Coated Tablet)<br>(Clopidogrel)                                                                  | S | Oral |                                              | Not Reported |
| Seresta (Oxazepam) (50 Mg,<br>Tablet) (Oxazepam)                                                                                                 | S | Oral | 10 Mg, Morning, 10 Mg<br>Noon, 25 Mg Evening | Not Reported |
| Zolpidem (Zolpidem) (Zolpidem)                                                                                                                   | S | Oral |                                              | Not Reported |
| Loxen (Nifedipine<br>Hydrochloride)                                                                                                              | S | Oral |                                              | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-May-2014              | 10168966      | EXPEDITED (15-DAY) | Y                  | OT              | AUR-APL-2014-05357   |                      | 54 YR      | Male       | ITA            |

| <u>Preferred Term</u>                                                                                                                                                           | <u>Product</u>                         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Akathisia; Anger;<br>Anhedonia; Anxiety;<br>Apathy; Bruxism; Bruxism;<br>Depression; Hypomania;<br>Middle Insomnia; Myalgia;<br>Nervousness; Sedation;<br>Tongue Biting; Tremor | Escitalopram (Escitalopram)            |              |            | S           |              | 10mg 1d)<br>5mg 1d |                 | Not Reported |
|                                                                                                                                                                                 | Valproate Sodium (Valproate<br>Sodium) |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                 | Amisulpride (Amisulpride)              |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                 | Lithium (Lithium)                      |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-May-2014              | 10168977      | EXPEDITED (15-DAY) | Y                  | OT              | AUR-APL-2014-05366   |                      | 44 YR      | Female     | ITA            |

| <u>Preferred Term</u>                                                                                                                                                                                   | <u>Product</u>                         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------|------------|-------------|--------------|-----------------------|-----------------|--------------|
| Agitation; Depression;<br>Drug Ineffective;<br>Dysphoria; Headache;<br>Irritability; Migraine;<br>Musculoskeletal Pain;<br>Neck Pain; Nervousness;<br>Tooth Erosion; Tooth<br>Fracture; Tremor; Trismus | Escitalopram                           |              |            | S           |              | 20mg 1d<br>4-10mg Day |                 | Not Reported |
|                                                                                                                                                                                                         | Valproate Sodium (Valproate<br>Sodium) |              |            | C           |              |                       |                 | Not Reported |
|                                                                                                                                                                                                         | Lithium (Lithium)                      |              |            | C           |              |                       |                 | Not Reported |
|                                                                                                                                                                                                         | Indomethacin (Indometacin)             |              |            | C           |              |                       |                 | Not Reported |
|                                                                                                                                                                                                         | Caffeine (Caffeine)                    |              |            | C           |              |                       |                 | Not Reported |

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

Prochlorperazine  
(Prochlorperazine)

C

Not Reported

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 12-May-2014              | 10166458      | EXPEDITED (15-DAY) |                    | OT              | AU-<br>ELI_LILLY_AND_COMP<br>ANY-AU201404010013 |                      |            | Male       | AUS            |

| <u>Preferred Term</u>                                                                                                                                   | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>       |
|---------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------------|
| Asthenia; Confusional State; Dizziness; Hypothermia; Increased Upper Airway Secretion; Paraesthesia; Pollakiuria; Pyrexia; Serotonin Syndrome; Tinnitus | Cymbalta             |              |            | S           | Unknown      | Unk, Unknown       |                 | Not Reported     |
|                                                                                                                                                         | Zyprexa              |              |            | S           | Unknown      | Unk, Unknown       |                 | Eli Lilly And Co |
|                                                                                                                                                         | Aropax               |              |            | S           | Unknown      | Unk, Unknown       |                 | Not Reported     |
|                                                                                                                                                         | Celebrex             |              |            | S           | Unknown      | Unk, Unknown       |                 | Not Reported     |
|                                                                                                                                                         | Cipramil /00582602/  |              |            | S           | Unknown      | Unk, Unknown       |                 | Not Reported     |
|                                                                                                                                                         | Efexor               |              |            | S           | Unknown      | Unk, Unknown       |                 | Not Reported     |
|                                                                                                                                                         | Endep                |              |            | S           | Unknown      | Unk, Unknown       |                 | Not Reported     |
|                                                                                                                                                         | Endone               |              |            | S           | Unknown      | Unk, Unknown       |                 | Not Reported     |
|                                                                                                                                                         | Lexapro              |              |            | S           | Unknown      | Unk, Unknown       |                 | Not Reported     |
|                                                                                                                                                         | Mogadon              |              |            | S           | Unknown      | Unk, Unknown       |                 | Not Reported     |
|                                                                                                                                                         | Naproxen             |              |            | S           | Unknown      | Unk, Unknown       |                 | Not Reported     |
|                                                                                                                                                         | Oxycontin            |              |            | S           | Unknown      | Unk, Unknown       |                 | Not Reported     |
|                                                                                                                                                         | Panadeine /00116401/ |              |            | S           | Unknown      | Unk, Unknown       |                 | Not Reported     |
|                                                                                                                                                         | Serepax              |              |            | S           | Unknown      | Unk, Unknown       |                 | Not Reported     |
|                                                                                                                                                         | Valium /00017001/    |              |            | S           | Unknown      | Unk, Unknown       |                 | Not Reported     |
|                                                                                                                                                         | Zoloft               |              |            | S           | Unknown      | Unk, Unknown       |                 | Not Reported     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------------|----------------------|------------|------------|----------------|
| 12-May-2014              | 10166513      | EXPEDITED (15-DAY) |                    | HO              | FR-ORION<br>CORPORATION ORION<br>PHARMA-ENTC2014-0157 |                      | 84 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|-------------------------|-----------------|--------------|
| Agitation; Anxiety;   | Stalevo        |              |            | S           | Oral         | Strength: 100/25/200 Mg |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                                             |                      |   |         |                          |              |
|-----------------------------------------------------------------------------|----------------------|---|---------|--------------------------|--------------|
| Behaviour Disorder;<br>Confusional State;<br>Hallucination;<br>Restlessness | Stalevo              | S | Oral    | Strength: 50/12.5/200 Mg | Not Reported |
|                                                                             | Tramadol             | S | Oral    |                          | Not Reported |
|                                                                             | Seroplex             | S | Oral    |                          | Not Reported |
|                                                                             | Seroplex             | S | Oral    |                          | Not Reported |
|                                                                             | Seroplex             | S | Oral    |                          | Not Reported |
|                                                                             | Calcidose Vitamine D | C | Unknown | Strength: 500 Mg         | Not Reported |
|                                                                             | Mopral               | C | Unknown |                          | Not Reported |
|                                                                             | Imovane              | C | Unknown |                          | Not Reported |
|                                                                             | Kardegic             | C | Unknown |                          | Not Reported |
|                                                                             | Levothyrox           | C | Unknown |                          | Not Reported |
|                                                                             | Seresta              | C | Unknown |                          | Not Reported |
|                                                                             | Paracetamol          | C | Unknown |                          | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 12-May-2014              | 10166612      | EXPEDITED (15-DAY) | HO                 |                 | FR-JNJFOC-20140419926 |                      | 66 YR      | Female     | FRA            |

| <u>Preferred Term</u>        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------|----------------|--------------|------------|-------------|--------------|--------------------------------------|-----------------|--------------|
| Coma; Prescribed<br>Overdose | Risperdal      |              |            | S           | Oral         |                                      |                 | Not Reported |
|                              | Depakote       |              |            | S           | Oral         |                                      |                 | Not Reported |
|                              | Alprazolam     |              |            | S           | Oral         |                                      |                 | Not Reported |
|                              | Tercian        |              |            | S           | Oral         |                                      |                 | Not Reported |
|                              | Seroplex       |              |            | S           | Oral         |                                      |                 | Not Reported |
|                              | Lepticur       |              |            | C           | Unknown      | 10 (Units Unspecified)<br>Once A Day |                 | Not Reported |
|                              | Mirtazapine    |              |            | C           | Unknown      | 15 (Units Unspecified)<br>Once A Day |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-May-2014              | 10167156      | EXPEDITED (15-DAY) | HO                 |                 | FR-FRI-1000067174    |                      | 84 YR      | Female     | FRA            |

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

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

|                                                                 |                                      |   |      |                               |              |
|-----------------------------------------------------------------|--------------------------------------|---|------|-------------------------------|--------------|
| Agitation; Behaviour Disorder; Confusional State; Off Label Use | Escitalopram                         | S | Oral | 20 Mg                         | Forest       |
|                                                                 | Escitalopram                         | S | Oral | 10 Mg                         | Forest       |
|                                                                 | Escitalopram                         | S | Oral | 5 Mg                          | Not Reported |
|                                                                 | Tramadol                             | S | Oral | 100 Mg                        | Not Reported |
|                                                                 | Stalevo                              | S | Oral | 3 Df                          | Not Reported |
|                                                                 | Calcidose Vitamine D 500 Mg / 400 Iu | C |      | 2 Df                          | Not Reported |
|                                                                 | Mopral                               | C |      | 40 Mg                         | Not Reported |
|                                                                 | Imovane                              | C |      | 7.5 Mg                        | Not Reported |
|                                                                 | Kardegic                             | C |      | 160 Mg                        | Not Reported |
|                                                                 | Levothyrox                           | C |      | 50 Mcg                        | Not Reported |
|                                                                 | Seresta                              | C |      | 20 Mg                         | Not Reported |
|                                                                 | Paracetamol                          | C | Oral | 2 Df Every 8 Hours, If Needed | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|------------------------------------------|----------------------|-----------------|--------------|----------------|
| 12-May-2014              | 10167652       | EXPEDITED (15-DAY) |                    | OT              | US-BRISTOL-MYERS SQUIBB COMPANY-20697843 |                      | 40 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Serotonin Syndrome       | Abilify        |                    |                    | S               |                                          |                      |                 | Not Reported |                |
|                          | Lexapro        |                    |                    | S               |                                          |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                                          | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------------------|-----------------|--------------|----------------|
| 13-May-2014                                                                                                                                                       | 10135910                      | EXPEDITED (15-DAY) |                    | HO, OT          | PHHY2014US049565     |                                           | 92 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                             | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                        | <u>Duration</u> | <u>Mfr</u>   |                |
| Adhesion; Anxiety; Arthralgia; Asthenia; Back Pain; Bursitis; Catatonia; Cerebrovascular Accident; Compression Fracture; Condition Aggravated; Confusional State; | Baclofen Intrathecal          |                    |                    | S               | Intrathecal          | 35.01 Ug/Day                              |                 | Not Reported |                |
|                                                                                                                                                                   | Amitriptyline Hcl Tablets Usp |                    |                    | S               |                      | 1 Df, Qhs (1 Tablet Of 50 Mg, At Bedtime) |                 | Novartis     |                |
|                                                                                                                                                                   | Lisinopril Tablets            |                    |                    | S               |                      | 1 Df/Daily (1 Tablet Of 20 Mg Daily)      |                 | Not Reported |                |

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

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |             |   |              |                                              |              |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|---|--------------|----------------------------------------------|--------------|
| Contusion; Conversion Disorder; Crepitations; Depression; Discomfort; Fall; Fluid Retention; Fractured Sacrum; Gait Disturbance; Gastrointestinal Sounds Abnormal; Headache; Hypoaacusis; Hypoaesthesia; Hypopnoea; Hypotension; Injection Site Pain; Joint Swelling; Lethargy; Mental Status Changes; Mobility Decreased; Muscle Rigidity; Musculoskeletal Pain; Neuralgia; Oedema; Oedema Peripheral; Osteoarthritis; Overdose; Oxygen Saturation Decreased; Pain; Pain In Extremity; Pallor; Performance Status Decreased; Radicular Pain; Rash; Respiratory Depression; Rotator Cuff Syndrome; Sciatica; Sedation; Sleep Disorder; Swelling; Tenderness; Therapy Non-Responder; Withdrawal Syndrome; Wound | Simvastatin | S |              | 1 Df, Daily (1 Tablet Of 40 Mg, Daily)       | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Clonidine   | S | Intrathecal  | 70.02 Ug/Day                                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Bupivacaine | S | Intrathecal  | 2.626 Mg/Day                                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Aspercream  | S |              | Unk Ukn, Prn (As Directed On Tube As Needed) | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Clobetasol  | S |              | Unk Ukn, Unk                                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Imitrex     | S | Subcutaneous | Unk Ukn, Prn (6 Mg/0.5 Injection As Needed)  | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Lexapro     | S |              | 1 Df, Daily (1 Tablet Daily)                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Lidoderm    | S |              | Unk Ukn, Unk (App Aa Daily)                  | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Toprol XL   | S |              | 1 Df, Daily (1 Tablet Of 50 Mg, Daily)       | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Tylenol     | S |              | Unk Ukn, Prn (When Necessary)                | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Valium      | S |              | Unk Ukn, Prn (When Necessary)                | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Zantac      | S |              | 1 Df, Qhs (One Df Of 150 Mg At Bedtime)      | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Diuretics   | S |              | Unk Ukn, Unk                                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Sufentanil  | S | Intrathecal  | 35.01 Ug, Daily                              | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Cymbalta    | S |              | 1 Df, Daily                                  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 13-May-2014              | 10170184      | EXPEDITED (15-DAY) |                    | HO, LT, OT      | TR-ACTAVIS-2014-09830 |                      | 29 YR      | Female     | TUR            |

| <u>Preferred Term</u>                                     | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u> |
|-----------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|---------------------------------|-----------------|------------|
| Coma; Hypotension; Intentional Overdose; Suicide Attempt; | Quetiapine (Unknown) |              |            | S           | Oral         | Estimated Ingeste Amount Of 9 G |                 | Actavis    |

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

|             |                        |   |      |                                     |                      |
|-------------|------------------------|---|------|-------------------------------------|----------------------|
| Tachycardia | Escitalopram (Unknown) | S | Oral | Estimated Ingested Amount Of 280 Mg | Not Reported         |
|             | Ibuprofen (Unknown)    | S | Oral | Estimated Ingested Amount Of 4g     | Actavis Mid Atlantic |
|             | Amoxicillin (Unknown)  | S | Oral | Estimated Ingested Amount Of 5 G    | Not Reported         |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 14-May-2014                       | 10102192               | EXPEDITED (15-DAY)        | Y                           | CA, OT                   | AUR-APL-2014-04726            |                               |                     | Unknown             | ITA                     |

| <a href="#">Preferred Term</a>                                | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|---------------------------------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Congenital Nose Malformation; Maternal Drugs Affecting Foetus | Escitalopram            |                       |                     | S                    | Transplacental        | 20mg (20mg, 1 In 1 D)       |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 14-May-2014                       | 10110272               | EXPEDITED (15-DAY)        | Y                           | CA, OT                   | AUR-APL-2014-04728            |                               |                     | Unknown             | ITA                     |

| <a href="#">Preferred Term</a>                       | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a>               | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|------------------------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-------------------------------------------|--------------------------|---------------------|
| Maternal Drugs Affecting Foetus; Necrotising Colitis | Escitalopram            |                       |                     | S                    | Transplacental        | 20 Mg ( 20 Mg, 1 In 1 D), Transplacental) |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 14-May-2014                       | 10171180               | EXPEDITED (15-DAY)        |                             | OT                       | IT-JNJFOC-20140504229         |                               | 50 YR               | Female              | ITA                     |

| <a href="#">Preferred Term</a>                                              | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|-----------------------------------------------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Intentional Product Misuse; Intentional Self-Injury; Sluggishness; Vomiting | Topamax                 |                       |                     | S                    | Oral                  |                             |                          | Not Reported        |
|                                                                             | Topamax                 |                       |                     | S                    | Oral                  |                             |                          | Not Reported        |
|                                                                             | Bromazepam              |                       |                     | S                    | Oral                  |                             |                          | Not Reported        |
|                                                                             | Keppra                  |                       |                     | S                    | Oral                  |                             |                          | Not Reported        |
|                                                                             | Citalopram              |                       |                     | S                    | Oral                  |                             |                          | Not Reported        |
|                                                                             | Cipralex                |                       |                     | S                    | Oral                  |                             |                          | Not Reported        |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                               | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                 | <u>Country</u> |
|--------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|-----------------|----------------------------|----------------|
| 14-May-2014                                            | 10171330               | EXPEDITED (15-DAY) |                    | HO              | BR-DRREDDYS-GPV/BRA/14/0040169 |                      | 13 YR           | Female                     | BRA            |
| <u>Preferred Term</u>                                  | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                 |                |
| Intentional Overdose;                                  | Risperidone 3mg Tablet |                    |                    | S               | Oral                           |                      |                 | Not Reported               |                |
| Overdose; Poisoning;                                   | Paxil                  |                    |                    | S               | Oral                           |                      |                 | Not Reported               |                |
| Suicidal Ideation; Suicide Attempt                     | Escitalopram           |                    |                    | S               | Oral                           |                      |                 | Not Reported               |                |
| <u>FDA Received Date</u>                               | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                 | <u>Country</u> |
| 15-May-2014                                            | 10023648               | EXPEDITED (15-DAY) | Y                  | OT              | ADR-2013-02289                 |                      | 74 YR           | Male                       | USA            |
| <u>Preferred Term</u>                                  | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                 |                |
| Chills; Drug Withdrawal Syndrome; Hyperhidrosis;       | Baclofen               | Y                  |                    | S               |                                |                      |                 | Anaзаohealth - Compounding |                |
| Insomnia; Muscle Spasticity; Muscle Tightness; Nausea; | Lipitor                |                    |                    | S               |                                |                      |                 | Not Reported               |                |
| Restlessness; Tremor; Vomiting                         | Celebrex               |                    |                    | S               |                                |                      |                 | Not Reported               |                |
|                                                        | Plavix                 |                    |                    | S               |                                |                      |                 | Not Reported               |                |
|                                                        | Colace                 |                    |                    | S               |                                |                      |                 | Not Reported               |                |
|                                                        | Lexapro                |                    |                    | S               |                                |                      |                 | Not Reported               |                |
|                                                        | Provigil               |                    |                    | S               |                                |                      |                 | Not Reported               |                |
|                                                        | Prilosec               |                    |                    | S               |                                |                      |                 | Not Reported               |                |
|                                                        | Flomax                 |                    |                    | S               |                                |                      |                 | Not Reported               |                |
| <u>FDA Received Date</u>                               | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                 | <u>Country</u> |
| 15-May-2014                                            | 10174273               | EXPEDITED (15-DAY) |                    | DE              | FR-FRI-1000067293              |                      | 88 YR           | Female                     | FRA            |
| <u>Preferred Term</u>                                  | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                 |                |
| Cerebral Haemorrhage;                                  | Escitalopram           |                    |                    | S               | Oral                           | 0.5 Df               |                 | Forest                     |                |
| Eye Haemorrhage                                        | Previscan (Fluindione) |                    |                    | S               | Oral                           | 1 Df                 |                 | Not Reported               |                |
|                                                        | Diffu K                |                    |                    | C               | Oral                           | 1 Df                 |                 | Not Reported               |                |
|                                                        | Lasilix Faible         |                    |                    | C               | Oral                           | 1 Df                 |                 | Not Reported               |                |

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

| <u>FDA Received Date</u>                                                                                                                            | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|--------------------|--------------------|-----------------|------------------------------|------------------------------------------|-----------------|--------------|----------------|
| 15-May-2014                                                                                                                                         | 10179228                                | EXPEDITED (15-DAY) | Y                  | OT              | AUR-APL-2014-05526           |                                          | 48 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                               | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Drug Withdrawal<br>Convulsions; Drug<br>Withdrawal Syndrome;<br>Generalised Tonic-Clonic<br>Seizure; Toxicity To<br>Various Agents; Tremor | Ceftriaxone                             |                    |                    | S               |                              |                                          |                 | Not Reported |                |
|                                                                                                                                                     | Escitalopram                            |                    |                    | S               |                              |                                          |                 | Not Reported |                |
|                                                                                                                                                     | Tramadol                                |                    |                    | S               |                              |                                          |                 | Not Reported |                |
|                                                                                                                                                     | Oxygen                                  |                    |                    | S               |                              | 30 Hbo2 At 2.4 Atm Abs<br>For Two 45-Min |                 | Not Reported |                |
|                                                                                                                                                     | Zolpidem (Zolpidem)                     |                    |                    | C               |                              |                                          |                 | Not Reported |                |
|                                                                                                                                                     | Metronidazole (Metronidazole)           |                    |                    | C               |                              |                                          |                 | Not Reported |                |
|                                                                                                                                                     | Acetaminophen\Hydrocodone<br>Bitartrate |                    |                    | C               |                              |                                          |                 | Not Reported |                |
|                                                                                                                                                     | Hydromorphone<br>(Hydromorphone)        |                    |                    | C               |                              |                                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                            | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-May-2014                                                                                                                                         | 10176124                                | NON-EXPEDITED      |                    |                 | US-PFIZER INC-<br>2014129421 |                                          | 53 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                               | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity;<br>Food Allergy                                                                                                              | Flagyl                                  |                    |                    | S               |                              | Unk                                      |                 | Pfizer       |                |
|                                                                                                                                                     | Amitriptyline                           |                    |                    | S               |                              | Unk                                      |                 | Not Reported |                |
|                                                                                                                                                     | Lexapro                                 |                    |                    | S               |                              | Unk                                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                            | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-May-2014                                                                                                                                         | 10176367                                | EXPEDITED (15-DAY) |                    | HO              | CH-NOVOPROD-<br>409517       |                                          | 60 YR           | Female       | CHE            |
| <u>Preferred Term</u>                                                                                                                               | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>   |                |
| Diarrhoea;<br>Hypoglycaemia;<br>Intentional Overdose;<br>Nausea; Suicide Attempt;<br>Vomiting                                                       | Novorapid                               |                    |                    | S               | Subcutaneous                 | 70 U                                     |                 | Novo Nordisk |                |
|                                                                                                                                                     | Co-Aprovel                              |                    |                    | S               | Unknown                      | Unk                                      |                 | Not Reported |                |
|                                                                                                                                                     | Zanidip                                 |                    |                    | S               | Unknown                      | Unk                                      |                 | Not Reported |                |
|                                                                                                                                                     | Calcimagon D3                           |                    |                    | S               | Unknown                      | Unk                                      |                 | Not Reported |                |

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

|                                                                               |                        |                    |                    |                 |                                             |                      |                 |              |                |
|-------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|---------------------------------------------|----------------------|-----------------|--------------|----------------|
| Cipralex /01588501/                                                           |                        |                    | S                  | Unknown         | Unk                                         | Not Reported         |                 |              |                |
| <u>FDA Received Date</u>                                                      | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-May-2014                                                                   | 10176655               | EXPEDITED (15-DAY) | DE                 |                 | CH-BAYER-2014-071390                        |                      | 83 YR           | Female       | CHE            |
| <u>Preferred Term</u>                                                         | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Thalamus Haemorrhage                                                          | Aspirin Cardio         |                    |                    | S               |                                             | 100 Mg, Qd           |                 | Bayer        |                |
|                                                                               | Cipralex               |                    |                    | S               | Oral                                        | 1 Df, Qd             |                 | Not Reported |                |
|                                                                               | Pantozol (Switzerland) |                    |                    | C               |                                             |                      |                 | Not Reported |                |
|                                                                               | Sotalol                |                    |                    | C               |                                             |                      |                 | Not Reported |                |
|                                                                               | Crestor                |                    |                    | C               |                                             |                      |                 | Not Reported |                |
|                                                                               | Euthyrox               |                    |                    | C               |                                             |                      |                 | Not Reported |                |
|                                                                               | Seroquel               |                    |                    | C               |                                             |                      |                 | Not Reported |                |
|                                                                               | Trittico               |                    |                    | C               |                                             |                      |                 | Not Reported |                |
|                                                                               | Zanidip                |                    |                    | C               |                                             |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                      | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-May-2014                                                                   | 10177310               | EXPEDITED (15-DAY) | CA                 |                 | US-FRI-1000067270                           |                      | < 1 DAY         | Female       | USA            |
| <u>Preferred Term</u>                                                         | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Congenital Anomaly;<br>Multiple Cardiac Defects;<br>Ventricular Septal Defect | Lexapro                |                    |                    | S               | Transplacental                              |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                      | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-May-2014                                                                   | 10177347               | EXPEDITED (15-DAY) | CA                 |                 | US-FRI-1000067302                           |                      | < 1 DAY         | Male         | USA            |
| <u>Preferred Term</u>                                                         | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Talipes                                                                       | Lexapro                |                    |                    | S               | Transplacental                              |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                      | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-May-2014                                                                   | 10102378               | EXPEDITED (15-DAY) | HO, LT             |                 | JP-ELI_LILLY_AND_COMP<br>ANY-JP201404002253 |                      | 73 YR           | Female       | JPN            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                               | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>       |
|-------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------------|
| Decreased Appetite;<br>Malaise; Neuroleptic<br>Malignant Syndrome; Off<br>Label Use | Zyprexa              |              |            | S           | Oral         | 5 Mg, Qd           |                 | Eli Lilly And Co |
|                                                                                     | Sulpiride            |              |            | S           | Oral         | 50 Mg, Tid         |                 | Not Reported     |
|                                                                                     | Tandospirone Citrate |              |            | S           | Oral         | 10 Mg, Tid         |                 | Not Reported     |
|                                                                                     | Tandospirone Citrate |              |            | S           |              |                    |                 | Not Reported     |
|                                                                                     | Lexapro              |              |            | S           | Oral         | 10 Mg, Qd          |                 | Not Reported     |
|                                                                                     | Granpam              |              |            | C           | Oral         | 1 Df, Tid          |                 | Not Reported     |
|                                                                                     | Celecox              |              |            | C           | Oral         | Unk                |                 | Not Reported     |
|                                                                                     | Epenard              |              |            | C           | Oral         | 1 Df, Tid          |                 | Not Reported     |
|                                                                                     | Cortril /00028601/   |              |            | C           | Oral         |                    |                 | Not Reported     |
|                                                                                     | Cortril /00028601/   |              |            | C           |              |                    |                 | Not Reported     |
|                                                                                     | Bazedoxifene         |              |            | C           | Unknown      | Unk                |                 | Not Reported     |
|                                                                                     | Mohrus L             |              |            | C           | Transdermal  | Unk                |                 | Not Reported     |
|                                                                                     | Mohrus               |              |            | C           | Transdermal  |                    |                 | Not Reported     |
|                                                                                     | Amlodipine           |              |            | C           | Oral         | Unk                |                 | Not Reported     |
|                                                                                     | Pioglitazone         |              |            | C           | Oral         | Unk                |                 | Not Reported     |
|                                                                                     | Rabeprazole Sodium   |              |            | C           | Oral         | Unk, Qd            |                 | Not Reported     |
|                                                                                     | Ursodeoxycholic Acid |              |            | C           | Oral         | 100 Mg, Tid        |                 | Not Reported     |
|                                                                                     | Rebamipide           |              |            | C           |              | 100 Mg, Tid        |                 | Not Reported     |
|                                                                                     | Crestor              |              |            | C           | Oral         | Unk                |                 | Not Reported     |
|                                                                                     | Primperan            |              |            | C           | Oral         | 1 Df, Qd           |                 | Not Reported     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-May-2014              | 10178833      | EXPEDITED (15-DAY) |                    | OT              | IT-UCBSA-121324      |                      |            | Female     | ITA            |

| <u>Preferred Term</u>                                               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Myoclonus; Oculogyric<br>Crisis; Therapeutic<br>Response Unexpected | Rotigotine     |              |            | S           |              |                               |                 | Not Reported |
|                                                                     | Rotigotine     |              |            | S           |              | Temporary Dosage<br>Reduction |                 | Not Reported |
|                                                                     | Rotigotine     |              |            | S           |              | 3 Months Later                |                 | Not Reported |

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

|                                                                                 |                |                    |                    |                 |                              |                      |                 |              |                |
|---------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| Escitalopram<br>Pyridoxine                                                      |                |                    | S<br>S             |                 | Not Reported<br>Not Reported |                      |                 |              |                |
| <u>FDA Received Date</u>                                                        | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-May-2014                                                                     | 10179328       | EXPEDITED (15-DAY) |                    | HO, LT          | SE-FRI-1000067409            |                      | 21 YR           | Female       | SWE            |
| <u>Preferred Term</u>                                                           | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depressed Level Of<br>Consciousness                                             | Escitalopram   |                    |                    | S               | Oral                         | 10-15 Mg Daily       |                 | Forest       |                |
|                                                                                 | Escitalopram   |                    |                    | S               |                              |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                        | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-May-2014                                                                     | 10182562       | DIRECT             |                    | DS              |                              |                      | 38 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                           | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Arthralgia                                                                      | Celexa         |                    |                    | S               |                              | 1 Per Day            |                 | Not Reported |                |
|                                                                                 | Lexapro        |                    |                    | S               |                              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                        | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-May-2014                                                                     | 10185049       | DIRECT             |                    | DS, LT, OT      |                              |                      | 13 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                           | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dental Caries; Dry Mouth;<br>Gingival Pain; Malaise;<br>Tooth Fracture; Trismus | Escitalopram   |                    |                    | S               | Oral                         |                      |                 | Camber       |                |
| <u>FDA Received Date</u>                                                        | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-May-2014                                                                     | 10184784       | EXPEDITED (15-DAY) |                    | OT              | PHHY2013FR072299             |                      | 85 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                           | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Disinhibition;<br>Hypersexuality                                                | Exelon Patch   |                    |                    | S               | Transdermal                  | 4.6 Mg, Qd           |                 | Novartis     |                |
|                                                                                 | Seroplex       |                    |                    | S               | Oral                         | 5 Mg, Qd             |                 | Not Reported |                |
|                                                                                 | Pradaxa        |                    |                    | S               | Oral                         | 110 Mg, Bid          |                 | Not Reported |                |

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| Doliprane                |                      |                  | S                  |                 | Oral                     |                      | Unk Unk, Prn    |              | Not Reported   |  |
|--------------------------|----------------------|------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|--|
| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |  |
| 21-May-2014              | 10185986             | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2014135334 |                      | 38 YR           | Female       | USA            |  |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |  |
| Drug Hypersensitivity    | Neurontin            |                  |                    | S               |                          | Unk                  |                 | Pfizer       |                |  |
|                          | Levothyroxine Sodium |                  |                    | S               |                          | Unk                  |                 | Pfizer       |                |  |
|                          | Lithium Carbonate    |                  |                    | S               |                          | Unk                  |                 | Pfizer       |                |  |
|                          | Stadol               |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |  |
|                          | Vicodin              |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |  |
|                          | Zofran               |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |  |
|                          | Lexapro              |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |  |
|                          | Lunesta              |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |  |
|                          | Zyrtec               |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |  |
|                          | Qvar                 |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |  |
|                          | Xopenex              |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |  |
|                          | Klonopin             |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |  |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 21-May-2014              | 10186247       | EXPEDITED (15-DAY) |                    | OT              | AU-MYLANLABS-2014S1010701 |                      |                 | Female     | AUS            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Withdrawal Syndrome | Loxalate       |                    |                    | S               |                           |                      |                 | Mylan      |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 21-May-2014              | 10186760       | EXPEDITED (15-DAY) |                    | OT              | PHHY2014FR060953     |                      |                 | Female     | FRA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

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|                                                                                                                                                        |                |                    |                    |                 |                            |                      |                 |              |                |
|--------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| Alopecia; Weight Decreased                                                                                                                             |                | Gilenya            |                    | S               | Oral                       |                      |                 |              | Novartis       |
|                                                                                                                                                        |                | Seroplex           |                    | S               |                            |                      |                 |              | Not Reported   |
| <u>FDA Received Date</u>                                                                                                                               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-May-2014                                                                                                                                            | 9676464        | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2013314105   |                      | 62 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dermatitis Contact; Drug Hypersensitivity                                                                                                              | Zoloft         |                    |                    | S               |                            | Unk                  |                 | Pfizer       |                |
|                                                                                                                                                        | Xanax          |                    |                    | S               |                            | Unk                  |                 | Pfizer       |                |
|                                                                                                                                                        | Valium         |                    |                    | S               |                            | Unk                  |                 | Not Reported |                |
|                                                                                                                                                        | Lexapro        |                    |                    | S               |                            | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-May-2014                                                                                                                                            | 10029195       | EXPEDITED (15-DAY) |                    | HO, LT, OT      | FR-ASTRAZENECA-2014SE19205 |                      | 44 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                                                                  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Disorientation; Epistaxis; Neuroleptic Malignant Syndrome; Renal Tubular Necrosis; Sinus Tachycardia; Thrombosis; Toxicity To Various Agents; Vomiting | Xeroquel       |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                                                                                                                        | Xeroquel       |                    |                    | S               | Oral                       | One Box              |                 | Not Reported |                |
|                                                                                                                                                        | Loxapac        |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                                                                                                                        | Seroplex       |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-May-2014                                                                                                                                            | 10190241       | EXPEDITED (15-DAY) |                    | LT              | FR-ASTRAZENECA-2014SE34862 |                      | 78 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                                  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Status Epilepticus                                                                                                                                     | Inexium        |                    |                    | S               | Oral                       |                      |                 | Astrazeneca  |                |
|                                                                                                                                                        | Levofloxacin   |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                                                                                                                        | Domperidone    |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                                                                                                                        | Seroplex       |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |

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|            |   |              |              |
|------------|---|--------------|--------------|
| Plavix     | C | Oral         | Not Reported |
| Levothyrox | C | Oral         | Not Reported |
| Amlor      | C | Oral         | Not Reported |
| Lovenox    | C | Subcutaneous | Not Reported |
| Alprazolam | C | Oral         | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-May-2014              | 9696139       | EXPEDITED (15-DAY) |                    | HO              | CN-FRI-1000051458    |                      | 63 YR      | Female     | CHN            |

| <u>Preferred Term</u>                                                                                                                  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Asthenia; Confusional State; Decreased Appetite; Gastroesophageal Reflux Disease; Muscle Tightness; Off Label Use; Parkinson'S Disease | Lexapro        |              |            | S           | Oral         | 5 Mg               |                 | Forest       |
|                                                                                                                                        | Lexapro        |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                                                                                                                        | Lexapro        |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                                                                                                                        | Zoloft         |              |            | C           | Oral         | 1 Df               |                 | Not Reported |
|                                                                                                                                        | Omeprazole     |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                                                        | Metoprolol     |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                                                        | Ludoxin        |              |            | C           | Oral         | 1 Df               |                 | Not Reported |
|                                                                                                                                        | Shenzhong      |              |            | C           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-May-2014              | 9928407       | EXPEDITED (15-DAY) | Y                  | OT              | AUR-APL-2014-01871   |                      | 54 YR      | Male       | GBR            |

| <u>Preferred Term</u>                                                                                                                                          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Depressed Mood; Depression; Drug Ineffective; Inhibitory Drug Interaction; Product Substitution Issue; Suicidal Ideation; Therapeutic Product Effect Decreased | Escitalopram   |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                | Gliclazide     |              |            | S           | Oral         |                    |                 | Not Reported |



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| <u>FDA Received Date</u>                                                                    | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|---------------------------------------------------------------------------------------------|-----------------------|--------------------|--------------------|-----------------|---------------------------------------------------------------|----------------------|-----------------|----------------------|----------------|
| 23-May-2014                                                                                 | 10191336              | EXPEDITED (15-DAY) |                    | OT              | FR-B.I.<br>PHARMACEUTICALS,I<br>NC./RIDGEFIELD-2014-<br>BI-21 |                      | 81 YR           | Male                 | FRA            |
| <u>Preferred Term</u>                                                                       | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Disinhibition;<br>Hypersexuality                                                            | Pradaxa               |                    |                    | S               | Oral                                                          | 220 Mg               |                 | Boehringer Ingelheim |                |
|                                                                                             | Exelon                |                    |                    | S               | Transdermal                                                   | 4.6 Mg               |                 | Not Reported         |                |
|                                                                                             | Seroplex              |                    |                    | S               | Oral                                                          | 5 Mg                 |                 | Not Reported         |                |
|                                                                                             | Doliprane             |                    |                    | S               | Oral                                                          |                      |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                                    | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 23-May-2014                                                                                 | 10197445              | DIRECT             |                    | LT              |                                                               |                      | 66 YR           | Female               | USA            |
| <u>Preferred Term</u>                                                                       | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Suicidal Ideation                                                                           | Lexapro 10 Mg         |                    |                    | S               |                                                               | 1; One Daily         |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                                    | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 23-May-2014                                                                                 | 10198443              | DIRECT             |                    |                 |                                                               |                      | 76 YR           | Female               | USA            |
| <u>Preferred Term</u>                                                                       | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Arthritis; Ear Pain;<br>Headache; Ligament Pain;<br>Muscle Spasms; Myalgia;<br>Nausea; Pain | Escitalopram          |                    |                    | S               | Oral                                                          |                      |                 | Torrent              |                |
|                                                                                             | Vitamin B3            |                    |                    | C               |                                                               |                      |                 | Not Reported         |                |
|                                                                                             | Red Yeast Rice        |                    |                    | C               |                                                               |                      |                 | Not Reported         |                |
|                                                                                             | Multivitamin          |                    |                    | C               |                                                               |                      |                 | Not Reported         |                |
|                                                                                             | Aromasin (Exemestane) |                    |                    | C               |                                                               |                      |                 | Not Reported         |                |
|                                                                                             | Prilosec (Omeprazole) |                    |                    | C               |                                                               |                      |                 | Not Reported         |                |
|                                                                                             | Mobic                 |                    |                    | C               |                                                               |                      |                 | Not Reported         |                |
|                                                                                             | Tramadol (Ultram)     |                    |                    | C               |                                                               |                      |                 | Not Reported         |                |
|                                                                                             | Metaxalone (Skelaxin) |                    |                    | C               |                                                               |                      |                 | Not Reported         |                |
|                                                                                             | Vitamin D3-1000       |                    |                    | C               |                                                               |                      |                 | Not Reported         |                |

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| <u>FDA Received Date</u>                                             | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------------|-----------------|--------------|----------------|
| 23-May-2014                                                          | 10198897                  | DIRECT             |                    |                 |                      |                                     | 31 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Depression;<br>Panic Attack; Product<br>Substitution Issue  | Escitalopram 20 Mg Camber |                    |                    | S               | Oral                 | 1 Pill Once Daily Taken By<br>Mouth |                 | Camber       |                |
| <u>FDA Received Date</u>                                             | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-May-2014                                                          | 9921150                   | EXPEDITED (15-DAY) |                    | OT              |                      | GB-ACCORD-021970                    | 54 YR           | Male         | GBR            |
| <u>Preferred Term</u>                                                | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Depressed Mood;<br>Inhibitory Drug Interaction;<br>Suicidal Ideation | Escitalopram              |                    |                    | S               |                      | 10-20mg                             |                 | Accord       |                |
|                                                                      | Gliclazide                |                    |                    | S               | Oral                 | Not Known (Prescribed By<br>Gp)     |                 | Accord       |                |
| <u>FDA Received Date</u>                                             | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-May-2014                                                          | 10195573                  | EXPEDITED (15-DAY) |                    | OT              |                      | PHHY2014US051377                    |                 | Male         | USA            |
| <u>Preferred Term</u>                                                | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Withdrawal<br>Syndrome;<br>Musculoskeletal Stiffness            | Lioresal Intratecal       |                    |                    | S               | Intrathecal          | 1400 Ug (Aprox.)/ Day               |                 | Not Reported |                |
|                                                                      | Baclofen                  |                    |                    | S               | Oral                 | Unk Ukn, Unk                        |                 | Not Reported |                |
|                                                                      | Gabapentin                |                    |                    | S               |                      | Unk Ukn, Unk                        |                 | Not Reported |                |
|                                                                      | Omeprazole                |                    |                    | S               |                      | Unk Ukn, Unk                        |                 | Novartis     |                |
|                                                                      | Lexapro                   |                    |                    | S               |                      | Unk Ukn, Unk                        |                 | Not Reported |                |
|                                                                      | Crestor                   |                    |                    | S               |                      | Unk Ukn, Unk                        |                 | Not Reported |                |
|                                                                      | Seroquel                  |                    |                    | S               |                      | Unk Ukn, Unk                        |                 | Not Reported |                |
|                                                                      | Flomax                    |                    |                    | S               |                      | Unk Ukn, Unk                        |                 | Not Reported |                |
|                                                                      | Macrochantin              |                    |                    | S               |                      | Unk Ukn, Unk                        |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                            | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------|--------------------|--------------------|--------------------|-----------------|-----------------------|--------------------------|-----------------|--------------|----------------|
| 27-May-2014                                                                                                                         | 10196371           | EXPEDITED (15-DAY) |                    | OT              | BE-JNJFOC-20140514817 |                          |                 | Male         | BEL            |
| <u>Preferred Term</u>                                                                                                               | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Balance Disorder; Memory Impairment; Musculoskeletal Stiffness; Poisoning; Product Use In Unapproved Indication; Somnolence; Tremor | Xeplion            |                    |                    | S               | Intramuscular         |                          |                 | Not Reported |                |
|                                                                                                                                     | Sipralexa          |                    |                    | S               | Unknown               |                          |                 | Not Reported |                |
|                                                                                                                                     | Trazolan           |                    |                    | S               | Unknown               | 100 Once A Day 0.5       |                 | Not Reported |                |
|                                                                                                                                     | Maniprex           |                    |                    | S               | Unknown               |                          |                 | Not Reported |                |
|                                                                                                                                     | Depakine           |                    |                    | S               | Unknown               |                          |                 | Not Reported |                |
|                                                                                                                                     | L-Thyroxine        |                    |                    | C               | Unknown               | 0.0250 Unspecified Units |                 | Not Reported |                |
|                                                                                                                                     | Xanax Retard       |                    |                    | C               | Unknown               | 0.5 Unspecified Units    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                            | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-May-2014                                                                                                                         | 10196697           | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000067556     |                          | 81 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                                               | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Disinhibition; Hypersexuality                                                                                                       | Escitalopram       |                    |                    | S               | Oral                  | 5 Mg                     |                 | Forest       |                |
|                                                                                                                                     | Exelon 4.6 Mg/24 H |                    |                    | S               | Transdermal           | 4.6 Mg                   |                 | Not Reported |                |
|                                                                                                                                     | Pradaxa            |                    |                    | S               | Oral                  | 220 Mg                   |                 | Not Reported |                |
|                                                                                                                                     | Doliprane          |                    |                    | S               | Oral                  | If Needed                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                            | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-May-2014                                                                                                                         | 10204595           | DIRECT             | Y                  | OT              |                       |                          | 26 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                               | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Palpitations; Product Substitution Issue; Therapeutic Response Decreased; Tremor                                                    | Escitalopram 20 Mg |                    |                    | S               | Oral                  | One Daily, Qd, Oral      |                 | Not Reported |                |
|                                                                                                                                     | Alprazolam         |                    |                    | C               |                       |                          |                 | Not Reported |                |
|                                                                                                                                     | B Complex + C      |                    |                    | C               |                       |                          |                 | Not Reported |                |
|                                                                                                                                     | Benicar            |                    |                    | C               |                       |                          |                 | Not Reported |                |
|                                                                                                                                     | Clindamycin        |                    |                    | C               |                       |                          |                 | Not Reported |                |
|                                                                                                                                     | Implanon           |                    |                    | C               |                       |                          |                 | Not Reported |                |

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|                                                                                                                                                                  |                | Lortab           |                    | C               |                      |                                      |                 |              | Not Reported   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|--------------------------------------|-----------------|--------------|----------------|
|                                                                                                                                                                  |                | Propranolol      |                    | C               |                      |                                      |                 |              | Not Reported   |
|                                                                                                                                                                  |                | Topiramate       |                    | C               |                      |                                      |                 |              | Not Reported   |
|                                                                                                                                                                  |                | Zetonna          |                    | C               |                      |                                      |                 |              | Not Reported   |
| <u>FDA Received Date</u>                                                                                                                                         | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-May-2014                                                                                                                                                      | 10206004       | DIRECT           |                    |                 |                      |                                      | 24 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                            | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Decreased Appetite; Food Allergy; Headache; Irritability; Nausea; Neck Pain; Product Dose Omission; Rash Generalised; Urticaria; Varicose Vein; Weight Increased | Escitalopram   |                  |                    | S               | Oral                 | 1 Pill/Day Once Daily Taken By Mouth | 4 MTH           | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                         | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-May-2014                                                                                                                                                      | 10206381       | DIRECT           |                    | OT              |                      |                                      | 77 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                            | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Diplopia; Transient Ischaemic Attack                                                                                                                             | Escitalopram   |                  |                    | S               | Oral                 | 1 Pill                               |                 | Teva         |                |
|                                                                                                                                                                  | Amitriptyline  |                  |                    | C               |                      |                                      |                 | Not Reported |                |
|                                                                                                                                                                  | Prilosec       |                  |                    | C               |                      |                                      |                 | Not Reported |                |
|                                                                                                                                                                  | Oxybuteron     |                  |                    | C               |                      |                                      |                 | Not Reported |                |
|                                                                                                                                                                  | Vitamin B12    |                  |                    | C               |                      |                                      |                 | Not Reported |                |
|                                                                                                                                                                  | 81 Mg Aspirin  |                  |                    | C               |                      |                                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                         | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-May-2014                                                                                                                                                      | 10206422       | DIRECT           |                    |                 |                      |                                      | 56 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                            | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective                                                                                                                                                 | Lexapro        |                  |                    | S               | Oral                 | One Tablet                           |                 | Not Reported |                |
|                                                                                                                                                                  | Xanax          |                  |                    | C               |                      |                                      |                 | Not Reported |                |
|                                                                                                                                                                  | Protonix       |                  |                    | C               |                      |                                      |                 | Not Reported |                |

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| Ambien                    |                | C                  |                    | Not Reported    |                      |                          |                 |              |                |
|---------------------------|----------------|--------------------|--------------------|-----------------|----------------------|--------------------------|-----------------|--------------|----------------|
| Brintellix                |                | C                  |                    | Not Reported    |                      |                          |                 |              |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-May-2014               | 10206450       | DIRECT             |                    | CA, DS, HO, LT  |                      |                          | 60 DAY          | Male         | USA            |
| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrial Septal Defect;     | Lexapro        |                    |                    | S               |                      |                          |                 | Not Reported |                |
| Maternal Drugs Affecting  | Flovent        |                    |                    | C               |                      |                          |                 | Not Reported |                |
| Foetus; Premature Baby;   | Flonase        |                    |                    | C               |                      |                          |                 | Not Reported |                |
| Pulmonary Arterial        | Albuterol      |                    |                    | C               |                      |                          |                 | Not Reported |                |
| Hypertension; Ventricular | Multivitamins  | Y                  |                    | C               |                      |                          |                 | Not Reported |                |
| Septal Defect             | Allegra        | Y                  |                    | C               |                      |                          |                 | Not Reported |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-May-2014               | 10077132       | EXPEDITED (15-DAY) |                    | OT              | US-FRI-1000066358    |                          | 78 YR           | Female       | USA            |
| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression;               | Lexapro        |                    |                    | S               | Oral                 | 20 Mg                    |                 | Forest       |                |
| Musculoskeletal Disorder  | Toprol XL      |                    |                    | C               |                      |                          |                 | Not Reported |                |
|                           | Prevacid       |                    |                    | C               |                      |                          |                 | Not Reported |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-May-2014               | 10172070       | EXPEDITED (15-DAY) |                    | HO, OT          | PHEH2013US023761     |                          |                 | Female       | USA            |
| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain; Asthenia; | Diovan         |                    |                    | S               | Oral                 | 325 Mg, Qd               |                 | Not Reported |                |
| Blood Pressure            | Diovan         |                    |                    | S               | Oral                 | 160 Mg, Qd               |                 | Not Reported |                |
| Decreased; Blood          | Diovan         |                    |                    | S               |                      | 80 Mg, Qd                |                 | Not Reported |                |
| Pressure Increased; Chest | Diovan         |                    |                    | S               |                      | 1/3 Of A Tablet          |                 | Not Reported |                |
| Pain; Concussion;         | Diovan         |                    |                    | S               |                      | Unk Ukn, Unk             |                 | Not Reported |                |
| Diarrhoea; Dizziness;     | Diovan         |                    |                    | S               |                      | 0.5 Df (Meto 50 Mg), Bid |                 | Not Reported |                |
| Erythema; Feeding         | Lopresor       |                    |                    | S               | Oral                 | Unk Ukn, Unk             |                 | Novartis     |                |
| Disorder; Foot Deformity; | Diltiazem      |                    |                    | S               |                      |                          |                 |              |                |
| Gait Disturbance;         |                |                    |                    |                 |                      |                          |                 |              |                |
| Gallbladder Disorder;     |                |                    |                    |                 |                      |                          |                 |              |                |

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

|                              |            |   |                                       |                                |              |
|------------------------------|------------|---|---------------------------------------|--------------------------------|--------------|
| Gastric Disorder; Gastritis; | Metoprolol | S |                                       | Unk Unk, Unk                   | Not Reported |
| Gastrointestinal Disorder;   | Metoprolol | S |                                       | Unk Unk, Unk                   | Not Reported |
| Hypotension; Lactose         | Metoprolol | S |                                       | 50 Mg, Unk                     | Not Reported |
| Intolerance; Limb            | Metoprolol | S |                                       | 100 Mg, Unk                    | Not Reported |
| Discomfort; Malaise;         | Metoprolol | S |                                       | 0.5 Df, (25 Mg Pill, Low Dose) | Not Reported |
| Muscle Spasms; Muscle        | Metoprolol | S |                                       | 0.75 Df, (25 Mg) Bid           | Not Reported |
| Tightness; Myalgia;          | Metoprolol | S |                                       | Unk Unk, Unk                   | Not Reported |
| Nausea; Neuropathy           | Metoprolol | S |                                       | Unk Unk, Unk                   | Not Reported |
| Peripheral; Pain; Pain In    | Metoprolol | S |                                       | Unk Unk, Unk                   | Not Reported |
| Extremity; Palpitations;     | Metoprolol | S |                                       | Unk Unk, Unk                   | Not Reported |
| Rash; Road Traffic           | Xanax      | S |                                       | Unk Unk, Unk                   | Not Reported |
| Accident; Skin               | Xanax      | S |                                       | Unk Unk, Unk                   | Not Reported |
| Discolouration; Sleep        | Bystolic   | S |                                       | Unk Unk, Unk                   | Not Reported |
| Disorder; Somnolence;        | Bystolic   | S |                                       | Unk Unk, Unk                   | Not Reported |
| Spider Vein;                 | Lexapro    | S |                                       | Unk Unk, Unk                   | Not Reported |
| Supraventricular             | Lexapro    | S |                                       | 0.5 Df, Bid (0.25 Mg)          | Not Reported |
| Tachycardia; Taste           | Lexapro    | S |                                       | (Over 60 Min)                  | Not Reported |
| Disorder; Tremor; Weight     | Kinevac    | S | Intravenous (not otherwise specified) | Unk Unk, Unk                   | Not Reported |
| Decreased; Wrong             | Kinevac    | S |                                       | Unk Unk, Unk                   | Not Reported |
| Technique In Product         | Kinevac    | S |                                       | Unk Unk, Unk                   | Not Reported |
| Usage Process                | Centrum    | C |                                       | Unk Unk, Unk                   | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-May-2014              | 10173685      | EXPEDITED (15-DAY) |                    | HO, LT          | FR-FRI-1000067322    |                      | 44 YR      | Male       | FRA            |

| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|----------------|--------------|------------|-------------|--------------|----------------------------------------|-----------------|--------------|
| Intentional Overdose;     | Escitalopram   |              |            | S           | Oral         | 20 Mg                                  |                 | Forest       |
| Neuroleptic Malignant     | Xeroquel       |              |            | S           | Oral         |                                        |                 | Not Reported |
| Syndrome; Renal Tubular   | Xeroquel       |              |            | S           | Oral         | Overdose Of 1 Box (Unknown Exact Dose) |                 | Not Reported |
| Necrosis; Suicide Attempt | Xeroquel       |              |            | S           | Oral         |                                        |                 | Not Reported |
|                           | Loxapac        |              |            | S           | Oral         |                                        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-May-2014              | 10200434      | EXPEDITED (15-DAY) |                    | LT              | FR-ROCHE-1404666     |                      | 61 YR      | Male       | FRA            |

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

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

|                                                    |           |   |         |              |
|----------------------------------------------------|-----------|---|---------|--------------|
| Electrocardiogram Qt Prolonged; Torsade De Pointes | Valium    | S | Unknown | Not Reported |
|                                                    | Xatral    | S | Unknown | Not Reported |
|                                                    | Seroplex  | S | Unknown | Not Reported |
|                                                    | Primperan | S | Unknown | Not Reported |

| <u>FDA Received Date</u>                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 28-May-2014                                | 10201103       | EXPEDITED (15-DAY) |                    | OT              | CN-FRI-1000067593    |                      | 52 YR           | Female     | CHN            |
| <u>Preferred Term</u>                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Abdominal Pain; Postmenopausal Haemorrhage | Lexapro        |                    |                    | S               | Oral                 | 5 Mg                 |                 | Forest     |                |

| <u>FDA Received Date</u> | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 28-May-2014              | 10201106               | EXPEDITED (15-DAY) |                    | DE              | CH-FRI-1000067596    |                      |                 | Female       | CHE            |
| <u>Preferred Term</u>    | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Thalamus Haemorrhage     | Escitalopram           |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                          | Aspirin Cardio         |                    |                    | S               | Oral                 | 100 Mg               |                 | Not Reported |                |
|                          | Pantozol (Switzerland) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Sotalol                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Crestor                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Euthyrox               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Seroquel               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Trittico               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Zanidip                |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 28-May-2014                                                    | 10201236       | EXPEDITED (15-DAY) |                    | HO              | CH-FRI-1000067594    |                      |                 | Female       | CHE            |
| <u>Preferred Term</u>                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Coronary Artery Disease; Drug Interaction; Epistaxis; Gingival | Escitalopram   |                    |                    | S               | Oral                 | 20 Mg                |                 | Forest       |                |
|                                                                | Escitalopram   |                    |                    | S               | Oral                 | 10 Mg                |                 | Not Reported |                |

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

|                                                                                |                     |   |         |         |              |
|--------------------------------------------------------------------------------|---------------------|---|---------|---------|--------------|
| Bleeding; Myocardial Ischaemia; Spontaneous Haematoma; Ventricular Hypokinesia | Dilzem              | S | Oral    | 90 Mg   | Not Reported |
|                                                                                | Aspirin             | S | Oral    | 100 Mg  | Not Reported |
|                                                                                | Efient              | S | Oral    | 10 Mg   | Not Reported |
|                                                                                | Lexotanil           | C | Oral    | 6 Mg    | Not Reported |
|                                                                                | Nitroderm           | C | Topical | 10 Mg   | Not Reported |
|                                                                                | Ulcogant            | C | Oral    | 1000 Mg | Not Reported |
|                                                                                | Laxoberon           | C | Oral    | 10 Mg   | Not Reported |
|                                                                                | Isoket              | C | Oral    | 1.25 Mg | Not Reported |
|                                                                                | Beloc-Zok           | C | Oral    | 25 Mg   | Not Reported |
|                                                                                | Dancor              | C | Oral    | 20 Mg   | Not Reported |
|                                                                                | Diovan              | C | Oral    | 80 Mg   | Not Reported |
|                                                                                | Nexium              | C | Oral    | 40 Mg   | Not Reported |
|                                                                                | Ezetrol             | C | Oral    | 10 Mg   | Not Reported |
|                                                                                | Ranexa              | C | Oral    | 750 Mg  | Not Reported |
|                                                                                | Atorvastatine       | C | Oral    | 80 Mg   | Not Reported |
|                                                                                | Lyrica              | C | Oral    | 75 Mg   | Not Reported |
|                                                                                | Paracetamol/ Codein | C | Oral    |         | Not Reported |
|                                                                                | Nsaid               | C |         |         | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>     | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|--------------------------|-------------------|------------------|--------------------|-----------------|------------------------------------------|----------------------|-----------------|----------------------|----------------|
| 28-May-2014              | 10201975          | NON-EXPEDITED    |                    |                 | US-BRISTOL-MYERS SQUIBB COMPANY-19800556 |                      | 91 YR           | Female               | USA            |
| <u>Preferred Term</u>    | <u>Product</u>    | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Blood Glucose Increased  | Abilify Tabs 5 Mg |                  |                    | S               |                                          |                      |                 | Not Reported         |                |
|                          | Metformin Hcl     |                  |                    | S               |                                          |                      |                 | Bristol Myers Squibb |                |
|                          | Lexapro           |                  |                    | S               |                                          |                      |                 | Not Reported         |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|------------|----------------|
| 28-May-2014              | 10202507       | EXPEDITED (15-DAY) |                    | HO, OT          | FR-ASTRAZENECA-2014SE35386 |                      | 61 YR           | Male       | FRA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |



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

|                                                  |                 |   |          |                            |              |
|--------------------------------------------------|-----------------|---|----------|----------------------------|--------------|
| Hallucination; Oedema;<br>Paralysis; Prostatitis | Xylocaine Jelly | S | Urethral |                            | Not Reported |
|                                                  | Seroplex        | S | Oral     |                            | Not Reported |
|                                                  | Seroplex        | S | Oral     |                            | Not Reported |
|                                                  | Haldol          | S | Oral     | 2mg/MI 275 Drops Per Day   | Not Reported |
|                                                  | Haldol          | S | Oral     |                            | Not Reported |
|                                                  | Bactrim Forte   | S | Oral     |                            | Not Reported |
|                                                  | Revatio         | C | Oral     |                            | Not Reported |
|                                                  | Xatral          | C | Oral     |                            | Not Reported |
|                                                  | Lasilix         | C | Oral     |                            | Not Reported |
|                                                  | Lepticur        | C | Oral     |                            | Not Reported |
|                                                  | Rivotril        | C | Oral     | 2.5 Mg/MI 40 Drops Per Day | Not Reported |
|                                                  | Seresta         | C | Oral     |                            | Not Reported |
|                                                  | Tegretol        | C | Oral     |                            | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-May-2014              | 10202576      | EXPEDITED (15-DAY) |                    | OT              | IT-FRI-1000067655    |                      | 79 YR      | Male       | ITA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hyponatraemia; Sopor  | Escitalopram   |              |            | S           |              |                    |                 | Forest       |
|                       | Escitalopram   |              |            | S           |              | 1/2 Tablet         |                 | Not Reported |
|                       | Perindopril    |              |            | S           | Oral         | 4 Mg               |                 | Not Reported |
|                       | Tachidol       |              |            | S           |              |                    |                 | Not Reported |
|                       | Amlodipine     |              |            | C           | Oral         | 10 Mg              |                 | Not Reported |
|                       | Ticlodipine    |              |            | C           |              |                    |                 | Not Reported |
|                       | Lasitane       |              |            | C           |              |                    |                 | Not Reported |
|                       | Megace         |              |            | C           |              |                    |                 | Not Reported |
|                       | Crestor        |              |            | C           | Oral         | 10 Mg              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-May-2014              | 10202706      | EXPEDITED (15-DAY) |                    | OT              | US-FRI-1000067606    |                      | 56 YR      | Female     | USA            |

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

| <u>Preferred Term</u>                                                                   | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|-----------------------------------------------------------------------------------------|-----------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|-----------------|--------------|----------------|
| Coeliac Disease                                                                         | Lexapro         |                    |                    | S               | Oral                          | 10 Mg                |                 | Forest       |                |
|                                                                                         | Mvi             |                    |                    | C               |                               |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-May-2014                                                                             | 10207773        | DIRECT             | Y                  | OT              |                               |                      | 53 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                   | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated;<br>Product Substitution Issue                                     | Generic Lexapro |                    |                    | S               | Oral                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-May-2014                                                                             | 9998226         | EXPEDITED (15-DAY) |                    | HO              | IT-MYLANLABS-<br>2014S1004708 |                      | 61 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                                   | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Abuse; Intentional<br>Self-Injury; Mydriasis;<br>Sopor; Unresponsive To<br>Stimuli | Alprazolam      |                    |                    | S               | Oral                          | 1 Df Total           |                 | Mylan        |                |
|                                                                                         | Cipralex        |                    |                    | S               | Oral                          | 80 Mg Total          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-May-2014                                                                             | 10070933        | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000066305             |                      | < 1 DAY         | Male         | USA            |
| <u>Preferred Term</u>                                                                   | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypospadias; Premature<br>Baby                                                          | Lexapro         |                    |                    | S               | Transplacental                |                      |                 | Forest       |                |
|                                                                                         | Acyclovir       |                    |                    | C               | Transplacental                |                      |                 | Not Reported |                |
|                                                                                         | Insulin         |                    |                    | C               | Transplacental                |                      |                 | Not Reported |                |
|                                                                                         | Betamethasone   |                    |                    | C               | Transplacental                |                      |                 | Not Reported |                |
|                                                                                         | Erythromycin    |                    |                    | C               | Transplacental                |                      |                 | Not Reported |                |
|                                                                                         | Ampicillin      |                    |                    | C               | Transplacental                |                      |                 | Not Reported |                |
|                                                                                         | Morphine        |                    |                    | C               | Transplacental                |                      |                 | Not Reported |                |
|                                                                                         | Nubain          |                    |                    | C               | Transplacental                |                      |                 | Not Reported |                |

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|                                                                               |                                                                 |                    |                    |                 |                       |                      |                 |              |                |
|-------------------------------------------------------------------------------|-----------------------------------------------------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| Vistaril                                                                      |                                                                 |                    | C                  |                 | Transplacental        |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                      | <u>Case #</u>                                                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-May-2014                                                                   | 10204789                                                        | EXPEDITED (15-DAY) |                    | OT              | IT-TEVA-482916ISR     |                      | 79 YR           | Male         | ITA            |
| <u>Preferred Term</u>                                                         | <u>Product</u>                                                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyponatremia; Sopor                                                           | Perindopril                                                     |                    |                    | S               | Oral                  | 4 Milligram Daily;   |                 | Ivax         |                |
|                                                                               | Lasitone - 25 Mg + 37 Mg Capsule Rigide - Sanofi-Aventis S.P.A. |                    |                    | S               |                       |                      |                 | Not Reported |                |
|                                                                               | Cipralex - Comprime Rivestite Con Film - H. Lundbeck A/S        |                    |                    | S               |                       |                      |                 | Not Reported |                |
|                                                                               | Crestor - Comprime Rivestite Con Film                           |                    |                    | C               | Oral                  | 10 Mg                |                 | Not Reported |                |
|                                                                               | Megace - 160 Mg Comprime                                        |                    |                    | C               |                       |                      |                 | Not Reported |                |
|                                                                               | Tachidol - Adulti 500 Mg/30 Mg Granulato Effervescente          |                    |                    | C               |                       |                      |                 | Not Reported |                |
|                                                                               | Ticlopidine Hydrochloride                                       |                    |                    | C               |                       |                      |                 | Not Reported |                |
|                                                                               | Amlodipine Besylate                                             |                    |                    | C               | Oral                  | 10 Mg                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                      | <u>Case #</u>                                                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-May-2014                                                                   | 10204884                                                        | NON-EXPEDITED      |                    | HO              | US-FRI-1000066304     |                      | 28 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                         | <u>Product</u>                                                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Exposure During Pregnancy; Premature Delivery; Premature Rupture Of Membranes | Lexapro                                                         |                    |                    | S               |                       | 20 Mg                |                 | Forest       |                |
|                                                                               | Acyclovir                                                       |                    |                    | C               |                       |                      |                 | Not Reported |                |
|                                                                               | Insulin                                                         |                    |                    | C               |                       |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                      | <u>Case #</u>                                                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-May-2014                                                                   | 10204931                                                        | EXPEDITED (15-DAY) |                    | HO              | FR-JNJFOC-20140510592 |                      | 61 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                         | <u>Product</u>                                                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hallucination; Oedema; Paralysis                                              | Haldol                                                          |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |

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

|               |   |                                       |                     |              |
|---------------|---|---------------------------------------|---------------------|--------------|
| Haldol        | S | Oral                                  |                     | Not Reported |
| Haldol        | S | Oral                                  |                     | Not Reported |
| Seroplex      | S | Unknown                               | 1 Tablets Per Day   | Not Reported |
| Seroplex      | S | Unknown                               | 1 Tablet Per Day    | Not Reported |
| Seroplex      | S | Unknown                               |                     | Not Reported |
| Bactrim Forte | S | Oral                                  |                     | Not Reported |
| Xylocaine     | S | Intravenous (not otherwise specified) |                     | Not Reported |
| Cymbalta      | C | Unknown                               |                     | Not Reported |
| Xatral        | C | Unknown                               |                     | Not Reported |
| Lasilix       | C | Unknown                               |                     | Not Reported |
| Rivotril      | C | Unknown                               |                     | Not Reported |
| Lepticur      | C | Unknown                               |                     | Not Reported |
| Dipiperon     | C | Unknown                               |                     | Not Reported |
| Seresta       | C | Unknown                               | 3.5 Tablets Per Day | Not Reported |
| Tegretol      | C | Unknown                               |                     | Not Reported |
| Revatio       | C | Unknown                               |                     | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-May-2014              | 10205118      | EXPEDITED (15-DAY) |                    | LT              | FR-FRI-1000067652    |                      |            | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Status Epilepticus    | Escitalopram   |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                       | Levofloxacin   |              |            | S           | Oral         | 500 Mg             |                 | Not Reported |
|                       | Inexium        |              |            | S           | Oral         | 40 Mg              |                 | Not Reported |
|                       | Domperidone    |              |            | S           | Oral         | 10 Mg              |                 | Not Reported |
|                       | Plavix         |              |            | C           |              | 1 Df               |                 | Not Reported |
|                       | Levothyrox     |              |            | C           |              | 75 Mcg             |                 | Not Reported |
|                       | Amlor          |              |            | C           |              | 5 Mg               |                 | Not Reported |
|                       | Lovenox        |              |            | C           | Other        | 40 lu              |                 | Not Reported |

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

|                                               |                    |                    |                    |                 |             |                      |                      |                 |              |                |  |
|-----------------------------------------------|--------------------|--------------------|--------------------|-----------------|-------------|----------------------|----------------------|-----------------|--------------|----------------|--|
| Alprazolam                                    |                    |                    | C                  |                 |             | 1 Mg                 |                      |                 | Not Reported |                |  |
| <u>FDA Received Date</u>                      | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> |             | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |  |
| 29-May-2014                                   | 10205121           | EXPEDITED (15-DAY) |                    | DE              |             | CH-BAYER-2014-075430 |                      | 75 YR           | Female       | CHE            |  |
| <u>Preferred Term</u>                         | <u>Product</u>     |                    | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u> | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |  |
| Cerebral Haemorrhage                          | Aspirin Cardio     |                    |                    |                 | S           | Oral                 | 100 Mg, Qd           |                 | Bayer        |                |  |
|                                               | Cipralext          |                    |                    |                 | S           | Oral                 | 5 Mg, Qd             |                 | Not Reported |                |  |
|                                               | Catapresan         |                    |                    |                 | C           | Oral                 | Unk                  |                 | Not Reported |                |  |
|                                               | Beloc [Metoprolol] |                    |                    |                 | C           | Oral                 | 50 Mg, Qd            |                 | Not Reported |                |  |
|                                               | Triatec (Ramipril) |                    |                    |                 | C           | Oral                 | 5 Mg, Qd             |                 | Not Reported |                |  |
|                                               | Adalat Cr          |                    |                    |                 | C           | Oral                 | 60 Mg, Qd            |                 | Bayer        |                |  |
|                                               | Clonazepam         |                    |                    |                 | C           |                      | Unk                  |                 | Not Reported |                |  |
| <u>FDA Received Date</u>                      | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> |             | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |  |
| 29-May-2014                                   | 10205238           | EXPEDITED (15-DAY) |                    | HO              |             | CA-FRI-1000067684    |                      |                 | Female       | CAN            |  |
| <u>Preferred Term</u>                         | <u>Product</u>     |                    | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u> | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |  |
| Dizziness; Head Titubation; Suicidal Ideation | Escitalopram       |                    |                    |                 | S           |                      | 15 Mg                |                 | Forest       |                |  |
|                                               | Escitalopram       |                    |                    |                 | S           |                      | 20 Mg                |                 | Not Reported |                |  |
|                                               | Escitalopram       |                    |                    |                 | S           |                      | 5 Mg                 |                 | Not Reported |                |  |
| <u>FDA Received Date</u>                      | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> |             | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |  |
| 29-May-2014                                   | 10205251           | EXPEDITED (15-DAY) |                    | DE, HO, LT, OT  |             | AU-FRI-1000066507    |                      | 17 YR           | Female       | AUS            |  |
| <u>Preferred Term</u>                         | <u>Product</u>     |                    | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u> | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |  |
| Off Label Use; Purpura; Thrombocytopenia      | Escitalopram       |                    |                    |                 | S           | Oral                 | 10 Mg                |                 | Forest       |                |  |
|                                               | Escitalopram       |                    |                    |                 | S           |                      |                      |                 | Forest       |                |  |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>    | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 29-May-2014                 | 10205253       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000067096    |                      | 36 YR           | Male         | FRA            |
| <u>Preferred Term</u>       | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dyskinesia; Muscle Rigidity | Escitalopram   |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                             | Loxapac        |                    |                    | S               | Oral                 | 45 Df                |                 | Not Reported |                |
|                             | Atarax         |                    |                    | S               | Oral                 | 150 Mg               |                 | Not Reported |                |
| <u>FDA Received Date</u>    | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-May-2014                 | 10205562       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000067658    |                      | 61 YR           | Male         | FRA            |
| <u>Preferred Term</u>       | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Oedema; Paralysis           | Escitalopram   |                    |                    | S               | Oral                 | 15 Mg                |                 | Forest       |                |
|                             | Escitalopram   |                    |                    | S               | Oral                 | 20 Mg                |                 | Not Reported |                |
|                             | Haldol         |                    |                    | S               | Oral                 | 275 Gtt              |                 | Not Reported |                |
|                             | Haldol         |                    |                    | S               | Oral                 | Dose Increased Nos   |                 | Not Reported |                |
|                             | Haldol         |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                             | Bactrim        |                    |                    | S               | Oral                 | 2 Df                 |                 | Not Reported |                |
|                             | Xylocaine      |                    |                    | S               | Urethral             | 2 Df                 |                 | Not Reported |                |
|                             | Revatio        |                    |                    | C               | Oral                 | 3 Df                 |                 | Not Reported |                |
|                             | Xatral         |                    |                    | C               | Oral                 | 1 Df                 |                 | Not Reported |                |
|                             | Lasilix        |                    |                    | C               | Oral                 | 1 Df                 |                 | Not Reported |                |
|                             | Lepticur       |                    |                    | C               | Oral                 | 1 Df                 |                 | Not Reported |                |
|                             | Rivotril       |                    |                    | C               | Oral                 | 40 Gtt               |                 | Not Reported |                |
|                             | Seresta        |                    |                    | C               | Oral                 | 3.5 Df               |                 | Not Reported |                |
|                             | Tegretol       |                    |                    | C               | Oral                 | 2 Df                 |                 | Not Reported |                |
|                             | Cymbalta       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                             | Dipiperon      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                             | Ceftriaxone    |                    |                    | C               |                      |                      |                 | Not Reported |                |

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

| <u>FDA Received Date</u>                                                                                       | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 29-May-2014                                                                                                    | 10205563               | EXPEDITED (15-DAY) |                    | DE              | FR-FRI-1000067646    |                      | 87 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                          | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated;<br>International Normalised<br>Ratio Increased; Shock<br>Haemorrhagic                    | Escitalopram           |                    |                    | S               | Oral                 |                      |                 | Forest       |                |
|                                                                                                                | Previscan (Fluindione) |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                | Furosemide             |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                | Diamicron              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                | Coversyl               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                | Lercanidipine          |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                | Eupressyl              |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                       | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-May-2014                                                                                                    | 10205573               | EXPEDITED (15-DAY) |                    | OT              | DE-FRI-1000067661    |                      | 46 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                                                                          | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hepatic Enzyme<br>Increased; Nausea; Pain                                                                      | Escitalopram           |                    |                    | S               | Oral                 | 20 Mg                |                 | Forest       |                |
|                                                                                                                | Escitalopram           |                    |                    | S               |                      |                      |                 | Forest       |                |
|                                                                                                                | Tavor (Lorazepam)      |                    |                    | C               | Oral                 | 1 Mg                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                       | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-May-2014                                                                                                    | 10207032               | DIRECT             |                    | HO, OT          |                      |                      | 34 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                          | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Amnesia; Anxiety;<br>Disturbance In Attention;<br>Mental Status Changes;<br>Seizure; Tremor; Vision<br>Blurred | Viibryd                |                    |                    | S               |                      | 2 Tbl By Mouth       |                 | Forest       |                |
|                                                                                                                | Escitalopram           |                    |                    | S               |                      |                      |                 | Mylan        |                |
|                                                                                                                | Imitrex                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                | Lido                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                | Prilocin               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                | Ibuprofen              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                | Ciprofloxacin          |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                | Ciclobenzapine         |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                | Meloxin                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                | Lexapro                |                    |                    | C               |                      |                      |                 | Not Reported |                |

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

|                          |   |              |
|--------------------------|---|--------------|
| Flexeril                 | C | Not Reported |
| Clindamycin              | C | Not Reported |
| Ibuprofen                | C | Not Reported |
| Vacinacion Afuria        | C | Not Reported |
| Xanax                    | C | Not Reported |
| Vitamin D Nos            | C | Not Reported |
| Meloxicam                | C | Not Reported |
| Clonazepam               | C | Not Reported |
| Bactrim                  | C | Not Reported |
| (Silfameth/Trimethoprim) |   |              |
| Tramadol                 | C | Not Reported |
| Keflex                   | C | Not Reported |
| Sumatriptan              | C | Not Reported |
| Atorvastatin             | C | Not Reported |
| Sumatriptan              | S | Not Reported |
| Cyclobenzaprine          | S | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-May-2014              | 10207029      | EXPEDITED (15-DAY) |                    | OT              | CN-FRI-1000022669    |                      |            | Male       | CHN            |

| <u>Preferred Term</u>          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Constipation;<br>Haematochezia | Lexapro        |              |            | S           | Oral         | 5 Mg               |                 | Forest     |
|                                | Lexapro        |              |            | S           | Oral         | 10 Mg              |                 | Forest     |
|                                | Lexapro        |              |            | S           | Oral         | 15 Mg              |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 30-May-2014              | 10208455      | NON-EXPEDITED    |                    |                 | US-PFIZER INC-<br>2014147321 |                      | 75 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Drug Hypersensitivity | Neurontin      |              |            | S           |              | Unk                |                 | Pfizer     |
|                       | Celebrex       |              |            | S           |              | Unk                |                 | Pfizer     |
|                       | Effexor        |              |            | S           |              | Unk                |                 | Pfizer     |
|                       | Amoxicillin    |              |            | S           |              | Unk                |                 | Pfizer     |
|                       | Lodine         |              |            | S           |              | Unk                |                 | Pfizer     |



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|  |                    |   |     |              |
|--|--------------------|---|-----|--------------|
|  | Indocin            | S | Unk | Not Reported |
|  | Cymbalta           | S | Unk | Not Reported |
|  | Hydroxychloroquine | S | Unk | Not Reported |
|  | Wellbutrin         | S | Unk | Not Reported |
|  | Thorazine          | S | Unk | Not Reported |
|  | Lexapro            | S | Unk | Not Reported |
|  | Vioxx              | S | Unk | Not Reported |
|  | Abilify            | S | Unk | Not Reported |
|  | Allopurinol        | S | Unk | Not Reported |
|  | Flexeril           | S | Unk | Not Reported |
|  | Clonazepam         | S | Unk | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-May-2014              | 10213727      | EXPEDITED (15-DAY) | Y                  | OT              | UCM201405-000087     |                      | 32 YR      | Male       | IND            |

| <u>Preferred Term</u>          | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                                                  | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------|-------------------|--------------|------------|-------------|--------------|-----------------------------------------------------------------------------------------------------|-----------------|--------------|
| Dystonia; Protrusion<br>Tongue | Divalproex Sodium |              |            | S           |              | 400 Mg Per Day In Divided<br>Doses, 400 Mg Per Day In<br>Divided Doses<br>900 Mg Per Day            |                 | Not Reported |
|                                | Sodium Phenytoin  |              |            | S           |              | 300 Mg Per Day In Divided<br>Doses, 300 Mg Per Day In<br>Divided Doses<br>600 Mg Per Day            |                 | Not Reported |
|                                | Escitalopram      |              |            | S           |              | 10 Mg Per Day, 10 Mg Per<br>Day<br>15 Mg Per Day, 15 Mg Per<br>Day<br>5 Mg Per Day, 5 Mg Per<br>Day |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>              | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------------------|----------------------|------------|------------|----------------|
| 01-Jun-2014              | 10209512      | EXPEDITED (15-DAY) |                    | OT              | TR-US-EMD SERONO,<br>INC.-7294936 |                      |            | Female     | TUR            |

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

| <u>Preferred Term</u>                                                                                          | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|----------------------------------------------------------------------------------------------------------------|-----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Diabetes Mellitus; Diabetic Neuropathy                                                                         | Rebif                 |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                | Beloc-Zok             |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                | Escitalopram          |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                | Thioctacid /00213801/ |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                | Suprafen              |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                       | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Jun-2014                                                                                                    | 10211721              | EXPEDITED (15-DAY) |                    | CA              | DE-FRI-1000067838    |                      | 1 DAY           | Female       | DEU            |
| <u>Preferred Term</u>                                                                                          | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Arachnoid Cyst; Cerebellar Hypoplasia; Foetal Exposure During Pregnancy; Subdural Hygroma; Vith Nerve Disorder | Escitalopram          |                    |                    | S               | Transplacental       | 10-15 Mg             |                 | Forest       |                |
|                                                                                                                | Ibuprofen             |                    |                    | C               | Transplacental       | 800 Mg, If Required  |                 | Not Reported |                |
|                                                                                                                | Meronem               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                | Folic Acid            |                    |                    | C               | Transplacental       |                      |                 | Not Reported |                |
|                                                                                                                | Dopegyt               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                | Anaesthetics          |                    |                    | C               | Transplacental       |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                       | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Jun-2014                                                                                                    | 10211728              | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000067835    |                      | < 1 DAY         | Female       | FRA            |
| <u>Preferred Term</u>                                                                                          | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Poor Sucking Reflex; Poor Weight Gain Neonatal; Somnolence                                                     | Escitalopram          |                    |                    | S               | Transplacental       | 10 Mg                |                 | Forest       |                |
|                                                                                                                | Lexomil Roche         |                    |                    | S               | Transplacental       | 3 Mg                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                       | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Jun-2014                                                                                                    | 10211730              | EXPEDITED (15-DAY) |                    | OT              | DE-FRI-1000067837    |                      | 29 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                                                                          | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bacterial Infection; Caesarean Section; Cervical Incompetence; Gestational Hypertension                        | Escitalopram          |                    |                    | S               | Oral                 | 10-15 Mg             |                 | Forest       |                |
|                                                                                                                | Ibuprofen             |                    |                    | C               | Oral                 | 800 Mg, If Required  |                 | Not Reported |                |

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Folic Acid

C

Oral

Not Reported

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Jun-2014              | 9732485       | EXPEDITED (15-DAY) |                    | HO, OT          | VAL_02842_2013       |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                   | <u>Product</u>                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                          | <u>Dosage Text</u>                                                                                                                                                                  | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|--------------|------------|-------------|---------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|--------------|
| Abdominal Discomfort;                                                                                                                                                                                                   | Lopressor                      |              |            | S           |                                       | (25 Mg, Df)                                                                                                                                                                         |                 | Not Reported |
| Abdominal Pain; Asthenia;                                                                                                                                                                                               | Diltiazem                      |              |            | S           |                                       | (Df [Regimen 1])                                                                                                                                                                    |                 | Not Reported |
| Blood Pressure Increased;                                                                                                                                                                                               | Xanax                          |              |            | S           |                                       | Df                                                                                                                                                                                  |                 | Not Reported |
| Chest Pain; Concussion;                                                                                                                                                                                                 | Bystolic                       |              |            | S           |                                       | (Df [Regimen 1])                                                                                                                                                                    |                 | Not Reported |
| Diarrhoea; Dizziness;                                                                                                                                                                                                   |                                |              |            |             |                                       | Unknown Until Not Continuing                                                                                                                                                        |                 |              |
| Dysgeusia; Eating Disorder; Erythema; Erythema; Feeling Abnormal; Gait                                                                                                                                                  | Lexapro (Not Specified)        |              |            | S           |                                       | Df Regimen 1                                                                                                                                                                        |                 | Not Reported |
| Disturbance; Gallbladder Disorder; Gastric Disorder; Gastritis; Gastrointestinal Disorder; Hypotension; Hypotension; Lactose Intolerance; Malaise; Muscle Spasms; Muscle Tightness; Myalgia; Nausea; Neuropathy         | Centrum / 07499601/ Metoprolol |              |            | C           |                                       |                                                                                                                                                                                     |                 | Not Reported |
| Peripheral; Pain; Pain In Extremity; Palpitations; Palpitations; Post Procedural Complication; Rash; Rash                                                                                                               |                                |              |            | S           |                                       | (Df)                                                                                                                                                                                |                 | Not Reported |
| Erythematous; Reaction To Excipient; Road Traffic Accident; Sleep Disorder; Somnolence; Spider Vein; Supraventricular Tachycardia; Tremor; Weight Decreased; Weight Decreased; Wrong Technique In Product Usage Process |                                |              |            | S           |                                       | (50 Mg, Regimen 3)<br>(100 Mg, Regimen 4)<br>(0.5 Df, Regimen 5)<br>(0.75 Df Bid, [Regimen 6])<br>(0.25 Df Bid, [Regimen 7])<br>(0.5 Df Bid, [Regimen 8])<br>(1 Df Bid [Regimen 9]) |                 |              |
|                                                                                                                                                                                                                         | Diovan (Not Specified)         |              |            | S           | Oral<br>Oral                          |                                                                                                                                                                                     |                 | Not Reported |
|                                                                                                                                                                                                                         | Kinevac                        |              |            | S           | Intravenous (not otherwise specified) | ([1/3 Tablet For 2-3 Weeks])<br>([Df Over 60 Min, Regimen 1])                                                                                                                       |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| 03-Jun-2014                                                                            | 9922660              | EXPEDITED (15-DAY) |                    | OT              | GB-FRI-1000054530            |                      | 54 YR           | Male         | GBR            |
| <u>Preferred Term</u>                                                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depressed Mood;<br>Inhibitory Drug Interaction;<br>Off Label Use; Suicidal<br>Ideation | Escitalopram         |                    |                    | S               | Oral                         |                      |                 | Forest       |                |
|                                                                                        | Gliclazide           |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Jun-2014                                                                            | 10214132             | EXPEDITED (15-DAY) |                    | DE              | ES-PFIZER INC-<br>2014150650 |                      | 87 YR           | Female       | ESP            |
| <u>Preferred Term</u>                                                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cerebral Haemorrhage;<br>Drug Interaction                                              | Trangorex            |                    |                    | S               | Oral                         | Unk                  |                 | Pfizer       |                |
|                                                                                        | Escitalopram Oxalate |                    |                    | S               | Oral                         | 20 Mg, Daily         |                 | Not Reported |                |
|                                                                                        | Sintrom              |                    |                    | S               | Oral                         | Unk                  |                 | Not Reported |                |
|                                                                                        | Acetylsalicylic Acid |                    |                    | S               | Oral                         | 100 Mg, Daily        |                 | Not Reported |                |
|                                                                                        | Atenolol             |                    |                    | C               |                              | Unk                  |                 | Not Reported |                |
|                                                                                        | Lantus               |                    |                    | C               |                              | Unk                  |                 | Not Reported |                |
|                                                                                        | Seguril              |                    |                    | C               |                              | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Jun-2014                                                                            | 10214981             | EXPEDITED (15-DAY) |                    | HO              | DE-FRI-1000067781            |                      |                 | Male         | DEU            |
| <u>Preferred Term</u>                                                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cerebellar Haemorrhage;<br>Tachycardia                                                 | Escitalopram         |                    |                    | S               | Oral                         | 5 Mg                 |                 | Forest       |                |
|                                                                                        | Escitalopram         |                    |                    | S               | Oral                         | 10 Mg                |                 | Not Reported |                |
|                                                                                        | Mirtazapin           |                    |                    | S               | Oral                         | 30 Mg                |                 | Not Reported |                |
|                                                                                        | Mirtazapin           |                    |                    | S               | Oral                         | 15 Mg                |                 | Not Reported |                |
|                                                                                        | Clexane              |                    |                    | S               | Other                        | 0.6 MI               |                 | Not Reported |                |

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|            |   |       |        |              |
|------------|---|-------|--------|--------------|
| Clexane    | S | Other | 1.2 MI | Not Reported |
| Clexane    | S | Other | 0.6 MI | Not Reported |
| Ebixa      | C | Oral  | 10 Mg  | Not Reported |
| Ebixa      | C | Oral  | 15 Mg  | Not Reported |
| Ebixa      | C | Oral  | 20 Mg  | Not Reported |
| Ebixa      | C | Oral  | 15 Mg  | Not Reported |
| Ebixa      | C | Oral  | 10 Mg  | Not Reported |
| Risperdal  | C | Oral  | 1 Mg   | Not Reported |
| Risperdal  | C | Oral  | 0.5 Mg | Not Reported |
| Bisoprolol | C | Oral  | 5 Mg   | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Jun-2014              | 10215143      | EXPEDITED (15-DAY) |                    | HO              | AU-FRI-1000067829    |                      | 58 YR      | Female     | AUS            |

| <u>Preferred Term</u>                                                                                                                                              | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|--------------|------------|-------------|--------------|-------------------------|-----------------|------------|
| Blood Glucose Decreased;<br>Blood Potassium<br>Decreased; Blood<br>Pressure Decreased;<br>Consciousness<br>Fluctuating; Overdose;<br>Respiratory Rate<br>Decreased | Lexapro Oral Solution |              |            | S           | Oral         | 900 Mg (90 MI) Two Days |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|------------|------------|----------------|
| 04-Jun-2014              | 10215394      | EXPEDITED (15-DAY) |                    | HO, OT          | CH-009507513-<br>1105USA03810 |                      | 20 YR      | Female     | CHE            |

| <u>Preferred Term</u>                                                                                                                       | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Lactic Acid<br>Increased; Continuous<br>Haemodiafiltration;<br>Intentional Overdose;<br>Metabolic Acidosis; Off<br>Label Use; Suicide | Janumet             |              |            | S           | Oral         | 180 Tablet Once    |                 | Merck        |
|                                                                                                                                             | Ciprallex           |              |            | S           |              | 20 Mg, Per Day     |                 | Not Reported |
|                                                                                                                                             | Solian              |              |            | C           | Oral         | 400 Mg, Bid        |                 | Not Reported |
|                                                                                                                                             | Temesta (Lorazepam) |              |            | C           | Oral         | 1 Mg Daily         |                 | Not Reported |

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

Attempt; Vomiting

| <u>FDA Received Date</u>                                                                                                  | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|--------------------------------------------------|--------------------------------|-----------------|--------------|----------------|
| 04-Jun-2014                                                                                                               | 10215771               | EXPEDITED (15-DAY) |                    | OT              | GB-LUPIN<br>PHARMACEUTICALS<br>INC.-E2B_00001718 |                                | 54 YR           | Male         | GBR            |
| <u>Preferred Term</u>                                                                                                     | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                     | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Depressed Mood;<br>Inhibitory Drug Interaction;<br>Suicidal Ideation                                                      | Escitalopram           |                    |                    | S               | Unknown                                          | 10-20mg Daily                  |                 | Not Reported |                |
|                                                                                                                           | Gliclazide             |                    |                    | S               | Oral                                             |                                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                  | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Jun-2014                                                                                                               | 10216310               | EXPEDITED (15-DAY) |                    | DE              | FR-FRI-1000067827                                |                                | 80 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                     | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                     | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Haemorrhagic Stroke;<br>International Normalised<br>Ratio Increased                                                       | Escitalopram           |                    |                    | S               | Oral                                             |                                |                 | Forest       |                |
|                                                                                                                           | Previscan (Fluindione) |                    |                    | S               | Oral                                             |                                |                 | Not Reported |                |
|                                                                                                                           | Lexomil                |                    |                    | C               |                                                  |                                |                 | Not Reported |                |
|                                                                                                                           | Pantoprazole           |                    |                    | C               |                                                  |                                |                 | Not Reported |                |
|                                                                                                                           | Coversyl               |                    |                    | C               |                                                  |                                |                 | Not Reported |                |
|                                                                                                                           | Amiodarone             |                    |                    | C               |                                                  |                                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                  | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Jun-2014                                                                                                               | 10218869               | DIRECT             |                    |                 |                                                  |                                | 29 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                     | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                     | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Economic<br>Problem; Feeling Jittery;<br>Hyperhidrosis; Nausea;<br>Nervousness; Product<br>Substitution Issue | Escitolopram 20 Forest |                    |                    | S               | Oral                                             | 3 Once Daily Taken By<br>Mouth | 3 DAY           | Forest       |                |
| <u>FDA Received Date</u>                                                                                                  | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Jun-2014                                                                                                               | 10219134               | DIRECT             |                    | HO              |                                                  |                                | 30 YR           | Female       | USA            |

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| <u>Preferred Term</u>                                                                                | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
|------------------------------------------------------------------------------------------------------|--------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------------------|-----------------|--------------|----------------|
| Dehydration; Dizziness; Palpitations; Skin Discolouration; Syncope; White Blood Cell Count Increased | Lexapro                              |                    |                    | S               | Oral                 | 1 Pill Once Daily Taken By Mouth |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                             | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Jun-2014                                                                                          | 10218377                             | EXPEDITED (15-DAY) |                    | DE              | ES-BAYER-2014-077955 |                                  | 87 YR           | Female       | ESP            |
| <u>Preferred Term</u>                                                                                | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Cerebral Haemorrhage                                                                                 | Adiro 100                            |                    |                    | S               | Oral                 | 100 Mg, Qd                       |                 | Bayer        |                |
|                                                                                                      | Sintrom                              |                    |                    | S               | Oral                 |                                  |                 | Not Reported |                |
|                                                                                                      | Escitalopram                         |                    |                    | S               | Oral                 | 20 Mg, Qd                        |                 | Not Reported |                |
|                                                                                                      | Trangorex                            |                    |                    | S               | Oral                 |                                  |                 | Not Reported |                |
|                                                                                                      | Atenolol                             |                    |                    | C               | Oral                 | 37.5 Mg, Bid                     |                 | Not Reported |                |
|                                                                                                      | Lantus                               |                    |                    | C               | Subcutaneous         | 10 lu, Qd                        |                 | Not Reported |                |
|                                                                                                      | Seguril                              |                    |                    | C               | Oral                 | 20 Mg, Bid                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                             | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Jun-2014                                                                                          | 10219045                             | EXPEDITED (15-DAY) |                    | OT              | US-SA-2014SA073410   |                                  | 48 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Generalised Tonic-Clonic Seizure                                                                     | Zolpidem Tartrate                    |                    |                    | S               | Unknown              |                                  |                 | Not Reported |                |
|                                                                                                      | Ceftriaxone                          |                    |                    | S               | Unknown              |                                  |                 | Not Reported |                |
|                                                                                                      | Metronidazole                        |                    |                    | S               | Unknown              |                                  |                 | Not Reported |                |
|                                                                                                      | Escitalopram                         |                    |                    | S               | Unknown              |                                  |                 | Not Reported |                |
|                                                                                                      | Tramadol Hydrochloride               |                    |                    | S               | Unknown              |                                  |                 | Not Reported |                |
|                                                                                                      | Acetaminophen\Hydrocodone Bitartrate |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                      | Oxygen                               |                    |                    | C               |                      | 30 Hyperbaric Oxygen Treatments  |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                            |                |                    |                    |                 |                                    |                      |                 |            |                |
|------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|------------------------------------|----------------------|-----------------|------------|----------------|
| Hydromorphone                                              |                |                    | C                  |                 |                                    | Not Reported         |                 |            |                |
| <u>FDA Received Date</u>                                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 05-Jun-2014                                                | 10220889       | DIRECT             |                    | OT              |                                    |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>                                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                       | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Chills; Tremor                                             | Lexapro        |                    |                    | S               |                                    |                      |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 06-Jun-2014                                                | 10220254       | EXPEDITED (15-DAY) |                    | DE, OT          | BR-ROCHE-1414343                   |                      | 85 YR           | Male       | BRA            |
| <u>Preferred Term</u>                                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                       | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Malignant Neoplasm Of<br>Unknown Primary Site;<br>Overdose | Rivotril       |                    |                    | S               | Unknown                            |                      |                 |            | Not Reported   |
|                                                            | Lexapro        |                    |                    | S               | Unknown                            |                      |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 06-Jun-2014                                                | 10220260       | EXPEDITED (15-DAY) |                    | HO, LT          | DE-DRREDDYS-<br>GER/GER/14/0040829 |                      | 26 YR           | Male       | DEU            |
| <u>Preferred Term</u>                                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                       | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Weight Increased                                           | Olanzapine     |                    |                    | S               | Oral                               |                      |                 |            | Not Reported   |
|                                                            | Olanzapine     |                    |                    | S               | Oral                               |                      |                 |            | Not Reported   |
|                                                            | Olanzapine     |                    |                    | S               | Oral                               |                      |                 |            | Not Reported   |
|                                                            | Olanzapine     |                    |                    | S               | Oral                               |                      |                 |            | Not Reported   |
|                                                            | Quetiapine     |                    |                    | S               |                                    |                      |                 |            | Not Reported   |
|                                                            | Cipralelex     |                    |                    | S               | Oral                               |                      |                 |            | Not Reported   |
|                                                            | Cipralelex     |                    |                    | S               | Oral                               |                      |                 |            | Not Reported   |
|                                                            | Cipralelex     |                    |                    | S               | Oral                               |                      |                 |            | Not Reported   |
|                                                            | Cipralelex     |                    |                    | S               | Oral                               |                      |                 |            | Not Reported   |
|                                                            | Lorazepam      |                    |                    | C               | Oral                               |                      |                 |            | Not Reported   |
|                                                            | Lorazepam      |                    |                    | C               | Oral                               |                      |                 |            | Not Reported   |
|                                                            | Lorazepam      |                    |                    | C               | Oral                               |                      |                 |            | Not Reported   |



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

|                                                                |                |                    |                    |                 |                      |                                      |                 |              |                |
|----------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|--------------------------------------|-----------------|--------------|----------------|
| Lorazepam                                                      |                |                    | C                  |                 | Oral                 |                                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Jun-2014                                                    | 10221049       | EXPEDITED (15-DAY) |                    | OT              | ZA-FRI-1000067895    |                                      | 16 YR           | Male         | ZAF            |
| <u>Preferred Term</u>                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Off Label Use; Seizure                                         | Escitalopram   |                    |                    | S               |                      |                                      |                 | Forest       |                |
|                                                                | Strattera      |                    |                    | C               |                      |                                      |                 | Not Reported |                |
|                                                                | Epitec         |                    |                    | C               |                      |                                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Jun-2014                                                    | 10221050       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000067878    |                                      | 51 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Overdose; Loss Of Consciousness; Suicide Attempt   | Escitalopram   |                    |                    | S               | Oral                 | 10 Mg                                |                 | Forest       |                |
|                                                                | Escitalopram   |                    |                    | S               | Oral                 | Overdose Of 28 Tablets (I.E. 280 Mg) |                 | Forest       |                |
|                                                                | Alprazolam     |                    |                    | C               |                      |                                      |                 | Not Reported |                |
|                                                                | Ixprim         |                    |                    | C               |                      |                                      |                 | Not Reported |                |
|                                                                | Doliprane      |                    |                    | C               |                      |                                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Jun-2014                                                    | 10221531       | EXPEDITED (15-DAY) |                    | OT              | CA-FRI-1000067974    |                                      |                 | Female       | CAN            |
| <u>Preferred Term</u>                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Dependence; Judgement Impaired; Mental Impairment; Stress | Escitalopram   |                    |                    | S               |                      |                                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Jun-2014                                                    | 10222996       | EXPEDITED (15-DAY) |                    | HO              | GXKR2014DE002161     |                                      |                 | Unknown      | DEU            |
| <u>Preferred Term</u>                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>   |                |

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

|                                        |                |   |              |             |              |
|----------------------------------------|----------------|---|--------------|-------------|--------------|
| Cerebellar Haemorrhage;<br>Tachycardia | Mirtazapine    | S | Oral         | 30 Mg, Unk  | Novartis     |
|                                        | Mirtazapine    | S | Oral         | 15 Mg, Unk  | Novartis     |
|                                        | Cipralex /Den/ | S | Oral         | 5 Mg, Unk   | Not Reported |
|                                        | Cipralex /Den/ | S | Oral         | 10 Mg, Unk  | Not Reported |
|                                        | Clexane        | S | Subcutaneous | 0.6 MI, Unk | Not Reported |
|                                        | Clexane        | S | Subcutaneous | 1.2 MI, Unk | Not Reported |
|                                        | Clexane        | S | Subcutaneous | 0.6 MI, Unk | Not Reported |
|                                        | Ebixa          | C | Oral         | 10 Mg, Unk  | Not Reported |
|                                        | Ebixa          | C | Oral         | 15 Mg, Unk  | Not Reported |
|                                        | Ebixa          | C | Oral         | 20 Mg, Unk  | Not Reported |
|                                        | Ebixa          | C | Oral         | 15 Mg, Unk  | Not Reported |
|                                        | Ebixa          | C | Oral         | 10 Mg, Unk  | Not Reported |
|                                        | Risperdal      | C | Oral         | 1 Mg, Unk   | Not Reported |
|                                        | Risperdal      | C | Oral         | 0.5 Mg, Unk | Not Reported |
|                                        | Bisoprolol     | C | Oral         | 5 Mg, Unk   | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 09-Jun-2014              | 10204843      | EXPEDITED (15-DAY) |                    | HO              | FR-PFIZER INC-2014144532 |                      | 37 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                             | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|----------------------------------------------------------------|-----------------|--------------|
| Mydriasis; Serotonin Syndrome; Somnolence; Suicide Attempt | Xanax          |              |            | S           | Oral         | 2 Mg, Single                                                   |                 | Pfizer       |
|                                                            | Lexomil Roche  |              |            | S           | Oral         | 180 Mg, Single                                                 |                 | Not Reported |
|                                                            | Myolastan      |              |            | S           | Oral         | 600 Mg, Single                                                 |                 | Not Reported |
|                                                            | Ixprim         |              |            | S           | Oral         | Paracetamol 650 Mg/<br>Tramadol Hydrochloride<br>75 Mg, Single |                 | Not Reported |
|                                                            | Seroplex       |              |            | S           | Oral         | 20 Mg, Single                                                  |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Jun-2014              | 10225165      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000068016    |                      | 96 YR      | Female     | FRA            |

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

| <u>Preferred Term</u>                                                              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|-----------------------------------|-----------------|--------------|
| Accidental Exposure To Product; Drug Interaction; Pneumonia Aspiration; Somnolence | Escitalopram   |              |            | S           | Oral         | 20 Mg                             |                 | Forest       |
|                                                                                    | Tranxene       |              |            | S           | Oral         | Intake Of 40 Mg Once              |                 | Not Reported |
|                                                                                    | Deroxat        |              |            | S           | Oral         | Intake Of 20 Mg Once              |                 | Not Reported |
|                                                                                    | Xanax          |              |            | S           |              | 3 Df                              |                 | Not Reported |
|                                                                                    | Zyprexa        |              |            | S           | Oral         | Intake Of 7.5 Mg Once             |                 | Not Reported |
|                                                                                    | Tardyferon     |              |            | C           | Oral         | 1 Df                              |                 | Not Reported |
|                                                                                    | Uvedose        |              |            | C           |              | 100,000 Iu - 1 Ampoule / 3 Months |                 | Not Reported |
|                                                                                    | Stilnox        |              |            | C           | Oral         | 0.5 Df                            |                 | Not Reported |
|                                                                                    | Dafalgan       |              |            | C           | Oral         | 3 Df                              |                 | Not Reported |
|                                                                                    | Movicol        |              |            | C           |              | 2 Df                              |                 | Not Reported |
|                                                                                    | Tanganil       |              |            | C           | Oral         | 2 Df                              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Jun-2014              | 10227182      | EXPEDITED (15-DAY) |                    | HO              | ES-BAYER-2014-080798 |                      | 87 YR      | Male       | ESP            |

| <u>Preferred Term</u>        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------|----------------|--------------|------------|-------------|--------------|-----------------------|-----------------|--------------|
| Acute Kidney Injury; Anaemia | Adiro 100      |              |            | S           | Oral         | 100 Mg, Qd            |                 | Bayer        |
|                              | Adiro 100      |              |            | S           |              |                       |                 | Bayer        |
|                              | Escitalopram   |              |            | S           | Oral         | 15 Mg, Qd             |                 | Not Reported |
|                              | Orfidal        |              |            | C           | Oral         |                       |                 | Not Reported |
|                              | Valdoxan       |              |            | C           | Oral         | 25 Mg, Qd             |                 | Not Reported |
|                              | Bicalutamide   |              |            | C           | Oral         | 50 Mg, Qd             |                 | Not Reported |
|                              | Eligard        |              |            | C           | Oral         | 45 Mg, Every 6 Months |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 10-Jun-2014              | 10227934      | EXPEDITED (15-DAY) |                    | HO              | FR-ASTRAZENECA-2014SE39519 |                      | 66 YR      | Male       | FRA            |

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

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

|                            |               |   |      |              |
|----------------------------|---------------|---|------|--------------|
| Decreased Appetite;        | Inexium       | S | Oral | Astrazeneca  |
| Diarrhoea;                 | Xarelto       | S | Oral | Not Reported |
| Hyponatraemia;             | Lasilix       | S | Oral | Not Reported |
| Inappropriate Antidiuretic | Seroplex      | S | Oral | Not Reported |
| Hormone Secretion;         | Befizal Sr    | C | Oral | Not Reported |
| Musculoskeletal Pain;      | Diffu K       | C |      | Not Reported |
| Weight Decreased           | Sotalol       | C | Oral | Not Reported |
|                            | Tardyferon    | C | Oral | Not Reported |
|                            | Amlodipine    | C | Oral | Not Reported |
|                            | Speciafoldine | C |      | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 10-Jun-2014              | 10228137      | EXPEDITED (15-DAY) | HO                 |                 | FR-JNJFOC-20140603031 |                      | 66 YR      | Male       | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hyponatraemia         | Xarelto        |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Lasilix        |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Seroplex       |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Inexium        |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Speciafoldine  |              |            | C           | Unknown      |                    |                 | Not Reported |
|                       | Amlodipine     |              |            | C           | Unknown      |                    |                 | Not Reported |
|                       | Tardyferon     |              |            | C           | Unknown      |                    |                 | Not Reported |
|                       | Sotalol        |              |            | C           | Unknown      |                    |                 | Not Reported |
|                       | Befizal        |              |            | C           | Unknown      |                    |                 | Not Reported |
|                       | Diffu K        |              |            | C           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 10-Jun-2014              | 10228712      | EXPEDITED (15-DAY) | HO                 |                 | DE-009507513-1406DEU002103 |                      | 74 YR      | Male       | DEU            |

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

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

|                                        |                             |   |              |              |              |
|----------------------------------------|-----------------------------|---|--------------|--------------|--------------|
| Cerebellar Haemorrhage;<br>Tachycardia | Mirtazapin Stada            | S | Oral         | 30 Mg, Qd    | Merck        |
|                                        | Mirtazapin Stada            | S | Oral         | 15 Unk, Unk  | Merck        |
|                                        | Cipralext                   | S | Oral         | 5 Mg, Qd     | Not Reported |
|                                        | Escitalopram                | S | Oral         | 10 Mg, Qd    | Not Reported |
|                                        | Clexane (Enoxaparin Sodium) | S | Subcutaneous | 1.2 MI, Qd   | Not Reported |
|                                        | Clexane (Enoxaparin Sodium) | S | Subcutaneous | 0.6 MI, Qd   | Not Reported |
|                                        | Ebixa                       | C | Oral         | 10 Mg, Qd    | Not Reported |
|                                        | Ebixa                       | C | Oral         | 15 Mg, Qd    | Not Reported |
|                                        | Ebixa                       | C | Oral         | 20 Unk, Unk  | Not Reported |
|                                        | Ebixa                       | C | Oral         | 15 Unk, Unk  | Not Reported |
|                                        | Ebixa                       | C | Oral         | 10 Unk, Unk  | Not Reported |
|                                        | Risperdal                   | C | Oral         | 1 Mg, Qd     | Not Reported |
|                                        | Risperdal                   | C | Oral         | 0.5 Unk, Unk | Not Reported |
|                                        | Bisoprolol                  | C | Oral         | 5 Mg, Qd     | Not Reported |

|                          |               |                    |                    |                 |                      |                      |            |            |                |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
| 11-Jun-2014              | 9395112       | EXPEDITED (15-DAY) |                    | OT              | PHFR2013IE002986     |                      | 71 YR      | Male       | IRL            |

|                        |                         |              |            |             |              |                    |                 |              |
|------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| <u>Preferred Term</u>  | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
| Cardiomyopathy;        | Clozaril                |              |            | S           | Oral         | Unk                |                 | Not Reported |
| Cyanosis; Dizziness;   | Clonazepam              |              |            | S           | Oral         | 0.5 Mg, Unk        |                 | Novartis     |
| Duodenal Ulcer;        | Escitalopram            |              |            | S           | Oral         | 10 Mg, Unk         |                 | Not Reported |
| Electrocardiogram Qt   | Clarithromycin          |              |            | S           |              | Unk                |                 | Not Reported |
| Prolonged; Gout; Lower | Donepezil Hydrochloride |              |            | S           | Oral         | 10 Mg, Unk         |                 | Not Reported |
| Respiratory Tract      |                         |              |            |             |              |                    |                 |              |
| Infection; Parkinson'S |                         |              |            |             |              |                    |                 |              |
| Disease; Pneumonia     |                         |              |            |             |              |                    |                 |              |

|                          |               |                    |                    |                 |                      |                      |            |            |                |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
| 11-Jun-2014              | 10230375      | EXPEDITED (15-DAY) |                    | OT              | JP-SA-2014SA076138   |                      |            | Unknown    | JPN            |

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

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

|         |         |   |         |              |
|---------|---------|---|---------|--------------|
| Seizure | Myslee  | S | Unknown | Not Reported |
|         | Meilax  | S | Oral    | Not Reported |
|         | Lexapro | S | Oral    | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Jun-2014              | 10230946      | EXPEDITED (15-DAY) |                    | LT, OT          | TR-FRI-1000068013    |                      | 41 YR      | Male       | TUR            |

| <u>Preferred Term</u>                                                          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|-------------------------|-----------------|--------------|
| Gait Disturbance;<br>Overdose; Somnolence;<br>Speech Disorder; Suicide Attempt | Escitalopram   |              |            | S           | Oral         |                         |                 | Forest       |
|                                                                                | Escitalopram   |              |            | S           |              | Overdose : Unknown Dose |                 | Forest       |
|                                                                                | Sulpir         |              |            | C           |              |                         |                 | Not Reported |
|                                                                                | Sulpir         |              |            | C           |              | Overdose : Unknown Dose |                 | Not Reported |
|                                                                                | Tegretol       |              |            | C           | Oral         |                         |                 | Not Reported |
|                                                                                | Tegretol       |              |            | C           |              | Overdose : Unknown Dose |                 | Not Reported |
|                                                                                | Irda           |              |            | C           |              |                         |                 | Not Reported |
|                                                                                | Irda           |              |            | C           |              | Overdose : Unknown Dose |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Jun-2014              | 10231327      | EXPEDITED (15-DAY) |                    | HO, LT          | FR-ROCHE-1415029     |                      | 49 YR      | Male       | FRA            |

| <u>Preferred Term</u>                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Bradycardia; Coma;<br>Vasoplegia Syndrome | Valium         |              |            | S           | Oral         |                    |                 | Not Reported |
|                                           | Seroplex       |              |            | S           | Oral         |                    |                 | Not Reported |
|                                           | Simvastatine   |              |            | S           | Oral         |                    |                 | Not Reported |
|                                           | Coversyl       |              |            | S           | Oral         |                    |                 | Not Reported |
|                                           | Zopiclone      |              |            | S           | Oral         |                    |                 | Not Reported |
|                                           | Zolpidem       |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Jun-2014              | 10232548      | NON-EXPEDITED    |                    |                 | US-TEVA-456513USA    |                      |            | Female     | USA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                                                                        | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
|------------------------------------------------------------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| Asthenia; Confusional State; Drug Hypersensitivity; Gait Disturbance; Hyperhidrosis; Musculoskeletal Stiffness; Palpitations | Escitalopram   |                  |                    | S               |                      | 10 Milligram Daily;  |                 | Ivax       |                |
| <u>FDA Received Date</u>                                                                                                     | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Jun-2014                                                                                                                  | 10232549       | NON-EXPEDITED    |                    |                 | US-TEVA-474418       | USA                  | 14 YR           | Female     | USA            |
| <u>Preferred Term</u>                                                                                                        | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective                                                                                                             | Escitalopram   |                  |                    | S               | Oral                 |                      |                 | Ivax       |                |
|                                                                                                                              | Escitalopram   |                  |                    | S               |                      |                      |                 | Ivax       |                |
| <u>FDA Received Date</u>                                                                                                     | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Jun-2014                                                                                                                  | 10232550       | NON-EXPEDITED    |                    |                 | US-TEVA-466687       | USA                  |                 | Unknown    | USA            |
| <u>Preferred Term</u>                                                                                                        | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Rash; Urticaria                                                                                                              | Escitalopram   |                  |                    | S               |                      |                      |                 | Ivax       |                |
| <u>FDA Received Date</u>                                                                                                     | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Jun-2014                                                                                                                  | 10232552       | NON-EXPEDITED    |                    | OT              | US-TEVA-458668       | USA                  |                 | Male       | USA            |
| <u>Preferred Term</u>                                                                                                        | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Anxiety; Drug Ineffective; Irritability; Suicidal Ideation; Therapeutic Response Changed; Tic                                | Escitalopram   |                  |                    | S               |                      |                      |                 | Ivax       |                |
|                                                                                                                              | Escitalopram   |                  |                    | S               |                      |                      |                 | Ivax       |                |
| <u>FDA Received Date</u>                                                                                                     | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Jun-2014                                                                                                                  | 10232555       | NON-EXPEDITED    |                    |                 | US-TEVA-467831       | USA                  |                 | Female     | USA            |

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| <u>Preferred Term</u>                     | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Laryngitis                                | Escitalopram   |                  |                    | S               | Oral                 | 20 Milligram Daily;  |                 | Ivax         |                |
|                                           | Levothyroxine  |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                           | Zocor          |                  |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                  | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Jun-2014                               | 10232557       | NON-EXPEDITED    |                    |                 | US-TEVA-476268       | USA                  |                 | Female       | USA            |
| <u>Preferred Term</u>                     | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety                                   | Escitalopram   |                  |                    | S               |                      |                      |                 | Ivax         |                |
| <u>FDA Received Date</u>                  | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Jun-2014                               | 10232558       | NON-EXPEDITED    |                    |                 | US-TEVA-468816       | USA                  |                 | Female       | USA            |
| <u>Preferred Term</u>                     | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective; Insomnia; Off Label Use | Escitalopram   |                  |                    | S               |                      |                      |                 | Ivax         |                |
| <u>FDA Received Date</u>                  | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Jun-2014                               | 10232563       | NON-EXPEDITED    |                    |                 | US-TEVA-476327       | USA                  |                 | Unknown      | USA            |
| <u>Preferred Term</u>                     | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Depression; Drug Ineffective     | Escitalopram   |                  |                    | S               |                      |                      |                 | Ivax         |                |
|                                           | Escitalopram   |                  |                    | S               |                      |                      |                 | Ivax         |                |
| <u>FDA Received Date</u>                  | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Jun-2014                               | 10232564       | NON-EXPEDITED    |                    |                 | US-TEVA-481609       | USA                  |                 | Female       | USA            |
| <u>Preferred Term</u>                     | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety                                   | Escitalopram   |                  |                    | S               |                      |                      |                 | Ivax         |                |



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| <u>FDA Received Date</u>                                                                 | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                                                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------|----------------------------------|--------------------|--------------------|-----------------|--------------------------|--------------------------------------------------------------------------|-----------------|--------------|----------------|
| 12-Jun-2014                                                                              | 10232565                         | NON-EXPEDITED      |                    |                 | US-TEVA-479190USA        |                                                                          |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                    | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                                                       | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Depression;<br>Therapeutic Product<br>Ineffective                               | Escitalopram                     |                    |                    | S               |                          |                                                                          |                 | Ivax         |                |
|                                                                                          | Escitalopram                     |                    |                    | S               |                          |                                                                          |                 | Ivax         |                |
| <u>FDA Received Date</u>                                                                 | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                                                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Jun-2014                                                                              | 10233766                         | EXPEDITED (15-DAY) |                    | OT              | US-ACTAVIS-2014-12235    |                                                                          | 59 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                    | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                                                       | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;<br>International Normalised<br>Ratio Fluctuation; Urinary<br>Retention | Escitalopram (Unknown)           |                    |                    | S               | Unknown                  | 5 Mg, Daily                                                              |                 | Not Reported |                |
|                                                                                          | Warfarin (Unknown)               |                    |                    | S               | Unknown                  | 4 Mg, Daily                                                              |                 | Not Reported |                |
|                                                                                          | Omeprazole (Watson Laboratories) |                    |                    | S               | Unknown                  | 20 Mg, Daily                                                             |                 | Watson       |                |
|                                                                                          | Furosemide                       |                    |                    | C               | Unknown                  | 40 Mg, Daily                                                             |                 | Not Reported |                |
|                                                                                          | Metoprolol Tartrate              |                    |                    | C               | Unknown                  | 50 Mg, Bid                                                               |                 | Not Reported |                |
|                                                                                          | Amiodarone                       |                    |                    | C               | Unknown                  | 200 Mg, Daily                                                            |                 | Not Reported |                |
|                                                                                          | Albuterol W/Ipratropium          |                    |                    | C               | Respiratory (inhalation) | 3 Ml; Inhale Contents Of 1 Vial Every 2 Hours, As Needed (2.5 Mg/0.5 Mg) |                 | Not Reported |                |
|                                                                                          | Docusate W/Senna                 |                    |                    | C               | Oral                     | 5/8.6 Mg Two Tablets Once A Day                                          |                 | Not Reported |                |
|                                                                                          | Humalog                          |                    |                    | C               | Unknown                  | 100 Units/MI                                                             |                 | Not Reported |                |
|                                                                                          | Nystop                           |                    |                    | C               | Topical                  | 100000 Units/G; Twice Daily To Bilateral Groin                           |                 | Not Reported |                |
|                                                                                          | Acetaminophen                    |                    |                    | C               | Unknown                  | 650 Mg As Needed                                                         |                 | Not Reported |                |
|                                                                                          | Bisacodyl                        |                    |                    | C               | Unknown                  | Suppositories 10 Mg, Daily, As Needed                                    |                 | Not Reported |                |
|                                                                                          | Guaifenesin                      |                    |                    | C               | Unknown                  | 600 Mg, Bid                                                              |                 | Not Reported |                |
|                                                                                          | Triamcinolone                    |                    |                    | C               | Topical                  | 0.1% Twice Daily                                                         |                 | Not Reported |                |

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|                                                                                                                                                                                                                                                                                                                                                                                                         | Fluticasone Propionate     | C                  | Unknown            | 220 Mg, Bid          |                      | Not Reported         |                 |              |                |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|--------------------|--------------------|----------------------|----------------------|----------------------|-----------------|--------------|----------------|
|                                                                                                                                                                                                                                                                                                                                                                                                         | Ondansetron                | C                  | Unknown            | 4 Mg, Q6h, As Needed |                      | Not Reported         |                 |              |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                                                                                | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>      | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Jun-2014                                                                                                                                                                                                                                                                                                                                                                                             | 10233827                   | EXPEDITED (15-DAY) |                    | HO                   | IT-BAYER-2014-083928 |                      | 48 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                   | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>          | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain Upper;<br>Drug Abuse; Psychomotor<br>Hyperactivity                                                                                                                                                                                                                                                                                                                                       | Aspirina                   |                    |                    | S                    | Oral                 | 3 Df, Once           |                 | Bayer        |                |
|                                                                                                                                                                                                                                                                                                                                                                                                         | Xanax                      |                    |                    | S                    | Oral                 | 20 MI, Once          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                         | Entact                     |                    |                    | S                    | Oral                 | 15 MI, Once          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                         | Anafranil                  |                    |                    | S                    | Oral                 | 3 Df, Once           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                                                                                | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>      | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Jun-2014                                                                                                                                                                                                                                                                                                                                                                                             | 10179343                   | EXPEDITED (15-DAY) |                    | OT                   | SE-FRI-1000067410    |                      | 71 YR           | Female       | SWE            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                   | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>          | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Arrhythmia;<br>Breast Pain; Burning<br>Sensation; Decreased<br>Appetite; Derealisation;<br>Eye Pain; Face Oedema;<br>Heart Rate Increased; Lip<br>Swelling; Localised<br>Oedema; Muscle Spasms;<br>Muscle Twitching; Nasal<br>Congestion; Pain In<br>Extremity; Paraesthesia;<br>Pyrexia; Seizure; Sleep<br>Disorder; Tinnitus; Vision<br>Blurred; Weight<br>Decreased; Withdrawal<br>Syndrome | Escitalopram               |                    |                    | S                    | Oral                 | 10 Mg                |                 | Forest       |                |
|                                                                                                                                                                                                                                                                                                                                                                                                         | Escitalopram               |                    |                    | S                    | Oral                 | 5 Mg                 |                 | Forest       |                |
|                                                                                                                                                                                                                                                                                                                                                                                                         | Escitalopram Oral Solution |                    |                    | S                    | Oral                 | 1.5 Gtt              |                 | Forest       |                |
|                                                                                                                                                                                                                                                                                                                                                                                                         | Oxascand                   |                    |                    | C                    |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                         | Imovane                    |                    |                    | C                    | Oral                 |                      |                 | Not Reported |                |

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| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 13-Jun-2014              | 10235075      | NON-EXPEDITED    |                    |                 | US-009507513-1406USA003372 |                      | 82 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Ineffective      | Mirtazapine              |              |            | S           |              |                    |                 | Merck        |
|                       | Diazepam                 |              |            | S           |              |                    |                 | Not Reported |
|                       | Fluoxetine               |              |            | S           |              |                    |                 | Not Reported |
|                       | Phenelzine Sulfate       |              |            | S           |              |                    |                 | Not Reported |
|                       | Bupropion Hydrochloride  |              |            | S           |              |                    |                 | Not Reported |
|                       | Olanzapine               |              |            | S           |              |                    |                 | Not Reported |
|                       | Escitalopram             |              |            | S           |              |                    |                 | Not Reported |
|                       | Quetiapine Fumarate      |              |            | S           |              |                    |                 | Not Reported |
|                       | Selegiline               |              |            | S           |              |                    |                 | Not Reported |
|                       | Sertraline Hydrochloride |              |            | S           |              |                    |                 | Not Reported |
|                       | Trazodone Hydrochloride  |              |            | S           |              |                    |                 | Not Reported |
|                       | Clonazepam               |              |            | S           |              |                    |                 | Not Reported |
|                       | Lorazepam                |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Jun-2014              | 10235617      | EXPEDITED (15-DAY) |                    | HO              | TW-FRI-1000068132    |                      | 24 YR      | Female     | TWN            |

| <u>Preferred Term</u>                                                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Ineffective;<br>Prescribed Overdose;<br>Sedation; Vision Blurred | Escitalopram   |              |            | S           |              | Overdose : 40 Mg   |                 | Forest       |
|                                                                       | Citalopram     |              |            | S           |              | Overdose: 60 Mg    |                 | Forest       |
|                                                                       | Aripiprazole   |              |            | S           |              | 20 Mg              |                 | Not Reported |
|                                                                       | Aripiprazole   |              |            | S           |              | 30 Mg              |                 | Not Reported |
|                                                                       | Sertraline     |              |            | C           |              | 150 Mg             |                 | Not Reported |
|                                                                       | Venlafaxine    |              |            | C           |              | 225 Mg             |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Jun-2014              | 10236972      | EXPEDITED (15-DAY) |                    | HO              | DE-TEVA-486290GER    |                      | 74 YR      | Male       | DEU            |

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

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|                                        |            |   |              |                         |              |
|----------------------------------------|------------|---|--------------|-------------------------|--------------|
| Cerebellar Haemorrhage;<br>Tachycardia | Mirtazapin | S | Oral         | 30 Milligram Daily;     | Teva         |
|                                        | Mirtazapin | S | Oral         | 15 Milligram Daily;     | Teva         |
|                                        | Cipralelex | S | Oral         | 5 Milligram Daily; 5 Mg | Not Reported |
|                                        | Cipralelex | S | Oral         | 10 Milligram Daily;     | Not Reported |
|                                        | Clexane    | S | Subcutaneous | .6 MI Daily;            | Not Reported |
|                                        | Clexane    | S | Subcutaneous | 1.2 MI Daily;           | Not Reported |
|                                        | Clexane    | S | Subcutaneous | .6 MI Daily;            | Not Reported |
|                                        | Ebixa      | C | Oral         | 10 Milligram Daily;     | Not Reported |
|                                        | Ebixa      | C | Oral         | 15 Milligram Daily;     | Not Reported |
|                                        | Ebixa      | C | Oral         | 20 Milligram Daily;     | Not Reported |
|                                        | Ebixa      | C | Oral         | 15 Milligram Daily;     | Not Reported |
|                                        | Ebixa      | C | Oral         | 10 Milligram Daily;     | Not Reported |
|                                        | Risperdal  | C | Oral         | 1 Milligram Daily;      | Not Reported |
|                                        | Risperdal  | C | Oral         | .5 Milligram Daily;     | Not Reported |
|                                        | Bisoprolol | C | Oral         | 5 Milligram Daily;      | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 16-Jun-2014              | 10238051      | EXPEDITED (15-DAY) |                    | HO              | DE-<br>ELI_LILLY_AND_COMP<br>ANY-DE201406001170 |                      | 48 YR      | Female     | DEU            |

| <u>Preferred Term</u>                                                                                                                                                                                                               | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>       |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------------|
| Abdominal Discomfort;<br>Abdominal Distension;<br>Bladder Disorder;<br>Constipation;<br>Gastrointestinal Sounds<br>Abnormal; Leukocytosis;<br>Pain; Paruresis; Urinary<br>Hesitation; Urinary<br>Incontinence; Urinary<br>Retention | Zyprexa           |              |            | S           | Oral         | 5 Mg, Qd           |                 | Eli Lilly And Co |
|                                                                                                                                                                                                                                     | Zyprexa           |              |            | S           | Oral         | 7.5 Mg, Qd         |                 | Eli Lilly And Co |
|                                                                                                                                                                                                                                     | Zyprexa           |              |            | S           | Oral         | 10 Mg, Qd          |                 | Eli Lilly And Co |
|                                                                                                                                                                                                                                     | Zyprexa           |              |            | S           | Oral         | 12.5 Mg, Qd        |                 | Eli Lilly And Co |
|                                                                                                                                                                                                                                     | Zyprexa           |              |            | S           | Oral         | 7.5 Mg, Qd         |                 | Eli Lilly And Co |
|                                                                                                                                                                                                                                     | Zyprexa           |              |            | S           | Oral         | 5 Mg, Qd           |                 | Eli Lilly And Co |
|                                                                                                                                                                                                                                     | Zyprexa           |              |            | S           | Oral         | 2.5 Mg, Qd         |                 | Eli Lilly And Co |
|                                                                                                                                                                                                                                     | Tavor (Lorazepam) |              |            | S           | Oral         | 1.5 Mg, Qd         |                 | Not Reported     |
|                                                                                                                                                                                                                                     | Tavor (Lorazepam) |              |            | S           | Oral         | 1 Mg, Qd           |                 | Not Reported     |

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|                   |   |      |             |              |
|-------------------|---|------|-------------|--------------|
| Tavor (Lorazepam) | S | Oral | 0.5 Mg, Qd  | Not Reported |
| Tavor (Lorazepam) | S | Oral | 0.25 Mg, Qd | Not Reported |
| Cipralelex        | S | Oral | 5 Mg, Qd    | Not Reported |
| Cipralelex        | S | Oral | 10 Mg, Qd   | Not Reported |
| Cipralelex        | S | Oral | 15 Mg, Qd   | Not Reported |
| Cipralelex        | S | Oral | 20 Mg, Qd   | Not Reported |

| <u>FDA Received Date</u>                              | <u>Case #</u>    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------|------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 16-Jun-2014                                           | 10238631         | EXPEDITED (15-DAY) |                    | HO              | CA-FRI-1000068059    |                      | 88 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                 | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cough; Drug Interaction;<br>Dyspnoea; Fall; Nightmare | Memantine        |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                                       | Memantine        |                    |                    | S               |                      |                      |                 | Forest       |                |
|                                                       | Escitalopram     |                    |                    | S               | Oral                 |                      |                 | Forest       |                |
|                                                       | Dextromethorphan |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                       | Vitamin B 12     |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                           | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|-----------------|--------------|----------------|
| 16-Jun-2014                                                                                                                                                                                                                                                                                                        | 10239507       | EXPEDITED (15-DAY) |                    | DS, HO, OT      | US-009507513-<br>2010SP040550 |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                              | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Amblyopia; Blood<br>Bicarbonate Decreased;<br>Carotid Artery<br>Thrombosis; Cerebral<br>Haemorrhage;<br>Depression;<br>Dysmenorrhoea;<br>Haemorrhagic Stroke;<br>Hepatic Enzyme<br>Increased; Insomnia;<br>Intracranial Venous Sinus<br>Thrombosis; Jaw Disorder;<br>Jugular Vein Thrombosis;<br>Libido Decreased; | Nuvaring       |                    |                    | S               | Vaginal                       | Every 3 Weeks        |                 | Merck        |                |
|                                                                                                                                                                                                                                                                                                                    | Lexapro        |                    |                    | S               |                               | Unk                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                    | Dilantin       |                    |                    | S               |                               |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                    | Advil          |                    |                    | C               |                               | 400 Mg, Tid          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                    | Hemp           |                    |                    | C               |                               |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Nausea; Parosmia; Post-Traumatic Stress Disorder; Premenstrual Syndrome; Seizure; Sinus Congestion; Transient Ischaemic Attack; Urticaria

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Jun-2014              | 10243822      | EXPEDITED (15-DAY) | Y                  | OT              | SYM-2014-21907       |                      | 48 YR      | Female     | USA            |

| <u>Preferred Term</u>            | <u>Product</u>                                  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------|-------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Generalised Tonic-Clonic Seizure | Zolpidem Tartrate (Zolpidem Tartrate)           |              |            | S           |              |                    |                 | Not Reported |
|                                  | Metronidazole (Metronidazole)                   |              |            | S           |              |                    |                 | Not Reported |
|                                  | Tramadol Hydrochloride (Tramadol Hydrochloride) |              |            | S           |              |                    |                 | Not Reported |
|                                  | Ceftriaxone (Ceftriaxone)                       |              |            | S           |              |                    |                 | Not Reported |
|                                  | Escitalopram Oxalate (Escitalopram Oxalate)     |              |            | S           |              |                    |                 | Not Reported |
|                                  | Vicodin (Paracetamol, Hydrocodone Bitartrate)   |              |            | C           |              |                    |                 | Not Reported |
|                                  | Oxygen (Oxygen)                                 |              |            | C           |              |                    |                 | Not Reported |
|                                  | Hydromorphone (Hydromorphone)                   |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 17-Jun-2014              | 10241297      | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2014162099 |                      | 63 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|-----------------------------------------------|-----------------|--------------|
| Vomiting              | Aromasin       |              |            | S           | Oral         | 25 Mg, 1x/Day                                 |                 | Pfizer       |
|                       | Lexapro        |              |            | S           | Oral         | 20 Mg, 1x/Day                                 |                 | Not Reported |
|                       | Compazine      |              |            | C           | Oral         | 5 Mg, Every 6 Hours As Needed                 |                 | Not Reported |
|                       | Cardura        |              |            | C           | Oral         | 2 Mg, 1x/Day                                  |                 | Not Reported |
|                       | Advair         |              |            | C           |              | Fluticasone 500mcg, Salmeterol 50mcg, 1 Puffs |                 | Not Reported |

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

|                                         |   |                          |                                                                                              |              |
|-----------------------------------------|---|--------------------------|----------------------------------------------------------------------------------------------|--------------|
| Combivent                               | C | Respiratory (inhalation) | Every 12 Hours<br>Ipratropium 18mcg,<br>Albuterol 103mcg, 2 Puffs<br>Every 6 Hours As Needed | Not Reported |
| Combivent                               | C | Respiratory (inhalation) | Ipratropium 20mcg,<br>Albuterol 100mcg, 1 Puffs<br>Every 6 Hours                             | Not Reported |
| Glucophage                              | C | Oral                     | 500 Mg, 2x/Day                                                                               | Not Reported |
| Singulair                               | C | Oral                     | 10 Mg, 1x/Day                                                                                | Not Reported |
| K-Dur                                   | C | Oral                     | 20 Meq, 1x/Day                                                                               | Not Reported |
| Klor-Con                                | C | Oral                     | 20 Meq, 1x/Day                                                                               | Not Reported |
| Demadex                                 | C | Oral                     | 40 Mg, Daily                                                                                 | Not Reported |
| Diovan Hct                              | C | Oral                     | 320mg, 12.5mg, 1df Once<br>Daily                                                             | Not Reported |
| Calan-Sr                                | C | Oral                     | 240 Mg, 2x/Day                                                                               | Not Reported |
| Diclofenac Sodium                       | C | Oral                     | 100 Mg, Daily                                                                                | Not Reported |
| Catapres                                | C | Oral                     | 0.3 Mg, 2x/Day                                                                               | Not Reported |
| Catapres                                | C | Oral                     | 0.3 Mg, Prn                                                                                  | Not Reported |
| Duoneb                                  | C |                          | Ipratropium 0.5mg,<br>Salbutamol 3 Mg, Every 6<br>Hours As Needed                            | Not Reported |
| Theodur                                 | C | Oral                     | 200 Mg, 2x/Day                                                                               | Not Reported |
| Hydrocortisone                          | C |                          | 2.5 %, 1x/Day                                                                                | Not Reported |
| Penlac                                  | C |                          | 8 %, Daily                                                                                   | Not Reported |
| Acetaminophen\Hydrocodone<br>Bitartrate | C | Oral                     | Hydrocodone 5mg,<br>Acetaminophen 300mg, 6<br>Hours As Needed                                | Not Reported |
| Proventil                               | C | Respiratory (inhalation) | 90 Ug, 2 Puffs Every 6<br>Hours As Needed                                                    | Not Reported |
| Ventolin                                | C | Respiratory (inhalation) | 90 Ug, 2 Puffs Every 6<br>Hours As Needed                                                    | Not Reported |

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

| <u>FDA Received Date</u>                                                                                          | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 17-Jun-2014                                                                                                       | 10241582                 | EXPEDITED (15-DAY) |                    | CA              | CH-SA-2014SA078925   |                      |                 | Female       | CHE            |
| <u>Preferred Term</u>                                                                                             | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Congenital Foot Malformation; Congenital Hand Malformation; Exposure During Pregnancy; Premature Baby; Syndactyly | Stilnox Cr               |                    |                    | S               | Transplacental       |                      |                 | Not Reported |                |
|                                                                                                                   | Fluoxetine Hydrochloride |                    |                    | S               | Transplacental       |                      |                 | Not Reported |                |
|                                                                                                                   | Valdoxan                 |                    |                    | S               | Transplacental       |                      |                 | Not Reported |                |
|                                                                                                                   | Cipralelex               |                    |                    | S               | Transplacental       |                      |                 | Not Reported |                |
|                                                                                                                   | Cipralelex               |                    |                    | S               | Transplacental       |                      |                 | Not Reported |                |
|                                                                                                                   | Dalmadorm                |                    |                    | S               | Transplacental       |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                          | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Jun-2014                                                                                                       | 10241683                 | EXPEDITED (15-DAY) |                    | HO              | DE-SA-2014SA074039   |                      | 74 YR           | Male         | DEU            |
| <u>Preferred Term</u>                                                                                             | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cerebellar Haemorrhage; Cold Sweat; Disorientation; Restlessness; Tachycardia                                     | Clexane                  |                    |                    | S               | Subcutaneous         |                      |                 | Not Reported |                |
|                                                                                                                   | Clexane                  |                    |                    | S               | Subcutaneous         |                      |                 | Not Reported |                |
|                                                                                                                   | Clexane                  |                    |                    | S               | Subcutaneous         |                      |                 | Not Reported |                |
|                                                                                                                   | Mirtazapine              |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                   | Mirtazapine              |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                   | Cipralelex               |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                   | Cipralelex               |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                   | Ebixa                    |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                   | Ebixa                    |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                   | Ebixa                    |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                   | Ebixa                    |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                   | Ebixa                    |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                   | Risperidone              |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                   | Risperidone              |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |



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

| Bisoprolol                                                                                   |                |                    | C                  | Oral            | Not Reported              |                      |                 |              |                |
|----------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
| <u>FDA Received Date</u>                                                                     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Jun-2014                                                                                  | 10242186       | EXPEDITED (15-DAY) |                    | HO              | CH-JNJFOC-20140603034     |                      | 88 YR           | Male         | CHE            |
| <u>Preferred Term</u>                                                                        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Acute Kidney Injury;<br>Electrocardiogram Qt<br>Prolonged;<br>Hypocalcaemia;<br>Hypokalaemia | Haldol         |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                                                                                              | Cipralelex     |                    |                    | S               | Unknown                   |                      |                 | Not Reported |                |
|                                                                                              | Crestor        |                    |                    | C               | Unknown                   |                      |                 | Not Reported |                |
|                                                                                              | Aspirin        |                    |                    | C               | Unknown                   |                      |                 | Not Reported |                |
|                                                                                              | Physiotens     |                    |                    | C               | Unknown                   |                      |                 | Not Reported |                |
|                                                                                              | Aprovel        |                    |                    | C               | Unknown                   |                      |                 | Not Reported |                |
|                                                                                              | Nexium         |                    |                    | C               | Unknown                   |                      |                 | Not Reported |                |
|                                                                                              | Amlodipine     |                    |                    | C               | Unknown                   |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Jun-2014                                                                                  | 10242560       | EXPEDITED (15-DAY) |                    | HO              | DE-MYLANLABS-2014S1013356 |                      | 74 YR           | Male         | DEU            |
| <u>Preferred Term</u>                                                                        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cerebellar Haemorrhage;<br>Tachycardia                                                       | Mirtazapin     |                    |                    | S               | Oral                      | 30 Mg                |                 | Mylan        |                |
|                                                                                              | Mirtazapin     |                    |                    | S               | Oral                      | 15 Mg                |                 | Mylan        |                |
|                                                                                              | Cipralelex     |                    |                    | S               | Oral                      | 5 Mg                 |                 | Not Reported |                |
|                                                                                              | Cipralelex     |                    |                    | S               | Oral                      | 10 Mg                |                 | Not Reported |                |
|                                                                                              | Clexane        |                    |                    | S               | Subcutaneous              | 0.6 MI               |                 | Not Reported |                |
|                                                                                              | Clexane        |                    |                    | S               | Subcutaneous              | 1.2 MI               |                 | Not Reported |                |
|                                                                                              | Clexane        |                    |                    | S               | Subcutaneous              | 0.6 MI               |                 | Not Reported |                |
|                                                                                              | Ebixa          |                    |                    | C               | Oral                      | 10 Mg                |                 | Not Reported |                |
|                                                                                              | Ebixa          |                    |                    | C               | Oral                      | 15 Mg                |                 | Not Reported |                |
|                                                                                              | Ebixa          |                    |                    | C               | Oral                      | 20 Mg                |                 | Not Reported |                |
|                                                                                              | Ebixa          |                    |                    | C               | Oral                      | 15 Mg                |                 | Not Reported |                |

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

|            |   |      |        |              |
|------------|---|------|--------|--------------|
| Ebixa      | C | Oral | 10 Mg  | Not Reported |
| Risperdal  | C | Oral | 1 Mg   | Not Reported |
| Risperdal  | C | Oral | 0.5 Mg | Not Reported |
| Bisoprolol | C | Oral | 5 Mg   | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 17-Jun-2014              | 10242706      | EXPEDITED (15-DAY) |                    | HO              | US-ABBVIE-14P-163-1245250-00 |                      | 78 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                  | <u>Product</u>                           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>      | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                                                   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------|--------------|------------|------------------|--------------|--------------------|-----------------|--------------------------------------------------------------|
| Amnesia; Dementia;<br>Depression; Device Issue;<br>Encephalopathy; Gait<br>Inability; Headache; Loss<br>Of Personal Independence<br>In Daily Activities;<br>Pseudodementia; Toxicity<br>To Various Agents;<br>Vomiting | Humira<br>Topamax<br>Lexapro<br>Tramadol |              |            | S<br>S<br>S<br>S |              |                    |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Jun-2014              | 10246024      | DIRECT           |                    | HO, LT          |                      |                      | 86 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                     | <u>Product</u>                                                                                       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>           | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                                                           |
|-------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------|--------------|------------|-----------------------|--------------|--------------------|-----------------|----------------------------------------------------------------------|
| Abnormal Dreams;<br>Agitation; Anxiety;<br>Depression; Overdose;<br>Somnolence; Speech<br>Disorder; Speech<br>Disorder; Suicidal Ideation | Lexapro 5 Mg. Escitalopram<br>Oxalate Q23624 Tablet Tev<br>Heart Meds<br>Aacex<br>Potassium<br>Vit D |              |            | S<br>C<br>C<br>C<br>C | Oral         |                    |                 | Teva<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Jun-2014              | 10246257      | DIRECT           |                    | HO              |                      |                      | 70 YR      | Female     | USA            |

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

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Feeling Abnormal; Loss Of Consciousness; Pallor

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Jun-2014              | 10214985      | EXPEDITED (15-DAY) |                    | HO              | DE-FRI-1000067783    |                      |            | Female     | DEU            |

| <u>Preferred Term</u>                                                               | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------|-------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| C-Reactive Protein Increased; Leukocytosis; Urinary Incontinence; Urinary Retention | Escitalopram      |              |            | S           | Oral         | 5 Mg               |                 | Forest       |
|                                                                                     | Escitalopram      |              |            | S           | Oral         | 10 Mg              |                 | Not Reported |
|                                                                                     | Escitalopram      |              |            | S           | Oral         | 15 Mg              |                 | Not Reported |
|                                                                                     | Escitalopram      |              |            | S           | Oral         | 20 Mg              |                 | Not Reported |
|                                                                                     | Zyprexa           |              |            | S           | Oral         | 5 Mg               |                 | Not Reported |
|                                                                                     | Zyprexa           |              |            | S           | Oral         | 7.5 Mg             |                 | Not Reported |
|                                                                                     | Zyprexa           |              |            | S           | Oral         | 10 Mg              |                 | Not Reported |
|                                                                                     | Zyprexa           |              |            | S           | Oral         | 12.5 Mg            |                 | Not Reported |
|                                                                                     | Zyprexa           |              |            | S           | Oral         | 7.5 Mg             |                 | Not Reported |
|                                                                                     | Zyprexa           |              |            | S           | Oral         | 5 Mg               |                 | Not Reported |
|                                                                                     | Zyprexa           |              |            | S           | Oral         | 2.5 Mg             |                 | Not Reported |
|                                                                                     | Tavor (Lorazepam) |              |            | S           | Oral         | 1.5 Mg             |                 | Not Reported |
|                                                                                     | Tavor (Lorazepam) |              |            | S           | Oral         | 1 Mg               |                 | Not Reported |
|                                                                                     | Tavor (Lorazepam) |              |            | S           | Oral         | 0.5 Mg             |                 | Not Reported |
|                                                                                     | Tavor (Lorazepam) |              |            | S           | Oral         | 0.25 Mg            |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 18-Jun-2014              | 10219904      | EXPEDITED (15-DAY) |                    | HO              | FR-PFIZER INC-2014151308 |                      | 96 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Accidental Exposure To Product; Drug Interaction; Pneumonia Aspiration; Somnolence | Xanax          |              |            | S           | Oral         | 1 Df, 3x/Day       |                 | Pfizer       |
|                                                                                    | Tranxene       |              |            | S           | Oral         | 40 Mg, Single      |                 | Not Reported |
|                                                                                    | Deroxat        |              |            | S           | Oral         | 20 Mg, Single      |                 | Not Reported |

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

|             |   |      |                                                     |              |
|-------------|---|------|-----------------------------------------------------|--------------|
| Seroplex    | S | Oral | 20 Mg, 1x/Day In The Evening                        | Not Reported |
| Zyprexa     | S | Oral | 7.5 Mg, Single                                      | Not Reported |
| Tareg       | C |      | 1 Df, Unk                                           | Not Reported |
| Kaleorid    | C |      | 1 Df, Unk                                           | Not Reported |
| Imurel      | C |      | 1 Df, Unk                                           | Not Reported |
| Chondrosulf | C |      | 1 Df, Unk                                           | Not Reported |
| Tardyferon  | C |      | 1 Df, 1x/Day In The Morning                         | Not Reported |
| Uvedose     | C |      | 100000 Iu, Every 3 Months                           | Not Reported |
| Stilnox     | C |      | 0.5 Df, 1x/Day At Bedtime                           | Not Reported |
| Dafalgan    | C |      | 1 Tablet In The Morning, At Noon And In The Evening | Not Reported |
| Movicol     | C |      | 2 Df, 1x/Day In The Morning                         | Not Reported |
| Tanganil    | C |      | 1 Tablet In The Morning And At Noon                 | Not Reported |

| <u>FDA Received Date</u>                                               | <u>Case #</u>    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------|------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 18-Jun-2014                                                            | 10221033         | EXPEDITED (15-DAY) |                    | HO, LT          | CA-PFIZER INC-2008062560 |                      | 52 YR           | Male         | CAN            |
| <u>Preferred Term</u>                                                  | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Calcium Decreased;                                               | Morphine Sulfate |                    |                    | S               | Oral                     | 30 Mg, Daily         |                 | Pfizer       |                |
| Blood Pressure Systolic Decreased; Bradycardia;                        | Morphine Sulfate |                    |                    | S               |                          | 100 Mg, Unk          |                 | Pfizer       |                |
| Drug Interaction;                                                      | Morphine Sulfate |                    |                    | S               |                          | 15 Mg, Unk           |                 | Pfizer       |                |
| Electrocardiogram Abnormal;                                            | Lorazepam        |                    |                    | S               | Oral                     | 1 Mg, Unk            |                 | Pfizer       |                |
| Electrocardiogram Qt Prolonged;                                        | Zopiclone        |                    |                    | S               | Oral                     | 15 Mg, Daily         |                 | Not Reported |                |
| Hyperkalaemia;                                                         | Escitalopram     |                    |                    | S               | Oral                     | 10 Mg, Daily         |                 | Not Reported |                |
| International Normalised Ratio Increased; Loss Of Consciousness; Nodal | Diazepam         |                    |                    | S               | Oral                     | 10 Mg, Unk           |                 | Not Reported |                |
|                                                                        | Oxycodone        |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |

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

|                                        |                            |   |      |                                       |              |
|----------------------------------------|----------------------------|---|------|---------------------------------------|--------------|
| Rhythm; Overdose; Sinus<br>Tachycardia | Oxycodone                  | S | Oral | 20 Mg, Unk                            | Not Reported |
|                                        | Oxycodone Extended Release | S | Oral | 10 Mg, Unk                            | Not Reported |
|                                        | Citalopram                 | S | Oral | Unk Mg, Unk                           | Not Reported |
|                                        | Acetaminophen/Oxycodone    | S | Oral | Acetaminophen 325mg,<br>Oxycodone 5mg | Not Reported |
|                                        | Altace                     | C | Oral |                                       | Not Reported |

| <u>FDA Received Date</u>                             | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------|----------------|------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
| 18-Jun-2014                                          | 10221720       | NON-EXPEDITED    |                    | HO              | FR-JNJFOC-<br>20140518574 |                      | 37 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Mydriasis; Somnolence;<br>Toxicity To Various Agents | Ixprim         |                  |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                                                      | Lexomil        |                  |                    | S               | Oral                      | 180 Mg               |                 | Not Reported |                |
|                                                      | Myolastam      |                  |                    | S               | Oral                      | 12 Tablets           |                 | Not Reported |                |
|                                                      | Xanax          |                  |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                                                      | Seroplex       |                  |                    | S               | Oral                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|---------------------------------------|-----------------|--------------|----------------|
| 18-Jun-2014                                            | 10243763       | EXPEDITED (15-DAY) |                    | HO, LT          | FR-FRI-1000068206    |                                       | 49 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Bradycardia; Coma;<br>Overdose; Vasoplegia<br>Syndrome | Escitalopram   |                    |                    | S               | Oral                 |                                       |                 | Forest       |                |
|                                                        | Escitalopram   |                    |                    | S               | Oral                 | Overdose Of 630 Mg Once               |                 | Not Reported |                |
|                                                        | Simvastatine   |                    |                    | S               | Oral                 |                                       |                 | Not Reported |                |
|                                                        | Simvastatine   |                    |                    | S               | Oral                 | Overdose Of 400 Mg Once               |                 | Not Reported |                |
|                                                        | Zopiclone      |                    |                    | S               | Oral                 |                                       |                 | Not Reported |                |
|                                                        | Zopiclone      |                    |                    | S               | Oral                 | Overdose Of 210 Mg Once               |                 | Not Reported |                |
|                                                        | Valium         |                    |                    | S               | Oral                 |                                       |                 | Not Reported |                |
|                                                        | Valium         |                    |                    | S               | Oral                 | Overdose Between 40 To<br>200 Mg Once |                 | Not Reported |                |

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

|                                                         | Coversyl                |                    | S                  | Oral            |                         |                      |                 | Not Reported |                |
|---------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|-------------------------|----------------------|-----------------|--------------|----------------|
|                                                         | Coversyl                |                    | S                  | Oral            | Overdose Of 550 Mg Once |                      |                 | Not Reported |                |
|                                                         | Zolpidem                |                    | S                  | Oral            |                         |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Jun-2014                                             | 10243817                | EXPEDITED (15-DAY) |                    | OT              | CA-FRI-1000068203       |                      | 49 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                   | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Road Traffic Accident                                   | Escitalopram            |                    |                    | S               | Oral                    | 10 Mg                |                 | Forest       |                |
|                                                         | Escitalopram            |                    |                    | S               | Oral                    | 20 Mg                |                 | Forest       |                |
| <u>FDA Received Date</u>                                | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Jun-2014                                             | 10243828                | EXPEDITED (15-DAY) |                    | OT              | CN-FRI-1000068204       |                      | 28 YR           | Male         | CHN            |
| <u>Preferred Term</u>                                   | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Mental Impairment; Poverty Of Thought Content | Lexapro                 |                    |                    | S               | Oral                    |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Jun-2014                                             | 10248810                | DIRECT             | Y                  | OT              |                         |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                   | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective; Product Substitution Issue            | Lexapro 20mg - Generic  |                    |                    | S               | Oral                    |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Jun-2014                                             | 10249031                | EXPEDITED (15-DAY) | Y                  | OT              | SYM-2014-22090          |                      | 53 YR           | Female       | FIN            |
| <u>Preferred Term</u>                                   | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Chest Pain;                                             | Voxra                   |                    |                    | S               |                         |                      |                 | Not Reported |                |
| Electrocardiogram T Wave                                | Duloxetine (Duloxetine) |                    |                    | S               |                         |                      |                 | Not Reported |                |

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

|                                           |                                                                                                                                                      |                      |                                                                  |
|-------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|------------------------------------------------------------------|
| Inversion; Headache;<br>Sinus Bradycardia | (Duloxetine)<br>Escitalopram (Escitalopram)<br>Micardis (Telmisartan)<br>Thyroxin (Levothyroxine<br>Sodium)<br>Diformin (Metformin<br>Hydrochloride) | S<br>C<br>C<br><br>C | Not Reported<br>Not Reported<br>Not Reported<br><br>Not Reported |
|-------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|------------------------------------------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 19-Jun-2014              | 10247511      | EXPEDITED (15-DAY) |                    | HO, OT          | FR-PFIZER INC-<br>2014165632 |                      | 81 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                                                                                                                                                           | <u>Product</u>                                                                                                                                                                                                                                                            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>                                                       | <u>Route</u>                                 | <u>Dosage Text</u>                                                                                    | <u>Duration</u> | <u>Mfr</u>                                                                                                                                                                                                 |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|------------|-------------------------------------------------------------------|----------------------------------------------|-------------------------------------------------------------------------------------------------------|-----------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Depressed Level Of<br>Consciousness;<br>Disturbance In Attention;<br>Eschar; Extensor Plantar<br>Response; Extrapryramidal<br>Disorder; Lung Infection;<br>Mydriasis; Overdose;<br>Renal Failure;<br>Somnolence | Lyrica<br>Contramal<br>Laroxyl<br>Seresta<br>Stilnox<br>Seroplex<br>Transipeg (Polyethylene Glycol<br>3350\Potassium<br>Chloride\Sodium<br>Bicarbonate\Sodium<br>Chloride\Sodium Sulfate<br>Anhydrous)<br>Doliprane<br>Kardegic<br>Modopar<br>Olmetec<br>Ostram<br>Xagrid |              |            | S<br>S<br>S<br>S<br>S<br>S<br>C<br><br>C<br>C<br>C<br>C<br>C<br>C | Oral<br>Oral<br>Oral<br>Oral<br>Oral<br>Oral | 1 Df, 2x/Day<br>1.5 Df, 2x/Day<br>6 Gtt, 3x/Day<br>1.5 Df, 1x/Day<br>1.5 Df, 1x/Day<br>1.5 Df, 1x/Day |                 | Pfizer<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br><br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 19-Jun-2014              | 10247678      | EXPEDITED (15-DAY) |                    | HO              | FR-PFIZER INC-<br>2014166450 |                      | 66 YR      | Female     | FRA            |

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

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

|                                                                     |                     |   |      |            |              |
|---------------------------------------------------------------------|---------------------|---|------|------------|--------------|
| Bradycardia; Coma;<br>Hypotension; Hypoxia;<br>Intentional Overdose | Amlor               | S | Oral | 30 Mg, Unk | Pfizer       |
|                                                                     | Metformin Hcl       | S | Oral | 5 G, Unk   | Pfizer       |
|                                                                     | Seroplex            | S | Oral | 40 Mg, Unk | Not Reported |
|                                                                     | Temesta (Lorazepam) | S |      | 35 Mg, Unk | Not Reported |
|                                                                     | Bromazepam          | S | Oral | Unk        | Not Reported |
|                                                                     | Tercian             | C |      |            | Not Reported |
|                                                                     | Micardis            | C |      |            | Not Reported |
|                                                                     | Bisoprolol          | C |      | 40 Mg, Unk | Not Reported |
|                                                                     | Tahor               | C |      | 20 Mg, Unk | Not Reported |
|                                                                     | Novonorm            | C |      |            | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Jun-2014              | 10248977      | DIRECT           |                    | DS, HO, LT, RI  |                      |                      | 35 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------------------------|-----------------|--------------|
| Abdominal Discomfort;<br>Abdominal Distension;<br>Autoimmune Hepatitis;           | Cymbalta       |              |            | S           | Oral         | 40 Mg, Once Daily, Taken<br>By Mouth |                 | Not Reported |
| Back Pain; Chromaturia;<br>Contusion; Dyspepsia;<br>Jaundice; Nausea;<br>Pruritus | Lexapro        |              |            | S           | Oral         | 10, Once Daily, Taken By<br>Mouth    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Jun-2014              | 10252380      | EXPEDITED (15-DAY) | Y                  | HO, LT, OT      | 2014000183           |                      | 49 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                              | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Acute Kidney Injury;                                               | Aceon                    |              |            | S           | Oral         |                    |                 | Not Reported |
| Bradycardia; Coma;<br>Intentional Overdose;<br>Vasoplegia Syndrome | Seroplex                 |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                    | Simvastatin(Simvastatin) |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                    | Diazepam                 |              |            | S           | Oral         |                    |                 | Not Reported |



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

|           |   |      |              |
|-----------|---|------|--------------|
| Zopiclone | S | Oral | Not Reported |
| Zolpidem  | S | Oral | Not Reported |
|           |   | Oral |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 20-Jun-2014              | 10248883      | EXPEDITED (15-DAY) |                    | CA              | US-JNJFOC-20140612358 |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                                                                              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Atrial Septal Defect; Cleft Lip; Cleft Lip And Palate; Foetal Exposure During Pregnancy; Ventricular Septal Defect | Topamax        |              |            | S           | Oral           | Mother'S Dosing    |                 | Not Reported |
|                                                                                                                    | Phenobarbital  |              |            | S           | Transplacental | Mother'S Dosing    |                 | Not Reported |
|                                                                                                                    | Mysoline       |              |            | S           | Transplacental | Mother'S Dosing    |                 | Not Reported |
|                                                                                                                    | Lexapro        |              |            | S           | Transplacental | Mother'S Dosing    |                 | Not Reported |
|                                                                                                                    | Multivitamins  |              |            | C           | Transplacental | Mother'S Dosing    |                 | Not Reported |
|                                                                                                                    | Folic Acid     |              |            | C           | Transplacental | Mother'S Dosing    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 20-Jun-2014              | 10248890      | EXPEDITED (15-DAY) |                    | CA, OT          | US-JNJFOC-20140611821 |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                                | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------|-------------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Cleft Palate; Foetal Exposure During Pregnancy; Otitis Media Chronic | Topamax           |              |            | S           | Transplacental |                    |                 | Not Reported |
|                                                                      | Lamictal          |              |            | S           | Transplacental |                    |                 | Not Reported |
|                                                                      | Lexapro           |              |            | S           | Transplacental |                    |                 | Not Reported |
|                                                                      | Prenatal Vitamins |              |            | C           | Unknown        |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------|----------------------|------------|------------|----------------|
| 20-Jun-2014              | 10249510      | EXPEDITED (15-DAY) |                    | HO              | FR-DSJP-DSE-2014-111942 |                      |            | Unknown    | FRA            |

| <u>Preferred Term</u>        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Fall; Hyponatraemia; Malaise | Coolmetec      |              |            | S           | Oral         | 1 Df, Qd           |                 | Not Reported |
|                              | Seroplex       |              |            | S           | Oral         | 10 Mg, Qd          |                 | Not Reported |

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

|  |           |   |      |          |  |  |  |              |
|--|-----------|---|------|----------|--|--|--|--------------|
|  | Lexomil   | S | Oral | 3 Mg, Qd |  |  |  | Not Reported |
|  | Cordarone | C |      |          |  |  |  | Not Reported |
|  | Coumadine | C |      |          |  |  |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Jun-2014              | 10249808      | EXPEDITED (15-DAY) |                    | HO              | DE-WATSON-2014-12956 |                      | 74 YR      | Male       | DEU            |

| <u>Preferred Term</u>                  | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------|-----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cerebellar Haemorrhage;<br>Tachycardia | Mirtazapine (Unknown) |              |            | S           | Oral         | 30 Mg, Daily       |                 | Watson       |
|                                        | Mirtazapine (Unknown) |              |            | S           | Oral         | 15 Mg, Daily       |                 | Watson       |
|                                        | Cipralext /01588501/  |              |            | S           | Oral         | 5 Mg, Daily        |                 | Not Reported |
|                                        | Cipralext /01588501/  |              |            | S           | Oral         | 10 Mg, Daily       |                 | Not Reported |
|                                        | Clexane               |              |            | S           | Subcutaneous | 0.6 MI, Daily      |                 | Not Reported |
|                                        | Clexane               |              |            | S           | Subcutaneous | 1.2 MI, Daily      |                 | Not Reported |
|                                        | Clexane               |              |            | S           | Subcutaneous | 0.6 MI, Daily      |                 | Not Reported |
|                                        | Ebixa                 |              |            | C           | Oral         | 10 Mg, Daily       |                 | Not Reported |
|                                        | Ebixa                 |              |            | C           | Oral         | 15 Mg, Daily       |                 | Not Reported |
|                                        | Ebixa                 |              |            | C           | Oral         | 20 Mg, Daily       |                 | Not Reported |
|                                        | Ebixa                 |              |            | C           | Oral         | 15 Mg, Daily       |                 | Not Reported |
|                                        | Ebixa                 |              |            | C           | Oral         | 10 Mg, Daily       |                 | Not Reported |
|                                        | Risperdal             |              |            | C           | Oral         | 1 Mg, Daily        |                 | Not Reported |
|                                        | Risperdal             |              |            | C           | Oral         | 0.5 Mg, Daily      |                 | Not Reported |
|                                        | Bisoprolol            |              |            | C           | Oral         | 5 Mg, Daily        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 20-Jun-2014              | 10250670      | EXPEDITED (15-DAY) |                    | HO, LT, OT      | CH-GLAXOSMITHKLINE-B1005735A |                      | 31 YR      | Male       | CHE            |

| <u>Preferred Term</u>                                              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                             | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|--------------------------------------------------------------------|----------------|--------------|------------|-------------|------------------------------------------|--------------------|-----------------|-----------------|
| Abdominal Pain Upper;<br>Depressed Level Of<br>Consciousness; Drug | Ondansetron    |              |            | S           | Intravenous (not<br>otherwise specified) |                    |                 | Glaxosmithkline |

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

|                                                                                                                                                                                                                                                                                             |                                                                                                                               |                                 |                                                                        |                                                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------|---------------------------------|------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------|
| Interaction;<br>Electrocardiogram Qt<br>Prolonged;<br>Electrocardiogram<br>Repolarisation<br>Abnormality; Generalised<br>Tonic-Clonic Seizure;<br>Hypokalaemia;<br>Hypomagnesaemia; Loss<br>Of Consciousness;<br>Torsade De Pointes;<br>Ventricular Hypokinesia;<br>Ventricular Tachycardia | Methadone<br>Escitalopram<br>Esomeprazole<br>Scopolamine Butylbromide<br>Dipyrone<br>Paracetamol (Acetaminophen)<br>Pethidine | S<br>S<br>C<br>C<br>C<br>C<br>C | Oral<br>Unknown<br>Unknown<br>Unknown<br>Unknown<br>Unknown<br>Unknown | Glaxosmithkline<br>Glaxosmithkline<br>Glaxosmithkline<br>Not Reported<br>Glaxosmithkline<br>Glaxosmithkline<br>Not Reported |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------|---------------------------------|------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------|

| <u>FDA Received Date</u>                                         | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 20-Jun-2014                                                      | 10252671       | DIRECT           | Y                  | OT              |                      |                      | 42 YR           | Male         | USA            |
| <u>Preferred Term</u>                                            | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Behaviour;<br>Aggression; Product<br>Substitution Issue | Escitalopram   |                  |                    | S               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                                             | <u>Case #</u>                                                                                                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>                           | <u>Mfr Control #</u>         | <u>503B Facility</u>                                                            | <u>Age</u>      | <u>Sex</u>                                                                                                                             | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------|--------------------|--------------------|-------------------------------------------|------------------------------|---------------------------------------------------------------------------------|-----------------|----------------------------------------------------------------------------------------------------------------------------------------|----------------|
| 23-Jun-2014                                                                                                                                                          | 10249224                                                                                                           | EXPEDITED (15-DAY) |                    | HO, OT                                    | FR-PFIZER INC-<br>2014163529 |                                                                                 | 65 YR           | Female                                                                                                                                 | FRA            |
| <u>Preferred Term</u>                                                                                                                                                | <u>Product</u>                                                                                                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                               | <u>Route</u>                 | <u>Dosage Text</u>                                                              | <u>Duration</u> | <u>Mfr</u>                                                                                                                             |                |
| Cheilitis; Cholestasis;<br>Dyshidrotic Eczema;<br>Eosinophilia; Erythema<br>Multiforme; Face Oedema;<br>Lichen Sclerosus; Vulval<br>Oedema; Vulvovaginal<br>Erythema | Lyrica<br>Seroplex<br>Effexor Lp<br>Bromazepam<br>Singulair<br>Telfast<br>Esomeprazole<br>Rinoclenil<br>Colchicine |                    |                    | S<br>S<br>C<br>C<br>C<br>C<br>C<br>C<br>C | Oral<br>Oral                 | 150 Mg, 2x/Day<br>5 Mg, 1x/Day<br>Unk<br>Unk<br>Unk<br>Unk<br>Unk<br>Unk<br>Unk |                 | Pfizer<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|---------------------------|-----------------|--------------|----------------|
| 23-Jun-2014                             | 10253627       | EXPEDITED (15-DAY) |                    | HO              | PHHY2014FR076700     |                           | 88 YR           | Female       | FRA            |
| <u>Preferred Term</u>                   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyponatraemia                           | Esidrex        |                    |                    | S               | Oral                 | 12.5 Mg, Qd               |                 | Not Reported |                |
|                                         | Seroplex       |                    |                    | S               | Oral                 | 5 Mg, Qd                  |                 | Not Reported |                |
|                                         | Seresta        |                    |                    | C               | Oral                 | 10 Mg, Tid If Necessary   |                 | Not Reported |                |
|                                         | Coumadine      |                    |                    | C               | Oral                 | 4 Mg, Qd                  |                 | Not Reported |                |
|                                         | Doliprane      |                    |                    | C               |                      | 1000 Mg, Tid If Necessary |                 | Not Reported |                |
| <u>FDA Received Date</u>                | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Jun-2014                             | 10257311       | DIRECT             |                    | DS              |                      |                           | 51 YR           | Female       | USA            |
| <u>Preferred Term</u>                   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Pressure Increased;<br>Chest Pain | Escitalopram   |                    |                    | S               | Oral                 |                           |                 | Lupin        |                |
| <u>FDA Received Date</u>                | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Jun-2014                             | 10234204       | NON-EXPEDITED      |                    | HO              | US-FRI-1000068061    |                           | 57 YR           | Female       | USA            |
| <u>Preferred Term</u>                   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |                |
| Off Label Use; Seizure;<br>Tremor       | Namenda Xr     |                    |                    | S               | Oral                 | 28 Mg                     |                 | Forest       |                |
|                                         | Namenda Xr     |                    |                    | S               |                      |                           |                 | Forest       |                |
|                                         | Namenda Xr     |                    |                    | S               |                      |                           |                 | Forest       |                |
|                                         | Namenda        |                    |                    | S               | Oral                 | 5 Mg                      |                 | Forest       |                |
|                                         | Namenda        |                    |                    | S               | Oral                 | 10 Mg                     |                 | Forest       |                |
|                                         | Namenda        |                    |                    | S               | Oral                 | 10 Mg Am, 5 Mg Pm         |                 | Forest       |                |
|                                         | Namenda        |                    |                    | S               | Oral                 | 10 Mg                     |                 | Forest       |                |
|                                         | Escitalopram   |                    |                    | S               | Oral                 | 5 Mg                      |                 | Not Reported |                |
|                                         | Escitalopram   |                    |                    | S               |                      |                           |                 | Not Reported |                |
|                                         | Vimpat         |                    |                    | S               |                      | 50 Mg                     |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|        |   |        |              |
|--------|---|--------|--------------|
| Vimpat | S | 100 Mg | Not Reported |
| Vimpat | S | 50 Mg  | Not Reported |
| Vimpat | S | 200 Mg | Not Reported |

| <u>FDA Received Date</u>                                                                                                                         | <u>Case #</u>   | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>              | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|------------------|--------------------|-----------------|-----------------------------------|----------------------|-----------------|--------------|----------------|
| 24-Jun-2014                                                                                                                                      | 10256149        | NON-EXPEDITED    |                    | LT, OT          | US-ZOGENIX, INC.-<br>2012ZX000043 |                      | 32 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                            | <u>Product</u>  | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                      | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Chest Discomfort; Drug Interaction; Dyspnoea; Feeling Abnormal; Nausea; Oral Discomfort; Pruritus Generalised; Seizure; Throat Tightness; Tremor | Sumavel Dosepro |                  |                    | S               |                                   |                      |                 | Zogenix      |                |
|                                                                                                                                                  | Lexapro         |                  |                    | S               | Oral                              |                      |                 | Not Reported |                |
|                                                                                                                                                  | Zonegran        |                  |                    | C               | Oral                              |                      |                 | Not Reported |                |
|                                                                                                                                                  | Neurontin       |                  |                    | C               | Oral                              |                      |                 | Not Reported |                |
|                                                                                                                                                  | Neurontin       |                  |                    | C               |                                   |                      |                 | Not Reported |                |
|                                                                                                                                                  | Restoril        |                  |                    | C               |                                   |                      |                 | Not Reported |                |
|                                                                                                                                                  | Pepcid          |                  |                    | C               |                                   |                      |                 | Not Reported |                |
|                                                                                                                                                  | Vitamin         |                  |                    | C               |                                   |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                      | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------|----------------------------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|-----------------|--------------|----------------|
| 24-Jun-2014                                                   | 10256639                         | EXPEDITED (15-DAY) |                    | HO              | FR-009507513-<br>1406FRA010219 |                      | 74 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                         | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Eosinophilia; Pyrexia; Rash Erythematous; Rash Maculo-Papular | Aerius (Desloratadine)           |                    |                    | S               | Oral                           | 5 Mg, Qd             |                 | Merck        |                |
|                                                               | Seroplex                         |                    |                    | S               | Oral                           | 10 Mg, Qd            |                 | Not Reported |                |
|                                                               | Fucidine (Fusidate Sodium)       |                    |                    | S               | Oral                           | Unk                  |                 | Not Reported |                |
|                                                               | Inexium (Esomeprazole Magnesium) |                    |                    | C               | Oral                           | 20 Mg, Qd            |                 | Not Reported |                |
|                                                               | Inexium (Esomeprazole Magnesium) |                    |                    | C               |                                | 20 Mg, Qd            |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 24-Jun-2014              | 10262149       | DIRECT           | Y                  | OT              |                      |                      |                 | Female     | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

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

|                                                                            |                      |   |      |  |  |  |  |  |  |              |
|----------------------------------------------------------------------------|----------------------|---|------|--|--|--|--|--|--|--------------|
| Drug Ineffective; Product Substitution Issue; Therapeutic Response Changed | Escitalopram Oxalate | S | Oral |  |  |  |  |  |  | Not Reported |
|                                                                            | Ibuprofen            | S |      |  |  |  |  |  |  | Not Reported |
|                                                                            | Cimetidine           | S |      |  |  |  |  |  |  | Not Reported |
|                                                                            | Pravastatin          | S |      |  |  |  |  |  |  | Not Reported |
|                                                                            | Lexapro              | S |      |  |  |  |  |  |  | Not Reported |
|                                                                            | Proair Hfa           | S |      |  |  |  |  |  |  | Not Reported |
|                                                                            | Trazodone            | S |      |  |  |  |  |  |  | Not Reported |
|                                                                            | Abilify              | S |      |  |  |  |  |  |  | Not Reported |
|                                                                            | Metformin            | S |      |  |  |  |  |  |  | Not Reported |
|                                                                            | Lisinopril           | S |      |  |  |  |  |  |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Jun-2014              | 10264794      | DIRECT           | Y                  | OT              |                      |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                                  | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anger; Drug Ineffective; Product Substitution Issue; Unevaluable Event | Escitalopram Oxalate |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Jun-2014              | 10266439      | DIRECT           |                    |                 |                      |                      | 38 YR      | Female     | USA            |

| <u>Preferred Term</u>                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Ill-Defined Disorder; Product Substitution Issue | Escitalopram   |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Jun-2014              | 10261537      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000068478    |                      | 65 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                                                               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cheilitis; Dyshidrotic Eczema; Eosinophilia; Erythema Multiforme; Face Oedema; Vulval Oedema; Vulvovaginal Erythema | Escitalopram   |              |            | S           | Oral         | 5 Mg               |                 | Forest       |
|                                                                                                                     | Lyrica         |              |            | S           | Oral         | 300 Mg             |                 | Not Reported |
|                                                                                                                     | Effexor        |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                     | Bromazepam     |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                     | Singulair      |              |            | C           |              |                    |                 | Not Reported |

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|              |   |              |
|--------------|---|--------------|
| Telfast      | C | Not Reported |
| Esomeprazole | C | Not Reported |
| Rinoclenil   | C | Not Reported |
| Colchicine   | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Jun-2014              | 10261606      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000068479    |                      | 81 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                                          | <u>Product</u>                                                                                                      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Depressed Level Of Consciousness;<br>Disturbance In Attention;<br>Off Label Use;<br>Somnolence | Escitalopram                                                                                                        |              |            | S           | Oral         | 1.5 Df             |                 | Forest       |
|                                                                                                | Contramal                                                                                                           |              |            | S           | Oral         | 3 Df               |                 | Not Reported |
|                                                                                                | Laroxyl                                                                                                             |              |            | S           | Oral         | 18 Gtt             |                 | Not Reported |
|                                                                                                | Lyrica                                                                                                              |              |            | S           | Oral         | 2 Df               |                 | Not Reported |
|                                                                                                | Seresta                                                                                                             |              |            | S           | Oral         | 1.5 Df             |                 | Not Reported |
|                                                                                                | Stilnox                                                                                                             |              |            | S           | Oral         | 1.5 Df             |                 | Not Reported |
|                                                                                                | Transipeg (Polyethylene Glycol 3350\Potassium Chloride\Sodium Bicarbonate\Sodium Chloride\Sodium Sulfate Anhydrous) |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                | Doliprane                                                                                                           |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                | Kardegic                                                                                                            |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                | Modopar                                                                                                             |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                | Modopar Lp                                                                                                          |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                | Olmotec                                                                                                             |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                | Ostram                                                                                                              |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                | Xagrid                                                                                                              |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Jun-2014              | 10261607      | EXPEDITED (15-DAY) |                    | DS, HO          | FR-FRI-1000068481    |                      | 82 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Haemorrhagic Stroke   | Escitalopram   |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                       | Lercan         |              |            | C           |              | 10 Mg              |                 | Not Reported |

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|                                                               | Indapamide                                        |                    | C                  |                 | 1.5 Mg               |                        | Not Reported    |              |                |
|---------------------------------------------------------------|---------------------------------------------------|--------------------|--------------------|-----------------|----------------------|------------------------|-----------------|--------------|----------------|
|                                                               | Coversyl                                          |                    | C                  |                 | 10 Mg                |                        | Not Reported    |              |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>                                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Jun-2014                                                   | 10261723                                          | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000068490    |                        | 52 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                         | <u>Product</u>                                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Neutropenia                                                   | Escitalopram                                      |                    |                    | S               | Oral                 |                        |                 | Forest       |                |
|                                                               | Paracetamol                                       |                    |                    | S               | Oral                 | 3 Grams                |                 | Not Reported |                |
|                                                               | Spasfon (Phloroglucinol, Trimethylphloroglucinol) |                    |                    | C               |                      |                        |                 | Not Reported |                |
|                                                               | Alprazolam                                        |                    |                    | C               |                      |                        |                 | Not Reported |                |
|                                                               | Fentanyl                                          |                    |                    | C               |                      |                        |                 | Not Reported |                |
|                                                               | Seretide                                          |                    |                    | C               |                      |                        |                 | Not Reported |                |
|                                                               | Spiriva                                           |                    |                    | C               |                      |                        |                 | Not Reported |                |
|                                                               | Lidocaine                                         |                    |                    | C               |                      |                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>                                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Jun-2014                                                   | 10263276                                          | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000068485    |                        | 66 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                         | <u>Product</u>                                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Bradycardia; Coma; Hypotension; Hypoxia; Intentional Overdose | Escitalopram                                      |                    |                    | S               | Oral                 |                        |                 | Forest       |                |
|                                                               | Escitalopram                                      |                    |                    | S               | Oral                 | Overdose Of 40 Mg Once |                 | Not Reported |                |
|                                                               | Metformin                                         |                    |                    | S               | Oral                 |                        |                 | Not Reported |                |
|                                                               | Metformin                                         |                    |                    | S               | Oral                 | Overdose Of 5 G Once   |                 | Not Reported |                |
|                                                               | Amlor                                             |                    |                    | S               | Oral                 |                        |                 | Not Reported |                |
|                                                               | Amlor                                             |                    |                    | S               | Oral                 | Overdose Of 30 Mg Once |                 | Not Reported |                |
|                                                               | Temesta (Lorazepam)                               |                    |                    | S               | Oral                 |                        |                 | Not Reported |                |
|                                                               | Temesta (Lorazepam)                               |                    |                    | S               | Oral                 | Overdose Of 35 Mg Once |                 | Not Reported |                |
|                                                               | Bromazepam                                        |                    |                    | S               | Oral                 |                        |                 | Not Reported |                |
|                                                               | Tercian                                           |                    |                    | C               |                      |                        |                 | Not Reported |                |
|                                                               | Novonorm                                          |                    |                    | C               |                      |                        |                 | Not Reported |                |
|                                                               | Micardis                                          |                    |                    | C               |                      |                        |                 | Not Reported |                |



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

|  |            |   |      |  |                        |  |  |              |
|--|------------|---|------|--|------------------------|--|--|--------------|
|  | Bisoprolol | C | Oral |  |                        |  |  | Not Reported |
|  | Bisoprolol | C | Oral |  | Overdose Of 40 Mg Once |  |  | Not Reported |
|  | Tahor      | C | Oral |  |                        |  |  | Not Reported |
|  | Tahor      | C | Oral |  | Overdose Of 20 Mg Once |  |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Jun-2014              | 10263369      | EXPEDITED (15-DAY) | DE                 |                 | FR-FRI-1000068498    |                      | < 1 DAY    | Female     | FRA            |

| <u>Preferred Term</u>                                                                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|------------|
| Abortion Induced;<br>Congenital Diaphragmatic<br>Hernia; Exposure During<br>Pregnancy | Escitalopram   |              |            | S           | Transplacental | 10 Mg              |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Jun-2014              | 10272678      | DIRECT           | Y                  | HO              |                      |                      | 60 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                              | <u>Product</u>                                                                                                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>                     | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                                                                                            |
|------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------|--------------|------------|---------------------------------|--------------|--------------------|-----------------|-------------------------------------------------------------------------------------------------------|
| Ankle Fracture;<br>Defaecation Urgency;<br>Diarrhoea; Dizziness; Dry<br>Mouth; Fall; Loss Of<br>Consciousness; Nausea;<br>Vomiting | Escitalopram<br>Metoprolol Tart<br>Potassium Cl<br>Lisinopril/Hctz<br>Amlodipine<br>Atorvastatin<br>Omeprazole |              |            | S<br>C<br>C<br>C<br>C<br>C<br>C | Oral         | 1, Qd, Oral        |                 | Mylan<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 30-Jun-2014              | 10238649      | EXPEDITED (15-DAY) |                    | HO              | FR-<br>ELI_LILLY_AND_COMP<br>ANY-FR201406001243 |                      | 96 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                                            | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>                       |
|--------------------------------------------------------------------------------------------------|---------------------|--------------|------------|-------------|--------------|---------------------------------|-----------------|----------------------------------|
| Accidental Exposure To<br>Product; Hypertension;<br>Pneumonia Aspiration;<br>Sepsis; Somnolence; | Zyprexa<br>Tranxene |              |            | S<br>S      | Oral<br>Oral | 7.5 Mg, Single<br>40 Mg, Single |                 | Eli Lilly And Co<br>Not Reported |

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

|                                              |            |   |         |                           |              |
|----------------------------------------------|------------|---|---------|---------------------------|--------------|
| Urticaria; Wrong Patient<br>Received Product | Deroxat    | S | Oral    | 20 Mg, Single             | Not Reported |
|                                              | Seroplex   | S | Oral    | 20 Mg, Qd                 | Not Reported |
|                                              | Xanax      | S | Oral    | 0.25 Mg, Tid              | Not Reported |
|                                              | Tardyferon | C |         | 1 Df, Each Morning        | Not Reported |
|                                              | Uvedose    | C | Unknown | 100000 Iu, Every 3 Months | Not Reported |
|                                              | Stilnox    | C | Unknown | 0.5 Df, Each Evening      | Not Reported |
|                                              | Dafalgan   | C | Unknown | 1 Df, Tid                 | Not Reported |
|                                              | Movicol    | C | Unknown | 2 Df, Each Morning        | Not Reported |
|                                              | Tanganil   | C |         | 1 Df, Bid                 | Not Reported |

|                          |               |                    |                    |                 |                      |                      |            |            |                |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
| 30-Jun-2014              | 10261990      | EXPEDITED (15-DAY) |                    | OT              | LT-TEVA-489827ISR    |                      | 32 YR      | Unknown    | LTU            |

|                       |                                                     |              |            |             |              |                     |                 |            |
|-----------------------|-----------------------------------------------------|--------------|------------|-------------|--------------|---------------------|-----------------|------------|
| <u>Preferred Term</u> | <u>Product</u>                                      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u> |
| Neutropenia           | Escitalopram Teva Ritecol May<br>Have -301-267-2955 |              |            | S           | Oral         | 10 Milligram Daily; |                 | Ivax       |

|                          |               |                  |                    |                 |                              |                      |            |            |                |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
| 30-Jun-2014              | 10267582      | NON-EXPEDITED    |                    |                 | US-PFIZER INC-<br>2014179435 |                      |            | Female     | USA            |

|                                       |                |              |            |             |              |                    |                 |              |
|---------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| <u>Preferred Term</u>                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
| Drug Ineffective; Drug<br>Intolerance | Lyrica         |              |            | S           |              | Unk                |                 | Pfizer       |
|                                       | Cymbalta       |              |            | S           |              | Unk                |                 | Not Reported |
|                                       | Lexapro        |              |            | S           |              | Unk                |                 | Not Reported |
|                                       | Savella        |              |            | S           |              | Unk                |                 | Not Reported |

|                          |               |                    |                    |                 |                          |                      |            |            |                |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
| 30-Jun-2014              | 10268233      | EXPEDITED (15-DAY) |                    | DE              | CH-BAYER-2014-<br>094891 |                      | 75 YR      | Female     | CHE            |

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

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

|                    |                    |   |      |                              |              |
|--------------------|--------------------|---|------|------------------------------|--------------|
| Cerebral Haematoma | Aspirin Cardio     | S | Oral | 100 Mg, Qd                   | Bayer        |
|                    | Cipralex           | S |      | 5 Mg, Qd                     | Not Reported |
|                    | Catapresan         | C | Oral | 1 +0.5 Tablet In The Morning | Not Reported |
|                    | Beloc [Metoprolol] | C |      | 50 Mg, Qd                    | Not Reported |
|                    | Triatec (Ramipril) | C |      | 5 Mg, Qd                     | Not Reported |
|                    | Adalat             | C |      | 60 Mg, Qd                    | Not Reported |
|                    | Calcium Acetate    | C |      | 750 Mg, Bid                  | Not Reported |

| <u>FDA Received Date</u>                    | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 30-Jun-2014                                 | 10268498       | EXPEDITED (15-DAY) |                    | HO              | MY-FRI-1000068561    |                      | 79 YR           | Male         | MYS            |
| <u>Preferred Term</u>                       | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Foaming At Mouth; Syncope | Lexapro        |                    |                    | S               | Oral                 |                      |                 | Forest       |                |
|                                             | Lexapro        |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>          | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 30-Jun-2014                       | 10273177       | DIRECT           | Y                  | OT              |                      |                      | 53 YR           | Female       | USA            |
| <u>Preferred Term</u>             | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anger; Product Substitution Issue | Escitalopram   |                  |                    | S               | Oral                 |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                      | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------|---------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 30-Jun-2014                                                   | 10273693                        | EXPEDITED (15-DAY) | Y                  | HO              | AUR-APL-2014-06748   |                      | 66 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                         | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bradycardia; Coma; Hypotension; Hypoxia; Intentional Overdose | Metformin (Metformin) Unknown   |                    |                    | S               | Oral                 | 5 G, Total, Oral     |                 | Not Reported |                |
|                                                               | Amlor (Amlodipine Besilate)     |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                               | Seroplex (Escitalopram Oxalate) |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                               | Temesta /00273201/              |                    |                    | S               |                      |                      |                 | Not Reported |                |

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

|  |                                     |   |      |  |  |  |  |              |
|--|-------------------------------------|---|------|--|--|--|--|--------------|
|  | Bromazepam (Bromazepam)             | S | Oral |  |  |  |  | Not Reported |
|  | Tercian /00759301/<br>(Cyamemazine) | C |      |  |  |  |  | Not Reported |
|  | Micardis (Telmisartan)              | C |      |  |  |  |  | Not Reported |
|  | Bisoprolol (Bisoprolol)             | C |      |  |  |  |  | Not Reported |
|  | Tahor (Atorvastatin Calcium)        | C |      |  |  |  |  | Not Reported |
|  | Novonorm (Repaglinide)              | C |      |  |  |  |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Jul-2014              | 10271246      | EXPEDITED (15-DAY) |                    | OT              | SE-FRI-1000068558    |                      | 57 YR      | Female     | SWE            |

| <u>Preferred Term</u>                                     | <u>Product</u>               | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>             |
|-----------------------------------------------------------|------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------------------|
| Anxiety; Product<br>Substitution Issue; Sleep<br>Disorder | Escitalopram<br>Escitalopram |              |            | S<br>C      |              |                    |                 | Forest<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Jul-2014              | 10271593      | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000068508    |                      | < 1 DAY    | Female     | USA            |

| <u>Preferred Term</u>          | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                     | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>       |
|--------------------------------|-------------------|--------------|------------|-------------|----------------------------------|--------------------|-----------------|------------------|
| Congenital Anomaly;<br>Talipes | Celexa<br>Lexapro |              |            | S<br>S      | Transplacental<br>Transplacental |                    |                 | Forest<br>Forest |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|------------|------------|----------------|
| 02-Jul-2014              | 9459793       | EXPEDITED (15-DAY) |                    | HO, LT          | BE-ASTRAZENECA-<br>2013SE62963 |                      | 65 YR      | Male       | BEL            |

| <u>Preferred Term</u>                                                                            | <u>Product</u>                      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                                   |
|--------------------------------------------------------------------------------------------------|-------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------------------------------|
| Apnoea; Labelled Drug-<br>Drug Interaction                                                       | Omeprazole<br>Escitalopram          |              |            | S<br>S      |              |                    |                 | Not Reported<br>Not Reported                 |
| Medication Error; Long Qt<br>Syndrome; Loss Of<br>Consciousness; Torsade<br>De Pointes; Vomiting | Tacrolimus<br>Sotalol<br>Bisoprolol |              |            | S<br>S<br>C |              |                    |                 | Not Reported<br>Not Reported<br>Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                  | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|--------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 02-Jul-2014                                                                                                               | 10151098                      | EXPEDITED (15-DAY) |                    | HO, LT          | FR-FRI-1000066975                                |                      | 85 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                     | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                     | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardio-Respiratory Arrest;<br>Electrocardiogram Qt<br>Prolonged; Fall; Torsade<br>De Pointes; Ventricular<br>Fibrillation | Escitalopram                  |                    |                    | S               | Oral                                             | 10 Mg                |                 | Forest       |                |
|                                                                                                                           | Xanax                         |                    |                    | S               | Oral                                             | 0.5 Mg               |                 | Not Reported |                |
|                                                                                                                           | Plavix                        |                    |                    | C               |                                                  |                      |                 | Not Reported |                |
|                                                                                                                           | Stagid                        |                    |                    | C               |                                                  |                      |                 | Not Reported |                |
|                                                                                                                           | Prior (Telmisartan)           |                    |                    | C               |                                                  |                      |                 | Not Reported |                |
|                                                                                                                           | Aricept                       |                    |                    | C               |                                                  |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                  | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Jul-2014                                                                                                               | 10235311                      | NON-EXPEDITED      |                    |                 | US-PFIZER INC-<br>2014162043                     |                      | 42 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                     | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                     | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity                                                                                                     | Zoloft                        |                    |                    | S               |                                                  | Unk                  |                 | Pfizer       |                |
|                                                                                                                           | Lexapro                       |                    |                    | S               |                                                  | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                  | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Jul-2014                                                                                                               | 10272288                      | NON-EXPEDITED      |                    |                 | US-LUPIN<br>PHARMACEUTICALS<br>INC.-E2B_00002001 |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                     | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                     | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Weight Increased                                                                                                          | Escitalopram Tablets Usp 10mg |                    |                    | S               |                                                  |                      |                 | Lupin        |                |
|                                                                                                                           | Naproxen                      |                    |                    | C               |                                                  |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                  | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Jul-2014                                                                                                               | 10272616                      | NON-EXPEDITED      |                    |                 | IN-LUPIN<br>PHARMACEUTICALS<br>INC.-2014-00996   |                      | 28 YR           | Male         | IND            |
| <u>Preferred Term</u>                                                                                                     | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                     | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Increased Appetite                                                                                                        | Stalopam                      |                    |                    | S               | Oral                                             |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|-------------------------------|--------------------|--------------------|-----------------|--------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 02-Jul-2014              | 10272624                      | NON-EXPEDITED      |                    |                 | US-LUPIN<br>PHARMACEUTICALS<br>INC.-E2B_00001879 |                      |                 | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                     | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Diarrhoea                | Escitalopram                  |                    |                    | S               |                                                  |                      |                 | Lupin        |                |
| <u>FDA Received Date</u> | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Jul-2014              | 10272631                      | NON-EXPEDITED      |                    |                 | US-LUPIN<br>PHARMACEUTICALS<br>INC.-E2B_00002068 |                      |                 | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                     | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Nausea                   | Escitalopram Tablets Usp 20mg |                    |                    | S               |                                                  |                      |                 | Lupin        |                |
|                          | Klonopin                      |                    |                    | C               | Unknown                                          |                      |                 | Not Reported |                |
|                          | Metoprolol                    |                    |                    | C               | Unknown                                          |                      |                 | Not Reported |                |
|                          | Ranitidine                    |                    |                    | C               | Unknown                                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Jul-2014              | 10272938                      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000068555                                |                      | 90 YR           | Female       | FRA            |
| <u>Preferred Term</u>    | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                     | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anaemia; Melaena         | Escitalopram                  |                    |                    | S               | Oral                                             | 5 Mg                 |                 | Forest       |                |
|                          | Arixtra                       |                    |                    | S               | Subcutaneous                                     | 2.5 Mg / 0.5 MI      |                 | Not Reported |                |
|                          | Plavix                        |                    |                    | S               | Oral                                             | 1 Df                 |                 | Not Reported |                |
|                          | Triatec (Ramipril)            |                    |                    | C               | Oral                                             | 2.5 Mg               |                 | Not Reported |                |
|                          | Seresta                       |                    |                    | C               | Oral                                             |                      |                 | Not Reported |                |
|                          | Risperdal                     |                    |                    | C               | Oral                                             | 1 Mg                 |                 | Not Reported |                |
|                          | Dafalgan                      |                    |                    | C               |                                                  |                      |                 | Not Reported |                |
|                          | Uvedose                       |                    |                    | C               | Oral                                             |                      |                 | Not Reported |                |
|                          | Durogesic                     |                    |                    | C               | Transdermal                                      | 0.3333 Df            |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                                                                                                                                        | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
| 02-Jul-2014                                                                                                                                                                                     | 10272964                             | EXPEDITED (15-DAY) |                    | DE              | FR-FRI-1000068557         |                      | 78 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                           | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Subdural Haematoma                                                                                                                                                            | Escitalopram                         |                    |                    | S               | Oral                      | 10 Mg                |                 | Forest       |                |
|                                                                                                                                                                                                 | Xarelto                              |                    |                    | S               | Oral                      | 15 Mg                |                 | Not Reported |                |
|                                                                                                                                                                                                 | Xarelto                              |                    |                    | S               |                           |                      |                 | Not Reported |                |
|                                                                                                                                                                                                 | Doliprane                            |                    |                    | C               |                           |                      |                 | Not Reported |                |
|                                                                                                                                                                                                 | Fixical                              |                    |                    | C               | Oral                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                        | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Jul-2014                                                                                                                                                                                     | 10273196                             | EXPEDITED (15-DAY) |                    | OT              | ES-MYLANLABS-2014S1014748 |                      | 77 YR           | Female       | ESP            |
| <u>Preferred Term</u>                                                                                                                                                                           | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Neuralgia                                                                                                                                                                                       | Escitalopram                         |                    |                    | S               | Oral                      |                      |                 | Mylan        |                |
|                                                                                                                                                                                                 | Indapamide                           |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                        | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Jul-2014                                                                                                                                                                                     | 10274089                             | EXPEDITED (15-DAY) |                    | CA              | DE-FRI-1000068656         |                      | < 1 DAY         | Male         | DEU            |
| <u>Preferred Term</u>                                                                                                                                                                           | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anal Atresia; Atrial Septal Defect; Ectopic Kidney; Foetal Exposure During Pregnancy; Patent Ductus Arteriosus; Prescribed Overdose; Ventricular Septal Defect; Vitello-Intestinal Duct Remnant | Escitalopram                         |                    |                    | S               | Transplacental            | 40 Mg                |                 | Forest       |                |
|                                                                                                                                                                                                 | Escitalopram                         |                    |                    | S               | Transplacental            | 10 Mg                |                 | Not Reported |                |
|                                                                                                                                                                                                 | Femibion [Minerals Nos;Vitamins Nos] |                    |                    | C               | Transplacental            |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                        | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Jul-2014                                                                                                                                                                                     | 10274090                             | EXPEDITED (15-DAY) |                    | OT              | DE-FRI-1000068655         |                      | 28 YR           | Female       | DEU            |

# FDA Adverse Event Reporting System

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| <u>Preferred Term</u>                                            | <u>Product</u>                                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |                |
|------------------------------------------------------------------|-------------------------------------------------|--------------------|--------------------|-----------------|----------------------|------------------------------------|-----------------|--------------|----------------|
| Caesarean Section; Foetal Distress Syndrome; Prescribed Overdose | Escitalopram                                    |                    |                    | S               | Oral                 | 40 Mg                              |                 | Forest       |                |
|                                                                  | Escitalopram                                    |                    |                    | S               | Oral                 | 10 Mg                              |                 | Forest       |                |
|                                                                  | Femibion [Minerals Nos;Vitamins Nos]            |                    |                    | C               | Oral                 |                                    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                         | <u>Case #</u>                                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Jul-2014                                                      | 10274418                                        | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000068626    |                                    | 74 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                            | <u>Product</u>                                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Eosinophilia; Pyrexia; Rash Erythematous; Rash Maculo-Papular    | Escitalopram                                    |                    |                    | S               | Oral                 | 10 Mg                              |                 | Forest       |                |
|                                                                  | Fucidine (Fusidic Acid)                         |                    |                    | S               | Oral                 |                                    |                 | Not Reported |                |
|                                                                  | Aerius (Desloratadine)                          |                    |                    | S               | Oral                 | 5 Mg                               |                 | Not Reported |                |
|                                                                  | Inexium                                         |                    |                    | C               | Oral                 | 20 Mg                              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                         | <u>Case #</u>                                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Jul-2014                                                      | 10280914                                        | DIRECT             |                    | DS              |                      |                                    | 53 YR           | Female       | USA            |
| <u>Preferred Term</u>                                            | <u>Product</u>                                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Joint Stiffness; Myalgia                                         | Escitalopram                                    |                    |                    | S               | Oral                 | 1 Tablet Once Daily Taken By Mouth |                 | Not Reported |                |
| <u>FDA Received Date</u>                                         | <u>Case #</u>                                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Jul-2014                                                      | 10270778                                        | EXPEDITED (15-DAY) | Y                  | OT              | AUR-APL-2014-06110   |                                    | 34 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                            | <u>Product</u>                                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Withdrawal Syndrome; Mania; Therapy Cessation               | Escitalopram 20 Mg (Escitalopram) Unknown, 20mg |                    |                    | S               |                      |                                    | 244 DAY         | Not Reported |                |



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| <u>FDA Received Date</u>                                                                           | <u>Case #</u>                                                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>                             | <u>Country</u> |
|----------------------------------------------------------------------------------------------------|----------------------------------------------------------------|--------------------|--------------------|-----------------|--------------------------------------------------|-------------------------------|-----------------|----------------------------------------|----------------|
| 03-Jul-2014                                                                                        | 10275291                                                       | NON-EXPEDITED      |                    |                 | US-LUPIN<br>PHARMACEUTICALS<br>INC.-E2B_00002126 |                               | 16 YR           | Female                                 | USA            |
| <u>Preferred Term</u>                                                                              | <u>Product</u>                                                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                     | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>                             |                |
| Feeling Jittery; Malaise;<br>Mydriasis; Vomiting                                                   | Escitalopram Tablets Usp 10mg<br>Vitamin B<br>Ortho Tri-Cyclen |                    |                    | S<br>C<br>C     | Unknown<br>Unknown                               |                               |                 | Lupin<br>Not Reported<br>Not Reported  |                |
| <u>FDA Received Date</u>                                                                           | <u>Case #</u>                                                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>                             | <u>Country</u> |
| 03-Jul-2014                                                                                        | 10275294                                                       | NON-EXPEDITED      |                    |                 | US-LUPIN<br>PHARMACEUTICALS<br>INC.-E2B_00002036 |                               |                 | Female                                 | USA            |
| <u>Preferred Term</u>                                                                              | <u>Product</u>                                                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                     | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>                             |                |
| Depersonalisation/Dereali<br>sation Disorder;<br>Disturbance In Attention;<br>Memory Impairment    | Escitalopram Tablets Usp 5mg                                   |                    |                    | S               |                                                  |                               |                 | Lupin                                  |                |
| <u>FDA Received Date</u>                                                                           | <u>Case #</u>                                                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>                             | <u>Country</u> |
| 03-Jul-2014                                                                                        | 10275322                                                       | NON-EXPEDITED      |                    |                 | US-LUPIN<br>PHARMACEUTICALS<br>INC.-2014-01116   |                               |                 | Male                                   | USA            |
| <u>Preferred Term</u>                                                                              | <u>Product</u>                                                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                     | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>                             |                |
| Withdrawal Syndrome                                                                                | Escitalopram Oxalate                                           |                    |                    | S               | Unknown                                          |                               |                 | Not Reported                           |                |
| <u>FDA Received Date</u>                                                                           | <u>Case #</u>                                                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>                             | <u>Country</u> |
| 03-Jul-2014                                                                                        | 10276216                                                       | EXPEDITED (15-DAY) |                    | HO, LT          | FR-PFIZER INC-<br>2014183671                     |                               | 80 YR           | Male                                   | FRA            |
| <u>Preferred Term</u>                                                                              | <u>Product</u>                                                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                     | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>                             |                |
| Brain Natriuretic Peptide<br>Increased; Dyspnoea;<br>Electrocardiogram Qt<br>Prolonged; Heart Rate | Cordarone<br>Seroplex<br>Isocard                               |                    |                    | S<br>S<br>C     | Oral<br>Oral                                     | 200 Mg, Daily<br>10 Mg, Daily |                 | Pfizer<br>Not Reported<br>Not Reported |                |

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|                                                       |                                                                             |                       |  |  |  |            |  |  |                                                                              |
|-------------------------------------------------------|-----------------------------------------------------------------------------|-----------------------|--|--|--|------------|--|--|------------------------------------------------------------------------------|
| Decreased; Malaise;<br>Syncope; Torsade De<br>Pointes | Vasten [Pravastatin Sodium]<br>Tramadol<br>Stilnox<br>Levothyrox<br>Inexium | C<br>C<br>C<br>C<br>C |  |  |  |            |  |  | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |
|                                                       |                                                                             |                       |  |  |  | 20 Mg, Unk |  |  |                                                                              |

| <u>FDA Received Date</u>                    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u>                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------|----------------------|--------------------|--------------------|-----------------|--------------------------------|--------------------------------------------|-----------------|--------------|----------------|
| 03-Jul-2014                                 | 10276394             | EXPEDITED (15-DAY) |                    | OT              | FR-ASTRAZENECA-<br>2014SE46538 |                                            | 87 YR           | Female       | FRA            |
| <u>Preferred Term</u>                       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyperkalaemia;<br>Ventricular Extrasystoles | Xeroquel             |                    |                    | S               | Oral                           |                                            |                 | Astrazeneca  |                |
|                                             | Seroplex             |                    |                    | S               | Oral                           |                                            |                 | Not Reported |                |
|                                             | Risperdal            |                    |                    | S               | Oral                           |                                            |                 | Not Reported |                |
|                                             | Calcidose Vitamine D |                    |                    | C               | Oral                           | 500mg/400 lu 2 Df Per<br>Day               |                 | Not Reported |                |
|                                             | Seresta              |                    |                    | C               | Oral                           | 10 Mg, If Needed, Three<br>Per Day Maximum |                 | Not Reported |                |
|                                             | Stilnox              |                    |                    | C               | Oral                           |                                            |                 | Not Reported |                |
|                                             | Talc Gifere          |                    |                    | C               |                                |                                            |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| 04-Jul-2014              | 10235323       | NON-EXPEDITED    |                    |                 | US-PFIZER INC-<br>2014162052 |                      | 75 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity    | Effexor        |                  |                    | S               |                              | Unk                  |                 | Pfizer       |                |
|                          | Ambien         |                  |                    | S               |                              | Unk                  |                 | Not Reported |                |
|                          | Avelox         |                  |                    | S               |                              | Unk                  |                 | Not Reported |                |
|                          | Buspar         |                  |                    | S               |                              | Unk                  |                 | Not Reported |                |
|                          | Celexa         |                  |                    | S               |                              | Unk                  |                 | Not Reported |                |
|                          | Codeine        |                  |                    | S               |                              | Unk                  |                 | Not Reported |                |
|                          | Demerol        |                  |                    | S               |                              | Unk                  |                 | Not Reported |                |
|                          | Keflex         |                  |                    | S               |                              | Unk                  |                 | Not Reported |                |

# FDA Adverse Event Reporting System

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|           |   |     |              |
|-----------|---|-----|--------------|
| Levaquin  | S | Unk | Not Reported |
| Lorazepam | S | Unk | Not Reported |
| Lexapro   | S | Unk | Not Reported |
| Remeron   | S | Unk | Not Reported |
| Talc      | S | Unk | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------------------------|----------------------|------------|------------|----------------|
| 04-Jul-2014              | 10277706      | NON-EXPEDITED    |                    |                 | US-LUPIN<br>PHARMACEUTICALS<br>INC.-2014-00862 |                      | 65 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                         | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Chest Discomfort;<br>Decreased Appetite;<br>Dyspnoea; Feeling Jittery;<br>Off Label Use;<br>Palpitations; Weight<br>Decreased | Viibryd              |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                               | Viibryd              |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                               | Viibryd              |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                               | Escitalopram Oxalate |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                               | Escitalopram Oxalate |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                               | Metformin            |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                                                                               | Zocor                |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                                                                               | Lasix                |              |            | C           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------------------------|----------------------|------------|------------|----------------|
| 04-Jul-2014              | 10277708      | NON-EXPEDITED    |                    |                 | AU-LUPIN<br>PHARMACEUTICALS<br>INC.-2014-00947 |                      |            | Male       | AUS            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Ineffective      | Escitalopram   |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Ramipril       |              |            | C           | Unknown      |                    |                 | Not Reported |
|                       | Simvastatin    |              |            | C           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>        | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-----------------------------|----------------------|------------|------------|----------------|
| 04-Jul-2014              | 10277710      | NON-EXPEDITED    |                    |                 | US-LUPIN<br>PHARMACEUTICALS |                      | 16 YR      | Male       | USA            |

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

INC.-E2B\_00001920

| <u>Preferred Term</u>                              | <u>Product</u>               | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u> |
|----------------------------------------------------|------------------------------|--------------|------------|-------------|--------------|------------------------|-----------------|------------|
| Alopecia; Wrong Technique In Product Usage Process | Escitalopram Tablets Usp 5mg |              |            | S           |              | Half Tablet Once A Day |                 | Lupin      |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 07-Jul-2014              | 10036004      | EXPEDITED (15-DAY) |                    | OT              | AT-<br>ELI_LILLY_AND_COMP<br>ANY-AT201403007233 |                      | 43 YR      | Female     | AUT            |

| <u>Preferred Term</u>                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>       |
|-------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------------|
| Amaurosis; Drug Interaction; Dry Mouth; Vertigo | Cymbalta       |              |            | S           | Unknown      | 30 Mg, Unknown     |                 | Eli Lilly And Co |
|                                                 | Cymbalta       |              |            | S           | Unknown      | 60 Mg, Unknown     |                 | Eli Lilly And Co |
|                                                 | Cymbalta       |              |            | S           | Unknown      | 120 Mg, Unknown    |                 | Eli Lilly And Co |
|                                                 | Cipralext      |              |            | S           | Unknown      | 10mg               |                 | Not Reported     |
|                                                 | Cipralext      |              |            | S           | Unknown      | 20mg               |                 | Not Reported     |
|                                                 | Cipralext      |              |            | S           | Unknown      | 10mg               |                 | Not Reported     |
|                                                 | Trittico Cr    |              |            | S           |              | 100mg              |                 | Not Reported     |
|                                                 | Trittico Cr    |              |            | S           |              | 150mg              |                 | Not Reported     |
|                                                 | Seroquel       |              |            | S           |              | 100mg              |                 | Not Reported     |
|                                                 | Seroquel       |              |            | S           |              | 150mg              |                 | Not Reported     |
|                                                 | Seroquel       |              |            | S           |              | 200mg              |                 | Not Reported     |
|                                                 | Seroquel Xr    |              |            | S           |              | 200mg              |                 | Not Reported     |
|                                                 | Seroquel Xr    |              |            | S           |              | 300mg              |                 | Not Reported     |
|                                                 | Seroquel Xr    |              |            | S           |              | 400mg              |                 | Not Reported     |
|                                                 | Lyrica         |              |            | S           | Unknown      | 150 Mg, Unknown    |                 | Not Reported     |
|                                                 | Valdoxan       |              |            | S           | Unknown      | 1 Df, Unknown      |                 | Not Reported     |
|                                                 | Rivotril       |              |            | C           |              | 0.5mg              |                 | Not Reported     |

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

|               |   |        |              |
|---------------|---|--------|--------------|
| Rivotril      | C | 1.0mg  | Not Reported |
| Rivotril      | C | 1.75mg | Not Reported |
| Rivotril      | C | 1.25mg | Not Reported |
| Rivotril      | C | 2.75mg | Not Reported |
| Rivotril      | C | 2.5mg  | Not Reported |
| Sirdalud      | C | 2mg    | Not Reported |
| Thrombo Ass   | C | 100mg  | Not Reported |
| Dominal Forte | C | 80mg   | Not Reported |
| Dominal Forte | C | 40mg   | Not Reported |
| Zoldem        | C | 10mg   | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Jul-2014              | 10244876      | EXPEDITED (15-DAY) |                    | HO              | CN-FRI-1000068209    |                      | 70 YR      | Female     | CHN            |

| <u>Preferred Term</u>                                                                                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|----------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Blood Sodium Decreased;<br>Drug Ineffective; Fall;<br>Fracture; Hyperhidrosis;<br>Urine Output Decreased | Lexapro        |              |            | S           | Oral         | 10 Mg              |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Jul-2014              | 10281839      | EXPEDITED (15-DAY) |                    | OT              | TR-FRI-1000068704    |                      | 16 YR      | Male       | TUR            |

| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Epilepsy; Off Label Use | Escitalopram   |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                         | Escitalopram   |              |            | S           |              |                    |                 | Forest       |
|                         | Depakin        |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Jul-2014              | 10282438      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000068671    |                      | 36 YR      | Female     | FRA            |

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

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                                            |              |   |      |       |              |
|----------------------------------------------------------------------------|--------------|---|------|-------|--------------|
| Brief Psychotic Disorder<br>With Marked Stressors;<br>Persecutory Delusion | Escitalopram | S | Oral | 10 Mg | Forest       |
|                                                                            | Mirtazapine  | C | Oral | 1 Df  | Not Reported |
|                                                                            | Baclofene    | C | Oral | 70 Mg | Not Reported |

| <u>FDA Received Date</u>                                                                          | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|-----------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 08-Jul-2014                                                                                       | 10228640             | EXPEDITED (15-DAY) |                    | OT              | US-ROXANE<br>LABORATORIES, INC.-<br>2014-RO-00881RO |                      |                 | Male         | USA            |
| <u>Preferred Term</u>                                                                             | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective; Epilepsy;<br>Feeling Abnormal; Product<br>Commingling; Product<br>Quality Issue | Morphine             |                    |                    | S               | Oral                                                |                      |                 | Roxane       |                |
|                                                                                                   | Escitalopram Oxalate |                    |                    | S               | Oral                                                |                      |                 | Not Reported |                |
|                                                                                                   | Escitalopram Oxalate |                    |                    | S               | Oral                                                |                      |                 | Not Reported |                |
|                                                                                                   | Klonopin             |                    |                    | C               | Unknown                                             |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                    | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>                                         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------|---------------------|--------------------|--------------------|-----------------|---------------------------|--------------------------------------------------------------|-----------------|--------------|----------------|
| 08-Jul-2014                                 | 10283559            | EXPEDITED (15-DAY) |                    | OT              | FR-JNJFOC-<br>20140618909 |                                                              | 87 YR           | Female       | FRA            |
| <u>Preferred Term</u>                       | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>                                           | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyperkalaemia;<br>Ventricular Extrasystoles | Risperdal           |                    |                    | S               | Oral                      |                                                              |                 | Not Reported |                |
|                                             | Xeroquel            |                    |                    | S               | Oral                      |                                                              |                 | Not Reported |                |
|                                             | Seroplex            |                    |                    | S               | Oral                      |                                                              |                 | Not Reported |                |
|                                             | Stilnox             |                    |                    | C               | Oral                      |                                                              |                 | Not Reported |                |
|                                             | Calcidose Vitamin D |                    |                    | C               | Oral                      | 500 Mg/400iu (Oral<br>Powder In Sachet-Dose)<br>At 2 Sachets |                 | Not Reported |                |
|                                             | Seresta             |                    |                    | C               | Oral                      |                                                              |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|---------------------------------------------------------------|----------------------|-----------------|------------|----------------|
| 08-Jul-2014              | 10283687       | EXPEDITED (15-DAY) |                    | HO              | FR-B.I.<br>PHARMACEUTICALS,I<br>NC./RIDGEFIELD-2014-<br>BI-30 |                      | 78 YR           | Female     | FRA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

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

|                                                                             |                     |        |              |      |                                      |
|-----------------------------------------------------------------------------|---------------------|--------|--------------|------|--------------------------------------|
| Condition Aggravated;<br>Fall; Subdural<br>Haematoma; Subdural<br>Haematoma | Pradaxa<br>Seroplex | S<br>S | Oral<br>Oral | 5 Mg | Boehringer Ingelheim<br>Not Reported |
|-----------------------------------------------------------------------------|---------------------|--------|--------------|------|--------------------------------------|

| <u>FDA Received Date</u>                                             | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>             | <u>Country</u> |
|----------------------------------------------------------------------|-------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|------------------------|----------------|
| 08-Jul-2014                                                          | 10284062          | EXPEDITED (15-DAY) |                    | HO, OT          | FR-PFIZER INC-<br>2014186367 |                      | 45 YR           | Female                 | FRA            |
| <u>Preferred Term</u>                                                | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>             |                |
| Hypokalaemia;<br>Somnolence; Toxicity To<br>Various Agents; Vomiting | Xanax<br>Seroplex |                    |                    | S<br>S          | Oral<br>Oral                 | Unk<br>Unk           |                 | Pfizer<br>Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>     | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|-------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 08-Jul-2014              | 10296279          | DIRECT           |                    |                 |                      |                      | 43 YR           | Male       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>    | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Amnesia                  | Lexapro 10mg Teva |                  |                    | S               | Oral                 |                      | 2 YR            | Teva       |                |

| <u>FDA Received Date</u>                                                                                                                    | <u>Case #</u>                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u>         | <u>503B Facility</u>                                  | <u>Age</u>      | <u>Sex</u>                                       | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|--------------------|--------------------|------------------|------------------------------|-------------------------------------------------------|-----------------|--------------------------------------------------|----------------|
| 09-Jul-2014                                                                                                                                 | 10216326                                   | EXPEDITED (15-DAY) |                    | HO               | CH-PFIZER INC-<br>2014146971 |                                                       | 47 YR           | Female                                           | CHE            |
| <u>Preferred Term</u>                                                                                                                       | <u>Product</u>                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>                 | <u>Dosage Text</u>                                    | <u>Duration</u> | <u>Mfr</u>                                       |                |
| Aggression; Drug<br>Interaction; Irritability;<br>Libido Decreased;<br>Localised Infection;<br>Obesity; Skin Infection;<br>Weight Increased | Lyrica<br>Lyrica<br>Cipralext<br>Cipralext |                    |                    | S<br>S<br>S<br>S | Oral<br>Oral<br>Oral<br>Oral | 75 Mg, 2x/Day<br>Unk<br>10 Mg, Daily<br>20 Mg, 1x/Day |                 | Pfizer<br>Pfizer<br>Not Reported<br>Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 09-Jul-2014              | 10288854       | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000068695    |                      | 87 YR           | Female     | FRA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

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

|                           |                      |   |      |                                    |              |
|---------------------------|----------------------|---|------|------------------------------------|--------------|
| Ventricular Extrasystoles | Escitalopram         | S | Oral | 15 Mg                              | Forest       |
|                           | Xeroquel             | S | Oral | 50 Mg                              | Not Reported |
|                           | Risperdal            | S | Oral | 1 Mg                               | Not Reported |
|                           | Calcidose Vitamine D | C | Oral | 2 Df                               | Not Reported |
|                           | Seresta              | C | Oral | On Request, 30 Mg Daily<br>Maximum | Not Reported |
|                           | Stilnox              | C | Oral | 10 Mg                              | Not Reported |
|                           | Talc De Venise       | C |      | One Application Of 120 G<br>Daily  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Jul-2014              | 10288923      | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000068667    |                      | < 1 DAY    | Male       | USA            |

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

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Jul-2014              | 10301807      | EXPEDITED (15-DAY) | Y                  | LT              | 2014HINLIT0592       |                      | 65 YR      | Male       | BEL            |

| <u>Preferred Term</u>     | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Apnoea; Drug Interaction; | Escitalopram            |              |            | S           |              |                    |                 | Not Reported |
| Electrocardiogram Qt      | Sotalol (Sotalol)       |              |            | S           |              |                    |                 | Not Reported |
| Prolonged; Hypokalaemia;  | Tacrolimus (Tacrolimus) |              |            | S           |              |                    |                 | Not Reported |
| Loss Of Consciousness;    | Omeprazole (Omeprazole) |              |            | S           |              |                    |                 | Not Reported |
| Pallor; Torsade De        | Mgso4 (Mgso4)           |              |            | C           |              |                    |                 | Not Reported |
| Pointes; Vomiting         |                         |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Jul-2014              | 10302056      | DIRECT           |                    |                 |                      |                      | 56 YR      | Female     | USA            |

| <u>Preferred Term</u>                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Chills; Frequent Bowel<br>Movements; | Lexapro        |              |            | S           | Oral         |                    | 2 YR            | Not Reported |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Gastrointestinal Pain;  
Head Discomfort;  
Hyperhidrosis; Influenza;  
Nausea

| <u>FDA Received Date</u>            | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------|-------------------------|--------------------|--------------------|-----------------|------------------------------------------|----------------------|-----------------|--------------|----------------|
| 10-Jul-2014                         | 10132324                | EXPEDITED (15-DAY) |                    | OT              | IT-MYLANLABS-2014S1009117                |                      | 72 YR           | Female       | ITA            |
| <u>Preferred Term</u>               | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrial Conduction Time Prolongation | Escitalopram Oxalate    |                    |                    | S               | Oral                                     | 20 Mg Daily          |                 | Not Reported |                |
|                                     | Mirtazapine             |                    |                    | S               | Oral                                     | 30 Mg Daily          |                 | Not Reported |                |
|                                     | Alprazolam              |                    |                    | S               | Oral                                     | 20 Gtt Daily         |                 | Mylan        |                |
|                                     | Moduretic               |                    |                    | C               | Oral                                     |                      |                 | Not Reported |                |
|                                     | Bisoprolol Hemifumarate |                    |                    | C               | Oral                                     |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>            | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Jul-2014                         | 10215149                | EXPEDITED (15-DAY) |                    | DE              | CH-FRI-1000067825                        |                      |                 | Female       | CHE            |
| <u>Preferred Term</u>               | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cerebral Haematoma                  | Escitalopram            |                    |                    | S               | Oral                                     | 5 Mg                 |                 | Forest       |                |
|                                     | Aspirin Cardio          |                    |                    | S               | Oral                                     | 100 Mg               |                 | Not Reported |                |
|                                     | Catapresan              |                    |                    | C               | Oral                                     |                      |                 | Not Reported |                |
|                                     | Beloc [Metoprolol]      |                    |                    | C               | Oral                                     | 50 Mg                |                 | Not Reported |                |
|                                     | Triatec (Ramipril)      |                    |                    | C               | Oral                                     | 5 Mg                 |                 | Not Reported |                |
|                                     | Adalat                  |                    |                    | C               | Oral                                     | 60 Mg                |                 | Not Reported |                |
|                                     | Acetaphos               |                    |                    | C               | Oral                                     | 2 Df                 |                 | Not Reported |                |
| <u>FDA Received Date</u>            | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Jul-2014                         | 10280300                | EXPEDITED (15-DAY) |                    | OT              | IT-ELI_LILLY_AND_COMP ANY-IT201406009192 |                      | 75 YR           | Unknown      | ITA            |
| <u>Preferred Term</u>               | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

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

|                                                           |                          |   |         |                |                  |
|-----------------------------------------------------------|--------------------------|---|---------|----------------|------------------|
| Extrasystoles; Sopor;<br>Syncope; Urinary<br>Incontinence | Cymbalta                 | S | Oral    | 60 Mg, Qd      | Eli Lilly And Co |
|                                                           | Entact                   | S | Unknown | 10 Mg, Unknown | Not Reported     |
|                                                           | Lacirex                  | C | Unknown | Unk, Unknown   | Not Reported     |
|                                                           | Provisacor               | C | Unknown | Unk, Unknown   | Not Reported     |
|                                                           | Indapamide W/Perindopril | C | Unknown | Unk, Unknown   | Not Reported     |
|                                                           | Pantorc                  | C | Unknown | Unk, Unknown   | Not Reported     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>        | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------------|----------------------|------------|------------|----------------|
| 10-Jul-2014              | 10295636      | EXPEDITED (15-DAY) |                    | OT              | US-TAKEDA-<br>2014TUS005708 |                      | 64 YR      | Female     | USA            |

| <u>Preferred Term</u>  | <u>Product</u>                                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------|------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Chronic Kidney Disease | Prevacid                                       |              |            | S           | Oral         | 15 Mg, Bid         |                 | Takeda       |
|                        | Advair                                         |              |            | S           | Other        | 1 Puff             |                 | Not Reported |
|                        | Ventolin Hfa                                   |              |            | S           | Other        | 2 Puff As Required |                 | Not Reported |
|                        | Ventolin Hfa                                   |              |            | S           | Other        | 2 Puff As Required |                 | Not Reported |
|                        | Bupropion Hydrochloride                        |              |            | S           | Oral         | 300 Mg, Qd         |                 | Not Reported |
|                        | Escitalopram Oxalate                           |              |            | S           | Oral         | 20 Mg, Qd          |                 | Not Reported |
|                        | Hydroxyzine Hydrochloride                      |              |            | S           | Oral         | 50 Mg, As Required |                 | Not Reported |
|                        | Esterified Estrogens And<br>Methyltestosterone |              |            | C           |              | Unk                |                 | Not Reported |
|                        | Lisinopril                                     |              |            | C           |              | Unk                |                 | Not Reported |
|                        | Trazodone /00447702/                           |              |            | C           |              | Unk                |                 | Not Reported |
|                        | Fluzone /01389801/                             |              |            | C           |              | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 11-Jul-2014              | 10297559      | EXPEDITED (15-DAY) |                    | HO              | AT-JNJFOC-<br>20140700171 |                      | 51 YR      | Male       | AUT            |

| <u>Preferred Term</u>                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Dysarthria; Dyskinesia;<br>Tongue Disorder | Risperdal      |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                            | Risperdal      |              |            | S           | Unknown      |                    |                 | Not Reported |

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

|           |   |         |        |              |
|-----------|---|---------|--------|--------------|
| Risperdal | S | Unknown |        | Not Reported |
| Risperdal | S | Unknown |        | Not Reported |
| Risperdal | S | Unknown | 2-3 Mg | Not Reported |
| Cipralex  | S | Unknown |        | Not Reported |
| Cipralex  | S | Unknown |        | Not Reported |
| Trittico  | S | Unknown |        | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Jul-2014              | 10297695      | EXPEDITED (15-DAY) |                    | HO, OT          | FR-FRI-1000068834    |                      | 72 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                 | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------|---------------------|--------------|------------|-------------|--------------|------------------------|-----------------|--------------|
| Dizziness; Drug Withdrawal Syndrome; Hyperhidrosis; Malaise; Overdose | Escitalopram        |              |            | S           | Oral         | Overdose: 40 Mg Daily. |                 | Forest       |
|                                                                       | Escitalopram        |              |            | S           | Oral         | 10 Mg                  |                 | Not Reported |
|                                                                       | Escitalopram        |              |            | S           | Oral         | 40 Mg                  |                 | Not Reported |
|                                                                       | Stilnox             |              |            | S           | Oral         | 40 Mg                  |                 | Not Reported |
|                                                                       | Stilnox             |              |            | S           | Oral         | 40 Mg                  |                 | Not Reported |
|                                                                       | Lysanxia            |              |            | S           | Oral         | 1 Mg                   |                 | Not Reported |
|                                                                       | Lysanxia            |              |            | S           | Oral         | 1 Mg                   |                 | Not Reported |
|                                                                       | Temesta (Lorazepam) |              |            | S           | Oral         |                        |                 | Not Reported |
|                                                                       | Temesta (Lorazepam) |              |            | S           | Oral         | 3.75 Mg                |                 | Not Reported |
|                                                                       | Temesta (Lorazepam) |              |            | S           | Oral         | 7.5 Mg                 |                 | Not Reported |
|                                                                       | Tahor               |              |            | C           |              | 40 Mg                  |                 | Not Reported |
|                                                                       | Levothyrox          |              |            | C           |              |                        |                 | Not Reported |
|                                                                       | Esomeprazole        |              |            | C           |              | 20 Mg                  |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------|----------------------|------------|------------|----------------|
| 11-Jul-2014              | 10298007      | EXPEDITED (15-DAY) |                    | OT              | DE-RANBAXY-2012R1-56327 |                      |            | Female     | DEU            |

| <u>Preferred Term</u> | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Congenital Anomaly In | Mycophenolate Mofetil |              |            | S           | Unknown      | 0.5 G, Daily       |                 | Not Reported |

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

|                     |              |   |         |     |              |
|---------------------|--------------|---|---------|-----|--------------|
| Offspring; Exposure | Escitalopram | S | Unknown | Unk | Not Reported |
| During Pregnancy;   | Lorazepam    | S | Unknown | Unk | Ranbaxy      |
| Premature Delivery  | Zolpidem     | S | Unknown | Unk | Ranbaxy      |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------|----------------------|------------|------------|----------------|
| 11-Jul-2014              | 10298119      | EXPEDITED (15-DAY) | CA                 |                 | DE-RANBAXY-2012R1-56326 |                      |            | Female     | DEU            |

| <u>Preferred Term</u>                                                                   | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------|-----------------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Foetal Exposure During Pregnancy; Oesophageal Atresia; Premature Baby; Tracheal Atresia | Mycophenolate Mofetil |              |            | S           | Transplacental | 0.5 G, Daily       |                 | Not Reported |
|                                                                                         | Escitalopram          |              |            | S           | Transplacental | Unk                |                 | Not Reported |
|                                                                                         | Lorazepam             |              |            | S           | Transplacental | Unk                |                 | Ranbaxy      |
|                                                                                         | Zolpidem              |              |            | S           | Transplacental | Unk                |                 | Ranbaxy      |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Jul-2014              | 10298447      | EXPEDITED (15-DAY) | CA, OT             |                 | US-FRI-1000068907    |                      | < 1 DAY    | Male       | USA            |

| <u>Preferred Term</u>                              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|----------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|------------|
| Atrial Septal Defect; Right Ventricular Dilatation | Lexapro        |              |            | S           | Transplacental |                    |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 14-Jul-2014              | 10302740      | EXPEDITED (15-DAY) | OT                 |                 | US-ABBVIE-13P-163-1108063-00 |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                                                                                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Arthralgia; Hallucination, Auditory; Hallucination, Visual; Hypoaesthesia; Nerve Injury; Pain In Extremity; Paraesthesia | Synthroid      |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                   | Protonix       |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                   | Lyrica         |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                   | Lipitor        |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                   | Detrol         |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                   | Remeron        |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                   | Abilify        |              |            | S           |              |                    |                 | Not Reported |

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

|  |           |   |  |  |  |  |  |  |              |
|--|-----------|---|--|--|--|--|--|--|--------------|
|  | Aldactone | S |  |  |  |  |  |  | Not Reported |
|  | Cymbalta  | S |  |  |  |  |  |  | Not Reported |
|  | Lexapro   | S |  |  |  |  |  |  | Not Reported |
|  | Zoloft    | S |  |  |  |  |  |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Jul-2014              | 10211748      | EXPEDITED (15-DAY) |                    | HO, OT          | 2014IE004283         |                      | 67 YR      | Male       | IRL            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | <u>Product</u>                            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|--------------|------------|-------------|--------------|--------------------------------|-----------------|--------------|
| Abscess; Allergy To Arthropod Sting; Alopecia; Anaphylactic Reaction; Breast Mass; Breast Tenderness; Chills; Contusion; Depression; Disturbance In Attention; Drug Interaction; Dry Mouth; Fatigue; Feeling Drunk; Furuncle; Gait Disturbance; Gynaecomastia; Headache; Hordeolum; Hordeolum; Hyperhidrosis; Hypotonia; Hypotonia; Insomnia; Onychoclasia; Peripheral Swelling; Pruritus; Rash; Sinus Disorder; Skin Disorder; Stress; Urinary Tract Infection; Urinary Tract Infection; Weight Increased | Eligard                                   |              |            | S           | Other        | 45 Mg, Once In 6 Months, Other |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Lexapro (Escitalopram Oxalate)            |              |            | S           | Oral         |                                |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Solpadol (Codeine Phosphate, Paracetamol) |              |            | C           |              |                                |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Ibuprofen                                 |              |            | C           |              |                                |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Elantan (Isosorbide Mononitrate)          |              |            | C           |              |                                |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Caprin (Acetylsalicylic Acid)             |              |            | C           |              |                                |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Boronex (Buspirone Hydrochloride)         |              |            | C           |              |                                |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Stilnoct (Zolpidem Tartrate)              |              |            | C           |              |                                |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Tamsulosin Hydrochloride                  |              |            | C           |              |                                |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | (Tamsulosin Hydrochloride)                |              |            |             |              |                                |                 |              |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Xenical (Orlistat)                        |              |            | C           |              |                                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 15-Jul-2014              | 10306323      | EXPEDITED (15-DAY) |                    | LT, OT          | BE-ACTAVIS-2014-15141 |                      | 65 YR      | Male       | BEL            |

| <u>Preferred Term</u>     | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction; Long Qt | Escitalopram (Unknown) |              |            | S           | Unknown      | Unk                |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                        |                      |   |         |     |        |
|----------------------------------------|----------------------|---|---------|-----|--------|
| Syndrome; Torsade De Pointes; Vomiting | Tacrolimus (Unknown) | S | Unknown | Unk | Watson |
|                                        | Omeprazole (Unknown) | S | Unknown | Unk | Watson |
|                                        | Sotalol (Unknown)    | S | Unknown | Unk | Watson |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Jul-2014              | 10306452      | EXPEDITED (15-DAY) |                    | HO              | US-FRI-1000068949    |                      | 78 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|------------------------|-----------------|--------------|
| Amnesia; Dementia; Depression; Encephalopathy; Gait Inability; Headache; Loss Of Personal Independence In Daily Activities; Pseudodementia; Toxicity To Various Agents; Vomiting | Lexapro        |              |            | S           |              |                        |                 | Forest       |
|                                                                                                                                                                                  | Humira         |              |            | S           |              | 40 Mg Every Other Week |                 | Not Reported |
|                                                                                                                                                                                  | Topamax        |              |            | S           |              |                        |                 | Not Reported |
|                                                                                                                                                                                  | Tramadol       |              |            | S           |              |                        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Jul-2014              | 10309920      | DIRECT           |                    | DS, HO, LT, OT  |                      |                      | 21 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|------------------------|-----------------|------------|
| Abdominal Pain; Agitation; Bipolar Disorder; Confusional State; Diarrhoea; Fear; Feeding Disorder; Hallucination; Heart Rate Increased; Heart Rate Irregular; Insomnia; Mania; Mental Impairment; Muscle Twitching; Schizophreniform Disorder; Seizure; Serotonin Syndrome; Vomiting; Withdrawal Syndrome | Lexapro        |              |            | S           | Oral         | 2 Pills Taken By Mouth | 5 DAY           | Forest     |

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

| <u>FDA Received Date</u>                                                                                                                                         | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|------------------------------|-----------------------------------------|-----------------|--------------|----------------|
| 15-Jul-2014                                                                                                                                                      | 10309945                  | DIRECT             |                    |                 |                              |                                         | 51 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                            | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                      | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Alcohol Use;<br>Blood Alcohol Increased;<br>Hostility; Imprisonment;<br>Loss Of Consciousness;<br>Memory Impairment; Road<br>Traffic Accident; Stress | Escitalopram 20mg Lexapro |                    |                    | S               | Oral                         | One Tablet At Bedtime<br>Taken By Mouth |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                         | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Jul-2014                                                                                                                                                      | 9798206                   | EXPEDITED (15-DAY) |                    | HO, OT          | FR-PFIZER INC-<br>2013374314 |                                         | 50 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                                            | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                      | <u>Duration</u> | <u>Mfr</u>   |                |
| Erythema Multiforme;<br>Stevens-Johnson<br>Syndrome; Toxic Skin<br>Eruption                                                                                      | Lyrica                    |                    |                    | S               | Oral                         | Unk                                     |                 | Pfizer       |                |
|                                                                                                                                                                  | Primperan                 |                    |                    | S               |                              | Unk                                     |                 | Not Reported |                |
|                                                                                                                                                                  | Seroplex                  |                    |                    | S               | Oral                         | Unk                                     |                 | Not Reported |                |
|                                                                                                                                                                  | Esomeprazole Sodium       |                    |                    | S               | Oral                         | 40 Mg, 1x/Day                           |                 | Not Reported |                |
|                                                                                                                                                                  | Oxynorm                   |                    |                    | S               |                              | 10 Mg Every 6 Hours (40<br>Mg Daily)    |                 | Not Reported |                |
|                                                                                                                                                                  | Crestor                   |                    |                    | C               | Oral                         | 20 Mg, 1x/Day                           |                 | Not Reported |                |
|                                                                                                                                                                  | Solumedrol                |                    |                    | C               |                              | Unk                                     |                 | Not Reported |                |
|                                                                                                                                                                  | Kardegic                  |                    |                    | C               |                              | 75 Mg                                   |                 | Not Reported |                |
|                                                                                                                                                                  | Plavix                    |                    |                    | C               |                              | 75 Mg                                   |                 | Not Reported |                |
|                                                                                                                                                                  | Lovenox                   |                    |                    | C               |                              | 4000 Iu Anti-Xa/0.4 MI                  |                 | Not Reported |                |
|                                                                                                                                                                  | Metoprolol Fumarate       |                    |                    | C               |                              | Unk                                     |                 | Not Reported |                |
|                                                                                                                                                                  | Insulin                   |                    |                    | C               |                              | Unk                                     |                 | Not Reported |                |
|                                                                                                                                                                  | Hexaspray                 |                    |                    | C               |                              | Unk                                     |                 | Not Reported |                |
|                                                                                                                                                                  | Hydroxyzine Hydrochloride |                    |                    | C               |                              | Unk                                     |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                    | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------|-----------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| 16-Jul-2014                                 | 10261722              | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000068489            |                      | 76 YR           | Male         | FRA            |
| <u>Preferred Term</u>                       | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Simple Partial Seizures                     | Escitalopram          |                    |                    | S               | Oral                         | 1 Df                 |                 | Forest       |                |
| <u>FDA Received Date</u>                    | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Jul-2014                                 | 10308086              | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000068832            |                      | 78 YR           | Female       | FRA            |
| <u>Preferred Term</u>                       | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated;<br>Subdural Haematoma | Escitalopram          |                    |                    | S               | Oral                         | 5 Mg                 |                 | Forest       |                |
|                                             | Pradaxa               |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                             | Coaprovel 300 / 25 Mg |                    |                    | C               |                              |                      |                 | Not Reported |                |
|                                             | Ezetrol               |                    |                    | C               |                              |                      |                 | Not Reported |                |
|                                             | Eucreas 50 / 1000 Mg  |                    |                    | C               |                              |                      |                 | Not Reported |                |
|                                             | Isoptine              |                    |                    | C               |                              |                      |                 | Not Reported |                |
|                                             | Lyrice                |                    |                    | C               |                              |                      |                 | Not Reported |                |
|                                             | Cystine B6 Bailleul   |                    |                    | C               |                              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                    | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Jul-2014                                 | 10308182              | EXPEDITED (15-DAY) |                    | OT              | BE-FRI-1000068987            |                      | 65 YR           | Male         | BEL            |
| <u>Preferred Term</u>                       | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Long Qt Syndrome                            | Escitalopram          |                    |                    | S               |                              |                      |                 | Forest       |                |
|                                             | Sotalol               |                    |                    | S               |                              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                    | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Jul-2014                                 | 10308382              | EXPEDITED (15-DAY) |                    | DE, HO          | FR-PFIZER INC-<br>2014192203 |                      | 88 YR           | Female       | FRA            |
| <u>Preferred Term</u>                       | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;<br>Haematoma              | Tahor                 |                    |                    | S               | Oral                         | 20 Mg, Daily         |                 | Pfizer       |                |
|                                             | Seroplex              |                    |                    | S               | Oral                         | 5 Mg, Daily          |                 | Not Reported |                |



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

|                                                                                                                     |   |      |                                           |              |
|---------------------------------------------------------------------------------------------------------------------|---|------|-------------------------------------------|--------------|
| Kardegic                                                                                                            | S | Oral | 75 Mg, Daily                              | Not Reported |
| Previscan (Fluindione)                                                                                              | S | Oral | 0.75 Df On Even Days, 0.5 Df On Odd Days  | Not Reported |
| Previscan (Fluindione)                                                                                              | S | Oral | 0.75 Df On Even Days, 0.25 Df On Odd Days | Not Reported |
| Furosemide                                                                                                          | C | Oral | 40 Mg, Daily                              | Not Reported |
| Detensiel                                                                                                           | C | Oral | 10 Mg, Daily                              | Not Reported |
| Amlodipine                                                                                                          | C | Oral | 1 Df, Daily                               | Not Reported |
| Ramipril                                                                                                            | C | Oral | 5 Mg, Daily                               | Not Reported |
| Esomeprazole                                                                                                        | C | Oral | Unk                                       | Not Reported |
| Transipeg (Polyethylene Glycol 3350\Potassium Chloride\Sodium Bicarbonate\Sodium Chloride\Sodium Sulfate Anhydrous) | C | Oral | 5.9 G, Daily                              | Not Reported |
| Doliprane                                                                                                           | C | Oral | 1000 Mg Tablet                            | Not Reported |

| <u>FDA Received Date</u>            | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|-------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------------------|-----------------|------------|----------------|
| 16-Jul-2014                         | 10312661       | DIRECT           |                    |                 |                      |                                  | 20 YR           | Male       | USA            |
| <u>Preferred Term</u>               | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u> |                |
| Anxiety; Product Substitution Issue | Escitalopram   |                  |                    | S               | Oral                 | 1 Pill Once Daily Taken By Mouth |                 | Torrent    |                |

| <u>FDA Received Date</u>                                                                                  | <u>Case #</u>                                                                                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 16-Jul-2014                                                                                               | 10313409                                                                                     | EXPEDITED (15-DAY) |                    | OT              | SYM-2014-23210       |                      | 56 YR           | Male         | CAN            |
| <u>Preferred Term</u>                                                                                     | <u>Product</u>                                                                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Constipation; Depression; Dizziness; Dry Mouth; Erection Increased; Fatigue; Increased Appetite; Muscular | Wellbutrin XI (Bupropion Hydrochloride) (Prolonged-Release Tablet) (Bupropion Hydrochloride) |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                           | Clonazepam                                                                                   |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |

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

|                                                                                              |                                                                                                  |   |      |              |
|----------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------|---|------|--------------|
| Weakness; Nausea;<br>Somnolence; Suicidal<br>Ideation; Tinnitus; Tremor;<br>Weight Increased | Escitalopram Oxalate<br>(Escitalopram Oxalate)                                                   | S | Oral | Not Reported |
|                                                                                              | Quetiapine Fumarate<br>(Quetiapine Fumarate)                                                     | S | Oral | Not Reported |
|                                                                                              | Echinacea Purpurea(Eschinacea<br>Purpurea)                                                       | C |      | Not Reported |
|                                                                                              | Horse Chestnut Extract<br>(Aesculus Hippocastanum<br>Extract)(Aesculus<br>Hippocastanum Extract) | C |      | Not Reported |
|                                                                                              | Milk Thistle                                                                                     | C |      | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Jul-2014              | 10152983      | EXPEDITED (15-DAY) |                    | HO, OT          | PHHY2014FR052784     |                      | 63 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                             | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|------------------------------------------|--------------------|-----------------|--------------|
| Accommodation Disorder;<br>Anxiety; Blood Pressure<br>Increased; Confusional<br>State; Drug Dependence;<br>Drug Ineffective;<br>Dyspepsia; Hallucination;<br>Headache; Insomnia;<br>Pain; Sleep Attacks;<br>Somnolence; Vomiting;<br>Withdrawal Syndrome | Baclofen       |              |            | S           |                                          | 270 Mg, Per Day    |                 | Not Reported |
|                                                                                                                                                                                                                                                          | Baclofen       |              |            | S           |                                          | 10 Mg, Unk         |                 | Not Reported |
|                                                                                                                                                                                                                                                          | Baclofen       |              |            | S           |                                          | 30 Mg, Per Day     |                 | Not Reported |
|                                                                                                                                                                                                                                                          | Oxazepam       |              |            | S           |                                          | 12.5 Mg, Per Day   |                 | Novartis     |
|                                                                                                                                                                                                                                                          | Oxazepam       |              |            | S           |                                          | 62.5 Mg, Per Day   |                 | Novartis     |
|                                                                                                                                                                                                                                                          | Escitalopram   |              |            | S           |                                          | 10 Mg, Per Day     |                 | Not Reported |
|                                                                                                                                                                                                                                                          | Zopiclone      |              |            | C           |                                          | 7.5 Mg, Per Day    |                 | Not Reported |
|                                                                                                                                                                                                                                                          | Nicardipine    |              |            | C           | Intravenous (not<br>otherwise specified) |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Jul-2014              | 10310662      | EXPEDITED (15-DAY) |                    | HO              | IT-FRI-1000068990    |                      | 19 YR      | Female     | ITA            |

| <u>Preferred Term</u>                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Drug Abuse; Overdose;<br>Slow Speech; Sopor | Escitalopram   |              |            | S           | Oral         |                    |                 | Forest     |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Jul-2014              | 10311384      | EXPEDITED (15-DAY) |                    | CA              | DE-FRI-1000069051    |                      |            | Female     | DEU            |

| <u>Preferred Term</u>                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u>                                                                       | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------|----------------|--------------|------------|-------------|----------------|------------------------------------------------------------------------------------------|-----------------|--------------|
| Foetal Exposure During Pregnancy; Talipes | Escitalopram   |              |            | S           | Transplacental | 20 Mg                                                                                    |                 | Forest       |
|                                           | Escitalopram   |              |            | S           | Transplacental | 10 Mg                                                                                    |                 | Not Reported |
|                                           | Thyronajod     |              |            | C           | Transplacental | 0.05 Mg Levothyroxine / 0.15 Mg/Day Potassium Iodide Per Day Taken From Monday To Friday |                 | Not Reported |
|                                           | Mirtazapin     |              |            | C           | Transplacental | 15 Mg/Day As Needed                                                                      |                 | Not Reported |
|                                           | Mirtazapin     |              |            | C           | Transplacental | 15 Mg                                                                                    |                 | Not Reported |
|                                           | Folio Jodfrei  |              |            | C           | Transplacental | 0.4 Mg                                                                                   |                 | Not Reported |
|                                           |                |              |            |             |                |                                                                                          |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 17-Jul-2014              | 10311558      | EXPEDITED (15-DAY) |                    | OT              | CA-GLAXOSMITHKLINE-A1081440A |                      | 56 YR      | Male       | CAN            |

| <u>Preferred Term</u>                                                                                                                                                                         | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Constipation; Depression; Dizziness; Dry Mouth; Erection Increased; Fatigue; Increased Appetite; Muscular Weakness; Nausea; Somnolence; Suicidal Ideation; Tinnitus; Tremor; Weight Increased | Wellbutrin XI               |              |            | S           | Oral         | 300mg Per Day      |                 | Glaxosmithkline |
|                                                                                                                                                                                               | Clonazepam                  |              |            | S           | Oral         | 1mg Per Day        |                 | Glaxosmithkline |
|                                                                                                                                                                                               | Escitalopram Oxalate        |              |            | S           | Oral         | 10mg Per Day       |                 | Glaxosmithkline |
|                                                                                                                                                                                               | Quetiapine Fumarate         |              |            | S           | Oral         | 200mg Per Day      |                 | Glaxosmithkline |
|                                                                                                                                                                                               | Echinacea Purpurea          |              |            | C           |              |                    |                 | Not Reported    |
|                                                                                                                                                                                               | Horse Chestnut Seed Extract |              |            | C           |              |                    |                 | Not Reported    |
|                                                                                                                                                                                               | Milk Thistle                |              |            | C           |              |                    |                 | Not Reported    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 17-Jul-2014              | 10311862      | EXPEDITED (15-DAY) |                    | HO              | FR-MYLANLABS-2014S1016022 |                      | 94 YR      | Male       | FRA            |

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

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

|                                                          |                    |   |      |              |
|----------------------------------------------------------|--------------------|---|------|--------------|
| Confusional State;<br>Delirium; Hallucination,<br>Visual | Risperidone        | S | Oral | Not Reported |
|                                                          | Seroplex           | S | Oral | Not Reported |
|                                                          | Dihydan            | C |      | Not Reported |
|                                                          | Alepsal /01606601/ | C |      | Not Reported |
|                                                          | Xarelto            | C |      | Not Reported |
|                                                          | Lasilix            | C |      | Not Reported |

| <u>FDA Received Date</u>                                             | <u>Case #</u>           | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|----------------------------------------------------------------------|-------------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 17-Jul-2014                                                          | 10312770                | DIRECT           |                    | OT              |                      |                      | 28 YR           | Female     | USA            |
| <u>Preferred Term</u>                                                | <u>Product</u>          | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Amnesia; Cognitive Disorder; Feeling Abnormal; Impaired Work Ability | Lexapro Or Escitalopram |                  |                    | S               | Oral                 | 1 Pill; Once Daily   |                 | Camber     |                |

| <u>FDA Received Date</u>                                                                                   | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------|--------------------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 18-Jul-2014                                                                                                | 6962634                              | EXPEDITED (15-DAY) |                    | HO              | US-PFIZER INC-2009187922 |                      | 48 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                      | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated; Dysarthria; Hypertension; Hypokalaemia; Mental Status Changes; Multiple Drug Therapy | Desvenlafaxine Succinate Monohydrate |                    |                    | S               | Oral                     | 50 Mg, 1x/Day        |                 | Pfizer       |                |
|                                                                                                            | Desvenlafaxine Succinate Monohydrate |                    |                    | S               | Oral                     | 100 Mg, 1x/Day       |                 | Pfizer       |                |
|                                                                                                            | Lyrica                               |                    |                    | S               | Oral                     | 75 Mg, 1x/Day        |                 | Pfizer       |                |
|                                                                                                            | Lyrica                               |                    |                    | S               |                          |                      |                 | Pfizer       |                |
|                                                                                                            | Lyrica                               |                    |                    | S               |                          |                      |                 | Pfizer       |                |
|                                                                                                            | Ibuprofen                            |                    |                    | S               | Oral                     | 800 Mg, 3x/Day       |                 | Pfizer       |                |
|                                                                                                            | Loratadine                           |                    |                    | S               | Oral                     | 10 Mg, 1x/Day        |                 | Pfizer       |                |
|                                                                                                            | Robaxin                              |                    |                    | S               | Oral                     | 750 Mg, 3x/Day       |                 | Pfizer       |                |
|                                                                                                            | Robaxin                              |                    |                    | S               |                          | Unknown              |                 | Pfizer       |                |
|                                                                                                            | Robaxin                              |                    |                    | S               |                          |                      |                 | Pfizer       |                |
|                                                                                                            | Clonazepam                           |                    |                    | S               | Oral                     | 1 Mg, 2x/Day         |                 | Not Reported |                |
|                                                                                                            | Clonazepam                           |                    |                    | S               |                          |                      |                 | Not Reported |                |

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

|  |             |   |             |                          |              |
|--|-------------|---|-------------|--------------------------|--------------|
|  | Lexapro     | S | Oral        | 20 Mg, 1x/Day            | Not Reported |
|  | Lexapro     | S |             |                          | Not Reported |
|  | Abilify     | S | Oral        | 15 Mg, 2x/Day            | Not Reported |
|  | Abilify     | S |             |                          | Not Reported |
|  | Abilify     | S |             |                          | Not Reported |
|  | Fluticasone | S |             | 2 Sprays Daily Route: In | Not Reported |
|  | Vicodin     | S | Oral        | 5/500 Prn                | Not Reported |
|  | Zestoretic  | S | Oral        | 20/12.5 Daily            | Not Reported |
|  | Ambien      | S | Oral        | 10 Mg, 1x/Day            | Not Reported |
|  | Vivelle     | S | Transdermal | 0.1 Mg, Unk              | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 18-Jul-2014              | 10313042       | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2014201663 |                      | 34 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity    | Effexor        |                  |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                          | Lexapro        |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                          | Prozac         |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                          | Dilaudid       |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                          | Zofran         |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                          | Carafate       |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |

| <u>FDA Received Date</u>              | <u>Case #</u>                         | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------|---------------------------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 18-Jul-2014                           | 10329320                              | DIRECT           | Y                  |                 |                      |                      | 17 YR           | Male         | USA            |
| <u>Preferred Term</u>                 | <u>Product</u>                        | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective;<br>Economic Problem | Escitalopram 10mg Aurobiudo<br>Pharma |                  |                    | S               | Oral                 |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Jul-2014              | 10330663      | DIRECT           |                    | OT              |                      |                      | 40 YR      | Male       | USA            |

# FDA Adverse Event Reporting System

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### Detailed Report

| <u>Preferred Term</u>                                                                                                                       | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------------------------------------------------------------------------------------------------|-----------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| Drug Ineffective; Product Substitution Issue                                                                                                | Generic Lexapro |                    |                    | S               |                       |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                    | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Jul-2014                                                                                                                                 | 9166696         | EXPEDITED (15-DAY) |                    | CA, OT          | US-FRI-1000043320     |                      | < 1 DAY         | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                       | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrial Septal Defect; Congenital Aortic Dilatation; Heart Disease Congenital; Transposition Of The Great Vessels; Ventricular Septal Defect | Lexapro         |                    |                    | S               | Transplacental        |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                                    | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Jul-2014                                                                                                                                 | 10133555        | EXPEDITED (15-DAY) |                    | LT              | IT-SA-2014SA050408    |                      | 45 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                                                                                       | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Abuse; Loss Of Consciousness; Respiratory Arrest                                                                                       | Lasix           |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                                                             | Entact          |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                    | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Jul-2014                                                                                                                                 | 10308135        | EXPEDITED (15-DAY) |                    | OT              | FR-JNJFOC-20140706670 |                      | 22 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                                                       | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Intentional Overdose; Seizure                                                                                             | Ixprim          |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                                                             | Seroplex        |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                                                             | Baclofen        |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                    | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Jul-2014                                                                                                                                 | 10329471        | EXPEDITED (15-DAY) |                    | OT              | CA-FRI-1000068988     |                      | 50 YR           | Female       | CAN            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                      | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|----------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Contusion; Fall;<br>Headache; Muscle<br>Haemorrhage                        | Escitalopram             |                    |                    | S               |                      | 10 Mg                |                 | Forest       |                |
|                                                                            | Citalopram               |                    |                    | S               |                      | 20 Mg                |                 | Forest       |                |
|                                                                            | Clomipramine             |                    |                    | S               |                      | 50 Mg                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Jul-2014                                                                | 10329569                 | EXPEDITED (15-DAY) |                    | OT              | AU-FRI-1000068993    |                      | 74 YR           | Female       | AUS            |
| <u>Preferred Term</u>                                                      | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aphasia; Confusional<br>State; Hemiparesis;<br>Syncope                     | Escitalopram             |                    |                    | S               |                      |                      |                 | Forest       |                |
|                                                                            | Atorvastatin             |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                            | Carvedilol Hydrochloride |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                            | Digoxin                  |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                            | Irbesartan               |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                            | Pantoprazole             |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                            | Sitagliptin-Metformin    |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                            | Solifenacin Succinate    |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                            | Strontium Ranelate       |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                            | Warfarin Sodium          |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Jul-2014                                                                | 10334261                 | EXPEDITED (15-DAY) | Y                  | OT              | US-ZYDUS-004131      |                      | 45 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                      | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Reversible Cerebral<br>Vasoconstriction<br>Syndrome; Serotonin<br>Syndrome | Escitalopram             |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Jul-2014                                                                | 10334525                 | EXPEDITED (15-DAY) | Y                  | OT              | 2014AP003615         |                      | 45 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                      | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Reversible Cerebral                                                        | Escitalopram Oxalate     |                    |                    | S               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Vasoconstriction (Escitalopram) Tablet  
 Syndrome; Subarachnoid  
 Haemorrhage

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Jul-2014              | 10338884      | EXPEDITED (15-DAY) | Y                  | OT              | 2014JUB00050         |                      | 34 YR      | Female     | ITA            |

| <u>Preferred Term</u>                                                                                                                                                                        | <u>Product</u>                         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abnormal Behaviour;<br>Delusion; Euphoric Mood;<br>Insomnia; Logorrhoea;<br>Mania; Psychomotor<br>Hyperactivity; Refusal Of<br>Treatment By Patient;<br>Restlessness; Withdrawal<br>Syndrome | Escitalopram (Escitalopram)<br>Unknown |              |            | S           | Oral         |                    | 244 DAY         | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Jul-2014              | 10089343      | EXPEDITED (15-DAY) | Y                  | DS              | AUR-APL-2014-04601   |                      | 37 YR      | Male       | AUS            |

| <u>Preferred Term</u>                                                                                                       | <u>Product</u>                                                                                             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Agitation; Disturbance In<br>Attention; Paraesthesia;<br>Product Use In<br>Unapproved Indication;<br>Sleep Disorder; Tremor | Auro-Quetiapine (Quetiapine)<br>Film-Coated Tablet, 25mg<br>Escitalopram Oxalate<br>Esomeprazole Magnesium |              |            | S           | Oral         | 1 D                |                 | Not Reported |
|                                                                                                                             |                                                                                                            |              |            | S           | Oral         | 1 D                |                 | Not Reported |
|                                                                                                                             |                                                                                                            |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Jul-2014              | 10288441      | EXPEDITED (15-DAY) |                    | DE              | FR-FRI-1000068769    |                      | 88 YR      | Female     | FRA            |

| <u>Preferred Term</u>                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anaemia; Melaena; Rectal<br>Haemorrhage | Escitalopram   |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                         | Xarelto        |              |            | S           | Oral         | 15 Mg              |                 | Not Reported |
|                                         | Lasilix        |              |            | C           | Oral         | 1 Df               |                 | Not Reported |
|                                         | Aldactone      |              |            | C           | Oral         | 1 Df On Even Days  |                 | Not Reported |



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

Bisoprolol

C

1 Df

Not Reported

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 22-Jul-2014              | 10330963      | EXPEDITED (15-DAY) |                    | HO, OT          | CA-JNJFOC-20140709019 |                      | 31 YR      | Female     | CAN            |

| <u>Preferred Term</u>                      | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                          | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------|-----------------------|--------------|------------|-------------|---------------------------------------|--------------------|-----------------|--------------|
| Bradycardia; Neutropenia; Pleural Effusion | Tylenol               |              |            | S           | Unknown                               |                    |                 | Not Reported |
|                                            | Avastin               |              |            | S           | Intravenous (not otherwise specified) |                    |                 | Not Reported |
|                                            | Carboplatin           |              |            | S           | Intravenous (not otherwise specified) |                    |                 | Not Reported |
|                                            | Carboplatin           |              |            | S           | Intravenous (not otherwise specified) |                    |                 | Not Reported |
|                                            | Cipralex              |              |            | S           | Unknown                               |                    |                 | Not Reported |
|                                            | Ciprofloxacin         |              |            | S           | Oral                                  |                    |                 | Not Reported |
|                                            | Docetaxel             |              |            | S           | Intravenous (not otherwise specified) |                    |                 | Not Reported |
|                                            | Docetaxel             |              |            | S           | Intravenous (not otherwise specified) |                    |                 | Not Reported |
|                                            | Herceptin             |              |            | S           | Intravenous (not otherwise specified) |                    |                 | Not Reported |
|                                            | Herceptin             |              |            | S           | Intravenous (not otherwise specified) |                    |                 | Not Reported |
|                                            | Morphine              |              |            | S           | Unknown                               |                    |                 | Not Reported |
|                                            | Codeine               |              |            | C           | Unknown                               |                    |                 | Not Reported |
|                                            | Docusate              |              |            | C           | Unknown                               |                    |                 | Not Reported |
|                                            | Gravol                |              |            | C           | Unknown                               |                    |                 | Not Reported |
|                                            | Unspecified Mouthwash |              |            | C           | Unknown                               |                    |                 | Not Reported |
|                                            | Senna                 |              |            | C           | Unknown                               |                    |                 | Not Reported |
|                                            | Trazodone             |              |            | C           | Unknown                               |                    |                 | Not Reported |
|                                            | Lactulose             |              |            | C           | Unknown                               |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                     | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------|-----------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 22-Jul-2014                                  | 10331577                          | EXPEDITED (15-DAY) |                    | OT              | JP-FRI-1000067650    |                      | 67 YR           | Male         | JPN            |
| <u>Preferred Term</u>                        | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrioventricular Block Complete; Bradycardia | Lexapro                           |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                              | Meilax                            |                    |                    | C               | Oral                 | 1 Mg                 |                 | Not Reported |                |
|                                              | Amlodipine                        |                    |                    | C               | Oral                 | 5 Mg                 |                 | Not Reported |                |
|                                              | Coversyl                          |                    |                    | C               | Oral                 | 4 Mg                 |                 | Not Reported |                |
|                                              | Zyloric                           |                    |                    | C               | Oral                 | 100 Mg               |                 | Not Reported |                |
| <u>FDA Received Date</u>                     | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Jul-2014                                  | 10332091                          | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000069119    |                      | 82 YR           | Male         | FRA            |
| <u>Preferred Term</u>                        | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Haemorrhage                | Escitalopram                      |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                              | Pradaxa                           |                    |                    | S               | Oral                 | 2 Df                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                     | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Jul-2014                                  | 10332860                          | EXPEDITED (15-DAY) |                    | DE, HO, OT      | PHHY2014FR088206     |                      | 32 YR           | Male         | FRA            |
| <u>Preferred Term</u>                        | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiogenic Shock; Vasoplegia Syndrome       | Loxen (Nicardipine Hydrochloride) |                    |                    | S               | Oral                 | 800 Mg, Single       |                 | Not Reported |                |
|                                              | Loxen Lp                          |                    |                    | S               | Oral                 | 4000 Mg, Single      |                 | Not Reported |                |
|                                              | Verapamil                         |                    |                    | S               | Oral                 | 1200 Mg, Single      |                 | Novartis     |                |
|                                              | Thyrozol                          |                    |                    | S               | Oral                 | 400 Mg, Single       |                 | Not Reported |                |
|                                              | Seroplex                          |                    |                    | S               | Oral                 | 560 Mg, Single       |                 | Not Reported |                |
|                                              | Noctamide                         |                    |                    | S               | Oral                 | 12 Mg, Single        |                 | Not Reported |                |

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| <u>FDA Received Date</u>                      | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------|---------------------------------------|--------------------|--------------------|-----------------|---------------------------------------|---------------------------|-----------------|--------------|----------------|
| 22-Jul-2014                                   | 10333119                              | EXPEDITED (15-DAY) |                    | HO              | CA-ROCHE-1435428                      |                           | 31 YR           | Female       | CAN            |
| <u>Preferred Term</u>                         | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |                |
| Bradycardia; Neutropenia;<br>Pleural Effusion | Avastin                               |                    |                    | S               | Intravenous (not otherwise specified) | Therapy Duration: 18 Days |                 | Not Reported |                |
|                                               | Herceptin                             |                    |                    | S               | Intravenous (not otherwise specified) |                           |                 | Not Reported |                |
|                                               | Carboplatin                           |                    |                    | S               | Intravenous (not otherwise specified) |                           |                 | Not Reported |                |
|                                               | Cipralex                              |                    |                    | S               | Unknown                               |                           |                 | Not Reported |                |
|                                               | Ciprofloxacin                         |                    |                    | S               | Oral                                  | Therapy Duration: 2 Days  |                 | Not Reported |                |
|                                               | Ciprofloxacin                         |                    |                    | S               | Intravenous (not otherwise specified) |                           |                 | Not Reported |                |
|                                               | Docetaxel                             |                    |                    | S               | Intravenous (not otherwise specified) |                           |                 | Not Reported |                |
|                                               | Docetaxel                             |                    |                    | S               | Intravenous (not otherwise specified) |                           |                 | Not Reported |                |
|                                               | Morphine                              |                    |                    | S               | Unknown                               | Therapy Duration: 3 Days  |                 | Not Reported |                |
|                                               | Tylenol                               |                    |                    | S               | Unknown                               |                           |                 | Not Reported |                |
|                                               | Piperacillin Sodium/Tazobactam Sodium |                    |                    | S               | Unknown                               |                           |                 | Not Reported |                |
|                                               | Tylenol #1 (Canada)                   |                    |                    | S               | Unknown                               |                           |                 | Not Reported |                |
|                                               | Codeine                               |                    |                    | C               | Unknown                               |                           |                 | Not Reported |                |
|                                               | Docusate                              |                    |                    | C               |                                       |                           |                 | Not Reported |                |
|                                               | Gravol                                |                    |                    | C               |                                       |                           |                 | Not Reported |                |
|                                               | Lactulose                             |                    |                    | C               | Unknown                               |                           |                 | Not Reported |                |
|                                               | Senna                                 |                    |                    | C               |                                       |                           |                 | Not Reported |                |
|                                               | Trazodone                             |                    |                    | C               | Unknown                               |                           |                 | Not Reported |                |
| <u>FDA Received Date</u>                      | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Jul-2014                                   | 10333221                              | EXPEDITED (15-DAY) |                    | OT              | DE-FRI-1000069118                     |                           | 28 YR           | Female       | DEU            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                                                             | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                     | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|--------------------------------------------------------|-----------------|--------------|----------------|
| Caesarean Section;<br>Obstructed Labour                                                                           | Escitalopram   |                    |                    | S               | Oral                 | 20 Mg                                                  |                 | Forest       |                |
|                                                                                                                   | Escitalopram   |                    |                    | S               | Oral                 | 5 Mg (Very Slow Dose<br>Reduction During<br>Pregnancy) |                 | Forest       |                |
|                                                                                                                   | Euthyrox       |                    |                    | C               | Oral                 | 88 Mcg                                                 |                 | Not Reported |                |
|                                                                                                                   | Gynvital       |                    |                    | C               | Oral                 | 0.4 Mg                                                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                          | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Jul-2014                                                                                                       | 10333350       | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000069144    |                                                        | < 1 DAY         | Female       | USA            |
| <u>Preferred Term</u>                                                                                             | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Multiple Cardiac Defects;<br>Truncus Arteriosus<br>Persistent                                                     | Lexapro        |                    |                    | S               | Transplacental       |                                                        |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                          | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Jul-2014                                                                                                       | 10337953       | DIRECT             | Y                  | OT              |                      |                                                        | 18 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                             | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Irritability; Mood Swings;<br>Product Substitution Issue;<br>Tearfulness; Therapeutic<br>Product Effect Decreased | Lexapro        |                    |                    | S               | Oral                 |                                                        | 6 MTH           | Cvs Caremark |                |
| <u>FDA Received Date</u>                                                                                          | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Jul-2014                                                                                                       | 10305545       | EXPEDITED (15-DAY) |                    | LT              | JP-FRI-1000068764    |                                                        | 76 YR           | Male         | JPN            |
| <u>Preferred Term</u>                                                                                             | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Activation Syndrome;<br>Suicide Attempt                                                                           | Lexapro        |                    |                    | S               | Oral                 | 10 Mg                                                  |                 | Forest       |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Jul-2014              | 10335754      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000069233    |                      | 88 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u>                                                                                                      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|---------------------------------------------------------------------------------------------------------------------|--------------|------------|-------------|--------------|--------------------------------------|-----------------|--------------|
| Haematoma             | Escitalopram                                                                                                        |              |            | S           | Oral         | 5 Mg                                 |                 | Forest       |
|                       | Kardegic                                                                                                            |              |            | S           | Oral         | 75 Mg                                |                 | Not Reported |
|                       | Tahor                                                                                                               |              |            | S           | Oral         | 20 Mg                                |                 | Not Reported |
|                       | Previscan (Fluindione)                                                                                              |              |            | S           | Oral         | 0.5 Df                               |                 | Not Reported |
|                       | Previscan (Fluindione)                                                                                              |              |            | S           | Oral         | 0.25 Df                              |                 | Not Reported |
|                       | Previscan (Fluindione)                                                                                              |              |            | S           | Oral         | 3/4 On Even Days And 1/2 On Odd Days |                 | Not Reported |
|                       | Furosemide                                                                                                          |              |            | C           | Oral         | 40 Mg                                |                 | Not Reported |
|                       | Detensiel                                                                                                           |              |            | C           | Oral         | 10 Mg                                |                 | Not Reported |
|                       | Amlodipine                                                                                                          |              |            | C           | Oral         | 1 Df                                 |                 | Not Reported |
|                       | Ramipril                                                                                                            |              |            | C           |              | 5 Mg                                 |                 | Not Reported |
|                       | Esomeprazole                                                                                                        |              |            | C           | Oral         |                                      |                 | Not Reported |
|                       | Transipeg (Polyethylene Glycol 3350\Potassium Chloride\Sodium Bicarbonate\Sodium Chloride\Sodium Sulfate Anhydrous) |              |            | C           | Oral         | 5.9 G                                |                 | Not Reported |
|                       | Doliprane                                                                                                           |              |            | C           | Oral         |                                      |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Jul-2014              | 10336200      | EXPEDITED (15-DAY) |                    | DE, HO, OT      | FR-FRI-1000069174    |                      | 32 YR      | Male       | FRA            |

| <u>Preferred Term</u>                            | <u>Product</u>                    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------|-----------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiogenic Shock; Overdose; Vasoplegia Syndrome | Escitalopram                      |              |            | S           | Oral         |                    |                 | Forest       |
|                                                  | Escitalopram                      |              |            | S           | Oral         | Overdose Of 560 Mg |                 | Forest       |
|                                                  | Loxen (Nicardipine Hydrochloride) |              |            | S           | Oral         |                    |                 | Not Reported |

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|                                   |   |      |                     |              |
|-----------------------------------|---|------|---------------------|--------------|
| Loxen (Nicardipine Hydrochloride) | S |      | Overdose Of 4800 Mg | Not Reported |
| Verapamil                         | S | Oral |                     | Not Reported |
| Verapamil                         | S | Oral | Overdose Of 1200 Mg | Not Reported |
| Thyrozol                          | S | Oral |                     | Not Reported |
| Thyrozol                          | S |      | Overdose Of 400 Mg  | Not Reported |
| Noctamide                         | S | Oral |                     | Not Reported |
| Noctamide                         | S |      | Overdose Of 12 Mg   | Not Reported |

| <u>FDA Received Date</u>                                                          | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|------------------------------------------------------|-----------------|--------------|----------------|
| 23-Jul-2014                                                                       | 10336995       | EXPEDITED (15-DAY) | CA                 |                 | DE-FRI-1000069135    |                                                      | < 1 DAY         | Female       | DEU            |
| <u>Preferred Term</u>                                                             | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Foetal Exposure During Pregnancy; Small For Dates Baby; Ventricular Septal Defect | Escitalopram   |                    |                    | S               | Transplacental       | 20 Mg                                                |                 | Forest       |                |
|                                                                                   | Escitalopram   |                    |                    | S               | Transplacental       | 5 Mg/Day (Very Slow Dose Reduction During Pregnancy) |                 | Not Reported |                |
|                                                                                   | Euthyrox       |                    |                    | C               | Transplacental       | 88 Mcg                                               |                 | Not Reported |                |
|                                                                                   | Gynvital       |                    |                    | C               | Transplacental       | 0.4 Mg                                               |                 | Not Reported |                |

| <u>FDA Received Date</u>                    | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------|----------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 23-Jul-2014                                 | 10337026       | EXPEDITED (15-DAY) | OT                 |                 | IT-PFIZER INC-2014204664 |                      | 75 YR           | Female       | ITA            |
| <u>Preferred Term</u>                       | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Arthralgia; Asthenia; Malaise; Parkinsonism | Efexor Er      |                    |                    | S               | Oral                     | 1 Df, Daily          |                 | Pfizer       |                |
|                                             | Cipralext      |                    |                    | S               | Oral                     | 1 Df, Daily          |                 | Not Reported |                |
|                                             | Orap           |                    |                    | S               | Oral                     | 1 Df, Daily          |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 23-Jul-2014              | 10337250       | EXPEDITED (15-DAY) | HO                 |                 | TR-MYLANLABS-2014S1016748 |                      | 31 YR           | Female     | TUR            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

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

|                          |              |   |      |         |              |
|--------------------------|--------------|---|------|---------|--------------|
| Anal Incontinence; Drug  | Escitalopram | S | Oral | Df=10mg | Mylan        |
| Interaction; Intentional | Escitalopram | S | Oral | Df=10mg | Mylan        |
| Overdose; Suicide        | Aripiprazole | S | Oral | Df=5mg  | Not Reported |
| Attempt; Urinary         | Aripiprazole | S | Oral | Df=5mg  | Not Reported |
| Incontinence             |              |   |      |         |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Jul-2014              | 10344724      | EXPEDITED (15-DAY) |                    | OT              | AUR-APL-2014-07749   |                      | 64 YR      | Female     | USA            |

| <u>Preferred Term</u>  | <u>Product</u>                                                                         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |
|------------------------|----------------------------------------------------------------------------------------|--------------|------------|-------------|--------------|------------------------------|-----------------|--------------|
| Chronic Kidney Disease | Escitalopram                                                                           |              |            | S           |              | 20 Mg, Once A Day, Unknown   |                 | Not Reported |
|                        | Prevacid                                                                               |              |            | S           | Oral         | 15 Mg, Two Times A Day, Oral |                 | Not Reported |
|                        | Hydroxyzine Hydrochloride                                                              |              |            | S           | Oral         |                              |                 | Not Reported |
|                        | Advair                                                                                 |              |            | S           |              | 1 Puff, Respiratory          |                 | Not Reported |
|                        | Ventolin Hfa                                                                           |              |            | S           |              | 2 Puff, Respiratory          |                 | Not Reported |
|                        | Bupropion Hydrochloride                                                                |              |            | S           | Oral         | 30 Mg, Once A Day, Oral      |                 | Not Reported |
|                        | Esterified Estrogens And Methyltestosterone (Estrogens Esterified, Methyltestosterone) |              |            | C           |              |                              |                 | Not Reported |
|                        | Unknown                                                                                |              |            |             |              |                              |                 |              |
|                        | Lisinopril (Lisinopril) Unknown                                                        |              |            | C           |              |                              |                 | Not Reported |
|                        | Trazodone (Trazodone)                                                                  |              |            | C           |              |                              |                 | Not Reported |
|                        | Unknown                                                                                |              |            |             |              |                              |                 |              |
|                        | Fluzone /00780601/ (Fluconazole) Unknown                                               |              |            | C           |              |                              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Jul-2014              | 10345348      | EXPEDITED (15-DAY) | Y                  | HO              | 2014HINLIT0645       |                      | 38 YR      | Female     | CHE            |

| <u>Preferred Term</u>                   | <u>Product</u>                        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------|---------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abdominal Pain; Clonus; Diarrhoea; Drug | Escitalopram (Escitalopram) (Unknown) |              |            | S           |              |                    | 244 DAY         | Not Reported |
| Interaction; Dysmetria;                 | Mirtazapine (Mirtazapine)             |              |            | S           |              | At Bed Time        |                 | Not Reported |

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

|                                                                                                                                          |                       |   |              |
|------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|---|--------------|
| Hyperreflexia; Irritability;<br>Persecutory Delusion;<br>Serotonin Syndrome;<br>Sleep Disorder; Toxicity<br>To Various Agents;<br>Tremor | Lorazepam (Lorazepam) | C | Not Reported |
|------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|---|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Jul-2014              | 10345362      | EXPEDITED (15-DAY) | Y                  | OT              | 2014HINLIT0637       |                      | 34 YR      | Male       | ISR            |

| <u>Preferred Term</u> | <u>Product</u>                   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Bruxism               | Escitalopram                     |              |            | S           |              | 20 Mg/D            |                 | Not Reported |
|                       | Carbamazepine<br>(Carbamazepine) |              |            | C           |              |                    |                 | Not Reported |
|                       | Clonazepam (Clonazepam)          |              |            | C           |              |                    |                 | Not Reported |
|                       | Zopiclone (Zopiclone)            |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 24-Jul-2014              | 6956961       | EXPEDITED (15-DAY) |                    | HO              | US-JNJFOC-<br>20090307044 |                      | 48 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                | <u>Product</u>                          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------|-----------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Asthenia; Dysarthria;<br>Headache; Hypertension;<br>Hypokalaemia; Mental<br>Status Changes; Multiple<br>Drug Therapy | Ibuprofen                               |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                      | Desvenlafaxine Succinate<br>Monohydrate |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                      | Desvenlafaxine Succinate<br>Monohydrate |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                      | Desvenlafaxine Succinate<br>Monohydrate |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                      | Desvenlafaxine Succinate<br>Monohydrate |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                      | Desvenlafaxine Succinate<br>Monohydrate |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                      | Desvenlafaxine Succinate<br>Monohydrate |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                      | Desvenlafaxine Succinate<br>Monohydrate |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                      | Desvenlafaxine Succinate<br>Monohydrate |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                      | Placebo                                 |              |            | S           | Oral         |                    |                 | Not Reported |



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

|             |   |                          |                 |              |
|-------------|---|--------------------------|-----------------|--------------|
| Placebo     | S | Oral                     |                 | Not Reported |
| Lexapro     | S | Oral                     |                 | Not Reported |
| Lexapro     | S | Oral                     |                 | Not Reported |
| Clonazepam  | S | Oral                     |                 | Not Reported |
| Clonazepam  | S | Oral                     |                 | Not Reported |
| Abilify     | S | Oral                     |                 | Not Reported |
| Abilify     | S | Oral                     |                 | Not Reported |
| Abilify     | S | Oral                     |                 | Not Reported |
| Fluticasone | S | Respiratory (inhalation) |                 | Not Reported |
| Loratadine  | S | Oral                     |                 | Not Reported |
| Vicodin     | S | Oral                     | 5/500 As Needed | Not Reported |
| Zestoretic  | S | Oral                     | 20/12.5 Daily   | Not Reported |
| Ambien      | S | Oral                     |                 | Not Reported |
| Vivelle     | S | Transdermal              |                 | Not Reported |
| Robaxin     | S | Oral                     |                 | Not Reported |
| Robaxin     | S | Oral                     |                 | Not Reported |
| Robaxin     | S | Oral                     |                 | Not Reported |
| Lyrica      | S | Oral                     |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|------------|------------|----------------|
| 24-Jul-2014              | 9804141       | EXPEDITED (15-DAY) |                    | HO              | FR-NAPPMUNDI-GBR-2013-0016791 |                      | 50 YR      | Female     | FRA            |

  

| <u>Preferred Term</u>                                                       | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------|-----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Erythema Multiforme;<br>Stevens-Johnson<br>Syndrome; Toxic Skin<br>Eruption | Oxynorm 10 Mg, Gelule |              |            | S           |              | 10 Mg, Qid         |                 | Purdue       |
|                                                                             | Primperan             |              |            | S           |              | Unk                |                 | Not Reported |
|                                                                             | Lyrica                |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                                                                             | Seroplex              |              |            | S           |              | Unk                |                 | Not Reported |
|                                                                             | Esomeprazole          |              |            | S           | Oral         | 40 Mg, Daily       |                 | Not Reported |
|                                                                             | Crestor               |              |            | C           |              | 20 Mg, Daily       |                 | Not Reported |

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|             |   |                        |              |
|-------------|---|------------------------|--------------|
| Kardegic    | C | 75 Mg, Unk             | Not Reported |
| Plavix      | C | 75 Mg, Unk             | Not Reported |
| Lovenox     | C | 4000 Ui Anti-Xa/0.4 MI | Not Reported |
| Metoprolol  | C |                        | Not Reported |
| Insulin     | C |                        | Not Reported |
| Hexaspray   | C |                        | Not Reported |
| Hydroxyzine | C |                        | Not Reported |
| Solumedrol  | C |                        | Not Reported |

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|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Jul-2014              | 9814573       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000052781    |                      | 50 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Erythema Multiforme;<br>Stevens-Johnson<br>Syndrome; Toxic Skin<br>Eruption | Escitalopram   |              |            | S           | Oral         |                    |                 | Forest       |
|                                                                             | Lyrice         |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                             | Esomeprazole   |              |            | S           | Oral         | 1 Df               |                 | Not Reported |
|                                                                             | Oxynorm        |              |            | S           |              | 4 Df               |                 | Not Reported |
|                                                                             | Primperan      |              |            | S           |              |                    |                 | Not Reported |
|                                                                             | Crestor        |              |            | C           | Oral         | 1 Df               |                 | Not Reported |
|                                                                             | Kardegic       |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                             | Plavix         |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                             | Lovenox        |              |            | C           |              |                    |                 | Not Reported |
|                                                                             | Metoprolol     |              |            | C           |              |                    |                 | Not Reported |
|                                                                             | Insulin        |              |            | C           |              |                    |                 | Not Reported |
|                                                                             | Hexaspray      |              |            | C           |              |                    |                 | Not Reported |
|                                                                             | Hydroxyzine    |              |            | C           |              |                    |                 | Not Reported |
|                                                                             | Solumedrol     |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Jul-2014              | 10243990      | EXPEDITED (15-DAY) |                    | OT              | JP-FRI-1000068205    |                      | 40 YR      | Female     | JPN            |

| <u>Preferred Term</u>         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Clonic Convulsion;<br>Seizure | Lexapro        |              |            | S           | Oral         | 10 Mg              |                 | Forest     |

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|  |         |   |      |       |              |
|--|---------|---|------|-------|--------------|
|  | Lexapro | S | Oral | 20 Mg | Forest       |
|  | Lexapro | S |      | 20 Mg | Forest       |
|  | Myslee  | S | Oral | 10 Mg | Not Reported |
|  | Myslee  | S | Oral | 10 Mg | Not Reported |
|  | Meilax  | S | Oral |       | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Jul-2014              | 10337406      | EXPEDITED (15-DAY) |                    | HO              | FR-ROCHE-1438872     |                      | 63 YR      | Female     | FRA            |

| <u>Preferred Term</u>     | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|--------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Acute Respiratory Failure | Valium             |              |            | S           | Oral         | 1%                 |                 | Not Reported |
|                           | Seroplex           |              |            | S           | Oral         |                    |                 | Not Reported |
|                           | Depakote           |              |            | S           | Oral         |                    |                 | Not Reported |
|                           | Loxen (France)     |              |            | S           | Oral         |                    |                 | Not Reported |
|                           | Tercian            |              |            | S           | Oral         |                    |                 | Not Reported |
|                           | Eupantol           |              |            | S           | Oral         |                    |                 | Not Reported |
|                           | Theralene (France) |              |            | S           | Oral         | 4%                 |                 | Not Reported |
|                           | Lepticur           |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Jul-2014              | 10340791      | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000069123    |                      | < 1 DAY    | Female     | USA            |

| <u>Preferred Term</u>                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|------------|
| Congenital Anomaly;<br>Encephalocele | Lexapro        |              |            | S           | Transplacental |                    |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 24-Jul-2014              | 10340878      | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1012582 |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Breath Odour; Drug    | Levothyroxine  |              |            | S           |              |                    |                 | Not Reported |

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

|                            |                     |   |  |  |  |  |  |  |              |
|----------------------------|---------------------|---|--|--|--|--|--|--|--------------|
| Interaction; Malaise; Skin | Levoxyl             | S |  |  |  |  |  |  | Not Reported |
| Odour Abnormal; Urinary    | Amlodipine Besilate | S |  |  |  |  |  |  | Mylan        |
| Tract Infection            | Lexapro             | S |  |  |  |  |  |  | Mylan        |
|                            | Synthroid           | S |  |  |  |  |  |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Jul-2014              | 10224073      | EXPEDITED (15-DAY) |                    | HO              | CN-FRI-1000067949    |                      | < 1 DAY    | Male       | CHN            |

| <u>Preferred Term</u>                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Foaming At Mouth; Foetal                   | Lexapro        |              |            | S           | Transplacental | 10 Mg              |                 | Forest       |
| Exposure During                            | Alprazolam     |              |            | C           | Transplacental | 1 Tablet           |                 | Not Reported |
| Pregnancy; Hand-Foot-<br>And-Mouth Disease |                |              |            |             |                |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Jul-2014              | 10342244      | EXPEDITED (15-DAY) |                    | HO              | CH-ACCORD-024916     |                      | 38 YR      | Female     | CHE            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|---------------------------|-----------------|--------------|
| Drug Interaction;     | Escitalopram   |              |            | S           |              | Increased Progressively   |                 | Accord       |
| Serotonin Syndrome    |                |              |            |             |              | Upto 20 Mg/D During First |                 |              |
|                       | Mirtazapine    |              |            | S           |              | 4 Months                  |                 |              |
|                       |                |              |            |             |              | At Bedtime                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------------|----------------------|------------|------------|----------------|
| 25-Jul-2014              | 10343594      | EXPEDITED (15-DAY) |                    | HO, OT          | US-<br>GLAXOSMITHKLINE-<br>A1082704A |                      | 44 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Depression            | Lamictal       |              |            | S           | Unknown      |                    |                 | Glaxosmithkline |
|                       | Lexapro        |              |            | S           | Unknown      |                    |                 | Not Reported    |
|                       | Geodon         |              |            | S           | Unknown      |                    |                 | Not Reported    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Jul-2014              | 10347132      | DIRECT           |                    | LT, OT          |                      |                      | 32 YR      | Male       | USA            |

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

| <u>Preferred Term</u>                                                                                                                                                                                                              | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|-------------------------|--------------------------|-----------------|--------------|----------------|
| Anger; Anxiety; Blood Pressure Increased; Cardiac Murmur; Dizziness; Drug Withdrawal Syndrome; Dyspnoea; Heart Rate Increased; Hyperhidrosis; Irritability; Mood Swings; Muscle Rigidity; Muscle Spasms; Musculoskeletal Stiffness | Lexapro        |                    |                    | S               | Oral                    |                          |                 | Accord       |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                           | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Jul-2014                                                                                                                                                                                                                        | 8001511        | EXPEDITED (15-DAY) |                    | OT              | US-RANBAXY-2011US-44588 |                          |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                              | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Amnesia; Withdrawal Syndrome                                                                                                                                                                                                       | Lorazepam      |                    |                    | S               | Oral                    | 1 Mg Tablet In Evening   |                 | Ranbaxy      |                |
|                                                                                                                                                                                                                                    | Lorazepam      |                    |                    | S               | Oral                    | 0.5 Mg Tablet In Morning |                 | Ranbaxy      |                |
|                                                                                                                                                                                                                                    | Tegretol       |                    |                    | S               | Unknown                 | 600 Mg, Unk              |                 | Not Reported |                |
|                                                                                                                                                                                                                                    | Lithium        |                    |                    | S               | Unknown                 | 750 Mg, Unk              |                 | Not Reported |                |
|                                                                                                                                                                                                                                    | Lexapro        |                    |                    | S               | Unknown                 | 10 Mg, Unk               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                           | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Jul-2014                                                                                                                                                                                                                        | 8403932        | EXPEDITED (15-DAY) |                    | OT              | GB-RANBAXY-2011R1-45218 |                          | 22 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                                                                                                                                                                              | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Disturbance In Social Behaviour; Oculogyric Crisis; Oculogyric Crisis                                                                                                                                                     | Risperidone    |                    |                    | S               | Oral                    | 1.5 Mg, Qd               |                 | Ranbaxy      |                |
|                                                                                                                                                                                                                                    | Risperidone    |                    |                    | S               | Oral                    | Unk                      |                 | Ranbaxy      |                |
|                                                                                                                                                                                                                                    | Risperidone    |                    |                    | S               | Oral                    | 1.5 Mg, Qd               |                 | Ranbaxy      |                |
|                                                                                                                                                                                                                                    | Cipralelex     |                    |                    | S               | Oral                    | 10 Mg, 1days             |                 | Not Reported |                |
|                                                                                                                                                                                                                                    | Cipralelex     |                    |                    | S               | Oral                    | 10 Mg, Bid               |                 | Not Reported |                |
|                                                                                                                                                                                                                                    | Orphenadrine   |                    |                    | C               | Unknown                 | 50 Mg, Tid               |                 | Not Reported |                |

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

| <u>FDA Received Date</u>                                                                            | <u>Case #</u>                                                                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 28-Jul-2014                                                                                         | 10151060                                                                          | EXPEDITED (15-DAY) |                    | HO              | DE-FRI-1000067036     |                      | 38 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                                                               | <u>Product</u>                                                                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Lower Limb Fracture                                                                                 | Lexapro                                                                           |                    |                    | S               |                       | 20 Mg                |                 | Forest       |                |
|                                                                                                     | Luaf41156                                                                         |                    |                    | S               |                       | Unk                  |                 | Not Reported |                |
|                                                                                                     | Blinded Placebo                                                                   |                    |                    | S               |                       | Unk                  |                 | Not Reported |                |
|                                                                                                     | Blinded Serequel Xr                                                               |                    |                    | S               |                       | Unk                  |                 | Not Reported |                |
|                                                                                                     | Nasic                                                                             |                    |                    | C               | Other                 | Unk, Prn             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                            | <u>Case #</u>                                                                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Jul-2014                                                                                         | 10267259                                                                          | NON-EXPEDITED      |                    | HO              | FR-JNJFOC-20140617353 |                      | 81 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                               | <u>Product</u>                                                                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depressed Level Of Consciousness; Disturbance In Attention; Drug Interaction; Mydriasis; Somnolence | Contramal                                                                         |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                     | Laroxyl                                                                           |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                     | Seroplex                                                                          |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                     | Seresta                                                                           |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                     | Stilnox                                                                           |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                     | Lyrica                                                                            |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                     | Doliprane                                                                         |                    |                    | C               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                     | Modopar                                                                           |                    |                    | C               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                     | Modopar                                                                           |                    |                    | C               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                     | Olmetec                                                                           |                    |                    | C               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                     | Calcium Phosphate                                                                 |                    |                    | C               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                     | Xagrid                                                                            |                    |                    | C               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                     | Transipeg (Polyethylene Glycol 3350)\Potassium Chloride\Sodium Bicarbonate\Sodium |                    |                    | C               | Oral                  |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Chloride\Sodium Sulfate  
Anhydrous)  
Kardegic  
Modopar

C Oral  
C Oral

Not Reported  
Not Reported

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Jul-2014              | 10344613      | EXPEDITED (15-DAY) |                    | OT              | IL-ACCORD-024983     |                      | 34 YR      | Male       | ISR            |

| <u>Preferred Term</u> | <u>Product</u>                              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                             |
|-----------------------|---------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------------------------|
| Bruxism               | Clonazepam<br>Escitalopram<br>Carbamazepine |              |            | C<br>S<br>C |              |                    |                 | Not Reported<br>Accord<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Jul-2014              | 10345634      | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000069332    |                      |            | Male       | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Seizure               | Escitalopram   |              |            | S           | Oral         |                    |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Jul-2014              | 10345686      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000069334    |                      | 68 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                                                         | <u>Product</u>                                                     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>               | <u>Route</u>                             | <u>Dosage Text</u>                                                                                                                   | <u>Duration</u> | <u>Mfr</u>                                                                 |
|-----------------------------------------------------------------------------------------------|--------------------------------------------------------------------|--------------|------------|---------------------------|------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------|-----------------|----------------------------------------------------------------------------|
| Overdose; Pneumonia<br>Aspiration; Renal Failure;<br>Suicide Attempt; Toxic<br>Encephalopathy | Escitalopram<br>Laroxyl<br>Laroxyl<br><br>Alprazolam<br>Actiskenan |              |            | S<br>S<br>S<br><br>S<br>S | Oral<br>Oral<br>Oral<br><br>Oral<br>Oral | Overdose Of 840 Mg Once<br>Overdose Of 1 Gram Once<br>Overdose Of 1.325 Gram<br>Once<br>Overdose Of 60 Mg Once<br>Overdose Of 280 Mg |                 | Forest<br>Not Reported<br>Not Reported<br><br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 28-Jul-2014              | 10345811      | EXPEDITED (15-DAY) |                    | LT              | US-PFIZER INC-<br>2014208279 |                      | 55 YR      | Male       | USA            |

# FDA Adverse Event Reporting System

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### Detailed Report

| <u>Preferred Term</u>                                                                     | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                             | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|------------------------------------------|--------------------|-----------------|--------------|
| Cerebral Haemorrhage;<br>Drug Interaction; Platelet<br>Dysfunction; Serotonin<br>Syndrome | Linezolid               |              |            | S           |                                          | Unk                |                 | Pfizer       |
|                                                                                           | Escitalopram Oxalate    |              |            | S           |                                          | 20 Mg, Unk         |                 | Not Reported |
|                                                                                           | Trazodone               |              |            | S           |                                          | Unk                |                 | Not Reported |
|                                                                                           | Fentanyl                |              |            | S           | Intravenous (not<br>otherwise specified) | Intermittent       |                 | Not Reported |
|                                                                                           | Vancomycin              |              |            | C           |                                          | Unk                |                 | Not Reported |
|                                                                                           | Piperacillin/Tazobactam |              |            | C           |                                          | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Jul-2014              | 10346134      | EXPEDITED (15-DAY) | Y                  | OT              | CH-FRI-1000069329    |                      |            | Female     | CHE            |

| <u>Preferred Term</u>                                                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|------------------------|-----------------|--------------|
| Myofascial Pain<br>Syndrome; Prescribed<br>Overdose; Prurigo; Stress | Escitalopram   |              |            | S           | Oral         | 10 Mg                  |                 | Forest       |
|                                                                      | Escitalopram   |              |            | S           | Oral         | 20 Mg                  |                 | Forest       |
|                                                                      | Escitalopram   |              |            | S           |              | Dose Reduced           |                 | Not Reported |
|                                                                      | Escitalopram   |              |            | S           |              | 20 Mg                  |                 | Not Reported |
|                                                                      | Escitalopram   |              |            | S           |              | 40 Mg                  |                 | Not Reported |
|                                                                      | Escitalopram   |              |            | S           |              | Dose Gradually Reduced |                 | Not Reported |
|                                                                      | St Johns Wort  |              |            | S           |              |                        |                 | Not Reported |
|                                                                      | Interferon Nos |              |            | S           |              |                        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Jul-2014              | 10349590      | EXPEDITED (15-DAY) |                    | HO              | 2014AP003715         |                      | 16 YR      | Female     | AUS            |

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

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>        | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------------|----------------------|------------|------------|----------------|
| 29-Jul-2014              | 8025820       | EXPEDITED (15-DAY) |                    | OT              | TW-RANBAXY-2011RR-<br>45826 |                      | 52 YR      | Female     | TWN            |



# FDA Adverse Event Reporting System

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| <u>Preferred Term</u>                                                                                                                    | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Akathisia; Extrapyramidal Disorder; Gait Disturbance; Muscle Rigidity; Psychomotor Retardation; Tremor                                   | Fluoxetine                 |                    |                    | S               | Unknown              | Unk                  |                 | Ranbaxy      |                |
|                                                                                                                                          | Sertraline                 |                    |                    | S               | Unknown              | Unk                  |                 | Ranbaxy      |                |
|                                                                                                                                          | Escitalopram               |                    |                    | S               | Unknown              | Unk                  |                 | Not Reported |                |
|                                                                                                                                          | Duloxetine                 |                    |                    | S               | Unknown              | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                 | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Jul-2014                                                                                                                              | 10271424                   | EXPEDITED (15-DAY) |                    | CA, HO          | IT-FRI-1000026311    |                      |                 | Male         | ITA            |
| <u>Preferred Term</u>                                                                                                                    | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anaemia; Dermatitis; Foetal Exposure During Pregnancy; Gastrooesophageal Reflux Disease; Rhinitis                                        | Escitalopram Oral Solution |                    |                    | S               | Transplacental       | 10 Mg                |                 | Forest       |                |
|                                                                                                                                          | Xanax                      |                    |                    | S               | Transplacental       | 5 Mg                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                 | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Jul-2014                                                                                                                              | 10348108                   | EXPEDITED (15-DAY) |                    | HO, OT          | PHHY2014JP090827     |                      | 46 YR           | Male         | JPN            |
| <u>Preferred Term</u>                                                                                                                    | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Chest Pain; Drug Interaction; Electrocardiogram Qt Prolonged; Sedation Complication; Ventricular Extrasystoles; Ventricular Fibrillation | Escitalopram               |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                          | Lansoprazole               |                    |                    | S               |                      |                      |                 | Novartis     |                |
|                                                                                                                                          | Aspirin                    |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                          | Atorvastatin               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                          | Clopidogrel                |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                 | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Jul-2014                                                                                                                              | 10348265                   | EXPEDITED (15-DAY) |                    | OT              | IT-FRI-1000022085    |                      |                 | Female       | ITA            |
| <u>Preferred Term</u>                                                                                                                    | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Adnexal Torsion; Depression; Gestational                                                                                                 | Escitalopram Oral Solution |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |

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| Diabetes; Hypothyroidism;<br>Infection; Pelvic Pain;<br>Pregnancy                                                                                                    | Xanax<br>Progesterone                                                                | C<br>C             | Oral               | 5 Mg                  |                              |                                                  |                 | Not Reported<br>Not Reported                                         |                |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|--------------------|--------------------|-----------------------|------------------------------|--------------------------------------------------|-----------------|----------------------------------------------------------------------|----------------|
| <u>FDA Received Date</u>                                                                                                                                             | <u>Case #</u>                                                                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>       | <u>Mfr Control #</u>         | <u>503B Facility</u>                             | <u>Age</u>      | <u>Sex</u>                                                           | <u>Country</u> |
| 29-Jul-2014                                                                                                                                                          | 10355205                                                                             | EXPEDITED (15-DAY) | Y                  | OT                    | AUR-APL-2014-07976           |                                                  | 61 YR           | Female                                                               | USA            |
| <u>Preferred Term</u>                                                                                                                                                | <u>Product</u>                                                                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>           | <u>Route</u>                 | <u>Dosage Text</u>                               | <u>Duration</u> | <u>Mfr</u>                                                           |                |
| Drug Hypersensitivity;<br>Gastritis Erosive; Hiatus<br>Hernia; Nausea; Product<br>Use In Unapproved<br>Indication                                                    | Escitalopram 5 Mg<br>(Escitalopram) Unknown, 5mg                                     |                    |                    | S                     | Oral<br>Oral                 |                                                  |                 | Not Reported                                                         |                |
| <u>FDA Received Date</u>                                                                                                                                             | <u>Case #</u>                                                                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>       | <u>Mfr Control #</u>         | <u>503B Facility</u>                             | <u>Age</u>      | <u>Sex</u>                                                           | <u>Country</u> |
| 30-Jul-2014                                                                                                                                                          | 10221047                                                                             | EXPEDITED (15-DAY) |                    | HO                    | CH-FRI-1000067893            |                                                  |                 | Female                                                               | CHE            |
| <u>Preferred Term</u>                                                                                                                                                | <u>Product</u>                                                                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>           | <u>Route</u>                 | <u>Dosage Text</u>                               | <u>Duration</u> | <u>Mfr</u>                                                           |                |
| Aggression; Irritability;<br>Libido Decreased;<br>Obesity; Weight<br>Increased; Wound<br>Infection                                                                   | Escitalopram<br>Escitalopram<br>Lyrica<br>Lyrica                                     |                    |                    | S<br>S<br>S<br>S      | Oral<br>Oral<br>Oral<br>Oral | 10 Mg<br>20 Mg<br>150 Mg<br>Dose Reduced By Half |                 | Forest<br>Forest<br>Not Reported<br>Not Reported                     |                |
| <u>FDA Received Date</u>                                                                                                                                             | <u>Case #</u>                                                                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>       | <u>Mfr Control #</u>         | <u>503B Facility</u>                             | <u>Age</u>      | <u>Sex</u>                                                           | <u>Country</u> |
| 30-Jul-2014                                                                                                                                                          | 10349103                                                                             | EXPEDITED (15-DAY) |                    | HO                    | PHHY2014CH091808             |                                                  | 38 YR           | Female                                                               | CHE            |
| <u>Preferred Term</u>                                                                                                                                                | <u>Product</u>                                                                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>           | <u>Route</u>                 | <u>Dosage Text</u>                               | <u>Duration</u> | <u>Mfr</u>                                                           |                |
| Abdominal Pain;<br>Diarrhoea; Drug<br>Interaction; Dyskinesia;<br>Dysmetria; Irritability;<br>Persecutory Delusion;<br>Serotonin Syndrome;<br>Suspiciousness; Tremor | Escitalopram<br>Escitalopram<br>Mirtazapine<br>Mirtazapine<br>Oral Contraceptive Nos |                    |                    | S<br>S<br>S<br>S<br>C |                              | 20 Mg/Day<br>15 Mg/Day                           |                 | Not Reported<br>Not Reported<br>Novartis<br>Novartis<br>Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------------------------------------------------------------|-----------------|--------------|----------------|
| 30-Jul-2014              | 10349174       | EXPEDITED (15-DAY) |                    | OT              | AE-ACCORD-025012     |                                                                            | 27 YR           | Female       | ARE            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Galactorrhoea            | Escitalopram   |                    |                    | S               |                      | Instructed To Increase The Dose Of Escitalopram To 10 Mg/Day After 4 Days. |                 | Accord       |                |
|                          | Clonazepam     |                    |                    | C               |                      |                                                                            |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                                                                                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|------------------------------|-----------------|--------------|----------------|
| 30-Jul-2014                                                                                                                                                                                                                         | 10349577       | EXPEDITED (15-DAY) |                    | OT              | CA-ROCHE-1441200     |                              | 33 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                                                                                                                                                                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Acute Hepatitis C; Alanine Amino transferase Increased; Aspartate Amino transferase Increased; Blood Alkaline Phosphatase Increased; Blood Bilirubin Increased; Gamma-Glutamyltransferase Increased; Lymphocyte Morphology Abnormal | Diazepam       |                    |                    | S               | Oral                 |                              |                 | Not Reported |                |
|                                                                                                                                                                                                                                     | Ciprallex      |                    |                    | S               | Oral                 | Therapy Duration: 2 Month(S) |                 | Not Reported |                |
|                                                                                                                                                                                                                                     | Oxazepam       |                    |                    | S               | Sublingual           |                              |                 | Not Reported |                |
|                                                                                                                                                                                                                                     | Suboxone       |                    |                    | S               | Sublingual           | Therapy Duration: 2 Day(S)   |                 | Not Reported |                |
|                                                                                                                                                                                                                                     | Suboxone       |                    |                    | S               | Sublingual           | Therapy Duration: 9 Day(S)   |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 30-Jul-2014              | 10350344       | EXPEDITED (15-DAY) |                    | HO              | US-PFIZER INC-2014210065 |                      | 44 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression               | Geodon         |                    |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                          | Lexapro        |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                          | Lamictal       |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                   | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------|---------------------|--------------------|--------------------|-----------------|------------------------------------------|-----------------------|-----------------|--------------|----------------|
| 30-Jul-2014                                                                | 10350990            | EXPEDITED (15-DAY) |                    | HO              | IT-WATSON-2014-16262                     |                       | 20 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                      | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Abuse; Sopor                                                          | Lorazepam (Unknown) |                    |                    | S               | Oral                                     | 20 MI, Total          |                 | Watson       |                |
|                                                                            | Cipralex /01588501/ |                    |                    | S               | Oral                                     | 140 Mg, Total         |                 | Not Reported |                |
|                                                                            | Talofen             |                    |                    | S               | Oral                                     | 40 Gtt Drop(S), Total |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                   | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-Jul-2014                                                                | 10353830            | EXPEDITED (15-DAY) |                    | OT              | IT-LUPIN PHARMACEUTICALS INC.-2014-01389 |                       |                 | Unknown      | ITA            |
| <u>Preferred Term</u>                                                      | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Foetal Exposure During Pregnancy; Low Birth Weight Baby                    | Escitalopram        |                    |                    | S               | Transplacental                           |                       |                 | Not Reported |                |
|                                                                            | Alprazolam          |                    |                    | S               | Transplacental                           |                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                   | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-Jul-2014                                                                | 10354609            | EXPEDITED (15-DAY) |                    | OT              | JP-TEVA-498375ISR                        |                       | 46 YR           | Male         | JPN            |
| <u>Preferred Term</u>                                                      | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Electrocardiogram Qt Prolonged; Ventricular Fibrillation | Lansoprazole        |                    |                    | S               | Unknown                                  |                       |                 | Teva         |                |
|                                                                            | Escitalopram        |                    |                    | S               | Unknown                                  |                       |                 | Not Reported |                |
|                                                                            | Aspirin             |                    |                    | C               | Unknown                                  | Controlled Release    |                 | Not Reported |                |
|                                                                            | Clopidogrel         |                    |                    | C               | Unknown                                  |                       |                 | Not Reported |                |
|                                                                            | Atorvastatin        |                    |                    | C               | Unknown                                  |                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                   | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-Jul-2014                                                                | 10354788            | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000069331                        |                       | 58 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                      | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |

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|                                  |                                   |   |      |                                        |  |  |              |
|----------------------------------|-----------------------------------|---|------|----------------------------------------|--|--|--------------|
| Chest Pain; Condition Aggravated | Escitalopram                      | S | Oral |                                        |  |  | Forest       |
|                                  | Verapamil                         | C |      | 60 Mg In Morning And 120 Mg In Evening |  |  | Not Reported |
|                                  | Aspegic [Acetylsalicylate Lysine] | C |      | 100 Mg                                 |  |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-Jul-2014              | 10355557      | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000069490    |                      | < 1 DAY    | Male       | USA            |

| <u>Preferred Term</u>             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|------------|
| Congenital Anomaly; Gastroschisis | Lexapro        |              |            | S           | Transplacental |                    |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-Jul-2014              | 10361084      | EXPEDITED (15-DAY) | Y                  | HO              | 2014HINLIT0672       |                      | 31 YR      | Female     | TUR            |

| <u>Preferred Term</u>                                                                | <u>Product</u>                    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------|-----------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anal Incontinence; Drug Interaction; Overdose; Suicide Attempt; Urinary Incontinence | Escitalopram                      |              |            | S           |              |                    |                 | Not Reported |
|                                                                                      | Aripiprazole                      |              |            | S           |              |                    |                 | Not Reported |
|                                                                                      | Active Charcoal (Active Charcoal) |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------|----------------------|------------|------------|----------------|
| 01-Aug-2014              | 9264778       | EXPEDITED (15-DAY) |                    | HO              | DE-RANBAXY-2013RR-68254 |                      | 39 YR      | Female     | DEU            |

| <u>Preferred Term</u>                  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Oedema Peripheral; Peripheral Swelling | Ibuprofen      |              | Y          | S           | Oral         | 1600 Mg, Daily     |                 | Ranbaxy      |
|                                        | CipraleX       |              |            | S           | Oral         | 20 Mg, Daily       |                 | Not Reported |
|                                        | Remergil       |              |            | S           | Oral         | 15 Mg, Daily       |                 | Not Reported |
|                                        | Remergil       |              |            | S           | Oral         | 30 Mg, Daily       |                 | Not Reported |
|                                        | Remergil       |              |            | S           | Oral         | 15 Mg, Daily       |                 | Not Reported |
|                                        | Pantozol       |              |            | C           | Oral         | 40 Mg, Daily       |                 | Not Reported |

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| <u>FDA Received Date</u>                                                                                                      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 01-Aug-2014                                                                                                                   | 10196740       | EXPEDITED (15-DAY) |                    | DE              | FR-FRI-1000067561     |                      | 79 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                         | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cerebral Haemorrhage                                                                                                          | Escitalopram   |                    |                    | S               | Oral                  | 1 Df                 |                 | Forest       |                |
|                                                                                                                               | Kardegic       |                    |                    | S               | Oral                  | 1 Df                 |                 | Not Reported |                |
|                                                                                                                               | Plavix         |                    |                    | S               | Oral                  | 1 Df                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Aug-2014                                                                                                                   | 10282455       | EXPEDITED (15-DAY) |                    | HO              | JP-FRI-1000068625     |                      | 45 YR           | Male         | JPN            |
| <u>Preferred Term</u>                                                                                                         | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Seizure                                                                                                                       | Lexapro        |                    |                    | S               | Oral                  | 10 Mg                |                 | Forest       |                |
|                                                                                                                               | Diazepam       |                    |                    | C               | Oral                  | 5 Mg                 |                 | Not Reported |                |
|                                                                                                                               | Flunitrazepam  |                    |                    | C               | Oral                  | 2 Mg                 |                 | Not Reported |                |
|                                                                                                                               | Brotizolam     |                    |                    | C               | Oral                  | 0.25 Mg              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Aug-2014                                                                                                                   | 10357006       | EXPEDITED (15-DAY) |                    | CA, HO, LT, OT  | US-JNJFOC-20140716605 |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                         | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aortic Stenosis; Atrial Septal Defect;                                                                                        | Topamax        |                    |                    | S               | Transplacental        |                      |                 | Not Reported |                |
| Cardiopulmonary Failure; Congenital Heart Valve Disorder; Foetal Exposure During Pregnancy; Hypoxia; Patent Ductus Arteriosus | Lexapro        |                    |                    | S               | Unknown               |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Aug-2014                                                                                                                   | 10357166       | EXPEDITED (15-DAY) |                    | HO              | IT-TEVA-494423ISR     |                      | 24 YR           | Male         | ITA            |

# FDA Adverse Event Reporting System

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### Detailed Report

| <u>Preferred Term</u>                                                                                                                                                                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| Anxiety; Nausea; Withdrawal Syndrome                                                                                                                                                  | Escitalopram Oxalate |                    |                    | S               | Oral                     | 10 Df Daily          |                 | Ivax         |                |
| <u>FDA Received Date</u>                                                                                                                                                              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Aug-2014                                                                                                                                                                           | 10357454             | EXPEDITED (15-DAY) |                    | OT              | BR-PFIZER INC-2014213260 |                      | 58 YR           | Female       | BRA            |
| <u>Preferred Term</u>                                                                                                                                                                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Pressure Abnormal; Coordination Abnormal; Depression; Dizziness; Drug Ineffective; Drug Ineffective; Dysstasia; Ear Pain; Gait Disturbance; Major Depression; Memory Impairment | Frontal              |                    |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                                                                                                                                                                                       | Frontal Xr           |                    |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                                                                                                                                                                                       | Pristiq              |                    |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                                                                                                                                                                                       | Efexor Xr            |                    |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                                                                                                                                                                                       | Rivotril             |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                                                                                                                                                                                       | Lexotan              |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                                                                                                                                                                                       | Prozac               |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                                                                                                                                                                                       | Cymbalta             |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                                                                                                                                                                                       | Lexapro              |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
| Donaren                                                                                                                                                                               |                      |                    | S                  |                 | Unk                      |                      | Not Reported    |              |                |
| <u>FDA Received Date</u>                                                                                                                                                              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Aug-2014                                                                                                                                                                           | 10357609             | EXPEDITED (15-DAY) |                    | HO              | IT-TEVA-497664ISR        |                      | 28 YR           | Male         | ITA            |
| <u>Preferred Term</u>                                                                                                                                                                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Abuse; Sopor                                                                                                                                                                     | Lorazepam Dorom      |                    |                    | S               | Oral                     | 10 MI Daily;         |                 | Ivax         |                |
|                                                                                                                                                                                       | Entact 10 Mg         |                    |                    | S               | Oral                     | 560 Milligram Daily; |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Aug-2014                                                                                                                                                                           | 9972706              | EXPEDITED (15-DAY) |                    | HO              | IT-FRI-1000060283        |                      | 52 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                                                                                                                                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                 |                            |   |      |                           |              |
|-------------------------------------------------|----------------------------|---|------|---------------------------|--------------|
| Drug Abuse; Overdose;<br>Sopor; Suicide Attempt | Escitalopram Oral Solution | S | Oral | Overdose : 7.5ml          | Forest       |
|                                                 | Alprazolam                 | S | Oral | Overdose: 1 Bottle        | Not Reported |
|                                                 | Alprazolam                 | S | Oral | Overdose: About 10 Tablet | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Aug-2014              | 10347100      | EXPEDITED (15-DAY) |                    | HO              | PHHY2014FR091196     |                      | 88 YR      | Male       | FRA            |

  

| <u>Preferred Term</u>                                     | <u>Product</u>               | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------|------------------------------|--------------|------------|-------------|--------------|--------------------------|-----------------|--------------|
| Hepatitis; International<br>Normalised Ratio<br>Increased | Tareg                        |              |            | S           | Oral         | 40 Mg, Qd                |                 | Novartis     |
|                                                           | Diffu K                      |              |            | S           | Oral         | 3 Df, In One Hour        |                 | Not Reported |
|                                                           | Lasilix                      |              |            | S           | Oral         | 60 Mg, Tid               |                 | Not Reported |
|                                                           | Tahor                        |              |            | S           | Oral         | 10 Mg, Qd                |                 | Not Reported |
|                                                           | Cordarone                    |              |            | S           | Oral         | 200 Mg, (5 Df In 7 Days) |                 | Not Reported |
|                                                           | Doliprane                    |              |            | S           | Oral         | Unk Ukn, Unk             |                 | Not Reported |
|                                                           | Imovane                      |              |            | S           |              | 7.5 Mg, Qd               |                 | Not Reported |
|                                                           | Previscan (Fluindione)       |              |            | S           | Oral         | 20 Mg, (0.5 Df Qd)       |                 | Not Reported |
|                                                           | Seroplex                     |              |            | S           | Oral         | 10 Mg, Qd                |                 | Not Reported |
|                                                           | Seresta                      |              |            | C           |              | Unk Ukn, Unk             |                 | Not Reported |
|                                                           | Lansoyl                      |              |            | C           |              | Unk Ukn, Unk             |                 | Not Reported |
|                                                           | Transipeg /01618701/         |              |            | C           |              | Unk Ukn, Unk             |                 | Not Reported |
|                                                           | Voltarene//Diclofenac Sodium |              |            | C           |              | Unk Ukn, Unk             |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Aug-2014              | 10351797      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000069330    |                      | 91 YR      | Female     | FRA            |

  

| <u>Preferred Term</u> | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Haematoma             | Escitalopram           |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                       | Previscan (Fluindione) |              |            | S           | Oral         | 10 Mg              |                 | Not Reported |
|                       | Novonorm               |              |            | C           | Oral         | 1 Df               |                 | Not Reported |
|                       | Cordarone              |              |            | C           | Oral         | 85.7143 Mg         |                 | Not Reported |



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

|  |           |   |      |       |  |              |
|--|-----------|---|------|-------|--|--------------|
|  | Lasilix   | C | Oral |       |  | Not Reported |
|  | Lercan    | C | Oral | 10 Mg |  | Not Reported |
|  | Ideos     | C | Oral |       |  | Not Reported |
|  | Movicol   | C | Oral |       |  | Not Reported |
|  | Doliprane | C | Oral | 3 G   |  | Not Reported |

| <u>FDA Received Date</u>                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------|----------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 04-Aug-2014                             | 10359740             | EXPEDITED (15-DAY) |                    | OT              | CH-MERCK-2011SP038021 |                      | 38 YR           | Female       | CHE            |
| <u>Preferred Term</u>                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;<br>Serotonin Syndrome | Mirtazapine          |                    |                    | S               | Oral                  | 15 Mg, Qd At Bedtime |                 | Merck        |                |
|                                         | Mirtazapine          |                    |                    | S               |                       |                      |                 | Merck        |                |
|                                         | Escitalopram Oxalate |                    |                    | S               | Oral                  | 20 Mg, Qd            |                 | Not Reported |                |
|                                         | Escitalopram Oxalate |                    |                    | S               |                       |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------------------|-----------------|--------------|----------------|
| 04-Aug-2014                                                  | 10360632       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000069525    |                                  | 51 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Coma; Conduction<br>Disorder; Confusional<br>State; Overdose | Escitalopram   |                    |                    | S               | Oral                 | 10 Mg                            |                 | Forest       |                |
|                                                              | Baclofene      |                    |                    | S               | Oral                 | Overdose Of 90 To 120<br>Mg Once |                 | Not Reported |                |
|                                                              | Lexomil        |                    |                    | S               | Oral                 | 6 Mg                             |                 | Not Reported |                |
|                                                              | Lexomil        |                    |                    | S               | Oral                 | 15 Mg                            |                 | Not Reported |                |
|                                                              | Mianserin      |                    |                    | S               |                      |                                  |                 | Not Reported |                |
|                                                              | Xanax          |                    |                    | C               |                      | On Request                       |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 04-Aug-2014              | 10360636       | EXPEDITED (15-DAY) |                    | HO, OT          | IN-FRI-1000069513    |                      | 40 YR           | Female     | IND            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

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

|                                                                                                                                                |                |                            |                    |                 |                           |                      |                     |              |                        |
|------------------------------------------------------------------------------------------------------------------------------------------------|----------------|----------------------------|--------------------|-----------------|---------------------------|----------------------|---------------------|--------------|------------------------|
| Drooling; Dysarthria;<br>Extrapyramidal Disorder;<br>Gaze Palsy; Hypokinesia                                                                   |                | Escitalopram<br>Clonazepam |                    | S<br>S          |                           |                      | 0.5 Mg At Nighttime |              | Forest<br>Not Reported |
| <u>FDA Received Date</u>                                                                                                                       | <u>Case #</u>  | <u>Case Type</u>           | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>          | <u>Sex</u>   | <u>Country</u>         |
| 04-Aug-2014                                                                                                                                    | 10361143       | EXPEDITED (15-DAY)         | Y                  | OT              | JP-MYLAN-<br>2014S1017594 |                      |                     | Unknown      | JPN                    |
| <u>Preferred Term</u>                                                                                                                          | <u>Product</u> | <u>Comp.</u>               | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u>     | <u>Mfr</u>   |                        |
| Drug Interaction;<br>Electrocardiogram Qt<br>Prolonged; Ventricular<br>Fibrillation                                                            | Lansoprazole   |                            |                    | S               | Unknown                   | Unk                  |                     | Mylan        |                        |
|                                                                                                                                                | Escitalopram   |                            |                    | S               | Unknown                   | Unk                  |                     | Mylan        |                        |
|                                                                                                                                                | Aspirin        |                            |                    | C               | Unknown                   | Unk                  |                     | Not Reported |                        |
|                                                                                                                                                | Clopidogrel    |                            |                    | C               | Unknown                   | Unk                  |                     | Not Reported |                        |
|                                                                                                                                                | Atorvastatin   |                            |                    | C               | Unknown                   | Unk                  |                     | Not Reported |                        |
| <u>FDA Received Date</u>                                                                                                                       | <u>Case #</u>  | <u>Case Type</u>           | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>          | <u>Sex</u>   | <u>Country</u>         |
| 04-Aug-2014                                                                                                                                    | 10364359       | DIRECT                     | Y                  | OT              |                           |                      |                     | Male         | USA                    |
| <u>Preferred Term</u>                                                                                                                          | <u>Product</u> | <u>Comp.</u>               | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u>     | <u>Mfr</u>   |                        |
| Anxiety; Depressive<br>Symptom; Product<br>Substitution Issue                                                                                  | Escitalopram   |                            |                    | S               |                           | Lexapro 20mg Daily   |                     | Not Reported |                        |
|                                                                                                                                                | Cymbalta       |                            |                    | C               |                           |                      |                     | Not Reported |                        |
|                                                                                                                                                | Lamictal       |                            |                    | C               |                           |                      |                     | Not Reported |                        |
|                                                                                                                                                | Vyvanse        |                            |                    | C               |                           |                      |                     | Not Reported |                        |
| <u>FDA Received Date</u>                                                                                                                       | <u>Case #</u>  | <u>Case Type</u>           | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>          | <u>Sex</u>   | <u>Country</u>         |
| 04-Aug-2014                                                                                                                                    | 10364437       | DIRECT                     |                    |                 |                           |                      | 50 YR               | Female       | USA                    |
| <u>Preferred Term</u>                                                                                                                          | <u>Product</u> | <u>Comp.</u>               | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u>     | <u>Mfr</u>   |                        |
| Anger; Anxiety; Condition<br>Aggravated; Depression;<br>Drug Ineffective; Panic<br>Attack; Product<br>Substitution Issue;<br>Suicidal Ideation | Escitalopram   |                            |                    | S               | Oral                      | 1 Pill Per Day       |                     | Not Reported |                        |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>  | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------|------------------------------|--------------------|--------------------|-----------------|--------------------------------|--------------------------|-----------------|--------------|----------------|
| 04-Aug-2014               | 10365292                     | EXPEDITED (15-DAY) | Y                  | LT              | AUR-APL-2014-08103             |                          | 55 YR           | Male         | USA            |
| <u>Preferred Term</u>     | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Culture Positive;   | Escitalopram 20 Mg           |                    |                    | S               |                                |                          |                 | Not Reported |                |
| Cerebral Haemorrhage;     | (Escitalopram) Unknown, 20mg |                    |                    |                 |                                |                          |                 |              |                |
| Drug Interaction;         | Fentanyl (Fentanyl)          |                    |                    | S               |                                |                          |                 | Not Reported |                |
| Enterococcal Infection;   | Linezolid (Linezolid)        |                    |                    | S               |                                |                          |                 | Not Reported |                |
| Platelet Dysfunction;     | Trazodone (Trazodone)        |                    |                    | S               |                                |                          |                 | Not Reported |                |
| Serotonin Syndrome;       | Piperacillina/Tazobactam     |                    |                    | C               |                                |                          |                 | Not Reported |                |
| Small Intestinal          | (Piperacillin Sodium,        |                    |                    |                 |                                |                          |                 |              |                |
| Obstruction; Unresponsive | Tazobactam Sodium)           |                    |                    |                 |                                |                          |                 |              |                |
| To Stimuli                | Vancomycin (Vancomycin)      |                    |                    | C               |                                |                          |                 | Not Reported |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Aug-2014               | 10366156                     | EXPEDITED (15-DAY) | Y                  | HO, LT          | JP2014K2966LIT                 |                          | 46 YR           | Male         | JPN            |
| <u>Preferred Term</u>     | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Acute Myocardial          | Lansoprazole World           |                    |                    | S               |                                | Unknown Daily Dosage     |                 | Not Reported |                |
| Infarction; Drug          | (Lansoprazole) Unknown       |                    |                    |                 |                                | Unknown Rt Of            |                 |              |                |
| Interaction;              |                              |                    |                    |                 |                                | Administration Unknown   |                 |              |                |
| Electrocardiogram Qt      |                              |                    |                    |                 |                                | Therapy Date             |                 |              |                |
| Prolonged; Sedation;      | Escitalopram World           |                    |                    | S               |                                | Unknown Daily Dosage     |                 | Not Reported |                |
| Ventricular Fibrillation  | (Escitalopram) Unknown       |                    |                    |                 |                                | (Route Of Administration |                 |              |                |
|                           |                              |                    |                    |                 |                                | Unknown Unknown          |                 |              |                |
|                           |                              |                    |                    |                 |                                | Therapy Dates            |                 |              |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Aug-2014               | 10280540                     | EXPEDITED (15-DAY) |                    | OT              | US-009507513-<br>1407USA002407 |                          |                 | Female       | USA            |
| <u>Preferred Term</u>     | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Lymphoma; Nausea          | Januvia                      |                    |                    | S               | Oral                           | Dosage Form: 50 Mg, Bid  |                 | Merck        |                |
|                           | Lorazepam                    |                    |                    | C               |                                |                          |                 | Not Reported |                |
|                           | Omeprazole                   |                    |                    | C               |                                |                          |                 | Merck        |                |
|                           | Valacyclovir Hydrochloride   |                    |                    | C               |                                |                          |                 | Not Reported |                |

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

|         |   |     |              |
|---------|---|-----|--------------|
| Aspirin | C | Unk | Not Reported |
| Lexapro | S | 40  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 05-Aug-2014              | 10338157      | EXPEDITED (15-DAY) |                    | HO, OT          | US-JNJFOC-20140710506 |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>                   | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction;<br>Serotonin Syndrome | Tramadol Hydrochloride |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                         | Fentanyl               |              |            | S           | Transdermal  |                    |                 | Not Reported |
|                                         | Citalopram             |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                         | Fluoxetine             |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                         | Sertraline             |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                         | Escitalopram           |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                         | Paroxetine             |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                         | Venlafaxine            |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                         | Duloxetine             |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                         | Trazodone              |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                         | Mirtazapine            |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                         | Buspirone              |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                         | Clomipramine           |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                         | Ondansetron            |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                         | Metoclopramide         |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                         | Granisetron            |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                         | Meperidine             |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                         | Methadone              |              |            | S           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Aug-2014              | 10365206      | EXPEDITED (15-DAY) |                    | OT              | PHHY2014KR093900     |                      | 62 YR      | Male       | KOR            |

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

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

|                                                                                                                                                                                                      |                |   |                                       |                                                          |  |  |  |              |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|---|---------------------------------------|----------------------------------------------------------|--|--|--|--------------|
| Clonus; Depressed Level Of Consciousness; Dizziness; Drug Interaction; Gaze Palsy; Headache; Heart Rate Increased; Nausea; Seizure; Serotonin Syndrome; Tachycardia; Tremor; Unresponsive To Stimuli | Escitalopram   | S |                                       |                                                          |  |  |  | Not Reported |
|                                                                                                                                                                                                      | Tramadol       | S | Intramuscular                         | 100 Mg, Unk                                              |  |  |  | Not Reported |
|                                                                                                                                                                                                      | Tramadol       | S | Intravenous (not otherwise specified) | 100 Mg, Unk                                              |  |  |  | Not Reported |
|                                                                                                                                                                                                      | Tramadol       | S | Intravenous (not otherwise specified) | Tramadol 100 Mg And Normal Saline 100 MI Over 10 Minutes |  |  |  | Not Reported |
|                                                                                                                                                                                                      | Ketorolac      | S |                                       |                                                          |  |  |  | Novartis     |
|                                                                                                                                                                                                      | Fentanyl       | S |                                       | 1000 Ug, Unk                                             |  |  |  | Not Reported |
|                                                                                                                                                                                                      | Fentanyl       | S | Intravenous drip                      | 0.3 Ug/Kg/H                                              |  |  |  | Not Reported |
|                                                                                                                                                                                                      | Fentanyl       | S | Intravenous bolus                     | 0.15 Ug/Kg/H                                             |  |  |  | Not Reported |
|                                                                                                                                                                                                      | Remifentanyl   | C | Intravenous drip                      | 200 Ug/Hr, Unk                                           |  |  |  | Not Reported |
|                                                                                                                                                                                                      | Propofol       | C | Intravenous (not otherwise specified) | 2 Mg/Kg, Unk                                             |  |  |  | Not Reported |
|                                                                                                                                                                                                      | Rocuronium     | C | Intravenous (not otherwise specified) | 0.8 Mg/Kg, Unk                                           |  |  |  | Not Reported |
|                                                                                                                                                                                                      | Rocuronium     | C |                                       | 15 Mg Was Injected Every Hour                            |  |  |  | Not Reported |
|                                                                                                                                                                                                      | Sevoflurane    | C |                                       |                                                          |  |  |  | Not Reported |
|                                                                                                                                                                                                      | Phenylephrine  | C | Intravenous drip                      | 80 Ug, Unk                                               |  |  |  | Not Reported |
|                                                                                                                                                                                                      | Ephedrine      | C | Intravenous drip                      | 10 Mg, Unk                                               |  |  |  | Not Reported |
|                                                                                                                                                                                                      | Normal Saline  | C |                                       | 950 MI, Unk                                              |  |  |  | Not Reported |
|                                                                                                                                                                                                      | Pyridostigmine | C | Intravenous (not otherwise specified) | 15 Mg, Unk                                               |  |  |  | Not Reported |
|                                                                                                                                                                                                      | Glycopyrrolate | C | Intravenous (not otherwise specified) | 0.4 Mg, Unk                                              |  |  |  | Not Reported |
|                                                                                                                                                                                                      | Buspirone      | C |                                       |                                                          |  |  |  | Not Reported |
|                                                                                                                                                                                                      | Quetiapine     | C |                                       |                                                          |  |  |  | Not Reported |
|                                                                                                                                                                                                      | Clonazepam     | C |                                       |                                                          |  |  |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 06-Aug-2014              | 10365210       | EXPEDITED (15-DAY) |                    | HO, OT          | CH-TEVA-498377ISR    |                      | 38 YR           | Female     | CHE            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

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

|                                                                                                          |              |   |         |                                            |      |
|----------------------------------------------------------------------------------------------------------|--------------|---|---------|--------------------------------------------|------|
| Abnormal Sleep-Related Event; Drug Interaction; Persecutory Delusion; Serotonin Syndrome; Suspiciousness | Escitalopram | S | Unknown | [Progressively Increased]; Up To 20 Mg/Day | Ivax |
|                                                                                                          | Escitalopram | S |         |                                            | Ivax |
|                                                                                                          | Mirtazapine  | S | Unknown | 15 Mg/Day; At Bedtime                      | Teva |
|                                                                                                          | Mirtazapine  | S | Unknown | 15 Mg/Day; At Bedtime                      | Teva |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 06-Aug-2014                       | 10365908               | EXPEDITED (15-DAY)        |                             | CA, DE                   | US-FRI-1000069544             |                               | < 1 DAY             | Male                | USA                     |

| <a href="#">Preferred Term</a>                       | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|------------------------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Congenital Renal Disorder; Encephalomalacia; Seizure | Lexapro                 |                       |                     | S                    | Transplacental        |                             |                          | Forest              |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 06-Aug-2014                       | 10365928               | EXPEDITED (15-DAY)        |                             | CA, DE                   | US-FRI-1000069549             |                               | < 1 DAY             | Male                | USA                     |

| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|-----------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Congenital Cardiovascular Anomaly | Lexapro                 |                       |                     | S                    | Transplacental        |                             |                          | Forest              |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 06-Aug-2014                       | 10366639               | EXPEDITED (15-DAY)        |                             | HO, LT                   | FR-FRI-1000069651             |                               | 40 YR               | Female              | FRA                     |

| <a href="#">Preferred Term</a>            | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a>      | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|-------------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|----------------------------------|--------------------------|---------------------|
| Anaemia; Coma; Overdose; Thrombocytopenia | Escitalopram            |                       |                     | S                    | Oral                  |                                  |                          | Forest              |
|                                           | Topiramate              |                       |                     | S                    | Oral                  |                                  |                          | Not Reported        |
|                                           | Zyprexa                 |                       |                     | S                    | Oral                  |                                  |                          | Not Reported        |
|                                           | Teralithe               |                       |                     | S                    | Oral                  |                                  |                          | Not Reported        |
|                                           |                         |                       |                     |                      |                       | Overdose Of An Unknown Dose Once |                          |                     |
|                                           | Fluoxetine              |                       |                     | S                    | Oral                  |                                  |                          | Not Reported        |
|                                           | Clomipramine            |                       |                     | S                    | Oral                  |                                  |                          | Not Reported        |

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

|                                                                                                                               |                |                    |                    |                 |                      |                                  |                 |              |                |
|-------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------------------|-----------------|--------------|----------------|
| Alprazolam                                                                                                                    |                |                    | S                  |                 | Oral                 |                                  | Not Reported    |              |                |
| <u>FDA Received Date</u>                                                                                                      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Aug-2014                                                                                                                   | 10367596       | DIRECT             |                    |                 |                      |                                  | 35 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                         | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Condition Aggravated; Depression; Economic Problem; Product Substitution Issue; Therapeutic Product Effect Decreased | Lexapro        |                    |                    | S               | Oral                 | 1 Pill Once Daily Taken By Mouth |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Aug-2014                                                                                                                   | 9402596        | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000046678    |                                  | 51 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                         | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Agranulocytosis                                                                                                               | Escitalopram   |                    |                    | S               | Oral                 | 10 Mg                            |                 | Forest       |                |
|                                                                                                                               | Lamictal       |                    |                    | S               | Oral                 | 25 Mg                            |                 | Not Reported |                |
|                                                                                                                               | Lamictal       |                    |                    | S               | Oral                 | 150 Mg                           |                 | Not Reported |                |
|                                                                                                                               | Kenzen         |                    |                    | S               | Oral                 | 4 Mg                             |                 | Not Reported |                |
|                                                                                                                               | Prozac         |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                               | Imovane        |                    |                    | C               | Oral                 | 7.5 Mg                           |                 | Not Reported |                |
|                                                                                                                               | Mopral         |                    |                    | C               | Oral                 | On Request                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Aug-2014                                                                                                                   | 10367681       | EXPEDITED (15-DAY) |                    | HO              | IT-FRI-1000069652    |                                  | 80 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                                                                         | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Bradyphrenia; Drug Interaction; Headache; Hypothyroidism; Toxicity To Various Agents;                                         | Escitalopram   |                    |                    | S               | Oral                 | 10 Mg                            |                 | Forest       |                |
|                                                                                                                               | Carbolithium   |                    |                    | S               | Oral                 | 600 Mg                           |                 | Not Reported |                |
|                                                                                                                               | Lamictal       |                    |                    | C               | Oral                 | 25 Mg                            |                 | Not Reported |                |

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

|        |                |   |      |         |              |
|--------|----------------|---|------|---------|--------------|
| Tremor | Novonorm       | C | Oral | 1 Mg    | Not Reported |
|        | Depakin-Chrono | C | Oral | 300 Mg  | Not Reported |
|        | Lendormin      | C | Oral | 0.25 Mg | Not Reported |
|        | Zocor          | C | Oral | 20 Mg   | Not Reported |

| <u>FDA Received Date</u>                                               | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 07-Aug-2014                                                            | 10368328       | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2014219225 |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Feeling Abnormal;<br>Headache; Nausea;<br>Nervousness;<br>Sluggishness | Chantix        |                  |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                                                                        | Lexapro        |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |

| <u>FDA Received Date</u>                                             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|---------------------------------------|----------------------|-----------------|--------------|----------------|
| 07-Aug-2014                                                          | 10368782       | EXPEDITED (15-DAY) |                    | HO, OT          | US-MYLANLABS-2014M1000121             |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cerebral Haemorrhage;<br>Platelet Dysfunction;<br>Serotonin Syndrome | Escitalopram   |                    |                    | S               |                                       | 20 Mg, Unk           |                 | Not Reported |                |
|                                                                      | Trazodone      |                    |                    | S               |                                       |                      |                 | Not Reported |                |
|                                                                      | Linezolid      |                    |                    | S               |                                       |                      |                 | Not Reported |                |
|                                                                      | Fentanyl       |                    |                    | S               | Intravenous (not otherwise specified) |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>             | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------|-----------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 07-Aug-2014                          | 10378253                    | EXPEDITED (15-DAY) | Y                  | OT              | 2014HINLIT0686       |                      | 27 YR           | Female       | ARE            |
| <u>Preferred Term</u>                | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Breast Engorgement;<br>Galactorrhoea | Escitalopram (Escitalopram) |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                      | Unknown                     |                    |                    |                 |                      |                      |                 |              |                |
|                                      | Clonazepam                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                      | Agomelantine                |                    |                    | C               |                      |                      |                 | Not Reported |                |



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

| <a href="#">FDA Received Date</a>                                                                                                                                                                                                                                                                                             | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>    | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|----------------------------------|--------------------------|---------------------|-------------------------|
| 08-Aug-2014                                                                                                                                                                                                                                                                                                                   | 10374577                | DIRECT                    |                             |                          |                               |                                  | 29 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>                                                                                                                                                                                                                                                                                                | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>      | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Decreased Activity; Depression; Loss Of Libido; Sexual Dysfunction; Suicidal Ideation                                                                                                                                                                                                                                         | Escitalopram 20 Mg Teva |                           |                             | S                        | Oral                          | 1 Pill Once Daily Taken By Mouth |                          | Teva                |                         |
| <a href="#">FDA Received Date</a>                                                                                                                                                                                                                                                                                             | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>    | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 11-Aug-2014                                                                                                                                                                                                                                                                                                                   | 10344942                | EXPEDITED (15-DAY)        | Y                           | DE, OT                   | AUR-APL-2014-07832            |                                  | 45 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                                                                                                                                                                                                                                                                | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>      | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Blood Pressure Increased; Brain Oedema; Cerebral Infarction; Clonus; Coma; Condition Aggravated; Confusional State; Decerebrate Posture; Headache; Heart Rate Abnormal; Hyperreflexia; Muscle Rigidity; Posterior Reversible Encephalopathy Syndrome; Reversible Cerebral Vasoconstriction Syndrome; Subarachnoid Haemorrhage | Escitalopram            |                           |                             | S                        |                               |                                  |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                                                                                                                                                                                                                             | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>    | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 11-Aug-2014                                                                                                                                                                                                                                                                                                                   | 10375654                | EXPEDITED (15-DAY)        |                             | HO                       | IT-TEVA-499003ISR             |                                  | 80 YR                    | Female              | ITA                     |
| <a href="#">Preferred Term</a>                                                                                                                                                                                                                                                                                                | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>      | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Bradyphrenia; Drug Interaction; Headache;                                                                                                                                                                                                                                                                                     | Carbolithium 300mg      |                           |                             | S                        | Oral                          | 2 Dosage Forms Daily;            |                          | Barr                |                         |

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

|                                                    |                       |   |      |                       |              |
|----------------------------------------------------|-----------------------|---|------|-----------------------|--------------|
| Hypothyroidism; Toxicity To Various Agents; Tremor | Ciprallex 10 Mg       | S | Oral | 1 Dosage Forms Daily; | Not Reported |
|                                                    | Lamictal 25 Mg        | C | Oral | 1 Dosage Forms Daily; | Not Reported |
|                                                    | Novonorm 1 Mg         | C | Oral | 1 Dosage Forms Daily; | Not Reported |
|                                                    | Depakin Chrono 300 Mg | C | Oral | 1 Dosage Forms Daily; | Not Reported |
|                                                    | Zocor 20 Mg           | C | Oral | 1 Dosage Forms Daily; | Not Reported |
|                                                    | Lendormin 0.25 Mg     | C |      | 1 Dosage Forms Daily; | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 11-Aug-2014              | 10375689      | NON-EXPEDITED    |                    |                 | US-ENDO<br>PHARMACEUTICALS<br>INC.-LISI20140038 |                      | 68 YR      | Female     | USA            |

| <u>Preferred Term</u>    | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|--------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cough; Throat Irritation | Lisinopril Tablets |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                          | Escitalopram       |              |            | S           | Oral         |                    |                 | Not Reported |
|                          | Trileptal          |              |            | C           | Unknown      | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------------|----------------------|------------|------------|----------------|
| 11-Aug-2014              | 10376151      | NON-EXPEDITED    |                    |                 | US-ASTRAZENECA-<br>2013SE63681 |                      | 64 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Acne; Acne; Anxiety; Feeling Abnormal; Insomnia; Joint Swelling; Nasal Oedema; Seborrhoea | Arimidex       |              |            | S           | Oral         |                    |                 | Zeneca       |
|                                                                                           | Lexapro        |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                           | Aromasin       |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                           | Femara         |              |            | S           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Aug-2014              | 10376597      | NON-EXPEDITED    |                    | OT              | US-FRI-1000069780    |                      | 36 YR      | Male       | USA            |

| <u>Preferred Term</u>                        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|----------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Balance Disorder; Dizziness; Ear Discomfort; | Lexapro        |              |            | S           | Oral         | 10 Mg              |                 | Forest     |

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

Fatigue; Feeling  
Abnormal; Gait  
Disturbance; Tinnitus;  
Tunnel Vision

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 11-Aug-2014                       | 10379310               | DIRECT                    |                             |                          |                               |                               | 66 YR               | Male                | USA                     |

| <a href="#">Preferred Term</a>                                                                     | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|----------------------------------------------------------------------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Anxiety; Condition<br>Aggravated; Depression;<br>Personality Change;<br>Product Substitution Issue | Lexapro                 |                       |                     | S                    |                       |                             |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 11-Aug-2014                       | 10381316               | EXPEDITED (15-DAY)        |                             | OT                       | 2014JUB00072                  |                               | 42 YR               | Male                | GBR                     |

| <a href="#">Preferred Term</a>                                          | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|-------------------------------------------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Aggression; Alcohol<br>Abuse; Anxiety; Impulsive<br>Behaviour; Paranoia | Escitalopram            |                       |                     | S                    |                       |                             |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 11-Aug-2014                       | 10381331               | EXPEDITED (15-DAY)        | Y                           | LT, OT                   | 2014JUB00071                  |                               | 41 YR               | Female              | GBR                     |

| <a href="#">Preferred Term</a>                                                                                  | <a href="#">Product</a>                | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|-----------------------------------------------------------------------------------------------------------------|----------------------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Alcohol Abuse;<br>Alcoholism; Impaired<br>Driving Ability;<br>Imprisonment; Mania;<br>Suicidal Ideation; Tremor | Escitalopram (Escitalopram)<br>Unknown |                       |                     | S                    |                       |                             |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 11-Aug-2014                       | 10381350               | EXPEDITED (15-DAY)        | Y                           | OT                       | 2014JUB00070                  |                               | 48 YR               | Female              | GBR                     |

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

| <u>Preferred Term</u>                                                                                                                                                                                | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|---------------------------------------|-------------------------|-----------------|--------------|----------------|
| Aggression; Alcoholism; Behaviour Disorder; Decreased Interest; Disturbance In Social Behaviour                                                                                                      | Escitalopram                |                    |                    | S               |                                       |                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                             | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Aug-2014                                                                                                                                                                                          | 10382332                    | EXPEDITED (15-DAY) | Y                  | HO              | 2472796                               |                         | 55 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Cerebral Haemorrhage; Drug Interaction; Enterococcal Infection; Intraventricular Haemorrhage; Pain; Platelet Count Decreased; Platelet Dysfunction; Serotonin Syndrome; Small Intestinal Obstruction | Fentanyl Citrate            |                    |                    | S               | Intravenous (not otherwise specified) | Not Otherwise Specified |                 | Not Reported |                |
|                                                                                                                                                                                                      | Linezolid                   |                    |                    | S               |                                       |                         |                 | Not Reported |                |
|                                                                                                                                                                                                      | Escitalopram                |                    |                    | S               |                                       |                         |                 | Not Reported |                |
|                                                                                                                                                                                                      | Trazodone                   |                    |                    | S               |                                       |                         |                 | Not Reported |                |
|                                                                                                                                                                                                      | Vancomycin                  |                    |                    | C               |                                       |                         |                 | Not Reported |                |
|                                                                                                                                                                                                      | Piperacillin And Tazobactam |                    |                    | C               |                                       |                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                             | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Aug-2014                                                                                                                                                                                          | 10378719                    | EXPEDITED (15-DAY) |                    |                 | US-FRI-1000069785                     |                         |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Parkinson'S Disease                                                                                                                                                                                  | Escitalopram                |                    |                    | S               |                                       |                         |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                                                                                             | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Aug-2014                                                                                                                                                                                          | 10379346                    | EXPEDITED (15-DAY) |                    | HO              | US-FRI-1000069797                     |                         | 55 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Cerebral Haemorrhage; Drug Interaction; Platelet Dysfunction; Serotonin Syndrome                                                                                                                     | Escitalopram                |                    |                    | S               |                                       |                         |                 | Forest       |                |
|                                                                                                                                                                                                      | Linezolid                   |                    |                    | S               |                                       |                         |                 | Not Reported |                |
|                                                                                                                                                                                                      | Trazodone                   |                    |                    | S               |                                       |                         |                 | Not Reported |                |

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|          |   |                                       |              |
|----------|---|---------------------------------------|--------------|
| Fentanyl | S | Intravenous (not otherwise specified) | Not Reported |
|----------|---|---------------------------------------|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Aug-2014              | 10380375      | DIRECT           |                    |                 |                      |                      | 48 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u> |
|---------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|------------|
| Anxiety; Depression; Drug Ineffective; Panic Attack; Product Substitution Issue | Lexapro        |              |            | S           | Oral         | 1 Pill Once Daily Taken By Mouth |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Aug-2014              | 10385722      | EXPEDITED (15-DAY) | Y                  | LT, OT          | 2014JUB00078         |                      | 65 YR      | Male       | BEL            |

| <u>Preferred Term</u>                                                                                                                                                  | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Apnoea; Electrocardiogram R On T Phenomenon; Hypokalaemia; Inhibitory Drug Interaction; Loss Of Consciousness; Pallor; Torsade De Pointes; Unevaluable Event; Vomiting | Escitalopram (Escitalopram) |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                        | Tacrolimus (Tacrolimus)     |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                        | Omeprazole (Omeprazole)     |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                        | Sotalol (Sotalol)           |              |            | S           |              | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Aug-2014              | 10380954      | EXPEDITED (15-DAY) |                    | OT              | JP-FRI-1000069791    |                      | 72 YR      | Female     | JPN            |

| <u>Preferred Term</u>         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Liver Function Test Increased | Lexapro        |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                               | Livalo         |              |            | C           | Oral         | 2 Mg               |                 | Not Reported |
|                               | Lipidil        |              |            | C           |              | 80 Mg              |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                              | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------|----------------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|-----------------|----------------|
| 13-Aug-2014                                                                                                                           | 10381898                   | EXPEDITED (15-DAY) |                    | DS, HO, LT      | NO-GLAXOSMITHKLINE-B1023176A |                      | 24 YR           | Female          | NOR            |
| <u>Preferred Term</u>                                                                                                                 | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Anxiety; Delusion;                                                                                                                    | Lamictal                   |                    |                    | S               |                              | 25mg Per Day         |                 | Glaxosmithkline |                |
| Depression; Incoherent;                                                                                                               | Lamictal                   |                    |                    | S               | Unknown                      | 50mg Per Day         |                 | Glaxosmithkline |                |
| Mania; Psychotic Disorder;                                                                                                            | Cipralext                  |                    |                    | S               |                              | 10mg Per Day         |                 | Glaxosmithkline |                |
| Substance-Induced Psychotic Disorder;                                                                                                 |                            |                    |                    |                 |                              |                      |                 |                 |                |
| Suicidal Ideation                                                                                                                     |                            |                    |                    |                 |                              |                      |                 |                 |                |
| <u>FDA Received Date</u>                                                                                                              | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 13-Aug-2014                                                                                                                           | 10382517                   | EXPEDITED (15-DAY) |                    | OT              | CA-FRI-1000069789            |                      |                 | Female          | CAN            |
| <u>Preferred Term</u>                                                                                                                 | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Diarrhoea; Hallucination;                                                                                                             | Escitalopram               |                    |                    | S               | Oral                         | 5 Mg                 |                 | Forest          |                |
| Muscle Spasms; Muscle Tightness; Muscle Twitching; Nausea; Restlessness; Serotonin Syndrome; Skin Burning Sensation; Tremor; Vomiting | Effexor Xr                 |                    |                    | S               | Oral                         | 37.5 Mg              |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                              | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 13-Aug-2014                                                                                                                           | 10382519                   | EXPEDITED (15-DAY) |                    | HO              | IT-FRI-1000069792            |                      | 40 YR           | Female          | ITA            |
| <u>Preferred Term</u>                                                                                                                 | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Drug Abuse; Overdose; Tachycardia                                                                                                     | Escitalopram Oral Solution |                    |                    | S               | Oral                         | Overdose: 15 Ml      |                 | Forest          |                |
|                                                                                                                                       | Mirtazapine                |                    |                    | S               | Oral                         | Overdose: 300 Mg     |                 | Not Reported    |                |
|                                                                                                                                       | Entact                     |                    |                    | C               |                              | 10 Mg                |                 | Not Reported    |                |

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| <u>FDA Received Date</u>                            | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------|--------------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------------------------------------------------------------|-----------------|--------------|----------------|
| 13-Aug-2014                                         | 10385004                       | DIRECT             |                    |                 |                      |                                                                                     | 26 YR           | Female       | USA            |
| <u>Preferred Term</u>                               | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Body Fat Disorder; Weight Increased                 | Escitalopram                   |                    |                    | S               | Oral                 | 1 Pill Once Daily Taken By Mouth                                                    |                 | Torrent      |                |
| <u>FDA Received Date</u>                            | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Aug-2014                                         | 10351143                       | EXPEDITED (15-DAY) |                    | DE, HO          | FR-SA-2014SA100500   |                                                                                     | 88 YR           | Male         | FRA            |
| <u>Preferred Term</u>                               | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Hepatitis; International Normalised Ratio Increased | Lasilix                        |                    |                    | S               | Oral                 |                                                                                     |                 | Not Reported |                |
|                                                     | Cordarone                      |                    |                    | S               | Oral                 | Start Date: Long Course, Dose: 1 Df, 5 In 7 Day                                     |                 | Not Reported |                |
|                                                     | Imovane                        |                    |                    | S               | Oral                 | Start Date: Long Course, Dose: 1 Df, 1 In 1 Day                                     |                 | Not Reported |                |
|                                                     | Paracetamol                    |                    |                    | S               | Oral                 | Start Date: Long Course                                                             |                 | Not Reported |                |
|                                                     | Diffu K                        |                    |                    | S               | Oral                 | Dose: 1 Df, 3 In 1 Hour                                                             |                 | Not Reported |                |
|                                                     | Tahor                          |                    |                    | S               | Oral                 | Start Date: Long Course, Tahor 10 Mg, Film Coated Tablet , 1 Df (1 Df , 1 In 1 Day) |                 | Not Reported |                |
|                                                     | Previscan (Fluindione)         |                    |                    | S               | Oral                 | Previscan 20 Mg, Comprime Secable, Dose: 0.5 Df (0.5 Df, 1 In 1 Jour(S))            |                 | Not Reported |                |
|                                                     | Tareg                          |                    |                    | S               | Oral                 | Start Date: Long Course                                                             |                 | Not Reported |                |
|                                                     | Seroplex                       |                    |                    | S               | Oral                 |                                                                                     |                 | Not Reported |                |
|                                                     | Oxazepam                       |                    |                    | C               |                      |                                                                                     |                 | Not Reported |                |
|                                                     | Oxazepam                       |                    |                    | C               |                      |                                                                                     |                 | Not Reported |                |
|                                                     | Lansoyl                        |                    |                    | C               |                      |                                                                                     |                 | Not Reported |                |
|                                                     | Doliprane                      |                    |                    | C               |                      |                                                                                     |                 | Not Reported |                |
|                                                     | Transipeg (Polyethylene Glycol |                    |                    | C               |                      |                                                                                     |                 | Not Reported |                |

# FDA Adverse Event Reporting System

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### Detailed Report

3350\Potassium  
Chloride\Sodium  
Bicarbonate\Sodium  
Chloride\Sodium Sulfate  
Anhydrous)  
Voltarene (Diclofenac Sodium)

C

Not Reported

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 14-Aug-2014              | 10384293      | NON-EXPEDITED    |                    | OT              | US-PFIZER INC-<br>2014225920 |                      | 64 YR      | Female     | USA            |

| <u>Preferred Term</u>             | <u>Product</u>  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------|-----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Electrocardiogram Qt<br>Prolonged | Fluconazole     |              |            | S           |              | Unk                |                 | Pfizer       |
|                                   | Ondansetron Hcl |              |            | S           |              | Unk                |                 | Pfizer       |
|                                   | Escitalopram    |              |            | S           |              | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Aug-2014              | 10384486      | EXPEDITED (15-DAY) |                    | OT              | CH-FRI-1000069788    |                      |            | Female     | CHE            |

| <u>Preferred Term</u>                   | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hepatocellular Injury; Off<br>Label Use | Escitalopram        |              |            | S           | Oral         | 20 Mg              |                 | Forest       |
|                                         | Escitalopram        |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                         | Zyprexa             |              |            | S           | Oral         | 2.5 Mg             |                 | Not Reported |
|                                         | Zyprexa             |              |            | S           | Oral         | 1.25 Mg            |                 | Not Reported |
|                                         | Co-Dafalgan         |              |            | S           | Oral         | 2000 Mg            |                 | Not Reported |
|                                         | Voltaren            |              |            | S           | Oral         | 150 Mg             |                 | Not Reported |
|                                         | Dalmadorm           |              |            | C           | Oral         | 30 Mg              |                 | Not Reported |
|                                         | Temesta (Lorazepam) |              |            | C           | Oral         |                    |                 | Not Reported |
| Tranxilium                              |                     |              | C          | Oral        | 5 Mg         |                    | Not Reported    |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Aug-2014              | 10384681      | EXPEDITED (15-DAY) |                    | HO              | PHHY2014IT096957     |                      | 40 YR      | Female     | ITA            |



# FDA Adverse Event Reporting System

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| <u>Preferred Term</u>                                                                         | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |                |
|-----------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|---------------------------------------|----------------------------------------|-----------------|--------------|----------------|
| Drug Abuse; Tachycardia                                                                       | Mirtazapine               |                    |                    | S               | Oral                                  | 300 Mg, Once/Single                    |                 | Novartis     |                |
|                                                                                               | Escitalopram              |                    |                    | S               | Oral                                  | 15 Ml, Once/Single                     |                 | Not Reported |                |
|                                                                                               | Entact                    |                    |                    | C               |                                       |                                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                      | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Aug-2014                                                                                   | 10385567                  | EXPEDITED (15-DAY) |                    | DE, OT          | US-BAXTER-2014BAX046552               |                                        | 55 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                         | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Culture Positive; Cerebral Haemorrhage                                                  | Vancomycin Injection, Usp |                    |                    | S               | Unknown                               |                                        |                 | Baxter       |                |
|                                                                                               | Piperacillin-Tazobactam   |                    |                    | S               |                                       |                                        |                 | Not Reported |                |
|                                                                                               | Linezolid                 |                    |                    | S               | Unknown                               |                                        |                 | Not Reported |                |
|                                                                                               | Fentanyl                  |                    |                    | S               | Intravenous (not otherwise specified) |                                        |                 | Not Reported |                |
|                                                                                               | Escitalopram              |                    |                    | S               | Unknown                               |                                        |                 | Not Reported |                |
|                                                                                               | Trazodone                 |                    |                    | S               | Unknown                               |                                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                      | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Aug-2014                                                                                   | 10386970                  | DIRECT             |                    |                 |                                       |                                        | 22 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                         | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Insomnia; Nausea; Paraesthesia; Psychomotor Hyperactivity; Restlessness; Somnolence; Vomiting | Escitalopram              |                    |                    | S               | Oral                                  | 1 Pill Daily Once Daily Taken By Mouth |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                      | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Aug-2014                                                                                   | 10390649                  | EXPEDITED (15-DAY) | Y                  | HO              | AUR-APL-2014-08418                    |                                        | 40 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                                         | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |                |

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

|                         |                               |   |      |                    |              |
|-------------------------|-------------------------------|---|------|--------------------|--------------|
| Drug Abuse; Tachycardia | Mirtazapine (Mirtazapine)     | S | Oral | 300mg, Total, Oral | Not Reported |
|                         | Escitalopram (Escitalopram)   | S | Oral | 15ml, Single, Oral | Not Reported |
|                         | Entact (Escitalopram Oxalate) | C |      |                    | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 15-Aug-2014              | 9931759       | EXPEDITED (15-DAY) |                    | OT              | AT-JNJFOC-20140211497 |                      | 48 YR      | Male       | AUT            |

| <u>Preferred Term</u>                                                        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|----------------------|-----------------|--------------|
| Hyperprolactinaemia;<br>Thrombophlebitis;<br>Thrombosis; Weight<br>Increased | Risperdal      |              |            | S           | Oral         |                      |                 | Not Reported |
|                                                                              | Risperdal      |              |            | S           | Oral         |                      |                 | Not Reported |
|                                                                              | Cipralex       |              |            | S           | Unknown      |                      |                 | Not Reported |
|                                                                              | Mirtabene      |              |            | S           | Unknown      |                      |                 | Not Reported |
|                                                                              | Mirtabene      |              |            | S           | Unknown      |                      |                 | Not Reported |
|                                                                              | Mirtabene      |              |            | S           | Unknown      | Started Since Months |                 | Not Reported |
|                                                                              | Mirtabene      |              |            | S           | Unknown      |                      |                 | Not Reported |
|                                                                              | Lyrica         |              |            | S           | Unknown      |                      |                 | Not Reported |
|                                                                              | Lyrica         |              |            | S           | Unknown      |                      |                 | Not Reported |
|                                                                              | Lyrica         |              |            | S           | Unknown      |                      |                 | Not Reported |
|                                                                              | Lyrica         |              |            | S           | Unknown      |                      |                 | Not Reported |
|                                                                              | Doxazosin      |              |            | S           | Unknown      |                      |                 | Not Reported |
|                                                                              | Doxazosin      |              |            | S           | Unknown      |                      |                 | Not Reported |
|                                                                              | Lamictal       |              |            | C           | Unknown      |                      |                 | Not Reported |
|                                                                              | Lamictal       |              |            | C           | Unknown      |                      |                 | Not Reported |
|                                                                              | Lamictal       |              |            | C           | Unknown      |                      |                 | Not Reported |
|                                                                              | Lamictal       |              |            | C           | Unknown      |                      |                 | Not Reported |
|                                                                              | Sertraline     |              |            | C           | Unknown      |                      |                 | Not Reported |
|                                                                              | Sertraline     |              |            | C           | Unknown      |                      |                 | Not Reported |
|                                                                              | Cipralex       |              |            | C           | Unknown      |                      |                 | Not Reported |
|                                                                              | Cipralex       |              |            | C           | Unknown      |                      |                 | Not Reported |
|                                                                              | Cipralex       |              |            | C           | Unknown      |                      |                 | Not Reported |

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

|  |           |   |         |                       |              |
|--|-----------|---|---------|-----------------------|--------------|
|  | Cipralex  | C | Unknown |                       | Not Reported |
|  | Rivotril  | C | Unknown |                       | Not Reported |
|  | Folsan    | C | Unknown | Started Since Months  | Not Reported |
|  | Folsan    | C | Unknown |                       | Not Reported |
|  | Nomexor   | C | Unknown | Started Since Months  | Not Reported |
|  | Ebrantil  | C | Unknown | Started Since Months  | Not Reported |
|  | Exforge   | C | Unknown | 5/160 Mg Since Months | Not Reported |
|  | Exforge   | C | Unknown | 10/160mg              | Not Reported |
|  | Fungoral  | C | Unknown |                       | Not Reported |
|  | Fungoral  | C | Unknown |                       | Not Reported |
|  | Ultrabase | C | Unknown | If Needed             | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 15-Aug-2014              | 10357085       | EXPEDITED (15-DAY) |                    | HO, OT          | FR-FRI-1000069495    |                      |                 | Male       | FRA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Hyponatraemia; Seizure   | Escitalopram   |                    |                    | S               |                      |                      |                 | Forest     |                |

| <u>FDA Received Date</u>                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|-----------------------|-----------------|--------------|----------------|
| 15-Aug-2014                                           | 10362868       | EXPEDITED (15-DAY) |                    | HO, OT          | CH-FRI-1000069579    |                       |                 | Female       | CHE            |
| <u>Preferred Term</u>                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Generalised Tonic-Clonic Seizure; Overdose; Pregnancy | Escitalopram   |                    |                    | S               | Oral                 | Overdose: 25 Mg Daily |                 | Forest       |                |
|                                                       | Escitalopram   |                    |                    | S               | Oral                 | 8 Mg Daily            |                 | Forest       |                |
|                                                       | Tramal         |                    |                    | S               |                      | 450 Mg                |                 | Not Reported |                |
|                                                       | Tramal         |                    |                    | S               |                      | 220 Mg Daily          |                 | Not Reported |                |
|                                                       | Zaldiar        |                    |                    | S               | Oral                 |                       |                 | Not Reported |                |
|                                                       | Stilnox        |                    |                    | C               |                      | 10 Mg                 |                 | Not Reported |                |
|                                                       | Heptaminol     |                    |                    | C               |                      |                       |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                           | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------|----------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 15-Aug-2014                                                                                                                        | 10387209                   | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000069874                               |                      | 81 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                              | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State;<br>Hypochloraemia;<br>Hyponatraemia                                                                             | Escitalopram               |                    |                    | S               | Oral                                            | 10 Mg                |                 | Forest       |                |
|                                                                                                                                    | Cotareg 80 Mg / 12.5 Mg    |                    |                    | S               | Oral                                            | 1 Df                 |                 | Not Reported |                |
|                                                                                                                                    | Glucophage                 |                    |                    | C               | Oral                                            | 1700 Mg              |                 | Not Reported |                |
|                                                                                                                                    | Coveram 10/10 Mg           |                    |                    | C               | Oral                                            | 1 Df                 |                 | Not Reported |                |
|                                                                                                                                    | Diffu K                    |                    |                    | C               | Oral                                            | 1 Df                 |                 | Not Reported |                |
|                                                                                                                                    | Tiorfan                    |                    |                    | C               | Oral                                            | 2 Df                 |                 | Not Reported |                |
|                                                                                                                                    | Mineral                    |                    |                    | C               |                                                 |                      |                 | Not Reported |                |
|                                                                                                                                    | Multi Vitamin              |                    |                    | C               |                                                 |                      |                 | Not Reported |                |
|                                                                                                                                    | Lasilix                    |                    |                    | C               |                                                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                           | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Aug-2014                                                                                                                        | 10387415                   | EXPEDITED (15-DAY) |                    | HO, LT, OT      | FR-<br>ELI_LILLY_AND_COMP<br>ANY-FR201408002852 |                      | 40 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                              | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anaemia; Coma;<br>Hypernatraemia;<br>Hypotension; Loss Of<br>Consciousness; Miosis;<br>Polyuria; Septic Shock;<br>Thrombocytopenia | Zyprexa                    |                    |                    | S               | Oral                                            | Unk, Unknown         |                 | Unknown      |                |
|                                                                                                                                    | Fluoxetine Hydrochloride   |                    |                    | S               | Oral                                            | Unk, Unknown         |                 | Not Reported |                |
|                                                                                                                                    | Topiramate                 |                    |                    | S               | Oral                                            | Unk, Unknown         |                 | Not Reported |                |
|                                                                                                                                    | Teralithe                  |                    |                    | S               | Oral                                            | Unk, Unknown         |                 | Not Reported |                |
|                                                                                                                                    | Seroplex                   |                    |                    | S               | Oral                                            | Unk, Unknown         |                 | Not Reported |                |
|                                                                                                                                    | Clomipramine Hydrochloride |                    |                    | S               | Oral                                            | Unk, Unknown         |                 | Not Reported |                |
|                                                                                                                                    | Alprazolam                 |                    |                    | S               | Oral                                            | Unk, Unknown         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                           | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Aug-2014                                                                                                                        | 10388228                   | EXPEDITED (15-DAY) |                    | HO              | CA-<br>GLAXOSMITHKLINE-<br>B1023874A            |                      | 182 DAY         | Female       | CAN            |
| <u>Preferred Term</u>                                                                                                              | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

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

|                                                                                                                                          |              |   |         |               |                 |
|------------------------------------------------------------------------------------------------------------------------------------------|--------------|---|---------|---------------|-----------------|
| Cyanosis; Exposure Via Breast Milk; Sleep Disorder; Somnolence; Somnolence; Staring; Tonic Convulsion; Unresponsive To Stimuli; Vomiting | Bupropion    | S | Unknown | 150mg Per Day | Glaxosmithkline |
|                                                                                                                                          | Escitalopram | S | Unknown | 10mg Per Day  | Glaxosmithkline |

| <u>FDA Received Date</u>                                                                          | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------|---------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 15-Aug-2014                                                                                       | 10393138                        | EXPEDITED (15-DAY) | Y                  | HO              | 2014HINLIT0696       |                      | 46 YR           | Male         | JPN            |
| <u>Preferred Term</u>                                                                             | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Electrocardiogram Qt Prolonged; Myocardial Infarction; Ventricular Fibrillation | Escitalopram (Escitalopram)     |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                   | Unknown                         |                    |                    |                 |                      |                      |                 |              |                |
|                                                                                                   | Lansoprazole (Lansoprazole)     |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                          | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Aug-2014                                                                                       | 10395191                        | DIRECT             |                    | OT              |                      |                      | 43 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                             | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Urticaria                                                                                         | Escitalopram Oxalate            |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                          | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Aug-2014                                                                                       | 10395819                        | DIRECT             |                    | OT              |                      |                      | 65 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                             | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Heart Rate Increased                                                                              | Lexapro 10 Mg Accord Healthcare |                    |                    | S               | Oral                 |                      |                 | Accord       |                |
| <u>FDA Received Date</u>                                                                          | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Aug-2014                                                                                       | 10434732                        | NON-EXPEDITED      | Y                  |                 | 2014TUS004560        |                      | 48 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                             | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

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

|          |                                  |   |      |              |
|----------|----------------------------------|---|------|--------------|
| Pruritus | Brintellix (Vortioxetine) Tablet | S | Oral | Not Reported |
|          | Lexapro (Escitalopram Oxalate)   | S | Oral | Not Reported |
|          | Lamictal (Lamotrigine)           | C |      | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Aug-2014              | 10434927      | NON-EXPEDITED    |                    |                 | 2014TUS002630        |                      | 60 YR      | Female     | USA            |

| <u>Preferred Term</u>                                          | <u>Product</u>                                              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------|-------------------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Crying; Disturbance In Attention; Feeling Of Despair; Headache | Brintellix (Vortioxetine) Tablet                            |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                | Escitalopram                                                |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                |                                                             |              |            |             | Oral         |                    |                 |              |
|                                                                |                                                             |              |            |             | Oral         |                    |                 |              |
|                                                                |                                                             |              |            |             | Oral         |                    |                 |              |
|                                                                | Trazodone (Trazodone)                                       |              |            | C           |              |                    |                 | Not Reported |
|                                                                | Prempro (Estrogens Conjugated, Medroxyprogesterone Acetate) |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------------------|----------------------|------------|------------|----------------|
| 16-Aug-2014              | 10388776      | NON-EXPEDITED    |                    |                 | US-LUPIN PHARMACEUTICALS INC.-2014-01272 |                      |            | Male       | USA            |

| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Gastrointestinal Disorder | Escitalopram   |              |            | S           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Aug-2014              | 10142089      | EXPEDITED (15-DAY) |                    | HO              | PHHY2014CA049304     |                      | 93 YR      | Male       | CAN            |

| <u>Preferred Term</u>                                                                                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Diarrhoea; Dizziness; Fall; Fatigue; Hyponatraemia; Orthostatic Hypotension; Osteoporosis; Poor Quality Sleep | Metoprolol     |              |            | S           |              | 50 Mg, Per Day     |                 | Novartis     |
|                                                                                                               | Metoprolol     |              |            | S           |              | 25 Mg, Per Day     |                 | Novartis     |
|                                                                                                               | Metoprolol     |              |            | S           |              | 12.5 Mg, Per Day   |                 | Novartis     |
|                                                                                                               | Pantoprazole   |              |            | S           |              | 40 Mg, Bid         |                 | Not Reported |
|                                                                                                               | Escitalopram   |              |            | S           |              | 10 Mg, Per Day     |                 | Not Reported |

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

|              |   |                    |              |
|--------------|---|--------------------|--------------|
| Escitalopram | S | 5 Mg, Per Day      | Not Reported |
| Telmisartan  | S | 80 Mg, Per Day     | Not Reported |
| Telmisartan  | S | 40 Mg, Daily       | Not Reported |
| Telmisartan  | S | 20 Mg, Daily       | Not Reported |
| Prednisone   | S | 5 Mg, Bid          | Not Reported |
| Prednisone   | S | 7.5 Mg, Qd         | Not Reported |
| Lorazepam    | S | 1 Mg, At Bedtime   | Not Reported |
| Lorazepam    | S | 0.5 Mg, Unk        | Not Reported |
| Lorazepam    | S | 0.25 Mg, Unk       | Not Reported |
| Loperamide   | C | 1 Mg, As Needed    | Not Reported |
| Tamsulosin   | C | 0.4 Mg, At Bedtime | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 18-Aug-2014              | 10391018               | EXPEDITED (15-DAY) |                    | HO              | IT-WATSON-2014-17697 |                      | 40 YR           | Female       | ITA            |
| <u>Preferred Term</u>    | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Abuse; Tachycardia  | Mirtazapine (Unknown)  |                    |                    | S               | Oral                 | 300 Mg, Unk          |                 | Watson       |                |
|                          | Escitalopram (Unknown) |                    |                    | S               | Oral                 | 15 MI, Unk           |                 | Not Reported |                |
|                          | Entact                 |                    |                    | C               |                      | 10 Mg                |                 | Not Reported |                |

| <u>FDA Received Date</u>        | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 18-Aug-2014                     | 10391479       | EXPEDITED (15-DAY) |                    | HO              | IN-FRI-1000069919    |                      | 63 YR           | Male         | IND            |
| <u>Preferred Term</u>           | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Hyponatraemia | Escitalopram   |                    |                    | S               |                      | 5 Mg                 |                 | Forest       |                |
|                                 | Escitalopram   |                    |                    | S               |                      | 10 Mg                |                 | Forest       |                |
|                                 | Olanzapine     |                    |                    | S               |                      | 5 Mg                 |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Aug-2014              | 10391480      | EXPEDITED (15-DAY) |                    | HO              | CA-TEVA-502067USA    |                      |            | Male       | CAN            |

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

| <u>Preferred Term</u>                                                                                                                                                                 | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|--------------------|--------------------|-----------------|----------------------|-----------------------------|-----------------|--------------|----------------|
| Anal Incontinence;<br>Diarrhoea; Fall;<br>Hyponatraemia;<br>Orthostatic Hypotension;<br>Sedation Complication;<br>Skin Laceration; Vitamin<br>B12 Deficiency; Vitamin D<br>Deficiency | Pantoprazole          |                    |                    | S               | Unknown              |                             |                 | Teva         |                |
|                                                                                                                                                                                       | Metoprolol            |                    |                    | S               | Unknown              | 50mg/Day                    |                 | Teva         |                |
|                                                                                                                                                                                       | Telmisartan           |                    |                    | S               | Unknown              | 80mg/Day                    |                 | Not Reported |                |
|                                                                                                                                                                                       | Lorazepam             |                    |                    | S               | Unknown              | 1mg At Bedtime As<br>Needed |                 | Not Reported |                |
|                                                                                                                                                                                       | Escitalopram          |                    |                    | S               |                      |                             |                 | Not Reported |                |
|                                                                                                                                                                                       | Tamsulosin            |                    |                    | C               | Unknown              | 0.4mg At Bedtime            |                 | Not Reported |                |
|                                                                                                                                                                                       | Prednisone            |                    |                    | C               | Unknown              |                             |                 | Not Reported |                |
|                                                                                                                                                                                       | Loperamide            |                    |                    | C               | Unknown              | 1mg As Needed               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                              | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Aug-2014                                                                                                                                                                           | 10391481              | EXPEDITED (15-DAY) |                    | OT              | US-FRI-1000069859    |                             |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                 | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Liver Disorder                                                                                                                                                                        | Lexapro Oral Solution |                    |                    | S               |                      |                             |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                                                                              | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Aug-2014                                                                                                                                                                           | 10391516              | EXPEDITED (15-DAY) |                    | DE              | BE-FRI-1000069917    |                             | 50 YR           | Male         | BEL            |
| <u>Preferred Term</u>                                                                                                                                                                 | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Death                                                                                                                                                                                 | Escitalopram          |                    |                    | S               | Oral                 |                             |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                                                                              | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Aug-2014                                                                                                                                                                           | 10391544              | EXPEDITED (15-DAY) |                    | DE              | BE-FRI-1000069935    |                             | 30 YR           | Female       | BEL            |
| <u>Preferred Term</u>                                                                                                                                                                 | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Death                                                                                                                                                                                 | Escitalopram          |                    |                    | S               | Oral                 | 20 Mg                       |                 | Forest       |                |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                        | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                        | <u>Age</u>      | <u>Sex</u>                         | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|------------------------------|---------------------------------------------|-----------------|------------------------------------|----------------|
| 18-Aug-2014                                                                                                                                     | 10395983                      | EXPEDITED (15-DAY) | Y                  | HO              | 2014AP003905                 |                                             | 93 YR           | Male                               | CAN            |
| <u>Preferred Term</u>                                                                                                                           | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>                         |                |
| Anal Incontinence;<br>Diarrhoea; Fall;<br>Hyponatraemia;<br>Orthostatic Hypotension;<br>Skin Laceration;<br>Somnolence; Vitamin D<br>Deficiency | Pantoprazole (Pantoprazole)   |                    |                    | S               |                              |                                             |                 | Not Reported                       |                |
|                                                                                                                                                 | Unknown                       |                    |                    |                 |                              |                                             |                 |                                    |                |
|                                                                                                                                                 | Apo-Telmisartan (Telmisartan) |                    |                    | S               |                              |                                             |                 | Not Reported                       |                |
|                                                                                                                                                 | Tablet                        |                    |                    |                 |                              |                                             |                 |                                    |                |
|                                                                                                                                                 | Apo-Metoprolol (Metoprolol)   |                    |                    | S               |                              |                                             |                 | Not Reported                       |                |
|                                                                                                                                                 | Tablet                        |                    |                    |                 |                              |                                             |                 |                                    |                |
|                                                                                                                                                 | Apo-Lorazepam (Lorazepam)     |                    |                    | S               |                              |                                             |                 | Not Reported                       |                |
|                                                                                                                                                 | Tablet                        |                    |                    |                 |                              |                                             |                 |                                    |                |
|                                                                                                                                                 | Escitalopram (Escitalopram)   |                    |                    | S               |                              |                                             |                 | Not Reported                       |                |
|                                                                                                                                                 | Tamsulosin (Tamsulosin)       |                    |                    | C               |                              |                                             |                 | Not Reported                       |                |
|                                                                                                                                                 | Prednisone (Prednisone)       |                    |                    | C               |                              |                                             |                 | Not Reported                       |                |
|                                                                                                                                                 | Loperamide (Loperamide)       |                    |                    | C               |                              |                                             |                 | Not Reported                       |                |
| <u>FDA Received Date</u>                                                                                                                        | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                        | <u>Age</u>      | <u>Sex</u>                         | <u>Country</u> |
| 18-Aug-2014                                                                                                                                     | 10396552                      | EXPEDITED (15-DAY) | Y                  | HO              | 2014JUB00087                 |                                             | 38 YR           | Female                             | USA            |
| <u>Preferred Term</u>                                                                                                                           | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>                         |                |
| Delusion; Drug Interaction;<br>Serotonin Syndrome                                                                                               | Escitalopram (Escitalopram)   |                    |                    | S               |                              |                                             | 122 DAY         | Not Reported                       |                |
|                                                                                                                                                 | Unknown                       |                    |                    |                 |                              |                                             |                 |                                    |                |
|                                                                                                                                                 | Mirtazapine (Mirtazapine)     |                    |                    | S               |                              |                                             |                 | Not Reported                       |                |
| <u>FDA Received Date</u>                                                                                                                        | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                        | <u>Age</u>      | <u>Sex</u>                         | <u>Country</u> |
| 18-Aug-2014                                                                                                                                     | 10399250                      | DIRECT             |                    |                 |                              |                                             | 68 YR           | Female                             | USA            |
| <u>Preferred Term</u>                                                                                                                           | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>                         |                |
| Suicidal Ideation; Tinnitus                                                                                                                     | Escitalopram                  |                    |                    | S               | Oral                         | 1 Tablet Daily Once Daily<br>Taken By Mouth |                 | Pharmacy Benefits<br>Manager (Pbm) |                |
| <u>FDA Received Date</u>                                                                                                                        | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                        | <u>Age</u>      | <u>Sex</u>                         | <u>Country</u> |
| 19-Aug-2014                                                                                                                                     | 10351390                      | EXPEDITED (15-DAY) |                    | DE, HO, OT      | FR-PFIZER INC-<br>2014207726 |                                             | 88 YR           | Male                               | FRA            |

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

| <u>Preferred Term</u>                                                                                                                            | <u>Product</u>                                                                                                      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------|--------------|------------|-------------|--------------|-----------------------------------------------|-----------------|--------------|
| Aspiration; Cardiac Failure; Hepatitis; Incorrect Route Of Product Administration; Infection; International Normalised Ratio Increased; Overdose | Tahor                                                                                                               |              |            | S           | Oral         | 10 Mg, 1x/Day                                 |                 | Pfizer       |
|                                                                                                                                                  | Cordarone                                                                                                           |              |            | S           | Oral         | 1000 Mg, Weekly (1 Df (200mg) 5 Times Weekly) |                 | Pfizer       |
|                                                                                                                                                  | Lasilix                                                                                                             |              |            | S           | Oral         | 60 Mg, 3x/Day                                 |                 | Not Reported |
|                                                                                                                                                  | Diffu K                                                                                                             |              |            | S           | Oral         | 1 Df, 3x/Day                                  |                 | Not Reported |
|                                                                                                                                                  | Paracetamol Arrow                                                                                                   |              |            | S           | Oral         | 1 G, As Needed (3 G Daily Maximum)            |                 | Not Reported |
|                                                                                                                                                  | Imovane                                                                                                             |              |            | S           | Oral         | 1 Df, Daily                                   |                 | Not Reported |
|                                                                                                                                                  | Previscan (Fluindione)                                                                                              |              |            | S           | Oral         | 10 Mg, Daily                                  |                 | Not Reported |
|                                                                                                                                                  | Tareg                                                                                                               |              |            | S           | Oral         | 40 Mg, Daily                                  |                 | Not Reported |
|                                                                                                                                                  | Seroplex                                                                                                            |              |            | S           | Oral         | 10 Mg, Daily                                  |                 | Not Reported |
|                                                                                                                                                  | Seresta                                                                                                             |              |            | C           |              | Unk                                           |                 | Not Reported |
|                                                                                                                                                  | Lansoyl                                                                                                             |              |            | C           |              | Unk                                           |                 | Not Reported |
|                                                                                                                                                  | Transipeg (Polyethylene Glycol 3350\Potassium Chloride\Sodium Bicarbonate\Sodium Chloride\Sodium Sulfate Anhydrous) |              |            | C           |              | Unk                                           |                 | Not Reported |
|                                                                                                                                                  | Voltarene (Diclofenac Sodium)                                                                                       |              |            | C           |              | Unk                                           |                 | Not Reported |
|                                                                                                                                                  | Doliprane                                                                                                           |              |            | C           |              | Unk                                           |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Aug-2014              | 10357099      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000069499    |                      | 88 YR      | Male       | FRA            |

| <u>Preferred Term</u>                               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hepatitis; International Normalised Ratio Increased | Escitalopram   |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                                     | Lasilix        |              |            | S           | Oral         | 180 Mg             |                 | Not Reported |
|                                                     | Diffu K        |              |            | S           | Oral         | 72 Df              |                 | Not Reported |
|                                                     | Tahor          |              |            | S           | Oral         | 10 Mg              |                 | Not Reported |

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

|                                                                                                                     |   |      |           |              |
|---------------------------------------------------------------------------------------------------------------------|---|------|-----------|--------------|
| Cordarone                                                                                                           | S | Oral | 0.7143 Df | Not Reported |
| Paracetamol Arrow                                                                                                   | S | Oral |           | Not Reported |
| Imovane                                                                                                             | S | Oral | 1 Df      | Not Reported |
| Previscan (Fluindione)                                                                                              | S | Oral | 0.5 Df    | Not Reported |
| Tareg                                                                                                               | S | Oral | 40 Mg     | Not Reported |
| Seresta                                                                                                             | C |      |           | Not Reported |
| Lansoyl                                                                                                             | C |      |           | Not Reported |
| Transipeg (Polyethylene Glycol 3350\Potassium Chloride\Sodium Bicarbonate\Sodium Chloride\Sodium Sulfate Anhydrous) | C |      |           | Not Reported |
| Voltarene (Diclofenac Sodium)                                                                                       | C |      |           | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Aug-2014              | 10393216      | EXPEDITED (15-DAY) | HO                 |                 | FR-FRI-1000069955    |                      | 74 YR      | Female     | FRA            |

| <u>Preferred Term</u>                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cerebral Haematoma;<br>Drug Interaction | Escitalopram   |              |            | S           | Oral         | 5 Mg               |                 | Forest       |
|                                         | Coumadine      |              |            | S           | Oral         | 9 Mg               |                 | Not Reported |
|                                         | Lovenox        |              |            | S           | Subcutaneous | 1.4 MI             |                 | Not Reported |
|                                         | Diltiazem Lp   |              |            | C           |              | 300 Mg             |                 | Not Reported |
|                                         | Xanax          |              |            | C           |              | 0.75               |                 | Not Reported |
|                                         | Omeprazole     |              |            | C           |              | 20 Mg              |                 | Not Reported |
|                                         | Digoxine       |              |            | C           |              | 0.125 Mg           |                 | Not Reported |
|                                         | Aprovel        |              |            | C           |              | 150 Mg             |                 | Not Reported |
|                                         | Temerit        |              |            | C           |              | 5 Mg               |                 | Not Reported |
|                                         | Doliprane      |              |            | C           |              | 4 Gram             |                 | Not Reported |
|                                         | Topalgic Lp    |              |            | C           |              | 300 Mg             |                 | Not Reported |
|                                         | Lasilix        |              |            | C           |              | 60 Mg              |                 | Not Reported |
|                                         | Diffu K        |              |            | C           |              | 4800 Mg            |                 | Not Reported |

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

|  |           |   |        |              |
|--|-----------|---|--------|--------------|
|  | Lyrica    | C | 50 Mg  | Not Reported |
|  | Laroxyl   | C | 15 Gtt | Not Reported |
|  | Imovane   | C | 7.5 Mg | Not Reported |
|  | Gaviscon  | C |        | Not Reported |
|  | Motilium  | C |        | Not Reported |
|  | Econazole | C | 1 Df   | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Aug-2014              | 10394086      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000069958    |                      | 57 YR      | Female     | FRA            |

| <u>Preferred Term</u>                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Coma; Intentional Overdose; Pneumonia Aspiration | Escitalopram   |              |            | S           | Oral         | 20 Mg              |                 | Forest       |
|                                                  | Escitalopram   |              |            | S           | Oral         | Overdose Nos.      |                 | Not Reported |
|                                                  | Alprazolam     |              |            | S           | Oral         | 0.75 Mg            |                 | Not Reported |
|                                                  | Alprazolam     |              |            | S           | Oral         | Overdose Nos.      |                 | Not Reported |
|                                                  | Zopiclone      |              |            | S           | Oral         | 1 Df               |                 | Not Reported |
|                                                  | Zopiclone      |              |            | S           | Oral         | Overdose Nos.      |                 | Not Reported |
|                                                  | Tercian        |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Aug-2014              | 10398425      | EXPEDITED (15-DAY) | Y                  | HO, OT          | 2014AP003976         |                      | 15 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                     | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Electrocardiogram Qt Prolonged; Intentional Overdose; Suicide Attempt; Torsade De Pointes | Escitalopram Oxalate |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Aug-2014              | 10399370      | EXPEDITED (15-DAY) | Y                  | HO, OT          | AUR-APL-2014-08671   |                      | 40 YR      | Female     | IND            |

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

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

|                                                                                                                                                          |                          |   |                              |              |
|----------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|---|------------------------------|--------------|
| Bradykinesia; Dysarthria;<br>Dysarthria; Extrapyramidal<br>Disorder; Hypokinesia;<br>Oculogyric Crisis;<br>Protrusion Tongue;<br>Salivary Hypersecretion | Escitalopram             | S | 5 Mg, Once A Day,<br>Unknown | Not Reported |
|                                                                                                                                                          | Clonazepam ( Clonazepam) | C |                              | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Aug-2014              | 10035877      | EXPEDITED (15-DAY) |                    | OT              | AT-FRI-1000060279    |                      |            | Female     | AUT            |

| <u>Preferred Term</u>                           | <u>Product</u>                          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------|-----------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Accommodation Disorder;<br>Dizziness; Dry Mouth | Escitalopram                            |              |            | S           |              | 10 Mg              |                 | Forest       |
|                                                 | Escitalopram                            |              |            | S           |              | 20 Mg              |                 | Not Reported |
|                                                 | Escitalopram                            |              |            | S           |              | 10 Mg              |                 | Not Reported |
|                                                 | Valdoxan                                |              |            | S           |              | 25 Mg              |                 | Not Reported |
|                                                 | Valdoxan                                |              |            | S           |              | 50 Mg              |                 | Not Reported |
|                                                 | Valdoxan                                |              |            | S           |              | 25 Mg              |                 | Not Reported |
|                                                 | Lyrica                                  |              |            | S           |              | 150 Mg             |                 | Not Reported |
|                                                 | Trittico                                |              |            | S           |              | 100 Mg             |                 | Not Reported |
|                                                 | Trittico                                |              |            | S           |              | 150 Mg             |                 | Not Reported |
|                                                 | Seroquel                                |              |            | S           |              | 100 Mg             |                 | Not Reported |
|                                                 | Seroquel                                |              |            | S           |              | 150 Mg             |                 | Not Reported |
|                                                 | Seroquel                                |              |            | S           |              | 200 Mg             |                 | Not Reported |
|                                                 | Seroquel                                |              |            | S           |              | 200 Mg             |                 | Not Reported |
|                                                 | Seroquel                                |              |            | S           |              | 300 Mg             |                 | Not Reported |
|                                                 | Seroquel                                |              |            | S           |              | 400 Mg             |                 | Not Reported |
|                                                 | Cymbalta                                |              |            | S           |              | 30 Mg              |                 | Not Reported |
|                                                 | Cymbalta                                |              |            | S           |              | 60 Mg              |                 | Not Reported |
|                                                 | Cymbalta                                |              |            | S           |              | 120 Mg             |                 | Not Reported |
|                                                 | Dominal (Prothipendyl<br>Hydrochloride) |              |            | C           |              | 80 Mg              |                 | Not Reported |
|                                                 | Dominal (Prothipendyl                   |              |            | C           |              | 40 Mg              |                 | Not Reported |

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

|                          |   |         |              |
|--------------------------|---|---------|--------------|
| Hydrochloride)<br>Zoldem | C | 10 Mg   | Not Reported |
| Zoldem                   | C | 10 Mg   | Not Reported |
| Rivotril                 | C | 0.5 Mg  | Not Reported |
| Rivotril                 | C | 1 Mg    | Not Reported |
| Rivotril                 | C | 1.75 Mg | Not Reported |
| Rivotril                 | C | 1.25 Mg | Not Reported |
| Rivotril                 | C | 2.75 Mg | Not Reported |
| Rivotril                 | C | 2.5 Mg  | Not Reported |
| Sirdalud                 | C | 2 Mg    | Not Reported |
| Thromboass               | C | 100 Mg  | Not Reported |
| Tolvon                   | C | 60 Mg   | Not Reported |
| Tolvon                   | C | 30 Mg   | Not Reported |
| Tolvon                   | C | 60 Mg   | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Aug-2014              | 10166903      | EXPEDITED (15-DAY) | Y                  | HO              | VAL_03094_2014       |                      | 93 YR      | Male       | CAN            |

| <u>Preferred Term</u>                                                                                                                                                                              | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                                                                                  | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|--------------|------------|-------------|--------------|-------------------------------------------------------------------------------------------------------------------------------------|-----------------|--------------|
| Affective Disorder;<br>Diarrhoea; Dizziness; Fall;<br>Fatigue; Hyponatraemia;<br>Mobility Decreased;<br>Orthostatic Hypotension;<br>Somnolence; Vitamin B12<br>Deficiency; Vitamin D<br>Deficiency | Metoprolol Tartrate |              |            | S           |              | 2 Weeks 0 Days Not<br>Continuing<br>1 Week 1 Cays Until Not<br>Continuing                                                           |                 | Not Reported |
|                                                                                                                                                                                                    | Pantoprazole        |              |            | S           |              | Until Not Continuing                                                                                                                |                 | Not Reported |
|                                                                                                                                                                                                    | Telmisartan         |              |            | S           |              |                                                                                                                                     |                 | Not Reported |
|                                                                                                                                                                                                    | Escitalopram        |              |            | S           |              | Until Not Continuing                                                                                                                |                 | Not Reported |
|                                                                                                                                                                                                    | Lorazepam           |              |            | S           |              | Bedtime<br>0.5mg At Bedtime 2<br>Weeks 0 Days Until Not<br>Continuig<br>0.25mg At Bedtime 2<br>Weeks 0 Days Until Not<br>Continuing |                 | Not Reported |

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

|              |                              |              |
|--------------|------------------------------|--------------|
| Tamsulosin   | C                            | Not Reported |
| Prednisolone | C                            | Not Reported |
| Loperamide   | C                            | Not Reported |
| Prednisone   | S                            | Not Reported |
|              | Unknown Until Not Continuing |              |
|              | Unknown Util Cotinuing       |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 20-Aug-2014              | 10395489      | EXPEDITED (15-DAY) | Y                  | HO              | CA-MYLANLABS-2014M1001725 |                      |            | Unknown    | CAN            |

| <u>Preferred Term</u>                                                                                                                                                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------------|-----------------|--------------|
| Anal Incontinence;<br>Diarrhoea; Dizziness; Fall;<br>Hyponatraemia;<br>Orthostatic Hypotension;<br>Sedation Complication;<br>Skin Laceration; Vitamin B12 Deficiency; Vitamin D Deficiency | Escitalopram   |              |            | S           | Unknown      | 10mg/Day                 |                 | Mylan        |
|                                                                                                                                                                                            | Pantoprazole   |              |            | S           | Unknown      |                          |                 | Not Reported |
|                                                                                                                                                                                            | Pantoprazole   |              |            | S           |              |                          |                 | Not Reported |
|                                                                                                                                                                                            | Telmisartan    |              |            | S           | Unknown      | 80mg/Day                 |                 | Not Reported |
|                                                                                                                                                                                            | Metoprolol     |              |            | S           | Unknown      | 50mg/Day                 |                 | Not Reported |
|                                                                                                                                                                                            | Lorazepam      |              |            | S           | Unknown      | 1mg At Bedtime As Needed |                 | Mylan        |
|                                                                                                                                                                                            | Tamsulosin     |              |            | C           | Unknown      | 0.4mg At Bedtime         |                 | Not Reported |
|                                                                                                                                                                                            | Prednisone     |              |            | C           | Unknown      |                          |                 | Not Reported |
|                                                                                                                                                                                            | Loperamide     |              |            | C           | Unknown      | 1mg As Needed            |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Aug-2014              | 10395790      | EXPEDITED (15-DAY) |                    | DE              | MX-FRI-1000070012    |                      | 75 YR      | Female     | MEX            |

| <u>Preferred Term</u>             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Lower Respiratory Tract Infection | Escitalopram   |              |            | S           |              |                    |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Aug-2014              | 10395917      | EXPEDITED (15-DAY) |                    | OT              | CH-FRI-1000070017    |                      | < 1 DAY    | Female     | CHE            |

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

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

|                                                                             |                     |   |                |        |              |
|-----------------------------------------------------------------------------|---------------------|---|----------------|--------|--------------|
| Foetal Exposure During Pregnancy; Foetal Macrosomia; Hypoglycaemia Neonatal | Escitalopram        | S | Transplacental | 20 Mg  | Forest       |
|                                                                             | Abilify             | S | Transplacental |        | Not Reported |
|                                                                             | Topamax             | S | Transplacental | 100 Mg | Not Reported |
|                                                                             | Temesta (Lorazepam) | S | Transplacental | 3 Mg   | Not Reported |
|                                                                             | Seroquel            | S | Transplacental | 200 Mg | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Aug-2014              | 10395927      | EXPEDITED (15-DAY) |                    | OT              | CH-FRI-1000070015    |                      |            | Female     | CHE            |

| <u>Preferred Term</u>           | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Gestational Diabetes; Pregnancy | Escitalopram        |              |            | S           |              | 10 Mg              |                 | Forest       |
|                                 | Abilify             |              |            | S           |              |                    |                 | Not Reported |
|                                 | Topamax             |              |            | S           |              | 100 Mg             |                 | Not Reported |
|                                 | Temesta (Lorazepam) |              |            | S           |              |                    |                 | Not Reported |
|                                 | Seroquel            |              |            | S           |              | 200 Mg             |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Aug-2014              | 10397144      | EXPEDITED (15-DAY) |                    | DE, LT          | FR-FRI-1000070013    |                      | 69 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                                           | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction; Haemorrhagic Stroke; International Normalised Ratio Increased | Escitalopram           |              |            | S           |              |                    |                 | Forest       |
|                                                                                 | Previscan (Fluindione) |              |            | S           |              |                    |                 | Not Reported |
|                                                                                 | Atorvastatin           |              |            | S           |              |                    |                 | Not Reported |
|                                                                                 | Kardegic               |              |            | S           |              |                    |                 | Not Reported |
|                                                                                 | Metoprolol             |              |            | C           |              |                    |                 | Not Reported |
|                                                                                 | Janumet                |              |            | C           |              |                    |                 | Not Reported |
|                                                                                 | Irbesartan             |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Aug-2014              | 10397444      | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000070004    |                      | < 1 DAY    | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|------------|
| Craniosynostosis      | Lexapro        |              |            | S           | Transplacental |                    |                 | Forest     |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                        | <u>Case #</u>                                                                                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|--------------------|--------------------|-----------------|------------------------------------------|----------------------|-----------------|--------------|----------------|
| 21-Aug-2014                                                                                                                                                     | 10399066                                                                                            | EXPEDITED (15-DAY) |                    | HO, LT, OT      | US-ACTAVIS-2014-17801                    |                      | 16 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                           | <u>Product</u>                                                                                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bundle Branch Block Right; Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Intentional Overdose; Lethargy; Sinus Bradycardia; Vomiting | Escitalopram (Unknown)                                                                              |                    |                    | S               | Oral                                     | 500 Mg, Single       |                 | Not Reported |                |
|                                                                                                                                                                 | Escitalopram (Unknown)                                                                              |                    |                    | S               |                                          |                      |                 | Not Reported |                |
|                                                                                                                                                                 | Tramadol Hydrochloride And Acetaminophen 37.5/325mg (Watson) (Tramadol Hydrochloride Acetaminophen) |                    |                    | S               | Oral                                     | Unk, 25 Tablets      |                 | Watson       |                |
|                                                                                                                                                                 | Hydrocodone-Acetaminophen (Watson Laboratories)                                                     |                    |                    | S               | Oral                                     | Unk                  |                 | Watson       |                |
| <u>FDA Received Date</u>                                                                                                                                        | <u>Case #</u>                                                                                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Aug-2014                                                                                                                                                     | 10400950                                                                                            | EXPEDITED (15-DAY) |                    | DE, OT          | US-GILEAD-2014-0112476                   |                      | 66 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                           | <u>Product</u>                                                                                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Death                                                                                                                                                           | Sovaldi                                                                                             |                    |                    | S               | Oral                                     | 400 Mg, Unk          |                 | Gilead       |                |
|                                                                                                                                                                 | Olysio                                                                                              |                    |                    | C               |                                          | Unk                  |                 | Not Reported |                |
|                                                                                                                                                                 | Aspirin /00002701/                                                                                  |                    |                    | S               | Oral                                     | 81 Mg, Unk           |                 | Not Reported |                |
|                                                                                                                                                                 | Procardia /00340701/                                                                                |                    |                    | S               | Oral                                     | 10 Mg, Unk           |                 | Not Reported |                |
|                                                                                                                                                                 | Lexapro                                                                                             |                    |                    | S               | Oral                                     | 10 Mg, Unk           |                 | Not Reported |                |
|                                                                                                                                                                 | Prilosec /00661201/                                                                                 |                    |                    | S               | Oral                                     | 40 Mg, Unk           |                 | Not Reported |                |
|                                                                                                                                                                 | Multivitamin /07504101/                                                                             |                    |                    | S               | Unknown                                  |                      |                 | Not Reported |                |
|                                                                                                                                                                 | Miralax /00754501/                                                                                  |                    |                    | C               |                                          |                      |                 | Not Reported |                |
|                                                                                                                                                                 | Megaoxiod                                                                                           |                    |                    | C               |                                          |                      |                 | Not Reported |                |
|                                                                                                                                                                 | Valtrax                                                                                             |                    |                    | C               |                                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                        | <u>Case #</u>                                                                                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Aug-2014                                                                                                                                                     | 8806652                                                                                             | EXPEDITED (15-DAY) |                    | DE, HO          | US-BRISTOL-MYERS SQUIBB COMPANY-15274749 |                      | 65 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                           | <u>Product</u>                                                                                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

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

|                                            |                               |   |                                       |                             |              |
|--------------------------------------------|-------------------------------|---|---------------------------------------|-----------------------------|--------------|
| Death; Deep Vein Thrombosis; Hyponatraemia | Ipilimumab                    | S | Intravenous (not otherwise specified) | No Of Courses: 02           | Not Reported |
|                                            | Lexapro                       | S |                                       |                             | Not Reported |
|                                            | Diovan Hct                    | C |                                       |                             | Not Reported |
|                                            | Enablex                       | C |                                       |                             | Not Reported |
|                                            | Flomax                        | C |                                       |                             | Not Reported |
|                                            | Aspirin                       | C |                                       |                             | Not Reported |
|                                            | Coreg                         | C |                                       |                             | Not Reported |
|                                            | Lanoxin                       | C |                                       |                             | Not Reported |
|                                            | Amaryl                        | C |                                       |                             | Not Reported |
|                                            | Lasix                         | C |                                       |                             | Not Reported |
|                                            | Ultram                        | C |                                       |                             | Not Reported |
|                                            | Zestril                       | C |                                       |                             | Not Reported |
|                                            | Nexium                        | C |                                       |                             | Not Reported |
|                                            | K-Dur                         | C |                                       |                             | Not Reported |
|                                            | Lortab                        | C |                                       |                             | Not Reported |
|                                            | Oxy-Ir                        | C |                                       |                             | Not Reported |
|                                            | Lipitor                       | C |                                       |                             | Not Reported |
|                                            | Losec                         | C |                                       |                             | Not Reported |
|                                            | Glyburide                     | C |                                       |                             | Not Reported |
|                                            | Fibercon                      | C |                                       |                             | Not Reported |
|                                            | Coumadin                      | C |                                       |                             | Not Reported |
|                                            | Lexapro                       | C |                                       |                             | Not Reported |
|                                            | Duragesic                     | C |                                       |                             | Not Reported |
|                                            | Lortab                        | C |                                       |                             | Not Reported |
|                                            | Digoxin                       | C |                                       |                             | Not Reported |
|                                            | Tramadol                      | C |                                       | Er                          | Not Reported |
|                                            | Carvedilol                    | C |                                       |                             | Not Reported |
|                                            | Hydrochlorothiazide\Valsartan | C |                                       |                             | Not Reported |
|                                            | Darifenacin Hydrobromide      | C |                                       |                             | Not Reported |
|                                            | Tamsulosin Hcl                | C |                                       |                             | Not Reported |
|                                            | Glimepiride                   | C |                                       |                             | Not Reported |
|                                            | Furosemide                    | C |                                       |                             | Not Reported |
|                                            | Escitalopram Oxalate          | C |                                       |                             | Not Reported |
|                                            | Apap                          | C |                                       | 1df=500 Unit Not Given.     | Not Reported |
|                                            | Hydrocodone                   | C |                                       | 1df=1df=7.5 Unit Not Given. | Not Reported |
|                                            | Atorvastatin Calcium          | C |                                       |                             | Not Reported |
|                                            | Lisinopril                    | C |                                       |                             | Not Reported |
|                                            | Oxycodone                     | C |                                       |                             | Not Reported |

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

Potassium  
Warfarin Sodium  
Esomeprazole Magnesium

C  
C  
C

Not Reported  
Not Reported  
Not Reported

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 22-Aug-2014              | 10290501      | NON-EXPEDITED    |                    | HO              | US-JNJFOC-20140701713 |                      | 78 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                  | <u>Product</u>                           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>      | <u>Route</u>                             | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                                                   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------|--------------|------------|------------------|------------------------------------------|--------------------|-----------------|--------------------------------------------------------------|
| Amnesia; Dementia;<br>Depression; Device Issue;<br>Encephalopathy; Gait<br>Inability; Headache; Loss<br>Of Personal Independence<br>In Daily Activities;<br>Pseudodementia; Toxicity<br>To Various Agents;<br>Vomiting | Topamax<br>Tramadol<br>Humira<br>Lexapro |              |            | S<br>S<br>S<br>S | Unknown<br>Unknown<br>Unknown<br>Unknown |                    |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Aug-2014              | 10401111      | EXPEDITED (15-DAY) |                    | OT              | IN-ACCORD-025469     |                      | 24 YR      | Female     | IND            |

| <u>Preferred Term</u> | <u>Product</u>             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>             |
|-----------------------|----------------------------|--------------|------------|-------------|--------------|---------------------------------------|-----------------|------------------------|
| Galactorrhoea         | Escitalopram<br>Clonazepam |              |            | S<br>C      |              | Drug Was Tapered Off<br>Over 2 Weeks. |                 | Accord<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 22-Aug-2014              | 10402513      | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2014231984 |                      | 70 YR      | Unknown    | USA            |

| <u>Preferred Term</u> | <u>Product</u>                                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>      | <u>Route</u> | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>                                       |
|-----------------------|-----------------------------------------------|--------------|------------|------------------|--------------|--------------------------|-----------------|--------------------------------------------------|
| Drug Hypersensitivity | Zoloft<br>Tramadol Hcl<br>Albuterol<br>Celexa |              |            | S<br>S<br>S<br>S |              | Unk<br>Unk<br>Unk<br>Unk |                 | Pfizer<br>Pfizer<br>Not Reported<br>Not Reported |

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

|  |           |   |     |              |
|--|-----------|---|-----|--------------|
|  | Dilaudid  | S | Unk | Not Reported |
|  | Lexapro   | S | Unk | Not Reported |
|  | Paxil     | S | Unk | Not Reported |
|  | Risperdal | S | Unk | Not Reported |
|  | Trazodone | S | Unk | Not Reported |

| <u>FDA Received Date</u>             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 22-Aug-2014                          | 10402680       | EXPEDITED (15-DAY) |                    | OT              | AU-FRI-1000070041    |                      | 68 YR           | Female       | AUS            |
| <u>Preferred Term</u>                | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Periorbital Oedema; Rash<br>Pruritic | Escitalopram   |                    |                    | S               |                      | 10 Mg                |                 | Forest       |                |
|                                      | Aspirin        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                      | Atenolol       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                      | Celecoxib      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                      | Omeprazole     |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                      | Spironolactone |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                | <u>Case #</u>                         | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------|---------------------------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 22-Aug-2014                                                             | 10405830                              | DIRECT           | Y                  |                 |                      |                      | 17 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                   | <u>Product</u>                        | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Depression; Drug<br>Ineffective; Product<br>Substitution Issue | Escitalopram 10mg Aurobiudo<br>Pharma |                  |                    | S               | Oral                 |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                        | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 22-Aug-2014                                                                                                     | 10409791                               | EXPEDITED (15-DAY) | Y                  | HO, OT          | AUR-APL-2014-08808   |                      | 15 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                           | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness;<br>Electrocardiogram Qt<br>Prolonged; Lethargy; Long<br>Qt Syndrome Congenital;<br>Overdose; Suicide | Escitalopram (Escitalopram)<br>Unknown |                    |                    | S               |                      |                      |                 | Not Reported |                |

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

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| <u>FDA Received Date</u>            | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|-------------------------------------|-------------------------------|--------------------|--------------------|-----------------|--------------------------------------------------|----------------------|-----------------|-----------------|----------------|
| 25-Aug-2014                         | 10405649                      | NON-EXPEDITED      |                    |                 | US-LUPIN<br>PHARMACEUTICALS<br>INC.-E2B_00002269 |                      |                 | Female          | USA            |
| <u>Preferred Term</u>               | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                     | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Arthropathy; Deformity              | Escitalopram Tablets Usp 5mg  |                    |                    | S               |                                                  |                      |                 | Lupin           |                |
|                                     | Escitalopram Tablets Usp 5mg  |                    |                    | S               |                                                  |                      |                 | Lupin           |                |
|                                     | Vyvanse                       |                    |                    | C               | Unknown                                          |                      |                 | Not Reported    |                |
|                                     | Vyvanse                       |                    |                    | C               |                                                  |                      |                 | Not Reported    |                |
|                                     | Klonopin                      |                    |                    | C               | Unknown                                          |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>            | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 25-Aug-2014                         | 10405697                      | NON-EXPEDITED      |                    |                 | US-LUPIN<br>PHARMACEUTICALS<br>INC.-E2B_00002293 |                      |                 | Female          | USA            |
| <u>Preferred Term</u>               | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                     | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Alopecia                            | Escitalopram Tablets Usp 10mg |                    |                    | S               |                                                  |                      |                 | Lupin           |                |
|                                     | Escitalopram Tablets Usp 10mg |                    |                    | S               |                                                  |                      |                 | Lupin           |                |
|                                     | Femring                       |                    |                    | C               | Unknown                                          |                      |                 | Not Reported    |                |
|                                     | Vitamin D3                    |                    |                    | C               | Unknown                                          |                      |                 | Not Reported    |                |
|                                     | Valium                        |                    |                    | C               |                                                  |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>            | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 25-Aug-2014                         | 10407152                      | EXPEDITED (15-DAY) |                    | HO              | US-<br>GLAXOSMITHKLINE-<br>A1086280A             |                      |                 | Female          | USA            |
| <u>Preferred Term</u>               | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                     | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Depression; Ill-Defined<br>Disorder | Lamictal                      |                    |                    | S               | Unknown                                          |                      |                 | Glaxosmithkline |                |
|                                     | Lamotrigine                   |                    |                    | S               | Unknown                                          |                      |                 | Glaxosmithkline |                |
|                                     | Lexapro                       |                    |                    | S               | Unknown                                          |                      |                 | Not Reported    |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|-----------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| 25-Aug-2014              | 10407620        | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2014236167   |                      | 53 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity    | Zoloft          |                    |                    | S               |                            | Unk                  |                 | Pfizer       |                |
|                          | Wellbutrin      |                    |                    | S               |                            | Unk                  |                 | Not Reported |                |
|                          | Lexapro.Oxalate |                    |                    | S               |                            | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Aug-2014              | 10407954        | EXPEDITED (15-DAY) |                    | DE, OT          | US-ASTRAZENECA-2014SE62905 |                      | 66 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Death; Headache          | Prilosec        |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                          | Aspirin         |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                          | Procardia XI    |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                          | Sovaldi         |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                          | Lexapro         |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                          | Multivitamin    |                    |                    | S               | Unknown                    |                      |                 | Not Reported |                |
|                          | Olysio          |                    |                    | C               |                            |                      |                 | Not Reported |                |
|                          | Miralax         |                    |                    | C               |                            |                      |                 | Not Reported |                |
|                          | Megaoxiod       |                    |                    | C               |                            |                      |                 | Not Reported |                |
|                          | Valtrax         |                    |                    | C               |                            |                      |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Aug-2014              | 10410321        | EXPEDITED (15-DAY) |                    | DE              | US-PFIZER INC-2014234493   |                      | 66 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Death; Headache          | Procardia XI    |                    |                    | S               | Oral                       | 10 Mg, Unk           |                 | Pfizer       |                |
|                          | Aspirin         |                    |                    | S               | Oral                       | 81 Mg, Unk           |                 | Not Reported |                |
|                          | Sovaldi         |                    |                    | S               | Oral                       | 400 Mg, Unk          |                 | Not Reported |                |

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

|  |          |   |      |            |              |
|--|----------|---|------|------------|--------------|
|  | Lexapro  | S | Oral | 10 Mg, Unk | Not Reported |
|  | Prilosec | S | Oral | 40 Mg, Unk | Not Reported |
|  | Olysio   | C |      | Unk        | Not Reported |
|  | Miralax  | C |      | Unk        | Not Reported |
|  | Valtrax  | C |      | Unk        | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Aug-2014              | 10416776      | EXPEDITED (15-DAY) | Y                  | OT              | US-H14001-14-00423   |                      | 55 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                           | <u>Product</u>                                                                                                                                              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>           | <u>Route</u>                             | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                                                                   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|------------|-----------------------|------------------------------------------|--------------------|-----------------|------------------------------------------------------------------------------|
| Cerebral Haemorrhage;<br>Drug Interaction;<br>Enterococcus Test<br>Positive; Intraventricular<br>Haemorrhage; Liver<br>Transplant; Platelet Count<br>Decreased; Platelet<br>Dysfunction; Serotonin<br>Syndrome; Small Intestinal<br>Obstruction | Fentanyl (Fentanyl)<br>Escitalopram (Escitalopram)<br>Trazodone (Trazodone)<br>Linezolid (Linezolid)<br>Vancomycin<br>Piperacillin-Tazobactam<br>(Pip/Tazo) |              |            | S<br>S<br>C<br>C<br>C | Intravenous (not<br>otherwise specified) |                    |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 27-Aug-2014              | 10388123      | EXPEDITED (15-DAY) |                    | HO              | ES-PFIZER INC-<br>2014223785 |                      | 76 YR      | Male       | ESP            |

| <u>Preferred Term</u>                           | <u>Product</u>                                                                                                        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>                          | <u>Route</u>                                                 | <u>Dosage Text</u>                                                                                                            | <u>Duration</u> | <u>Mfr</u>                                                                                                             |
|-------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------|--------------|------------|--------------------------------------|--------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------|-----------------|------------------------------------------------------------------------------------------------------------------------|
| Inappropriate Antidiuretic<br>Hormone Secretion | Lyrica<br>Escitalopram Oxalate<br>Carvedilol<br>Omeprazole<br>Atorvastatin<br>Tamsulosin<br>Furosemide<br>Allopurinol |              |            | S<br>S<br>C<br>C<br>C<br>C<br>C<br>C | Oral<br>Oral<br>Oral<br>Oral<br>Oral<br>Oral<br>Oral<br>Oral | 75 Mg, 1x/Day<br>10 Mg, 1x/Day<br>12.5 Mg, 2x/Day<br>20 Mg, 1x/Day<br>20 Mg, 1x/Day<br>Unk<br>40 Mg, 1x/Day<br>100 Mg, 1x/Day |                 | Pfizer<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |

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

|  |          |   |            |                |              |
|--|----------|---|------------|----------------|--------------|
|  | Losartan | C | Oral       | 50 Mg, 1x/Day  | Not Reported |
|  | Adiro    | C |            | 100 Mg, 1x/Day | Not Reported |
|  | Orfidal  | C | Oral       | 1 Mg, 1x/Day   | Not Reported |
|  | Sintrom  | C | Oral       | Unk            | Not Reported |
|  | Xalacom  | C | Ophthalmic | 1 Drop 1x/Day  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 27-Aug-2014              | 10411430       | NON-EXPEDITED    |                    | HO              | IN-LUPIN<br>PHARMACEUTICALS<br>INC.-2014-01441 |                      | 63 YR           | Male         | IND            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyponatraemia            | Olanzapine     |                  |                    | S               | Unknown                                        | 5mg                  |                 | Not Reported |                |
|                          | Escitalopram   |                  |                    | S               | Unknown                                        | 5mg                  |                 | Not Reported |                |
|                          | Escitalopram   |                  |                    | S               | Unknown                                        | 10mg                 |                 | Not Reported |                |

| <u>FDA Received Date</u>                                          | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| 27-Aug-2014                                                       | 10411662       | EXPEDITED (15-DAY) |                    | HO              | FR-MERCK-<br>1408FRA012897 |                      | 49 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                             | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Paraesthesia; Poisoning<br>Deliberate; Somnolence;<br>Tachycardia | Norset         |                    |                    | S               | Oral                       | 16 Df, Once          |                 | Merck        |                |
|                                                                   | Paracetamol    |                    |                    | S               | Oral                       | 8000 Mg, Once        |                 | Not Reported |                |
|                                                                   | Tercian        |                    |                    | S               | Oral                       | 16 Df, Once          |                 | Not Reported |                |
|                                                                   | Seroplex       |                    |                    | S               | Oral                       | 4 Df, Once           |                 | Not Reported |                |

| <u>FDA Received Date</u>                | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------|----------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|-----------------|--------------|----------------|
| 27-Aug-2014                             | 10412702       | EXPEDITED (15-DAY) |                    | HO              | FR-ASTRAZENECA-<br>2014SE62593 |                      | 87 YR           | Female       | FRA            |
| <u>Preferred Term</u>                   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Failure; Fall;<br>Hyponatraemia | Inexium        |                    |                    | S               | Oral                           |                      |                 | Astrazeneca  |                |
|                                         | Seroplex       |                    |                    | S               | Oral                           |                      |                 | Not Reported |                |



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

|              |   |      |              |
|--------------|---|------|--------------|
| Furosemide   | S | Oral | Not Reported |
| Coversyl     | S | Oral | Not Reported |
| Amlor        | C | Oral | Not Reported |
| Pravastatine | C | Oral | Not Reported |
| Stresam      | C | Oral | Not Reported |
| Xanax        | C | Oral | Not Reported |
| Zyprexa      | C | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Aug-2014              | 10413251      | EXPEDITED (15-DAY) |                    | OT              | SE-FRI-1000070207    |                      | 25 YR      | Female     | SWE            |

| <u>Preferred Term</u>                                                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Depressed Mood;<br>Personality Change;<br>Suicidal Ideation | Escitalopram   |              |            | S           | Oral         | 5 Mg               |                 | Forest       |
|                                                                      | Escitalopram   |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                                                      | Escitalopram   |              |            | S           | Oral         | Dose Reduced       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Aug-2014              | 10413993      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000070144    |                      | 56 YR      | Female     | FRA            |

| <u>Preferred Term</u>                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Erythema; Pruritus; Rash<br>Scarlatiniform | Escitalopram   |              |            | S           | Oral         | 5 Mg               |                 | Forest       |
|                                            | Alprazolam     |              |            | S           | Oral         | 0.25 Mg            |                 | Not Reported |
|                                            | Atarax         |              |            | S           | Oral         | 25 Mg              |                 | Not Reported |
|                                            | Kardegic       |              |            | C           | Oral         |                    |                 | Not Reported |
|                                            | Olmotec        |              |            | C           |              |                    |                 | Not Reported |
|                                            | Tahor          |              |            | C           | Oral         |                    |                 | Not Reported |
|                                            | Imovane        |              |            | C           | Oral         |                    |                 | Not Reported |
|                                            | Lansoyl        |              |            | C           |              |                    |                 | Not Reported |

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

| <a href="#">FDA Received Date</a>                                                      | <a href="#">Case #</a>      | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>            | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|----------------------------------------------------------------------------------------|-----------------------------|---------------------------|-----------------------------|--------------------------|------------------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 27-Aug-2014                                                                            | 10415930                    | DIRECT                    |                             | OT                       |                                          |                               | 35 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                         | <a href="#">Product</a>     | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                    | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Feeling Jittery                                                                        | Lexapro Generic 10mg        |                           |                             | S                        | Oral                                     |                               |                          | Mylan               |                         |
|                                                                                        | Lexapro Generic 10mg        |                           |                             | S                        | Oral                                     |                               |                          | Teva                |                         |
| <a href="#">FDA Received Date</a>                                                      | <a href="#">Case #</a>      | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>            | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 27-Aug-2014                                                                            | 10418427                    | EXPEDITED (15-DAY)        | Y                           | DE, OT                   | 2014JUB00090                             |                               | 55 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>                                                         | <a href="#">Product</a>     | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                    | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Cerebral Haemorrhage;<br>Drug Interaction; Platelet<br>Disorder; Serotonin<br>Syndrome | Escitalopram (Escitalopram) |                           |                             | S                        |                                          |                               |                          | Not Reported        |                         |
|                                                                                        | Unknown                     |                           |                             | S                        |                                          |                               |                          | Not Reported        |                         |
|                                                                                        | Trazodone (Trazodone)       |                           |                             | S                        |                                          |                               |                          | Not Reported        |                         |
|                                                                                        | Fentanyl (Fentanyl)         |                           |                             |                          | Intravenous (not<br>otherwise specified) |                               |                          | Not Reported        |                         |
|                                                                                        | Linezolid (Linezolid)       |                           |                             | S                        |                                          |                               |                          | Not Reported        |                         |
|                                                                                        | Vancomycin                  |                           |                             | C                        |                                          |                               |                          | Not Reported        |                         |
|                                                                                        | Piperacillin Tazobactam     |                           |                             | C                        |                                          |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                      | <a href="#">Case #</a>      | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>            | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 27-Aug-2014                                                                            | 10419495                    | EXPEDITED (15-DAY)        | Y                           | OT                       | 2014HINLIT0719                           |                               | 24 YR                    | Female              | IND                     |
| <a href="#">Preferred Term</a>                                                         | <a href="#">Product</a>     | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                    | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Galactorrhoea;<br>Hyperprolactinaemia                                                  | Escitalopram (Escitalopram) |                           |                             | S                        |                                          |                               |                          | Not Reported        |                         |
|                                                                                        | Unknown                     |                           |                             |                          |                                          |                               |                          |                     |                         |
|                                                                                        | Clonazepam (Clonazepam)     |                           |                             | C                        |                                          |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                      | <a href="#">Case #</a>      | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>            | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 27-Aug-2014                                                                            | 10419511                    | EXPEDITED (15-DAY)        |                             | OT                       | AUR-APL-2014-08982                       |                               | 62 YR                    | Female              | GBR                     |
| <a href="#">Preferred Term</a>                                                         | <a href="#">Product</a>     | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                    | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |

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

|                                              |                                                |   |      |              |
|----------------------------------------------|------------------------------------------------|---|------|--------------|
| Arthralgia; Balance Disorder; Condition      | Escitalopram 10 Mg (Escitalopram)Unknown, 10mg | S | Oral | Not Reported |
| Aggravated; Dizziness;                       | Fluoxetine (Fluoxetine)                        | C |      | Not Reported |
| Exposure During                              | Glucosamine (Glucosamine)                      | C |      | Not Reported |
| Pregnancy; Foetal Growth                     | Lamotrigine (Lamotrigine)                      | C |      | Not Reported |
| Restriction; Hypoglycaemia; Myalgia; Vertigo | Trazodone (Trazodone)                          | C |      | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 28-Aug-2014              | 8952274       | EXPEDITED (15-DAY) |                    | HO              | US-009507513-1211USA011531 |                      | 64 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                         | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|--------------------------|--------------|------------|-------------|--------------|--------------------------------------------|-----------------|--------------|
| Urosepsis             | Temozolomide             |              |            | S           | Oral         | 320 Mg, Days 1-5 Of Repeated 28 Day Cycles |                 | Merck        |
|                       | Study Drug (Unspecified) |              |            | S           |              | 0.8 Unk, Unk                               |                 | Not Reported |
|                       | Pantoprazole             |              |            | C           |              |                                            |                 | Not Reported |
|                       | Haloperidol              |              |            | C           |              |                                            |                 | Not Reported |
|                       | Enoxaparin Sodium        |              |            | C           |              |                                            |                 | Not Reported |
|                       | Ceftriaxone Sodium       |              |            | C           |              |                                            |                 | Not Reported |
|                       | Vancomycin               |              |            | C           |              |                                            |                 | Not Reported |
|                       | Levothyroxine Sodium     |              |            | C           |              |                                            |                 | Not Reported |
|                       | Celecoxib                |              |            | C           |              |                                            |                 | Not Reported |
|                       | Citalopram               |              |            | C           |              |                                            |                 | Not Reported |
|                       | Codeine                  |              |            | C           |              |                                            |                 | Not Reported |
|                       | Prednisone               |              |            | C           |              |                                            |                 | Merck        |
|                       | Alprazolam               |              |            | C           |              |                                            |                 | Not Reported |
|                       | Fluconazole              |              |            | C           |              |                                            |                 | Not Reported |
|                       | Acyclovir                |              |            | C           |              |                                            |                 | Not Reported |
|                       | Clindamycin              |              |            | C           |              |                                            |                 | Not Reported |
|                       | Gabapentin               |              |            | C           |              |                                            |                 | Not Reported |
|                       | Levetiracetam            |              |            | C           |              |                                            |                 | Not Reported |
|                       | Heparin                  |              |            | C           |              |                                            |                 | Not Reported |
|                       | Sodium Chloride          |              |            | C           |              |                                            |                 | Not Reported |
|                       | Acetaminophen            |              |            | C           |              |                                            |                 | Not Reported |
|                       | Nystatin                 |              |            | C           |              |                                            |                 | Not Reported |
|                       | Ondansetron              |              |            | C           |              |                                            |                 | Not Reported |
|                       | Phenytoin                |              |            | C           |              |                                            |                 | Not Reported |
|                       | Escitalopram Oxalate     |              |            | S           |              |                                            |                 | Not Reported |

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

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Aug-2014              | 10416105      | EXPEDITED (15-DAY) |                    | HO              | NL-FRI-1000070241    |                      |            | Female     | NLD            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Extrasystoles         | Lexapro        |              |            | S           | Oral         |                    |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Aug-2014              | 10416184      | EXPEDITED (15-DAY) |                    | HO, LT          | FR-FRI-1000070202    |                      | 69 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                                                                                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Confusional State;<br>Delusion; Drug Interaction;<br>Extrapyramidal Disorder;<br>Hyperhidrosis;<br>Hypertension; Myoclonus;<br>Serotonin Syndrome | Escitalopram   |              |            | S           | Oral         | 5 Mg               |                 | Forest       |
|                                                                                                                                                   | Effexor Lp     |              |            | S           | Oral         | 37.5 Mg            |                 | Not Reported |
|                                                                                                                                                   | Tramadol       |              |            | S           | Oral         | 200 Mg             |                 | Not Reported |
|                                                                                                                                                   | Anastrozole    |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                   | Noroxine       |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                   | Lexomil Roche  |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                   | Dafalgan       |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                   | Fumafer        |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                   | Speciafoldine  |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Aug-2014              | 10417036      | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000070118    |                      | < 1 DAY    | Male       | USA            |

| <u>Preferred Term</u>                                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|------------|
| Congenital Jaw Malformation; Talipes; Ventricular Septal Defect | Lexapro        |              |            | S           | Transplacental |                    |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 29-Aug-2014              | 10418087      | EXPEDITED (15-DAY) |                    | HO              | AU-009507513-1408AUS015411 |                      | 74 YR      | Female     | AUS            |

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

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

|                                                  |                           |   |      |            |              |
|--------------------------------------------------|---------------------------|---|------|------------|--------------|
| Aphasia; Confusional State; Hemiparesis; Syncope | Sitagliptin Phosphate (+) | S | Oral | Unk        | Merck        |
|                                                  | Metformin Hydrochloride   | S |      | Unk        | Not Reported |
|                                                  | Atorvastatin              | S |      | Unk        | Not Reported |
|                                                  | Digoxin                   | S |      | Unk        | Not Reported |
|                                                  | Escitalopram              | S |      | Unk        | Not Reported |
|                                                  | Irbesartan                | S |      | Unk        | Not Reported |
|                                                  | Pantoprazole              | S |      | Unk        | Not Reported |
|                                                  | Solifenacin Succinate     | S |      | Unk        | Not Reported |
|                                                  | Strontium Ranelate        | S |      | 2 G, Daily | Not Reported |
|                                                  | Warfarin Sodium           | S |      | Unk        | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Aug-2014              | 10418104      | EXPEDITED (15-DAY) |                    | OT              | GB-FRI-1000070286    |                      | 62 YR      | Female     | GBR            |

| <u>Preferred Term</u>                                                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Arthralgia; Balance Disorder; Condition Aggravated; Dizziness; Myalgia; Vertigo | Escitalopram   |              |            | S           | Oral         | 10 Mg Daily        |                 | Forest       |
|                                                                                 | Fluoxetine     |              |            | C           |              |                    |                 | Not Reported |
|                                                                                 | Glucosamine    |              |            | C           |              |                    |                 | Not Reported |
|                                                                                 | Lamotrigine    |              |            | C           |              |                    |                 | Not Reported |
|                                                                                 | Trazodone      |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Aug-2014              | 10419314      | EXPEDITED (15-DAY) |                    | DE              | US-BAYER-2014-126461 |                      | 66 YR      | Female     | USA            |

| <u>Preferred Term</u>                                 | <u>Product</u>                           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------|------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Death; Headache; Product Use In Unapproved Indication | Bayer Aspirin Regimen Adult Low Strength |              | Y          | S           | Oral         | 81 Mg Daily, Unk   |                 | Bayer        |
|                                                       | Procardia                                |              |            | S           | Oral         | 10 Mg, Unk         |                 | Not Reported |
|                                                       | Lexapro                                  |              |            | S           | Oral         | 10 Mg, Unk         |                 | Not Reported |
|                                                       | Prilosec                                 |              |            | S           | Oral         | 40 Mg, Unk         |                 | Not Reported |
|                                                       | Multivitamins                            |              |            | S           |              | Unknowwn           |                 | Not Reported |
|                                                       | Miralax                                  |              |            | C           |              |                    |                 | Not Reported |
|                                                       | Valtrax                                  |              |            | C           |              |                    |                 | Not Reported |

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

| <u>FDA Received Date</u>                                                                                                                          | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u>                                                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|---------------------------------|---------------------------------------------------------------------|-----------------|--------------|----------------|
| 30-Aug-2014                                                                                                                                       | 10421172                | EXPEDITED (15-DAY) |                    | HO, LT          | FR-AUROBINDO-AUR-APL-2014-09124 |                                                                     | 69 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                             | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>                                                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State;<br>Delusion; Drug Interaction;<br>Extrapyramidal Disorder;<br>Hyperhidrosis;<br>Hypertension; Myoclonus;<br>Serotonin Syndrome | Tramadol                |                    |                    | S               | Oral                            | 100 Mg, Two Times A Day                                             |                 | Aurobindo    |                |
|                                                                                                                                                   | Effexor                 |                    |                    | S               | Oral                            | 37.5 Mg, Once A Day                                                 |                 | Not Reported |                |
|                                                                                                                                                   | Seroplex                |                    |                    | S               | Oral                            | 5 Mg, Once A Day                                                    |                 | Not Reported |                |
|                                                                                                                                                   | Anastrozole             |                    |                    | C               | Unknown                         | Unk                                                                 |                 | Not Reported |                |
|                                                                                                                                                   | Noroxin                 |                    |                    | C               | Unknown                         | 400 Mg, Unk                                                         |                 | Not Reported |                |
|                                                                                                                                                   | Lexomil                 |                    |                    | C               | Unknown                         | Unk                                                                 |                 | Not Reported |                |
|                                                                                                                                                   | Dafalgan                |                    |                    | C               | Unknown                         | Unk                                                                 |                 | Not Reported |                |
|                                                                                                                                                   | Fumafer                 |                    |                    | C               | Unknown                         | Unk                                                                 |                 | Not Reported |                |
|                                                                                                                                                   | Speciafoldine           |                    |                    | C               | Unknown                         | Unk                                                                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                          | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u>                                                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Sep-2014                                                                                                                                       | 10381446                | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2014184988        |                                                                     | 49 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                             | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>                                                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Disease Progression;<br>Pain; Pain In Extremity;<br>Restless Legs Syndrome                                                                        | Lyrica                  |                    |                    | S               | Oral                            | 200 Mg, 3x/Day                                                      |                 | Pfizer       |                |
|                                                                                                                                                   | Lexapro                 |                    |                    | S               | Oral                            | 10 Mg, 1x/Day                                                       |                 | Not Reported |                |
|                                                                                                                                                   | Mirapex                 |                    |                    | C               |                                 | Unk                                                                 |                 | Not Reported |                |
|                                                                                                                                                   | Klonopin                |                    |                    | C               |                                 | Unk                                                                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                          | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u>                                                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Sep-2014                                                                                                                                       | 10426958                | DIRECT             |                    | DS              |                                 |                                                                     | 55 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                             | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>                                                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Cognitive Disorder                                                                                                                                | Escitalopram 10mg/20 Mg |                    |                    | S               | Oral                            | 1 10 Mg And 1 20 Mg<br>Once Daily Taken By<br>Mouth Duration: 1 1/2 | 1.5 YR          | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| Years                                |                          |                    |                    |                 |                                 |                                                    |                 |              |                |
|--------------------------------------|--------------------------|--------------------|--------------------|-----------------|---------------------------------|----------------------------------------------------|-----------------|--------------|----------------|
| <u>FDA Received Date</u>             | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u>                               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Sep-2014                          | 10429852                 | DIRECT             |                    | HO, LT, OT      |                                 |                                                    | 62 YR           | Female       | USA            |
| <u>Preferred Term</u>                | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>                                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Chest Pain; Pulmonary Embolism       | Lexapro                  |                    |                    | S               | Oral                            | 10 Mg Halved 1/2 Table/ 6 Days Once A Day By Mouth |                 | Forest       |                |
|                                      | Vitamin D Nos            |                    |                    | C               |                                 |                                                    |                 | Not Reported |                |
|                                      | Warfarin Sodium          |                    |                    | C               |                                 |                                                    |                 | Not Reported |                |
|                                      | Vitamin D                |                    |                    | C               |                                 |                                                    |                 | Not Reported |                |
| <u>FDA Received Date</u>             | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u>                               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Sep-2014                          | 10425844                 | EXPEDITED (15-DAY) |                    | OT              | US-AUROBINDO-AUR-APL-2014-09290 |                                                    | 62 YR           | Male         | USA            |
| <u>Preferred Term</u>                | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>                                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Serotonin Syndrome | Escitalopram             |                    |                    | S               | Unknown                         | Unk                                                |                 | Aurobindo    |                |
|                                      | Methylene Blue           |                    |                    | S               | Unknown                         | 1 Mg/Kg, In 2 Consecutive Doses (Total Of 2mg/Kg)  |                 | Not Reported |                |
|                                      | Aspirin                  |                    |                    | C               | Unknown                         | Unk                                                |                 | Not Reported |                |
|                                      | Metoprolol               |                    |                    | C               | Unknown                         | Unk                                                |                 | Not Reported |                |
|                                      | Atorvastatin             |                    |                    | C               | Unknown                         | Unk                                                |                 | Not Reported |                |
|                                      | Furosemide               |                    |                    | C               | Unknown                         | Unk                                                |                 | Not Reported |                |
|                                      | Lamotrigine              |                    |                    | C               | Unknown                         | Unk                                                |                 | Not Reported |                |
|                                      | Salbutamol W/Ipratropium |                    |                    | C               | Unknown                         | Unk                                                |                 | Not Reported |                |
|                                      | Nitroglycerin            |                    |                    | C               | Sublingual                      | Unk, As Needed                                     |                 | Not Reported |                |
|                                      | Lisinopril               |                    |                    | C               | Unknown                         | Unk                                                |                 | Not Reported |                |
| <u>FDA Received Date</u>             | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u>                               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Sep-2014                          | 10427340                 | EXPEDITED (15-DAY) |                    | DE              | US-FRI-1000070255               |                                                    | 66 YR           | Female       | USA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                                                                                                                                    | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>   |                |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|------------------------------------------|-----------------|--------------|----------------|
| Death; Headache                                                                                                                                                                          | Lexapro                 |                    |                    | S               | Oral                 | 10 Mg                                    |                 | Forest       |                |
|                                                                                                                                                                                          | Sovaldi                 |                    |                    | S               | Oral                 | 400 Mg                                   |                 | Not Reported |                |
|                                                                                                                                                                                          | Aspirin                 |                    |                    | S               | Oral                 | 81 Mg                                    |                 | Not Reported |                |
|                                                                                                                                                                                          | Procardia XI            |                    |                    | S               | Oral                 | 10 Mg                                    |                 | Not Reported |                |
|                                                                                                                                                                                          | Prilosec                |                    |                    | S               | Oral                 | 40 Mg                                    |                 | Not Reported |                |
|                                                                                                                                                                                          | Multivitamin            |                    |                    | S               |                      |                                          |                 | Not Reported |                |
|                                                                                                                                                                                          | Olysio                  |                    |                    | C               |                      |                                          |                 | Not Reported |                |
|                                                                                                                                                                                          | Miralax                 |                    |                    | C               |                      |                                          |                 | Not Reported |                |
|                                                                                                                                                                                          | Megaoxiod               |                    |                    | C               |                      |                                          |                 | Not Reported |                |
|                                                                                                                                                                                          | Valtrex                 |                    |                    | C               |                      |                                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                 | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Sep-2014                                                                                                                                                                              | 10427864                | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000070233    |                                          | < 1 DAY         | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                    | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrial Septal Defect;<br>Congenital Anomaly;<br>Patent Ductus Arteriosus;<br>Right Ventricular<br>Hypertrophy;<br>Supraventricular<br>Tachycardia; Wolff-<br>Parkinson-White<br>Syndrome | Lexapro                 |                    |                    | S               | Transplacental       |                                          |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                                                                                 | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Sep-2014                                                                                                                                                                              | 10430636                | DIRECT             |                    | OT              |                      |                                          | 68 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                    | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Condition<br>Aggravated; Depression;<br>Disturbance In Attention;<br>Dyskinesia; Feeling<br>Abnormal; Impaired                                                                | Escitalopram 10 Mg Teva |                    |                    | S               | Oral                 | 1.5 Pills, Once Daily,<br>Taken By Mouth |                 | Teva         |                |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Driving Ability; Insomnia;  
Product Substitution Issue;  
Restless Legs Syndrome;  
Restlessness

| <u>FDA Received Date</u>                                                                                                                                                   | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u>                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|--------------------|--------------------|-----------------|-------------------------|-------------------------------------------|-----------------|--------------|----------------|
| 04-Sep-2014                                                                                                                                                                | 10154009                              | EXPEDITED (15-DAY) |                    | HO              | CA-RANBAXY-2014US-80901 |                                           | 93 YR           | Male         | CAN            |
| <u>Preferred Term</u>                                                                                                                                                      | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>                        | <u>Duration</u> | <u>Mfr</u>   |                |
| Diarrhoea; Dizziness; Fall; Fatigue; Hyponatraemia; Off Label Use; Orthostatic Hypotension; Osteoporosis; Poor Quality Sleep; Vitamin B12 Deficiency; Vitamin D Deficiency | Pantoprazole                          |                    |                    | S               | Unknown                 | 40 Mg, Bid                                |                 | Ranbaxy      |                |
|                                                                                                                                                                            | Metoprolol                            |                    |                    | S               | Unknown                 | Dose Decreased To 25 Mg, Qd               |                 | Ipca         |                |
|                                                                                                                                                                            | Metoprolol                            |                    |                    | S               | Unknown                 | Dose Decreased To 12.5 Mg, Qd             |                 | Ipca         |                |
|                                                                                                                                                                            | Metoprolol                            |                    |                    | S               | Unknown                 | 12.5 Mg, Qd                               |                 | Ipca         |                |
|                                                                                                                                                                            | Escitalopram (Ngx)                    |                    |                    | S               | Unknown                 | Dose Decreased To 5 Mg, Qd                |                 | Not Reported |                |
|                                                                                                                                                                            | Escitalopram (Ngx)                    |                    |                    | S               | Unknown                 | 5 Mg, Qd                                  |                 | Not Reported |                |
|                                                                                                                                                                            | Lorazepam (Ngx) (Lorazepam) Unknown   |                    |                    | S               | Unknown                 | 1 Mg At Bedtime; Dose Decreased To 0.5 Mg |                 | Not Reported |                |
|                                                                                                                                                                            | Lorazepam (Ngx) (Lorazepam) Unknown   |                    |                    | S               | Unknown                 | 0.5 Mg; Dose Decreased To 0.25 Mg         |                 | Not Reported |                |
|                                                                                                                                                                            | Lorazepam (Ngx) (Lorazepam) Unknown   |                    |                    | S               | Unknown                 | 0.25 Mg                                   |                 | Not Reported |                |
|                                                                                                                                                                            | Prednisone (Ngx) (Prednisone) Unknown |                    |                    | S               | Unknown                 | Dose Decreased To 7.5 Mg, Qd              |                 | Not Reported |                |
|                                                                                                                                                                            | Prednisone (Ngx) (Prednisone) Unknown |                    |                    | S               | Unknown                 | Dose Increased To 5 Mg, Bid               |                 | Not Reported |                |
|                                                                                                                                                                            | Telmisartan (Ngx)                     |                    |                    | S               | Unknown                 | Dose Decreased To 40 Mg, Qd               |                 | Not Reported |                |
|                                                                                                                                                                            | Telmisartan (Ngx)                     |                    |                    | S               | Unknown                 | Dose Decreased To 20 Mg, Qd               |                 | Not Reported |                |
|                                                                                                                                                                            | Telmisartan (Ngx)                     |                    |                    | S               | Unknown                 | 20 Mg, Qd                                 |                 | Not Reported |                |
|                                                                                                                                                                            | Loperamide                            |                    |                    | C               | Unknown                 | 1 Mg, Prn                                 |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                                                                    |                |                    |                    |                 |                                 |                             |                 |              |                |
|----------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|---------------------------------|-----------------------------|-----------------|--------------|----------------|
| Tamsulosin Cr                                                                                      |                |                    | C                  | Unknown         | 0.4 Mg, Qd; At Bedtime          |                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                           | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Sep-2014                                                                                        | 10429577       | EXPEDITED (15-DAY) |                    | HO              | CA-EISAI INC-E3810-07388-SPO-CA |                             | < 1 DAY         | Unknown      | CAN            |
| <u>Preferred Term</u>                                                                              | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Withdrawal Syndrome Neonatal; Exposure During Pregnancy; Trismus                              | Rabeprazole    |                    |                    | S               | Transplacental                  | Unknown                     |                 | Not Reported |                |
|                                                                                                    | Quetiapine     |                    |                    | S               | Transplacental                  | Unknown                     |                 | Not Reported |                |
|                                                                                                    | Escitalopram   |                    |                    | S               | Transplacental                  | Unknown                     |                 | Not Reported |                |
|                                                                                                    | Nortriptyline  |                    |                    | S               | Transplacental                  | Unknown                     |                 | Not Reported |                |
|                                                                                                    | Gabapentin     |                    |                    | S               | Transplacental                  | Unknown                     |                 | Not Reported |                |
|                                                                                                    | Benzotropine   |                    |                    | S               | Transplacental                  | Unknown                     |                 | Not Reported |                |
|                                                                                                    | Zopiclone      |                    |                    | S               | Transplacental                  | Unknown                     |                 | Not Reported |                |
|                                                                                                    | Methadone      |                    |                    | S               | Transplacental                  | Unknown                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                           | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Sep-2014                                                                                        | 10431042       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000070382               |                             | 49 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                              | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Overdose; Paraesthesia; Poisoning Deliberate; Somnolence; Suicide Attempt; Tachycardia | Escitalopram   |                    |                    | S               | Oral                            | Overdose 4 Df Once Nos.     |                 | Forest       |                |
|                                                                                                    | Paracetamol    |                    |                    | S               | Oral                            | Overdose 8,000 Mg Once Nos. |                 | Not Reported |                |
|                                                                                                    | Tercian        |                    |                    | S               | Oral                            | Overdose 4,000 Mg Once Nos. |                 | Not Reported |                |
|                                                                                                    | Norset         |                    |                    | S               | Oral                            | Overdose 2,400 Mg Once Nos. |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                           | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Sep-2014                                                                                        | 10432409       | DIRECT             |                    | DE              |                                 |                             |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                              | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |

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

|                                                                                                                        |                             |                    |                    |                 |                                          |                                                          |                 |              |                |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|------------------------------------------|----------------------------------------------------------|-----------------|--------------|----------------|
| Anxiety; Feeling Jittery;<br>Product Substitution Issue                                                                |                             | Generic Lexapro    |                    | S               |                                          | Not Reported                                             |                 |              |                |
| <u>FDA Received Date</u>                                                                                               | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>                                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Sep-2014                                                                                                            | 10436062                    | EXPEDITED (15-DAY) | Y                  | HO, OT          | US-ZYDUS-004433                          |                                                          | 15 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                  | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>                                       | <u>Duration</u> | <u>Mfr</u>   |                |
| Electrocardiogram Qt Prolonged; Intentional Overdose; Long Qt Syndrome Congenital; Suicide Attempt; Torsade De Pointes | Escitalopram (Escitalopram) |                    |                    | S               |                                          |                                                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                               | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>                                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Sep-2014                                                                                                            | 10436565                    | EXPEDITED (15-DAY) | Y                  | HO              | TW-ZYDUS-004487                          |                                                          | 24 YR           | Female       | TWN            |
| <u>Preferred Term</u>                                                                                                  | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>                                       | <u>Duration</u> | <u>Mfr</u>   |                |
| Sedation; Vision Blurred                                                                                               | Escitalopram (Escitalopram) |                    |                    | S               |                                          | 40.00mg - 1.0days                                        |                 | Not Reported |                |
|                                                                                                                        | Aripiprazole (Aripiprazole) |                    |                    | S               |                                          | 20.0mg 1.0days                                           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                               | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>                                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Sep-2014                                                                                                            | 10432126                    | EXPEDITED (15-DAY) |                    | HO, OT          | FR-BRISTOL-MYERS SQUIBB COMPANY-21347430 |                                                          | 46 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                  | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>                                       | <u>Duration</u> | <u>Mfr</u>   |                |
| Gambling Disorder; Persistent Depressive Disorder; Suicidal Ideation                                                   | Abilify                     |                    |                    | S               | Oral                                     | May09-May10:15mg<br>May10-Sep13:10mg<br>Feb14-Jul14:15mg |                 | Not Reported |                |
|                                                                                                                        | Lamictal                    |                    |                    | S               | Oral                                     | 1df: 200 To 300mg                                        |                 | Not Reported |                |
|                                                                                                                        | Seroplex                    |                    |                    | S               | Oral                                     |                                                          |                 | Not Reported |                |
|                                                                                                                        | Nozinan                     |                    |                    | S               | Oral                                     |                                                          |                 | Not Reported |                |
|                                                                                                                        | Teralithe                   |                    |                    | S               | Oral                                     |                                                          |                 | Not Reported |                |

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

| <u>FDA Received Date</u>                          | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------|---------------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| 05-Sep-2014                                       | 10434404            | EXPEDITED (15-DAY) | Y                  | HO              | CH-FRI-1000070435          |                      |                 | Female       | CHE            |
| <u>Preferred Term</u>                             | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Contusion; Deep Vein Thrombosis;                  | Memantine           |                    |                    | S               | Oral                       | 1 Df                 |                 | Forest       |                |
| Electrocardiogram Qt Prolonged; Fall; Head Injury | Escitalopram        |                    |                    | S               | Oral                       | 10 Mg                |                 | Forest       |                |
|                                                   | Fludex (Indapamide) |                    |                    | S               | Oral                       | 1.5 Mg               |                 | Not Reported |                |
|                                                   | Beloc [Metoprolol]  |                    |                    | C               |                            |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                          | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Sep-2014                                       | 10434426            | EXPEDITED (15-DAY) |                    | HO              | US-ASTRAZENECA-2014SE64724 |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                             | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypotonia; Tachypnoea; Thrombocytopenia; Trismus  | Quetiapine          |                    |                    | S               | Transplacental             |                      |                 | Not Reported |                |
|                                                   | Quetiapine          |                    |                    | S               | Transplacental             |                      |                 | Not Reported |                |
|                                                   | Quetiapine          |                    |                    | S               | Transplacental             |                      |                 | Not Reported |                |
|                                                   | Quetiapine          |                    |                    | S               | Transplacental             |                      |                 | Not Reported |                |
|                                                   | Quetiapine          |                    |                    | S               | Transplacental             |                      |                 | Not Reported |                |
|                                                   | Quetiapine          |                    |                    | S               | Transplacental             |                      |                 | Not Reported |                |
|                                                   | Escitalopram        |                    |                    | S               | Transplacental             |                      |                 | Not Reported |                |
|                                                   | Escitalopram        |                    |                    | S               | Transplacental             |                      |                 | Not Reported |                |
|                                                   | Escitalopram        |                    |                    | S               | Transplacental             |                      |                 | Not Reported |                |
|                                                   | Benzotropine        |                    |                    | S               | Transplacental             |                      |                 | Not Reported |                |
|                                                   | Gabapentin          |                    |                    | S               | Transplacental             |                      |                 | Not Reported |                |
|                                                   | Gabapentin          |                    |                    | S               | Transplacental             |                      |                 | Not Reported |                |
|                                                   | Gabapentin          |                    |                    | S               | Transplacental             |                      |                 | Not Reported |                |
|                                                   | Methadone           |                    |                    | S               | Transplacental             |                      |                 | Not Reported |                |
|                                                   | Nortriptyline       |                    |                    | S               | Transplacental             |                      |                 | Not Reported |                |
|                                                   | Nortriptyline       |                    |                    | S               | Transplacental             |                      |                 | Not Reported |                |

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

|                                                                                                                                                                      | Nortriptyline       |                    | S                  | Transplacental  |                              |                                                                                  |                 | Not Reported    |                |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|--------------------|--------------------|-----------------|------------------------------|----------------------------------------------------------------------------------|-----------------|-----------------|----------------|
|                                                                                                                                                                      | Rabeprazole         |                    | S                  | Transplacental  |                              |                                                                                  |                 | Not Reported    |                |
|                                                                                                                                                                      | Zopiclone           |                    | S                  | Transplacental  |                              |                                                                                  |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                                                             | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                                                             | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 05-Sep-2014                                                                                                                                                          | 10434432            | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2014246172     |                                                                                  | 52 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                                                                                                                | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                                                               | <u>Duration</u> | <u>Mfr</u>      |                |
| Drug Hypersensitivity                                                                                                                                                | Effexor             |                    |                    | S               |                              | Unk                                                                              |                 | Pfizer          |                |
|                                                                                                                                                                      | Buspar              |                    |                    | S               |                              | Unk                                                                              |                 | Not Reported    |                |
|                                                                                                                                                                      | Lexapro             |                    |                    | S               |                              | Unk                                                                              |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                                                             | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                                                             | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 05-Sep-2014                                                                                                                                                          | 10434573            | NON-EXPEDITED      |                    | HO              | US-ASTRAZENECA-2014SE65729   |                                                                                  |                 | Female          | USA            |
| <u>Preferred Term</u>                                                                                                                                                | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                                                               | <u>Duration</u> | <u>Mfr</u>      |                |
| Anxiety; Depressed Mood; Drug Ineffective For Unapproved Indication; Flat Affect; Insomnia; Product Use In Unapproved Indication; Weight Decreased; Weight Increased | Quetiapine Fumurate |                    |                    | S               | Oral                         | Dosage Being Reduced By 50 Mg Next Three Weeks, Then It Will Be Reduced By 25 Mg |                 | Not Reported    |                |
|                                                                                                                                                                      | Lexapro             |                    |                    | S               | Unknown                      | Unknown Unk                                                                      |                 | Not Reported    |                |
|                                                                                                                                                                      | Geodon              |                    |                    | S               | Unknown                      | Unknown Unk                                                                      |                 | Not Reported    |                |
|                                                                                                                                                                      | Lamictal            |                    |                    | C               |                              | Nr                                                                               |                 | Not Reported    |                |
|                                                                                                                                                                      | Xanax               |                    |                    | C               |                              | Nr                                                                               |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                                                             | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                                                             | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 08-Sep-2014                                                                                                                                                          | 10345693            | EXPEDITED (15-DAY) |                    | HO              | CA-GLAXOSMITHKLINE-A1081273A |                                                                                  |                 | Female          | CAN            |
| <u>Preferred Term</u>                                                                                                                                                | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                                                               | <u>Duration</u> | <u>Mfr</u>      |                |
| Anxiety; Asthenia; Bone Disorder; Chest                                                                                                                              | Advair              |                    |                    | S               | Respiratory (inhalation)     |                                                                                  |                 | Glaxosmithkline |                |

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

|                           |                          |   |         |                 |
|---------------------------|--------------------------|---|---------|-----------------|
| Discomfort; Cough;        | Ventolin                 | S | Unknown | Glaxosmithkline |
| Cyanosis; Decreased       | Spiriva                  | S | Unknown | Not Reported    |
| Appetite; Depression;     | Clarithromycin           | S | Unknown | Glaxosmithkline |
| Diarrhoea; Dizziness;     | Atrovent                 | S | Unknown | Glaxosmithkline |
| Drug Ineffective;         | Seebri Breezhaler        | S | Unknown | Glaxosmithkline |
| Dyspnoea; Dyspnoea        | Unknown Drug For Anxiety | S | Unknown | Not Reported    |
| Exertional; Emphysema;    | Prednisone               | S | Unknown | Glaxosmithkline |
| Fall; Fatigue; Headache;  | Aerochamber              | S | Unknown | Glaxosmithkline |
| Hiatus Hernia;            | Cipralax                 | S |         | Glaxosmithkline |
| Hypoaesthesia; Infection; | Unknown Antihypertensive | C | Unknown | Not Reported    |
| Insomnia; Lung Infection; | Agent                    | C |         |                 |
| Malaise; Overdose; Pain;  | Gaba                     | C | Unknown | Not Reported    |
| Panic Reaction;           | Unknown Medication       | C | Unknown | Glaxosmithkline |
| Pneumonia; Pruritus;      | Clonazepam               | C |         | Glaxosmithkline |
| Restlessness; Thinking    | Meloxicam                | C |         | Glaxosmithkline |
| Abnormal; Tremor          |                          |   |         |                 |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Sep-2014              | 10435383      | EXPEDITED (15-DAY) |                    | OT              | NO-ACCORD-025647     |                      | 36 YR      | Female     | NOR            |

| <u>Preferred Term</u>      | <u>Product</u>  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|-----------------|--------------|------------|-------------|--------------|-------------------------|-----------------|--------------|
| Decreased Appetite;        | Escitalopram    |              |            | S           | Oral         | Started On 10 Mg Daily  |                 | Accord       |
| Diarrhoea; Disturbance In  |                 |              |            |             |              | From 14-Aug-2013 And    |                 |              |
| Attention; Dizziness; Drug |                 |              |            |             |              | Increase To 15 Mg Daily |                 |              |
| Interaction; Dry Mouth;    |                 |              |            |             |              | From 13-Nov-2013        |                 |              |
| Headache; Heart Rate       | Montelukast     |              |            | S           | Oral         | Seasonal                |                 | Accord       |
| Irregular; Hyperhidrosis;  | Panodil         |              |            | C           | Oral         |                         |                 | Not Reported |
| Hypersomnia; Memory        | Seretide Diskus |              |            | C           | Respiratory  |                         |                 | Not Reported |
| Impairment;                |                 |              |            |             | (inhalation) |                         |                 |              |
| Musculoskeletal Pain;      |                 |              |            |             |              |                         |                 |              |
| Myalgia; Nausea;           |                 |              |            |             |              |                         |                 |              |
| Paraesthesia;              |                 |              |            |             |              |                         |                 |              |
| Paraesthesia; Pyrexia;     |                 |              |            |             |              |                         |                 |              |
| Restlessness;              |                 |              |            |             |              |                         |                 |              |
| Somnolence; Tinnitus;      |                 |              |            |             |              |                         |                 |              |
| Vomiting                   |                 |              |            |             |              |                         |                 |              |

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

| <u>FDA Received Date</u>                                                    | <u>Case #</u>                                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                         | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
|-----------------------------------------------------------------------------|--------------------------------------------------------|--------------------|--------------------|-----------------|--------------------------------------------------------------|----------------------------|-----------------|----------------------------------------------|----------------|
| 08-Sep-2014                                                                 | 10436788                                               | NON-EXPEDITED      |                    |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>19547744              |                            | 61 YR           | Female                                       | USA            |
| <u>Preferred Term</u>                                                       | <u>Product</u>                                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                 | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Poor Quality Sleep                                                          | Abilify<br>Lamictal<br>Lexapro                         |                    |                    | S<br>S<br>S     |                                                              |                            |                 | Not Reported<br>Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                    | <u>Case #</u>                                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                         | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 08-Sep-2014                                                                 | 10437165                                               | NON-EXPEDITED      |                    |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>20340592              |                            |                 | Female                                       | USA            |
| <u>Preferred Term</u>                                                       | <u>Product</u>                                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                 | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Nausea                                                                      | Abilify Tabs<br>Remeron<br>Lexapro                     |                    |                    | S<br>S<br>S     |                                                              |                            |                 | Not Reported<br>Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                    | <u>Case #</u>                                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                         | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 08-Sep-2014                                                                 | 10437916                                               | NON-EXPEDITED      |                    |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>21075593              |                            |                 | Unknown                                      | USA            |
| <u>Preferred Term</u>                                                       | <u>Product</u>                                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                 | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Hepatic Enzyme<br>Increased                                                 | Abilify<br>Ciprallex<br>Zeldox                         |                    |                    | S<br>S<br>S     |                                                              | 1 Df= 20 Units Nos.        |                 | Not Reported<br>Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                    | <u>Case #</u>                                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                         | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 08-Sep-2014                                                                 | 10438106                                               | EXPEDITED (15-DAY) |                    | OT              | CA-MUNDIPHARMA DS<br>AND<br>PHARMACOVIGILANCE<br>-CAN-2014-0 |                            | 56 YR           | Female                                       | CAN            |
| <u>Preferred Term</u>                                                       | <u>Product</u>                                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                 | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Abdominal Discomfort;<br>Anxiety; Asthenia; Balance<br>Disorder; Diarrhoea; | Butrans Transdermal Patch<br>Butrans Transdermal Patch |                    |                    | S<br>S          | Transdermal<br>Transdermal                                   | 10 Mcg, Q1h<br>20 Mcg, Q1h |                 | Purdue<br>Purdue                             |                |

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

|                             |                           |   |             |                |              |
|-----------------------------|---------------------------|---|-------------|----------------|--------------|
| Disorientation;             | Butrans Transdermal Patch | S | Transdermal | 15 Mcg, Q1h    | Purdue       |
| Disturbance In Attention;   | Butrans Transdermal Patch | S | Transdermal | 5 Mcg, Q1h     | Purdue       |
| Dizziness; Drug             | Cesamet                   | S | Oral        | 0.25 Mg, Daily | Not Reported |
| Interaction; Dyspnoea;      | Baclofen                  | S | Unknown     | 20 Mg, Tid     | Not Reported |
| Euphoric Mood; Gait         | Baclofen                  | S | Unknown     | 10 Mg, Unk     | Not Reported |
| Disturbance; Hallucination; | Clonazepam                | S | Oral        | 1 Mg, Tid      | Not Reported |
| Headache; Hypopnoea;        | Escitalopram Oxalate      | S | Oral        | 10 Mg, Daily   | Not Reported |
| Muscle Spasms;              | Escitalopram Oxalate      | S | Oral        | 20 Mg, Unk     | Not Reported |
| Palpitations; Pulse         | Bisoprolol                | C | Unknown     | Unk            | Not Reported |
| Pressure Increased;         | Cipro /00697201/          | C | Unknown     | Unk            | Not Reported |
| Somnolence; Urinary Tract   | Furosemide                | C | Unknown     | Unk            | Not Reported |
| Infection; Vomiting         | Wellbutrin XI             | C | Unknown     | Unk            | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>     | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|-------------------|------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 08-Sep-2014              | 10438329          | NON-EXPEDITED    |                    |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>19150010 |                      | 38 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>    | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective; Hunger | Abilify           |                  |                    | S               |                                                 |                      |                 | Not Reported |                |
|                          | Abilify           |                  |                    | S               |                                                 |                      |                 | Not Reported |                |
|                          | Lexapro           |                  |                    | S               |                                                 |                      |                 | Not Reported |                |
|                          | Lexapro           |                  |                    | S               |                                                 |                      |                 | Not Reported |                |
|                          | Xarelto           |                  |                    | C               |                                                 |                      |                 | Not Reported |                |
|                          | Atorvastatin      |                  |                    | C               |                                                 |                      |                 | Not Reported |                |
|                          | Hctz              |                  |                    | C               |                                                 |                      |                 | Not Reported |                |
|                          | Vitamin B Complex |                  |                    | C               |                                                 |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 08-Sep-2014              | 10438510       | NON-EXPEDITED    |                    |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>20573317 |                      | 14 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Circumstance Or          | Abilify Tabs   |                  |                    | S               |                                                 |                      |                 | Not Reported |                |
| Information Capable Of   | Abilify Tabs   |                  |                    | S               |                                                 |                      |                 | Not Reported |                |



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

|                       |              |   |      |              |
|-----------------------|--------------|---|------|--------------|
| Leading To Medication | Escitalopram | S | Oral | Not Reported |
| Error                 | Escitalopram | S | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 08-Sep-2014              | 10438714       | NON-EXPEDITED    |                    |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>19878776 |                      |                 | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Weight Increased         | Abilify        |                  |                    | S               |                                                 |                      |                 | Not Reported |                |
|                          | Lexapro        |                  |                    | S               |                                                 |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                                                                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|-------------------------------------------------|--------------------------------------------------------------------------------------|-----------------|--------------|----------------|
| 08-Sep-2014              | 10439071       | NON-EXPEDITED    |                    |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>19911197 |                                                                                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                                                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Weight Increased         | Abilify Tabs   |                  |                    | S               |                                                 |                                                                                      |                 | Not Reported |                |
|                          | Lexapro        |                  |                    | S               |                                                 | Therapy Started With 2mg<br>And Then Increased To<br>5mg And Then Stopped At<br>10mg |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 08-Sep-2014              | 10439087       | NON-EXPEDITED    |                    |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>19915842 |                      | 27 YR           | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Rash                     | Abilify        |                  |                    | S               |                                                 |                      |                 | Not Reported |                |
|                          | Lexapro        |                  |                    | S               |                                                 |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|------------|----------------|
| 08-Sep-2014              | 10439109       | NON-EXPEDITED    |                    | HO              | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>19928027 |                      | 15 YR           | Female     | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

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|        |              |   |      |                                  |              |
|--------|--------------|---|------|----------------------------------|--------------|
| Tremor | Abilify      | S | Oral | Dose Reduced To 10mg.<br>Ongoing | Not Reported |
|        | Escitalopram | S |      |                                  |              |
|        | Risperdal    | S | Oral |                                  | Not Reported |
|        | Synthroid    | S |      |                                  |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 08-Sep-2014              | 10439183      | NON-EXPEDITED    |                    | HO              | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>21197223 |                      | 59 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                               | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>                   |
|-------------------------------------------------------------------------------------|--------------------|--------------|------------|-------------|--------------|----------------------------------------|-----------------|------------------------------|
| Confusional State;<br>Memory Impairment;<br>Myocardial Infarction; Off<br>Label Use | Abilify Tabs       |              |            | S           | Oral         | Ongoing 10mg Tabs Ndc-<br>59148-008-13 |                 | Not Reported                 |
|                                                                                     | Abilify Tabs       |              |            | S           | Oral         | Ongoing 10mg Tabs Ndc-<br>59148-008-13 |                 | Not Reported                 |
|                                                                                     | Lexapro<br>Lexapro |              |            | S<br>S      |              |                                        |                 | Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 08-Sep-2014              | 10439224      | NON-EXPEDITED    |                    |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>21210414 |                      | 42 YR      | Female     | USA            |

| <u>Preferred Term</u>                                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Crying; Dizziness;<br>Myalgia; Reduced Facial<br>Expression | Abilify        |              |            | S           |              |                    |                 | Not Reported |
|                                                             | Buspar         |              |            | S           |              |                    |                 | Not Reported |
|                                                             | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 08-Sep-2014              | 10439949      | NON-EXPEDITED    |                    |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>19391846 |                      | 20 YR      | Female     | USA            |

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

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                         | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                    | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------|-------------------------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|-----------------------------------------|-----------------|----------------------------------------------|----------------|
| 08-Sep-2014                                                                                      | 10440253                                  | NON-EXPEDITED      |                    |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>20698767 |                                         | 59 YR           | Female                                       | USA            |
| <u>Preferred Term</u>                                                                            | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                      | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Back Pain; Headache                                                                              | Abilify<br>Zoloft<br>Lexapro              |                    |                    | S<br>S<br>S     |                                                 |                                         |                 | Not Reported<br>Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                         | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                    | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 08-Sep-2014                                                                                      | 10441695                                  | EXPEDITED (15-DAY) |                    | HO, LT          | GXKR2014DE003404                                |                                         |                 | Unknown                                      | DEU            |
| <u>Preferred Term</u>                                                                            | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                      | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Myoclonus; Pyrexia;<br>Serotonin Syndrome;<br>Sinus Tachycardia                                  | Mirtazapine<br>Escitalopram<br>Amantadine |                    |                    | S<br>S<br>S     | Oral<br>Oral<br>Oral                            | 15 Mg, Unk<br>10 Mg, Unk<br>100 Mg, Unk |                 | Not Reported<br>Not Reported<br>Novartis     |                |
| <u>FDA Received Date</u>                                                                         | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                    | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 08-Sep-2014                                                                                      | 10445456                                  | NON-EXPEDITED      |                    | HO, OT          | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>19467513 |                                         | 57 YR           | Female                                       | USA            |
| <u>Preferred Term</u>                                                                            | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                      | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Adverse Event;<br>Dissociation; Feeling<br>Abnormal; Myalgia; Panic<br>Attack; Suicidal Ideation | Abilify<br>Lexapro                        |                    |                    | S<br>S          |                                                 |                                         |                 | Not Reported<br>Not Reported                 |                |
| <u>FDA Received Date</u>                                                                         | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                    | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 09-Sep-2014                                                                                      | 9882581                                   | EXPEDITED (15-DAY) |                    | OT              | JP-FRI-1000053960                               |                                         | 29 YR           | Female                                       | JPN            |
| <u>Preferred Term</u>                                                                            | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                      | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Hepatic Function<br>Abnormal                                                                     | Lexapro<br>Pariet                         |                    |                    | S<br>C          | Oral<br>Oral                                    | 10 Mg<br>10 Mg                          |                 | Forest<br>Not Reported                       |                |

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|                                                                                             | Solanax                |                    | C                  | Oral            | 0.4 Mg                     |                      |                 | Not Reported |                |
|---------------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
|                                                                                             | Wypax                  |                    | C                  | Oral            | 3 Mg                       |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                    | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Sep-2014                                                                                 | 10416076               | EXPEDITED (15-DAY) |                    | OT              | RS-FRI-1000070203          |                      |                 | Female       | SRB            |
| <u>Preferred Term</u>                                                                       | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Galactorrhoea                                                                               | Escitalopram           |                    |                    | S               | Oral                       |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                    | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Sep-2014                                                                                 | 10441421               | EXPEDITED (15-DAY) |                    | HO, OT          | CH-ASTRAZENECA-2014SE65539 |                      | 36 YR           | Male         | CHE            |
| <u>Preferred Term</u>                                                                       | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Delusion;<br>Drug Interaction;<br>Hallucination, Visual;<br>Psychiatric Symptom | Seroquel               |                    |                    | S               | Oral                       |                      |                 | Zeneca       |                |
|                                                                                             | Seroquel               |                    |                    | S               | Oral                       |                      |                 | Zeneca       |                |
|                                                                                             | Cipralelex             |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                                                             | Cipralelex             |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                                                             | Coversum N             |                    |                    | C               | Oral                       |                      |                 | Not Reported |                |
|                                                                                             | Pantozol (Switzerland) |                    |                    | C               |                            |                      |                 | Not Reported |                |
|                                                                                             | Trittico               |                    |                    | C               | Oral                       |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                    | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Sep-2014                                                                                 | 10442436               | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2014248073   |                      | 61 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                       | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity                                                                       | Zoloft                 |                    |                    | S               |                            | Unk                  |                 | Pfizer       |                |
|                                                                                             | Lexapro                |                    |                    | S               |                            | Unk                  |                 | Not Reported |                |
|                                                                                             | Duragesic              |                    |                    | S               |                            | Unk                  |                 | Not Reported |                |

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| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 09-Sep-2014              | 10443151      | EXPEDITED (15-DAY) |                    | HO, LT, OT      | CH-009507513-1409CHE001074 |                      | 77 YR      | Male       | CHE            |

| <u>Preferred Term</u>                               | <u>Product</u>                            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                          | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------|-------------------------------------------|--------------|------------|-------------|---------------------------------------|------------------------|-----------------|--------------|
| Cardioversion; Long Qt Syndrome; Torsade De Pointes | Remeron                                   |              |            | S           | Oral                                  | 30 Mg, Qd              |                 | Merck        |
|                                                     | Remeron                                   |              |            | S           | Oral                                  | 15 Mg, Qd              |                 | Merck        |
|                                                     | Isentress                                 |              |            | S           | Oral                                  | 400 Mg, Bid            |                 | Merck        |
|                                                     | Cipralelex                                |              |            | S           | Oral                                  | 10 Mg, Qd              |                 | Not Reported |
|                                                     | Temesta (Lorazepam)                       |              |            | S           | Oral                                  | 0.25 Mg, Qd            |                 | Not Reported |
|                                                     | Pantozol (Pantoprazole Sodium)            |              |            | S           | Oral                                  | 40 Mg, Qd              |                 | Not Reported |
|                                                     | Prezista                                  |              |            | S           | Oral                                  | 600 Mg, Bid            |                 | Not Reported |
|                                                     | Norvir                                    |              |            | S           | Oral                                  | 100 Mg, Bid            |                 | Not Reported |
|                                                     | Kivexa                                    |              |            | S           | Oral                                  | 600/300 Mg, Once Daily |                 | Not Reported |
|                                                     | Piperacillin Sodium (+) Tazobactam Sodium |              |            | S           | Intravenous (not otherwise specified) | Unk                    |                 | Not Reported |
|                                                     | Madopar                                   |              |            | C           |                                       | Unk                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Sep-2014              | 10443749      | DIRECT           | Y                  | OT              |                      |                      | 25 YR      | Female     | USA            |

| <u>Preferred Term</u>                 | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------|--------------------|--------------|------------|-------------|--------------|-------------------------|-----------------|--------------|
| Dizziness; Product Substitution Issue | Escitalopram 20 Mg |              |            | S           | Oral         | 1 Tab Daily Po 6 Months | 6 MTH           | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 10-Sep-2014              | 10429887      | EXPEDITED (15-DAY) |                    | HO, OT          | DE-JNJFOC-20140821976 |                      |            | Female     | DEU            |

| <u>Preferred Term</u>                                             | <u>Product</u>   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------|------------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Decreased Activity; Foetal Exposure During Pregnancy; Respiratory | Risperdal Consta |              |            | S           | Transplacental |                    |                 | Not Reported |
|                                                                   | Cipralelex       |              |            | S           | Transplacental |                    |                 | Not Reported |

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|                |          |   |                |              |
|----------------|----------|---|----------------|--------------|
| Rate Decreased | Clozapin | S | Transplacental | Not Reported |
|----------------|----------|---|----------------|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Sep-2014              | 10444450      | EXPEDITED (15-DAY) |                    | OT              | NO-FRI-1000070487    |                      | 36 YR      | Female     | NOR            |

| <u>Preferred Term</u>           | <u>Product</u>  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------|-----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Decreased Appetite;             | Escitalopram    |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
| Disturbance In Attention;       | Escitalopram    |              |            | S           | Oral         | 15 Mg              |                 | Forest       |
| Dizziness; Headache;            | Montelukast     |              |            | S           | Oral         | Seasonal (10 Mg)   |                 | Not Reported |
| Heart Rate Irregular;           | Montelukast     |              |            | S           |              |                    |                 | Not Reported |
| Hyperhidrosis;                  | Seretide Diskus |              |            | C           |              | 2 Df               |                 | Not Reported |
| Hypersomnia;                    | Panodil         |              |            | C           | Oral         | 2 Gram             |                 | Not Reported |
| Hypersomnia; Memory Impairment; |                 |              |            |             |              |                    |                 |              |
| Musculoskeletal Pain;           |                 |              |            |             |              |                    |                 |              |
| Nausea; Paraesthesia;           |                 |              |            |             |              |                    |                 |              |
| Paraesthesia; Pyrexia;          |                 |              |            |             |              |                    |                 |              |
| Restlessness;                   |                 |              |            |             |              |                    |                 |              |
| Somnolence; Tinnitus;           |                 |              |            |             |              |                    |                 |              |
| Vomiting                        |                 |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 10-Sep-2014              | 10445835      | EXPEDITED (15-DAY) |                    | HO              | US-ASTRAZENECA-2014SE67251 |                      | 81 YR      | Male       | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|------------------------|-----------------|--------------|
| Confusional State;    | Cokenzen       |              |            | S           | Oral         | 1 Df, Qd (16mg/12.5mg) |                 | Astrazeneca  |
| Hyponatraemia         | Seroplex       |              |            | S           | Unknown      | Unk                    |                 | Not Reported |
|                       | Ogast          |              |            | C           | Oral         |                        |                 | Not Reported |
|                       | Creon          |              |            | C           |              | Unk                    |                 | Not Reported |
|                       | Sulfarlem      |              |            | C           |              | Unk                    |                 | Not Reported |
|                       | Doliprane      |              |            | C           |              |                        |                 | Not Reported |
|                       | Azopt          |              |            | C           |              | Unk                    |                 | Not Reported |
|                       | Crestor        |              |            | C           |              | Unk                    |                 | Not Reported |
|                       | Amlor          |              |            | C           |              | Unk                    |                 | Not Reported |

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|                                                   |                      |                    |                    |                 |                                          |                      |                 |              |                |
|---------------------------------------------------|----------------------|--------------------|--------------------|-----------------|------------------------------------------|----------------------|-----------------|--------------|----------------|
| Ixprim                                            |                      | C                  |                    | Unk             |                                          | Not Reported         |                 |              |                |
| <u>FDA Received Date</u>                          | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Sep-2014                                       | 10314580             | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2014200494                 |                      | 50 YR           | Female       | USA            |
| <u>Preferred Term</u>                             | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity                             | Zoloft               |                    |                    | S               |                                          | Unk                  |                 | Pfizer       |                |
|                                                   | Diclofenac Epolamine |                    |                    | S               |                                          | Unk                  |                 | Unknown      |                |
|                                                   | Wellbutrin           |                    |                    | S               |                                          | Unk                  |                 | Not Reported |                |
|                                                   | Prozac               |                    |                    | S               |                                          | Unk                  |                 | Not Reported |                |
|                                                   | Lexapro              |                    |                    | S               |                                          | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                          | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Sep-2014                                       | 10416063             | EXPEDITED (15-DAY) |                    | OT              | RS-FRI-1000070205                        |                      |                 | Female       | SRB            |
| <u>Preferred Term</u>                             | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Self-Injurious Ideation; Violence-Related Symptom | Escitalopram         |                    |                    | S               | Oral                                     | 5 Mg                 |                 | Forest       |                |
|                                                   | Escitalopram         |                    |                    | S               | Oral                                     | 10 Mg                |                 | Forest       |                |
|                                                   | Escitalopram         |                    |                    | S               | Oral                                     | 15 Mg                |                 | Forest       |                |
|                                                   | Bromazepam           |                    |                    | C               |                                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                          | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Sep-2014                                       | 10446435             | NON-EXPEDITED      |                    |                 | IN-LUPIN PHARMACEUTICALS INC.-2014-01359 |                      | 60 YR           | Male         | IND            |
| <u>Preferred Term</u>                             | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Tremor                                            | Stalopam             |                    |                    | S               | Oral                                     |                      |                 | Not Reported |                |
|                                                   | Amlodipine           |                    |                    | C               | Oral                                     |                      |                 | Not Reported |                |
|                                                   | Deplatt              |                    |                    | C               | Oral                                     |                      |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------|----------------------------------|--------------------|--------------------|-----------------|--------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 11-Sep-2014                                             | 10446462                         | NON-EXPEDITED      |                    |                 | US-LUPIN<br>PHARMACEUTICALS<br>INC.-E2B_00002324 |                      | 74 YR           | Female       | USA            |
| <u>Preferred Term</u>                                   | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                     | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Diarrhoea; Pruritus                                     | Escitalopram Tablets Usp 10mg    |                    |                    | S               |                                                  |                      |                 | Lupin        |                |
|                                                         | Synthroid                        |                    |                    | C               |                                                  |                      |                 | Not Reported |                |
|                                                         | Hctz                             |                    |                    | C               | Unknown                                          |                      |                 | Not Reported |                |
|                                                         | Pepcid                           |                    |                    | C               |                                                  |                      |                 | Not Reported |                |
|                                                         | Estradiol Patch                  |                    |                    | C               | Transdermal                                      | 1/2 Patch            |                 | Not Reported |                |
|                                                         | Aspirin                          |                    |                    | C               |                                                  |                      |                 | Not Reported |                |
|                                                         | Coq10                            |                    |                    | C               | Unknown                                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Sep-2014                                             | 10446908                         | EXPEDITED (15-DAY) |                    | HO, LT, OT      | HR-TEVA-506628ISR                                |                      | 61 YR           | Male         | HRV            |
| <u>Preferred Term</u>                                   | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                     | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Renal Cyst; Serum Ferritin Increased; Urinary Retention | Serpentil [Escitalopram Oxalate] |                    |                    | S               | Oral                                             | 10 Milligram Daily;  |                 | Ivax         |                |
|                                                         | Lunata                           |                    |                    | C               | Oral                                             |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Sep-2014                                             | 10447046                         | EXPEDITED (15-DAY) |                    | DE              | FR-FRI-1000070449                                |                      | 78 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                   | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                     | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Subdural Haematoma                                      | Escitalopram                     |                    |                    | S               |                                                  | 20 Mg                |                 | Forest       |                |
|                                                         | Kardegic                         |                    |                    | S               |                                                  | 75 Mg                |                 | Not Reported |                |
|                                                         | Previscan (Fluindione)           |                    |                    | S               |                                                  | 20 Mg                |                 | Not Reported |                |
|                                                         | Depamide                         |                    |                    | C               |                                                  | 900 Mg               |                 | Not Reported |                |
|                                                         | Pulmicort Turbuhaler             |                    |                    | C               | Other                                            | 2 Df                 |                 | Not Reported |                |
|                                                         | Nisis                            |                    |                    | C               |                                                  | 80 Mg                |                 | Not Reported |                |
|                                                         | Furosemide Bayer                 |                    |                    | C               |                                                  | 40 Mg                |                 | Not Reported |                |



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|  |                 |   |         |              |
|--|-----------------|---|---------|--------------|
|  | Bisoprolol      | C | 10 Mg   | Not Reported |
|  | Metformine      | C | 2550 Mg | Not Reported |
|  | Zopiclone Alter | C | 5 Mg    | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Sep-2014              | 10447650      | EXPEDITED (15-DAY) |                    | OT              | AU-FRI-1000070557    |                      | 37 YR      | Female     | AUS            |

| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anhedonia; Product Use    | Escitalopram   |              |            | S           |              |                    |                 | Forest       |
| In Unapproved Indication; | Olanzapine     |              |            | C           |              | 1250 Mcg           |                 | Not Reported |
| Suicidal Behaviour        | Olanzapine     |              |            | C           |              | 2.5 Mg             |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Sep-2014              | 10448271      | EXPEDITED (15-DAY) |                    | HO              | CH-FRI-1000070547    |                      |            | Male       | CHE            |

| <u>Preferred Term</u>                                                  | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Aggression; Delusion;<br>Hallucination, Visual;<br>Psychiatric Symptom | Escitalopram           |              |            | S           | Oral         | 5 Mg Daily         |                 | Forest       |
|                                                                        | Escitalopram           |              |            | S           |              | 10 Mg Daily        |                 | Forest       |
|                                                                        | Seroquel               |              |            | S           | Oral         | 300 Mg Daily       |                 | Not Reported |
|                                                                        | Seroquel               |              |            | S           | Oral         | 200 Mg Daily       |                 | Not Reported |
|                                                                        | Coversum N             |              |            | C           | Oral         | 2.5 Mg Daily       |                 | Not Reported |
|                                                                        | Pantozol (Switzerland) |              |            | C           | Oral         | 40 Mg Daily        |                 | Not Reported |
|                                                                        | Trittico               |              |            | C           | Oral         | 25 Mg Daily        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Sep-2014              | 10448384      | EXPEDITED (15-DAY) |                    | HO, OT          | DE-FRI-1000070535    |                      | 30 YR      | Female     | DEU            |

| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u> |
|------------------------|----------------|--------------|------------|-------------|--------------|------------------------|-----------------|------------|
| Caesarean Section;     | Escitalopram   |              |            | S           | Oral         | 15 Mg                  |                 | Forest     |
| Clostridial Infection; | Escitalopram   |              |            | S           | Oral         | Gradually Reduced To 1 |                 | Forest     |
| Morning Sickness;      |                |              |            |             |              |                        |                 |            |

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

|                                                                                                                                  |                                    |                    |                    |                 |                      |                                  |                 |              |                |
|----------------------------------------------------------------------------------------------------------------------------------|------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------------------|-----------------|--------------|----------------|
| Obstructed Labour;<br>Pyelonephritis                                                                                             |                                    | Gynvital           | C                  | Oral            | Mg/Day<br>0.4 Mg     |                                  | Not Reported    |              |                |
| <u>FDA Received Date</u>                                                                                                         | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Sep-2014                                                                                                                      | 10448404                           | EXPEDITED (15-DAY) |                    | CA, OT          | DE-FRI-1000070534    |                                  | 1 DAY           | Male         | DEU            |
| <u>Preferred Term</u>                                                                                                            | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Congenital Hearing Disorder;<br>Electrocardiogram Qt Prolonged; Foetal Exposure During Pregnancy                                 | Escitalopram                       |                    |                    | S               | Transplacental       | 15 Mg                            |                 | Forest       |                |
|                                                                                                                                  | Escitalopram                       |                    |                    | S               | Transplacental       | Gradually Reduced To 1 Mg/Day    |                 | Not Reported |                |
|                                                                                                                                  | Neurobion                          |                    |                    | C               | Transplacental       |                                  |                 | Not Reported |                |
|                                                                                                                                  | Vitamins                           |                    |                    | C               | Transplacental       | 0.4 Mg                           |                 | Not Reported |                |
|                                                                                                                                  | Cefuroxime                         |                    |                    | C               | Transplacental       |                                  |                 | Not Reported |                |
|                                                                                                                                  | Metronidazole                      |                    |                    | C               | Transplacental       |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                         | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Sep-2014                                                                                                                      | 10449552                           | DIRECT             |                    | OT              |                      |                                  | 36 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                            | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Discomfort; Abnormal Dreams; Agitation; Dry Mouth; Irritability; Irritable Bowel Syndrome; Job Dissatisfaction; Nausea | Escitalopram 10 Mg Lupin Pharmaceu |                    |                    | S               | Oral                 | 1 Pill Once Daily Taken By Mouth |                 | Lupin        |                |
| <u>FDA Received Date</u>                                                                                                         | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Sep-2014                                                                                                                      | 10452146                           | EXPEDITED (15-DAY) | Y                  | HO, LT          | 2014/062             |                                  | 63 YR           | Male         | IND            |
| <u>Preferred Term</u>                                                                                                            | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Decreased Appetite; Dehydration; Depression;                                                                           | Olanzapine                         |                    |                    | S               |                      | 5mg/Day, Unk & Unk               |                 | Not Reported |                |
|                                                                                                                                  | Escitalopram                       |                    |                    | S               |                      | 10mg/Day Unk & Unk               |                 | Not Reported |                |

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Disorientation; Gait  
Disturbance; Hallucination;  
Auditory; Hyponatraemia;  
Lethargy; Muscle Spasms;  
Nausea; Pallor; Sleep  
Disorder; Tachycardia;  
Urinary Retention; White  
Blood Cell Count  
Increased

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Sep-2014              | 10334974      | EXPEDITED (15-DAY) |                    | HO, LT          | PHHY2014CA088425     |                      |            | Female     | CAN            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | <u>Product</u>                                                                                         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>                    | <u>Route</u>                | <u>Dosage Text</u>                                   | <u>Duration</u> | <u>Mfr</u>                                                                                   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|--------------|------------|--------------------------------|-----------------------------|------------------------------------------------------|-----------------|----------------------------------------------------------------------------------------------|
| Asthenia; Chest<br>Discomfort; Chronic<br>Obstructive Pulmonary<br>Disease; Cough;<br>Decreased Appetite;<br>Depression; Diarrhoea;<br>Drug Ineffective;<br>Dyspnoea; Fatigue;<br>Feeling Abnormal; Gait<br>Disturbance; General<br>Physical Health<br>Deterioration; Hernia Pain;<br>Hiatus Hernia;<br>Hypoaesthesia; Insomnia;<br>Lung Infection; Malaise;<br>Moaning; Mobility<br>Decreased; Pain; Panic<br>Disorder; Poor Quality<br>Sleep; Pruritus;<br>Restlessness; Skin<br>Discolouration | Seebri Breezhaler<br><br>Clarithromycin<br>Cipraxel//Escitalopram<br>Prednisone<br>Advair<br>Meloxicam |              |            | S<br><br>S<br>S<br>C<br>C<br>C | Respiratory<br>(inhalation) | Unk Unk, Unk<br><br>Unk Unk, Unk<br><br>Unk Unk, Unk |                 | Not Reported<br><br>Novartis<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Sep-2014              | 10449563      | EXPEDITED (15-DAY) |                    | OT              | DE-FRI-1000070544    |                      | 45 YR      | Male       | DEU            |

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

| <u>Preferred Term</u>                                                                                                                                                                                                                  | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>             |                |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|--------------------|--------------------|-----------------|------------------------------|------------------------|-----------------|------------------------|----------------|
| Atrial Fibrillation;<br>Depersonalisation/Dereali<br>sation Disorder;<br>Glycosylated Haemoglobin<br>Increased;<br>Hypercholesterolaemia;<br>Hypertriglyceridaemia;<br>Migraine With Aura;<br>Weight Increased;<br>Withdrawal Syndrome | Escitalopram Oral Solution |                    |                    | S               | Oral                         | Changing Dosages       |                 | Forest                 |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                               | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>             | <u>Country</u> |
| 12-Sep-2014                                                                                                                                                                                                                            | 10450279                   | EXPEDITED (15-DAY) |                    | OT              | DE-FRI-1000070576            |                        |                 | Female                 | DEU            |
| <u>Preferred Term</u>                                                                                                                                                                                                                  | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>             |                |
| Foetal Exposure During<br>Pregnancy; Tachycardia<br>Foetal                                                                                                                                                                             | Escitalopram               |                    |                    | S               | Transplacental               | 10 Mg                  |                 | Forest                 |                |
|                                                                                                                                                                                                                                        | Folio                      |                    |                    | C               | Transplacental               | 0.4 Mg                 |                 | Not Reported           |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                               | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>             | <u>Country</u> |
| 12-Sep-2014                                                                                                                                                                                                                            | 10450971                   | EXPEDITED (15-DAY) |                    | HO, OT          | FR-PFIZER INC-<br>2014250545 |                        | 51 YR           | Female                 | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                  | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>             |                |
| Aggression; Agitation; Fall;<br>Head Injury; Hypotension;<br>Hypotonia; Pneumonia<br>Aspiration; Toxicity To<br>Various Agents                                                                                                         | Xanax                      |                    |                    | S               | Oral                         | 7.5 Mg (30 Df), Single |                 | Pfizer                 |                |
|                                                                                                                                                                                                                                        | Seroplex                   |                    |                    | S               | Oral                         | 280 Mg (28 Df), Single |                 | Not Reported           |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                               | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>             | <u>Country</u> |
| 12-Sep-2014                                                                                                                                                                                                                            | 10452152                   | DIRECT             | Y                  |                 |                              |                        | 56 YR           | Female                 | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                  | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>             |                |
| Cognitive Disorder;<br>Depression; Somnolence                                                                                                                                                                                          | Escitalopram               |                    |                    | S               | Oral                         | 1 Tablet, Qd, Oral     |                 | Bluepoint Laboratories |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                     | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 12-Sep-2014                                                                                                  | 10453222       | DIRECT           |                    | DS, HO, LT      |                      |                      | 21 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                        | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Conversion Disorder;<br>Crying; Economic<br>Problem; Hallucination,<br>Auditory; Product<br>Dispensing Error | Lexapro        |                  |                    | S               | Oral                 |                      | 2 WEEK          | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                                              | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 12-Sep-2014                                                                                                                                                           | 10455531                       | EXPEDITED (15-DAY) |                    | LT, OT          | 2014JUB00131         |                      | 62 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                 | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Drug<br>Interaction;<br>Encephalopathy;<br>Metabolic Acidosis;<br>Pulseless Electrical<br>Activity; Serotonin<br>Syndrome; Unresponsive<br>To Stimuli | Escitalopram                   |                    |                    | S               |                      | 1 Mg/Kg Twice        |                 | Not Reported |                |
|                                                                                                                                                                       | Methylene Blue                 |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                       | Aspirin (Acetylsalicylic Acid) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                       | Metoprolol (Metoprolol)        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                       | Lisinopril (Lisinopril)        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                       | Atorvastatin (Atorvastatin)    |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                       | Furosemide (Furosemide)        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                       | Insulin (Insulin)              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                       | Lamotrigine (Lamotrigine)      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                       | Ipratropium-Albuterol          |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                       | (Ipratropium And Albuterol     |                    |                    |                 |                      |                      |                 |              |                |
|                                                                                                                                                                       | Nitroglycerin (Nitroglycerin)  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                       | Midazolam (Midazolam)          |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                       | Fentanyl (Fentanyl)            |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                       | Vecuronium (Vecuronium)        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                       | Phenylephrine (Phenylephrine)  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                       | Vasopressin (Vasopressin)      |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 12-Sep-2014              | 10456882       | EXPEDITED (15-DAY) | Y                  | HO, OT          | 2014JUB00129         |                      | 182 DAY         | Female     | CAN            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

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|                                                                                                                                                                                                     |              |   |              |              |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|---|--------------|--------------|
| Altered State Of Consciousness; Cyanosis; Drug Interaction; Drug Screen Positive; Hypertonia; Maternal Exposure During Breast Feeding; Seizure Like Phenomena; Sleep Disorder; Somnolence; Vomiting | Bupropion    | S | Transmammary | Not Reported |
|                                                                                                                                                                                                     | Escitalopram | S | Transmammary | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Sep-2014              | 10470463      | NON-EXPEDITED    | Y                  | OT              | 2013AP009971         |                      | 59 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Urinary Retention     | Escitalopram Oxalate     |              |            | S           |              |                    | 5 DAY           | Not Reported |
|                       | Cefalexin                |              |            | C           |              |                    |                 | Not Reported |
|                       | Ranitidine               |              |            | C           |              |                    |                 | Not Reported |
|                       | Digoxin                  |              |            | C           |              |                    |                 | Not Reported |
|                       | Lisinopril               |              |            | C           |              |                    |                 | Not Reported |
|                       | Nystatin                 |              |            | C           |              |                    |                 | Not Reported |
|                       | Warfarin                 |              |            | C           |              |                    |                 | Not Reported |
|                       | Diphenhydramine          |              |            | C           |              |                    |                 | Not Reported |
|                       | Metoprolol Tartrate      |              |            | C           |              |                    |                 | Not Reported |
|                       | Amiodarone               |              |            | C           |              |                    |                 | Not Reported |
|                       | Furosemide               |              |            | C           |              |                    |                 | Not Reported |
|                       | Nystop                   |              |            | C           |              |                    |                 | Not Reported |
|                       | Salbutamol W/Ipratropium |              |            | C           |              |                    |                 | Not Reported |
|                       | Insulin Lispro           |              |            | C           |              |                    |                 | Not Reported |
|                       | Paracetamol              |              |            | C           |              |                    |                 | Not Reported |
|                       | Milk Of Magnesia         |              |            | C           |              |                    |                 | Not Reported |
|                       | Bisacodyl                |              |            | C           |              |                    |                 | Not Reported |
|                       | Omeprazole               |              |            | C           |              |                    |                 | Not Reported |
|                       | Guaifenesin              |              |            | C           |              |                    |                 | Not Reported |
|                       | Triamcinolone            |              |            | S           |              |                    |                 | Not Reported |
|                       | Fluticasone Propionate   |              |            | C           |              |                    |                 | Not Reported |
|                       | Warfarin                 |              |            | C           |              |                    |                 | Not Reported |
|                       | Ondansetron              |              |            | C           |              |                    |                 | Not Reported |

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| <u>FDA Received Date</u>                                                           | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 15-Sep-2014                                                                        | 10451972             | EXPEDITED (15-DAY) |                    | HO, LT          | DE-AUROBINDO-AUR-APL-2014-09510                 |                      | 58 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                                              | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Myoclonus; Procalcitonin Increased; Pyrexia; Serotonin Syndrome; Sinus Tachycardia | Mirtazapine 15mg     |                    |                    | S               | Oral                                            | 15 Mg, Unk           |                 | Aurobindo    |                |
|                                                                                    | Escitalopram 10 Mg   |                    |                    | S               | Oral                                            | 10 Mg, Unk           |                 | Aurobindo    |                |
|                                                                                    | Amantadin /00055901/ |                    |                    | S               | Oral                                            | 100 Mg, Unk          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                           | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Sep-2014                                                                        | 10452287             | EXPEDITED (15-DAY) |                    | HO, OT          | IN-PAR<br>PHARMACEUTICAL,<br>INC-2014SCPR009380 |                      |                 | Unknown      | IND            |
| <u>Preferred Term</u>                                                              | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dehydration; Gait Disturbance;                                                     | Olanzapine           |                    |                    | S               | Unknown                                         | 5 Mg, / Day          |                 | Par          |                |
| Hyponatraemia;                                                                     | Olanzapine           |                    |                    | S               |                                                 |                      |                 | Par          |                |
| Leukocytosis; Pallor;                                                              | Escitalopram         |                    |                    | S               | Unknown                                         | 10 Mg, Unk           |                 | Not Reported |                |
| Tachycardia; Urinary Retention                                                     | Escitalopram         |                    |                    | S               |                                                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                           | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Sep-2014                                                                        | 10452357             | EXPEDITED (15-DAY) |                    | OT              | NL-RANBAXY-2014RR-85255                         |                      |                 | Unknown      | NLD            |
| <u>Preferred Term</u>                                                              | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression                                                                         | Venlafaxine          |                    |                    | S               | Unknown                                         | Unk                  |                 | Not Reported |                |
|                                                                                    | Citalopram           |                    |                    | S               | Unknown                                         | Unk                  |                 | Not Reported |                |
|                                                                                    | Escitalopram         |                    |                    | S               | Unknown                                         | Unk                  |                 | Not Reported |                |
|                                                                                    | Sertraline           |                    |                    | S               | Unknown                                         | Unk                  |                 | Ranbaxy      |                |
|                                                                                    | Paroxetine           |                    |                    | S               | Unknown                                         | Unk                  |                 | Not Reported |                |
|                                                                                    | Fluoxetine           |                    |                    | S               | Unknown                                         | Unk                  |                 | Ranbaxy      |                |
|                                                                                    | Fluvoxamine          |                    |                    | S               | Unknown                                         | Unk                  |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                               | <u>Case #</u>   | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------|-----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 15-Sep-2014                                                            | 10456609        | DIRECT           |                    | OT              |                      |                      | 38 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                  | <u>Product</u>  | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Product Substitution Issue;<br>Therapeutic Product Effect<br>Decreased | Generic Lexapro |                  |                    | S               | Oral                 |                      | 4 MTH           | Not Reported |                |

| <u>FDA Received Date</u>                                                                                           | <u>Case #</u>                                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|--------------------|--------------------|-----------------|----------------------|---------------------------------------------|-----------------|--------------|----------------|
| 15-Sep-2014                                                                                                        | 10459487                                      | EXPEDITED (15-DAY) | Y                  | LT              | US-H14001-14-00526   |                                             | 62 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                              | <u>Product</u>                                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Drug<br>Interaction;<br>Encephalopathy;<br>Pulseless Electrical<br>Activity; Serotonin<br>Syndrome | Escitalopram (Escitalopram)                   |                    |                    | S               |                      |                                             |                 | Not Reported |                |
|                                                                                                                    | Methylene Blue<br>(Methylthioninium Chloride) |                    |                    | S               |                      | 2 Mg/Kg (1 Mg/Kg, Two<br>Consecutive Doses) |                 | Not Reported |                |
|                                                                                                                    | Aspirin (Acetylsalicylic Acid)                |                    |                    | C               |                      |                                             |                 | Not Reported |                |
|                                                                                                                    | Metoprolol (Metoprolol)                       |                    |                    | C               |                      |                                             |                 | Not Reported |                |
|                                                                                                                    | Lisinopril (Lisinopril)                       |                    |                    | C               |                      |                                             |                 | Not Reported |                |
|                                                                                                                    | Atorvastatin (Atorvastatin)                   |                    |                    | C               |                      |                                             |                 | Not Reported |                |
|                                                                                                                    | Furosemide (Furosemide)                       |                    |                    | C               |                      |                                             |                 | Not Reported |                |
|                                                                                                                    | Insulin (Insulin)                             |                    |                    | C               |                      |                                             |                 | Not Reported |                |
|                                                                                                                    | Lamotrigine (Lamotrigine)                     |                    |                    | C               |                      |                                             |                 | Not Reported |                |
|                                                                                                                    | Ipratropium-Albuterol<br>(Combivent)          |                    |                    | C               |                      |                                             |                 | Not Reported |                |
|                                                                                                                    | Nitroglycerin (Glyceryl Trinitrate)           |                    |                    | C               |                      |                                             |                 | Not Reported |                |
|                                                                                                                    | Midazolam (Midazolam)                         |                    |                    | C               |                      |                                             |                 | Not Reported |                |
|                                                                                                                    | Fentanyl (Fentanyl)                           |                    |                    | C               |                      |                                             |                 | Not Reported |                |
|                                                                                                                    | Vecuronium (Vecuronium)                       |                    |                    | C               |                      |                                             |                 | Not Reported |                |
|                                                                                                                    | Isoflurane (Isoflurane)                       |                    |                    | C               |                      |                                             |                 | Not Reported |                |
|                                                                                                                    | Phenylephrine (Phenylephrine)                 |                    |                    | C               |                      |                                             |                 | Not Reported |                |
|                                                                                                                    | Vasopressin (Vasopressin)                     |                    |                    | C               |                      |                                             |                 | Not Reported |                |
|                                                                                                                    | Propofol (Propofol)                           |                    |                    | C               |                      |                                             |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Sep-2014              | 10507542      | NON-EXPEDITED    | Y                  | OT              | 2013-US-002139       |                      | 31 YR      | Female     | USA            |



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| <u>Preferred Term</u>                                                                                                  | <u>Product</u>                                    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Depression; Insomnia;<br>Intentional Product<br>Misuse; Off Label Use;<br>Ovarian Cyst Ruptured;<br>Sedation; Vomiting | Xyrem (Sodium Oxybate) Oral<br>Solution, 500mg/ML |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                        |                                                   |              |            |             | Oral         |                    |                 |              |
|                                                                                                                        |                                                   |              |            |             | Oral         |                    |                 |              |
|                                                                                                                        |                                                   |              |            |             | Oral         |                    |                 |              |
|                                                                                                                        | Lexapro (Escitalopram Oxalate)                    |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                        | Loratadine                                        |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Sep-2014              | 10507660      | NON-EXPEDITED    |                    | OT              | 2013-US-002032       |                      | 57 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>                       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|--------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hypertension          | Xyrem                                |              |            | S           | Oral         |                    |                 | Not Reported |
|                       |                                      |              |            |             | Oral         |                    |                 |              |
|                       |                                      |              |            |             | Oral         |                    |                 |              |
|                       | Escitalopram                         |              |            | S           |              |                    |                 | Not Reported |
|                       | Lisinopril (Lisinopril)              |              |            | C           |              |                    |                 | Not Reported |
|                       | Tramadol (Tramadol<br>Hydrochloride) |              |            | C           |              |                    |                 | Not Reported |
|                       | Lanoxin (Digoxin)                    |              |            | C           |              |                    |                 | Not Reported |
|                       | Maxalt (Rizatriptan Benzoate)        |              |            | C           |              |                    |                 | Not Reported |
|                       | Gemfibrozil (Gemfibrozil)            |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Sep-2014              | 10395289      | EXPEDITED (15-DAY) |                    | OT              | PHHY2014BR103094     |                      | 76 YR      | Female     | BRA            |

| <u>Preferred Term</u>                                                                                                                                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|------------------------------------|-----------------|--------------|
| Asthenia; Cataract; Eye<br>Swelling; Eyelash<br>Discolouration; Fatigue;<br>Nervousness; Panic<br>Reaction; Tremor; Visual<br>Impairment; Weight<br>Decreased | Stalevo        |              |            | S           | Oral         | 100 Mg, Tid (Three Times<br>A Day) |                 | Orion        |
|                                                                                                                                                               | Stalevo        |              |            | S           | Oral         | 100 Mg, Qid (Four Times<br>A Day)  |                 | Orion        |
|                                                                                                                                                               | Stalevo        |              |            | S           | Oral         | 150 Mg, Tid (Three Times<br>A Day) |                 | Orion        |
|                                                                                                                                                               | Velija         |              |            | S           |              | Unk                                |                 | Not Reported |

# FDA Adverse Event Reporting System

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### Detailed Report

|                              |   |                                |              |
|------------------------------|---|--------------------------------|--------------|
| Exodus//Escitalopram Oxalate | S | Unk                            | Not Reported |
| Rivotril                     | S | Unk                            | Not Reported |
| Puran                        | S | 1 Df, Daily (One Tablet Daily) | Not Reported |
| Lansoprazole                 | S | 1 Df, Daily (One Tablet Daily) | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Sep-2014              | 10457610      | EXPEDITED (15-DAY) |                    | OT              | GB-FRI-1000070642    |                      | 50 YR      | Female     | GBR            |

| <u>Preferred Term</u>                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Hepatic Mass; Liver Function Test Increased | Escitalopram   |              |            | S           | Oral         | 10 Mg Daily        |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Sep-2014              | 10460951      | EXPEDITED (15-DAY) | Y                  | HO, OT          | 2014EDG00011         |                      | 182 DAY    | Female     | CAN            |

| <u>Preferred Term</u>                                                                                                                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cyanosis; Drug Interaction; Exposure Via Breast Milk; Hypertonia; Seizure; Sleep Disorder; Somnolence; Staring; Unresponsive To Stimuli; Vomiting | Bupropion      |              |            | S           | Transmammary |                    |                 | Not Reported |
|                                                                                                                                                   | Escitalopram   |              |            | S           | Transmammary |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Sep-2014              | 8970488       | EXPEDITED (15-DAY) |                    | OT              | CN-FRI-1000041073    |                      | 50 YR      | Male       | CHN            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Seizure               | Lexapro        |              |            | S           | Oral         | 20 Mg              |                 | Forest       |
|                       | Lexapro        |              |            | S           | Oral         | 15 Mg              |                 | Forest       |
|                       | Lexapro        |              |            | S           | Oral         | 10 Mg              |                 | Not Reported |

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

|                                                                                          | Lexapro              |                    | S                  | Oral            |                                                 |                       |                 | Not Reported |                |
|------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|-------------------------------------------------|-----------------------|-----------------|--------------|----------------|
|                                                                                          | Buspirone            |                    | C                  |                 |                                                 |                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                 | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Sep-2014                                                                              | 10446192             | EXPEDITED (15-DAY) |                    | HO, OT          | GB-AUROBINDO-AUR-<br>APL-2014-09558             |                       | 44 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                                    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Blister; Cheilitis; Mucosal<br>Inflammation; Stevens-<br>Johnson Syndrome;<br>Stomatitis | Ramipril             |                    |                    | S               | Unknown                                         | Unk                   |                 | Aurobindo    |                |
|                                                                                          | Escitalopram Oxalate |                    |                    | S               | Unknown                                         | Unk                   |                 | Not Reported |                |
|                                                                                          | Forxiga              |                    |                    | S               | Oral                                            | 5 Mg, Daily           |                 | Not Reported |                |
|                                                                                          | Flucloxacillin       |                    |                    | C               | Unknown                                         | Unk                   |                 | Not Reported |                |
|                                                                                          | Codeine              |                    |                    | C               | Unknown                                         | Unk                   |                 | Not Reported |                |
|                                                                                          | Fucibet              |                    |                    | C               | Unknown                                         | Unk                   |                 | Not Reported |                |
|                                                                                          | Humalog              |                    |                    | C               | Unknown                                         | Unk                   |                 | Not Reported |                |
|                                                                                          | Lantus               |                    |                    | C               | Unknown                                         | Unk                   |                 | Not Reported |                |
|                                                                                          | Paracetamol          |                    |                    | C               | Unknown                                         | Unk                   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                 | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Sep-2014                                                                              | 10459676             | EXPEDITED (15-DAY) |                    | HO              | FR-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>21396494 |                       | 49 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Off Label Use; Pyrexia;<br>Renal Failure;<br>Rhabdomyolysis                              | Abilify              |                    |                    | S               |                                                 |                       |                 | Not Reported |                |
|                                                                                          | Imovane              |                    |                    | S               | Oral                                            |                       |                 | Not Reported |                |
|                                                                                          | Mianserin            |                    |                    | S               | Oral                                            | 1 Df = 120 Units Nos. |                 | Not Reported |                |
|                                                                                          | Seroplex             |                    |                    | S               |                                                 | In Morning            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                 | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Sep-2014                                                                              | 10232571             | NON-EXPEDITED      |                    |                 | US-TEVA-483929USA                               |                       |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |

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|                                                                                                                                                                                            |              |   |      |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|---|------|
| Anxiety; Back Pain;<br>Depressed Mood; Drug<br>Ineffective;<br>Hypersensitivity; Insomnia;<br>Irritability; Respiratory<br>Disorder; Therapeutic<br>Response Changed;<br>Thinking Abnormal | Escitalopram | S | Ivax |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|---|------|

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 18-Sep-2014                       | 10461072               | NON-EXPEDITED             |                             |                          | US-TEVA-489121USA             |                               |                     | Female              | USA                     |

| <a href="#">Preferred Term</a>                                | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|---------------------------------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Abdominal Pain;<br>Gastrointestinal Disorder;<br>Mood Altered | Escitalopram            |                       |                     | S                    |                       |                             |                          | Ivax                |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 18-Sep-2014                       | 10461073               | NON-EXPEDITED             |                             |                          | US-TEVA-491718USA             |                               |                     | Female              | USA                     |

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

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 18-Sep-2014                       | 10461075               | NON-EXPEDITED             |                             |                          | US-TEVA-497699USA             |                               |                     | Female              | USA                     |

| <a href="#">Preferred Term</a>                        | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|-------------------------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Anxiety; Drug Ineffective;<br>Headache; Malaise; Pain | Escitalopram            |                       |                     | S                    | Unknown               |                             |                          | Ivax                |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 18-Sep-2014                       | 10461076               | NON-EXPEDITED             |                             |                          | US-TEVA-502664USA             |                               |                     | Female              | USA                     |

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

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|                                                                                                                  |                |                    |                    |                 |                      |                      |                 |              |                |
|------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Malaise                                                                                                          | Escitalopram   | S                  | Unknown            | Ivax            |                      |                      |                 |              |                |
| <u>FDA Received Date</u>                                                                                         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Sep-2014                                                                                                      | 10461078       | NON-EXPEDITED      |                    |                 | US-TEVA-504297USA    |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bradyphrenia; Dizziness;<br>Fatigue; Feeling Drunk;<br>Headache; Paraesthesia;<br>Somnolence; Speech<br>Disorder | Escitalopram   |                    |                    | S               | Unknown              |                      |                 | Ivax         |                |
| <u>FDA Received Date</u>                                                                                         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Sep-2014                                                                                                      | 10461781       | EXPEDITED (15-DAY) |                    | OT              | SI-FRI-1000070641    |                      |                 | Male         | SVN            |
| <u>Preferred Term</u>                                                                                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Epilepsy                                                                                                         | Escitalopram   |                    |                    | S               | Oral                 |                      |                 | Forest       |                |
|                                                                                                                  | Dabigatran     |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                  | Spironolactone |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                  | Furosemide     |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Sep-2014                                                                                                      | 10461990       | NON-EXPEDITED      |                    | HO              | US-FRI-1000070610    |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Ill-Defined<br>Disorder                                                                              | Lexapro        |                    |                    | S               |                      |                      |                 | Forest       |                |
|                                                                                                                  | Lamotrigine    |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Sep-2014                                                                                                      | 10462624       | EXPEDITED (15-DAY) |                    | OT              | JP-FRI-1000070146    |                      | 29 YR           | Male         | JPN            |
| <u>Preferred Term</u>                                                                                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Creatine<br>Phosphokinase Increased;                                                                       | Lexapro        |                    |                    | S               | Oral                 | 20 Mg                |                 | Forest       |                |

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

|                                                                                                               |                                                                                       |                                 |                                                      |                                                                               |                                                                                                        |
|---------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|---------------------------------|------------------------------------------------------|-------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|
| Blood Pressure<br>Decreased; Depressed<br>Level Of Consciousness;<br>Overdose; Somnolence;<br>Suicide Attempt | Lexapro<br>Brotizolam<br>Depakene-R<br>Tasmolin<br>Seroquel<br>Seroquel<br>Pantethine | S<br>S<br>S<br>S<br>S<br>S<br>C | Oral<br>Oral<br>Oral<br>Oral<br>Oral<br>Oral<br>Oral | Overdose: 140 Mg<br>1.75 Mg<br>2800 Mg<br>7 Mg<br>1400 Mg<br>700 Mg<br>700 Mg | Forest<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |
|---------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|---------------------------------|------------------------------------------------------|-------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Sep-2014              | 10463870      | DIRECT           | Y                  |                 |                      |                      | 14 YR      | Female     | USA            |

| <u>Preferred Term</u>                                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Drug Ineffective;<br>Product Substitution Issue | Lexapro        |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Sep-2014              | 10466648      | EXPEDITED (15-DAY) | Y                  | HO              | 2014JUB00135         |                      | 63 YR      | Male       | IND            |

| <u>Preferred Term</u>                                                                                                                                                               | <u>Product</u>             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------------------------|
| Asthenia; Dehydration;<br>Disorientation; Gait<br>Disturbance;<br>Hyponatraemia; Lethargy;<br>Muscle Spasms; Muscle<br>Spasms; Nausea; Pallor;<br>Tachycardia; Urinary<br>Retention | Olanzapine<br>Escitalopram |              |            | S<br>S      |              |                    | 730 DAY         | Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Sep-2014              | 10384484      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000069787    |                      | 80 YR      | Male       | FRA            |

| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Bradycardia; Confusional | Escitalopram   |              |            | S           | Oral         |                    |                 | Forest     |

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

|                                                      |              |   |      |      |              |
|------------------------------------------------------|--------------|---|------|------|--------------|
| State; Incorrect Dose Administered; Medication Error | Escitalopram | S | Oral | 2 Df | Not Reported |
|                                                      | Mono-Tildiem | S | Oral |      | Not Reported |
|                                                      | Mono-Tildiem | S | Oral | 2 Df | Not Reported |
|                                                      | Coversyl     | S | Oral |      | Not Reported |
|                                                      | Coversyl     | S | Oral | 2 Df | Not Reported |
|                                                      | Diamicron    | S | Oral |      | Not Reported |
|                                                      | Diamicron    | S | Oral | 2 Df | Not Reported |

| <u>FDA Received Date</u>                | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|-----------------------------------------|----------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 19-Sep-2014                             | 10464261       | EXPEDITED (15-DAY) |                    | OT              | AU-MYLANLABS-2014M1003863 |                      |                 | Unknown    | AUS            |
| <u>Preferred Term</u>                   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Choking Sensation; Discomfort; Dyspnoea | Loxalate       |                    |                    | S               |                           | 0.5 Df, Hs           |                 | Mylan      |                |

| <u>FDA Received Date</u>                                               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 19-Sep-2014                                                            | 10464396       | EXPEDITED (15-DAY) |                    | HO, OT          | FR-PFIZER INC-2014256728 |                      | 31 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Coma; Mydriasis; Overdose; Rhabdomyolysis; Somnolence; Suicide Attempt | Xanax          |                    |                    | S               | Oral                     | Unk                  |                 | Pfizer       |                |
|                                                                        | Seroplex       |                    |                    | S               | Oral                     | Unk                  |                 | Not Reported |                |
|                                                                        | Noctamide      |                    |                    | S               | Oral                     | Unk                  |                 | Not Reported |                |
|                                                                        | Lorazepam      |                    |                    | S               | Oral                     | Unk                  |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 19-Sep-2014                                                                    | 10465310       | EXPEDITED (15-DAY) |                    | HO, OT          | GB-FRI-1000070779    |                      | 44 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blister; Cheilitis; Mucosal Inflammation; Stevens-Johnson Syndrome; Stomatitis | Escitalopram   |                    |                    | S               | Oral                 |                      |                 | Forest       |                |
|                                                                                | Forxiga        |                    |                    | S               | Oral                 | 5 Mg Once Daily      |                 | Not Reported |                |
|                                                                                | Ramipril       |                    |                    | S               |                      |                      |                 | Not Reported |                |

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

|                |   |              |
|----------------|---|--------------|
| Codeine        | C | Not Reported |
| Flucloxacillin | C | Not Reported |
| Fucibet        | C | Not Reported |
| Humalog        | C | Not Reported |
| Lantus         | C | Not Reported |
| Paracetamol    | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Sep-2014              | 10465368      | EXPEDITED (15-DAY) |                    | HO              | AU-FRI-1000070835    |                      | 22 YR      | Female     | AUS            |

| <u>Preferred Term</u>        | <u>Product</u>  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------|-----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Lip Swelling; Swollen Tongue | Escitalopram    |              |            | S           |              |                    |                 | Forest       |
|                              | Ketoprofen      |              |            | C           |              |                    |                 | Not Reported |
|                              | Panadeine Forte |              |            | C           |              |                    |                 | Not Reported |
|                              | Zoladex         |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Sep-2014              | 10465627      | EXPEDITED (15-DAY) |                    | HO, OT          | SI-FRI-1000028224    |                      | 86 YR      | Male       | SVK            |

| <u>Preferred Term</u>                                     | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Delirium; Hallucination, Olfactory; Hallucination, Visual | Escitalopram         |              |            | S           | Oral         | 5 Mg               |                 | Forest       |
|                                                           | Escitalopram         |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                                           | Quetiapine           |              |            | C           |              | 500 Mg             |                 | Not Reported |
|                                                           | Lamotrigine          |              |            | C           |              | 400 Mg             |                 | Not Reported |
|                                                           | Valproic Acid        |              |            | C           |              |                    |                 | Not Reported |
|                                                           | Distraneurin         |              |            | C           | Oral         | 400 Mg             |                 | Not Reported |
|                                                           | Litalir              |              |            | C           | Oral         | 2000 Mg            |                 | Not Reported |
|                                                           | Acetylsalicylic Acid |              |            | C           | Oral         | 100 Mg             |                 | Not Reported |
|                                                           | Digoxin              |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                           | Carvedilol           |              |            | C           | Oral         | 3 Mg               |                 | Not Reported |
|                                                           | Pantoprazole         |              |            | C           | Oral         | 20 Mg              |                 | Not Reported |
|                                                           | Iron (Iii)-Hydroxide |              |            | C           |              | 200 Mg             |                 | Not Reported |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Sep-2014              | 10465741      | EXPEDITED (15-DAY) |                    | HO              | CH-FRI-1000070843    |                      |            | Male       | CHE            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                            | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|---------------------------------------------------------------|-----------------|--------------|
| Cerebral Haemorrhage  | Escitalopram   |              |            | S           | Oral         | 10 Mg Daily                                                   |                 | Forest       |
|                       | Aspirin Cardio |              |            | S           | Oral         | 100 Mg Daily                                                  |                 | Not Reported |
|                       | Competact      |              |            | C           | Oral         | 1 Tablet Of 850 Mg Metformin Hci/15 Mg Pioglitazone Hci Daily |                 | Not Reported |
|                       | Amaryl         |              |            | C           | Oral         | 2 Mg Daily                                                    |                 | Not Reported |
|                       | Amaryl         |              |            | C           | Oral         | 1 Mg Daily                                                    |                 | Not Reported |
|                       | Beloc-Zok      |              |            | C           | Oral         | 25 Mg Daily                                                   |                 | Not Reported |
|                       | Zytiga         |              |            | C           | Oral         | 1000 Mg Daily                                                 |                 | Not Reported |
|                       | Prednisone     |              |            | C           | Oral         | 10 Mg Daily                                                   |                 | Not Reported |
|                       | Lucrin Depot   |              |            | C           | Subcutaneous | 1 Pre-Filled Syringe Every 3 Months                           |                 | Not Reported |
|                       | Xgeva          |              |            | C           | Subcutaneous | 1 Single Subcutaneous Injection Every 3 Months                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Sep-2014              | 10466201      | DIRECT           |                    | HO, OT          |                      |                      | 46 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Dizziness; Headache; Muscle Twitching; Musculoskeletal Disorder; Myoclonus; Tic; Vision Blurred | Lexapro        |              |            | S           |              |                    |                 | Teva       |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------------------|----------------------|------------|------------|----------------|
| 21-Sep-2014              | 10413136      | EXPEDITED (15-DAY) |                    | HO, OT          | GB-BRISTOL-MYERS SQUIBB COMPANY-21313549 |                      | 44 YR      | Female     | GBR            |

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

| <u>Preferred Term</u>                                                          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>           |
|--------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------|
| Blister; Cheilitis; Mucosal Inflammation; Stevens-Johnson Syndrome; Stomatitis | Forxiga        |              |            | S           | Oral         |                    |                 | Bristol Myers Squibb |
|                                                                                | Ramipril       |              |            | S           |              |                    |                 | Not Reported         |
|                                                                                | Escitalopram   |              |            | S           |              |                    |                 | Not Reported         |
|                                                                                | Flucloxacillin |              |            | C           |              |                    |                 | Not Reported         |
|                                                                                | Codeine        |              |            | C           |              |                    |                 | Not Reported         |
|                                                                                | Fucibet        |              |            | C           |              |                    |                 | Not Reported         |
|                                                                                | Humalog        |              |            | C           |              |                    |                 | Not Reported         |
|                                                                                | Lantus         |              |            | C           |              |                    |                 | Not Reported         |
|                                                                                | Paracetamol    |              |            | C           |              |                    |                 | Not Reported         |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Sep-2014              | 8664732       | EXPEDITED (15-DAY) |                    | DE              | CA-FRI-1000037008    |                      | 75 YR      | Female     | CAN            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|-------------------------|-----------------|--------------|
| Amnesia; Balance Disorder; Chest Pain; Confusional State; Crying; Drug Dependence; Fatigue; Hyperacusis; Hyponatraemia; Insomnia; Loss Of Personal Independence In Daily Activities; Myocardial Infarction; Pain In Extremity; Social Fear; Torsade De Pointes | Escitalopram   |              |            | S           | Oral         |                         |                 | Forest       |
|                                                                                                                                                                                                                                                                | Apo-Triazide   |              |            | C           |              | 25 Mg/50 Mg             |                 | Not Reported |
|                                                                                                                                                                                                                                                                | Lorazepam      |              |            | C           | Oral         | Daily Dose Not Reported |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Sep-2014              | 10235471      | EXPEDITED (15-DAY) |                    | LT              | JP-FRI-1000068010    |                      | 75 YR      | Male       | JPN            |

| <u>Preferred Term</u>             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Decreased Appetite; Hyponatraemia | Lexapro        |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                   | Lexapro        |              |            | S           | Oral         | 20 Mg              |                 | Forest       |
|                                   | Reflex         |              |            | C           | Oral         | 15 Mg              |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                  |   |      |         |              |
|------------------|---|------|---------|--------------|
| Magmitt          | C | Oral | 1980 Mg | Not Reported |
| Shinluck         | C | Oral |         | Not Reported |
| Halcion          | C | Oral |         | Not Reported |
| Amoban           | C | Oral | 7.5 Mg  | Not Reported |
| Depas (Etizolam) | C | Oral | 0.5 Mg  | Not Reported |
| Ensure Liquid    | C | Oral |         | Not Reported |

| <u>FDA Received Date</u>                    | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|---------------------------------------------|-------------------------------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|-----------------|----------------|
| 22-Sep-2014                                 | 10270923                                  | EXPEDITED (15-DAY) |                    | OT              | US-GLAXOSMITHKLINE-A1079200A |                      | 64 YR           | Female          | USA            |
| <u>Preferred Term</u>                       | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Chronic Kidney Disease;<br>Dental Operation | Advair                                    |                    |                    | S               | Respiratory (inhalation)     | 1puff Twice Per Day  |                 | Glaxosmithkline |                |
|                                             | Ventolin Hfa                              |                    |                    | S               | Respiratory (inhalation)     | 2puff As Required    |                 | Glaxosmithkline |                |
|                                             | Bupropion                                 |                    |                    | S               | Oral                         | 300mg In The Morning |                 | Unknown         |                |
|                                             | Escitalopram Oxalate                      |                    |                    | S               | Oral                         | 20mg Per Day         |                 | Unknown         |                |
|                                             | Hydroxyzine Hcl                           |                    |                    | S               | Oral                         | 50mg As Required     |                 | Unknown         |                |
|                                             | Proair Hfa                                |                    |                    | S               | Respiratory (inhalation)     | 2puff As Required    |                 | Glaxosmithkline |                |
|                                             | Prevacid                                  |                    |                    | S               | Oral                         | 15mg Twice Per Day   |                 | Glaxosmithkline |                |
|                                             | Esterified Estrogens + Methyltestosterone |                    |                    | C               |                              |                      |                 | Not Reported    |                |
|                                             | Lisinopril                                |                    |                    | C               |                              |                      |                 | Not Reported    |                |
|                                             | Trazodone Hcl                             |                    |                    | C               |                              |                      |                 | Not Reported    |                |
|                                             | Fluzone Vaccine                           |                    |                    | C               |                              |                      |                 | Not Reported    |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 22-Sep-2014              | 10387857       | EXPEDITED (15-DAY) | Y                  | HO, LT, OT      | ADR-2014-01402       |                      | 35 YR           | Female       | CHE            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Altered State Of         | Lioresal       |                    |                    | S               |                      |                      |                 | Not Reported |                |

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

|                          |                         |   |              |
|--------------------------|-------------------------|---|--------------|
| Consciousness; Clonus;   | Ciprallex Cp            | S | Not Reported |
| Device Connection Issue; | Dafalgan                | S | Not Reported |
| Device Leakage; Disease  | Importal Solution 30 MI | S | Not Reported |
| Recurrence; Headache;    | Clexane                 | S | Not Reported |
| Movement Disorder;       |                         |   |              |
| Muscle Spasticity; Tonic |                         |   |              |
| Clonic Movements;        |                         |   |              |
| Underdose                |                         |   |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------------------------------------------|----------------------|------------|------------|----------------|
| 22-Sep-2014              | 10401120      | EXPEDITED (15-DAY) |                    | OT              | BR-ORION<br>CORPORATION ORION<br>PHARMA-ENTC2014-<br>0309 |                      | 76 YR      | Female     | BRA            |

| <u>Preferred Term</u>                  | <u>Product</u>               | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------|------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Asthenia; Eye Swelling;                | Stalevo                      |              |            | S           | Oral         |                    |                 | Not Reported |
| Eyelash Discolouration;                | Stalevo                      |              |            | S           | Oral         |                    |                 | Not Reported |
| Fatigue; Nervousness;                  | Stalevo                      |              |            | S           | Oral         |                    |                 | Not Reported |
| Panic Reaction; Tremor;                | Velija                       |              |            | S           | Unknown      |                    |                 | Not Reported |
| Visual Impairment; Weight<br>Decreased | Exodus//Escitalopram Oxalate |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                        | Rivotril                     |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                        | Puran                        |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                        | Lansoprazole                 |              |            | S           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Sep-2014              | 10457576      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000070649    |                      | 88 YR      | Male       | FRA            |

| <u>Preferred Term</u> | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anaemia; Condition    | Escitalopram           |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
| Aggravated; Melaena   | Previscan (Fluindione) |              |            | S           | Oral         | 20 Mg              |                 | Not Reported |
|                       | Plavix                 |              |            | S           | Oral         | 75 Mg              |                 | Not Reported |
|                       | Orocald3               |              |            | C           |              |                    |                 | Not Reported |
|                       | Nebivolol              |              |            | C           |              |                    |                 | Not Reported |
|                       | Crestor                |              |            | C           |              |                    |                 | Not Reported |

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

|                                                                             |                      | Lasilix            |                    | C               |                          |                      |                 |              | Not Reported   |
|-----------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
|                                                                             |                      | Uvedose            |                    | C               |                          |                      |                 |              | Not Reported   |
|                                                                             |                      | Voltarene Actigo   |                    | C               |                          |                      |                 |              | Not Reported   |
| <u>FDA Received Date</u>                                                    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Sep-2014                                                                 | 10466780             | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2014261730 |                      | 47 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity                                                       | Effexor              |                    |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                                                                             | Lexapro              |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                                                                             | Cymbalta             |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                                                                             | Buspar               |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                                                                             | Celexa               |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Sep-2014                                                                 | 10466988             | EXPEDITED (15-DAY) |                    | CA              | FR-SA-2014SA128018       |                      | 1 DAY           | Female       | FRA            |
| <u>Preferred Term</u>                                                       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrioventricular Septal Defect; Exposure During Pregnancy                   | Zolpidem Tartrate    |                    |                    | S               | Transplacental           |                      |                 | Not Reported |                |
|                                                                             | Seroplex             |                    |                    | S               | Transplacental           |                      |                 | Not Reported |                |
|                                                                             | Lexomil              |                    |                    | S               | Transplacental           |                      |                 | Not Reported |                |
|                                                                             | Atarax               |                    |                    | S               | Transplacental           |                      |                 | Not Reported |                |
|                                                                             | Circadin             |                    |                    | S               | Transplacental           |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Sep-2014                                                                 | 10467106             | EXPEDITED (15-DAY) |                    | OT              | SE-ACTAVIS-2014-20167    |                      | 95 YR           | Female       | SWE            |
| <u>Preferred Term</u>                                                       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State; Dementia; Fatigue; Personality Change; Visual Impairment | Risperidon Actavis   |                    |                    | S               | Unknown                  | 0.5 Mg, Daily        |                 | Watson       |                |
|                                                                             | Risperidon Actavis   |                    |                    | S               | Unknown                  | .025 Mg, Daily       |                 | Watson       |                |
|                                                                             | Cipralext /01588501/ |                    |                    | S               | Unknown                  | Unk                  |                 | Not Reported |                |

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

|  |            |   |         |     |  |              |
|--|------------|---|---------|-----|--|--------------|
|  | Furosemide | C | Unknown | Unk |  | Not Reported |
|  | Loratadine | C | Unknown | Unk |  | Not Reported |
|  | Sobril     | C | Unknown | Unk |  | Not Reported |

| <u>FDA Received Date</u>                | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|-----------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 22-Sep-2014                             | 10467523       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000070836    |                      | 54 YR           | Male       | FRA            |
| <u>Preferred Term</u>                   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Hypokalaemia;<br>Hyponatraemia; Seizure | Escitalopram   |                    |                    | S               | Oral                 |                      |                 | Forest     |                |

| <u>FDA Received Date</u>                                                       | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 22-Sep-2014                                                                    | 10467754               | EXPEDITED (15-DAY) |                    | HO, OT          | GB-WATSON-2014-20216 |                      | 44 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                          | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blister; Cheilitis; Mucosal Inflammation; Stevens-Johnson Syndrome; Stomatitis | Escitalopram (Unknown) |                    |                    | S               | Unknown              | Unk                  |                 | Not Reported |                |
|                                                                                | Ramipril (Unknown)     |                    |                    | S               | Unknown              | Unk                  |                 | Watson       |                |
|                                                                                | Forxiga                |                    |                    | S               | Oral                 | 5 Mg, Daily          |                 | Not Reported |                |
|                                                                                | Codeine                |                    |                    | C               | Unknown              | Unk                  |                 | Not Reported |                |
|                                                                                | Flucloxacillin         |                    |                    | C               | Unknown              | Unk                  |                 | Not Reported |                |
|                                                                                | Fucibet                |                    |                    | C               | Unknown              | Unk                  |                 | Not Reported |                |
|                                                                                | Humalog                |                    |                    | C               | Unknown              | Unk                  |                 | Not Reported |                |
|                                                                                | Lantus                 |                    |                    | C               | Unknown              | Unk                  |                 | Not Reported |                |
|                                                                                | Paracetamol            |                    |                    | C               | Unknown              | Unk                  |                 | Not Reported |                |

| <u>FDA Received Date</u>                    | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---------------------------------------------|----------------------|------------------|--------------------|-----------------|----------------------|---------------------------------------|-----------------|------------|----------------|
| 22-Sep-2014                                 | 10469861             | DIRECT           |                    | OT              |                      |                                       | 50 YR           | Male       | USA            |
| <u>Preferred Term</u>                       | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u> |                |
| Amnesia; Frustration<br>Tolerance Decreased | Lexapro 20 Mg Camber |                  |                    | S               | Oral                 | 1 Tablet Once Daily Taken<br>By Mouth |                 | Camber     |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                  | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------------------------------------------|-----------------|--------------|----------------|
| 23-Sep-2014                                                                                                                                               | 10468842                    | EXPEDITED (15-DAY) |                    | OT              | SI-ACCORD-025938     |                                                                   | 85 YR           | Male         | SVN            |
| <u>Preferred Term</u>                                                                                                                                     | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                | <u>Duration</u> | <u>Mfr</u>   |                |
| Abulia; Anxiety; Delirium;<br>Disorientation; Fatigue;<br>Hallucination;<br>Hallucination, Olfactory;<br>Hallucination, Visual;<br>Insomnia; Restlessness | Clomethiazole/Clomethiazole |                    |                    | S               |                      | In Single Evening Dose                                            |                 | Not Reported |                |
|                                                                                                                                                           | Edisilate                   |                    |                    |                 |                      |                                                                   |                 |              |                |
|                                                                                                                                                           | Lamotrigine                 |                    |                    | S               |                      |                                                                   |                 | Not Reported |                |
|                                                                                                                                                           | Digoxin                     |                    |                    | C               |                      |                                                                   |                 | Not Reported |                |
|                                                                                                                                                           | Escitalopram                |                    |                    | S               |                      | Initially Received 5 Mg<br>Daily Then Increased To<br>10mg Daily. |                 | Accord       |                |
|                                                                                                                                                           | Fluphenazine                |                    |                    | S               |                      |                                                                   |                 | Not Reported |                |
|                                                                                                                                                           | Hydroxycarbamide            |                    |                    | C               |                      |                                                                   |                 | Not Reported |                |
|                                                                                                                                                           | Carvedilol/Carvedilol       |                    |                    | C               |                      |                                                                   |                 | Not Reported |                |
|                                                                                                                                                           | Hydrochloride               |                    |                    |                 |                      |                                                                   |                 |              |                |
|                                                                                                                                                           | Quetiapine                  |                    |                    | S               |                      |                                                                   |                 | Accord       |                |
|                                                                                                                                                           | Ferric Hydroxide Colloidal  |                    |                    | C               |                      |                                                                   |                 | Not Reported |                |
|                                                                                                                                                           | Valproic Acid               |                    |                    | S               |                      |                                                                   |                 | Not Reported |                |
|                                                                                                                                                           | Pantoprazole                |                    |                    | C               |                      |                                                                   |                 | Not Reported |                |
|                                                                                                                                                           | Acetylsalicylic Acid        |                    |                    | C               |                      |                                                                   |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 23-Sep-2014                                                                                | 10471595       | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000070811    |                      | < 1 DAY         | Female     | USA            |
| <u>Preferred Term</u>                                                                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Cardiac Disorder;<br>Congenital Anomaly;<br>Gastrointestinal Injury;<br>Neural Tube Defect | Lexapro        |                    |                    | S               | Transplacental       |                      |                 | Forest     |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 24-Sep-2014              | 9166612        | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000043307    |                      | < 1 DAY         | Male       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Developmental Delay;     | Lexapro        |                    |                    | S               | Transplacental       |                      |                 | Forest     |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Hypoplastic Right Heart  
Syndrome; Hypospadias

| <u>FDA Received Date</u>                                      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 24-Sep-2014                                                   | 10403942       | EXPEDITED (15-DAY) |                    | HO              | FR-BAUSCH-SYM-2014-24310 |                      | 80 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                         | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bradycardia; Confusional State                                | Mono-Tildiem   |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                                                               | Mono-Tildiem   |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                                                               | Coversyl       |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                                                               | Coversyl       |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                                                               | Diamicron      |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                                                               | Diamicron      |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                                                               | Seroplex       |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                                                               | Seroplex       |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Sep-2014                                                   | 10472565       | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2014260385 |                      | 42 YR           | Female       | USA            |
| <u>Preferred Term</u>                                         | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Irritability; Potentiating Drug Interaction | Chantix        |                    |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                                                               | Lexapro        |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                                                               | Celexa         |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Sep-2014                                                   | 10473762       | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000070809        |                      | < 1 DAY         | Male         | USA            |
| <u>Preferred Term</u>                                         | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Congenital Anomaly; Talipes                                   | Lexapro        |                    |                    | S               | Transplacental           |                      |                 | Forest       |                |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <a href="#">FDA Received Date</a>                                                                              | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|----------------------------------------------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 24-Sep-2014                                                                                                    | 10474404                | EXPEDITED (15-DAY)        |                             | CA                       | US-FRI-1000070813             |                               | < 1 DAY                  | Male                | USA                     |
| <a href="#">Preferred Term</a>                                                                                 | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Congenital Tricuspid Valve Atresia; Dextrocardia; Heart Injury; Pulmonary Artery Atresia; Univentricular Heart | Lexapro                 |                           |                             | S                        |                               |                               |                          | Forest              |                         |
| <a href="#">FDA Received Date</a>                                                                              | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 24-Sep-2014                                                                                                    | 10475171                | DIRECT                    |                             |                          |                               |                               | 14 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                                                 | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Ineffective; Product Substitution Issue                                                                   | Lexapro                 |                           |                             | S                        | Oral                          |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                              | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 25-Sep-2014                                                                                                    | 10156927                | EXPEDITED (15-DAY)        |                             | DE, OT                   | FR-JNJFOC-20140419656         |                               | 45 YR                    | Male                | FRA                     |
| <a href="#">Preferred Term</a>                                                                                 | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Coma; Drug Interaction; Drug Interaction                                                                       | Topalgic (France)       |                           |                             | S                        | Oral                          |                               |                          | Not Reported        |                         |
|                                                                                                                | Durogesic               |                           |                             | S                        | Transdermal                   |                               |                          | Not Reported        |                         |
|                                                                                                                | Tercian                 |                           |                             | S                        | Oral                          |                               |                          | Not Reported        |                         |
|                                                                                                                | Imovane                 |                           |                             | S                        | Oral                          |                               |                          | Not Reported        |                         |
|                                                                                                                | Oxynorm                 |                           |                             | S                        | Oral                          |                               |                          | Not Reported        |                         |
|                                                                                                                | Lyrica                  |                           |                             | S                        | Oral                          |                               |                          | Not Reported        |                         |
|                                                                                                                | Seroplex                |                           |                             | S                        | Oral                          |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                              | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 25-Sep-2014                                                                                                    | 10476060                | EXPEDITED (15-DAY)        |                             | OT                       | CA-FRI-1000070930             |                               |                          | Female              | CAN                     |

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

| <u>Preferred Term</u>                                                                                                                                    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                              | <u>Duration</u> | <u>Mfr</u>   |                |
|----------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------------------------|-----------------|--------------|----------------|
| Gastric Ulcer; Off Label Use                                                                                                                             | Escitalopram         |                    |                    | S               | Oral                 | 5 Mg Daily; Started 4 Years Ago (Nos)           |                 | Forest       |                |
|                                                                                                                                                          | Escitalopram         |                    |                    | S               | Oral                 | 5 Mg Daily; Discontinued About A Year Ago (Nos) |                 | Forest       |                |
|                                                                                                                                                          | Crestor              |                    |                    | S               |                      |                                                 |                 | Not Reported |                |
|                                                                                                                                                          | Metformin            |                    |                    | C               |                      | Daily Dose Not Reported.                        |                 | Not Reported |                |
|                                                                                                                                                          | Rosuvastatin         |                    |                    | C               |                      |                                                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                 | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Sep-2014                                                                                                                                              | 9166668              | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000043318    |                                                 | < 1 DAY         | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                              | <u>Duration</u> | <u>Mfr</u>   |                |
| Congenital Anomaly; Fallot'S Tetralogy; Right Aortic Arch                                                                                                | Lexapro              |                    |                    | S               | Transplacental       |                                                 |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                                                 | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Sep-2014                                                                                                                                              | 10478940             | EXPEDITED (15-DAY) |                    | OT              | AU-FRI-1000070931    |                                                 |                 | Female       | AUS            |
| <u>Preferred Term</u>                                                                                                                                    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                              | <u>Duration</u> | <u>Mfr</u>   |                |
| Dementia; Somnolence                                                                                                                                     | Escitalopram         |                    |                    | S               |                      |                                                 |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                                                 | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Sep-2014                                                                                                                                              | 10483585             | EXPEDITED (15-DAY) | Y                  | OT              | 2014HINLIT0819       |                                                 | 86 YR           | Male         | SVN            |
| <u>Preferred Term</u>                                                                                                                                    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                              | <u>Duration</u> | <u>Mfr</u>   |                |
| Acute Myocardial Infarction; Anxiety; Atrial Fibrillation; Cardiac Failure; Cognitive Disorder; Delirium; Disorientation; Fear; Gastrooesophageal Reflux | Escitalopram         |                    |                    | S               |                      |                                                 |                 | Not Reported |                |
|                                                                                                                                                          | Clomethiazole        |                    |                    | C               |                      |                                                 |                 | Not Reported |                |
|                                                                                                                                                          | Hydroxyurea          |                    |                    | C               |                      |                                                 |                 | Not Reported |                |
|                                                                                                                                                          | Acetylsalicylic Acid |                    |                    | C               |                      |                                                 |                 | Not Reported |                |
|                                                                                                                                                          | Digoxin              |                    |                    | C               |                      |                                                 |                 | Not Reported |                |
|                                                                                                                                                          | Carvedilol           |                    |                    | C               |                      |                                                 |                 | Not Reported |                |
|                                                                                                                                                          | Pantoprazole         |                    |                    | C               |                      |                                                 |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Disease; Hallucination,  
Olfactory; Hallucination,  
Visual; Insomnia;  
Insomnia;  
Myeloproliferative  
Neoplasm; Restlessness;  
Thrombocytosis

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Sep-2014              | 10480325      | EXPEDITED (15-DAY) |                    | DS, OT          | US-ROCHE-1466189     |                      | 74 YR      | Female     | USA            |

| <u>Preferred Term</u>      | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Bladder Prolapse; | Klonopin                  |              |            | S           | Oral         | 1 Pill             |                 | Not Reported |
| Blood Pressure Increased;  | Klonopin                  |              |            | S           | Oral         | Half A Pill        |                 | Not Reported |
| Drug Dependence; Drug      | Lexapro                   |              |            | S           | Unknown      |                    |                 | Not Reported |
| Ineffective;               | Miralax                   |              |            | C           |              |                    |                 | Not Reported |
| Hypoaesthesia;             | Senna                     |              |            | C           |              |                    |                 | Not Reported |
| Neuropathy Peripheral;     | Neurontin (United States) |              |            | C           | Unknown      |                    |                 | Not Reported |
| Sciatica; Seizure          | Colace                    |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 29-Sep-2014              | 10480339      | EXPEDITED (15-DAY) |                    | DE, HO, OT      | CH-JNJFOC-20140913506 |                      | 84 YR      | Female     | CHE            |

| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Antidepressant Drug Level  | Durogesic      |              |            | S           | Transdermal  |                    |                 | Not Reported |
| Increased; Confusional     | Durogesic      |              |            | S           | Transdermal  |                    |                 | Not Reported |
| State; Death; Dehydration; | Durogesic      |              |            | S           | Transdermal  |                    |                 | Not Reported |
| Dysphagia; Dyspnoea;       | Durogesic      |              |            | S           | Transdermal  |                    |                 | Not Reported |
| General Physical Health    | Durogesic      |              |            | S           | Transdermal  |                    |                 | Not Reported |
| Deterioration; Intestinal  | Cipralelex     |              |            | S           | Oral         |                    |                 | Not Reported |
| Obstruction; Parkinsonian  | Cipralelex     |              |            | S           | Oral         |                    |                 | Not Reported |
| Crisis; Psychomotor        | Cipralelex     |              |            | S           | Oral         |                    |                 | Not Reported |
| Hyperactivity; Urinary     | Cipralelex     |              |            | S           | Oral         |                    |                 | Not Reported |
| Retention; Urinary Tract   | Cipralelex     |              |            | S           | Oral         |                    |                 | Not Reported |
| Infection                  | Cipralelex     |              |            | S           | Oral         |                    |                 | Not Reported |

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

|                     |   |                                          |              |
|---------------------|---|------------------------------------------|--------------|
| Madopar Liq 62.5    | S | Oral                                     | Not Reported |
| Madopar Liq 62.5    | S | Oral                                     | Not Reported |
| Madopar Liq 62.5    | S | Oral                                     | Not Reported |
| Haldol              | C | Intravenous (not<br>otherwise specified) | Not Reported |
| Aspirin             | C | Oral                                     | Not Reported |
| Temesta (Lorazepam) | C | Oral                                     | Not Reported |
| Temesta (Lorazepam) | C | Oral                                     | Not Reported |
| Temesta (Lorazepam) | C | Oral                                     | Not Reported |
| Temesta (Lorazepam) | C | Oral                                     | Not Reported |
| Temesta (Lorazepam) | C | Oral                                     | Not Reported |
| Temesta (Lorazepam) | C | Oral                                     | Not Reported |
| Temesta (Lorazepam) | C | Oral                                     | Not Reported |
| Temesta (Lorazepam) | C | Oral                                     | Not Reported |
| Temesta (Lorazepam) | C | Oral                                     | Not Reported |
| Laxoberon           | C | Oral                                     | Not Reported |
| Morphine Hcl        | C | Oral                                     | Not Reported |
| Lyrica              | C | Oral                                     | Not Reported |
| Glucophage          | C | Oral                                     | Not Reported |
| Dafalgan            | C | Oral                                     | Not Reported |
| Amlodipine          | C | Oral                                     | Not Reported |
| Concor              | C | Oral                                     | Not Reported |
| Motilium            | C | Oral                                     | Not Reported |
| Zofran              | C | Oral                                     | Not Reported |
| Monuril             | C | Oral                                     | Not Reported |
| Anexate             | C | Intravenous (not<br>otherwise specified) | Not Reported |
| Midazolam           | C | Intravenous (not<br>otherwise specified) | Not Reported |
| Furadantine         | C | Oral                                     | Not Reported |

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

|            |   |           |              |
|------------|---|-----------|--------------|
| Quetiapine | C | Oral      | Not Reported |
| Nitroderm  | C | Cutaneous | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Sep-2014              | 10481923      | EXPEDITED (15-DAY) |                    | HO, OT          | PHHY2014US125461     |                      | 19 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Agitation;<br>Cardiomyopathy; Ejection<br>Fraction Decreased;<br>Paranoia; Suicide Attempt;<br>Tachycardia; Treatment<br>Failure | Clozapine      |              |            | S           |              | 25 Mg, Per Day     |                 | Not Reported |
|                                                                                                                                  | Clozapine      |              |            | S           |              | 50 Mg, Per Day     |                 | Not Reported |
|                                                                                                                                  | Clozapine      |              |            | S           |              | 75 Mg, Per Day     |                 | Not Reported |
|                                                                                                                                  | Clozapine      |              |            | S           |              | 100 Mg, Per Day    |                 | Not Reported |
|                                                                                                                                  | Clozapine      |              |            | S           |              | 125 Mg, Per Day    |                 | Not Reported |
|                                                                                                                                  | Clozapine      |              |            | S           |              | 150 Mg, Per Day    |                 | Not Reported |
|                                                                                                                                  | Clozapine      |              |            | S           |              | 250 Mg, Per Day    |                 | Not Reported |
|                                                                                                                                  | Risperidone    |              |            | S           |              | 2 Mg, Per Day      |                 | Novartis     |
|                                                                                                                                  | Haloperidol    |              |            | S           |              | 5 Mg, Per Day      |                 | Not Reported |
|                                                                                                                                  | Haloperidol    |              |            | S           |              | 10 Mg, Per Day     |                 | Not Reported |
|                                                                                                                                  | Haloperidol    |              |            | S           |              | 20 Mg, Per Day     |                 | Not Reported |
|                                                                                                                                  | Escitalopram   |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                  | Citalopram     |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                  | Fluphenazine   |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                  | Lorazepam      |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                  | Quetiapine     |              |            | S           |              | 50 Mg, Per Day     |                 | Not Reported |
|                                                                                                                                  | Clonazepam     |              |            | S           |              | 0.25 Mg, Per Day   |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Sep-2014              | 10482032      | EXPEDITED (15-DAY) |                    | HO, OT          | GB-TEVA-508148ISR    |                      | 44 YR      | Female     | GBR            |

| <u>Preferred Term</u>                                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blister; Cheilitis; Mucosal<br>Inflammation; Stevens-<br>Johnson Syndrome; | Ramipril       |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                            | Escitalopram   |              |            | S           | Unknown      |                    |                 | Ivax         |

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

|            |                |   |      |                    |              |
|------------|----------------|---|------|--------------------|--------------|
| Stomatitis | Forxiga        | S | Oral | 5 Milligram Daily; | Not Reported |
|            | Codeine        | C |      |                    | Not Reported |
|            | Flucloxacillin | C |      |                    | Not Reported |
|            | Fucibet        | C |      |                    | Not Reported |
|            | Humalog        | C |      |                    | Not Reported |
|            | Lantus         | C |      |                    | Not Reported |
|            | Paracetamol    | C |      |                    | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Sep-2014              | 10482763      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000071035    |                      | 79 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                                                                                                            | <u>Product</u>                                    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Acute Kidney Injury;<br>Cholestasis; Drug<br>Reaction With Eosinophilia<br>And Systemic Symptoms;<br>International Normalised<br>Ratio Increased | Escitalopram                                      |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                                                                                                                                  | Allopurinol                                       |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                  | Colchimax (France)                                |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                  | Previscan (Fluindione)                            |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                  | Celiprolol                                        |              |            | C           |              | 200 Mg             |                 | Not Reported |
|                                                                                                                                                  | Furosemide                                        |              |            | C           |              | 20 Mg              |                 | Not Reported |
|                                                                                                                                                  | Glucophage                                        |              |            | C           |              | 500 Mg             |                 | Not Reported |
|                                                                                                                                                  | Tahor                                             |              |            | C           |              | 10 Mg              |                 | Not Reported |
|                                                                                                                                                  | Coaprovel (Hydrochlorothiazide<br>And Irbesartan) |              |            | C           |              | 300 / 25 Mg        |                 | Not Reported |
|                                                                                                                                                  | Noctamide                                         |              |            | C           |              | 2 Mg               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Sep-2014              | 10483871      | DIRECT           |                    | DS, OT          |                      |                      | 38 YR      | Unknown    | USA            |

| <u>Preferred Term</u>                                                            | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------|-------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Decreased<br>Activity; Depression;<br>Headache; Palpitations;<br>Tremor | Escitalopram 20mg |              |            | S           | Oral         | 1 Tablet           |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                       | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------------------------------|----------------------|-----------------|--------------|----------------|
| 30-Sep-2014                                                                    | 10424296                | EXPEDITED (15-DAY) |                    | OT              | PHHY2014BR110496                             |                      |                 | Male         | BRA            |
| <u>Preferred Term</u>                                                          | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Epilepsy                                                                       | Trileptal               |                    |                    | S               | Oral                                         | 1.5 Df, Bid          |                 | Novartis     |                |
|                                                                                | Trileptal               |                    |                    | S               |                                              |                      |                 | Novartis     |                |
|                                                                                | Reconter                |                    |                    | S               | Oral                                         | 1 Df, Daily          |                 | Not Reported |                |
|                                                                                | Reconter                |                    |                    | S               |                                              |                      |                 | Not Reported |                |
|                                                                                | Gardenal//Phenobarbital |                    |                    | S               | Oral                                         | 1 Df, Daily          |                 | Not Reported |                |
|                                                                                | Gardenal//Phenobarbital |                    |                    | S               |                                              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                       | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Sep-2014                                                                    | 10465075                | EXPEDITED (15-DAY) |                    | HO, OT          | GB-MYLANLABS-2014M1004022                    |                      |                 | Unknown      | GBR            |
| <u>Preferred Term</u>                                                          | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blister; Cheilitis; Mucosal Inflammation; Stevens-Johnson Syndrome; Stomatitis | Escitalopram Oxalate    |                    |                    | S               | Unknown                                      | Unk                  |                 | Not Reported |                |
|                                                                                | Forxiga                 |                    |                    | S               | Oral                                         | 5 Mg, Qd             |                 | Not Reported |                |
|                                                                                | Forxiga                 |                    |                    | S               |                                              |                      |                 | Not Reported |                |
|                                                                                | Ramipril                |                    |                    | S               | Unknown                                      |                      |                 | Not Reported |                |
|                                                                                | Codeine                 |                    |                    | C               |                                              |                      |                 | Not Reported |                |
|                                                                                | Flucloxacillin          |                    |                    | C               |                                              |                      |                 | Not Reported |                |
|                                                                                | Fucibet                 |                    |                    | C               |                                              |                      |                 | Not Reported |                |
|                                                                                | Humalog                 |                    |                    | C               |                                              |                      |                 | Not Reported |                |
|                                                                                | Lantus                  |                    |                    | C               |                                              |                      |                 | Not Reported |                |
|                                                                                | Paracetamol             |                    |                    | C               |                                              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                       | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Sep-2014                                                                    | 10484161                | EXPEDITED (15-DAY) |                    | OT              | US-ROXANE LABORATORIES, INC.-2014-RO-01483RO |                      | 43 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                          | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Feeling Abnormal; Stereotypy                                                   | Ropinirole              |                    |                    | S               | Unknown                                      |                      |                 | Roxane       |                |
|                                                                                | Quetiapine Fumarate     |                    |                    | S               | Unknown                                      | 25 Mg                |                 | Roxane       |                |

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

|                    |   |         |        |              |
|--------------------|---|---------|--------|--------------|
| Rasagiline         | S | Unknown | 1 Mg   | Not Reported |
| Clonazepam         | S | Unknown | 1 Mg   | Not Reported |
| Venlafaxine        | S | Unknown | 75 Mg  | Not Reported |
| Escitalopram       | S | Unknown | 10 Mg  | Not Reported |
| Carbidopa/Levodopa | S | Unknown | 200 Mg | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>    | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|------------------|------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 30-Sep-2014              | 10484318         | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2014268978 |                      | 59 YR           | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u>   | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity    | Zoloft           |                  |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                          | Celebrex         |                  |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                          | Morphine Sulfate |                  |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                          | Citalopram       |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                          | Lexapro          |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |

| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 30-Sep-2014               | 10484587             | EXPEDITED (15-DAY) |                    | OT              | ES-FRI-1000071081    |                      | 48 YR           | Male         | ESP            |
| <u>Preferred Term</u>     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Behaviour;       | Escitalopram         |                    |                    | S               |                      |                      |                 | Forest       |                |
| Aggression; Depression;   | Diazepam             |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Hallucination; Insomnia;  | Clopidrogel          |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Nightmare; Psychomotor    | Bisoprolol           |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Hyperactivity; Suicidal   | Ramipril             |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Ideation; Suicide Attempt | Crestor              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                           | Omeprazole           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                           | Acetylsalicylic Acid |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 30-Sep-2014              | 10485265       | EXPEDITED (15-DAY) |                    | OT              | CH-FRI-1000071086    |                      |                 | Female     | CHE            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                              |              |   |      |             |              |
|----------------------------------------------|--------------|---|------|-------------|--------------|
| Leukopenia;<br>Monocytopenia;<br>Neutropenia | Escitalopram | S | Oral | 10 Mg Daily | Forest       |
|                                              | Remeron      | S | Oral | 30 Mg Daily | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Sep-2014              | 10485268      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000071033    |                      | 26 YR      | Male       | FRA            |

| <u>Preferred Term</u> | <u>Product</u>   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                      | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|------------------|--------------|------------|-------------|--------------|---------------------------------------------------------|-----------------|--------------|
| Hepatocellular Injury | Escitalopram     |              |            | S           | Oral         | 20 Mg                                                   |                 | Forest       |
|                       | Olanzapine Mylan |              |            | S           | Oral         | 10 Mg                                                   |                 | Not Reported |
|                       | Valium Roche     |              |            | C           | Oral         | Daily Dose Tapered For Withdrawal (40 Mg To 5 Mg Daily) |                 | Not Reported |
|                       | Atarax           |              |            | C           | Oral         |                                                         |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 01-Oct-2014              | 10223994      | EXPEDITED (15-DAY) |                    | HO              | IT-PFIZER INC-2014153735 |                      | 48 YR      | Female     | ITA            |

| <u>Preferred Term</u>                                                        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abdominal Pain Upper;<br>Drug Abuse; Dyspepsia;<br>Psychomotor Hyperactivity | Xanax          |              |            | S           | Oral         | 20 MI, Total       |                 | Pfizer       |
|                                                                              | Entact         |              |            | S           | Oral         | 15 MI, Total       |                 | Not Reported |
|                                                                              | Anafranil      |              |            | S           | Oral         | 3 Df, Total        |                 | Not Reported |
|                                                                              | Aspirina       |              |            | S           | Oral         | 3 Df, Total        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Oct-2014              | 10306546      | EXPEDITED (15-DAY) |                    | OT              | US-TEVA-493379USA    |                      | 63 YR      | Female     | USA            |

| <u>Preferred Term</u>                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>             | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u> |
|---------------------------------------------|----------------|--------------|------------|-------------|--------------------------|---------------------------------|-----------------|------------|
| Chronic Kidney Disease;<br>Dental Operation | Proair Hfa     |              |            | S           | Respiratory (inhalation) | 2 Puffs As Needed Every 4 Hours |                 | Ivax       |
|                                             | Bupropion      |              |            | S           | Oral                     | 300 Milligram Daily;            |                 | Teva       |
|                                             | Escitalopram   |              |            | S           | Oral                     | 20 Milligram Daily;             |                 | Ivax       |

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

|                            |   |                          |                                 |              |
|----------------------------|---|--------------------------|---------------------------------|--------------|
| Hydroxyzine                | S | Oral                     | As Needed/X3/Day                | Barr         |
| Lansoprazole               | S | Oral                     | 30 Milligram Daily;             | Not Reported |
| Ventolin Hfa-Cfc           | S | Respiratory (inhalation) | 2 Puffs As Needed Every 4 Hours | Not Reported |
| Advair                     | S |                          | 1 Puff                          | Not Reported |
| Est . Estrogen             | C |                          |                                 | Not Reported |
| W/M.Testosterone           |   |                          |                                 |              |
| Lisinopril                 | C |                          |                                 | Not Reported |
| Trazodone Hydrochloride    | C |                          |                                 | Not Reported |
| Seasonal Influenza Vaccine | C |                          |                                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Oct-2014              | 10487655      | EXPEDITED (15-DAY) | CA                 |                 | FR-FRI-1000071153    |                      |            | Female     | FRA            |

| <u>Preferred Term</u>                                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Atrioventricular Septal Defect; Exposure During Pregnancy | Escitalopram   |              |            | S           | Transplacental | 10 Mg              |                 | Forest       |
|                                                           | Stilnox        |              |            | S           | Transplacental | 10 Mg              |                 | Not Reported |
|                                                           | Lexomil        |              |            | S           | Transplacental |                    |                 | Not Reported |
|                                                           | Atarax         |              |            | S           | Transplacental |                    |                 | Not Reported |
|                                                           | Circadin       |              |            | S           | Transplacental | 10 Mg              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Oct-2014              | 10515970      | NON-EXPEDITED    | HO                 |                 | 2014005164           |                      | 57 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------------|-----------------|--------------|
| Tremor                | Vimpat         |              |            | S           | Oral         |                          |                 | Not Reported |
|                       |                |              |            |             | Oral         |                          |                 |              |
|                       | Namenda        |              |            | S           | Oral         |                          |                 | Not Reported |
|                       |                |              |            |             | Oral         |                          |                 |              |
|                       |                |              |            |             | Oral         | 10 Mg Am And 5mg P, Oral |                 |              |
|                       | Namenda        |              |            | S           | Oral         |                          |                 | Not Reported |

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

|                          |                               |                    |                    |                 |                      |                      |                 |              |                |
|--------------------------|-------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Escitalopram             |                               |                    | S                  |                 | Oral                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Oct-2014              | 10516492                      | NON-EXPEDITED      | Y                  | HO              | AUR-APL-2014-08330   |                      | 54 YR           | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Suicidal Ideation        | Escitalopram 10 Mg            |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                          | (Escitalopram) Unknown, 10 Mg |                    |                    |                 |                      |                      |                 |              |                |
|                          | Atorvastatin Calcium          |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                          | (Atorvastatin Calcium)        |                    |                    |                 |                      |                      |                 |              |                |
|                          | Trazodone (Trazodone) Tablet  |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                          | Invega                        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Bumetanide                    |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Isosorbide Mononitrate        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Lantus                        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Labetalol                     |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Losartan                      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Simvastatin                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Aspirin                       |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Oct-2014              | 9790863                       | EXPEDITED (15-DAY) |                    | LT              | IT-FRI-1000052566    |                      | 38 YR           | Male         | ITA            |
| <u>Preferred Term</u>    | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Coma; Drug Interaction   | Escitalopram Oral Solution    |                    |                    | S               | Oral                 | 5 Drops Daily        |                 | Forest       |                |
|                          | Invega                        |                    |                    | S               | Oral                 | 9 Mg                 |                 | Not Reported |                |
|                          | Venlafaxine                   |                    |                    | S               | Oral                 | 150 Mg               |                 | Not Reported |                |
|                          | Depakin                       |                    |                    | S               | Oral                 | 750 Mg               |                 | Not Reported |                |
|                          | Akineton                      |                    |                    | S               | Oral                 | 4 Mg                 |                 | Not Reported |                |
|                          | Tranquirit 0,5%               |                    |                    | S               | Oral                 | 20 Gtt               |                 | Not Reported |                |
|                          | Lorazepam Abc                 |                    |                    | S               | Oral                 | 7.5 Mg               |                 | Not Reported |                |
|                          | Ethanol                       |                    |                    | C               |                      |                      |                 | Not Reported |                |

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

| <u>FDA Received Date</u>                                                                                                      | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------|-------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 02-Oct-2014                                                                                                                   | 10489433          | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000071065    |                      | 1 DAY           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                         | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrial Septal Defect;<br>Cardiac Murmur;<br>Congenital Anomaly; Right<br>Atrial Enlargement; Right<br>Ventricular Enlargement | Lexapro           |                    |                    | S               | Transplacental       |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                      | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Oct-2014                                                                                                                   | 10489839          | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000048097    |                      | 82 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                         | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Inappropriate Antidiuretic<br>Hormone Secretion;<br>Medication Error                                                          | Escitalopram      |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                                                                                                               | Perindopril       |                    |                    | S               | Oral                 | 2 Mg                 |                 | Not Reported |                |
|                                                                                                                               | Indapamide        |                    |                    | S               | Oral                 | 0.625 Mg             |                 | Not Reported |                |
|                                                                                                                               | Bisoprolol        |                    |                    | C               |                      | 5 Mg                 |                 | Not Reported |                |
|                                                                                                                               | Kardegic          |                    |                    | C               |                      | 75 Mg                |                 | Not Reported |                |
|                                                                                                                               | Cacit Vitamine D3 |                    |                    | C               |                      | 1 Df                 |                 | Not Reported |                |
|                                                                                                                               | Zopiclone         |                    |                    | C               |                      | 1 Df                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                      | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Oct-2014                                                                                                                   | 10489989          | EXPEDITED (15-DAY) |                    | HO              | IT-FRI-1000071178    |                      | 3 YR            | Female       | ITA            |
| <u>Preferred Term</u>                                                                                                         | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Product Administration<br>Error; Vomiting                                                                                     | Escitalopram      |                    |                    | S               | Oral                 |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                      | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Oct-2014                                                                                                                   | 10490405          | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000071073    |                      |                 | Female       | USA            |

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

| <u>Preferred Term</u>                                                                                                                                      | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
|------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|--------------------|--------------------|-----------------|--------------------------|------------------------|-----------------|--------------|----------------|
| Fallot'S Tetralogy; Low Set Ears; Patent Ductus Arteriosus; Pulmonary Hypoplasia; Right Aortic Arch; Umbilical Cord Abnormality; Ventricular Septal Defect | Lexapro                                 |                    |                    | S               |                          |                        |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                                                   | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Oct-2014                                                                                                                                                | 10490455                                | EXPEDITED (15-DAY) |                    | OT              | US-BAUSCH-BL-2014-005784 |                        | 63 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                      | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Chronic Kidney Disease; Dental Operation                                                                                                                   | Bupropion Hydrochloride                 |                    |                    | S               | Oral                     |                        |                 | Not Reported |                |
|                                                                                                                                                            | Advair                                  |                    |                    | S               |                          | 250/50 Mcg, 1 Puff Bid |                 | Not Reported |                |
|                                                                                                                                                            | Proair Hfa                              |                    |                    | S               |                          |                        |                 | Not Reported |                |
|                                                                                                                                                            | Escitalopram Oxalate                    |                    |                    | S               | Oral                     |                        |                 | Not Reported |                |
|                                                                                                                                                            | Hydroxyzine Hydrochloride               |                    |                    | S               | Oral                     | As Needed              |                 | Not Reported |                |
|                                                                                                                                                            | Ventolin                                |                    |                    | S               |                          |                        |                 | Not Reported |                |
|                                                                                                                                                            | Prevacid                                |                    |                    | S               | Oral                     |                        |                 | Not Reported |                |
|                                                                                                                                                            | Methyltestosterone/Estrogens Esterified |                    |                    | C               |                          |                        |                 | Not Reported |                |
|                                                                                                                                                            | Methyltestosterone/Estrogens Esterified |                    |                    | C               |                          |                        |                 | Not Reported |                |
|                                                                                                                                                            | Lisinopril                              |                    |                    | C               |                          |                        |                 | Not Reported |                |
| Trazodone Hydrochloride                                                                                                                                    |                                         |                    | C                  |                 |                          |                        | Not Reported    |              |                |
| Fluzone                                                                                                                                                    |                                         |                    | C                  |                 |                          |                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                   | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Oct-2014                                                                                                                                                | 10491001                                | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000071134        |                        | < 1 DAY         | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                      | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrial Septal Defect; Congenital Anomaly; Heart Disease Congenital                                                                                         | Lexapro                                 |                    |                    | S               | Transplacental           |                        |                 | Forest       |                |

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

| <u>FDA Received Date</u>                                                  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
|---------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------------|-----------------|------------------|----------------|
| 03-Oct-2014                                                               | 10495071             | EXPEDITED (15-DAY) |                    | OT              | FR-<br>ELI_LILLY_AND_COMP<br>ANY-FR201409007977 |                            | 71 YR           | Female           | FRA            |
| <u>Preferred Term</u>                                                     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>       |                |
| Condition Aggravated;<br>Thrombocytopenia                                 | Zyprexa              |                    |                    | S               | Oral                                            | 10 Mg, Qd                  |                 | Eli Lilly And Co |                |
|                                                                           | Seroplex             |                    |                    | S               | Oral                                            | 5 Mg, Unk                  |                 | Not Reported     |                |
|                                                                           | Lovenox              |                    |                    | S               | Subcutaneous                                    | Unk, Unknown               |                 | Not Reported     |                |
| <u>FDA Received Date</u>                                                  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 03-Oct-2014                                                               | 10495078             | EXPEDITED (15-DAY) |                    | HO, OT          | FR-<br>ELI_LILLY_AND_COMP<br>ANY-FR201409007993 |                            | 75 YR           | Male             | FRA            |
| <u>Preferred Term</u>                                                     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>       |                |
| Hyperhidrosis; Pallor;<br>Syncope; Tachycardia;<br>Ventricular Arrhythmia | Zyprexa              |                    |                    | S               | Oral                                            | 5 Mg, Qd                   |                 | Eli Lilly And Co |                |
|                                                                           | Seroplex             |                    |                    | S               | Unknown                                         | 10 Mg, Qd                  |                 | Not Reported     |                |
|                                                                           | Trivastal /00397201/ |                    |                    | C               | Unknown                                         | 20 Mg, Qd                  |                 | Not Reported     |                |
|                                                                           | Tadenan              |                    |                    | C               | Unknown                                         | 50 Mg, Qd                  |                 | Not Reported     |                |
| <u>FDA Received Date</u>                                                  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 03-Oct-2014                                                               | 10497919             | DIRECT             | Y                  |                 |                                                 |                            | 14 YR           | Female           | USA            |
| <u>Preferred Term</u>                                                     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>       |                |
| Drug Ineffective; Product<br>Substitution Issue                           | Lexapro              |                    |                    | S               | Oral                                            | 20 Mg By Mouth             |                 | Not Reported     |                |
| <u>FDA Received Date</u>                                                  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 06-Oct-2014                                                               | 10501412             | DIRECT             |                    |                 |                                                 |                            | 21 YR           | Female           | USA            |
| <u>Preferred Term</u>                                                     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>       |                |
| Anxiety; Depression                                                       | Lexapro 10 Mg        |                    |                    | S               | Oral                                            | 1 Pill Once Daily Taken By |                 | Not Reported     |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Mouth

| <u>FDA Received Date</u>  | <u>Case #</u>                 | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------|-------------------------------|------------------|--------------------|-----------------|--------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 07-Oct-2014               | 10501321                      | NON-EXPEDITED    |                    |                 | IT-LUPIN<br>PHARMACEUTICALS<br>INC.-2014-01353   |                      | 42 YR           | Female       | ITA            |
| <u>Preferred Term</u>     | <u>Product</u>                | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                     | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depressive Symptom;       | Escitalopram                  |                  |                    | S               | Unknown                                          |                      |                 | Not Reported |                |
| Drug Ineffective;         | Venlafaxine                   |                  |                    | S               | Unknown                                          |                      |                 | Not Reported |                |
| Headache; Therapeutic     | Tamoxifen                     |                  |                    | C               | Unknown                                          |                      |                 | Not Reported |                |
| Product Effect Decreased; |                               |                  |                    |                 |                                                  |                      |                 |              |                |
| Weight Increased          |                               |                  |                    |                 |                                                  |                      |                 |              |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                 | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Oct-2014               | 10501325                      | NON-EXPEDITED    |                    |                 | US-LUPIN<br>PHARMACEUTICALS<br>INC.-E2B_00002341 |                      | 26 YR           | Female       | USA            |
| <u>Preferred Term</u>     | <u>Product</u>                | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                     | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Dyspnoea;      | Escitalopram Tablets Usp 20mg |                  |                    | S               |                                                  |                      |                 | Lupin        |                |
| Heart Rate Increased;     | Escitalopram Tablets Usp 20mg |                  |                    | S               |                                                  |                      |                 | Lupin        |                |
| Intentional Underdose;    | Escitalopram Tablets Usp 20mg |                  |                    | S               |                                                  |                      |                 | Lupin        |                |
| Panic Attack              | Escitalopram Tablets Usp 20mg |                  |                    | S               |                                                  |                      |                 | Lupin        |                |
|                           | Protonix                      |                  |                    | C               | Unknown                                          |                      |                 | Not Reported |                |
|                           | Synthroid                     |                  |                    | C               | Unknown                                          |                      |                 | Not Reported |                |
|                           | Gabapentin                    |                  |                    | C               | Unknown                                          |                      |                 | Not Reported |                |
|                           | Ranitidine                    |                  |                    | C               | Unknown                                          |                      |                 | Not Reported |                |
|                           | Zyrtec                        |                  |                    | C               | Unknown                                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                 | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Oct-2014               | 10501348                      | NON-EXPEDITED    |                    | HO, LT          | DE-LUPIN<br>PHARMACEUTICALS<br>INC.-E2B_00002465 |                      | 58 YR           | Female       | DEU            |
| <u>Preferred Term</u>     | <u>Product</u>                | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                     | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Myoclonus; Pyrexia;       | Mirtazapin                    |                  |                    | S               | Oral                                             |                      |                 | Not Reported |                |
| Serotonin Syndrome;       |                               |                  |                    |                 |                                                  |                      |                 |              |                |

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

|                   |              |   |      |              |
|-------------------|--------------|---|------|--------------|
| Sinus Tachycardia | Escitalopram | S | Oral | Not Reported |
|                   | Amantadin    | S | Oral | Not Reported |

| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------|----------------|------------------|--------------------|-----------------|------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 07-Oct-2014                | 10501502       | NON-EXPEDITED    |                    |                 | IT-LUPIN<br>PHARMACEUTICALS<br>INC.-2014-01390 |                      | 35 YR           | Female       | ITA            |
| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective; Exposure | Escitalopram   |                  |                    | S               | Unknown                                        |                      |                 | Not Reported |                |
| During Pregnancy; Major    | Clonazepam     |                  |                    | C               | Unknown                                        |                      |                 | Not Reported |                |
| Depression                 | Lorazepam      |                  |                    | C               | Unknown                                        |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>       | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|---------------------|------------------|--------------------|-----------------|----------------------|------------------------------------------------------|-----------------|--------------|----------------|
| 07-Oct-2014              | 10503655            | DIRECT           |                    | HO              |                      |                                                      | 77 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>      | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain; Dry      | Meloxicam 15mg      |                  |                    | S               | Oral                 |                                                      |                 | Not Reported |                |
| Mouth; Feeling Abnormal; | Baby Aspirin        |                  |                    | S               |                      |                                                      |                 | Not Reported |                |
| Hyponatraemia;           | Lexapro             |                  |                    | S               |                      |                                                      |                 | Not Reported |                |
| Hypovolaemia; Migraine;  | Lisinopril          |                  |                    | S               |                      |                                                      |                 | Not Reported |                |
| Myalgia; Nausea;         | Ciproflaxin         |                  |                    | S               |                      |                                                      |                 | Not Reported |                |
| Somnolence; Tremor;      | Crestor             |                  |                    | S               |                      |                                                      |                 | Astrazeneca  |                |
| Urinary Tract Infection; | Remeron             |                  |                    | S               |                      | 15 Mg, 30, Once Daily,<br>Mouth                      |                 | Not Reported |                |
| Withdrawal Syndrome      | Xalatan             |                  |                    | C               |                      |                                                      |                 | Not Reported |                |
|                          | Lexapro             |                  |                    | C               | Oral                 | 10-20 Mg Through The<br>Years 30 Once Daily<br>Mouth |                 | Not Reported |                |
|                          | Norvasc             |                  |                    | C               |                      |                                                      |                 | Not Reported |                |
|                          | Apple Cider Vinegar |                  |                    | C               |                      |                                                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Oct-2014              | 10504544      | DIRECT           | Y                  | DS              |                      |                      | 62 YR      | Female     | USA            |



# FDA Adverse Event Reporting System

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### Detailed Report

| <a href="#">Preferred Term</a>                                 | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
|----------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Anxiety; Product Label Issue; Tendon Rupture                   | Lexapro                 |                           |                             | S                        | Oral                          | 1 Per Day                     |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                              | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 08-Oct-2014                                                    | 10086372                | EXPEDITED (15-DAY)        |                             | HO                       | US-FRI-1000051980             |                               | 43 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                 | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Hepatitis Acute; Pancreatitis; Toxicity To Various Agents      | Escitalopram            |                           |                             | S                        | Oral                          | 20 Mg                         |                          | Forest              |                         |
|                                                                | Luaf41156               |                           |                             | S                        | Oral                          | 3 Mg                          |                          | Not Reported        |                         |
|                                                                | Luaf41156               |                           |                             | S                        | Oral                          | 3 Mg                          |                          | Not Reported        |                         |
|                                                                | Luaf41156               |                           |                             | S                        | Oral                          | .50 Unk, Daily Dose           |                          | Not Reported        |                         |
|                                                                | Luaf41156               |                           |                             | S                        | Oral                          | 1 Mg                          |                          | Not Reported        |                         |
|                                                                | Luaf41156               |                           |                             | S                        | Oral                          | 2 Mg                          |                          | Not Reported        |                         |
|                                                                | Tylenol                 |                           |                             | C                        | Oral                          | 400 Mg                        |                          | Not Reported        |                         |
|                                                                | Imitrex                 |                           |                             | C                        | Oral                          | 50 Mg, Unk                    |                          | Not Reported        |                         |
|                                                                | Ventolin                |                           |                             | C                        |                               | 10 Mcg, Unk                   |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                              | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 08-Oct-2014                                                    | 10465393                | EXPEDITED (15-DAY)        |                             | HO                       | FR-PFIZER INC-2014256625      |                               | 30 YR                    | Male                | FRA                     |
| <a href="#">Preferred Term</a>                                 | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Confusional State; Hyponatraemia; Overdose; Serotonin Syndrome | Xanax                   |                           |                             | S                        | Oral                          | Unk                           |                          | Pfizer              |                         |
|                                                                | Escitalopram Oxalate    |                           |                             | S                        | Oral                          | Unk                           |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                              | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 08-Oct-2014                                                    | 10503899                | EXPEDITED (15-DAY)        |                             | HO, LT, OT               | AU-JNJFOC-20141001220         |                               |                          | Unknown             | AUS                     |
| <a href="#">Preferred Term</a>                                 | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |

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

|                      |                              |   |         |              |
|----------------------|------------------------------|---|---------|--------------|
| Poisoning Deliberate | Paracetamol                  | S | Unknown | Not Reported |
|                      | Diazepam                     | S | Unknown | Not Reported |
|                      | Quetiapine                   | S | Unknown | Not Reported |
|                      | Temazepam                    | S |         | Not Reported |
|                      | Alprazolam                   | S | Unknown | Not Reported |
|                      | Opioids                      | S | Unknown | Not Reported |
|                      | Escitalopram                 | S | Unknown | Not Reported |
|                      | Sertraline                   | S | Unknown | Not Reported |
|                      | Venlafaxine                  | S | Unknown | Not Reported |
|                      | Desvenlafaxine               | S | Unknown | Not Reported |
|                      | Duloxetine                   | S | Unknown | Not Reported |
|                      | Zolpidem                     | S | Unknown | Not Reported |
|                      | Zopiclone                    | S | Unknown | Not Reported |
|                      | Tricyclic Antidepressant Nos | S | Unknown | Not Reported |
|                      | Nsaids                       | S | Unknown | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Oct-2014              | 10504856      | EXPEDITED (15-DAY) |                    | OT              | GB-FRI-1000071227    |                      | 41 YR      | Female     | GBR            |

| <u>Preferred Term</u>                              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|----------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Alcohol Abuse; Mania;<br>Suicidal Ideation; Tremor | Escitalopram   |              |            | S           |              |                    |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Oct-2014              | 10505062      | EXPEDITED (15-DAY) |                    | HO              | FR-SA-2014SA136949   |                      | 46 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|-----------------------------------|-----------------|--------------|
| Neutropenia           | Doliprane      |              |            | S           | Oral         | Form: Powder For Oral<br>Solution |                 | Not Reported |
|                       | Tranxene       |              |            | S           | Oral         |                                   |                 | Not Reported |
|                       | Flagyl         |              |            | S           | Unknown      |                                   |                 | Not Reported |

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

|                       |   |                                       |              |
|-----------------------|---|---------------------------------------|--------------|
| Lovenox               | S | Subcutaneous                          | Not Reported |
| Inexium               | S | Oral                                  | Not Reported |
| Seroplex              | S | Oral                                  | Not Reported |
| Ceftriaxone Panpharma | S | Intravenous (not otherwise specified) | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Oct-2014              | 10505101      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000071289    |                      | 82 YR      | Male       | FRA            |

| <u>Preferred Term</u>            | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------|--------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Neutropenia;<br>Thrombocytopenia | Escitalopram       |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                  | Metoject           |              |            | S           | Subcutaneous | 2.1429 Mg          |                 | Not Reported |
|                                  | Orelox             |              |            | S           | Oral         |                    |                 | Not Reported |
|                                  | Cortancyl          |              |            | S           | Oral         | 0.5 Df             |                 | Not Reported |
|                                  | Augmentin          |              |            | S           | Oral         | 3 G                |                 | Not Reported |
|                                  | Kardegic           |              |            | C           |              |                    |                 | Not Reported |
|                                  | Tahor              |              |            | C           |              |                    |                 | Not Reported |
|                                  | Furosemide         |              |            | C           |              |                    |                 | Not Reported |
|                                  | Ramipril           |              |            | C           |              |                    |                 | Not Reported |
|                                  | Erythropoietin     |              |            | C           |              |                    |                 | Not Reported |
|                                  | Inexium            |              |            | C           |              |                    |                 | Not Reported |
|                                  | Methylprednisolone |              |            | C           |              |                    |                 | Not Reported |
|                                  | Speciafoldine      |              |            | C           |              |                    |                 | Not Reported |
|                                  | Mag 2              |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Oct-2014              | 10505673      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000071291    |                      | 68 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                                          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|----------------------|-----------------|--------------|
| Accidental Overdose;<br>Drug Interaction;<br>Haematuria; Rectal<br>Haemorrhage | Escitalopram   |              |            | S           |              |                      |                 | Forest       |
|                                                                                | Pradaxa        |              |            | S           | Oral         | Overdose 220 Mg/Day. |                 | Not Reported |
|                                                                                | Pradaxa        |              |            | S           |              |                      |                 | Not Reported |
|                                                                                | Kardegic       |              |            | S           | Oral         | 75 Mg                |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>                    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------|-----------------------------------|--------------------|--------------------|-----------------|---------------------------|-----------------------------------------|-----------------|--------------|----------------|
| 08-Oct-2014                                                                             | 10507291                          | DIRECT             |                    |                 |                           |                                         | 46 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                   | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>                      | <u>Duration</u> | <u>Mfr</u>   |                |
| Chills; Emotional Disorder; Migraine; Palpitations; Product Substitution Issue; Pyrexia | Escitalopram 10mg Lupin Pharmaceu |                    |                    | S               | Oral                      | 1 Pill, Once Daily, Taken By Mouth      |                 | Lupin        |                |
| <u>FDA Received Date</u>                                                                | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>                    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Oct-2014                                                                             | 10259940                          | EXPEDITED (15-DAY) |                    | HO              | IT-FRI-1000068484         |                                         | 48 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                                   | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>                      | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain Upper; Drug Abuse; Psychomotor Hyperactivity                             | Escitalopram Oral Solution        |                    |                    | S               | Oral                      | 15 MI Of 20 Mg/MI In 1 Single Dose      |                 | Forest       |                |
|                                                                                         | Xanax                             |                    |                    | S               | Oral                      | Overdose: 20 MI Of 0.75 Mg/MI           |                 | Not Reported |                |
|                                                                                         | Anafranil                         |                    |                    | S               | Oral                      | Overdose: 225 Mg (3 Tablets Of 75 Mg)   |                 | Not Reported |                |
|                                                                                         | Aspirina                          |                    |                    | S               | Oral                      | Overdose: 1500 Mg (3 Tablets Of 500 Mg) |                 | Not Reported |                |
|                                                                                         | Baygon (Insecticides Substance)   |                    |                    | S               | Oral                      | Overdose: 3 Tablespoons                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>                    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Oct-2014                                                                             | 10507783                          | EXPEDITED (15-DAY) |                    | OT              | DE-FRI-1000071344         |                                         | 76 DAY          | Male         | DEU            |
| <u>Preferred Term</u>                                                                   | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>                      | <u>Duration</u> | <u>Mfr</u>   |                |
| Exposure Via Breast Milk; Transaminases Increased                                       | Escitalopram                      |                    |                    | S               | Transmammary              | 8 Mg                                    |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>                    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Oct-2014                                                                             | 10507844                          | EXPEDITED (15-DAY) |                    | CA, DE, OT      | US-MYLANLABS-2014M1006176 |                                         |                 | Unknown      | USA            |

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| <u>Preferred Term</u>                                  | <u>Product</u>                                              | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|--------------------------------------------------------|-------------------------------------------------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Death; Exposure During Pregnancy; Pulmonary Hypoplasia | Citalopram                                                  |                  |                    | S               | Transplacental       | Unk                  |                 | Not Reported |                |
|                                                        | Lexapro                                                     |                  |                    | S               | Transplacental       | Unk                  |                 | Not Reported |                |
|                                                        | Celexa /00582602/                                           |                  |                    | S               | Transplacental       | Unk                  |                 | Not Reported |                |
|                                                        | Escitalopram                                                |                  |                    | S               | Transplacental       | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                               | <u>Case #</u>                                               | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Oct-2014                                            | 10540480                                                    | NON-EXPEDITED    |                    | RI, OT          | 1000054686           |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                  | <u>Product</u>                                              | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Suicidal Ideation                                      | Lexapro (Escitalopram Oxalate)                              |                  |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                               | <u>Case #</u>                                               | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Oct-2014                                            | 10540481                                                    | NON-EXPEDITED    |                    | RI, OT          | 1000060345           |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                  | <u>Product</u>                                              | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Amnesia; Serotonin Syndrome                            | Lexapro (Escitalopram Oxalate)                              |                  |                    | S               |                      | - Stopped            |                 | Not Reported |                |
|                                                        | Triptans                                                    |                  |                    | S               |                      | - Stopped            |                 | Not Reported |                |
|                                                        | Yasmin (Drospirenone W/ Ethinylestradiol)                   |                  |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                               | <u>Case #</u>                                               | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Oct-2014                                            | 10540486                                                    | NON-EXPEDITED    | Y                  | RI, OT          | 1000060443           |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                  | <u>Product</u>                                              | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Inappropriate Antidiuretic Hormone Secretion           | Escitalopram (Escitalopram Oxalate) (10 Milligram, Tablets) |                  |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                               | <u>Case #</u>                                               | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Oct-2014                                            | 10540501                                                    | NON-EXPEDITED    | Y                  | RI, OT          | 1000064796           |                      | 61 YR           | Male         | USA            |
| <u>Preferred Term</u>                                  | <u>Product</u>                                              | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

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|                                                            |                                                             |                                |                    |                 |                      |                      |                 |              |                |
|------------------------------------------------------------|-------------------------------------------------------------|--------------------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Urinary Retention                                          |                                                             | Lexapro (Escitalopram Oxalate) |                    | S               |                      | Not Reported         |                 |              |                |
| <u>FDA Received Date</u>                                   | <u>Case #</u>                                               | <u>Case Type</u>               | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Oct-2014                                                | 10540513                                                    | NON-EXPEDITED                  |                    | RI, OT          | 1000067275           |                      | 43 YR           | Male         | USA            |
| <u>Preferred Term</u>                                      | <u>Product</u>                                              | <u>Comp.</u>                   | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Crying; Dizziness; Fatigue; Paraesthesia; Weight Increased | Lexapro                                                     |                                |                    | S               | Oral<br>Oral         |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                   | <u>Case #</u>                                               | <u>Case Type</u>               | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Oct-2014                                                | 10540526                                                    | NON-EXPEDITED                  | Y                  | HO              | 1000067726           |                      | 59 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                      | <u>Product</u>                                              | <u>Comp.</u>                   | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Syncope                                                    | Escitalopram (Escitalopram Oxalate) (10 Milligram, Tablets) |                                |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                            | Placebo (Placebo)                                           |                                |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                            | Naprosyn (Naproxen)                                         |                                |                    | C               |                      |                      |                 | Not Reported |                |
|                                                            | Atenolol                                                    |                                |                    | C               |                      |                      |                 | Not Reported |                |
|                                                            | Hydrochlorothiazide                                         |                                |                    | C               |                      |                      |                 | Not Reported |                |
|                                                            | Simvastatin                                                 |                                |                    | C               |                      |                      |                 | Not Reported |                |
|                                                            | Maalox (Magnesium Hydroxide, Aluminum Hydroxide)            |                                |                    | C               |                      |                      |                 | Not Reported |                |
|                                                            | Aspirin (Acetylsalicylic Acid)                              |                                |                    | C               |                      |                      |                 | Not Reported |                |
|                                                            | Prazosin Hydrochloride                                      |                                |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                   | <u>Case #</u>                                               | <u>Case Type</u>               | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Oct-2014                                                | 10540555                                                    | NON-EXPEDITED                  | Y                  | HO              | 1000068283           |                      | 34 YR           | Female       | USA            |
| <u>Preferred Term</u>                                      | <u>Product</u>                                              | <u>Comp.</u>                   | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Gastrointestinal Haemorrhage                               | Lexapro                                                     |                                |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                            | Prilosec (Omeprazole)                                       |                                |                    | C               |                      |                      |                 | Not Reported |                |
|                                                            | Vitamin B12                                                 |                                |                    | C               |                      |                      |                 | Not Reported |                |
|                                                            | Iron                                                        |                                |                    | C               |                      |                      |                 | Not Reported |                |

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| <u>FDA Received Date</u>           | <u>Case #</u>                                               | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------|-------------------------------------------------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 09-Oct-2014                        | 10540568                                                    | NON-EXPEDITED    | Y                  | RI, OT          | 1000068859           |                      | 34 YR           | Female       | DNK            |
| <u>Preferred Term</u>              | <u>Product</u>                                              | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abortion Spontaneous;<br>Pregnancy | Escitalopram (Escitalopram Oxalate) (10 Milligram, Tablets) |                  |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                    | Luaf41156                                                   |                  |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                    | Blinded Placebo                                             |                  |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                    | Blinded Serequel Xr                                         |                  |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                    | Tylenol Paracetamol (Paracetamol)                           |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                    | Devils Claw                                                 |                  |                    | S               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>                  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|--------------------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 09-Oct-2014              | 10540592                       | NON-EXPEDITED    | Y                  | HO, RI, OT      | 1000068941           |                      | 44 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>                 | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression               | Lexapro (Escitalopram Oxalate) |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                          | Lamictal (Lamotrigine)         |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                          | Geodon                         |                  |                    | S               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                              | <u>Case #</u>                                          | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------|--------------------------------------------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 09-Oct-2014                                           | 10540603                                               | NON-EXPEDITED    |                    | RI, OT          | 1000069677           |                      | 50 YR           | Male         | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u>                                         | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Fall;<br>Hyperhidrosis; Skin<br>Laceration | Lexapro (Escitalopram Oxalate) (10 Milligram, Tablets) |                  |                    | S               | Oral                 |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 09-Oct-2014              | 10540614       | NON-EXPEDITED    | Y                  | RI, OT          | 1000048132           |                      |                 | Male       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

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|                                                                                                |                                                             |                                |                    |                 |                      |                               |                 |            |                |
|------------------------------------------------------------------------------------------------|-------------------------------------------------------------|--------------------------------|--------------------|-----------------|----------------------|-------------------------------|-----------------|------------|----------------|
| Delirium; Orthostatic Hypotension                                                              |                                                             | Lexapro (Escitalopram Oxalate) |                    | S               |                      | Not Reported                  |                 |            |                |
| <u>FDA Received Date</u>                                                                       | <u>Case #</u>                                               | <u>Case Type</u>               | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 09-Oct-2014                                                                                    | 10540619                                                    | NON-EXPEDITED                  |                    | RI, OT          | 1000049356           |                               | 49 YR           | Female     | USA            |
| <u>Preferred Term</u>                                                                          | <u>Product</u>                                              | <u>Comp.</u>                   | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective; Suicidal Ideation                                                            | Lexapro                                                     |                                |                    | S               | Oral                 |                               |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                                                       | <u>Case #</u>                                               | <u>Case Type</u>               | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 09-Oct-2014                                                                                    | 10540642                                                    | NON-EXPEDITED                  | Y                  | HO              | 1000049954           |                               | 22 YR           | Male       | USA            |
| <u>Preferred Term</u>                                                                          | <u>Product</u>                                              | <u>Comp.</u>                   | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u> |                |
| Blood Testosterone Decreased; Crying; Depression; Mania; Sexual Dysfunction; Suicidal Ideation | Lexapro (Escitalopram Oxalate)                              |                                |                    | S               |                      |                               |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                                                       | <u>Case #</u>                                               | <u>Case Type</u>               | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 09-Oct-2014                                                                                    | 10540672                                                    | NON-EXPEDITED                  |                    | HO              | 1000050814           |                               | 15 YR           | Female     | USA            |
| <u>Preferred Term</u>                                                                          | <u>Product</u>                                              | <u>Comp.</u>                   | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u> |                |
| Amnesia; Insomnia; Tremor                                                                      | Escitalopram (Escitalopram Oxalate) (10 Milligram, Tablets) |                                |                    | S               | Oral                 | 15mg (15 Mg, 1 In 1 D), Oral  |                 |            | Not Reported   |
|                                                                                                | Escitalopram (Escitalopram Oxalate) (10 Milligram, Tablets) |                                |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral |                 |            | Not Reported   |
|                                                                                                | Risperdal (Risperidone)                                     |                                |                    | S               |                      |                               |                 |            | Not Reported   |
|                                                                                                | Abilify (Aripiprazole)                                      |                                |                    | S               |                      |                               |                 |            | Not Reported   |
|                                                                                                | Synthroid (Levothyroxine Sodium)                            |                                |                    | C               |                      |                               |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                                                       | <u>Case #</u>                                               | <u>Case Type</u>               | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 09-Oct-2014                                                                                    | 10540694                                                    | NON-EXPEDITED                  |                    | RI, OT          | 1000050921           |                               | 71 YR           | Male       | USA            |



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| <u>Preferred Term</u>                                                   | <u>Product</u>                                                 | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------------------------------------------|----------------------------------------------------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Drug Ineffective; Suicidal Ideation                                     | Escitalopram (Escitalopram Oxalate) (20 Milligram, Tablets)    |                  |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                         | Percocet (Acetaminophen, Oxycodone) (Acetaminophen, Oxycodone) |                  |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                | <u>Case #</u>                                                  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Oct-2014                                                             | 10540710                                                       | NON-EXPEDITED    |                    | RI, OT          | 1000051465           |                      | 31 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                   | <u>Product</u>                                                 | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Crying; Drug Ineffective; Headache; Muscle Twitching; Suicidal Ideation | Escitalopram (Escitalopram Oxalate) (10 Milligram, Tablets)    |                  |                    | S               | Oral                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                | <u>Case #</u>                                                  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Oct-2014                                                             | 10540737                                                       | NON-EXPEDITED    |                    | RI, OT          | 1000051476           |                      | 74 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                   | <u>Product</u>                                                 | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Diarrhoea; Urinary Retention                                            | Lexapro                                                        |                  |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                         | Xanax (Alprazolam)                                             |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                         | Metoprolol                                                     |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                         | Atrovent (Ipratropium Bromide)                                 |                  |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                | <u>Case #</u>                                                  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Oct-2014                                                             | 10540746                                                       | NON-EXPEDITED    |                    | HO, RI, OT      | 1000052137           |                      | 65 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                   | <u>Product</u>                                                 | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Pancreatitis                                                            | Lexapro (Escitalopram Oxalate) (20 Milligram, Tablets)         |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                         | Armour Thyroid (Thyroid)                                       |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                         | Levothyroxine (Levothyroxine Sodium)                           |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                         | Zolpidem Tartrate                                              |                  |                    | C               |                      |                      |                 | Not Reported |                |

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| <a href="#">FDA Received Date</a>                      | <a href="#">Case #</a>         | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>   | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|--------------------------------------------------------|--------------------------------|---------------------------|-----------------------------|--------------------------|---------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 09-Oct-2014                                            | 10540755                       | NON-EXPEDITED             |                             | DE                       | 1000052528                      |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>                         | <a href="#">Product</a>        | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>           | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Completed Suicide                                      | Lexapro (Escitalopram Oxalate) |                           |                             | S                        |                                 |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                      | <a href="#">Case #</a>         | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>   | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 09-Oct-2014                                            | 10540843                       | NON-EXPEDITED             | Y                           | DE                       | 1000052700                      |                               | 59 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                         | <a href="#">Product</a>        | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>           | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Completed Suicide                                      | Lexapro                        |                           |                             | S                        |                                 |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                      | <a href="#">Case #</a>         | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>   | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 10-Oct-2014                                            | 9675058                        | EXPEDITED (15-DAY)        |                             | HO                       | JP-FRI-1000050799               |                               | 48 YR                    | Male                | JPN                     |
| <a href="#">Preferred Term</a>                         | <a href="#">Product</a>        | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>           | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Atrioventricular Block                                 | Lexapro                        |                           |                             | S                        | Oral                            | 20 Mg                         |                          | Forest              |                         |
|                                                        | Reflex                         |                           |                             | C                        | Oral                            |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                      | <a href="#">Case #</a>         | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>   | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 10-Oct-2014                                            | 10367670                       | EXPEDITED (15-DAY)        |                             | HO                       | CH-FRI-1000069654               |                               |                          | Female              | CHE                     |
| <a href="#">Preferred Term</a>                         | <a href="#">Product</a>        | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>           | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Lower Gastrointestinal Haemorrhage; Normocytic Anaemia | Escitalopram                   |                           |                             | S                        | Oral                            | 10 Mg                         |                          | Forest              |                         |
|                                                        | Ponstan                        |                           |                             | S                        | Oral                            |                               |                          | Not Reported        |                         |
|                                                        | Magnesium                      |                           |                             | C                        |                                 |                               |                          | Not Reported        |                         |
|                                                        | Vitamins                       |                           |                             | C                        |                                 |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                      | <a href="#">Case #</a>         | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>   | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 10-Oct-2014                                            | 10468910                       | EXPEDITED (15-DAY)        |                             | HO                       | FR-AUROBINDO-AUR-APL-2014-10095 |                               | 26 YR                    | Male                | FRA                     |

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

| <u>Preferred Term</u>                                                                                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Chills; Confusional State;<br>Hyponatraemia; Mydriasis;<br>Overdose; Serotonin<br>Syndrome; Tachycardia | Escitalopram   |              |            | S           | Oral         | Unk                |                 | Aurobindo    |
|                                                                                                         | Xanax          |              |            | S           | Oral         | 0.25 Mg, Unk       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------|----------------------|------------|------------|----------------|
| 10-Oct-2014              | 10510064      | EXPEDITED (15-DAY) |                    | OT              | US-AUROBINDO-AUR-<br>APL-2014-07749 |                      | 64 YR      | Female     | USA            |

| <u>Preferred Term</u>  | <u>Product</u>                                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |
|------------------------|------------------------------------------------|--------------|------------|-------------|-----------------------------|------------------------|-----------------|--------------|
| Chronic Kidney Disease | Escitalopram 20 Mg                             |              |            | S           | Unknown                     | 20 Mg, Once A Day      |                 | Aurobindo    |
|                        | Prevacid                                       |              |            | S           | Oral                        | 15 Mg, Two Times A Day |                 | Not Reported |
|                        | Hydroxyzine Hydrochloride                      |              |            | S           | Oral                        | 50 Mg, As Necessary    |                 | Not Reported |
|                        | Advair                                         |              |            | S           | Respiratory<br>(inhalation) | 1 Puff                 |                 | Not Reported |
|                        | Advair                                         |              |            | S           | Respiratory<br>(inhalation) | 1puff, Unk             |                 | Not Reported |
|                        | Ventolin Hfa                                   |              |            | S           | Respiratory<br>(inhalation) | 2 Puff                 |                 | Not Reported |
|                        | Ventolin Hfa                                   |              |            | S           | Respiratory<br>(inhalation) | 2 Puff,                |                 | Not Reported |
|                        | Bupropion Hydrochloride                        |              |            | S           | Oral                        | 30 Mg, Once A Day      |                 | Not Reported |
|                        | Esterified Estrogens And<br>Methyltestosterone |              |            | C           | Unknown                     |                        |                 | Not Reported |
|                        | Lisinopril                                     |              |            | C           | Unknown                     |                        |                 | Not Reported |
|                        | Trazodone                                      |              |            | C           | Unknown                     |                        |                 | Not Reported |
|                        | Fluzone /00780601/                             |              |            | C           | Unknown                     | Unk                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 12-Oct-2014              | 10699864      | EXPEDITED (15-DAY) |                    | DE              | US-APOTEX-<br>2014AP003615 |                      | 45 YR      | Female     | USA            |

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

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

|                                                                                             |                            |   |         |              |              |
|---------------------------------------------------------------------------------------------|----------------------------|---|---------|--------------|--------------|
| Reversible Cerebral Vasoconstriction Syndrome; Serotonin Syndrome; Subarachnoid Haemorrhage | Escitalopram Oxalate       | S | Unknown | 10 Mg, Daily | Apotex       |
|                                                                                             | Hydrocodone                | S | Unknown |              | Not Reported |
|                                                                                             | Hydromorphone              | S | Unknown |              | Not Reported |
|                                                                                             | Dihydroergotamine Mesilate | S | Unknown |              | Not Reported |

| <u>FDA Received Date</u>                                                                    | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|-----------------|--------------|----------------|
| 13-Oct-2014                                                                                 | 10512941                 | EXPEDITED (15-DAY) |                    | HO              | IT-DRREDDYS-GER/ITL/14/0043465 |                      | 74 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                                       | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bradycardia; Bradykinesia; Bradyphrenia; Electrocardiogram Qt Prolonged; Hypotension; Sopor | Quetiapine               |                    |                    | S               | Oral                           |                      |                 | Not Reported |                |
|                                                                                             | Ciprallex                |                    |                    | S               | Oral                           |                      |                 | Not Reported |                |
|                                                                                             | Prazene                  |                    |                    | S               | Oral                           |                      |                 | Not Reported |                |
|                                                                                             | Paroxetine Hydrochloride |                    |                    | S               | Oral                           |                      |                 | Not Reported |                |
|                                                                                             | Lasix                    |                    |                    | C               |                                |                      |                 | Not Reported |                |
|                                                                                             | Foster                   |                    |                    | C               |                                |                      |                 | Not Reported |                |
|                                                                                             | Stilnox                  |                    |                    | C               |                                |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                    | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|-----------------|--------------|----------------|
| 13-Oct-2014                                                                                 | 10513167                      | EXPEDITED (15-DAY) |                    | HO              | IT-AUROBINDO-AUR-APL-2014-10775 |                      | 74 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                                       | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bradycardia; Bradykinesia; Bradyphrenia; Electrocardiogram Qt Prolonged; Hypotension; Sopor | Paroxetine Film-Coated Tablet |                    |                    | S               | Oral                            | 1.5 Df, Daily        |                 | Aurobindo    |                |
|                                                                                             | Ciprallex /01588501/          |                    |                    | S               | Oral                            | 1 Df, Daily          |                 | Not Reported |                |
|                                                                                             | Prazene                       |                    |                    | S               | Oral                            | 1 Df, Daily          |                 | Not Reported |                |
|                                                                                             | Quetiapine Fumarate           |                    |                    | S               | Oral                            | 300 Mg, Daily        |                 | Not Reported |                |
|                                                                                             | Foster /06206901/             |                    |                    | C               | Unknown                         | Unk                  |                 | Not Reported |                |
|                                                                                             | Lasix /00032601/              |                    |                    | C               | Unknown                         | Unk                  |                 | Not Reported |                |
|                                                                                             | Stilnox                       |                    |                    | C               | Unknown                         | Unk                  |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Oct-2014              | 10514626      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000071462    |                      | 46 YR      | Female     | FRA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u> | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>     | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-----------------------|--------------|------------|-------------|------------------|--------------------|-----------------|--------------|
| Neutropenia           | Escitalopram          |              |            | S           |                  |                    |                 | Forest       |
|                       | Inexium               |              |            | S           | Oral             | 20 Mg              |                 | Not Reported |
|                       | Doliprane             |              |            | S           | Oral             |                    |                 | Not Reported |
|                       | Tranxene              |              |            | S           | Oral             |                    |                 | Not Reported |
|                       | Ceftriaxone Panpharma |              |            | S           | Intravenous drip |                    |                 | Not Reported |
|                       | Flagyl                |              |            | S           |                  | 1500 Mg            |                 | Not Reported |
|                       | Lovenox               |              |            | S           | Subcutaneous     | 0.4 MI             |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Oct-2014              | 10514969      | EXPEDITED (15-DAY) |                    | HO              | PHHY2014AT130620     |                      | 79 YR      | Female     | AUT            |

| <u>Preferred Term</u>                                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction;<br>Hyponatraemia; Serotonin<br>Syndrome | Tegretol       |              |            | S           | Unknown      | 200 Mg, Bid        |                 | Novartis     |
|                                                           | Cipralex /Gfr/ |              |            | S           | Unknown      | 20 Mg, Qd          |                 | Not Reported |
|                                                           | Trittico       |              |            | S           | Unknown      | 75 Mg, Qd          |                 | Not Reported |
|                                                           | Lasix          |              |            | S           | Unknown      | 40 Mg, Qd          |                 | Not Reported |
|                                                           | Tramal         |              |            | S           | Unknown      | 1 Df, Bid          |                 | Not Reported |
|                                                           | Plavix         |              |            | C           |              | 75 Mg, Qd          |                 | Not Reported |
|                                                           | Norvasc        |              |            | C           |              | 5 Mg, Qd           |                 | Not Reported |
|                                                           | Dancor         |              |            | C           |              | 10 Mg, Bid         |                 | Not Reported |
|                                                           | Glucophage     |              |            | C           |              | 500 Mg, Bid        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Oct-2014              | 9899050       | EXPEDITED (15-DAY) |                    | HO, OT          | CA-FRI-1000054197    |                      |            | Male       | CAN            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hepatitis Acute       | Escitalopram   |              |            | S           |              | 20 Mg              |                 | Forest       |
|                       | Avapro         |              |            | S           |              | 300 Mg             |                 | Not Reported |

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

|  |                                                             |   |      |                         |              |
|--|-------------------------------------------------------------|---|------|-------------------------|--------------|
|  | Blinded Investigational Medicinal Product (Imp) Non-Partner | S | Oral | 600 Mg                  | Not Reported |
|  | Blinded Investigational Medicinal Product (Imp) Non-Partner | S | Oral | 450 Mg                  | Not Reported |
|  | Aspirin                                                     | C |      | Daily Dose Not Reported | Not Reported |
|  | Hydrochlorothiazine                                         | C |      | Daily Dose Not Reported | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Oct-2014              | 10248729      | EXPEDITED (15-DAY) |                    | HO              | B0997620A            |                      | 96 YR      | Female     | FRA            |

| <u>Preferred Term</u>                         | <u>Product</u>               | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------|------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Areflexia; C-Reactive Protein Increased;      | Paroxetine Hydrochloride     |              |            | S           | Oral         | Single Dose        |                 | Not Reported |
| Disturbance In Attention;                     | Clorazepate Dipotassium      |              |            | S           | Oral         | Single Dose        |                 | Not Reported |
| Drug Interaction; Extensor                    | Escitalopram Oxalate         |              |            | S           | Oral         | At Night           |                 | Not Reported |
| Plantar Response;                             | Alprazolam                   |              |            | S           | Oral         |                    |                 | Not Reported |
| Hypertension; Lung Disorder; Medication       | Olanzapine                   |              |            | S           | Oral         | Single Dose        |                 | Not Reported |
| Error; Rales; Red Blood Cell Count Decreased; | Valsartan                    |              |            | C           |              |                    |                 | Not Reported |
| Respiratory Tract                             | Potassium Chloride           |              |            | C           |              |                    |                 | Not Reported |
| Congestion; Sepsis;                           | Azathioprine                 |              |            | C           |              |                    |                 | Not Reported |
| Somnolence; Urticaria;                        | Chondroitin Sulfate (Bovine) |              |            | C           |              |                    |                 | Not Reported |
| Wrong Patient Received Product                | Tardyferon                   |              |            | C           |              |                    |                 | Not Reported |
|                                               | Colecalciferol               |              |            | C           |              |                    |                 | Not Reported |
|                                               | Zolpidem                     |              |            | C           |              |                    |                 | Not Reported |
|                                               | Paracetamol                  |              |            | C           |              |                    |                 | Not Reported |
|                                               | Movicol                      |              |            | C           |              |                    |                 | Not Reported |
|                                               | Acetylleucine                |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 14-Oct-2014              | 10311974      | EXPEDITED (15-DAY) | Y                  | OT              | US-MYLANLABS-2014S1016336 |                      | 45 YR      | Female     | USA            |

| <u>Preferred Term</u>                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Accident; Coma;                      | Escitalopram   |              |            | S           | Unknown      | 10 Mg, Qd          |                 | Not Reported |
| Reversible Cerebral Vasoconstriction | Hydrocodone    |              |            | S           | Unknown      |                    |                 | Not Reported |
| Syndrome; Serotonin                  | Hydromorphone  |              |            | S           | Unknown      |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                  |                                                  |                            |                    |                 |                                                               |                      |                 |                      |                |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------|----------------------------|--------------------|-----------------|---------------------------------------------------------------|----------------------|-----------------|----------------------|----------------|
| Syndrome; Subarachnoid Haemorrhage                                                                                                                                                               |                                                  | Dihydroergotamine Mesilate |                    | S               | Unknown                                                       |                      | Not Reported    |                      |                |
| <u>FDA Received Date</u>                                                                                                                                                                         | <u>Case #</u>                                    | <u>Case Type</u>           | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 14-Oct-2014                                                                                                                                                                                      | 10487994                                         | EXPEDITED (15-DAY)         |                    | HO              | FR-B.I.<br>PHARMACEUTICALS,I<br>NC./RIDGEFIELD-2014-<br>BI-46 |                      | 68 YR           | Male                 | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                            | <u>Product</u>                                   | <u>Comp.</u>               | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Accidental Overdose;<br>Haematuria; Rectal<br>Haemorrhage                                                                                                                                        | Pradaxa                                          |                            |                    | S               | Oral                                                          | 220 Mg               |                 | Boehringer Ingelheim |                |
|                                                                                                                                                                                                  | Seroplex                                         |                            |                    | S               | Oral                                                          |                      |                 | Not Reported         |                |
|                                                                                                                                                                                                  | Kardegic                                         |                            |                    | S               | Oral                                                          | 75 Mg                |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                                                                                                                                         | <u>Case #</u>                                    | <u>Case Type</u>           | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 14-Oct-2014                                                                                                                                                                                      | 10515434                                         | EXPEDITED (15-DAY)         |                    | OT              | US-AUROBINDO-AUR-<br>APL-2014-07976                           |                      | 61 YR           | Female               | USA            |
| <u>Preferred Term</u>                                                                                                                                                                            | <u>Product</u>                                   | <u>Comp.</u>               | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Drug Hypersensitivity;<br>Gastritis Erosive; Hiatus<br>Hernia; Nausea; Product<br>Use In Unapproved<br>Indication                                                                                | Escitalopram 5 Mg<br>(Escitalopram) Unknown, 5mg |                            |                    | S               | Oral                                                          | 5 Mg, Unk            |                 | Aurobindo            |                |
|                                                                                                                                                                                                  | Escitalopram 5 Mg<br>(Escitalopram) Unknown, 5mg |                            |                    | S               | Oral                                                          | 10 Mg, Unk           |                 | Aurobindo            |                |
|                                                                                                                                                                                                  | Lexapro                                          |                            |                    | S               | Oral                                                          | 10 Mg, Daily         |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                                                                                                                                         | <u>Case #</u>                                    | <u>Case Type</u>           | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 14-Oct-2014                                                                                                                                                                                      | 10516016                                         | EXPEDITED (15-DAY)         |                    | HO              | PHHY2014SI129440                                              |                      | 86 YR           | Male                 | SVN            |
| <u>Preferred Term</u>                                                                                                                                                                            | <u>Product</u>                                   | <u>Comp.</u>               | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Abnormal Behaviour;<br>Acute Myocardial<br>Infarction; Aggression;<br>Angiopathy; Anxiety; Atrial<br>Fibrillation; Cardiac<br>Failure; Cognitive<br>Disorder; Cyclothymic<br>Disorder; Delirium; | Valproic Acid                                    |                            |                    | S               | Unknown                                                       | 1000 Mg, Bid         |                 | Novartis             |                |
|                                                                                                                                                                                                  | Amitryptiline Hcl                                |                            |                    | S               | Unknown                                                       |                      |                 | Not Reported         |                |
|                                                                                                                                                                                                  | Thioridazine                                     |                            |                    | S               | Unknown                                                       |                      |                 | Not Reported         |                |
|                                                                                                                                                                                                  | Citalopram                                       |                            |                    | S               | Unknown                                                       | 60 Mg, Daily         |                 | Not Reported         |                |
|                                                                                                                                                                                                  | Quetiapine                                       |                            |                    | S               | Unknown                                                       | 500 Mg, Daily        |                 | Not Reported         |                |
|                                                                                                                                                                                                  | Lamotrigine                                      |                            |                    | S               | Unknown                                                       | 200 Mg, Bid          |                 | Not Reported         |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                       |                      |   |         |               |              |
|-------------------------------------------------------------------------------------------------------|----------------------|---|---------|---------------|--------------|
| Depressed Mood;<br>Disorientation; Drug<br>Ineffective;                                               | Lamotrigine          | S | Unknown | 400 Mg, Bid   | Not Reported |
| Gastroesophageal Reflux<br>Disease; Hallucination,<br>Olfactory; Hallucination,<br>Visual; Hypomania; | Escitalopram         | S | Unknown | 5 Mg, Qd      | Not Reported |
| Insomnia; Mood Altered;<br>Myeloproliferative<br>Neoplasm; Psychomotor<br>Hyperactivity;              | Escitalopram         | S | Unknown | 10 Mg, Daily  | Not Reported |
| Restlessness; Suicide<br>Attempt; Urinary<br>Incontinence                                             | Fluphenazine         | S | Unknown | 3 Mg, Daily   | Not Reported |
|                                                                                                       | Clomethiazole        | S | Unknown | 400 Mg, Qd    | Not Reported |
|                                                                                                       | Acetylsalicylic Acid | C | Unknown | 100 Mg, Unk   | Not Reported |
|                                                                                                       | Pantoprazole         | C | Unknown | 20 Mg, Unk    | Not Reported |
|                                                                                                       | Carvedilol           | C | Unknown | 3 Mg, Unk     | Not Reported |
|                                                                                                       | Digoxin              | C | Unknown | 0.1 Mg, Unk   | Not Reported |
|                                                                                                       | Diazepam             | C | Unknown | 2 Mg, Daily   | Not Reported |
|                                                                                                       | Hydroxyurea          | C | Unknown | 1000 Mg, Bid  | Not Reported |
|                                                                                                       | Esomeprazole         | C | Unknown |               | Not Reported |
|                                                                                                       | Folic Acid           | C | Unknown |               | Not Reported |
|                                                                                                       | Carbamazepine        | C | Unknown | 800 Mg, Bid   | Not Reported |
|                                                                                                       | Olanzapine           | C | Unknown | 10 Mg, Unk    | Not Reported |
|                                                                                                       | Mianserin            | C | Unknown | 30 Mg, Unk    | Not Reported |
|                                                                                                       | Midazolam            | C | Unknown | 7.5 Mg, Unk   | Not Reported |
|                                                                                                       | Omeprazole           | C | Unknown | 20 Mg, Unk    | Not Reported |
|                                                                                                       | Ticlopidine          | C | Unknown | 250 Mg, Daily | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|-----------------------|--------------------|--------------------|-----------------|------------------------------------------|----------------------|-----------------|--------------|----------------|
| 14-Oct-2014              | 10516408              | EXPEDITED (15-DAY) |                    | HO              | FR-ASTRAZENECA-<br>2014SE75885           |                      | 46 YR           | Female       | FRA            |
| <u>Preferred Term</u>    | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Neutropenia              | Inexium               |                    |                    | S               | Oral                                     |                      |                 | Not Reported |                |
|                          | Doliprane             |                    |                    | S               | Oral                                     |                      |                 | Not Reported |                |
|                          | Tranxene              |                    |                    | S               | Oral                                     |                      |                 | Not Reported |                |
|                          | Ceftriaxone Panpharma |                    |                    | S               | Intravenous (not<br>otherwise specified) |                      |                 | Not Reported |                |
|                          | Seroplex              |                    |                    | S               | Oral                                     |                      |                 | Not Reported |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|         |   |              |              |
|---------|---|--------------|--------------|
| Lovenox | S | Subcutaneous | Not Reported |
| Flagyl  | S | Unknown      | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Oct-2014              | 10516539      | EXPEDITED (15-DAY) |                    | HO              | IT-TEVA-514322ISR    |                      | 74 YR      | Female     | ITA            |

| <u>Preferred Term</u>                                                                                   | <u>Product</u>                                                            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Bradycardia; Bradykinesia;<br>Bradyphrenia;<br>Electrocardiogram Qt<br>Prolonged; Hypotension;<br>Sopor | Quetiapine                                                                |              |            | S           | Oral         | 300 Mg Daily       |                 | Teva         |
|                                                                                                         | Paroxetine                                                                |              |            | S           | Oral         | 1.5 Df Daily       |                 | Teva         |
|                                                                                                         | Ciprallex - Compresse Rivestite<br>Con Film Da 10 Mg -<br>H.Lundbeck A/S  |              |            | S           | Oral         | 1 Df Daily         |                 | Not Reported |
|                                                                                                         | Prazene - 20 Mg Compresse -<br>Pfizer Italia S.R.L.                       |              |            | S           | Oral         | 1 Df Daily         |                 | Not Reported |
|                                                                                                         | Lasix - 25 Mg Compresse                                                   |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                         | Foster - 100/6 Microgrammi -<br>Soluzione Pressurizzata Per<br>Inalazione |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                         | Stilnox - 10 Mg Compresse<br>Rivestite Con Film                           |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Oct-2014              | 10516707      | EXPEDITED (15-DAY) |                    | OT              | IT-TEVA-515090ISR    |                      | 36 YR      | Male       | ITA            |

| <u>Preferred Term</u>     | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|-----------------------|--------------|------------|-------------|--------------|--------------------------------------|-----------------|--------------|
| Drug Interaction; Seizure | Escitalopram          |              |            | S           | Unknown      | 10 Milligram Daily; 10<br>Mg/Day     |                 | Ivax         |
|                           | Telaprevir            |              |            | S           | Unknown      | 2250 Milligram Daily;                |                 | Not Reported |
|                           | Peginterferon Alfa-2a |              |            | S           | Unknown      | 180 Microg Weekly                    |                 | Not Reported |
|                           | Ribavirin             |              |            | C           | Unknown      | 1000 Milligram Daily; 1000<br>Mg/Day |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Oct-2014              | 10517392      | EXPEDITED (15-DAY) |                    | HO              | US-FRI-1000071499    |                      | 58 YR      | Female     | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                                  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                          | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|---------------------------------------|-----------------------------------------------|-----------------|--------------|
| Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Albumin Increased; Drug Interaction; Gamma-Glutamyltransferase Increased; Liver Injury | Lexapro        |              |            | S           | Oral                                  |                                               |                 | Forest       |
|                                                                                                                                                                        | Cobimetinib    |              |            | S           | Oral                                  |                                               |                 | Not Reported |
|                                                                                                                                                                        | Cobimetinib    |              |            | S           | Oral                                  | 60 Mg                                         |                 | Not Reported |
|                                                                                                                                                                        | Vemurafenib    |              |            | S           | Oral                                  | Dose Reduced, Most Recent Dose On 22/Jul/2013 |                 | Not Reported |
|                                                                                                                                                                        | Vemurafenib    |              |            | S           | Oral                                  | Dose Reduced (960 Mg)                         |                 | Not Reported |
|                                                                                                                                                                        | Claritin       |              |            | C           | Oral                                  |                                               |                 | Not Reported |
|                                                                                                                                                                        | Benadryl       |              |            | C           | Oral                                  |                                               |                 | Not Reported |
|                                                                                                                                                                        | Tylenol        |              |            | C           | Oral                                  |                                               |                 | Not Reported |
|                                                                                                                                                                        | Tylenol        |              |            | C           |                                       |                                               |                 | Not Reported |
|                                                                                                                                                                        | Cymbalta       |              |            | C           | Oral                                  |                                               |                 | Not Reported |
|                                                                                                                                                                        | Saline         |              |            | C           | Intravenous (not otherwise specified) |                                               |                 | Not Reported |
|                                                                                                                                                                        | Omeprazole     |              |            | C           | Oral                                  |                                               |                 | Not Reported |
|                                                                                                                                                                        | Nitroglycerin  |              |            | C           | Sublingual                            |                                               |                 | Not Reported |
|                                                                                                                                                                        | Xanax          |              |            | C           | Oral                                  |                                               |                 | Not Reported |
|                                                                                                                                                                        | Esomeprazole   |              |            | C           | Oral                                  |                                               |                 | Not Reported |
|                                                                                                                                                                        | Ibuprofen      |              |            | C           | Oral                                  |                                               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Oct-2014              | 10518902      | DIRECT           | Y                  | OT              |                      |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Drug Hypersensitivity; Product Quality Issue; Product Substitution Issue | Escitalopram   |              |            | S           | Oral         |                    |                 | Unknown    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Oct-2014              | 10518908      | DIRECT           |                    |                 |                      |                      |            | Unknown    | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                   | <u>Product</u>                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
|-----------------------------------------------------------------------------------------|--------------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------------------------|----------------|
| Anxiety; Malaise; Product Dispensing Error; Wrong Product Administered                  | Lexapro<br>Enalapril Maleate               |                    |                    | S<br>S          |                      |                      |                 | Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                | <u>Case #</u>                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 14-Oct-2014                                                                             | 10519203                                   | DIRECT             | Y                  |                 |                      |                      | 34 YR           | Female                       | USA            |
| <u>Preferred Term</u>                                                                   | <u>Product</u>                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Fatigue; Therapeutic Response Changed; Therapy Non-Responder                            | Escitalopram                               |                    |                    | S               | Oral                 |                      |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                                                                | <u>Case #</u>                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 14-Oct-2014                                                                             | 10522622                                   | EXPEDITED (15-DAY) | Y                  | OT              | 2014JUB00159         |                      | 40 YR           | Female                       | IND            |
| <u>Preferred Term</u>                                                                   | <u>Product</u>                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Bradykinesia; Dysarthria; Extrapryamidal Disorder; Oculogyric Crisis; Protrusion Tongue | Escitalopram (Escitalopram)<br>Unknown     |                    |                    | S               |                      |                      | 1 DAY           | Not Reported                 |                |
| <u>FDA Received Date</u>                                                                | <u>Case #</u>                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 14-Oct-2014                                                                             | 10522664                                   | EXPEDITED (15-DAY) | Y                  | HO              | 2014HINLIT0913       |                      | 57 YR           | Female                       | ESP            |
| <u>Preferred Term</u>                                                                   | <u>Product</u>                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Hyponatraemia                                                                           | Escitalopram (Escitalopram)<br>Unknown     |                    |                    | S               |                      |                      |                 | Not Reported                 |                |
|                                                                                         | Haloperidol (Haloperidol)<br>(Haloperidol) |                    |                    | S               |                      |                      |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                                                                | <u>Case #</u>                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 15-Oct-2014                                                                             | 10329823                                   | EXPEDITED (15-DAY) |                    | OT              | US-TEVA-495453USA    |                      | 45 YR           | Female                       | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                          | <u>Product</u>                                                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|------------------------------------------------------------------------------------------------|----------------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Reversible Cerebral Vasoconstriction Syndrome                                                  | Escitalopram                                                   |                    |                    | S               | Unknown              |                      |                 | Ivax         |                |
| <u>FDA Received Date</u>                                                                       | <u>Case #</u>                                                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Oct-2014                                                                                    | 10519046                                                       | EXPEDITED (15-DAY) |                    | HO              | JP-FRI-1000071464    |                      | 86 YR           | Male         | JPN            |
| <u>Preferred Term</u>                                                                          | <u>Product</u>                                                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Fear; Musculoskeletal Stiffness; Tremor                                                        | Lexapro                                                        |                    |                    | S               | Oral                 | 10mg                 |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                       | <u>Case #</u>                                                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Oct-2014                                                                                    | 10519213                                                       | EXPEDITED (15-DAY) |                    | CA              | FR-FRI-1000071544    |                      |                 | Female       | FRA            |
| <u>Preferred Term</u>                                                                          | <u>Product</u>                                                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Congenital Hand Malformation; Exposure During Pregnancy; Microcephaly; Psychomotor Retardation | Escitalopram                                                   |                    |                    | S               | Transplacental       |                      |                 | Forest       |                |
|                                                                                                | Lamotrigine                                                    |                    |                    | S               | Transplacental       |                      |                 | Not Reported |                |
|                                                                                                | Bromazepam                                                     |                    |                    | S               | Transplacental       |                      |                 | Not Reported |                |
|                                                                                                | Dexeryl (Glycerol And White Soft Paraffin And Liquid Paraffin) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                | Magne B6                                                       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                | Acide Folique                                                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                | Ferrograd                                                      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                | Fixical                                                        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                | Metoclopramide                                                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                | Zymad                                                          |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                | Dosiseptine                                                    |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                | Diprosone                                                      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                | Doliprane                                                      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                | Doliprane                                                      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                | Doliprane                                                      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                | Doliprane                                                      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                | Helicidine                                                     |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                | Pivalone /00803802/                                            |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                | Pivalone /00803802/                                            |                    |                    | C               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                      |   |              |
|------------------------------------------------------|---|--------------|
| Amoxicilline                                         | C | Not Reported |
| Budesonide                                           | C | Not Reported |
| Physiodose                                           | C | Not Reported |
| Ventoline                                            | C | Not Reported |
| Econazole                                            | C | Not Reported |
| Spasfon (Phloroglucinol,<br>Trimethylphloroglucinol) | C | Not Reported |
| Gaviscon                                             | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Oct-2014              | 10520010      | EXPEDITED (15-DAY) |                    | HO              | PHHY2014IT131839     |                      |            | Female     | ITA            |

| <u>Preferred Term</u>                                                                                        | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Bradycardia; Bradykinesia;<br>Bradyphrenia;<br>Electrocardiogram Qt<br>Prolonged; Hypotension;<br>Somnolence | Paroxetine Sandoz       |              |            | S           | Oral         | 1.5 Df, Qd         |                 | Novartis     |
|                                                                                                              | Quetiapine              |              |            | S           | Oral         | 300 Mg, Qd         |                 | Not Reported |
|                                                                                                              | Ciprallex//Escitalopram |              |            | S           | Oral         | 1 Df, Qd           |                 | Not Reported |
|                                                                                                              | Prazene                 |              |            | S           | Oral         | 1 Df, Qd           |                 | Not Reported |
|                                                                                                              | Lasix                   |              |            | C           | Unknown      | Unk Ukn, Unk       |                 | Not Reported |
|                                                                                                              | Foster                  |              |            | C           | Unknown      | Unk Ukn, Unk       |                 | Not Reported |
|                                                                                                              | Stilnox                 |              |            | C           | Unknown      | Unk Ukn, Unk       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>              | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------------------|----------------------|------------|------------|----------------|
| 15-Oct-2014              | 10520704      | EXPEDITED (15-DAY) |                    | DE, HO          | US-NAPPMUNDI-GBR-<br>2014-0022689 |                      | 45 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                    | <u>Product</u>                           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                             | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------|------------------------------------------|--------------|------------|-------------|------------------------------------------|--------------------|-----------------|--------------|
| Cerebral Infarction;<br>Cerebral Vasoconstriction;<br>Serotonin Syndrome | Hydromorphone Hcl (Similar To<br>19-892) |              |            | S           | Unknown                                  | Unk, See Text      |                 | Purdue       |
|                                                                          | Hydromorphone Hcl (Similar To<br>19-892) |              |            | S           |                                          |                    |                 | Purdue       |
|                                                                          | Escitalopram                             |              |            | S           |                                          |                    |                 | Not Reported |
|                                                                          | 9-Tetrahydrocannabinol                   |              |            | S           |                                          |                    |                 | Not Reported |
|                                                                          | Anticoagulation Medication               |              |            | C           |                                          |                    |                 | Not Reported |
|                                                                          | Dihydroergotamine                        |              |            | C           | Intravenous (not<br>otherwise specified) |                    |                 | Not Reported |
|                                                                          | Dihydroergotamine                        |              |            | C           |                                          |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                       | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 16-Oct-2014                                                                    | 10431912                      | EXPEDITED (15-DAY) |                    | HO, OT          | GB-PFIZER INC-2014246713 |                      | 44 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                          | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blister; Cheilitis; Mucosal Inflammation; Stevens-Johnson Syndrome; Stomatitis | Ramipril                      |                    |                    | S               | Unknown                  | Unk                  |                 | Pfizer       |                |
|                                                                                | Escitalopram Oxalate          |                    |                    | S               | Unknown                  | Unk                  |                 | Not Reported |                |
|                                                                                | Forxiga                       |                    |                    | S               | Oral                     | 5 Mg, 1x/Day         |                 | Not Reported |                |
|                                                                                | Flucloxacillin                |                    |                    | C               |                          | Unk                  |                 | Not Reported |                |
|                                                                                | Codeine                       |                    |                    | C               |                          | Unk                  |                 | Not Reported |                |
|                                                                                | Fucibet                       |                    |                    | C               |                          | Unk                  |                 | Not Reported |                |
|                                                                                | Humalog                       |                    |                    | C               |                          | Unk                  |                 | Not Reported |                |
|                                                                                | Lantus                        |                    |                    | C               |                          | Unk                  |                 | Not Reported |                |
|                                                                                | Paracetamol                   |                    |                    | C               |                          | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                       | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Oct-2014                                                                    | 10521882                      | EXPEDITED (15-DAY) |                    | HO              | PHHY2014ES134107         |                      | 53 YR           | Female       | ESP            |
| <u>Preferred Term</u>                                                          | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyponatraemia                                                                  | Venlafaxine                   |                    |                    | S               | Unknown                  | 150 Mg, Qd           |                 | Not Reported |                |
|                                                                                | Citalopram                    |                    |                    | S               | Unknown                  | 20 Mg, Qd            |                 | Not Reported |                |
|                                                                                | Escitalopram                  |                    |                    | S               | Unknown                  | 10 Mg, Qd            |                 | Not Reported |                |
|                                                                                | Amiloride+Hydrochlorothiazide |                    |                    | S               | Unknown                  | 1 Df, Qd             |                 | Not Reported |                |
|                                                                                | Enalapril                     |                    |                    | S               | Unknown                  |                      |                 | Not Reported |                |
|                                                                                | Olanzapine                    |                    |                    | S               | Unknown                  | 5 Mg, Qd             |                 | Novartis     |                |
|                                                                                | Haloperidol                   |                    |                    | S               | Unknown                  | 20 Drp, Qd           |                 | Not Reported |                |
|                                                                                | Haloperidol                   |                    |                    | S               | Unknown                  | 10 Drp, Qd           |                 | Not Reported |                |
|                                                                                | Agomelatine                   |                    |                    | C               | Unknown                  | 25 Mg, Qd            |                 | Not Reported |                |
|                                                                                | Clorazepate Dipotassium       |                    |                    | C               | Unknown                  | 10 Mg, Tid           |                 | Not Reported |                |
|                                                                                | Clorazepate Dipotassium       |                    |                    | C               |                          | 10 Mg, Qd            |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Oct-2014              | 10523166      | EXPEDITED (15-DAY) |                    | HO              | CH-FRI-1000071524    |                      |            | Female     | CHE            |

| <u>Preferred Term</u>                                   | <u>Product</u>                     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>  | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------|------------------------------------|--------------|------------|-------------|---------------|--------------------|-----------------|--------------|
| Gastrointestinal<br>Haemorrhage;<br>Hypochromic Anaemia | Escitalopram                       |              |            | S           | Oral          |                    |                 | Forest       |
|                                                         | Marcoumar                          |              |            | S           | Oral          | 3 Mg               |                 | Not Reported |
|                                                         | Pantozol (Switzerland)             |              |            | C           | Oral          |                    |                 | Not Reported |
|                                                         | Torasemid                          |              |            | C           | Oral          | 5 Mg               |                 | Not Reported |
|                                                         | Mirtazapin                         |              |            | C           | Oral          | 30 Mg              |                 | Not Reported |
|                                                         | Quetiapin                          |              |            | C           | Oral          | 25 Mg              |                 | Not Reported |
|                                                         | Vi-De 3                            |              |            | C           | Oral          |                    |                 | Not Reported |
|                                                         | Duphalac                           |              |            | C           | Oral          | 5 MI               |                 | Not Reported |
|                                                         | Vitarubin Superconc.               |              |            | C           | Intramuscular | 11.111 Ug          |                 | Not Reported |
|                                                         | Dafalgan                           |              |            | C           | Oral          |                    |                 | Not Reported |
|                                                         | Fentanyl Matrix Transdermal System |              |            | C           | Transdermal   | 4 Ug               |                 | Not Reported |
|                                                         | Dospir                             |              |            | C           | Other         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 17-Oct-2014              | 10524826      | EXPEDITED (15-DAY) |                    | HO              | FR-PFIZER INC-2014282449 |                      | 86 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Fall; Hip Fracture    | Lyrice                 |              |            | S           | Oral         | Unk                |                 | Pfizer       |
|                       | Tramadol Hcl           |              |            | S           | Oral         | Unk                |                 | Pfizer       |
|                       | Seroplex               |              |            | S           | Oral         | 10 Mg, 1x/Day      |                 | Not Reported |
|                       | Ebixa                  |              |            | S           | Oral         | 10 Mg, 1x/Day      |                 | Not Reported |
|                       | Previscan (Fluindione) |              |            | C           |              |                    |                 | Not Reported |
|                       | Insulin                |              |            | C           |              |                    |                 | Not Reported |
|                       | Furosemide             |              |            | C           |              |                    |                 | Not Reported |
|                       | Amlodipine             |              |            | C           |              |                    |                 | Not Reported |
|                       | Nebivolol              |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                            | Coaprovel              |                    |                    | C               |                        |                      |                 |              | Not Reported   |
|----------------------------|------------------------|--------------------|--------------------|-----------------|------------------------|----------------------|-----------------|--------------|----------------|
|                            | Dafalgan               |                    |                    | C               |                        |                      |                 |              | Not Reported   |
| <u>FDA Received Date</u>   | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Oct-2014                | 10525947               | EXPEDITED (15-DAY) |                    | DS              | FR-FRI-1000071634      |                      | 67 YR           | Male         | FRA            |
| <u>Preferred Term</u>      | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cerebral Haematoma         | Escitalopram           |                    |                    | S               | Oral                   | 15 Mg                |                 | Forest       |                |
|                            | Previscan (Fluindione) |                    |                    | S               | Oral                   | 10 Mg                |                 | Not Reported |                |
|                            | Urbanyl                |                    |                    | C               |                        |                      |                 | Not Reported |                |
|                            | Mopral                 |                    |                    | C               |                        |                      |                 | Not Reported |                |
|                            | Zamudol                |                    |                    | C               |                        |                      |                 | Not Reported |                |
|                            | Fenofibrate            |                    |                    | C               |                        |                      |                 | Not Reported |                |
|                            | Bisoprolol             |                    |                    | C               |                        |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>   | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Oct-2014                | 10699994               | EXPEDITED (15-DAY) |                    | HO              | IT-APOTEX-2014AP005103 |                      | 74 YR           | Female       | ITA            |
| <u>Preferred Term</u>      | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrioventricular Block;    | Paroxetine             |                    |                    | S               | Oral                   | 1.5 Df, Daily        |                 | Apotex       |                |
| Bradycardia; Bradykinesia; | Quetiapine             |                    |                    | S               | Oral                   | 300 Mg, Daily        |                 | Apotex       |                |
| Bradyphrenia;              | Ciprallex /01588502/   |                    |                    | S               | Oral                   | 1 Df, Daily          |                 | Not Reported |                |
| Electrocardiogram Qt       | Prazene                |                    |                    | S               | Oral                   | 1 Df, Unk            |                 | Not Reported |                |
| Prolonged; Hypotension;    | Lasix /00032601/       |                    |                    | C               | Unknown                |                      |                 | Not Reported |                |
| Sopor                      | Foster /06206901/      |                    |                    | C               | Unknown                |                      |                 | Not Reported |                |
|                            | Stilnox                |                    |                    | C               | Unknown                |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>   | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Oct-2014                | 9651872                | EXPEDITED (15-DAY) |                    | OT              | CH-SA-2013SA107718     |                      | 33 YR           | Female       | CHE            |
| <u>Preferred Term</u>      | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Exposure During Pregnancy  | Stilnox                |                    |                    | S               | Unknown                |                      |                 | Not Reported |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|               |   |         |              |
|---------------|---|---------|--------------|
| Pristinamycin | S | Unknown | Not Reported |
| Ciprofloxacin | S | Unknown | Not Reported |
| Ibuprofen     | S | Unknown | Not Reported |
| Ketoprofen    | S | Unknown | Not Reported |
| Zaldiar       | S | Unknown | Not Reported |
| Cipralex      | S | Unknown | Not Reported |
| Augmentin     | C | Unknown | Not Reported |
| Dafalgan      | C | Unknown | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------|----------------------|------------|------------|----------------|
| 20-Oct-2014              | 10527172      | EXPEDITED (15-DAY) |                    | HO              | FR-AUROBINDO-AUR-<br>APL-2014-11054 |                      | 86 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Fall; Hip Fracture    | Tramadol               |              |            | S           | Oral         | Unk                |                 | Aurobindo    |
|                       | Lyrica                 |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                       | Seroplex               |              |            | S           | Oral         | 10 Mg, Once A Day  |                 | Not Reported |
|                       | Ebixa                  |              |            | S           | Oral         | 10 Mg, Once A Day  |                 | Not Reported |
|                       | Previscan (Fluindione) |              |            | C           | Unknown      | 20 Mg, Unk         |                 | Not Reported |
|                       | Insulin                |              |            | C           | Unknown      | Unk                |                 | Not Reported |
|                       | Furosemide             |              |            | C           | Unknown      | Unk                |                 | Not Reported |
|                       | Amlodipine             |              |            | C           | Unknown      | Unk                |                 | Not Reported |
|                       | Nebivolol              |              |            | C           | Unknown      | Unk                |                 | Not Reported |
|                       | Coaprovel              |              |            | C           | Unknown      | Unk                |                 | Not Reported |
|                       | Dafalgan               |              |            | C           | Unknown      | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Oct-2014              | 10527724      | EXPEDITED (15-DAY) |                    | HO              | CH-FRI-1000071632    |                      |            | Female     | CHE            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Gastrointestinal      | Escitalopram   |              |            | S           | Oral         | 10 Mg              |                 | Forest     |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                             |                               |   |      |              |              |
|---------------------------------------------|-------------------------------|---|------|--------------|--------------|
| Haemorrhage; Melaena;<br>Shock Haemorrhagic | Clexane                       | S | Oral | 40 Mg Daily  | Not Reported |
|                                             | Aspirin Cardio                | S |      | 100 Mg Daily | Not Reported |
|                                             | Novalgine (Metamizole Sodium) | C |      |              | Not Reported |
|                                             | Tazobac                       | C |      |              | Not Reported |
|                                             | Piperacillin                  | C |      |              | Not Reported |

| <u>FDA Received Date</u>                           | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 20-Oct-2014                                        | 10527986       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000071636    |                      | 83 YR           | Female       | FRA            |
| <u>Preferred Term</u>                              | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Pruritus Generalised;<br>Rash Vesicular; Urticaria | Escitalopram   |                    |                    | S               | Oral                 | 20 Mg                |                 | Forest       |                |
|                                                    | Lexomil        |                    |                    | C               | Oral                 | 1 Df                 |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                                                                          | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------------------------|----------------------|-----------------|-----------------|----------------|
| 20-Oct-2014                                                                                                                                                                                       | 10528164             | EXPEDITED (15-DAY) |                    | HO, OT          | SI-GLAXOSMITHKLINE-<br>SI2014GSK004262 |                      | 86 YR           | Male            | SVN            |
| <u>Preferred Term</u>                                                                                                                                                                             | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Aggression; Anxiety;<br>Cognitive Disorder;<br>Delirium; Disorientation;<br>Fear; Hallucination, Visual;<br>Insomnia; Insomnia;<br>Psychomotor<br>Hyperactivity;<br>Restlessness;<br>Restlessness | Escitalopram         |                    |                    | S               |                                        | 10 Mg, Qd            |                 | Glaxosmithkline |                |
|                                                                                                                                                                                                   | Clomethiazole        |                    |                    | S               |                                        |                      |                 | Not Reported    |                |
|                                                                                                                                                                                                   | Hydroxyurea          |                    |                    | S               |                                        | 100 Mg, Bid          |                 | Not Reported    |                |
|                                                                                                                                                                                                   | Acetylsalicylic Acid |                    |                    | S               |                                        | 100 Mg, Unk          |                 | Not Reported    |                |
|                                                                                                                                                                                                   | Digoxin              |                    |                    | S               |                                        | 0.1 Mg, Unk          |                 | Glaxosmithkline |                |
|                                                                                                                                                                                                   | Carvedilol           |                    |                    | S               |                                        | 3 Mg, Unk            |                 | Glaxosmithkline |                |
|                                                                                                                                                                                                   | Pantoprazole         |                    |                    | S               |                                        | 20 Mg, Unk           |                 | Not Reported    |                |
|                                                                                                                                                                                                   | Iron                 |                    |                    | S               |                                        | 200 Mg, Unk          |                 | Not Reported    |                |
|                                                                                                                                                                                                   | Citalopram           |                    |                    | S               |                                        | 60 Mg, Unk           |                 | Glaxosmithkline |                |
|                                                                                                                                                                                                   | Amitriptyline        |                    |                    | C               |                                        |                      |                 | Not Reported    |                |
|                                                                                                                                                                                                   | Thioridazine         |                    |                    | C               |                                        |                      |                 | Not Reported    |                |
|                                                                                                                                                                                                   | Haloperidol          |                    |                    | C               |                                        |                      |                 | Not Reported    |                |
|                                                                                                                                                                                                   | Carbamazepine        |                    |                    | C               |                                        | 800 Mg, Bid          |                 | Glaxosmithkline |                |
|                                                                                                                                                                                                   | Lamotrigine          |                    |                    | C               |                                        | 400 Mg, Unk          |                 | Glaxosmithkline |                |
|                                                                                                                                                                                                   | Olanzapine           |                    |                    | C               |                                        | 10 Mg, Unk           |                 | Glaxosmithkline |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|               |   |              |                 |
|---------------|---|--------------|-----------------|
| Mianserin     | C | 30 Mg, Unk   | Not Reported    |
| Midazolam     | C | 7.5 Mg, Unk  | Not Reported    |
| Omeprazole    | C | 20 Mg, Unk   | Glaxosmithkline |
| Ticlopidine   | C | 250 Mg, Unk  | Not Reported    |
| Hydroxyurea   | C |              | Glaxosmithkline |
| Valproic Acid | C | 1000 Mg, Bid | Not Reported    |
| Quetiapine    | C | 500 Mg, Unk  | Glaxosmithkline |
| Pantoprazole  | S | 20 Mg, Unk   | Glaxosmithkline |
| Flufenazine   | C |              | Not Reported    |
| Folic Acid    | C |              | Glaxosmithkline |

| <u>FDA Received Date</u>                     | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|----------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|---------------------------------------|-----------------|------------|----------------|
| 20-Oct-2014                                  | 10529980       | DIRECT           |                    | OT              |                      |                                       | 49 YR           | Male       | USA            |
| <u>Preferred Term</u>                        | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u> |                |
| Ejaculation Failure;<br>Erectile Dysfunction | Escitalopram   |                  |                    | S               | Oral                 | 1 Pill, Once Daily, Taken<br>By Mouth |                 | Teva       |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| 21-Oct-2014              | 10530155       | NON-EXPEDITED    |                    |                 | US-PFIZER INC-<br>2013337301 |                      |                 | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity    | Amoxicillin    |                  |                    | S               |                              | Unk                  |                 | Pfizer       |                |
|                          | Effexor Xr     |                  |                    | S               |                              | Unk                  |                 | Pfizer       |                |
|                          | Darvon         |                  |                    | S               |                              | Unk                  |                 | Not Reported |                |
|                          | Lexapro        |                  |                    | S               |                              | Unk                  |                 | Not Reported |                |
|                          | Luvox          |                  |                    | S               |                              | Unk                  |                 | Not Reported |                |
|                          | Paxil          |                  |                    | S               |                              | Unk                  |                 | Not Reported |                |
|                          | Prozac         |                  |                    | S               |                              | Unk                  |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                           | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|--------------------------------|----------------------------|-----------------|--------------|----------------|
| 21-Oct-2014                                                                                                                                        | 10530349             | EXPEDITED (15-DAY) |                    | OT              | GB-DRREDDYS-GER/UKI/14/0043749 |                            | 49 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                                                                                              | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Confusional State; Dyskinesia; Headache; Insomnia; Labelled Drug-Drug Interaction Medication Error; Mental Disorder; Serotonin Syndrome | Omeprazole           |                    |                    | S               |                                |                            |                 | Not Reported |                |
|                                                                                                                                                    | Escitalopram         |                    |                    | S               |                                |                            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                           | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Oct-2014                                                                                                                                        | 10530694             | EXPEDITED (15-DAY) |                    | HO              | IT-ACTAVIS-2014-22184          |                            | 74 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                                                                                              | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>   |                |
| Bradycardia; Bradykinesia; Bradyphrenia; Electrocardiogram Qt Prolonged; Hypotension; Sopor                                                        | Quetiapine (Unknown) |                    |                    | S               | Oral                           | 300 Mg, Daily              |                 | Actavis      |                |
|                                                                                                                                                    | Paroxetine (Unknown) |                    |                    | S               | Oral                           | 1.5 Dosage Unit Daily      |                 | Not Reported |                |
|                                                                                                                                                    | Cipralext /01588501/ |                    |                    | S               | Oral                           | 1 Dosage Unit Daily        |                 | Not Reported |                |
|                                                                                                                                                    | Prazene              |                    |                    | S               | Oral                           | 1 Dosage Unit Daily        |                 | Not Reported |                |
|                                                                                                                                                    | Lasix /00032601/     |                    |                    | C               | Unknown                        |                            |                 | Not Reported |                |
|                                                                                                                                                    | Foster /00500401/    |                    |                    | C               | Unknown                        |                            |                 | Not Reported |                |
|                                                                                                                                                    | Stilnox              |                    |                    | C               | Unknown                        |                            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                           | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Oct-2014                                                                                                                                        | 10532738             | EXPEDITED (15-DAY) |                    | HO              | ES-MYLANLABS-2014M1007769      |                            |                 | Unknown      | ESP            |
| <u>Preferred Term</u>                                                                                                                              | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>   |                |
| Behaviour Disorder; Depression; Hyperkalaemia; Hyponatraemia; Mania; Psychomotor                                                                   | Venlafaxine          |                    |                    | S               | Unknown                        | 150mg/Day; Delayed Release |                 | Not Reported |                |
|                                                                                                                                                    | Citalopram           |                    |                    | S               | Unknown                        | 20mg/D                     |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                  |                               |   |         |                                                 |              |
|----------------------------------|-------------------------------|---|---------|-------------------------------------------------|--------------|
| Hyperactivity; Suicidal Ideation | Olanzapine                    | S | Unknown | 5mg/Day                                         | Not Reported |
|                                  | Enalapril                     | S | Unknown |                                                 | Not Reported |
|                                  | Escitalopram                  | S | Unknown | 10mg/Day                                        | Not Reported |
|                                  | Haloperidol                   | S | Unknown | 20 Drops /Day                                   | Mylan        |
|                                  | Amiloride,Hydrochlorothiazide | S | Unknown | Amiloride/Hydrochlorothiazide 5/50 G 1capsule/D | Mylan        |
|                                  | Agomelatine                   | C | Unknown | 25mg/Day;                                       | Not Reported |
|                                  | Dipotassium Clorazepate       | C | Unknown | 10mg: 3 Capsule/Day                             | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Oct-2014              | 10534491      | DIRECT           | Y                  |                 |                      |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                                      | <u>Product</u>  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------|-----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Depressed Mood; Depression; Nightmare; Product Substitution Issue | Generic Lexapro |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------|----------------------|------------|------------|----------------|
| 21-Oct-2014              | 10699969      | EXPEDITED (15-DAY) |                    | HO, OT          | ES-APOTEX-2014AP005244 |                      | 53 YR      | Female     | ESP            |

| <u>Preferred Term</u>                                                                          | <u>Product</u>                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------|--------------------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Depression; Hyperkalaemia; Hyponatraemia; Mania; Psychomotor Hyperactivity; Suicidal Behaviour | Venlafaxine                    |              |            | S           | Unknown      | 150 Mg, Per Day; Delayed Release |                 | Apotex       |
|                                                                                                | Citalopram                     |              |            | S           | Unknown      | 20 Mg, Per Day                   |                 | Apotex       |
|                                                                                                | Enalapril                      |              |            | S           | Unknown      |                                  |                 | Apotex       |
|                                                                                                | Escitalopram Apotex            |              |            | S           | Unknown      | 10 Mg, Per Day                   |                 | Apotex       |
|                                                                                                | Olanzapine                     |              |            | S           | Unknown      | 5 Mg, Per Day                    |                 | Apotex       |
|                                                                                                | Haloperidol                    |              |            | S           | Unknown      | 20 Gtt, Per Day                  |                 | Not Reported |
|                                                                                                | Haloperidol                    |              |            | S           | Unknown      | 10 Gtt, Per Day                  |                 | Not Reported |
|                                                                                                | Hydrochlorothiazide, Amiloride |              |            | S           | Unknown      | 1 Df,                            |                 | Not Reported |
|                                                                                                | Agomelatine                    |              |            | C           | Unknown      | 25 Mg, Per Day                   |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                            |                            |                    |                    |                 |                          |                      |                 |              |                |
|--------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| Dipotassium Clorazepate                                                                                                                    |                            |                    | C                  | Unknown         | 3 Df, Daily              | Not Reported         |                 |              |                |
| <u>FDA Received Date</u>                                                                                                                   | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Oct-2014                                                                                                                                | 10361185                   | EXPEDITED (15-DAY) | Y                  | DE, HO          | 2014HINLIT0673           |                      | 45 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                      | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Brain Oedema; Cerebral Infarction; Cerebral Vasoconstriction; Coma; Posterior Reversible Encephalopathy Syndrome; Subarachnoid Haemorrhage | Escitalopram               |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                                                                                                                            | Dihydroergotamine Mesilate |                    |                    | C               |                          |                      |                 | Not Reported |                |
|                                                                                                                                            | Hydromorphone              |                    |                    | C               |                          |                      |                 | Not Reported |                |
|                                                                                                                                            | Verapamil                  |                    |                    | C               |                          |                      |                 | Not Reported |                |
|                                                                                                                                            | Nicardipine                |                    |                    | C               |                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                   | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Oct-2014                                                                                                                                | 10533927                   | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000071670        |                      | 86 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                      | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Fall; Hip Fracture                                                                                                                         | Escitalopram               |                    |                    | S               | Oral                     | 1 Df                 |                 | Forest       |                |
|                                                                                                                                            | Memantine                  |                    |                    | S               | Oral                     | 1 Df                 |                 | Forest       |                |
|                                                                                                                                            | Lyrica                     |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                                                                                                                                            | Tramadol                   |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                                                                                                                                            | Previscan (Fluindione)     |                    |                    | C               | Oral                     |                      |                 | Not Reported |                |
|                                                                                                                                            | Insuline                   |                    |                    | C               |                          |                      |                 | Not Reported |                |
|                                                                                                                                            | Furosemide                 |                    |                    | C               |                          |                      |                 | Not Reported |                |
|                                                                                                                                            | Amlodipine                 |                    |                    | C               |                          |                      |                 | Not Reported |                |
|                                                                                                                                            | Nebivolol                  |                    |                    | C               |                          |                      |                 | Not Reported |                |
|                                                                                                                                            | Coaprovel                  |                    |                    | C               |                          |                      |                 | Not Reported |                |
|                                                                                                                                            | Dafalgan                   |                    |                    | C               |                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                   | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Oct-2014                                                                                                                                | 10535006                   | EXPEDITED (15-DAY) |                    | OT              | AT-PFIZER INC-2014288356 |                      | 70 YR           | Male         | AUT            |
| <u>Preferred Term</u>                                                                                                                      | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

**FDA Adverse Event Reporting System  
Freedom of Information Act (FOIA)  
Detailed Report**

|                   |                     |   |              |              |
|-------------------|---------------------|---|--------------|--------------|
| Urinary Retention | Norvasc             | S | 5 Mg, Unk    | Pfizer       |
|                   | Norvasc             | S | 10 Mg, Unk   | Pfizer       |
|                   | Norvasc             | S | 7.5 Mg, Unk  | Pfizer       |
|                   | Norvasc             | S | 5 Mg, Unk    | Pfizer       |
|                   | Norvasc             | S | 7.5 Mg, Unk  | Pfizer       |
|                   | Norvasc             | S | 5 Mg, Unk    | Pfizer       |
|                   | Dominal Forte       | S | 80 Mg, Unk   | Not Reported |
|                   | Dominal Forte       | S | 160 Mg, Unk  | Not Reported |
|                   | Cipralex            | S | 15 Mg, Unk   | Not Reported |
|                   | Cipralex            | S | 20 Mg, Unk   | Not Reported |
|                   | Cipralex            | S | 30 Mg, Unk   | Not Reported |
|                   | Temesta (Lorazepam) | C | 1 Mg, Unk    | Not Reported |
|                   | Temesta             | C | 2 Mg, Unk    | Not Reported |
|                   | Temesta             | C | 2.5 Mg, Unk  | Not Reported |
|                   | Temesta             | C | 1.75 Mg, Unk | Not Reported |
|                   | Temesta             | C | 1 Mg, Unk    | Not Reported |
|                   | Temesta             | C | 0.5 Mg, Unk  | Not Reported |
|                   | Temesta             | C | 1 Mg, Unk    | Not Reported |
|                   | Temesta             | C | 0.5 Mg, Unk  | Not Reported |
|                   | Sortis              | C | 40 Mg, Unk   | Not Reported |
|                   | Finasteride         | C | 5 Mg, Unk    | Not Reported |
|                   | Lyrica              | C | 100 Mg, Unk  | Not Reported |
|                   | Lyrica              | C | 200 Mg, Unk  | Not Reported |
|                   | Lyrica              | C | 300 Mg, Unk  | Not Reported |
|                   | Lyrica              | C | 75 Mg, Unk   | Not Reported |
|                   | Alna Retard         | C | 0.8 Mg, Unk  | Not Reported |
|                   | Alna Retard         | C | 0.4 Mg, Unk  | Not Reported |
|                   | Alna Retard         | C | 0.8 Mg, Unk  | Not Reported |
|                   | Cal-D-Vita          | C | 1 Df, Unk    | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                  |   |                |              |
|------------------|---|----------------|--------------|
| Zoldem           | C | 10 Mg, Unk     | Not Reported |
| Zoldem           | C | 20 Mg, Unk     | Not Reported |
| Zoldem           | C | 15 Mg, Unk     | Not Reported |
| Zoldem           | C | 10 Mg, Unk     | Not Reported |
| Mirtabene        | C | 45 Mg, Unk     | Not Reported |
| Mirtabene        | C | 60 Mg, Unk     | Not Reported |
| Mirtabene        | C | 30 Mg, Unk     | Not Reported |
| Mirtabene        | C | 15 Mg, Unk     | Not Reported |
| Bretaris Genuair | C | 1 Df, 1x/Day   | Not Reported |
| Tenormin         | C | 50 Mg, Unk     | Not Reported |
| Tenormin         | C | 25 Mg, Unk     | Not Reported |
| Oleovit-D3       | C | 50 Gtt, Weekly | Not Reported |
| Molaxole         | C | 1 Df, Unk      | Not Reported |
| Maxi Kalz Vit D3 | C | 1 Df, Unk      | Not Reported |
| Tritace          | C | 5 Mg, Unk      | Not Reported |
| Tritace          | C | 10 Mg, Unk     | Not Reported |
| Tritace          | C | 5 Mg, Unk      | Not Reported |
| Circadin         | C | 2 Mg, Unk      | Not Reported |
| Atorvalan        | C | 40 Mg, Unk     | Not Reported |
| Sirdalud         | C | 8 Mg, Unk      | Not Reported |
| Sirdalud         | C | 4 Mg, Unk      | Not Reported |
| Sirdalud         | C | 2 Mg, Unk      | Not Reported |
| Mogadon          | C | 1 Df, Unk      | Not Reported |
| Tritazide        | C | 5 Mg, Unk      | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                        | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-------------------------------------------------------------|----------------------|------------|------------|----------------|
| 22-Oct-2014              | 10536634      | NON-EXPEDITED    |                    |                 | US-RECKITT<br>BENCKISER<br>PHARMACEUTICAL,<br>INC-RB-68632- |                      |            | Unknown    | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|



## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                |               |   |            |                        |                   |
|----------------------------------------------------------------|---------------|---|------------|------------------------|-------------------|
| Drug Abuse; Irritability;<br>Paranoia; Self Esteem<br>Inflated | Suboxone Film | S | Sublingual | Suboxone Film          | Reckitt Benckiser |
|                                                                | Xanax         | S | Oral       | Dosing Details Unknown | Not Reported      |
|                                                                | Lexapro       | S | Oral       | Dosing Details Unknown | Not Reported      |
|                                                                | Serax         | S | Oral       | Dosing Details Unknown | Not Reported      |
|                                                                | Motrin        | S | Unknown    | Dosing Details Unknown | Not Reported      |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Oct-2014              | 10538061      | DIRECT           | Y                  |                 |                      |                      | 23 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Fatigue; Hypersomnia;<br>Product Substitution Issue;<br>Sedation; Somnolence | Escitalopram   |              |            | S           | Oral         | 1 Am               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Oct-2014              | 10538017      | EXPEDITED (15-DAY) |                    | HO              | ES-TEVA-516544ISR    |                      | 53 YR      | Female     | ESP            |

| <u>Preferred Term</u> | <u>Product</u>                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                    | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|--------------------------------|--------------|------------|-------------|--------------|-------------------------------------------------------|-----------------|--------------|
| Hyponatraemia         | Venlafaxine                    |              |            | S           | Unknown      | 150 Milligram Daily;<br>150mg/Day; Delayed<br>Release |                 | Not Reported |
|                       | Citalopram                     |              |            | S           | Unknown      | 20 Milligram Daily; 20mg/D                            |                 | Not Reported |
|                       | Olanzapine                     |              |            | S           | Unknown      | 5 Milligram Daily; 5mg/Day                            |                 | Teva         |
|                       | Enalapril                      |              |            | S           | Unknown      |                                                       |                 | Not Reported |
|                       | Escitalopram                   |              |            | S           | Unknown      | 10 Milligram Daily;<br>10mg/Day                       |                 | Not Reported |
|                       | Hydrochlorothiazide, Amiloride |              |            | S           | Unknown      | Amiloride/Hydrochlorotiazid<br>e 5/50 G 1capsule/D    |                 | Not Reported |
|                       | Haloperidol                    |              |            | S           | Unknown      | 20 Drops /Day                                         |                 | Not Reported |
|                       | Agomelatine                    |              |            | C           | Unknown      | 25 Milligram Daily;<br>25mg/Day;                      |                 | Not Reported |
|                       | Dipotassium Clorazepate        |              |            | C           | Unknown      | 10 Milligram Daily; 10mg:                             |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

3 Capsule/Day

| <u>FDA Received Date</u>                                                | <u>Case #</u>                       | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------|-------------------------------------|------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 23-Oct-2014                                                             | 10539484                            | NON-EXPEDITED    |                    | HO, LT          | SE-JNJFOC-20141012166 |                      | 23 YR           | Female       | SWE            |
| <u>Preferred Term</u>                                                   | <u>Product</u>                      | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depressed Level Of Consciousness;                                       | Reactine (Cetirizine Hydrochloride) |                  | Y                  | S               | Oral                  |                      |                 | Not Reported |                |
| Electrocardiogram Abnormal; Muscle Twitching; Poisoning; Somnolence     | Reactine (Cetirizine Hydrochloride) |                  |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                         | Postafen (Meclozine Hydrochloride)  |                  |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                         | Tavegyl                             |                  |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                         | Cipralext                           |                  |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                         | Loratadine                          |                  |                    | S               | Oral                  |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                | <u>Case #</u>                       | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Oct-2014                                                             | 10540825                            | DIRECT           | Y                  |                 |                       |                      | 6 DAY           | Female       | USA            |
| <u>Preferred Term</u>                                                   | <u>Product</u>                      | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Foetal Exposure During Pregnancy; Limb Deformity; Limb Reduction Defect | Lexapro                             |                  |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                         | Lexapro                             |                  |                    | C               |                       |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                | <u>Case #</u>                       | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Oct-2014                                                             | 10554026                            | NON-EXPEDITED    | Y                  |                 | AP356-01251-SPO-US    |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                   | <u>Product</u>                      | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety                                                                 | Belvix                              |                  |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                         | Lexapro                             |                  |                    | S               |                       |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>       | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------|-----------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 23-Oct-2014                    | 10567955                    | NON-EXPEDITED      | Y                  | OT              | AUR-APL-2014-08868   |                      | 64 YR           | Female       | USA            |
| <u>Preferred Term</u>          | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Electrocardiogram Qt Prolonged | Fluconazole (Fluconazole)   |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                | Ondansetron (Ondansetron)   |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                | Escitalopram (Escitalopram) |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>       | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Oct-2014                    | 10567960                    | NON-EXPEDITED      |                    | OT              | AUR-APU-2014-07307   |                      | 57 YR           | Female       | USA            |
| <u>Preferred Term</u>          | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Seizure; Tremor                | Escitalopram (Escitalopram) |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>       | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Oct-2014                    | 8434788                     | EXPEDITED (15-DAY) |                    | CA, HO, OT      | US-FRI-1000028169    |                      | < 1 DAY         | Male         | USA            |
| <u>Preferred Term</u>          | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrial Septal Defect;          | Lexapro                     |                    |                    | S               | Transplacental       | 10 Mg                |                 | Forest       |                |
| Atrioventricular Block         | Lexapro                     |                    |                    | S               |                      |                      |                 | Forest       |                |
| Complete; Autism               |                             |                    |                    |                 |                      |                      |                 |              |                |
| Spectrum Disorder;             |                             |                    |                    |                 |                      |                      |                 |              |                |
| Coarctation Of The Aorta;      |                             |                    |                    |                 |                      |                      |                 |              |                |
| Device Malfunction;            |                             |                    |                    |                 |                      |                      |                 |              |                |
| Hypovolaemia; Inguinal         |                             |                    |                    |                 |                      |                      |                 |              |                |
| Hernia; Premature Baby;        |                             |                    |                    |                 |                      |                      |                 |              |                |
| Pulmonary Artery               |                             |                    |                    |                 |                      |                      |                 |              |                |
| Stenosis; Respiratory          |                             |                    |                    |                 |                      |                      |                 |              |                |
| Distress; Right Ventricular    |                             |                    |                    |                 |                      |                      |                 |              |                |
| Hypertrophy; Umbilical         |                             |                    |                    |                 |                      |                      |                 |              |                |
| Cord Abnormality;              |                             |                    |                    |                 |                      |                      |                 |              |                |
| Ventricular Septal Defect      |                             |                    |                    |                 |                      |                      |                 |              |                |
| <u>FDA Received Date</u>       | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Oct-2014                    | 8588850                     | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000030905    |                      | < 1 DAY         | Male         | USA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <a href="#">Preferred Term</a>                                                                                                                                                                  | <a href="#">Product</a>                                                                                   | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>            | <a href="#">Duration</a> | <a href="#">Mfr</a>                                                    |                         |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|----------------------------------------|--------------------------|------------------------------------------------------------------------|-------------------------|
| Atrial Septal Defect;<br>Patent Ductus Arteriosus                                                                                                                                               | Lexapro                                                                                                   |                           |                             | S                        | Transplacental                |                                        |                          | Forest                                                                 |                         |
| <a href="#">FDA Received Date</a>                                                                                                                                                               | <a href="#">Case #</a>                                                                                    | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>          | <a href="#">Age</a>      | <a href="#">Sex</a>                                                    | <a href="#">Country</a> |
| 24-Oct-2014                                                                                                                                                                                     | 8589308                                                                                                   | EXPEDITED (15-DAY)        |                             | CA                       | US-FRI-1000030897             |                                        | < 1 DAY                  | Female                                                                 | USA                     |
| <a href="#">Preferred Term</a>                                                                                                                                                                  | <a href="#">Product</a>                                                                                   | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>            | <a href="#">Duration</a> | <a href="#">Mfr</a>                                                    |                         |
| Atrial Septal Defect;<br>Neonatal Cardiac Failure;<br>Patent Ductus Arteriosus;<br>Pulmonary Artery Stenosis<br>Congenital; Transposition<br>Of The Great Vessels;<br>Ventricular Septal Defect | Lexapro                                                                                                   |                           |                             | S                        | Transplacental                |                                        |                          | Forest                                                                 |                         |
| <a href="#">FDA Received Date</a>                                                                                                                                                               | <a href="#">Case #</a>                                                                                    | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>          | <a href="#">Age</a>      | <a href="#">Sex</a>                                                    | <a href="#">Country</a> |
| 24-Oct-2014                                                                                                                                                                                     | 10303478                                                                                                  | EXPEDITED (15-DAY)        |                             | OT                       | DK-FRI-1000068968             |                                        | 56 YR                    | Male                                                                   | DNK                     |
| <a href="#">Preferred Term</a>                                                                                                                                                                  | <a href="#">Product</a>                                                                                   | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>            | <a href="#">Duration</a> | <a href="#">Mfr</a>                                                    |                         |
| Atrioventricular Block First<br>Degree; Bundle Branch<br>Block Right;<br>Electrocardiogram Qt<br>Prolonged                                                                                      | Escitalopram<br>Cisordinol Tabletter<br>Nozinan<br>Cozaar Comp 100mg+12.5mg<br>Cisordinol Depot Injektion |                           |                             | S<br>C<br>C<br>C<br>C    | Oral                          | 10 Mg<br>10mg+0+0+20mg                 |                          | Forest<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |                         |
| <a href="#">FDA Received Date</a>                                                                                                                                                               | <a href="#">Case #</a>                                                                                    | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>          | <a href="#">Age</a>      | <a href="#">Sex</a>                                                    | <a href="#">Country</a> |
| 24-Oct-2014                                                                                                                                                                                     | 10313515                                                                                                  | EXPEDITED (15-DAY)        |                             | HO                       | FR-JNJFOC-<br>20140705319     |                                        | 46 YR                    | Male                                                                   | FRA                     |
| <a href="#">Preferred Term</a>                                                                                                                                                                  | <a href="#">Product</a>                                                                                   | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>            | <a href="#">Duration</a> | <a href="#">Mfr</a>                                                    |                         |
| Jaundice Cholestatic                                                                                                                                                                            | Concerta<br>Augmentin                                                                                     |                           |                             | S<br>S                   | Oral<br>Oral                  |                                        |                          | Not Reported<br>Not Reported                                           |                         |
|                                                                                                                                                                                                 |                                                                                                           |                           |                             |                          |                               | At The Beginning Of May<br>For 8 Days. |                          |                                                                        |                         |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|            |   |      |                                         |
|------------|---|------|-----------------------------------------|
| Augmentin  | S | Oral | Not Reported                            |
| Seroplex   | S | Oral | Not Reported                            |
| Lysanxia   | S | Oral | Not Reported                            |
| Coversyl   | S | Oral | Not Reported                            |
| Ibuprofene | S | Oral | 1 Or 2 Tablet Per Month<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Oct-2014              | 10342773      | EXPEDITED (15-DAY) | HO                 |                 | IT-FRI-1000069305    |                      | 20 YR      | Female     | ITA            |

| <u>Preferred Term</u>                                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Abuse; Overdose;<br>Product Use In<br>Unapproved Indication;<br>Sopor | Escitalopram   |              |            | S           | Oral         | Overdose: 140 Mg   |                 | Forest       |
|                                                                            | Lorazepam      |              |            | S           | Oral         | Overdose: 20 MI    |                 | Not Reported |
|                                                                            | Talofen        |              |            | S           | Oral         | Overdose: 40       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Oct-2014              | 10382522      | EXPEDITED (15-DAY) |                    | OT              | US-SA-2014SA068800   |                      | 80 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Potassium<br>Decreased; Drug<br>Interaction; Myalgia; Pain<br>In Extremity; Pollakiuria;<br>Polymyalgia Rheumatica;<br>Productive Cough | Multaq         |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                                               | Multaq         |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                                               | Escitalopram   |              |            | S           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Oct-2014              | 10444069      | EXPEDITED (15-DAY) | Y                  | OT              | ADR-2014-01569       |                      | 54 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                 | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------|-----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Pressure Diastolic<br>Increased; Device Power<br>Source Issue; Drug<br>Withdrawal Syndrome; Hot | Baclofen              | Y            |            | S           |              | 56.17 Mcg/Day      |                 | Not Reported |
|                                                                                                       | Clonidine Intrathecal |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                       | Dilaudid 0.9 Mg/MI    |              |            | S           |              | 0.9 Mg/MI (0.22977 |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                  |             |   |              |                              |              |
|--------------------------------------------------|-------------|---|--------------|------------------------------|--------------|
| Flush; Muscle Spasms;<br>Muscle Spasticity; Pain | Bupivacaine | S |              | Mg/Day                       |              |
|                                                  |             |   |              | 5.6 Mg/MI (1.4297<br>Mg/Day) | Not Reported |
|                                                  | Flomax      | S |              |                              | Not Reported |
|                                                  | Lexapro     | S |              | Day                          | Not Reported |
|                                                  | Copazone    | S | Subcutaneous |                              | Not Reported |
|                                                  | Vicodin     | S |              |                              | Not Reported |
|                                                  | Baclofen    | S |              |                              | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Oct-2014              | 10252646      | EXPEDITED (15-DAY) |                    | CA, OT          | CH-FRI-1000068377    |                      | < 1 DAY    | Female     | CHE            |

| <u>Preferred Term</u>                                                                                                                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u>                               | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------------------------------------|-----------------|--------------|
| Congenital Foot<br>Malformation; Congenital<br>Hand Malformation; Foetal<br>Exposure During<br>Pregnancy; Premature<br>Baby; Syndactyly | Escitalopram   |              |            | S           | Transplacental | 20 Mg                                            |                 | Forest       |
|                                                                                                                                         | Escitalopram   |              |            | S           | Transplacental | 10 Mg, Decreased To 10<br>Mg At End Of Pregnancy |                 | Forest       |
|                                                                                                                                         | Valdoxan       |              |            | S           | Transplacental | 25 Mg                                            |                 | Not Reported |
|                                                                                                                                         | Dalmadorm      |              |            | S           | Transplacental | 15-30 Mg Daily                                   |                 | Not Reported |
|                                                                                                                                         | Stilnox Cr     |              |            | S           | Transplacental | 12.5 Mg                                          |                 | Not Reported |
|                                                                                                                                         | Fluoxetin      |              |            | S           | Transplacental |                                                  |                 | Not Reported |
|                                                                                                                                         | Aspirin        |              |            | C           | Transplacental | 100 Mg                                           |                 | Not Reported |
|                                                                                                                                         | Utrogestan     |              |            | C           | Transplacental |                                                  |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Oct-2014              | 10485264      | EXPEDITED (15-DAY) |                    | HO              | CH-FRI-1000071084    |                      |            | Female     | CHE            |

| <u>Preferred Term</u>                                                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Antidepressant Drug Level<br>Increased; Confusional<br>State; Psychomotor<br>Hyperactivity | Escitalopram   |              |            | S           | Oral         | 5 Mg               |                 | Forest     |
|                                                                                            | Escitalopram   |              |            | S           | Oral         | 10 Mg              |                 | Forest     |
|                                                                                            | Escitalopram   |              |            | S           | Oral         | 20 Mg              |                 | Forest     |
|                                                                                            | Escitalopram   |              |            | S           | Oral         | 15 Mg              |                 | Forest     |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                     |   |                   |                                                                |              |
|---------------------|---|-------------------|----------------------------------------------------------------|--------------|
| Escitalopram        | S | Oral              | 10 Mg                                                          | Not Reported |
| Durogesic           | S | Topical           | 12 Microg/H 1x/3 Days                                          | Not Reported |
| Durogesic           | S | Topical           | 25 Microg/H 1x/3 Days                                          | Not Reported |
| Durogesic           | S | Topical           | 50 Microg/H 1x/3days                                           | Not Reported |
| Durogesic           | S | Topical           | 25 Microg/H 1x/3 Days                                          | Not Reported |
| Durogesic           | S | Topical           |                                                                | Not Reported |
| Madopar             | S | Oral              | 500 Mg                                                         | Not Reported |
| Madopar             | S | Oral              | 1000 Mg                                                        | Not Reported |
| Madopar             | S | Oral              | 500 Mg                                                         | Not Reported |
| Madopar             | S | Oral              |                                                                | Not Reported |
| Aspirine            | C | Oral              | 100 Mg                                                         | Not Reported |
| Temesta (Lorazepam) | C | Oral              | 0.5 Mg                                                         | Not Reported |
| Temesta (Lorazepam) | C | Other             | 1 Mg Daily, At The End Of Her Life, Increased Up To 3 Mg Daily | Not Reported |
| Temesta (Lorazepam) | C | Other             | 3 Mg                                                           | Not Reported |
| Laxoberon           | C | Oral              | 5 Mg                                                           | Not Reported |
| Morphine Hcl        | C | Oral              | 30 Mg                                                          | Not Reported |
| Lyrica              | C | Oral              | 50 Mg                                                          | Not Reported |
| Glucophage          | C | Oral              | 1000 Mg (In Addition: 500 Mg Daily)                            | Not Reported |
| Dafalgan            | C | Oral              | 1500 Mg                                                        | Not Reported |
| Amlodipine          | C | Oral              | 5 Mg                                                           | Not Reported |
| Concor              | C | Oral              | 2.5 Mg                                                         | Not Reported |
| Motilium            | C | Oral              | 30 Mg                                                          | Not Reported |
| Zofran              | C | Oral              | 12 Mg                                                          | Not Reported |
| Monuril             | C | Oral              | 3 G                                                            | Not Reported |
| Anexate             | C | Other             | 0.4 Mg                                                         | Not Reported |
| Midazolam           | C | Intravenous bolus | 1.5 Mg                                                         | Not Reported |
| Furadantine         | C | Oral              | 300 Mg                                                         | Not Reported |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                             | Quetiapine         | C                  | Oral               | 6 Mg            |                                     | Not Reported         |                 |              |                |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|--------------------|--------------------|-----------------|-------------------------------------|----------------------|-----------------|--------------|----------------|
|                                                                                                                                                             | Nitroderm          | C                  | Cutaneous          | 10 Mg           |                                     | Not Reported         |                 |              |                |
|                                                                                                                                                             | Haldol             | C                  | Other              | 1 Mg            |                                     | Not Reported         |                 |              |                |
| <u>FDA Received Date</u>                                                                                                                                    | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Oct-2014                                                                                                                                                 | 10542503           | EXPEDITED (15-DAY) |                    | OT              | GB-AUROBINDO-AUR-<br>APL-2014-11120 |                      | 49 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                                                                                                       | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Confusional State; Dyskinesia; Headache; Insomnia; Labelled Drug-Drug Interaction Medication Error; Malaise; Mental Disorder; Serotonin Syndrome | Escitalopram 20 Mg |                    |                    | S               | Unknown                             | 20 Mg, Once A Day    |                 | Aurobindo    |                |
|                                                                                                                                                             | Omeprazole 40mg    |                    |                    | S               | Unknown                             | 40 Mg, Once A Day    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                    | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Oct-2014                                                                                                                                                 | 10543508           | NON-EXPEDITED      |                    |                 | US-PFIZER INC-<br>2014290750        |                      | 38 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                       | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Somnolence                                                                                                                                       | Lyrica             |                    |                    | S               |                                     | 75 Mg, 1x/Day        |                 | Pfizer       |                |
|                                                                                                                                                             | Lyrica             |                    |                    | S               |                                     |                      |                 | Pfizer       |                |
|                                                                                                                                                             | Lexapro            |                    |                    | S               |                                     | 10 Mg, 1x/Day        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                    | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Oct-2014                                                                                                                                                 | 10548653           | DIRECT             | Y                  | HO              |                                     |                      | 18 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                       | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State; Hypertension; Speech Disorder; Tachycardia; Tremor                                                                                       | Lexapro            |                    |                    | S               | Oral                                | 1 Tablet             |                 | Unknown      |                |
|                                                                                                                                                             | Levothyroxine      |                    |                    | C               |                                     |                      |                 | Not Reported |                |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <a href="#">FDA Received Date</a>                                    | <a href="#">Case #</a>      | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|----------------------------------------------------------------------|-----------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 27-Oct-2014                                                          | 10551100                    | EXPEDITED (15-DAY)        |                             | OT                       | IT-ZYDUS-003908               |                               | 36 YR                    | Male                | ITA                     |
| <a href="#">Preferred Term</a>                                       | <a href="#">Product</a>     | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Interaction; Seizure                                            | Escitalopram (Escitalopram) |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
|                                                                      | Telaprevir (Telaprevir)     |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
|                                                                      | Peginterferon Alfa 2a       |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                    | <a href="#">Case #</a>      | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 28-Oct-2014                                                          | 10547528                    | EXPEDITED (15-DAY)        |                             | OT                       | GB-ACCORD-026593              |                               | 49 YR                    | Female              | GBR                     |
| <a href="#">Preferred Term</a>                                       | <a href="#">Product</a>     | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Labelled Drug-Drug Interaction Medication Error; Serotonin Syndrome  | Escitalopram                |                           |                             | S                        |                               |                               |                          | Accord              |                         |
|                                                                      | Omeprazole                  |                           |                             | S                        |                               |                               |                          | Accord              |                         |
| <a href="#">FDA Received Date</a>                                    | <a href="#">Case #</a>      | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 28-Oct-2014                                                          | 10548402                    | EXPEDITED (15-DAY)        |                             | CA                       | US-FRI-1000071735             |                               | < 1 DAY                  | Male                | USA                     |
| <a href="#">Preferred Term</a>                                       | <a href="#">Product</a>     | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Atrioventricular Septal Defect; Cleft Lip; Ventricular Septal Defect | Lexapro                     |                           |                             | S                        | Transplacental                |                               |                          | Forest              |                         |
| <a href="#">FDA Received Date</a>                                    | <a href="#">Case #</a>      | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 28-Oct-2014                                                          | 10548489                    | EXPEDITED (15-DAY)        |                             | CA                       | US-FRI-1000071745             |                               | < 1 DAY                  | Female              | USA                     |
| <a href="#">Preferred Term</a>                                       | <a href="#">Product</a>     | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Fallot'S Tetralogy                                                   | Lexapro                     |                           |                             | S                        | Transplacental                |                               |                          | Forest              |                         |
| <a href="#">FDA Received Date</a>                                    | <a href="#">Case #</a>      | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 28-Oct-2014                                                          | 10548660                    | EXPEDITED (15-DAY)        |                             | HO, OT                   | FR-SHIRE-FR201407186          |                               | 90 YR                    | Female              | FRA                     |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u> | <u>Product</u>   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|------------------|--------------|------------|-------------|--------------|---------------------------------|-----------------|--------------|
| Haemarthrosis         | Xagrid           |              |            | S           | Oral         | 1 Mg, 1x/Day:Qd (2 Df, 0.5 Mg)  |                 | Shire        |
|                       | Plavix           |              |            | S           | Oral         | Unk, Unknown                    |                 | Not Reported |
|                       | Plavix           |              |            | S           | Oral         | Unk, Unknown                    |                 | Not Reported |
|                       | Seroplex         |              |            | S           | Oral         | 1 Df, 1x/Day:Qd                 |                 | Not Reported |
|                       | Loxen /00639802/ |              |            | C           | Unknown      | 20 Mg, 1x/Day:Qd                |                 | Not Reported |
|                       | Paracetamol      |              |            | C           | Unknown      | 1 To 3/Day, As Req'D            |                 | Not Reported |
|                       | Oxybutynin       |              |            | C           | Unknown      | Unk, Unknown                    |                 | Not Reported |
|                       | Lorazepam        |              |            | C           | Unknown      | 2.5 Mg, 1x/Day:Qd               |                 | Not Reported |
|                       | Uvedose          |              |            | C           | Unknown      | 1 Ampoule, Other (Once A Month) |                 | Not Reported |
|                       | Econazole        |              |            | C           | Unknown      | 2 Applications, Other (Per Day) |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Oct-2014              | 10548860      | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000071747    |                      | < 1 DAY    | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|------------|
| Talipes               | Lexapro        |              |            | S           | Transplacental |                    |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Oct-2014              | 10549028      | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000071749    |                      | < 1 DAY    | Male       | USA            |

| <u>Preferred Term</u>                                                  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|------------------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|------------|
| Congenital Tricuspid Valve Atresia; Transposition Of The Great Vessels | Lexapro        |              |            | S           | Transplacental |                    |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Oct-2014              | 10549048      | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000071792    |                      | < 1 DAY    | Male       | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| Arachnoid Cyst; Arnold-Chiari Malformation; Growth Hormone Deficiency; Pineal Gland Cyst                                                                                       | Lexapro        |                    |                    | S               | Transplacental       |                      |                 | Forest     |                |
| <u>FDA Received Date</u>                                                                                                                                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 28-Oct-2014                                                                                                                                                                    | 10549364       | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000071751    |                      | < 1 DAY         | Male       | USA            |
| <u>Preferred Term</u>                                                                                                                                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Limb Asymmetry; Talipes                                                                                                                                                        | Lexapro        |                    |                    | S               | Transplacental       |                      |                 | Forest     |                |
| <u>FDA Received Date</u>                                                                                                                                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 28-Oct-2014                                                                                                                                                                    | 10549913       | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000071753    |                      | < 1 DAY         | Female     | USA            |
| <u>Preferred Term</u>                                                                                                                                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Atrial Septal Defect; Cardiac Failure Congestive; Congenital Pulmonary Valve Atresia; Hypoplastic Right Heart Syndrome; Patent Ductus Arteriosus; Tricuspid Valve Incompetence | Lexapro        |                    |                    | S               | Transplacental       |                      |                 | Forest     |                |
| <u>FDA Received Date</u>                                                                                                                                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 28-Oct-2014                                                                                                                                                                    | 10550011       | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000071755    |                      | < 1 DAY         | Male       | USA            |
| <u>Preferred Term</u>                                                                                                                                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Talipes                                                                                                                                                                        | Lexapro        |                    |                    | S               | Transplacental       |                      |                 | Forest     |                |
| <u>FDA Received Date</u>                                                                                                                                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 28-Oct-2014                                                                                                                                                                    | 10550259       | EXPEDITED (15-DAY) |                    | OT              | PHHY2014GB138178     |                      | 49 YR           | Female     | GBR            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                                                                                              | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|----------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| Agitation; Confusional State; Dyskinesia; Headache; Insomnia; Labelled Drug-Drug Interaction Medication Error; Mental Disorder; Serotonin Syndrome | Omeprazole          |                    |                    | S               |                          | 40 Mg, Qd            |                 | Novartis     |                |
|                                                                                                                                                    | Escitalopram        |                    |                    | S               |                          | 20 Mg, Qd            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                           | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Oct-2014                                                                                                                                        | 10554005            | EXPEDITED (15-DAY) |                    | OT              | 2014SA068800             |                      | 80 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                              | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Potassium Decreased; Drug Interaction; Macular Degeneration; Myalgia; Pollakiuria; Polymyalgia Rheumatica; Sputum Increased                  | Multaq              |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                                                                                                                                                    | Escitalopram        |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                           | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Oct-2014                                                                                                                                        | 10551230            | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000071757        |                      | < 1 DAY         | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                              | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrial Septal Defect; Ventricular Septal Defect                                                                                                    | Lexapro             |                    |                    | S               | Transplacental           |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                                           | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Oct-2014                                                                                                                                        | 10551594            | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2014296998 |                      | 81 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                              | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity                                                                                                                              | Lyrica              |                    |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                                                                                                                                                    | Metoprolol Tartrate |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |

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|  |                   |  |   |  |     |  |              |
|--|-------------------|--|---|--|-----|--|--------------|
|  | Potassium Citrate |  | S |  | Unk |  | Unknown      |
|  | Singulair         |  | S |  | Unk |  | Not Reported |
|  | Lexapro           |  | S |  | Unk |  | Not Reported |
|  | Lasix             |  | S |  | Unk |  | Not Reported |
|  | Clinoril          |  | S |  | Unk |  | Not Reported |

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| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 29-Oct-2014                       | 10552469               | EXPEDITED (15-DAY)        | CA                          |                          | US-FRI-1000071760             |                               | < 1 DAY             | Male                | USA                     |

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| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Craniosynostosis               | Lexapro                 |                       |                     | S                    | Transplacental        |                             |                          | Forest              |

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| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 29-Oct-2014                       | 10552529               | EXPEDITED (15-DAY)        | CA                          |                          | US-FRI-1000071762             |                               | < 1 DAY             | Male                | USA                     |

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| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Talipes                        | Lexapro                 |                       |                     | S                    | Transplacental        |                             |                          | Forest              |

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| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 29-Oct-2014                       | 10552572               | EXPEDITED (15-DAY)        | CA                          |                          | US-FRI-1000071764             |                               | < 1 DAY             | Female              | USA                     |

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| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Patent Ductus Arteriosus       | Lexapro                 |                       |                     | S                    | Transplacental        |                             |                          | Forest              |

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| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 29-Oct-2014                       | 10552656               | EXPEDITED (15-DAY)        | CA                          |                          | US-FRI-1000071766             |                               | < 1 DAY             | Male                | USA                     |

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| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Fallot'S Tetralogy             | Lexapro                 |                       |                     | S                    | Transplacental        |                             |                          | Forest              |

# FDA Adverse Event Reporting System

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### Detailed Report

| <u>FDA Received Date</u>                                                                  | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------|-----------------------------------------|--------------------|--------------------|-----------------|-----------------------|-------------------------------------|-----------------|--------------|----------------|
| 30-Oct-2014                                                                               | 10434647                                | NON-EXPEDITED      |                    | HO, OT          | US-JNJFOC-20140803194 |                                     | 59 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                     | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Extra Dose Administered;<br>Liver Injury; Toxicity To<br>Various Agents                   | Tylenol Extra Strength                  |                    | Y                  | S               | Unknown               |                                     |                 | Not Reported |                |
|                                                                                           | Tylenol Extra Strength                  |                    |                    | S               | Unknown               | 6 To 8 Pills, Every 4 To 6<br>Hours |                 | Not Reported |                |
|                                                                                           | Lexapro                                 |                    |                    | S               | Unknown               |                                     |                 | Not Reported |                |
|                                                                                           | Pamelor                                 |                    |                    | S               | Unknown               |                                     |                 | Not Reported |                |
|                                                                                           | Hydrochlorothiazide                     |                    |                    | S               | Unknown               |                                     |                 | Not Reported |                |
|                                                                                           | Acetaminophen\Hydrocodone<br>Bitartrate |                    |                    | S               | Unknown               |                                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                  | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Oct-2014                                                                               | 10555830                                | EXPEDITED (15-DAY) |                    | HO              | CZ-FRI-1000071981     |                                     | 67 YR           | Female       | CZE            |
| <u>Preferred Term</u>                                                                     | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Headache;<br>Hypochloraemia;<br>Hypokalaemia;<br>Hyponatraemia;<br>Presyncope             | Escitalopram                            |                    |                    | S               | Oral                  | 10 Mg                               |                 | Forest       |                |
|                                                                                           | Cancombino 32 Mg/12.5 Mg                |                    |                    | S               |                       |                                     |                 | Not Reported |                |
|                                                                                           | Lexaurin                                |                    |                    | C               |                       |                                     |                 | Not Reported |                |
|                                                                                           | Zocor 20 Mg                             |                    |                    | C               |                       |                                     |                 | Not Reported |                |
|                                                                                           | Concor Cor 2.5 Mg                       |                    |                    | C               |                       |                                     |                 | Not Reported |                |
|                                                                                           | Anopyrin 100 Mg                         |                    |                    | C               |                       |                                     |                 | Not Reported |                |
|                                                                                           | Kapidin 10 Mg                           |                    |                    | C               |                       |                                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                  | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Oct-2014                                                                               | 10555831                                | EXPEDITED (15-DAY) |                    | OT              | GB-FRI-1000071979     |                                     | 49 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                                     | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Confusional<br>State; Dyskinesia;<br>Headache; Insomnia;<br>Labelled Drug-Drug | Escitalopram                            |                    |                    | S               | Oral                  | 20 Mg Once Daily                    |                 | Forest       |                |
|                                                                                           | Omeprazole                              |                    |                    | S               |                       | 40 Mg Once Daily                    |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Interaction Medication  
Error; Mental Disorder;  
Serotonin Syndrome

| <a href="#">FDA Received Date</a>                                                  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|------------------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 30-Oct-2014                                                                        | 10555857                | EXPEDITED (15-DAY)        |                             | CA                       | US-FRI-1000071768             |                               | < 1 DAY                  | Male                | USA                     |
| <a href="#">Preferred Term</a>                                                     | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Talipes                                                                            | Lexapro                 |                           |                             | S                        | Transplacental                |                               |                          | Forest              |                         |
| <a href="#">FDA Received Date</a>                                                  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 30-Oct-2014                                                                        | 10555861                | EXPEDITED (15-DAY)        |                             | CA                       | US-FRI-1000071776             |                               | < 1 DAY                  | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                     | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Aortic Stenosis; Bicuspid Aortic Valve                                             | Lexapro                 |                           |                             | S                        | Transplacental                |                               |                          | Forest              |                         |
| <a href="#">FDA Received Date</a>                                                  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 30-Oct-2014                                                                        | 10555863                | EXPEDITED (15-DAY)        |                             | CA                       | US-FRI-1000071770             |                               | < 1 DAY                  | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                     | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Atrial Septal Defect; Patent Ductus Arteriosus; Transposition Of The Great Vessels | Lexapro                 |                           |                             | S                        | Transplacental                |                               |                          | Forest              |                         |
| <a href="#">FDA Received Date</a>                                                  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 30-Oct-2014                                                                        | 10555866                | EXPEDITED (15-DAY)        |                             | CA                       | US-FRI-1000071778             |                               | < 1 DAY                  | Male                | USA                     |
| <a href="#">Preferred Term</a>                                                     | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Transposition Of The Great Vessels                                                 | Lexapro                 |                           |                             | S                        | Transplacental                |                               |                          | Forest              |                         |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <a href="#">FDA Received Date</a>                                               | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|---------------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 30-Oct-2014                                                                     | 10555869                | EXPEDITED (15-DAY)        |                             | CA                       | US-FRI-1000071780             |                               | < 1 DAY                  | Male                | USA                     |
| <a href="#">Preferred Term</a>                                                  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Pulmonary Valve Stenosis                                                        | Lexapro                 |                           |                             | S                        | Transplacental                |                               |                          | Forest              |                         |
| <a href="#">FDA Received Date</a>                                               | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 30-Oct-2014                                                                     | 10555938                | EXPEDITED (15-DAY)        |                             | CA                       | US-FRI-1000071782             |                               | < 1 DAY                  | Male                | USA                     |
| <a href="#">Preferred Term</a>                                                  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Ventricular Septal Defect                                                       | Lexapro                 |                           |                             | S                        | Transplacental                |                               |                          | Forest              |                         |
| <a href="#">FDA Received Date</a>                                               | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 30-Oct-2014                                                                     | 10555942                | EXPEDITED (15-DAY)        |                             | CA                       | US-FRI-1000071784             |                               | < 1 DAY                  | Male                | USA                     |
| <a href="#">Preferred Term</a>                                                  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Plagiocephaly; Scoliosis; Skull Malformation; Spina Bifida Occulta; Torticollis | Lexapro                 |                           |                             | S                        | Transplacental                |                               |                          | Forest              |                         |
| <a href="#">FDA Received Date</a>                                               | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 30-Oct-2014                                                                     | 10555948                | EXPEDITED (15-DAY)        |                             | CA                       | US-FRI-1000071786             |                               | < 1 DAY                  | Male                | USA                     |
| <a href="#">Preferred Term</a>                                                  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Fallot'S Tetralogy                                                              | Lexapro                 |                           |                             | S                        | Transplacental                |                               |                          | Forest              |                         |
| <a href="#">FDA Received Date</a>                                               | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 30-Oct-2014                                                                     | 10555949                | EXPEDITED (15-DAY)        |                             | CA                       | US-FRI-1000071788             |                               | < 1 DAY                  | Male                | USA                     |
| <a href="#">Preferred Term</a>                                                  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
|                                                                                 |                         |                           |                             |                          |                               |                               |                          |                     |                         |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                       |                             |                           |                             |                          |                               |                               |                          |                     |                         |
|-------------------------------------------------------------------------------------------------------|-----------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Cleft Palate                                                                                          | Lexapro                     |                           | S                           | Transplacental           |                               |                               |                          | Forest              |                         |
| <a href="#">FDA Received Date</a>                                                                     | <a href="#">Case #</a>      | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 30-Oct-2014                                                                                           | 10555956                    | EXPEDITED (15-DAY)        |                             | CA                       | US-FRI-1000071790             |                               | < 1 DAY                  | Male                | USA                     |
| <a href="#">Preferred Term</a>                                                                        | <a href="#">Product</a>     | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Hydrocephalus; Spina Bifida                                                                           | Lexapro                     |                           |                             | S                        | Transplacental                |                               |                          |                     | Forest                  |
| <a href="#">FDA Received Date</a>                                                                     | <a href="#">Case #</a>      | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 30-Oct-2014                                                                                           | 10559979                    | EXPEDITED (15-DAY)        | Y                           | HO                       | 2014JUB00177                  |                               | 53 YR                    | Female              | ESP                     |
| <a href="#">Preferred Term</a>                                                                        | <a href="#">Product</a>     | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Anhedonia; Decreased Appetite; Depressed Mood; Depression; Hyponatraemia; Insomnia; Suicidal Ideation | Olanzapine (Olanzapine)     |                           |                             | S                        |                               |                               |                          |                     | Not Reported            |
|                                                                                                       | Unknown                     |                           |                             | S                        |                               |                               |                          |                     | Not Reported            |
|                                                                                                       | Escitalopram (Escitalopram) |                           |                             | S                        |                               |                               |                          |                     | Not Reported            |
|                                                                                                       | Unknown                     |                           |                             | S                        |                               |                               |                          |                     | Not Reported            |
|                                                                                                       | Enalapril (Enalapril)       |                           |                             | C                        |                               |                               |                          |                     | Not Reported            |
|                                                                                                       | Clorazepate Dipotassium     |                           |                             | C                        |                               |                               |                          |                     | Not Reported            |
|                                                                                                       | Agomelatine                 |                           |                             | C                        |                               |                               |                          |                     | Not Reported            |
| <a href="#">FDA Received Date</a>                                                                     | <a href="#">Case #</a>      | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 31-Oct-2014                                                                                           | 10248032                    | EXPEDITED (15-DAY)        |                             | CA                       | DK-FRI-1000068339             |                               | < 1 DAY                  | Female              | DNK                     |
| <a href="#">Preferred Term</a>                                                                        | <a href="#">Product</a>     | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Foetal Exposure During Pregnancy; Polydactyly                                                         | Escitalopram                |                           |                             | S                        | Transplacental                | 5 Mg                          |                          |                     | Forest                  |
|                                                                                                       | Eltroxin                    |                           |                             | C                        | Transplacental                | 242.8571 Mcg                  |                          |                     | Not Reported            |
| <a href="#">FDA Received Date</a>                                                                     | <a href="#">Case #</a>      | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 31-Oct-2014                                                                                           | 10549313                    | EXPEDITED (15-DAY)        |                             | HO                       | FR-FRI-1000070639             |                               | 82 YR                    | Male                | FRA                     |
| <a href="#">Preferred Term</a>                                                                        | <a href="#">Product</a>     | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Agranulocytosis; Bacterial                                                                            | Escitalopram                |                           |                             | S                        | Oral                          | 5 Mg                          |                          |                     | Forest                  |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|        |           |   |      |       |              |
|--------|-----------|---|------|-------|--------------|
| Sepsis | Mianserin | S | Oral | 40 Mg | Not Reported |
|        | Aricept   | C |      | 15 Mg | Not Reported |
|        | Zopiclone | C |      | 10 Mg | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 31-Oct-2014              | 10549833      | EXPEDITED (15-DAY) |                    | OT              | GB-ASTRAZENECA-2014SE79413 |                      | 49 YR      | Female     | GBR            |

| <u>Preferred Term</u>                                                                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Dyskinesia; Insomnia; Labelled Drug-Drug Interaction Medication Error; Mental Disorder; Serotonin Syndrome | Omeprazole     |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                            | Escitalopram   |              |            | S           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------------|----------------------|------------|------------|----------------|
| 31-Oct-2014              | 10558498      | EXPEDITED (15-DAY) |                    | OT              | US-GLAXOSMITHKLINE-US2014GSK015491 |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                     | <u>Product</u>                              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|-------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Agoraphobia; Arthritis; Crying; Depression; Enuresis; Fatigue; Feeling Jittery; Peripheral Vascular Disorder; Personality Change; Vertigo | Wellbutrin                                  |              |            | S           | Oral         |                    |                 | Glaxosmithkline |
|                                                                                                                                           | Xyrem                                       |              |            | S           | Oral         | 4.5 G, Qd          |                 | Not Reported    |
|                                                                                                                                           | Xyrem                                       |              |            | S           |              |                    |                 | Not Reported    |
|                                                                                                                                           | Topamax                                     |              |            | S           |              |                    |                 | Not Reported    |
|                                                                                                                                           | Zanaflex                                    |              |            | S           |              |                    |                 | Not Reported    |
|                                                                                                                                           | Xanax                                       |              |            | S           |              |                    |                 | Not Reported    |
|                                                                                                                                           | Roxicodone                                  |              |            | S           |              |                    |                 | Not Reported    |
|                                                                                                                                           | Spiriva                                     |              |            | S           |              |                    |                 | Not Reported    |
|                                                                                                                                           | Lexapro                                     |              |            | S           |              |                    |                 | Not Reported    |
|                                                                                                                                           | Albuterol                                   |              |            | S           |              |                    |                 | Glaxosmithkline |
|                                                                                                                                           | Elavil Tablet (Amitriptyline Hydrochloride) |              |            | S           |              |                    |                 | Not Reported    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 31-Oct-2014              | 10558533      | EXPEDITED (15-DAY) |                    | HO, OT          | FR-PFIZER INC-2014296115 |                      | 65 YR      | Male       | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                                                                                                                            |                                                                                                                                    |   |              |                |              |
|------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------|---|--------------|----------------|--------------|
| Constipation; Fall;<br>Gastrointestinal Sounds<br>Abnormal; Major<br>Depression; Malaise;<br>Orthostatic Hypotension;<br>Tachycardia; Treatment<br>Failure | Xanax                                                                                                                              | S | Oral         | 0.5 Mg, 4x/Day | Pfizer       |
|                                                                                                                                                            | Mirtazapine                                                                                                                        | S | Oral         | 30 Mg, 1x/Day  | Not Reported |
|                                                                                                                                                            | Loxapac                                                                                                                            | S | Oral         | 20 Gtt, 3x/Day | Not Reported |
|                                                                                                                                                            | Loxapac                                                                                                                            | S | Oral         | 45 Gtt, Daily  | Not Reported |
|                                                                                                                                                            | Risperdal                                                                                                                          | S | Oral         | 2 Mg, 1x/Day   | Not Reported |
|                                                                                                                                                            | Risperdal                                                                                                                          | S | Oral         | 4 Mg, 1x/Day   | Not Reported |
|                                                                                                                                                            | Noctamid                                                                                                                           | S | Oral         | 2 Mg, Daily    | Not Reported |
|                                                                                                                                                            | Seroplex                                                                                                                           | S |              | Unk            | Not Reported |
|                                                                                                                                                            | Transipeg (Polyethylene Glycol<br>3350\Potassium<br>Chloride\Sodium<br>Bicarbonate\Sodium<br>Chloride\Sodium Sulfate<br>Anhydrous) | C | Oral         | 5.9 G, Daily   | Not Reported |
|                                                                                                                                                            | Lansoyl                                                                                                                            | C | Oral         | Unk            | Not Reported |
|                                                                                                                                                            | Fraxiparine                                                                                                                        | C | Subcutaneous | 1 Df, Daily    | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 31-Oct-2014              | 10562216      | EXPEDITED (15-DAY) | Y                  | OT              | GB-DEXPHARM-<br>20140675 |                      | 49 YR      | Female     | GBR            |

| <u>Preferred Term</u>                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                      | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------|----------------|--------------|------------|-------------|--------------|-----------------------------------------|-----------------|--------------|
| Drug Interaction;<br>Serotonin Syndrome | Omeprazole     |              |            | S           |              | 3cp Dosages / Interval: 1<br>In 1 Days  | 48 DAY          | Not Reported |
|                                         | Escitalopram   |              |            | S           |              | Sep. Dosages / Interval: 1<br>In 1 Days |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|------------|------------|----------------|
| 03-Nov-2014              | 10559418      | EXPEDITED (15-DAY) |                    | OT              | GB-MYLANLABS-<br>2014M1008220 |                      |            | Unknown    | GBR            |

| <u>Preferred Term</u>                                               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Agitation; Confusional<br>State; Dyskinesia;<br>Headache; Insomnia; | Omeprazole     |              |            | S           |              | 40 Mg, Qd          |                 | Not Reported |
|                                                                     | Escitalopram   |              |            | S           |              | 20 Mg, Qd          |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Labelled Drug-Drug  
Interaction Medication  
Error; Mental Disorder;  
Serotonin Syndrome

| <u>FDA Received Date</u>                                                                                               | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|------------------------------|----------------------------------|-----------------|--------------|----------------|
| 03-Nov-2014                                                                                                            | 10559717                 | NON-EXPEDITED      |                    |                 | US-PFIZER INC-<br>2014301466 |                                  |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective                                                                                                       | Zoloft                   |                    |                    | S               |                              | 12.5 Mg, Unk                     |                 | Pfizer       |                |
|                                                                                                                        | Zoloft                   |                    |                    | S               |                              | 50 Mg, Daily                     |                 | Pfizer       |                |
|                                                                                                                        | Effexor                  |                    |                    | S               |                              | Unk                              |                 | Pfizer       |                |
|                                                                                                                        | Lexapro                  |                    |                    | S               |                              | Unk                              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                               | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Nov-2014                                                                                                            | 10559751                 | NON-EXPEDITED      |                    |                 | US-PFIZER INC-<br>2014301389 |                                  |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Dry Eye; Fatigue;<br>Insomnia; Loss Of<br>Personal Independence In<br>Daily Activities; Pain;<br>Visual Acuity Reduced | Gabapentin               |                    |                    | S               |                              | 300 Mg, Unk                      |                 | Pfizer       |                |
|                                                                                                                        | Tramadol Hcl             |                    |                    | S               |                              | 1/2 Of A 50 Mg Tablet,<br>2x/Day |                 | Unknown      |                |
|                                                                                                                        | Lexapro                  |                    |                    | S               |                              | Unk                              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                               | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Nov-2014                                                                                                            | 10560059                 | EXPEDITED (15-DAY) |                    | HO              | US-SA-2014SA148250           |                                  | 48 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated;<br>Dysarthria; Hypertension;<br>Hypokalaemia; Mental<br>Status Changes; Multiple<br>Drug Therapy | Ambien                   |                    |                    | S               | Oral                         |                                  |                 | Not Reported |                |
|                                                                                                                        | Desvenlafaxine Succinate |                    |                    | S               | Oral                         |                                  |                 | Not Reported |                |
|                                                                                                                        | Desvenlafaxine Succinate |                    |                    | S               | Oral                         |                                  |                 | Not Reported |                |
|                                                                                                                        | Lyrica                   |                    |                    | S               | Oral                         |                                  |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|             |   |                          |                                |
|-------------|---|--------------------------|--------------------------------|
| Ibuprofen   | S | Oral                     | Not Reported                   |
| Lexapro     | S | Oral                     | Not Reported                   |
| Clonazepam  | S | Oral                     | Not Reported                   |
| Abilify     | S | Oral                     | Not Reported                   |
| Vicodin     | S | Oral                     | Dose: 5/500<br>Not Reported    |
| Fluticasone | S | Respiratory (inhalation) | Dose: 2 Sprays<br>Not Reported |
| Loratadine  | S | Oral                     | Not Reported                   |
| Vivelle     | S | Transdermal              | Not Reported                   |
| Robaxin     | S | Oral                     | Not Reported                   |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Nov-2014              | 10560980      | EXPEDITED (15-DAY) |                    | OT              | GB-WATSON-2014-23239 |                      | 49 YR      | Female     | GBR            |

| <u>Preferred Term</u>                                                                                                                              | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Agitation; Confusional State; Dyskinesia; Headache; Insomnia; Labelled Drug-Drug Interaction Medication Error; Mental Disorder; Serotonin Syndrome | Omeprazole (Unknown)   |              |            | S           | Unknown      | 40 Mg, Daily       |                 | Watson       |
|                                                                                                                                                    | Escitalopram (Unknown) |              |            | S           | Unknown      | 20 Mg, Daily       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Nov-2014              | 10562522      | DIRECT           | Y                  | OT              |                      |                      |            | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|-------------------------|-----------------|--------------|
| Drug Ineffective      | Escitalopram   |              |            | S           | Oral         | 1 Tablet By Mouth Daily |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------|----------------------|------------|------------|----------------|
| 04-Nov-2014              | 10561949      | EXPEDITED (15-DAY) |                    | OT              | CH-RANBAXY-2014RR-86889 |                      | 39 YR      | Male       | CHE            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                             |              |   |         |              |              |
|-----------------------------|--------------|---|---------|--------------|--------------|
| Drug Abuse; Suicide Attempt | Fluoxetine   | S | Unknown | 20 Mg, Daily | Ranbaxy      |
|                             | Escitalopram | S | Unknown | Unk          | Not Reported |
|                             | Lorazepam    | S | Unknown | 10 Mg        | Ranbaxy      |
|                             | Quetiapine   | S | Unknown | 250 Mg       | Not Reported |
|                             | Acemetacin   | S | Unknown | 90 Mg        | Not Reported |

| <u>FDA Received Date</u>     | <u>Case #</u>                 | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------|-------------------------------|------------------|--------------------|-----------------|--------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 04-Nov-2014                  | 10562093                      | NON-EXPEDITED    |                    |                 | US-LUPIN<br>PHARMACEUTICALS<br>INC.-E2B_00002586 |                      | 46 YR           | Female       | USA            |
| <u>Preferred Term</u>        | <u>Product</u>                | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                     | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Chills; Dizziness; Flushing; | Escitalopram Tablets Usp 20mg |                  |                    | S               |                                                  |                      |                 | Lupin        |                |
| Headache; Palpitations;      | Escitalopram Tablets Usp 20mg |                  |                    | S               |                                                  |                      |                 | Lupin        |                |
| Product Substitution Issue;  | Zyrted Otc                    |                  |                    | C               |                                                  |                      |                 | Not Reported |                |
| Pyrexia                      |                               |                  |                    |                 |                                                  |                      |                 |              |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 04-Nov-2014              | 10562987       | EXPEDITED (15-DAY) |                    | DE, HO          | GB-FRI-1000071978    |                      | 81 YR           | Female       | GBR            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Behaviour;      | Escitalopram   |                    |                    | S               | Oral                 | 5 Mg                 |                 | Forest       |                |
| Anxiety; Hallucination   | Escitalopram   |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                          | Escitalopram   |                    |                    | S               | Oral                 | 10 Mg                |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|-------------------|--------------------|--------------------|-----------------|----------------------|-----------------------|-----------------|--------------|----------------|
| 05-Nov-2014              | 10357080          | EXPEDITED (15-DAY) |                    | DS              | IT-FRI-1000069493    |                       | 80 YR           | Male         | ITA            |
| <u>Preferred Term</u>    | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Prescribed Overdose;     | Escitalopram      |                    |                    | S               | Oral                 | 20 Mg                 |                 | Forest       |                |
| Visual Acuity Reduced    | Escitalopram      |                    |                    | S               | Oral                 | Overdose: 40 Mg Daily |                 | Forest       |                |
|                          | Escitalopram      |                    |                    | S               | Oral                 | 20 Mg                 |                 | Forest       |                |
|                          | Tavor (Lorazepam) |                    |                    | S               | Oral                 | 1.5 Mg                |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Tavor (Lorazepam)

S

Oral

2 Unit Dose Per Day

Not Reported

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------|----------------------|------------|------------|----------------|
| 05-Nov-2014              | 10530015      | EXPEDITED (15-DAY) |                    | OT              | IN-AUROBINDO-AUR-<br>APL-2014-11087 |                      | 23 YR      | Female     | IND            |

| <u>Preferred Term</u>                                                                                                                                        | <u>Product</u>                        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Antisocial Behaviour;<br>Anxiety; Crying;<br>Decreased Appetite;<br>Decreased Interest; Drug<br>Ineffective; Dystonia;<br>Mood Altered; Oculogyric<br>Crisis | Escitalopram Oxalate Tablets 10<br>Mg |              |            | S           | Unknown      | 10 Mg, Daily       |                 | Aurobindo    |
|                                                                                                                                                              | Amisulpride Tablets                   |              |            | S           | Unknown      | Upto 1000 Mg, Unk  |                 | Not Reported |
|                                                                                                                                                              | Aripiprazole                          |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                                              | Aripiprazole                          |              |            | S           | Unknown      | 30 Mg, Daily       |                 | Not Reported |
|                                                                                                                                                              | Aripiprazole                          |              |            | S           | Unknown      | 30 Mg, Daily       |                 | Not Reported |
|                                                                                                                                                              | Olanzapine                            |              |            | S           | Unknown      | 7.5 Mg, Daily      |                 | Not Reported |
|                                                                                                                                                              | Olanzapine                            |              |            | S           | Unknown      | 15 Mg, Daily       |                 | Not Reported |
|                                                                                                                                                              | Olanzapine                            |              |            | S           | Unknown      | 20 Mg, Daily       |                 | Not Reported |
|                                                                                                                                                              | Paliperidone                          |              |            | S           | Unknown      | 3 Mg, Unk          |                 | Not Reported |
| Propranolol                                                                                                                                                  |                                       |              | S          | Unknown     | 40 Mg, Daily |                    | Not Reported    |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 05-Nov-2014              | 10530112      | NON-EXPEDITED    |                    |                 | US-PFIZER INC-<br>2014284792 |                      | 66 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Hypersensitivity | Lipitor        |              |            | S           |              | Unk                |                 | Pfizer       |
|                       | Meloxicam      |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Theophylline   |              |            | S           |              | Unk                |                 | Pfizer       |
|                       | Asa            |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Cogentin       |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Bactrim Ds     |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Lexapro        |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Omega          |              |            | S           |              | Unk                |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|              |   |     |              |
|--------------|---|-----|--------------|
| Trazodone    | S | Unk | Not Reported |
| Progesterone | S | Unk | Not Reported |
| Seroquel     | S | Unk | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------|----------------------|------------|------------|----------------|
| 05-Nov-2014              | 10564757      | EXPEDITED (15-DAY) |                    | HO, OT          | FR-AUROBINDO-AUR-<br>APL-2014-11540 |                      | 65 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                                                                                                 | <u>Product</u>                          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Constipation; Fall;<br>Gastrointestinal Sounds<br>Abnormal; Malaise;<br>Orthostatic Hypotension;<br>Tachycardia; Treatment<br>Failure | Mirtazapine Film-Coated Tablet<br>15 Mg |              |            | S           | Oral         | 2 Df, Daily        |                 | Aurobindo    |
|                                                                                                                                       | Risperdal                               |              |            | S           | Oral         | 1 Df, Daily        |                 | Not Reported |
|                                                                                                                                       | Risperdal                               |              |            | S           | Oral         | 2 Df, Daily        |                 | Not Reported |
|                                                                                                                                       | Xanax                                   |              |            | S           | Oral         | 4 Df, Unk          |                 | Not Reported |
|                                                                                                                                       | Noctamide                               |              |            | S           | Oral         | 1 Df, Unk          |                 | Not Reported |
|                                                                                                                                       | Loxapac /00401801/                      |              |            | S           | Oral         | 60 Gtt, Unk        |                 | Not Reported |
|                                                                                                                                       | Loxapac /00401801/                      |              |            | S           | Oral         | 45 Gtt, Daily      |                 | Not Reported |
|                                                                                                                                       | Lansoyl                                 |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                                                       | Transipeg /00754501/                    |              |            | C           | Unknown      | 1 Df, Daily        |                 | Not Reported |
|                                                                                                                                       | Fraxiparine /01437702/                  |              |            | C           | Subcutaneous | 1 Df, Daily        |                 | Not Reported |
|                                                                                                                                       | Seroplex                                |              |            | S           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Nov-2014              | 10564787      | EXPEDITED (15-DAY) |                    | DE, HO          | GB-ACCORD-026758     |                      | 81 YR      | Female     | GBR            |

| <u>Preferred Term</u>                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                               | <u>Duration</u> | <u>Mfr</u> |
|-----------------------------------------------|----------------|--------------|------------|-------------|--------------|----------------------------------------------------------------------------------|-----------------|------------|
| Abnormal Behaviour;<br>Anxiety; Hallucination | Escitalopram   |              |            | S           | Oral         | Initially Given 5 Mg Then<br>Dose Increased To 10 Mg<br>Daily From Unknown Date. |                 | Accord     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------|----------------------|------------|------------|----------------|
| 05-Nov-2014              | 10565035      | EXPEDITED (15-DAY) |                    | DE, HO          | GB-AUROBINDO-AUR-<br>APL-2014-11441 |                      | 81 YR      | Female     | GBR            |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                   | <u>Product</u>                                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------------|------------------------------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------|-----------------|--------------|----------------|
| Abnormal Behaviour;<br>Anxiety; Death;<br>Hallucination | Escitalopram                                   |                    |                    | S               | Oral                 | 5 Mg, Daily                   |                 | Aurobindo    |                |
|                                                         | Escitalopram                                   |                    |                    | S               | Oral                 | Unk                           |                 | Aurobindo    |                |
|                                                         | Escitalopram                                   |                    |                    | S               | Oral                 | Unk                           |                 | Aurobindo    |                |
|                                                         | Escitalopram                                   |                    |                    | S               | Oral                 | 10 Mg, Daily                  |                 | Aurobindo    |                |
| <u>FDA Received Date</u>                                | <u>Case #</u>                                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Nov-2014                                             | 10566406                                       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000072053    |                               | 90 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                   | <u>Product</u>                                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Depressed Level Of<br>Consciousness;<br>Somnolence      | Escitalopram                                   |                    |                    | S               | Oral                 | 1 Df                          |                 | Forest       |                |
|                                                         | Memantine                                      |                    |                    | S               | Oral                 | 1 Df                          |                 | Forest       |                |
|                                                         | Tranxene                                       |                    |                    | S               | Oral                 | 2 Df                          |                 | Not Reported |                |
|                                                         | Lorazepam                                      |                    |                    | S               | Oral                 | 0.5 Df                        |                 | Not Reported |                |
|                                                         | Risperdal                                      |                    |                    | C               | Oral                 | 0.5 Df                        |                 | Not Reported |                |
|                                                         | Coumadine                                      |                    |                    | C               | Oral                 | 1 Df                          |                 | Not Reported |                |
|                                                         | Nicorandil                                     |                    |                    | C               | Oral                 | 2 Df                          |                 | Not Reported |                |
|                                                         | Lamaline<br>(Acetaminophen\Caffeine\Opium<br>) |                    |                    | C               |                      | If Pain 4 Df Daily            |                 | Not Reported |                |
|                                                         | Lovenox                                        |                    |                    | C               | Subcutaneous         | 8000 Iu/0.8 MI Daily          |                 | Not Reported |                |
|                                                         | Augmentin                                      |                    |                    | C               |                      | 2 Grams Then 3 Grams<br>Daily |                 | Not Reported |                |
|                                                         | Lasilix Retard                                 |                    |                    | C               | Oral                 | 1 Df                          |                 | Not Reported |                |
|                                                         | Allopurinol                                    |                    |                    | C               | Oral                 | 1 Df                          |                 | Not Reported |                |
|                                                         | Sotalol                                        |                    |                    | C               | Oral                 | 0.5 Df                        |                 | Not Reported |                |
|                                                         | Ramipril                                       |                    |                    | C               | Oral                 | 1 Df                          |                 | Not Reported |                |
|                                                         | Urapidil                                       |                    |                    | C               | Oral                 | 2 Df                          |                 | Not Reported |                |
|                                                         | Pantoprazole                                   |                    |                    | C               |                      | 1 Df                          |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                 | <u>Case #</u>          | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|------------------------------------------------------------------------------------------|------------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 05-Nov-2014                                                                              | 10567700               | DIRECT           |                    | DS              |                      |                      | 60 YR           | Male       | USA            |
| <u>Preferred Term</u>                                                                    | <u>Product</u>         | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Crying; Drug Ineffective;<br>Hypersomnia; Living<br>Alone; Product<br>Substitution Issue | Escitalopram 10mg Teva |                  |                    | S               | Oral                 |                      |                 | Teva       |                |

| <u>FDA Received Date</u>                                                      | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------|---------------------------------|--------------------|--------------------|-----------------|----------------------------|-----------------------------------|-----------------|--------------|----------------|
| 05-Nov-2014                                                                   | 10704776                        | EXPEDITED (15-DAY) |                    | OT              | US-APOTEX-<br>2014AP005482 |                                   | 62 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                         | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Drug<br>Interaction;<br>Encephalopathy;<br>Serotonin Syndrome | Escitalopram Oxalate            |                    |                    | S               | Unknown                    | Unk                               |                 | Apotex       |                |
|                                                                               | Methylthioninium Chloride       |                    |                    | S               | Unknown                    | 1 Mg/Kg, Two Consecutive<br>Doses |                 | Not Reported |                |
|                                                                               | Sodium Carbonate                |                    |                    | S               | Unknown                    | 50 Meq, Unk                       |                 | Not Reported |                |
|                                                                               | Aspirin                         |                    |                    | C               | Unknown                    | Unk                               |                 | Not Reported |                |
|                                                                               | Metoprolol                      |                    |                    | C               | Unknown                    | Unk                               |                 | Not Reported |                |
|                                                                               | Lisinopril                      |                    |                    | C               | Unknown                    | Unk                               |                 | Not Reported |                |
|                                                                               | Atorvastatin                    |                    |                    | C               | Unknown                    | Unk                               |                 | Not Reported |                |
|                                                                               | Furosemide                      |                    |                    | C               | Unknown                    | Unk                               |                 | Not Reported |                |
|                                                                               | Insulin                         |                    |                    | C               | Unknown                    | Unk                               |                 | Not Reported |                |
|                                                                               | Lamotrigine                     |                    |                    | C               | Unknown                    | Unk                               |                 | Not Reported |                |
|                                                                               | Ipratropium Bromide, Salbutamol |                    |                    | C               | Unknown                    | Unk                               |                 | Not Reported |                |
|                                                                               | Nitroglycerin                   |                    |                    | C               | Sublingual                 | Unk                               |                 | Not Reported |                |
|                                                                               | Midazolam                       |                    |                    | C               | Unknown                    |                                   |                 | Not Reported |                |
|                                                                               | Fentanyl                        |                    |                    | C               | Unknown                    |                                   |                 | Not Reported |                |
|                                                                               | Vecuronium Bromide              |                    |                    | C               | Unknown                    |                                   |                 | Not Reported |                |
|                                                                               | Isoflurane                      |                    |                    | C               | Unknown                    |                                   |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|               |   |         |                |              |
|---------------|---|---------|----------------|--------------|
| Phenylephrine | C | Unknown | 40 Mg, Unk     | Not Reported |
| Phenylephrine | C | Other   | 120mcg/Min     | Not Reported |
| Vasopressin   | C | Other   | 0.04 Units/Min | Not Reported |
| Propofol      | C | Other   |                | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------|----------------------|------------|------------|----------------|
| 06-Nov-2014              | 10421171      | EXPEDITED (15-DAY) |                    | DS, HO          | FR-AUROBINDO-AUR-<br>APL-2014-09144 |                      | 51 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                                                 | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Epilepsy; Injury; Loss Of Consciousness; Malaise; Product Substitution Issue; Vertigo | Escitalopram Arrow 10 Mg |              |            | S           | Oral         | 10 Mg, Once A Day  |                 | Aurobindo    |
|                                                                                       | Escitalopram Arrow 10 Mg |              |            | S           | Oral         | 7.5 Mg, Daily      |                 | Aurobindo    |
|                                                                                       | Depakine Chrono          |              |            | C           | Unknown      | 2 Df, Once A Day   |                 | Not Reported |
|                                                                                       | Stablon                  |              |            | C           | Unknown      | Unk                |                 | Not Reported |
|                                                                                       | Seroplex                 |              |            | C           | Unknown      | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Nov-2014              | 10569145      | EXPEDITED (15-DAY) |                    | HO              | PHHY2014CH142254     |                      | 80 YR      | Male       | CHE            |

| <u>Preferred Term</u>                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Diarrhoea Haemorrhagic; Lower Gastrointestinal Haemorrhage | Exelon Patch   |              |            | S           | Transdermal  | 18 Mg, Unk         |                 | Novartis     |
|                                                            | Aspirin Bayer  |              |            | S           | Oral         | 100 Mg, Qd         |                 | Not Reported |
|                                                            | Cipralex /Den/ |              |            | S           | Oral         | 0.5 Df, Qd         |                 | Not Reported |
|                                                            | Pantoprazol    |              |            | C           | Unknown      | 40 Mg, Qd          |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Nov-2014              | 10570178      | DIRECT           |                    | OT              |                      |                      | 60 YR      | Female     | USA            |

| <u>Preferred Term</u>                                          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u> |
|----------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|------------------------------------|-----------------|------------|
| Depressed Mood; Depression; Hypophagia; Impaired Work Ability; | Escitalopram   |              |            | S           | Oral         | 1 Pill, Once Daily, Taken By Mouth |                 | Torrent    |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Mental Impairment;  
Product Substitution Issue;  
Social Problem;  
Somnolence; Suicidal  
Ideation

| <u>FDA Received Date</u>           | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------|----------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 07-Nov-2014                        | 9665374        | EXPEDITED (15-DAY) |                    | OT              | CH-JNJFOC-20131019132 |                      | 34 YR           | Female       | CHE            |
| <u>Preferred Term</u>              | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Maternal Exposure During Pregnancy | Ibuprofen      |                    |                    | S               | Unknown               |                      |                 | Not Reported |                |
|                                    | Zaldiar        |                    |                    | S               | Unknown               |                      |                 | Not Reported |                |
|                                    | Ketoprofen     |                    |                    | S               | Unknown               |                      |                 | Not Reported |                |
|                                    | Ciprofloxacin  |                    |                    | S               | Unknown               |                      |                 | Not Reported |                |
|                                    | Stilnox        |                    |                    | S               | Unknown               |                      |                 | Not Reported |                |
|                                    | Cipralext      |                    |                    | S               | Unknown               |                      |                 | Not Reported |                |
|                                    | Pristinamycin  |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |
|                                    | Augmentin      |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |
|                                    | Dafalgan       |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>           | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Nov-2014                        | 10571787       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000072210     |                      | 86 YR           | Female       | FRA            |
| <u>Preferred Term</u>              | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Somnolence       | Escitalopram   |                    |                    | S               | Oral                  | 1 Df                 |                 | Forest       |                |
|                                    | Loxapac        |                    |                    | S               | Oral                  | 13 Df                |                 | Not Reported |                |
|                                    | Loxapac        |                    |                    | S               | Oral                  | 9 Df                 |                 | Not Reported |                |
|                                    | Alprazolam     |                    |                    | S               |                       | 0.75 Mg              |                 | Not Reported |                |
|                                    | Alprazolam     |                    |                    | S               |                       | 1 Df                 |                 | Not Reported |                |
|                                    | Risperidone    |                    |                    | S               | Oral                  | 1.5 Mg               |                 | Not Reported |                |
|                                    | Risperidone    |                    |                    | S               |                       | 1 Mg                 |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                |   |                                          |              |
|----------------|---|------------------------------------------|--------------|
| Ebixa          | C | 1 Df                                     | Not Reported |
| Spironolactone | C | 1 Df                                     | Not Reported |
| Uvedose        | C | 1 Ampoule (100,000 Iu)<br>Every 3 Months | Not Reported |
| Lumigan        | C | 1 Drop Daily In Each Eye                 | Not Reported |

| <u>FDA Received Date</u>                                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| 07-Nov-2014                                                | 10572137       | EXPEDITED (15-DAY) |                    | HO              | DE-ASTRAZENECA-2014SE83461 |                      | 76 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Pressure Decreased; Orthostatic Intolerance; Syncope | Seroquel       |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                            | Seroquel       |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                            | Escitalopram   |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                            | Ass            |                    |                    | C               | Oral                       |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 07-Nov-2014              | 10573083       | DIRECT           |                    | OT              |                      |                      | 18 YR           | Female       |                |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alopecia; Alopecia       | Escitalopram   |                  |                    | S               | Oral                 | 1 Pill               |                 | Not Reported |                |

| <u>FDA Received Date</u>                                      | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 07-Nov-2014                                                   | 10573215       | DIRECT           |                    |                 |                      |                      | 27 YR           | Male       | USA            |
| <u>Preferred Term</u>                                         | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Amnesia; Feeling Abnormal; Feeling Abnormal; Thought Blocking | Escitalopram   |                  |                    | S               | Oral                 | 1 Pill               |                 | Forest     |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u>                         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|-------------------------|----------------------------------------------|-----------------|--------------|----------------|
| 10-Nov-2014                                                                                             | 10366721             | EXPEDITED (15-DAY) |                    | HO              | IT-MERCK-1408ITA001723  |                                              | 40 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                                                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>                           | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Abuse; Tachycardia                                                                                 | Mirtazapine          |                    |                    | S               | Oral                    | 300 Mg, Once                                 |                 | Merck        |                |
|                                                                                                         | Mirtazapine          |                    |                    | S               |                         |                                              |                 | Merck        |                |
|                                                                                                         | Escitalopram Oxalate |                    |                    | S               | Oral                    | 15 MI, Once                                  |                 | Not Reported |                |
|                                                                                                         | Escitalopram Oxalate |                    |                    | S               |                         |                                              |                 | Not Reported |                |
|                                                                                                         | Entact               |                    |                    | C               | Oral                    |                                              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u>                         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Nov-2014                                                                                             | 10572871             | EXPEDITED (15-DAY) |                    | HO              | CA-RANBAXY-2014US-77290 |                                              | 83 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                                                                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>                           | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Depressed Mood; Dizziness; Fall; Hypotension; Orthostatic Hypotension; Pain; Visual Impairment | Amlodipine           |                    |                    | S               | Unknown                 | 2.5 Mg, Bid                                  |                 | Ranbaxy      |                |
|                                                                                                         | Furosemide           |                    |                    | S               | Unknown                 | 40 Mg, Every Morning                         |                 | Ipca         |                |
|                                                                                                         | Escitalopram         |                    |                    | S               | Unknown                 | 10 Mg, Qd (Am)                               |                 | Not Reported |                |
|                                                                                                         | Escitalopram         |                    |                    | S               |                         |                                              |                 | Not Reported |                |
|                                                                                                         | Metoprolol           |                    |                    | S               | Unknown                 | 25 Mg, Bid                                   |                 | Ipca         |                |
|                                                                                                         | Metoprolol           |                    |                    | S               |                         |                                              |                 | Ipca         |                |
|                                                                                                         | Zopiclone            |                    |                    | S               | Unknown                 | 5 Mg, Qd (Bed Time)                          |                 | Not Reported |                |
|                                                                                                         | Nitroglycerin        |                    |                    | S               | Transdermal             | 2 On At 9 Am And Off At 10 Pm, Rotating Site |                 | Not Reported |                |
|                                                                                                         | Oxazepam             |                    |                    | S               | Unknown                 | 2 Df, Qd (Bed Time)                          |                 | Not Reported |                |
|                                                                                                         | Atorvastatin         |                    |                    | C               | Unknown                 | 80 Mg (Bed Time)                             |                 | Not Reported |                |
|                                                                                                         | Atorvastatin         |                    |                    | C               |                         |                                              |                 | Not Reported |                |
|                                                                                                         | Atorvastatin         |                    |                    | C               |                         |                                              |                 | Not Reported |                |
|                                                                                                         | Acetaminophen        |                    |                    | C               | Unknown                 | 500 Mg, Qid                                  |                 | Not Reported |                |
|                                                                                                         | Clopidogrel          |                    |                    | C               | Unknown                 | 75 Mg, Qd (Every Morning)                    |                 | Not Reported |                |
|                                                                                                         | Clopidogrel          |                    |                    | C               |                         |                                              |                 | Not Reported |                |
|                                                                                                         | Clopidogrel          |                    |                    | C               |                         |                                              |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                            |   |         |                           |              |
|----------------------------|---|---------|---------------------------|--------------|
| Codeine, Acetaminophen     | C | Unknown | 30 Mg, Twice Daily, Prn   | Not Reported |
| Hydroxychloroquine Sulfate | C | Unknown | 200 Mg, Qd (Supper)       | Not Reported |
| Pantoprazole               | C | Unknown | 40 Mg, Qd (Every Morning) | Not Reported |
| Polyethylene Glycol        | C | Unknown | Unk, Prn                  | Not Reported |
| Ramipril                   | C | Unknown | 5 Mg, Qd (Every Morning)  | Not Reported |
| Nitroglycerin              | C | Unknown | Unk, Prn                  | Not Reported |
| Vitamin D Nos              | C | Unknown | 1000 Iu (Daily)           | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Nov-2014              | 10573461      | EXPEDITED (15-DAY) |                    | HO              | IT-TEVA-519861ISR    |                      | 69 YR      | Female     | ITA            |

| <u>Preferred Term</u>    | <u>Product</u>                       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|--------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Bradycardia; Hypotension | Lorazepam                            |              |            | S           | Oral         |                    |                 | Ivax         |
|                          | Cipralex - H. Lundbeck A/S           |              |            | S           | Oral         |                    |                 | Not Reported |
|                          | Olmesartan Medoxomil                 |              |            | S           | Oral         |                    |                 | Not Reported |
|                          | Eutirox                              |              |            | C           |              |                    |                 | Not Reported |
|                          | Formistin (Cetirizine Hydrochloride) |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Nov-2014              | 10574334      | EXPEDITED (15-DAY) |                    | OT              | US-TEVA-520232USA    |                      | 62 YR      | Male       | USA            |

| <u>Preferred Term</u>                | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                             | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------|---------------------------|--------------|------------|-------------|--------------|------------------------------------------------|-----------------|--------------|
| Drug Interaction; Serotonin Syndrome | Escitalopram              |              |            | S           | Unknown      |                                                |                 | Ivax         |
|                                      | Methylthioninium Chloride |              |            | S           | Unknown      | 1 Mg/Kg In 2 Consecutive Doses (Total 2 Mg/Kg) |                 | Not Reported |
|                                      | Aspirin                   |              |            | C           | Unknown      |                                                |                 | Not Reported |
|                                      | Metoprolol                |              |            | C           | Unknown      |                                                |                 | Not Reported |
|                                      | Lisinopril                |              |            | C           | Unknown      |                                                |                 | Not Reported |
|                                      | Atorvastatin              |              |            | C           | Unknown      |                                                |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |                                 |   |            |                |              |
|--|---------------------------------|---|------------|----------------|--------------|
|  | Furosemide                      | C | Unknown    |                | Not Reported |
|  | Insulin                         | C | Unknown    |                | Not Reported |
|  | Lamotrigine                     | C | Unknown    |                | Not Reported |
|  | Ipratropium Bromide, Salbutamol | C | Unknown    |                | Not Reported |
|  | Nitroglycerin                   | C | Sublingual | As Needed      | Not Reported |
|  | Midazolam                       | C | Unknown    |                | Not Reported |
|  | Fentanyl                        | C | Unknown    |                | Not Reported |
|  | Vecuronium Bromide              | C | Unknown    |                | Not Reported |
|  | Isoflurane                      | C | Unknown    |                | Not Reported |
|  | Phenylephrine                   | C | Unknown    | 40mg           | Not Reported |
|  | Phenylephrine                   | C | Other      | 120mcg/Min     | Not Reported |
|  | Vasopressin                     | C | Other      | 0.04 Units/Min | Not Reported |
|  | Propofol                        | C | Other      |                | Not Reported |

| <u>FDA Received Date</u>                                             | <u>Case #</u>                          | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                           | <u>Country</u> |
|----------------------------------------------------------------------|----------------------------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------------------------------|----------------|
| 10-Nov-2014                                                          | 10575766                               | DIRECT           |                    | LT, OT          |                      |                      | 60 YR           | Female                               | USA            |
| <u>Preferred Term</u>                                                | <u>Product</u>                         | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                           |                |
| Burning Sensation;<br>Dizziness; Dysstasia;<br>Hyperhidrosis; Nausea | Escitalopram<br>Oxybutynin<br>Prilosec |                  |                    | S<br>C<br>C     | Oral                 | By Mouth At Bedtime  |                 | Teva<br>Not Reported<br>Not Reported |                |

| <u>FDA Received Date</u>                                                                            | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 10-Nov-2014                                                                                         | 10575978       | DIRECT           |                    |                 |                      |                      | 40 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                               | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective;<br>Headache; Product<br>Quality Issue; Product<br>Substitution Issue;<br>Sedation | Escitalopram   |                  |                    | S               | Oral                 |                      |                 | Not Reported |                |



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| <u>FDA Received Date</u>                                                                                                                                                    | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|-------------------------------------|--------------------------|-----------------|--------------|----------------|
| 11-Nov-2014                                                                                                                                                                 | 9688343                     | EXPEDITED (15-DAY) |                    | LT              | US-DRREDDYS-<br>USA/USA/13/0035516  |                          | 29 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                       | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                        | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Brain Injury; Cardiac Arrest; Coma Scale Abnormal; Hypotension; Overdose; Pulseless Electrical Activity; Tachycardia                                                        | Quetiapine Fumarate Tablets |                    |                    | S               | Oral                                |                          |                 | Not Reported |                |
|                                                                                                                                                                             | Ibuprofen                   |                    |                    | S               | Oral                                |                          |                 | Not Reported |                |
|                                                                                                                                                                             | Desvenlafaxine              |                    |                    | S               | Oral                                |                          |                 | Not Reported |                |
|                                                                                                                                                                             | Escitalopram                |                    |                    | S               | Oral                                |                          |                 | Not Reported |                |
|                                                                                                                                                                             | Bupropion                   |                    |                    | S               | Unknown                             |                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                    | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Nov-2014                                                                                                                                                                 | 10574965                    | EXPEDITED (15-DAY) |                    | HO              | IT-AUROBINDO-AUR-<br>APL-2014-08418 |                          | 40 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                                                                                                                       | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                        | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Abuse; Tachycardia                                                                                                                                                     | Mirtazapine                 |                    |                    | S               | Oral                                | 300 Mg, Total            |                 | Aurobindo    |                |
|                                                                                                                                                                             | Escitalopram                |                    |                    | S               | Oral                                | 15 Ml, Single            |                 | Aurobindo    |                |
|                                                                                                                                                                             | Entact                      |                    |                    | C               | Unknown                             | 28, Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                    | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Nov-2014                                                                                                                                                                 | 10575035                    | EXPEDITED (15-DAY) |                    | HO, OT          | US-AUROBINDO-AUR-<br>APL-2014-11637 |                          | 62 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                       | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                        | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Drug Interaction; Encephalopathy; Hyperthermia; Hypotension; Muscle Rigidity; Nystagmus; Pupillary Reflex Impaired; Serotonin Syndrome; Vasoplegia Syndrome | Escitalopram                |                    |                    | S               | Unknown                             | Unk                      |                 | Aurobindo    |                |
|                                                                                                                                                                             | Methylene Blue              |                    |                    | S               | Unknown                             | 1 Mg/Kg, (Total 2 Mg/Kg) |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

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| <u>FDA Received Date</u>                                                                           | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|----------------------------|---------------------------|-----------------|--------------|----------------|
| 11-Nov-2014                                                                                        | 10577583                    | EXPEDITED (15-DAY) |                    | HO, OT          | DE-ASTRAZENECA-2014SE84162 |                           | 63 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                                                              | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain Upper;<br>Drug Interaction;<br>Headache;<br>Hyponatraemia;<br>Hypotension; Vomiting | Seroquel Xr                 |                    |                    | S               | Oral                       |                           |                 | Zeneca       |                |
|                                                                                                    | Seroquel Xr                 |                    |                    | S               | Oral                       |                           |                 | Zeneca       |                |
|                                                                                                    | Seroquel Xr                 |                    |                    | S               | Oral                       |                           |                 | Zeneca       |                |
|                                                                                                    | Seroquel Xr                 |                    |                    | S               | Oral                       |                           |                 | Zeneca       |                |
|                                                                                                    | Tegretal                    |                    |                    | S               | Oral                       |                           |                 | Not Reported |                |
|                                                                                                    | Tegretal                    |                    |                    | S               | Oral                       |                           |                 | Not Reported |                |
|                                                                                                    | Tegretal                    |                    |                    | S               | Oral                       |                           |                 | Not Reported |                |
|                                                                                                    | Tegretal                    |                    |                    | S               | Oral                       |                           |                 | Not Reported |                |
|                                                                                                    | Tegretal                    |                    |                    | S               | Oral                       |                           |                 | Not Reported |                |
|                                                                                                    | Tegretal                    |                    |                    | S               | Oral                       |                           |                 | Not Reported |                |
|                                                                                                    | Tegretal                    |                    |                    | S               | Oral                       |                           |                 | Not Reported |                |
|                                                                                                    | Ramipril                    |                    |                    | S               | Oral                       |                           |                 | Not Reported |                |
|                                                                                                    | Hydrochlorothiazid (Non Az) |                    |                    | S               | Oral                       |                           |                 | Not Reported |                |
|                                                                                                    | Ciprallex                   |                    |                    | S               | Oral                       |                           |                 | Not Reported |                |
|                                                                                                    | Simvastatin                 |                    |                    | C               | Oral                       |                           |                 | Not Reported |                |
|                                                                                                    | Metoprolol                  |                    |                    | C               | Oral                       |                           |                 | Not Reported |                |
|                                                                                                    | Vesikur                     |                    |                    | C               | Oral                       |                           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                           | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Nov-2014                                                                                        | 10578619                    | DIRECT             |                    | DS              |                            |                           | 60 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                              | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Depression;<br>Irritability; Malaise                                                      | Escitalopram                |                    |                    | S               | Oral                       | Once Daily Taken By Mouth |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

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| <u>FDA Received Date</u>                                                   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 11-Nov-2014                                                                | 10578678       | DIRECT           |                    |                 |                      |                      | 60 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                      | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated;<br>Disease Recurrence;<br>Product Substitution Issue | Escitalopram   |                  |                    | S               |                      | 1 1/2                |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 12-Nov-2014                                                                         | 10578792             | EXPEDITED (15-DAY) |                    | DE, LT, OT      | IE-JNJFOC-20141102841 |                      | 89 YR           | Female       | IRL            |
| <u>Preferred Term</u>                                                               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dysphagia;<br>Gastrointestinal<br>Haemorrhage;<br>Pneumonia; Sepsis;<br>Tachycardia | Xarelto              |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                     | Xarelto              |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                     | Lexapro              |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                     | Paracetamol          |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |
|                                                                                     | Metoprolol Tartrate  |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |
|                                                                                     | Cordarone            |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |
|                                                                                     | Galfer               |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |
|                                                                                     | Atorvastatin Calcium |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |
|                                                                                     | Cozaar               |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |
|                                                                                     | Protium              |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |
|                                                                                     | Protium              |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |
|                                                                                     | Zimovane             |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |
|                                                                                     | Lanoxin              |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|------------|----------------|
| 12-Nov-2014              | 10579328       | EXPEDITED (15-DAY) |                    | OT              | DE-JNJFOC-20141101332 |                      | 31 YR           | Female     | DEU            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

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| Chest Discomfort;<br>Palpitations; Ventricular<br>Extrasystoles                                                           | Risperdal      | S                  | Oral               | Not Reported    |                            |                                          |                 |              |                |
|---------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------------|------------------------------------------|-----------------|--------------|----------------|
|                                                                                                                           | Escitalopram   | S                  | Oral               | Not Reported    |                            |                                          |                 |              |                |
| <u>FDA Received Date</u>                                                                                                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Nov-2014                                                                                                               | 10704742       | EXPEDITED (15-DAY) |                    | HO              | AU-APOTEX-<br>2014AP003715 |                                          | 16 YR           | Female       | AUS            |
| <u>Preferred Term</u>                                                                                                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Behaviour                                                                                                        | Escitalopram   |                    |                    | S               |                            | 10 Mg Qd                                 |                 | Apotex       |                |
| <u>FDA Received Date</u>                                                                                                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Nov-2014                                                                                                               | 10103775       | EXPEDITED (15-DAY) |                    | DS              | CA-FRI-1000066808          |                                          | 57 YR           | Male         | CAN            |
| <u>Preferred Term</u>                                                                                                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Alcohol Increased;<br>Drug Interaction; Fatigue;<br>Feeling Drunk;<br>Haemochromatosis;<br>Impaired Driving Ability | Escitalopram   |                    |                    | S               | Oral                       |                                          |                 | Forest       |                |
|                                                                                                                           | Escitalopram   |                    |                    | S               |                            |                                          |                 | Forest       |                |
|                                                                                                                           | Alcohol        |                    |                    | S               | Oral                       | Took 5-6 Beers Of 33<br>Centiliters Each |                 | Not Reported |                |
|                                                                                                                           | Vimovo         |                    |                    | C               |                            | 200mg /50 Mg                             |                 | Not Reported |                |
|                                                                                                                           | Apo-Oxazepam   |                    |                    | C               |                            | Dose Not Reported.                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Nov-2014                                                                                                               | 10329288       | EXPEDITED (15-DAY) |                    | OT              | CA-FRI-1000068980          |                                          | 49 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                                                                                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>   |                |
| Diarrhoea; Drug<br>Ineffective; Dyskinesia;<br>Serotonin Syndrome;<br>Tachycardia; Toxicity To<br>Various Agents          | Escitalopram   |                    |                    | S               | Oral                       | 20 Mg                                    |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Nov-2014                                                                                                               | 10329486       | EXPEDITED (15-DAY) |                    | HO, LT, OT      | CA-FRI-1000068984          |                                          | 44 YR           | Male         | CAN            |

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| <u>Preferred Term</u>                                                                                          | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
|----------------------------------------------------------------------------------------------------------------|----------------------------|--------------------|--------------------|-----------------|--------------------------|---------------------------------|-----------------|--------------|----------------|
| Cerebrovascular Accident;<br>Mobility Decreased                                                                | Escitalopram               |                    |                    | S               | Oral                     | 10 Mg                           |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                       | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Nov-2014                                                                                                    | 10329558                   | NON-EXPEDITED      |                    | DS              | CA-FRI-1000068986        |                                 | 45 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                                                                          | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Disturbance In Attention;<br>Somnolence                                                                        | Escitalopram               |                    |                    | S               | Oral                     | 10 Mg                           |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                       | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Nov-2014                                                                                                    | 10329911                   | EXPEDITED (15-DAY) |                    | OT              | CA-FRI-1000069031        |                                 | 32 YR           | Male         | CAN            |
| <u>Preferred Term</u>                                                                                          | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Pericarditis                                                                                                   | Escitalopram               |                    |                    | S               | Oral                     | 10 Mg                           |                 | Forest       |                |
|                                                                                                                | Colchicine                 |                    |                    | C               |                          | 0.6 Mg (Frequency Not Reported) |                 | Not Reported |                |
|                                                                                                                | Tamsulosin Cr              |                    |                    | C               |                          | 0.4 Mg (Frequency Not Reported) |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                       | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Nov-2014                                                                                                    | 10581811                   | EXPEDITED (15-DAY) |                    | OT              | DE-FRI-1000072302        |                                 |                 | Female       | DEU            |
| <u>Preferred Term</u>                                                                                          | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Glucose Increased;<br>Diabetes Mellitus<br>Inadequate Control;<br>Therapeutic Product Effect<br>Variable | Escitalopram Oral Solution |                    |                    | S               | Oral                     |                                 |                 | Forest       |                |
|                                                                                                                | Insulin Analogues          |                    |                    | C               | Intramuscular            |                                 |                 | Not Reported |                |
|                                                                                                                | Antidepressants            |                    |                    | C               |                          |                                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                       | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Nov-2014                                                                                                    | 10582223                   | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-2014311285 |                                 | 49 YR           | Female       | USA            |

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| <u>Preferred Term</u>                                                                                   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                                                          | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------------|-----------------------------------------------------------------------------|-----------------|--------------|----------------|
| Blood Cholesterol Increased; Dry Mouth; Oropharyngeal Pain; Type 2 Diabetes Mellitus; Visual Impairment | Lyrica         |                    |                    | S               |                            | 300 Mg, 2x/Day                                                              |                 | Pfizer       |                |
|                                                                                                         | Effexor Xr     |                    |                    | S               |                            | 225 Mg, Daily (75mg Capsule And A 150mg Capsule Together)                   |                 | Pfizer       |                |
|                                                                                                         | Ibuprofen      |                    |                    | S               |                            | 800mg In The Morning And 1200                                               |                 | Pfizer       |                |
|                                                                                                         | Metformin Hcl  |                    |                    | S               |                            | 100 Mg, Daily                                                               |                 | Pfizer       |                |
|                                                                                                         | Simvastatin    |                    |                    | S               |                            | 40 Mg, Unk                                                                  |                 | Not Reported |                |
|                                                                                                         | Valium         |                    |                    | S               |                            | 5 Mg, 3x/Day                                                                |                 | Not Reported |                |
|                                                                                                         | Aspirin        |                    |                    | S               |                            | 162 Mg, 1x/Day (81mg 2 Tablets At Night)                                    |                 | Not Reported |                |
|                                                                                                         | Tizanidine     |                    |                    | S               |                            | 8 Mg, 3x/Day                                                                |                 | Not Reported |                |
|                                                                                                         | Seroquel       |                    |                    | S               |                            | 50mg Twice Daily In The Morning And Noon, And 200mg At Nightunk Unk, 3x/Day |                 | Not Reported |                |
|                                                                                                         | Seroquel       |                    |                    | S               |                            |                                                                             |                 | Not Reported |                |
|                                                                                                         | Lexapro        |                    |                    | S               |                            | 20 Mg, 1x/Day                                                               |                 | Not Reported |                |
|                                                                                                         | Topamax        |                    |                    | S               |                            | 100 Mg, Daily (Daily In The Morning )                                       |                 | Not Reported |                |
|                                                                                                         | Demadex        |                    |                    | S               |                            | 20 Mg, Daily                                                                |                 | Not Reported |                |
|                                                                                                         | Fentanyl       |                    |                    | S               |                            | 50 Mg, Every 48 Hours                                                       |                 | Not Reported |                |
|                                                                                                         | Oxycodone Apap |                    |                    | S               |                            | 10/325mg 1 Of Them 3 Times Daily As Needed                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                                                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Nov-2014                                                                                             | 10582443       | EXPEDITED (15-DAY) |                    | HO              | FR-ASTRAZENECA-2014SE84611 |                                                                             |                 | Female       | FRA            |
| <u>Preferred Term</u>                                                                                   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                                                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Fall; Hypokalaemia; Hyponatraemia                                                                       | Inexium        |                    |                    | S               | Oral                       |                                                                             |                 | Astrazeneca  |                |
|                                                                                                         | Fortzaar       |                    |                    | S               | Oral                       |                                                                             |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |             |   |      |              |
|--|-------------|---|------|--------------|
|  | Seroplex    | S | Oral | Not Reported |
|  | Seroplex    | S | Oral | Not Reported |
|  | Logimax     | C |      | Not Reported |
|  | Paracetamol | C |      | Not Reported |
|  | Pravastatin | C |      | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Nov-2014              | 10582512      | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000072337    |                      | 35 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                             | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------|--------------------|--------------|------------|-------------|--------------|---------------------------------|-----------------|--------------|
| Hyperhidrosis; Medication Error; Nausea; Product Dispensing Error | Escitalopram       |              |            | S           | Unknown      | 30 Mg                           |                 | Forest       |
|                                                                   | Seresta            |              |            | C           | Unknown      | 30 Mg/ Day Plus 10 Mg If Needed |                 | Not Reported |
|                                                                   | Efferalgan Codeine |              |            | C           | Unknown      |                                 |                 | Not Reported |
|                                                                   | Imovane            |              |            | C           | Unknown      |                                 |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Nov-2014              | 10329543      | EXPEDITED (15-DAY) |                    | OT              | CA-FRI-1000068985    |                      | 26 YR      | Female     | CAN            |

| <u>Preferred Term</u>                                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Chills; Insomnia; Somnolence; Suicidal Ideation; Tremor | Escitalopram   |              |            | S           | Oral         | 10 Mg              |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Nov-2014              | 10583878      | EXPEDITED (15-DAY) |                    | HO, LT          | FR-FRI-1000072344    |                      | 78 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Bradycardia; Drug Interaction; Electrocardiogram Qt Prolonged; Malaise | Escitalopram   |              |            | S           | Oral         | 1 Df Dosage Form   |                 | Forest       |
|                                                                        | Cordarone      |              |            | S           | Oral         | 1 Df Dosage Form   |                 | Not Reported |
|                                                                        | Zofenilduo     |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                            | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------|-----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 14-Nov-2014                                                                         | 10585205        | EXPEDITED (15-DAY) |                    | OT              | DE-FRI-1000072300    |                      |                 | Female       | DEU            |
| <u>Preferred Term</u>                                                               | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alopecia; Nocturia;<br>Oedema Peripheral                                            | Escitalopram    |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                                                                     | Olanzapin       |                    |                    | S               | Oral                 | 2.5 Mg               |                 | Not Reported |                |
|                                                                                     | Quilonum Retard |                    |                    | S               | Oral                 | 450 Mg               |                 | Not Reported |                |
|                                                                                     | Quilonum Retard |                    |                    | S               | Oral                 | 675 Mg               |                 | Not Reported |                |
|                                                                                     | Quilonum Retard |                    |                    | S               | Oral                 | 900 Mg               |                 | Not Reported |                |
|                                                                                     | Quilonum Retard |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                            | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Nov-2014                                                                         | 10585767        | EXPEDITED (15-DAY) |                    | DE, LT          | IE-FRI-1000072258    |                      | 89 YR           | Female       | IRL            |
| <u>Preferred Term</u>                                                               | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dysphagia;<br>Gastrointestinal<br>Haemorrhage;<br>Pneumonia; Sepsis;<br>Tachycardia | Lexapro         |                    |                    | S               | Sublingual           | 10 Mg                |                 | Forest       |                |
|                                                                                     | Xarelto         |                    |                    | S               | Oral                 | 15 Mg                |                 | Not Reported |                |
|                                                                                     | Lanoxin Pg      |                    |                    | C               |                      | 62.5 Mcg             |                 | Not Reported |                |
|                                                                                     | Metoprolol      |                    |                    | C               | Oral                 | 50 Mg                |                 | Not Reported |                |
|                                                                                     | Cordarone X     |                    |                    | C               | Oral                 | 100 Mg               |                 | Not Reported |                |
|                                                                                     | Paracetamol     |                    |                    | C               |                      | 4 Mg                 |                 | Not Reported |                |
|                                                                                     | Atorvastatin    |                    |                    | C               |                      | 10 Mg                |                 | Not Reported |                |
|                                                                                     | Cozaar          |                    |                    | C               |                      | 25 Mg                |                 | Not Reported |                |
|                                                                                     | Protium         |                    |                    | C               |                      | 40 Mg                |                 | Not Reported |                |
|                                                                                     | Zimovane        |                    |                    | C               |                      | 3.75 Mg              |                 | Not Reported |                |
|                                                                                     | Galfer          |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                            | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Nov-2014                                                                         | 10586872        | DIRECT             |                    |                 |                      |                      | 52 YR           | Female       | USA            |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                                                                                                     | <u>Product</u>                                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>                                        | <u>Duration</u> | <u>Mfr</u>   |                |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------|--------------------|--------------------|-----------------|---------------------------------|-----------------------------------------------------------|-----------------|--------------|----------------|
| Depressed Mood; Listless; Malaise; Malaise; Product Physical Issue; Product Quality Issue; Tremor                                                         | Escitalopram 10 Mg. Teva                              |                    |                    | S               | Oral                            | 1.5 Pills, Once Daily, Taken By Mouth                     |                 | Teva         |                |
| <u>FDA Received Date</u>                                                                                                                                  | <u>Case #</u>                                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u>                                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Nov-2014                                                                                                                                               | 10589558                                              | EXPEDITED (15-DAY) | Y                  | HO, OT          | US-ZYDUS-005491                 |                                                           | 62 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                     | <u>Product</u>                                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>                                        | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Drug Interaction; Encephalopathy; Hypotension; Pulseless Electrical Activity; Serotonin Syndrome; Systemic Inflammatory Response Syndrome | Escitalopram (Escitalopram)                           |                    |                    | S               |                                 |                                                           | 1 DAY           | Not Reported |                |
|                                                                                                                                                           | Methylthioninium Chloride (Methylthioninium Chloride) |                    |                    | S               |                                 |                                                           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                  | <u>Case #</u>                                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u>                                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Nov-2014                                                                                                                                               | 10586019                                              | EXPEDITED (15-DAY) |                    | OT              | US-AUROBINDO-AUR-APL-2014-12046 |                                                           | 49 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                     | <u>Product</u>                                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>                                        | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Cholesterol Increased; Dry Mouth; Oropharyngeal Pain; Type 2 Diabetes Mellitus; Visual Impairment                                                   | Metformin                                             |                    |                    | S               | Unknown                         | 100 Mg, Daily                                             |                 | Aurobindo    |                |
|                                                                                                                                                           | Simvastatin 40mg                                      |                    |                    | S               | Unknown                         | 40 Mg, Unk                                                |                 | Aurobindo    |                |
|                                                                                                                                                           | Lyrica                                                |                    |                    | S               | Unknown                         | 300 Mg, Two Times A Day                                   |                 | Not Reported |                |
|                                                                                                                                                           | Effexor Xr                                            |                    |                    | S               | Unknown                         | 225 Mg (75mg Capsule And A 150mg Capsule Together), Daily |                 | Not Reported |                |
|                                                                                                                                                           | Ibuprofen                                             |                    |                    | S               | Unknown                         | 800mg In The Morning And 1200, Daily                      |                 | Not Reported |                |
|                                                                                                                                                           | Valium /00017001/                                     |                    |                    | S               | Unknown                         | 5 Mg, 3 Times A Day                                       |                 | Not Reported |                |
|                                                                                                                                                           | Aspirin                                               |                    |                    | S               | Unknown                         | 162 Mg (81 Mg 2 Tablets At Night), Once A Day             |                 | Not Reported |                |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                      |   |         |                                                                         |              |
|----------------------|---|---------|-------------------------------------------------------------------------|--------------|
| Tizanidine           | S | Unknown | 8 Mg, 3 Times A Day                                                     | Not Reported |
| Seroquel             | S | Unknown | 300 Mg, Daily (50mg Twice Daily In The Morning And Noon 200mg At Night) | Not Reported |
| Seroquel             | S |         |                                                                         | Not Reported |
| Lexapro              | S | Unknown | 20 Mg, Once A Day                                                       | Not Reported |
| Topamax              | S | Unknown | 100 Mg, Every Morning                                                   | Not Reported |
| Demadex /01036501/   | S | Unknown | 20 Mg, Daily                                                            | Not Reported |
| Fentanyl             | S | Unknown | 50 Unk, Every 48 Hours, Unk                                             | Not Reported |
| Oxycodone /00045603/ | S | Unknown | 10/325mg 1 Of Them 3 Times Daily As Needed                              | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Nov-2014              | 9772468       | EXPEDITED (15-DAY) | Y                  | OT              | 2013-US-003939       |                      | 37 YR      | Female     | USA            |

| <u>Preferred Term</u>                                             | <u>Product</u>                      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------|-------------------------------------|--------------|------------|-------------|--------------|------------------------|-----------------|--------------|
| Drug Interaction; Headache; Pain In Extremity; Serotonin Syndrome | Xyrem                               |              |            | S           | Oral         | Dose Adjustments, Oral |                 | Not Reported |
|                                                                   |                                     |              |            |             | Oral         |                        |                 |              |
|                                                                   |                                     |              |            |             | Oral         |                        |                 |              |
|                                                                   |                                     |              |            |             | Oral         |                        |                 |              |
|                                                                   | Lexapro                             |              |            | S           | Oral         |                        |                 | Not Reported |
|                                                                   |                                     |              |            |             | Oral         |                        |                 |              |
|                                                                   | Tramadol                            |              |            | S           | Oral         |                        |                 | Not Reported |
|                                                                   | Vyvanse (Lisdexamfetamine Mesilate) |              |            | C           |              |                        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Nov-2014              | 10329093      | EXPEDITED (15-DAY) |                    | HO              | CA-FRI-1000068971    |                      | 83 YR      | Female     | CAN            |

| <u>Preferred Term</u>                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Abdominal Pain Upper; Balance Disorder; | Escitalopram   |              |            | S           |              | 10 Mg              |                 | Forest     |
|                                         | Escitalopram   |              |            | S           |              |                    |                 | Forest     |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                          |                     |   |             |                          |              |
|--------------------------|---------------------|---|-------------|--------------------------|--------------|
| Bradycardia; Dizziness;  | Amlodipine          | S |             | 5 Mg                     | Not Reported |
| Drug Ineffective; Fall;  | Amlodipine          | S |             | 2.5 Mg                   | Not Reported |
| Headache; Hypotension;   | Codeine Phosphate   | S |             | 90 Mg                    | Not Reported |
| Mobility Decreased;      | Codeine Phosphate   | S |             | 60 Mg                    | Not Reported |
| Nausea; Orthostatic      | Furosemide          | S |             | 40 Mg                    | Not Reported |
| Hypotension; Pain; Panic | Furosemide          | S |             | 20 Mg                    | Not Reported |
| Attack; Sleep Disorder   | Glyceryl Trinitrate | S | Transdermal | 0.8 Mg                   | Not Reported |
|                          | Glyceryl Trinitrate | S | Transdermal | 0.4 Mg                   | Not Reported |
|                          | Metoprolol          | S |             | 25 Mg                    | Not Reported |
|                          | Metoprolol          | S |             | 50 Mg                    | Not Reported |
|                          | Oxazepam            | S |             | 20 Mg                    | Not Reported |
|                          | Ramipril            | S |             | 5 Mg                     | Not Reported |
|                          | Zopiclone           | S |             | 5 Mg                     | Not Reported |
|                          | Zopiclone           | S |             | 2.5 Mg                   | Not Reported |
|                          | Vitamin C           | C |             | Daily Dose Not Reported. | Not Reported |
|                          | Pantoprazole        | C |             | Daily Dose Not Reported. | Not Reported |
|                          | Acetaminophen       | C |             | Daily Dose Not Reported. | Not Reported |
|                          | Atorvastatin        | C |             | Daily Dose Not Reported. | Not Reported |
|                          | Clopidogrel         | C |             | Daily Dose Not Reported. | Not Reported |
|                          | Vitamin D Nos       | C |             | Daily Dose Not Reported. | Not Reported |
|                          | Polyethylene Glycol | C |             | Daily Dose Not Reported. | Not Reported |
|                          | Rabeprazole         | C |             | Daily Dose Not Reported. | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Nov-2014              | 10329265      | EXPEDITED (15-DAY) |                    |                 | CA-FRI-1000068977    |                      | 57 YR      | Male       | CAN            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------------|-----------------|--------------|
| Tremor                | Escitalopram   |              |            | S           | Oral         | 10 Mg                    |                 | Forest       |
|                       | Escitalopram   |              |            | S           |              |                          |                 | Forest       |
|                       | Apo-Oxazepam   |              |            | C           |              | Daily Dose Not Reported. |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                  |                          |                           |                             |                          |                                                            |                               |                          |                     |                         |
|------------------------------------------------------------------|--------------------------|---------------------------|-----------------------------|--------------------------|------------------------------------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Vimovo                                                           |                          |                           | C                           |                          | 500/20 Mg                                                  |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>                              | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 17-Nov-2014                                                      | 10586321                 | EXPEDITED (15-DAY)        |                             | LT                       | GB-MACLEODS<br>PHARMACEUTICALS<br>US LTD-<br>MAC2014001463 |                               |                          | Unknown             | GBR                     |
| <a href="#">Preferred Term</a>                                   | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                                      | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Breast Hyperplasia;<br>Lobular Breast Carcinoma<br>In Situ       | Escitalopram 10mg Tablet |                           |                             | S                        | Oral                                                       | 10 Mg, Unk                    |                          | Macleods            |                         |
| <a href="#">FDA Received Date</a>                                | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>                              | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 17-Nov-2014                                                      | 10586323                 | EXPEDITED (15-DAY)        |                             | CA                       | GB-MACLEODS<br>PHARMACEUTICALS<br>US LTD-<br>MAC2014001467 |                               |                          | Unknown             | GBR                     |
| <a href="#">Preferred Term</a>                                   | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                                      | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Maternal Drugs Affecting<br>Foetus; Ventricular Septal<br>Defect | Escitalopram 20mg Tablet |                           |                             | S                        | Transplacental                                             | 20 Mg, Unk                    |                          | Macleods            |                         |
|                                                                  | Escitalopram 20mg Tablet |                           |                             | S                        |                                                            |                               |                          | Macleods            |                         |
| <a href="#">FDA Received Date</a>                                | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>                              | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 17-Nov-2014                                                      | 10586652                 | EXPEDITED (15-DAY)        |                             | LT                       | GB-AUROBINDO-AUR-<br>APL-2014-11948                        |                               | 50 YR                    | Female              | GBR                     |
| <a href="#">Preferred Term</a>                                   | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                                      | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Breast Hyperplasia;<br>Lobular Breast Carcinoma<br>In Situ       | Escitalopram 10 Mg       |                           |                             | S                        | Oral                                                       | 10 Mg, Unk                    |                          | Aurobindo           |                         |
| <a href="#">FDA Received Date</a>                                | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>                              | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 17-Nov-2014                                                      | 10588500                 | EXPEDITED (15-DAY)        |                             | HO                       | FR-SA-2014SA154059                                         |                               | 67 YR                    | Female              | FRA                     |
| <a href="#">Preferred Term</a>                                   | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                                      | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Abdominal Wall                                                   | Lovenox                  |                           |                             | S                        | Sunconjunctival                                            |                               |                          | Not Reported        |                         |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                   |                        |   |      |                           |  |              |
|-------------------------------------------------------------------|------------------------|---|------|---------------------------|--|--------------|
| Haematoma; Abdominal Wall Haematoma; Acute Kidney Injury; Anaemia | Kardegic               | S | Oral |                           |  | Not Reported |
|                                                                   | Previscan (Fluindione) | S | Oral |                           |  | Not Reported |
|                                                                   | Seroplex               | S | Oral |                           |  | Not Reported |
|                                                                   | Eupressyl              | C |      | 60 Mg                     |  | Not Reported |
|                                                                   | Levothyrox             | C |      | 100 Mcg, Divisible Tablet |  | Not Reported |
|                                                                   | Amlodipine             | C |      |                           |  | Not Reported |
|                                                                   | Valsartan              | C |      |                           |  | Not Reported |
|                                                                   | Esidrex                | C |      |                           |  | Not Reported |
|                                                                   | Esomeprazole           | C |      |                           |  | Not Reported |
|                                                                   | Haldol                 | C |      |                           |  | Not Reported |
|                                                                   | Seresta                | C |      | 50 Mg, Divisible Tablet   |  | Not Reported |
|                                                                   | Augmentin              | C |      |                           |  | Not Reported |

| <u>FDA Received Date</u>                             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 17-Nov-2014                                          | 10588559       | EXPEDITED (15-DAY) |                    | LT              | GB-TEVA-521895ISR    |                      | 50 YR           | Female     | GBR            |
| <u>Preferred Term</u>                                | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Breast Hyperplasia; Lobular Breast Carcinoma In Situ | Escitalopram   |                    |                    | S               | Oral                 |                      |                 | Ivax       |                |

| <u>FDA Received Date</u>                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 17-Nov-2014                                                    | 10588675       | EXPEDITED (15-DAY) |                    | HO, LT          | FR-FRI-1000072393    |                      | 91 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Ecchymosis; Melaena; Shock Haemorrhagic; Spontaneous Haematoma | Escitalopram   |                    |                    | S               | Oral                 | 5 Mg                 |                 | Forest       |                |
|                                                                | Pradaxa        |                    |                    | S               | Oral                 | 220 Mg               |                 | Not Reported |                |
|                                                                | Mono-Tildiem   |                    |                    | S               | Oral                 | 200 Mg               |                 | Not Reported |                |
|                                                                | Xanax          |                    |                    | C               | Oral                 | 0.5 Mg               |                 | Not Reported |                |
|                                                                | Dafalgan       |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Nov-2014              | 10589900      | DIRECT           |                    | OT              |                      |                      | 67 YR      | Female     | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                                                                 | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| Abdominal Pain Upper;<br>Condition Aggravated;<br>Dysstasia; Gait<br>Disturbance;<br>Gastrointestinal<br>Haemorrhage;<br>Haemoglobin Decreased;<br>Product Substitution Issue;<br>Withdrawal Syndrome | Escitalopram 20mg |                    |                    | S               |                              | 1/Day                |                 | Aurobindo    |                |
| <u>FDA Received Date</u>                                                                                                                                                                              | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Nov-2014                                                                                                                                                                                           | 10589213          | EXPEDITED (15-DAY) |                    | LT              | GB-ACCORD-027001             |                      | 50 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                                                                                                                                                 | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Lobular Breast Carcinoma<br>In Situ                                                                                                                                                                   | Escitalopram      |                    |                    | S               | Oral                         |                      |                 | Accord       |                |
| <u>FDA Received Date</u>                                                                                                                                                                              | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Nov-2014                                                                                                                                                                                           | 10590999          | EXPEDITED (15-DAY) |                    | OT              | 2014SP003637                 |                      | 334 DAY         | Male         | CHE            |
| <u>Preferred Term</u>                                                                                                                                                                                 | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Exposure During<br>Pregnancy; Premature<br>Baby                                                                                                                                                       | Latuda            |                    |                    | S               | Transplacental               |                      |                 | Not Reported |                |
|                                                                                                                                                                                                       | Abilify           |                    |                    | S               | Transplacental               |                      |                 | Not Reported |                |
|                                                                                                                                                                                                       | Cipralext         |                    |                    | S               | Transplacental               |                      |                 | Not Reported |                |
|                                                                                                                                                                                                       | Citalopram        |                    |                    | S               | Transplacental               |                      |                 | Not Reported |                |
|                                                                                                                                                                                                       | Edronax           |                    |                    | S               | Transplacental               |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                              | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Nov-2014                                                                                                                                                                                           | 10591571          | NON-EXPEDITED      |                    |                 | US-PFIZER INC-<br>2014317245 |                      | 64 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                 | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Insomnia; Tardive                                                                                                                                                                                     | Pristiq           |                    |                    | S               |                              | 50 Mg, 1x/Day        |                 | Pfizer       |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                          |                             |                    |                    |                 |                      |                      |                 |              |                |
|--------------------------|-----------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Dyskinesia; Tic          |                             | Escitalopram       |                    | S               |                      | 10 Mg, 1x/Day        |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Nov-2014              | 10595248                    | EXPEDITED (15-DAY) | Y                  | HO              | 2014HINLIT0995       |                      | 62 YR           | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiovascular Disorder; | Escitalopram (Escitalopram) |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Drug Interaction;        | Unknown                     |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Encephalopathy;          | Methylthioninium Chloride   |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Hyperthermia; Muscle     | Phenylephrine Unknown       |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Rigidity;                | Vasopressin                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Phaeochromocytoma;       | Propofol Infusion           |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Serotonin Syndrome       | Sodium Bicarbonate Unknown  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Norepinephrine Infusion     |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Nov-2014              | 10571983                    | EXPEDITED (15-DAY) |                    | HO              | CH-FRI-1000072214    |                      |                 | Male         | CHE            |
| <u>Preferred Term</u>    | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Diarrhoea Haemorrhagic;  | Escitalopram                |                    |                    | S               | Oral                 | 5 Mg                 |                 | Forest       |                |
| Lower Gastrointestinal   | Aspirin                     |                    |                    | S               | Oral                 | 100 Mg               |                 | Not Reported |                |
| Haemorrhage              | Exelon Patch                |                    |                    | S               | Transdermal          |                      |                 | Not Reported |                |
|                          | Pantoprazol                 |                    |                    | C               |                      | 40 Mg                |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Nov-2014              | 10593432                    | EXPEDITED (15-DAY) |                    | DE, OT          | FR-SA-2014SA156832   |                      | 85 YR           | Female       | FRA            |
| <u>Preferred Term</u>    | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Acute Kidney Injury;     | Prednisone                  |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
| Hypokalaemia;            | Lasilix                     |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
| Hyponatraemia;           | Cordarone                   |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
| International Normalised | Bisoce                      |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
| Ratio Increased; Torsade |                             |                    |                    |                 |                      |                      |                 |              |                |
| De Pointes; Ventricular  |                             |                    |                    |                 |                      |                      |                 |              |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|              |                        |   |      |                |              |
|--------------|------------------------|---|------|----------------|--------------|
| Fibrillation | Previscan (Fluindione) | S | Oral |                | Not Reported |
|              | Co Olmetec             | S | Oral |                | Not Reported |
|              | Seroplex               | S | Oral |                | Not Reported |
|              | Lercan                 | C | Oral | Strength: 10mg | Not Reported |
|              | Inexium                | C | Oral | Strength: 40mg | Not Reported |

| <u>FDA Received Date</u>                                                                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 19-Nov-2014                                                                                                    | 10594145       | EXPEDITED (15-DAY) |                    | HO              | US-FRI-1000072267    |                      | 12 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anger; Cyst; Drug Level Above Therapeutic; Headache; Mania; Off Label Use; Unevaluable Event; Weight Increased | Lexapro        |                    |                    | S               | Oral                 |                      |                 | Forest       |                |
|                                                                                                                | Abilify        |                    |                    | S               | Oral                 | 3 Mg                 |                 | Not Reported |                |

| <u>FDA Received Date</u>          | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------|----------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 20-Nov-2014                       | 10391456             | EXPEDITED (15-DAY) |                    | HO              | IT-MYLAN-2014M1001126 |                      |                 | Unknown      | ITA            |
| <u>Preferred Term</u>             | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Abuse; Overdose; Tachycardia | Mirtazapine          |                    |                    | S               | Oral                  | 300 Mg, Total        |                 | Not Reported |                |
|                                   | Escitalopram Oxalate |                    |                    | S               | Oral                  | 15 MI, Total         |                 | Not Reported |                |
|                                   | Entact               |                    |                    | C               |                       | Unk                  |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 20-Nov-2014                                                                                                            | 10472699       | EXPEDITED (15-DAY) |                    | OT              | US-FRI-1000070736    |                      | 88 YR           | Male       | USA            |
| <u>Preferred Term</u>                                                                                                  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Aphasia; Asthenia; Confusional State; Drug Ineffective; Dyspnoea; Dysstasia; Fatigue; Gait Disturbance; Hallucination; | Lexapro        |                    |                    | S               | Oral                 | 5mg                  |                 | Forest     |                |
|                                                                                                                        | Lexapro        |                    |                    | S               | Oral                 | 10mg                 |                 | Forest     |                |
|                                                                                                                        | Lexapro        |                    |                    | S               | Oral                 | 5mg                  |                 | Forest     |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|           |          |   |      |      |              |
|-----------|----------|---|------|------|--------------|
| Nightmare | Lexapro  | S | Oral | 10mg | Forest       |
|           | Lexapro  | S | Oral | 5mg  | Forest       |
|           | Rapaflo  | C |      |      | Not Reported |
|           | Timolol  | C |      |      | Not Reported |
|           | Travatan | C |      |      | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Nov-2014              | 10595147      | EXPEDITED (15-DAY) |                    | HO              | FR-UCBSA-2014018762  |                      | 55 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                                               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                          | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|---------------------------------------|-----------------------|-----------------|--------------|
| C-Reactive Protein Increased; Cholestasis; Hepatocellular Injury; Jaundice; Pyrexia | Kepra          |              |            | S           | Intravenous (not otherwise specified) | 500 Mg, 2x/Day (Bid)  |                 | Ucb          |
|                                                                                     | Augmentin      |              |            | S           | Intravenous (not otherwise specified) | 1 G, 3x/Day (Tid)     |                 | Not Reported |
|                                                                                     | Seresta        |              |            | S           | Oral                                  | 50 Mg, 3x/Day (Tid)   |                 | Not Reported |
|                                                                                     | Seroplex       |              |            | S           | Oral                                  | 20 G, Once Daily (Qd) |                 | Not Reported |
|                                                                                     | Nicobion       |              |            | S           | Oral                                  | 1 Df, 2x/Day (Bid)    |                 | Not Reported |
|                                                                                     | Tranxene       |              |            | S           | Intravenous (not otherwise specified) | Unk                   |                 | Not Reported |
|                                                                                     | Paracetamol    |              |            | S           | Intravenous (not otherwise specified) | Unk                   |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Nov-2014              | 10595796      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000072518    |                      | 51 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hypotension; Hypotonia; Intentional Overdose; Suicide Attempt | Escitalopram   |              |            | S           | Oral         | 20 Mg              |                 | Forest       |
|                                                               | Escitalopram   |              |            | S           | Oral         | Overdose: 400 Mg.  |                 | Forest       |
|                                                               | Lamotrigine    |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Nov-2014              | 10596022      | EXPEDITED (15-DAY) |                    | LT              | GB-FRI-1000072505    |                      | 50 YR      | Female     | GBR            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <a href="#">Preferred Term</a>                                       | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
|----------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Breast Hyperplasia;<br>Lobular Breast Carcinoma<br>In Situ           | Escitalopram            |                           |                             | S                        | Oral                          | 10 Mg                         |                          | Forest              |                         |
| <a href="#">FDA Received Date</a>                                    | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 20-Nov-2014                                                          | 10596374                | EXPEDITED (15-DAY)        |                             | CA                       | US-FRI-1000072487             |                               | < 1 DAY                  | Male                | USA                     |
| <a href="#">Preferred Term</a>                                       | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Hypospadias                                                          | Lexapro                 |                           |                             | S                        | Transplacental                |                               |                          | Forest              |                         |
| <a href="#">FDA Received Date</a>                                    | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 20-Nov-2014                                                          | 10596375                | EXPEDITED (15-DAY)        |                             | CA                       | US-FRI-1000072488             |                               | < 1 DAY                  | Female              | USA                     |
| <a href="#">Preferred Term</a>                                       | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Synostosis                                                           | Lexapro                 |                           |                             | S                        | Transplacental                |                               |                          | Forest              |                         |
| <a href="#">FDA Received Date</a>                                    | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 20-Nov-2014                                                          | 10596607                | EXPEDITED (15-DAY)        |                             | HO, LT                   | FR-BAUSCH-BL-2014-008711      |                               | 92 YR                    | Female              | FRA                     |
| <a href="#">Preferred Term</a>                                       | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Ecchymosis; Melaena;<br>Shock Haemorrhagic;<br>Spontaneous Haematoma | Mono-Tildiem            |                           |                             | S                        | Oral                          |                               |                          | Not Reported        |                         |
|                                                                      | Pradaxa                 |                           |                             | S                        | Oral                          |                               |                          | Not Reported        |                         |
|                                                                      | Seroplex                |                           |                             | S                        | Oral                          |                               |                          | Not Reported        |                         |
|                                                                      | Xanax                   |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
|                                                                      | Dafalgan                |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                    | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 20-Nov-2014                                                          | 10596667                | EXPEDITED (15-DAY)        |                             | DE, HO                   | FR-DSJP-DSE-2014-128994       |                               |                          | Unknown             | FRA                     |
| <a href="#">Preferred Term</a>                                       | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                        |                            |   |      |              |              |
|----------------------------------------------------------------------------------------|----------------------------|---|------|--------------|--------------|
| Acute Kidney Injury;                                                                   | Coolmetec 40 Mg/ 25 Mg     | S | Oral | 40/25 Mg, Qd | Not Reported |
| Hypokalaemia;                                                                          | Bisoprolol                 | S | Oral | 2.5 Mg, Qd   | Not Reported |
| Hyponatraemia;                                                                         | Previscan (Pentoxifylline) | S | Oral | 20 Mg, Unk   | Not Reported |
| International Normalised Ratio Increased; Torsade De Pointes; Ventricular Fibrillation | Prednisone                 | S | Oral |              | Not Reported |
|                                                                                        | Lasilix /00032601/         | S | Oral | 80 Mg, Qd    | Not Reported |
|                                                                                        | Seroplex                   | S | Oral | 10 Mg, Qd    | Not Reported |
|                                                                                        | Cordarone                  | S | Oral | 200 Mg, Qd   | Not Reported |
|                                                                                        | Lercan                     | C | Oral | 10 Mg, Qd    | Not Reported |
|                                                                                        | Inexium /01479302/         | C | Oral | 40 Mg, Qd    | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Nov-2014              | 10597373      | DIRECT           | Y                  | RI              |                      |                      | 42 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|------------------------|-----------------|--------------|
| Affective Disorder;                                                                                                                                | Escitalopram   |              |            | S           | Oral         | 20mg Qd Up To 1 1/2 Qd |                 | Not Reported |
| Anticholinergic Syndrome; Condition Aggravated; Crying; Headache; Product Substitution Issue; Sleep Disorder; Therapeutic Product Effect Decreased | Xanax          |              |            | C           |              | Po                     |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Nov-2014              | 10597862      | DIRECT           |                    |                 |                      |                      | 60 YR      | Female     | USA            |

| <u>Preferred Term</u>                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Insomnia; Product Substitution Issue | Escitalopram   |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Nov-2014              | 10598046      | DIRECT           |                    | OT              |                      |                      | 81 YR      | Male       | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                                                                        | <u>Product</u>                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>                         |                |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|--------------------|--------------------|-----------------|----------------------|---------------------------------------|-----------------|------------------------------------|----------------|
| Abnormal Behaviour;<br>Aggression; Memory<br>Impairment                                                                                                                                                      | Escitalopram                               |                    |                    | S               | Oral                 | 10mg 1 Per Day Mouth                  |                 | Camber                             |                |
|                                                                                                                                                                                                              | Oral Inhaler                               |                    |                    | C               |                      |                                       |                 | Not Reported                       |                |
|                                                                                                                                                                                                              | Lunesta                                    |                    |                    | C               |                      |                                       |                 | Not Reported                       |                |
|                                                                                                                                                                                                              | Ativan                                     |                    |                    | C               |                      |                                       |                 | Not Reported                       |                |
|                                                                                                                                                                                                              | Omnaris                                    |                    |                    | C               |                      |                                       |                 | Not Reported                       |                |
|                                                                                                                                                                                                              | Lisinopril                                 |                    |                    | C               |                      |                                       |                 | Not Reported                       |                |
|                                                                                                                                                                                                              | Wellbutrin                                 |                    |                    | C               |                      |                                       |                 | Not Reported                       |                |
|                                                                                                                                                                                                              | Flonase                                    |                    |                    | C               |                      |                                       |                 | Not Reported                       |                |
|                                                                                                                                                                                                              | Metoprolol Tartrate                        |                    |                    | C               |                      |                                       |                 | Not Reported                       |                |
|                                                                                                                                                                                                              | Norvasc                                    |                    |                    | C               |                      |                                       |                 | Not Reported                       |                |
|                                                                                                                                                                                                              | Advair Diskus                              |                    |                    | C               |                      |                                       |                 | Not Reported                       |                |
|                                                                                                                                                                                                              | Fish Oil                                   |                    |                    | C               |                      |                                       |                 | Not Reported                       |                |
| <u>FDA Received Date</u>                                                                                                                                                                                     | <u>Case #</u>                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u>                         | <u>Country</u> |
| 20-Nov-2014                                                                                                                                                                                                  | 10598071                                   | DIRECT             |                    | HO              |                      |                                       | 22 YR           | Female                             | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                        | <u>Product</u>                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>                         |                |
| Diarrhoea; Self-Injurious<br>Ideation; Withdrawal<br>Syndrome                                                                                                                                                | Escitalopram 20mg                          |                    |                    | S               | Oral                 | 1 Pill, Once Daily, Taken<br>By Mouth |                 | Pharmacy Benefits<br>Manager (Pbm) |                |
|                                                                                                                                                                                                              |                                            |                    |                    |                 |                      |                                       |                 |                                    |                |
| <u>FDA Received Date</u>                                                                                                                                                                                     | <u>Case #</u>                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u>                         | <u>Country</u> |
| 20-Nov-2014                                                                                                                                                                                                  | 10601721                                   | EXPEDITED (15-DAY) | Y                  | HO              | IPC201411-000608     |                                       | 62 YR           | Male                               | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                        | <u>Product</u>                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>                         |                |
| Cardiac Arrest; Drug<br>Interaction;<br>Encephalopathy;<br>Hyperthermia;<br>Hypotension; Muscle<br>Rigidity; Myocardial<br>Infarction; Nystagmus;<br>Pulseless Electrical<br>Activity; Serotonin<br>Syndrome | Furosemide                                 |                    |                    | S               |                      | Therapy - Stopped                     |                 | Not Reported                       |                |
|                                                                                                                                                                                                              | Metoprolol Tartrate                        |                    |                    | S               |                      |                                       |                 | Not Reported                       |                |
|                                                                                                                                                                                                              | Aspirin (Acetylsalicylic Acid)             |                    |                    | S               |                      |                                       |                 | Not Reported                       |                |
|                                                                                                                                                                                                              | (Acetylsalicylic Acid)                     |                    |                    |                 |                      |                                       |                 |                                    |                |
|                                                                                                                                                                                                              | Lisinopril (Lisinopril) (Lisinopril)       |                    |                    | S               |                      |                                       |                 | Not Reported                       |                |
|                                                                                                                                                                                                              | Atorvastatin (Atorvastatin)                |                    |                    | S               |                      |                                       |                 | Not Reported                       |                |
|                                                                                                                                                                                                              | (Atorvastatin)                             |                    |                    |                 |                      |                                       |                 |                                    |                |
|                                                                                                                                                                                                              | Insulin                                    |                    |                    | S               |                      |                                       |                 | Not Reported                       |                |
|                                                                                                                                                                                                              | Escitalopram (Escitalopram)                |                    |                    | S               |                      |                                       |                 | Not Reported                       |                |
|                                                                                                                                                                                                              | Lamotrigine (Lamotrigine)<br>(Lamotrigine) |                    |                    | S               |                      |                                       |                 | Not Reported                       |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                       |   |                                     |              |
|-----------------------|---|-------------------------------------|--------------|
| Ipratropium/Albuterol | S | (As Needed)                         | Not Reported |
| Nitroglycerin         | S | Sublingual (As Needed ), Sublingual | Not Reported |
| Methylene Blue        | S | 1mg/Kg In 2 Consecutive Doses       | Not Reported |

| <u>FDA Received Date</u>                                                                                                                                                            | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|-----------------|--------------|----------------|
| 21-Nov-2014                                                                                                                                                                         | 10444589                | EXPEDITED (15-DAY) |                    | OT              | US-FRI-1000070495               |                      | 34 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                               | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective; Libido Decreased; Multiple Sclerosis Relapse; Optic Neuritis; Urinary Tract Infection                                                                             | Lexapro                 |                    |                    | S               | Oral                            | 20 Mg                |                 | Forest       |                |
|                                                                                                                                                                                     | Lexapro                 |                    |                    | S               | Oral                            |                      |                 | Forest       |                |
|                                                                                                                                                                                     | Lexapro                 |                    |                    | S               | Oral                            | 20 Mg                |                 | Not Reported |                |
|                                                                                                                                                                                     | Gilenya                 |                    |                    | C               |                                 |                      |                 | Not Reported |                |
|                                                                                                                                                                                     | Sprintec                |                    |                    | C               |                                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                            | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Nov-2014                                                                                                                                                                         | 10597044                | EXPEDITED (15-DAY) |                    | DS              | GB-ACCORD-027077                |                      | 32 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                                                                                                                               | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain; Akathisia; Anxiety; Disturbance In Attention; Drug Withdrawal Syndrome; Insomnia; Muscle Twitching; Nasal Discomfort; Pain In Extremity; Psoriasis; Skin Irritation | Escitalopram            |                    |                    | S               | Oral                            |                      |                 | Accord       |                |
|                                                                                                                                                                                     | Cerazette (Desogestrel) |                    |                    | C               |                                 |                      |                 | Not Reported |                |
|                                                                                                                                                                                     | Levothyroxine           |                    |                    | C               |                                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                            | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Nov-2014                                                                                                                                                                         | 10597078                | EXPEDITED (15-DAY) |                    | DS              | GB-AUROBINDO-AUR-APL-2014-12034 |                      | 32 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                                                                                                                               | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain; Aggression; Agitation;                                                                                                                                              | Escitalopram 20 Mg      |                    |                    | S               | Oral                            | 20 Mg, Unk           |                 | Aurobindo    |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                                             |                         |   |         |     |              |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|---|---------|-----|--------------|
| Akathisia; Anxiety;<br>Disturbance In Attention;<br>Drug Withdrawal<br>Syndrome; Insomnia;<br>Muscle Spasms; Muscle<br>Twitching; Nasal<br>Discomfort; Pain In<br>Extremity; Psoriasis;<br>Restlessness; Skin<br>Irritation | Cerazette (Desogestrel) | C | Unknown | Unk | Not Reported |
|                                                                                                                                                                                                                             | Thyroxine Sodium        | C | Unknown | Unk | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------|----------------------|------------|------------|----------------|
| 21-Nov-2014              | 10597082      | EXPEDITED (15-DAY) |                    | CA, OT          | GB-AUROBINDO-AUR-<br>APL-2014-12035 |                      |            | Unknown    | GBR            |

| <u>Preferred Term</u>                                             | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-------------------------------------------------------------------|--------------------|--------------|------------|-------------|----------------|--------------------|-----------------|------------|
| Foetal Exposure During<br>Pregnancy; Ventricular<br>Septal Defect | Escitalopram 20 Mg |              |            | S           | Transplacental | 20 Mg, Unk         |                 | Aurobindo  |
|                                                                   | Escitalopram 20 Mg |              |            | S           |                |                    |                 | Aurobindo  |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 21-Nov-2014              | 10597954      | EXPEDITED (15-DAY) |                    | DE, HO, OT      | FR-PFIZER INC-<br>2014319909 |                      | 85 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Acute Kidney Injury;                                 | Cordarone              |              |            | S           | Oral         | 200 Mg, 1x/Day     |                 | Pfizer       |
| Hypokalaemia;                                        | Coolmetec              |              |            | S           | Oral         | 1 Df, 1x/Day       |                 | Not Reported |
| Hyponatraemia;                                       | Prednisone             |              |            | S           | Oral         | Unk                |                 | Not Reported |
| International Normalised<br>Ratio Increased; Torsade | Lasilix                |              |            | S           | Oral         | 80 Mg, 1x/Day      |                 | Not Reported |
| De Pointes; Ventricular<br>Fibrillation              | Bisoce                 |              |            | S           | Oral         | 2.5 Mg, 1x/Day     |                 | Not Reported |
|                                                      | Previscan (Fluindione) |              |            | S           | Oral         | 20 Mg, Unk         |                 | Not Reported |
|                                                      | Seroplex               |              |            | S           | Oral         | 10 Mg, 1x/Day      |                 | Not Reported |
|                                                      | Lercan                 |              |            | C           |              | Unk                |                 | Not Reported |
|                                                      | Inexium                |              |            | C           |              | 40 Mg, Unk         |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                              | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------|---------------------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 21-Nov-2014                                                           | 10598606                              | EXPEDITED (15-DAY) |                    | HO              | SE-PFIZER INC-2014320299 |                      | 47 YR           | Female       | SWE            |
| <u>Preferred Term</u>                                                 | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alcohol Poisoning; Suicidal Ideation; Toxicity To Various Agents      | Provera                               |                    |                    | S               | Oral                     | 20 Mg, Unk           |                 | Pfizer       |                |
|                                                                       | Fluanxol "Lundbeck"                   |                    |                    | S               | Oral                     | 2 Mg And 1000 Mg     |                 | Not Reported |                |
|                                                                       | Seroquel                              |                    |                    | S               | Oral                     | 600 Mg, Unk          |                 | Not Reported |                |
|                                                                       | Lergigan (Promethazine Hydrochloride) |                    |                    | S               | Oral                     | 50 Mg, Unk           |                 | Not Reported |                |
|                                                                       | Cipralex                              |                    |                    | S               | Oral                     | 20 Mg, Unk           |                 | Not Reported |                |
|                                                                       | Propavan                              |                    |                    | S               | Oral                     | 50 Mg, Unk           |                 | Not Reported |                |
|                                                                       | Zopiclone                             |                    |                    | S               | Oral                     | 15 Mg, Unk           |                 | Not Reported |                |
|                                                                       | Ergenyl                               |                    |                    | S               | Oral                     | 2000 Mg, Unk         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                              | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Nov-2014                                                           | 10598626                              | EXPEDITED (15-DAY) |                    | OT              | AU-FRI-1000072582        |                      | 60 YR           | Male         | AUS            |
| <u>Preferred Term</u>                                                 | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenopia; Depressed Level Of Consciousness; Nausea; Tremor; Vertigo | Escitalopram                          |                    |                    | S               | Oral                     | 5 Mg                 |                 | Forest       |                |
| <u>FDA Received Date</u>                                              | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Nov-2014                                                           | 10598706                              | EXPEDITED (15-DAY) |                    | OT              | DE-FRI-1000072546        |                      | 29 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                                 | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Pregnancy; Vaginal Infection                                          | Escitalopram                          |                    |                    | S               | Oral                     | 10 Mg                |                 | Forest       |                |
|                                                                       | Citalopram                            |                    |                    | C               | Oral                     |                      |                 | Not Reported |                |
|                                                                       | L-Thyroxin                            |                    |                    | C               | Oral                     | 50 Mcg               |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                         | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------|-----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 21-Nov-2014                                                                                                                      | 10599534              | EXPEDITED (15-DAY) |                    | OT              | DE-FRI-1000072551    |                      | < 1 DAY         | Male         | DEU            |
| <u>Preferred Term</u>                                                                                                            | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Apgar Score Low; Foetal Exposure During Pregnancy; Hypotonia Neonatal; Meconium In Amniotic Fluid; Respiratory Disorder Neonatal | Escitalopram          |                    |                    | S               | Transplacental       | 10 Mg                |                 | Forest       |                |
|                                                                                                                                  | Citalopram            |                    |                    | C               | Transplacental       |                      |                 | Not Reported |                |
|                                                                                                                                  | L-Thyroxin            |                    |                    | C               | Transplacental       | 50 Mcg               |                 | Not Reported |                |
|                                                                                                                                  | Cefaclor              |                    |                    | C               | Transplacental       | Dosage Unknown       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                         | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Nov-2014                                                                                                                      | 10599829              | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000072584    |                      | 67 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                            | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Wall Haematoma; Abdominal Wall Haematoma; Acute Kidney Injury; Anaemia; Drug Interaction; Overdose                     | Escitalopram          |                    |                    | S               | Oral                 | 20 Mg                |                 | Forest       |                |
|                                                                                                                                  | Previscan (Fluidione) |                    |                    | S               | Oral                 | 15 Mg                |                 | Not Reported |                |
|                                                                                                                                  | Lovenox               |                    |                    | S               | Subcutaneous         | 16000 Iu             |                 | Not Reported |                |
|                                                                                                                                  | Kardegic              |                    |                    | S               | Oral                 | 75 Mg                |                 | Not Reported |                |
|                                                                                                                                  | Eupressyl             |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                                  | Levothyrox            |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                                  | Amlodipine            |                    |                    | C               | Unknown              |                      |                 | Not Reported |                |
|                                                                                                                                  | Valsartan             |                    |                    | C               | Unknown              |                      |                 | Not Reported |                |
|                                                                                                                                  | Esidrex               |                    |                    | C               | Unknown              |                      |                 | Not Reported |                |
|                                                                                                                                  | Esomeprazole          |                    |                    | C               | Unknown              |                      |                 | Not Reported |                |
|                                                                                                                                  | Haldol                |                    |                    | C               | Unknown              |                      |                 | Not Reported |                |
|                                                                                                                                  | Seresta               |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                                  | Augmentin             |                    |                    | C               | Unknown              |                      |                 | Not Reported |                |



# FDA Adverse Event Reporting System

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| <u>FDA Received Date</u>                                     | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
| 21-Nov-2014                                                  | 10599831                    | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000072602         |                      | 83 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                        | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Wall<br>Haematoma; Blood Loss<br>Anaemia           | Escitalopram                |                    |                    | S               | Oral                      | 1 Df                 |                 | Forest       |                |
|                                                              | Previscan (Fluindione)      |                    |                    | S               | Oral                      | Inr Target 2 To 3    |                 | Not Reported |                |
|                                                              | Lasilix                     |                    |                    | C               |                           |                      |                 | Not Reported |                |
|                                                              | Hyperium                    |                    |                    | C               |                           |                      |                 | Not Reported |                |
|                                                              | Exforge                     |                    |                    | C               |                           |                      |                 | Not Reported |                |
|                                                              | Esidrex                     |                    |                    | C               |                           |                      |                 | Not Reported |                |
|                                                              | Tahor                       |                    |                    | C               |                           |                      |                 | Not Reported |                |
|                                                              | Modopar                     |                    |                    | C               |                           |                      |                 | Not Reported |                |
|                                                              | Ceris                       |                    |                    | C               |                           |                      |                 | Not Reported |                |
|                                                              | Tanganil                    |                    |                    | C               |                           |                      |                 | Not Reported |                |
|                                                              | Daflon (Diosmin/Hesperidin) |                    |                    | C               |                           |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Nov-2014                                                  | 10600868                    | DIRECT             | Y                  |                 |                           |                      | 57 YR           | Male         | USA            |
| <u>Preferred Term</u>                                        | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Headache; Nausea;<br>Product Substitution Issue;<br>Vomiting | Escitalopram                |                    |                    | S               |                           |                      | 18 MTH          | Not Reported |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Nov-2014                                                  | 10638673                    | NON-EXPEDITED      | Y                  |                 | 163-10004-14082967        |                      | 54 YR           | Female       | USA            |
| <u>Preferred Term</u>                                        | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Affect Lability; Crying;<br>Depression; Mood Swings          | Otezla                      |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                                                              | Lexapro                     |                    |                    | S               |                           |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Nov-2014                                                  | 10600280                    | EXPEDITED (15-DAY) |                    | LT              | GB-MYLANLABS-2014M1010836 |                      |                 | Unknown      | GBR            |

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| <u>Preferred Term</u>                                      | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                        | <u>Dosage Text</u>                              | <u>Duration</u> | <u>Mfr</u>   |                |
|------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|-------------------------------------|-------------------------------------------------|-----------------|--------------|----------------|
| Breast Hyperplasia;<br>Lobular Breast Carcinoma<br>In Situ | Escitalopram           |                    |                    | S               | Oral                                | 10 Mg, Unk                                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                   | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u>                            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Nov-2014                                                | 10236156               | EXPEDITED (15-DAY) |                    |                 | FR-FRI-1000068089                   |                                                 |                 | Female       | FRA            |
| <u>Preferred Term</u>                                      | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                        | <u>Dosage Text</u>                              | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective;<br>Headache; Nausea;<br>Sinusitis        | Escitalopram           |                    |                    | S               | Oral                                | 5 Mg                                            |                 | Forest       |                |
|                                                            | Escitalopram           |                    |                    | S               | Oral                                | 10 Mg                                           |                 | Forest       |                |
| <u>FDA Received Date</u>                                   | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u>                            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Nov-2014                                                | 10600553               | EXPEDITED (15-DAY) |                    | OT              | FR-AUROBINDO-AUR-<br>APL-2014-12312 |                                                 | 87 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                      | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                        | <u>Dosage Text</u>                              | <u>Duration</u> | <u>Mfr</u>   |                |
| Fall                                                       | Venlafaxine Arrow Lp   |                    |                    | S               | Oral                                | 37.5 Mg, Daily                                  |                 | Aurobindo    |                |
|                                                            | Venlafaxine Arrow Lp   |                    |                    | S               | Oral                                | 75 Mg, Daily                                    |                 | Aurobindo    |                |
|                                                            | Venlafaxine Arrow Lp   |                    |                    | S               | Oral                                | 150 Mg, Daily                                   |                 | Aurobindo    |                |
|                                                            | Seroplex               |                    |                    | S               | Oral                                | 1 Df, Unk                                       |                 | Not Reported |                |
|                                                            | Movicol /01749801/     |                    |                    | C               | Oral                                | 1 Df, Daily                                     |                 | Not Reported |                |
|                                                            | Diffu K                |                    |                    | C               | Oral                                | 4 Df, Daily                                     |                 | Not Reported |                |
|                                                            | Mecir                  |                    |                    | C               | Oral                                | 1 Df, Daily                                     |                 | Not Reported |                |
|                                                            | Previscan (Fluindione) |                    |                    | C               | Oral                                | ¼ Tablet Every 2 Days, ½<br>Tablet Every 2 Days |                 | Not Reported |                |
|                                                            | Tahor                  |                    |                    | C               | Oral                                | 1 Df, Daily                                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                   | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u>                            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Nov-2014                                                | 10600557               | EXPEDITED (15-DAY) |                    | HO, OT          | DE-AUROBINDO-AUR-<br>APL-2014-12215 |                                                 | 63 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                      | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                        | <u>Dosage Text</u>                              | <u>Duration</u> | <u>Mfr</u>   |                |

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|                                                                         |                       |   |         |                |              |
|-------------------------------------------------------------------------|-----------------------|---|---------|----------------|--------------|
| Blood Potassium Decreased; Drug Interaction; Hyponatraemia; Hypotension | Hydrochlorothiazide   | S | Oral    | 5.75 Mg, Daily | Aurobindo    |
|                                                                         | Ramipril 2.5mg        | S | Unknown | 2.5 Mg, Daily  | Aurobindo    |
|                                                                         | Seroquel Xr           | S | Oral    | 200 Mg, Daily  | Not Reported |
|                                                                         | Seroquel Xr           | S | Oral    | 300 Mg, Daily  | Not Reported |
|                                                                         | Seroquel Xr           | S | Oral    | 400 Mg, Daily  | Not Reported |
|                                                                         | Seroquel Xr           | S | Oral    | 500 Mg, Daily  | Not Reported |
|                                                                         | Tegretal              | S | Oral    | 600 Mg, Daily  | Not Reported |
|                                                                         | Tegretal              | S | Oral    | 500 Mg, Daily  | Not Reported |
|                                                                         | Tegretal              | S | Oral    | 400 Mg, Daily  | Not Reported |
|                                                                         | Tegretal              | S | Oral    | 300 Mg, Daily  | Not Reported |
|                                                                         | Tegretal              | S | Oral    | 200 Mg, Daily  | Not Reported |
|                                                                         | Tegretal              | S | Oral    | 100 Mg, Daily  | Not Reported |
|                                                                         | Ciprallex /01588501/  | S | Oral    | 10 Mg, Daily   | Not Reported |
|                                                                         | Metoprolol            | C | Unknown | Unk            | Not Reported |
|                                                                         | Solifenacin Succinate | C | Unknown | Unk            | Not Reported |
|                                                                         | Simvastatin           | C | Unknown | Unk            | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Nov-2014              | 10602134      | EXPEDITED (15-DAY) |                    | DS              | GB-FRI-1000072606    |                      | 32 YR      | Female     | GBR            |

| <u>Preferred Term</u>                                                                                                                                                                                            | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abdominal Pain; Akathisia; Anxiety; Disturbance In Attention; Drug Withdrawal Syndrome; Insomnia; Muscle Spasms; Muscle Twitching; Nasal Discomfort; Pain In Extremity; Psoriasis; Restlessness; Skin Irritation | Escitalopram            |              |            | S           | Oral         | 20 Mg Daily        |                 | Forest       |
|                                                                                                                                                                                                                  | Cerazette (Desogestrel) |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                  | Thyroxine Sodium        |              |            | C           |              |                    |                 | Not Reported |

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| <u>FDA Received Date</u>                             | <u>Case #</u>                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------|---------------------------------------------|--------------------|--------------------|-----------------|----------------------|-----------------------------------|-----------------|--------------|----------------|
| 24-Nov-2014                                          | 10602307                                    | EXPEDITED (15-DAY) |                    | OT              | PHHY2014CH148766     |                                   | 22 YR           | Female       | CHE            |
| <u>Preferred Term</u>                                | <u>Product</u>                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |                |
| Maternal Exposure During Pregnancy                   | Ritaline                                    |                    |                    | S               | Nasal                |                                   |                 | Not Reported |                |
|                                                      | Norlevo                                     |                    |                    | S               | Oral                 | 1 Df, Unk                         |                 | Not Reported |                |
|                                                      | Cocaine                                     |                    |                    | S               | Unknown              |                                   |                 | Not Reported |                |
|                                                      | Cipralex /Den/                              |                    |                    | S               | Oral                 | 10 Mg, Qd, At Irregular Intervals |                 | Not Reported |                |
|                                                      | Ecstasy                                     |                    |                    | S               | Oral                 |                                   |                 | Not Reported |                |
|                                                      | Cannabis Sativa Subsp. Sativa Flowering Top |                    |                    | S               | Unknown              |                                   |                 | Not Reported |                |
|                                                      | Temesta (Lorazepam)                         |                    |                    | S               | Oral                 |                                   |                 | Not Reported |                |
| <u>FDA Received Date</u>                             | <u>Case #</u>                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Nov-2014                                          | 10602443                                    | EXPEDITED (15-DAY) |                    | HO              | FR-SA-2014SA160462   |                                   | 38 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                | <u>Product</u>                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |                |
| Amnesia; Nausea; Seizure; Vomiting                   | Stilnox                                     |                    |                    | S               | Oral                 |                                   |                 | Not Reported |                |
|                                                      | Seroplex                                    |                    |                    | S               | Oral                 |                                   |                 | Not Reported |                |
| <u>FDA Received Date</u>                             | <u>Case #</u>                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Nov-2014                                          | 10602760                                    | EXPEDITED (15-DAY) |                    | CA              | GB-TEVA-522776ISR    |                                   | 27 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                | <u>Product</u>                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |                |
| Exposure During Pregnancy; Ventricular Septal Defect | Escitalopram                                |                    |                    | S               | Oral                 |                                   |                 | Ivax         |                |
| <u>FDA Received Date</u>                             | <u>Case #</u>                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Nov-2014                                          | 10603173                                    | EXPEDITED (15-DAY) |                    | DS              | GB-TEVA-522765ISR    |                                   | 32 YR           | Female       | GBR            |

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| <u>Preferred Term</u>                                                                                                                                                                                            | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| Abdominal Pain; Akathisia; Anxiety; Disturbance In Attention; Drug Withdrawal Syndrome; Insomnia; Muscle Spasms; Muscle Twitching; Nasal Discomfort; Pain In Extremity; Psoriasis; Restlessness; Skin Irritation | Escitalopram                  |                    |                    | S               | Oral                     |                      |                 | Ivax         |                |
|                                                                                                                                                                                                                  | Cerazette (Desogestrel)       |                    |                    | C               |                          |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                  | Thyroxine Sodium              |                    |                    | C               |                          |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                  |                               |                    |                    |                 |                          |                      |                 |              |                |
| <u>FDA Received Date</u>                                                                                                                                                                                         | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Nov-2014                                                                                                                                                                                                      | 10618633                      | EXPEDITED (15-DAY) | Y                  | HO              | IL-ZYDUS-005535          |                      | 34 YR           | Male         | ISR            |
| <u>Preferred Term</u>                                                                                                                                                                                            | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bruxism                                                                                                                                                                                                          | Clonazepam                    |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                  | Escitalopram (Escitalopram)   |                    |                    | S               |                          | 1.0 Days             |                 | Not Reported |                |
|                                                                                                                                                                                                                  | Carbamazepine (Carbamazepine) |                    |                    | C               |                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                         | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Nov-2014                                                                                                                                                                                                      | 10519094                      | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2014282189 |                      | 44 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                            | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Adjustment Disorder With Depressed Mood; Erectile Dysfunction; Male Sexual Dysfunction                                                                                                                           | Pristiq                       |                    |                    | S               | Oral                     | 50 Mg, 1x/Day        |                 | Pfizer       |                |
|                                                                                                                                                                                                                  | Zoloft                        |                    |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                                                                                                                                                                                                                  | Prozac                        |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                                                                                                                                                                                                                  | Wellbutrin                    |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                                                                                                                                                                                                                  | Lexapro                       |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                                                                                                                                                                                                                  | Celexa                        |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                                                                                                                                                                                                                  | Simvastatin                   |                    |                    | C               | Oral                     | 40 Mg, 1x/Day        |                 | Not Reported |                |
|                                                                                                                                                                                                                  | Xanax                         |                    |                    | C               |                          | 0.5 Mg, 3x/Day       |                 | Not Reported |                |

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| <u>FDA Received Date</u>                      | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------|---------------------------------------|--------------------|--------------------|-----------------|---------------------------------|------------------------|-----------------|--------------|----------------|
| 25-Nov-2014                                   | 10591590                              | EXPEDITED (15-DAY) |                    | HO              | IT-FRI-1000072432               |                        |                 | Male         | ITA            |
| <u>Preferred Term</u>                         | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Ureterolithiasis                              | Escitalopram                          |                    |                    | S               | Oral                            | 10 Mg                  |                 | Forest       |                |
|                                               | Escitalopram Oral Solution            |                    |                    | S               | Oral                            | 5 Gtt                  |                 | Forest       |                |
|                                               | Depakin                               |                    |                    | C               |                                 | 150 Mg                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                      | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Nov-2014                                   | 10606318                              | EXPEDITED (15-DAY) |                    | HO, OT          | DE-AUROBINDO-AUR-APL-2014-12451 |                        | 42 YR           | Female       | DEU            |
| <u>Preferred Term</u>                         | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Apathy; Delusion; Depression; Feeling Guilty  | Mirtazapine                           |                    |                    | S               | Unknown                         | Unk                    |                 | Aurobindo    |                |
|                                               | Escitalopram                          |                    |                    | S               | Unknown                         | Unk                    |                 | Aurobindo    |                |
| <u>FDA Received Date</u>                      | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Nov-2014                                   | 10606606                              | EXPEDITED (15-DAY) |                    | HO              | SE-ABBVIE-14P-150-1311868-00    |                        | 47 YR           | Female       | SWE            |
| <u>Preferred Term</u>                         | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Suicidal Ideation; Toxicity To Various Agents | Ergenyl                               |                    |                    | S               | Oral                            | 2000 Mg Total          |                 | Not Reported |                |
|                                               | Propavan                              |                    |                    | S               | Oral                            | 50 Mg Total            |                 | Not Reported |                |
|                                               | Provera                               |                    |                    | S               | Oral                            | 20 Mg Total            |                 | Not Reported |                |
|                                               | Fluanxol                              |                    |                    | S               | Oral                            | 2 Mg And 1000 Mg Total |                 | Not Reported |                |
|                                               | Seroquel                              |                    |                    | S               | Oral                            | 600 Mg Total           |                 | Not Reported |                |
|                                               | Lergigan (Promethazine Hydrochloride) |                    |                    | S               | Oral                            | 50 Mg Total            |                 | Not Reported |                |
|                                               | Zopiclone                             |                    |                    | S               | Oral                            | 15 Mg Total            |                 | Not Reported |                |
|                                               | Ciprallex                             |                    |                    | S               | Oral                            | 20 Mg Total            |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 25-Nov-2014                                                    | 10607195       | EXPEDITED (15-DAY) |                    | HO              | NL-FRI-1000072625    |                      | 26 YR           | Male         | NLD            |
| <u>Preferred Term</u>                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hiccups; Muscle Twitching                                      | Escitalopram   |                    |                    | S               | Oral                 | 5 Mg                 |                 | Forest       |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Nov-2014                                                    | 10607213       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000072628    |                      | 76 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Melaena                                      | Escitalopram   |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                                                | Xarelto        |                    |                    | S               | Oral                 | 20 Mg                |                 | Not Reported |                |
|                                                                | Kardegic       |                    |                    | S               | Oral                 | 75 Mg                |                 | Not Reported |                |
|                                                                | Lasilix        |                    |                    | C               | Oral                 | 40 Mg                |                 | Not Reported |                |
|                                                                | Bisoce         |                    |                    | C               | Oral                 | 3.75 Mg              |                 | Not Reported |                |
|                                                                | Paracetamol    |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Nov-2014                                                    | 10607266       | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000072652    |                      | 50 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Fatigue; Optic Neuritis                                        | Escitalopram   |                    |                    | S               |                      | 10 Mg                |                 | Forest       |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Nov-2014                                                    | 10608220       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000072671    |                      | 65 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Gastric Ulcer; Gastrointestinal Haemorrhage; | Escitalopram   |                    |                    | S               | Oral                 |                      |                 | Forest       |                |
|                                                                | Kardegic       |                    |                    | S               | Oral                 | 1 Df Dosage Form     |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|           |            |   |                                       |              |
|-----------|------------|---|---------------------------------------|--------------|
| Haematoma | Lantus     | C | 40 Iu In Evening                      | Not Reported |
|           | Humalog    | C | 16 Iu In Morning, Noon<br>And Evening | Not Reported |
|           | Alprazolam | C | 0.25 Mg In Evening                    | Not Reported |
|           | Zolpidem   | C | 10 Mg In Evening                      | Not Reported |
|           | Crestor    | C | 5 Mg In Evening                       | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Nov-2014              | 10608342      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000072638    |                      | 55 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                          | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------|----------------|--------------|------------|-------------|---------------------------------------|--------------------|-----------------|--------------|
| C-Reactive Protein Increased; Cell Death; Cholestasis; Jaundice; Pyrexia | Escitalopram   |              |            | S           | Oral                                  | 20 Mg              |                 | Forest       |
|                                                                          | Augmentin      |              |            | S           | Intravenous (not otherwise specified) | 3 Gram             |                 | Not Reported |
|                                                                          | Seresta        |              |            | S           | Oral                                  | 150 Mg             |                 | Not Reported |
|                                                                          | Keppra         |              |            | S           | Intravenous (not otherwise specified) | 1000 Mg            |                 | Not Reported |
|                                                                          | Nicobion       |              |            | S           | Oral                                  | 2 Df               |                 | Not Reported |
|                                                                          | Tranxene       |              |            | S           | Intravenous (not otherwise specified) | 200 Mg             |                 | Not Reported |
|                                                                          | Tranxene       |              |            | S           | Intravenous (not otherwise specified) | 250 Mg             |                 | Not Reported |
|                                                                          | Paracetamol    |              |            | S           | Intravenous (not otherwise specified) |                    |                 | Not Reported |
|                                                                          | Multivitamins  |              |            | C           | Unknown                               |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Nov-2014              | 10608421      | EXPEDITED (15-DAY) |                    | HO              | DE-TEVA-523368GER    |                      | 23 YR      | Male       | DEU            |

| <u>Preferred Term</u>                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u> |
|---------------------------------------------|----------------|--------------|------------|-------------|--------------|---------------------|-----------------|------------|
| Aggression; Restlessness; Suicidal Ideation | Doxepin        |              |            | S           | Oral         | 25 Milligram Daily; |                 | Teva       |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|            |   |      |                     |              |
|------------|---|------|---------------------|--------------|
| Cipralelex | S | Oral | 20 Milligram Daily; | Not Reported |
| Cipralelex | S | Oral | 10 Milligram Daily; | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 25-Nov-2014              | 10608474      | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2014322366 |                      | 54 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                   | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|------------------------------------------------------|-----------------|--------------|
| Feeling Abnormal      | Effexor Xr     |              |            | S           |              | 150 Mg, 1x/Day                                       |                 | Pfizer       |
|                       | Effexor Xr     |              |            | S           |              |                                                      |                 | Pfizer       |
|                       | Effexor Xr     |              |            | S           |              |                                                      |                 | Pfizer       |
|                       | Effexor Xr     |              |            | S           |              |                                                      |                 | Pfizer       |
|                       | Lyrica         |              |            | S           |              | 150 Mg, Daily (50 Mg In Morning And 100 Mg At Night) |                 | Pfizer       |
|                       | Lyrica         |              |            | S           |              |                                                      |                 | Pfizer       |
|                       | Lyrica         |              |            | S           |              |                                                      |                 | Pfizer       |
|                       | Lexapro        |              |            | S           |              | 20 Mg, 1x/Day                                        |                 | Not Reported |
|                       | Lexapro        |              |            | S           |              |                                                      |                 | Not Reported |
|                       | Prednisone     |              |            | C           |              | 10 Mg, Daily                                         |                 | Not Reported |
|                       | Aspirin        |              |            | C           |              | 325 Mg, Unk                                          |                 | Not Reported |
|                       | Clonazepam     |              |            | C           |              | 1 Mg, 2x/Day                                         |                 | Not Reported |
|                       | Atarax         |              |            | C           |              | 50 Mg, As Needed                                     |                 | Not Reported |
|                       | Zanaflex       |              |            | C           |              | 4 Mg, As Needed                                      |                 | Not Reported |
|                       | Percocet       |              |            | C           |              | (10/325 Mg "Half To One" Every Six Hours As Needed)  |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 25-Nov-2014              | 10608961      | EXPEDITED (15-DAY) |                    | CA              | GB-MYLANLABS-2014M1010884 |                      |            | Unknown    | GBR            |

| <u>Preferred Term</u>                                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Exposure During Pregnancy; Ventricular Septal Defect | Escitalopram   |              |            | S           | Oral         | 20 Mg, Unk         |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                         | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
| 25-Nov-2014                                                                                                                                                                                                      | 10608964                     | EXPEDITED (15-DAY) |                    | DS              | GB-MYLANLABS-2014M1010883 |                      |                 | Unknown      | GBR            |
| <u>Preferred Term</u>                                                                                                                                                                                            | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain; Akathisia; Anxiety; Disturbance In Attention; Drug Withdrawal Syndrome; Insomnia; Muscle Spasms; Muscle Twitching; Nasal Discomfort; Pain In Extremity; Psoriasis; Restlessness; Skin Irritation | Escitalopram                 |                    |                    | S               | Oral                      | 20 Mg, Unk           |                 | Not Reported |                |
|                                                                                                                                                                                                                  | Cerazette (Desogestrel)      |                    |                    | C               |                           | Unk                  |                 | Not Reported |                |
|                                                                                                                                                                                                                  | Thyroxine Sodium             |                    |                    | C               |                           | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                         | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Nov-2014                                                                                                                                                                                                      | 10615252                     | DIRECT             | Y                  | OT              |                           |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                            | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective                                                                                                                                                                                                 | Lexapro 20 Mg Camber         |                    |                    | S               | Oral                      | One                  |                 | Not Reported |                |
|                                                                                                                                                                                                                  | Paxil 20 Mg Tablet Aurobindo |                    |                    | S               | Oral                      | One                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                         | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Nov-2014                                                                                                                                                                                                      | 10434463                     | EXPEDITED (15-DAY) |                    | HO              | SE-FRI-1000070377         |                      | 84 YR           | Female       | SWE            |
| <u>Preferred Term</u>                                                                                                                                                                                            | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrioventricular Block Second Degree; Electrocardiogram Pq Interval Prolonged; Syncope                                                                                                                           | Escitalopram                 |                    |                    | S               |                           | 10 Mg                |                 | Forest       |                |
|                                                                                                                                                                                                                  | Behepan [Cyanocobalamin]     |                    |                    | C               |                           |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                  | Folacin [Folic Acid]         |                    |                    | C               |                           |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                  | Kalcipos-D Forte             |                    |                    | C               |                           |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                  | Norspan                      |                    |                    | C               |                           |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                  | Waran                        |                    |                    | C               |                           |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                  | Alvedon                      |                    |                    | C               |                           |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                  | Importal Ex-Lax              |                    |                    | C               | Oral                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                   | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 26-Nov-2014                                                                                                                                                | 10513752                | EXPEDITED (15-DAY) |                    | LT              | RO-TEVA-514088ISR    |                      | 68 YR           | Female       | ROM            |
| <u>Preferred Term</u>                                                                                                                                      | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Decreased Appetite; Hyperhidrosis; Irritability; Palpitations; Psychomotor Hyperactivity; Restlessness; Sleep Disorder; Tremor                    | Escitalopram Teva 10 Mg |                    |                    | S               | Oral                 | 10 Milligram Daily;  |                 | Ivax         |                |
|                                                                                                                                                            | Escitalopram Teva 10 Mg |                    |                    | S               |                      |                      |                 | Ivax         |                |
|                                                                                                                                                            | Rivotril 2 Mg           |                    |                    | C               | Oral                 | 2 Milligram Daily;   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                   | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Nov-2014                                                                                                                                                | 10610565                | EXPEDITED (15-DAY) |                    | DE              | FR-FRI-1000072631    |                      | 85 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                                      | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Acute Kidney Injury; Drug Interaction; Hypokalaemia; Hyponatraemia; International Normalised Ratio Increased; Torsade De Pointes; Ventricular Fibrillation | Escitalopram            |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                                                                                                                                            | Bisoce                  |                    |                    | S               | Oral                 | 2.5 Mg               |                 | Not Reported |                |
|                                                                                                                                                            | Previscan (Fluindione)  |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                                                            | Prednisone              |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                                                            | Lasilix                 |                    |                    | S               | Oral                 | 2 Df                 |                 | Not Reported |                |
|                                                                                                                                                            | Coolmetec               |                    |                    | S               | Oral                 | 40 Mg/25 Mg Daily    |                 | Not Reported |                |
|                                                                                                                                                            | Cordarone               |                    |                    | S               | Oral                 | 1 Df                 |                 | Not Reported |                |
|                                                                                                                                                            | Lercan                  |                    |                    | C               | Oral                 | 1 Df                 |                 | Not Reported |                |
|                                                                                                                                                            | Inexium                 |                    |                    | C               | Oral                 | 1 Df                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                   | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Nov-2014                                                                                                                                                | 10611105                | EXPEDITED (15-DAY) |                    | OT              | RS-FRI-1000072689    |                      | 61 YR           | Female       | SRB            |
| <u>Preferred Term</u>                                                                                                                                      | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Arrhythmia                                                                                                                                                 | Escitalopram            |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|          |   |      |         |              |
|----------|---|------|---------|--------------|
| Indapres | C | Oral | 0.75 Mg | Not Reported |
| Corvitol | C | Oral | 25 Mg   | Not Reported |
| Ksalol   | C | Oral | 0.5 Mg  | Not Reported |

| <u>FDA Received Date</u>                               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------|----------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
| 26-Nov-2014                                            | 10611596       | EXPEDITED (15-DAY) |                    | HO, LT          | BE-MYLANLABS-2014M1011840 |                      |                 | Unknown      | BEL            |
| <u>Preferred Term</u>                                  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Long Qt Syndrome; Torsade De Pointes | Escitalopram   |                    |                    | S               | Unknown                   |                      |                 | Not Reported |                |
|                                                        | Omeprazole     |                    |                    | S               | Unknown                   |                      |                 | Not Reported |                |
|                                                        | Tacrolimus     |                    |                    | S               | Unknown                   |                      |                 | Not Reported |                |
|                                                        | Sotalol        |                    |                    | S               | Unknown                   |                      |                 | Not Reported |                |
|                                                        | Bisoprolol     |                    |                    | C               | Unknown                   |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                            | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------|---------------------------------------|--------------------|--------------------|-----------------|----------------------|------------------------|-----------------|--------------|----------------|
| 26-Nov-2014                                                         | 10611726                              | EXPEDITED (15-DAY) |                    | HO              | SE-FRI-1000072715    |                        | 47 YR           | Female       | SWE            |
| <u>Preferred Term</u>                                               | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Overdose; Suicidal Ideation; Toxicity To Various Agents | Escitalopram                          |                    |                    | S               | Oral                 |                        |                 | Forest       |                |
|                                                                     | Fluanxol                              |                    |                    | S               | Oral                 | Overdose: Unknown Dose |                 | Not Reported |                |
|                                                                     | Provera                               |                    |                    | S               | Oral                 | Overdose: 20 Mg Once   |                 | Not Reported |                |
|                                                                     | Seroquel                              |                    |                    | S               | Oral                 | Overdose: 600 Mg Once  |                 | Not Reported |                |
|                                                                     | Lergigan (Promethazine Hydrochloride) |                    |                    | S               | Oral                 | Overdose: 50 Mg Once   |                 | Not Reported |                |
|                                                                     | Propavan 25 Mg Tablett                |                    |                    | S               | Oral                 | Overdose: 50 Mg Once   |                 | Not Reported |                |
|                                                                     | Zopiclone                             |                    |                    | S               | Oral                 | Overdose: 15 Mg Once   |                 | Not Reported |                |
|                                                                     | Ergenyl                               |                    |                    | S               | Oral                 | Overdose: 2000 Mg Once |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Nov-2014              | 10619028      | EXPEDITED (15-DAY) | Y                  | HO, OT          | ADR-2014-02233       |                      | 34 YR      | Female     | FRA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>        | <u>Product</u>                  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------|---------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Amnesia; Anal                | Lioresal                        |              |            | S           |              |                    |                 | Not Reported |
| Incontinence;                | Tercian                         |              |            | S           |              |                    |                 | Not Reported |
| Craniocerebral Injury; Fall; | Imovane (Zopiclone)             |              |            | S           | Oral         |                    |                 | Not Reported |
| Loss Of Consciousness;       | Seroplex (Escitalopram Oxalate) |              |            | S           | Oral         |                    |                 | Not Reported |
| Periorbital Haemorrhage;     |                                 |              |            |             |              |                    |                 |              |
| Urinary Incontinence;        |                                 |              |            |             |              |                    |                 |              |
| Wound Infection; Wound       |                                 |              |            |             |              |                    |                 |              |
| Necrosis                     |                                 |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Nov-2014              | 10621529      | DIRECT           |                    | HO              |                      |                      | 14 YR      | Female     | USA            |

| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Chest Pain;      | Escitalopram   |              |            | S           | Oral         |                    |                 | Not Reported |
| Fatigue; Feeling          |                |              |            |             |              |                    |                 |              |
| Abnormal; Feeling         |                |              |            |             |              |                    |                 |              |
| Abnormal; Feeling         |                |              |            |             |              |                    |                 |              |
| Abnormal; Hallucination;  |                |              |            |             |              |                    |                 |              |
| Headache; Heart Rate      |                |              |            |             |              |                    |                 |              |
| Increased; Hyperhidrosis; |                |              |            |             |              |                    |                 |              |
| Hypertension; Insomnia;   |                |              |            |             |              |                    |                 |              |
| Mydriasis; Nausea; Panic  |                |              |            |             |              |                    |                 |              |
| Attack; Psychotic         |                |              |            |             |              |                    |                 |              |
| Behaviour                 |                |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------|----------------------|------------|------------|----------------|
| 27-Nov-2014              | 10612122      | EXPEDITED (15-DAY) |                    | HO              | ES-AUROBINDO-AUR-<br>APL-2014-12470 |                      | 66 YR      | Male       | ESP            |

| <u>Preferred Term</u>      | <u>Product</u>   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|------------------|--------------|------------|-------------|--------------|-----------------------------|-----------------|--------------|
| Confusional State; Drug    | Escitalopram     |              |            | S           | Oral         | 7.5 Mg, Once A Day          |                 | Aurobindo    |
| Interaction; Parkinsonism; | Mirtazapine 30mg |              |            | S           | Oral         | 30 Mg, Once A Day           |                 | Aurobindo    |
| Persecutory Delusion;      | Orfidal          |              |            | S           | Oral         | 0.75 Mg, Two Times A<br>Day |                 | Not Reported |
| Rhabdomyolysis             | Enalapril        |              |            | C           | Oral         | 10 Mg, Once A Day           |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| Duodart                                       |                                       |                    | C                  |                 | Oral                                         | Unk                  |                 | Not Reported |                |
|-----------------------------------------------|---------------------------------------|--------------------|--------------------|-----------------|----------------------------------------------|----------------------|-----------------|--------------|----------------|
| <u>FDA Received Date</u>                      | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Nov-2014                                   | 10612849                              | EXPEDITED (15-DAY) |                    | HO              | SE-ASTRAZENECA-2014SE88302                   |                      | 47 YR           | Female       | SWE            |
| <u>Preferred Term</u>                         | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Suicidal Ideation; Toxicity To Various Agents | Seroquel                              |                    |                    | S               | Oral                                         |                      |                 | Zeneca       |                |
|                                               | Seroquel                              |                    |                    | S               | Oral                                         |                      |                 | Zeneca       |                |
|                                               | Provera                               |                    |                    | S               | Oral                                         |                      |                 | Not Reported |                |
|                                               | Provera                               |                    |                    | S               | Oral                                         |                      |                 | Not Reported |                |
|                                               | Fluanxol                              |                    |                    | S               | Oral                                         |                      |                 | Not Reported |                |
|                                               | Fluanxol                              |                    |                    | S               | Oral                                         |                      |                 | Not Reported |                |
|                                               | Lergigan (Promethazine Hydrochloride) |                    |                    | S               | Oral                                         |                      |                 | Not Reported |                |
|                                               | Lergigan (Promethazine Hydrochloride) |                    |                    | S               | Oral                                         |                      |                 | Not Reported |                |
|                                               | Cipralelex                            |                    |                    | S               | Oral                                         |                      |                 | Not Reported |                |
|                                               | Cipralelex                            |                    |                    | S               | Oral                                         |                      |                 | Not Reported |                |
|                                               | Propavan                              |                    |                    | S               | Oral                                         |                      |                 | Not Reported |                |
|                                               | Propavan                              |                    |                    | S               | Oral                                         |                      |                 | Not Reported |                |
|                                               | Zopiclone                             |                    |                    | S               | Oral                                         |                      |                 | Not Reported |                |
|                                               | Zopiclone                             |                    |                    | S               | Oral                                         |                      |                 | Not Reported |                |
|                                               | Ergenyl                               |                    |                    | S               | Oral                                         |                      |                 | Not Reported |                |
|                                               | Ergenyl                               |                    |                    | S               | Oral                                         |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                      | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Dec-2014                                   | 10616033                              | EXPEDITED (15-DAY) |                    | OT              | IN-ROXANE LABORATORIES, INC.-2014-RO-01798RO |                      | 49 YR           | Female       | IND            |
| <u>Preferred Term</u>                         | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Major Depression; Parkinsonism; Tardive       | Propranolol                           |                    |                    | S               | Unknown                                      | 10 Mg                |                 | Roxane       |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                         |              |   |         |         |              |
|-------------------------|--------------|---|---------|---------|--------------|
| Dyskinesia; Torticollis | Amisulpride  | S | Unknown | 50 Mg   | Not Reported |
|                         | Levosulpride | S | Unknown | 100 Mg  | Not Reported |
|                         | Escitalopram | S | Unknown |         | Not Reported |
|                         | Paroxetine   | S | Unknown | 12.5 Mg | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Dec-2014              | 10617982      | EXPEDITED (15-DAY) |                    | HO, OT          | PHHY2014CA154126     |                      | 63 YR      | Female     | CAN            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                            | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>             | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------------------|--------------------------------|-----------------|--------------|
| Asthenia; Bone Disorder;<br>Chest Discomfort; Cough;<br>Cyanosis; Decreased<br>Appetite; Depression;<br>Diarrhoea; Dizziness;<br>Drug Ineffective;<br>Dyspnoea Exertional;<br>Emphysema; Fall; Fatigue;<br>Headache; Hiatus Hernia;<br>Hypoaesthesia; Insomnia;<br>Malaise; Overdose; Pain;<br>Panic Reaction;<br>Pneumonia; Pruritus;<br>Pulmonary Mass; Tremor | Seebri Breezhaler       |              |            | S           | Unknown                  |                                |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                  | Clarithromycin          |              |            | S           | Unknown                  |                                |                 | Novartis     |
|                                                                                                                                                                                                                                                                                                                                                                  | Atrovent                |              |            | S           | Unknown                  |                                |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                  | Advair Diskus           |              |            | S           | Respiratory (inhalation) | Unk Unk, Bid                   |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                  | Advair Diskus           |              |            | S           | Respiratory (inhalation) | Unk                            |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                  | Advair Diskus           |              |            | S           | Respiratory (inhalation) | Unk                            |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                  | Ventolin Cr             |              |            | S           | Unknown                  |                                |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                  | Spiriva                 |              |            | S           | Unknown                  |                                |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                  | Prednisone              |              |            | S           | Unknown                  | 4 Df, Unk (4 Puffers Everyday) |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                  | Ciprallex//Escitalopram |              |            | S           | Unknown                  |                                |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                  | Clonazepam              |              |            | C           | Unknown                  |                                |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                  | Meloxicam               |              |            | C           | Unknown                  |                                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Dec-2014              | 10622205      | DIRECT           | Y                  |                 |                      |                      | 44 YR      | Male       | USA            |

| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Agitation; Depression; | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                   |          |   |              |
|---------------------------------------------------|----------|---|--------------|
| Loss Of Personal Independence In Daily Activities | Lamictal | C | Not Reported |
|---------------------------------------------------|----------|---|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Dec-2014              | 10361181      | EXPEDITED (15-DAY) |                    | HO              | IT-FRI-1000069501    |                      | 28 YR      | Male       | ITA            |

| <u>Preferred Term</u>       | <u>Product</u>  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------|-----------------|--------------|------------|-------------|--------------|---------------------------------------------|-----------------|--------------|
| Drug Abuse; Overdose; Sopor | Escitalopram    |              |            | S           | Oral         | Overdose: 560 Mg Once.                      |                 | Forest       |
|                             | Lorazepam Dorom |              |            | S           | Oral         | Overdose: 10 MI Of Form Strength 20mg/10 MI |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Dec-2014              | 10591870      | EXPEDITED (15-DAY) |                    | CA, OT          | GB-ACCORD-027058     |                      |            | Unknown    | GBR            |

| <u>Preferred Term</u>                                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|------------|
| Foetal Exposure During Pregnancy; Ventricular Septal Defect | Escitalopram   |              |            | S           | Transplacental |                    |                 | Accord     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Dec-2014              | 10619521      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000072751    |                      | 38 YR      | Female     | FRA            |

| <u>Preferred Term</u>              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Amnesia; Nausea; Seizure; Vomiting | Escitalopram   |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                    | Stilnox        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                    | Alprazolam     |              |            | C           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 02-Dec-2014              | 10620296      | EXPEDITED (15-DAY) |                    | CA              | FR-ASTRAZENECA-2014SE91786 |                      | < 1 DAY    | Male       | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                           |                                    |   |                |                     |              |
|---------------------------|------------------------------------|---|----------------|---------------------|--------------|
| Patent Ductus Arteriosus; | Tenoretic                          | S | Transplacental | 50 Mg/12.5 Mg Daily | Zeneca       |
| Trisomy 21; Ventricular   | Abilify                            | S | Transplacental |                     | Not Reported |
| Septal Defect             | Seroplex                           | S | Transplacental |                     | Not Reported |
|                           | Parkinane                          | S | Transplacental |                     | Not Reported |
|                           | Tercian                            | S | Transplacental |                     | Not Reported |
|                           | Loxen (Niacardipine Hydrochloride) | C | Transplacental |                     | Not Reported |
|                           | Loxapac                            | C | Transplacental |                     | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 02-Dec-2014              | 10620511       | EXPEDITED (15-DAY) |                    | OT              | US-FRI-1000072761    |                      |                 | Female     | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Peripheral Nerve Injury  | Lexapro        |                    |                    | S               |                      |                      |                 |            | Forest         |

| <u>FDA Received Date</u>                      | <u>Case #</u>                                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|-----------------------------------------------|-------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 02-Dec-2014                                   | 10625371                                              | EXPEDITED (15-DAY) | Y                  | OT              | IPC201411-000637     |                      | 49 YR           | Female     | IND            |
| <u>Preferred Term</u>                         | <u>Product</u>                                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Parkinsonism; Tardive Dyskinesia; Torticollis | Propranolol Hydrochloride (Propranolol Hydrochloride) |                    |                    | S               |                      |                      |                 |            | Not Reported   |
|                                               | Amisulpride (Amisulpride)                             |                    |                    | S               |                      |                      |                 |            | Not Reported   |
|                                               | Levosulpiride (Levosulpiride)                         |                    |                    | S               |                      |                      |                 |            | Not Reported   |
|                                               | Escitalopram (Escitalopram)                           |                    |                    | S               |                      |                      |                 |            | Not Reported   |
|                                               | Paroxetine (Paroxetine)                               |                    |                    | S               |                      |                      |                 |            | Not Reported   |
|                                               | Eltroxine                                             |                    |                    | S               |                      |                      |                 |            | Not Reported   |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|-------------------------|----------------------|-----------------|------------|----------------|
| 03-Dec-2014              | 10554940       | EXPEDITED (15-DAY) |                    | HO              | IT-DSJP-DSE-2014-127259 |                      |                 | Unknown    | ITA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                          |                      |   |      |           |              |
|--------------------------|----------------------|---|------|-----------|--------------|
| Bradycardia; Hypotension | Olmesartan Medoxomil | S | Oral | 10 Mg, Qd | Not Reported |
|                          | Cipraxel             | S | Oral | 10 Mg, Qd | Not Reported |
|                          | Lorazepam            | S | Oral | 1 Mg, Qd  | Not Reported |
|                          | Eutirox              | C |      | Unk       | Not Reported |
|                          | Formistin            | C |      | Unk       | Not Reported |

| <u>FDA Received Date</u>                                                              | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------|--------------------|--------------------|--------------------|-----------------|---------------------------------|--------------------------|-----------------|--------------|----------------|
| 03-Dec-2014                                                                           | 10605549           | EXPEDITED (15-DAY) |                    | OT              | IT-AUROBINDO-AUR-APL-2014-12252 |                          | 58 YR           | Male         | ITA            |
| <u>Preferred Term</u>                                                                 | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Anhedonia; Crying; Depressed Mood; Hypersomnia; Middle Insomnia; Nausea; Parkinsonism | Escitalopram 20 Mg |                    |                    | S               | Unknown                         | 20 Mg, Daily             |                 | Aurobindo    |                |
|                                                                                       | Escitalopram 20 Mg |                    |                    | S               |                                 |                          |                 | Aurobindo    |                |
|                                                                                       | Agomelatine        |                    |                    | S               | Unknown                         | 25 Mg, Daily, At Bedtime |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                                | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|--------------------|--------------------|-----------------|----------------------|-------------------------------------|-----------------|--------------|----------------|
| 03-Dec-2014                                                                                                                                             | 10622450        | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000072793    |                                     | 17 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                                   | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Analgesic Drug Level Increased; Hypotension; Hypothermia; Intentional Overdose; Overdose; Poisoning Deliberate; Tachycardia; Toxicity To Various Agents | Escitalopram    |                    |                    | S               | Oral                 | Overdose Of 5 Tablets Of 10 Mg Once |                 | Forest       |                |
|                                                                                                                                                         | Dafalgan Codein |                    |                    | S               | Oral                 | Overdose Of 16 Grams Once           |                 | Not Reported |                |
|                                                                                                                                                         | Loxapac         |                    |                    | S               | Oral                 | Overdose Of 5 Df Once               |                 | Not Reported |                |

| <u>FDA Received Date</u>               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|----------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 03-Dec-2014                            | 10623067       | EXPEDITED (15-DAY) |                    | LT              | SA-FRI-1000072777    |                      | 70 YR           | Female     | SAU            |
| <u>Preferred Term</u>                  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Delusion; Neutropenia; Suicide Attempt | Escitalopram   |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest     |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                                                | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 03-Dec-2014                                                                                                                                                                                                                                                                                                                                                             | 10623414       | EXPEDITED (15-DAY) |                    | CA              | FR-FRI-1000072805    |                      | 3 DAY           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Foetal Exposure During Pregnancy; Patent Ductus Arteriosus; Trisomy 21; Ventricular Septal Defect                                                                                                                                                                                                                                                                       | Escitalopram   |                    |                    | S               | Transplacental       | 1 Df Dosage Form     |                 | Forest       |                |
|                                                                                                                                                                                                                                                                                                                                                                         | Abilify        |                    |                    | S               | Transplacental       | 15 Mg                |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                         | Parkinane      |                    |                    | S               | Transplacental       | 1 Df Dosage Form     |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                         | Tenoretic      |                    |                    | S               | Transplacental       | 50/12.5 Mg           |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                         | Tercian        |                    |                    | S               | Transplacental       | 1 Df Dosage Form     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                                                | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Dec-2014                                                                                                                                                                                                                                                                                                                                                             | 10631609       | EXPEDITED (15-DAY) | Y                  | HO              | BE-DEXPHARM-20140964 |                      | 65 YR           | Male         |                |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Chloride Decreased; Blood Lactate Dehydrogenase Increased; Depression; Drug Interaction; Drug Intolerance; Haematocrit Decreased; Haemoglobin Decreased; Hypokalaemia; Long Qt Syndrome; Loss Of Consciousness; Platelet Count Increased; Protein Total Decreased; Red Blood Cell Count Decreased; Torsade De Pointes; Vomiting; White Blood Cell Count Increased | Escitalopram   |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                         | Omeprazole     |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                         | Sotalol        |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                         | Tacrolimus     |                    |                    | S               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                   | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 03-Dec-2014                                                                | 10636609               | DIRECT             | Y                  |                 |                          |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                      | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective; Product Substitution Issue; Therapeutic Response Changed | Lexapro 20mg - Generic |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                   | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Dec-2014                                                                | 10587894               | EXPEDITED (15-DAY) |                    | HO, OT          | DE-PFIZER INC-2014314683 |                      | 63 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                                      | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Potassium Decreased; Drug Interaction; Hyponatraemia; Hypotension    | Ramipril               |                    |                    | S               | Oral                     | 2.5 Mg, Daily        |                 | Pfizer       |                |
|                                                                            | Seroquel Xr            |                    |                    | S               | Oral                     | 200 Mg, Daily        |                 | Not Reported |                |
|                                                                            | Seroquel Xr            |                    |                    | S               | Oral                     | 300 Mg, Daily        |                 | Not Reported |                |
|                                                                            | Seroquel Xr            |                    |                    | S               | Oral                     | 400 Mg, Daily        |                 | Not Reported |                |
|                                                                            | Seroquel Xr            |                    |                    | S               | Oral                     | 500 Mg, Daily        |                 | Not Reported |                |
|                                                                            | Tegretal               |                    |                    | S               | Oral                     | 600 Mg, Daily        |                 | Not Reported |                |
|                                                                            | Tegretal               |                    |                    | S               | Oral                     | 500 Mg, Daily        |                 | Not Reported |                |
|                                                                            | Tegretal               |                    |                    | S               | Oral                     | 400 Mg, Daily        |                 | Not Reported |                |
|                                                                            | Tegretal               |                    |                    | S               | Oral                     | 300 Mg, Daily        |                 | Not Reported |                |
|                                                                            | Tegretal               |                    |                    | S               | Oral                     | 200 Mg, Daily        |                 | Not Reported |                |
|                                                                            | Tegretal               |                    |                    | S               | Oral                     | 100 Mg, Daily        |                 | Not Reported |                |
|                                                                            | Hydrochlorothiazid     |                    |                    | S               | Oral                     | 5.75 Mg, Daily       |                 | Not Reported |                |
|                                                                            | Ciprallex              |                    |                    | S               | Oral                     | 10 Mg, Daily         |                 | Not Reported |                |
|                                                                            | Simvastatin            |                    |                    | C               |                          | Unk                  |                 | Not Reported |                |
|                                                                            | Metoprolol             |                    |                    | C               |                          | Unk                  |                 | Not Reported |                |
|                                                                            | Solifenacin Succinate  |                    |                    | C               |                          | Unk                  |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|---------------------------------------------------------|--------------------------------------|--------------------|--------------------|-----------------|---------------------------------------------------------------|----------------------|-----------------|----------------------|----------------|
| 04-Dec-2014                                             | 10626333                             | EXPEDITED (15-DAY) |                    | DE              | US-B.I.<br>PHARMACEUTICALS,I<br>NC./RIDGEFIELD-2014-<br>BI-58 |                      | 31 YR           | Female               | USA            |
| <u>Preferred Term</u>                                   | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Completed Suicide                                       | Meloxicam                            |                    |                    | S               | Oral                                                          |                      |                 | Boehringer Ingelheim |                |
|                                                         | Lamotrigine                          |                    |                    | S               | Oral                                                          |                      |                 | Not Reported         |                |
|                                                         | Escitalopram                         |                    |                    | S               | Oral                                                          |                      |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 04-Dec-2014                                             | 10626637                             | EXPEDITED (15-DAY) |                    | HO              | FR-ASTRAZENECA-<br>2014SE93175                                |                      |                 | Female               | FRA            |
| <u>Preferred Term</u>                                   | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Dyspnoea; Exposure<br>During Pregnancy;<br>Hypertension | Tenoretic                            |                    |                    | S               | Oral                                                          | 50 Mg/12.5 Mg Daily  |                 | Zeneca               |                |
|                                                         | Abilify                              |                    |                    | S               | Unknown                                                       |                      |                 | Not Reported         |                |
|                                                         | Seroplex                             |                    |                    | S               | Unknown                                                       |                      |                 | Not Reported         |                |
|                                                         | Parkinane                            |                    |                    | S               | Unknown                                                       |                      |                 | Not Reported         |                |
|                                                         | Tercian                              |                    |                    | S               | Unknown                                                       |                      |                 | Not Reported         |                |
|                                                         | Loxen (Nicardipine<br>Hydrochloride) |                    |                    | C               |                                                               |                      |                 | Not Reported         |                |
|                                                         | Loxapac                              |                    |                    | C               |                                                               |                      |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 04-Dec-2014                                             | 10626935                             | NON-EXPEDITED      |                    |                 | US-PFIZER INC-<br>2014331104                                  |                      |                 | Female               | USA            |
| <u>Preferred Term</u>                                   | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Tremor                                                  | Neurontin                            |                    |                    | S               |                                                               | Taking Off And On    |                 | Pfizer               |                |
|                                                         | Acetaminophen                        |                    |                    | S               |                                                               | Unk                  |                 | Not Reported         |                |
|                                                         | Escitalopram                         |                    |                    | S               |                                                               | Unk                  |                 | Not Reported         |                |

# FDA Adverse Event Reporting System

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### Detailed Report

| <u>FDA Received Date</u>                                               | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|------------------------------------------------------------------------|--------------------|--------------------|--------------------|-----------------|------------------------------------------|------------------------|-----------------|----------------------|----------------|
| 05-Dec-2014                                                            | 10561477           | EXPEDITED (15-DAY) |                    | HO, OT          | US-FRI-1000071722                        |                        | 46 YR           | Female               | USA            |
| <u>Preferred Term</u>                                                  | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>           |                |
| Epistaxis; Haematocrit Decreased; Haemoglobin Decreased; Off Label Use | Lexapro            |                    |                    | S               | Oral                                     | 20 Mg                  |                 | Forest               |                |
|                                                                        | Lexapro            |                    |                    | S               |                                          |                        |                 | Forest               |                |
|                                                                        | Ibuprofen          |                    |                    | S               |                                          | 800 Mg 1-2 Times Daily |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                               | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 05-Dec-2014                                                            | 10627861           | NON-EXPEDITED      |                    |                 | US-BRISTOL-MYERS SQUIBB COMPANY-20845426 |                        | 49 YR           | Female               | USA            |
| <u>Preferred Term</u>                                                  | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>           |                |
| Drug Hypersensitivity                                                  | Pravastatin Sodium |                    |                    | S               | Oral                                     |                        |                 | Bristol Myers Squibb |                |
|                                                                        | Zoloft             |                    |                    | S               |                                          |                        |                 | Not Reported         |                |
|                                                                        | Methocarbamol      |                    |                    | S               |                                          |                        |                 | Not Reported         |                |
|                                                                        | Zocor              |                    |                    | S               |                                          |                        |                 | Not Reported         |                |
|                                                                        | Reglan             |                    |                    | S               |                                          |                        |                 | Sandoz               |                |
|                                                                        | Lexapro            |                    |                    | S               |                                          |                        |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                               | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 05-Dec-2014                                                            | 10628654           | NON-EXPEDITED      |                    |                 | US-BRISTOL-MYERS SQUIBB COMPANY-21447321 |                        | 18 YR           | Female               | USA            |
| <u>Preferred Term</u>                                                  | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>           |                |
| Adverse Event                                                          | Abilify            |                    |                    | S               |                                          |                        |                 | Not Reported         |                |
|                                                                        | Lexapro            |                    |                    | S               |                                          |                        |                 | Not Reported         |                |
|                                                                        | Vyvanse            |                    |                    | C               |                                          |                        |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                               | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 05-Dec-2014                                                            | 10628662           | NON-EXPEDITED      |                    |                 | US-BRISTOL-MYERS SQUIBB COMPANY-21543871 |                        | 38 YR           | Male                 | USA            |
| <u>Preferred Term</u>                                                  | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>           |                |

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|                                          |                               |                    |                    |                 |                                                 |                                    |                 |                                              |                |
|------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|------------------------------------|-----------------|----------------------------------------------|----------------|
| Akathisia                                |                               | Abilify            |                    | S               |                                                 |                                    |                 | Not Reported                                 |                |
|                                          |                               | Lexapro            |                    | S               |                                                 |                                    |                 | Not Reported                                 |                |
| <u>FDA Received Date</u>                 | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 05-Dec-2014                              | 10629283                      | NON-EXPEDITED      |                    |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>21337001 |                                    | 52 YR           | Female                                       | USA            |
| <u>Preferred Term</u>                    | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Headache; Vaginal<br>Haemorrhage         | Abilify<br>Lexapro            |                    |                    | S<br>S          |                                                 |                                    |                 | Not Reported<br>Not Reported                 |                |
| <u>FDA Received Date</u>                 | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 05-Dec-2014                              | 10630319                      | NON-EXPEDITED      |                    |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>21265541 |                                    | 42 YR           | Female                                       | USA            |
| <u>Preferred Term</u>                    | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Anxiety                                  | Abilify                       |                    |                    | S               |                                                 | Dose Increased From 2mg<br>To 5 Mg |                 | Not Reported                                 |                |
|                                          | Lamictal<br>Lexapro           |                    |                    | S<br>S          |                                                 |                                    |                 | Not Reported<br>Not Reported                 |                |
| <u>FDA Received Date</u>                 | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 05-Dec-2014                              | 10631340                      | NON-EXPEDITED      |                    |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>21497037 |                                    |                 | Unknown                                      | USA            |
| <u>Preferred Term</u>                    | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Drug Interaction                         | Abilify<br>Lexapro<br>Inderal |                    |                    | S<br>S<br>S     |                                                 |                                    |                 | Not Reported<br>Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                 | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 05-Dec-2014                              | 10633778                      | EXPEDITED (15-DAY) |                    | HO, LT, OT      | CA-TEVA-526260USA                               |                                    | 55 YR           | Female                                       | CAN            |
| <u>Preferred Term</u>                    | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Burning Sensation; Hot<br>Flush; Nausea; | Teva-Escitalopram             |                    |                    | S               | Oral                                            | 10 Milligram Daily;                |                 | Ivax                                         |                |

# FDA Adverse Event Reporting System

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Paraesthesia Oral;  
Paraesthesia Oral;  
Pharyngeal Oedema;  
Pruritus; Urticaria;  
Vomiting

| <a href="#">FDA Received Date</a>                              | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|----------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 05-Dec-2014                                                    | 10633976                | EXPEDITED (15-DAY)        |                             | OT                       | BE-FRI-1000072858             |                               |                          | Unknown             | BEL                     |
| <a href="#">Preferred Term</a>                                 | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Decreased Interest;<br>Diarrhoea; Fatigue;<br>Weight Increased | Escitalopram            |                           |                             | S                        | Oral                          |                               |                          | Forest              |                         |
| <a href="#">FDA Received Date</a>                              | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 05-Dec-2014                                                    | 10635175                | EXPEDITED (15-DAY)        |                             | OT                       | FR-FRI-1000072882             |                               |                          | Female              | FRA                     |
| <a href="#">Preferred Term</a>                                 | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Gestational Diabetes; Pre-Eclampsia; Pregnancy                 | Escitalopram            |                           |                             | S                        | Oral                          | 1 Df Dosage Form              |                          | Forest              |                         |
|                                                                | Imovane                 |                           |                             | S                        |                               | 1 Df Dosage Form              |                          | Not Reported        |                         |
|                                                                | Alprazolam              |                           |                             | S                        |                               | 1 Df Dosage Form              |                          | Not Reported        |                         |
|                                                                | Progesterone            |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                              | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 05-Dec-2014                                                    | 10635176                | EXPEDITED (15-DAY)        |                             | CA                       | FR-FRI-1000072880             |                               | < 1 DAY                  | Female              | FRA                     |
| <a href="#">Preferred Term</a>                                 | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Foetal Exposure During Pregnancy; Foetal Growth Restriction    | Escitalopram            |                           |                             | S                        |                               | 1 Df Dosage Form              |                          | Forest              |                         |
|                                                                | Imovane                 |                           |                             | S                        |                               | 1 Df Dosage Form              |                          | Not Reported        |                         |
|                                                                | Alprazolam              |                           |                             | S                        |                               | 1 Df Dosage Form              |                          | Not Reported        |                         |
|                                                                | Progesterone            |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                     | <u>Case #</u>                                                                                                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 05-Dec-2014                                                                                                                                  | 10635607                                                                                                            | EXPEDITED (15-DAY) |                    | HO              | FR-ALLERGAN-1424561US |                      | 86 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                        | <u>Product</u>                                                                                                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Parathyroid Hormone Increased; Blood Phosphorus Decreased; Electrocardiogram Abnormal; Hallucination, Visual; Hypercalcaemia; Vomiting | Ganfort Eye Drops, Solution                                                                                         |                    |                    | S               | Ophthalmic            | 300mg/MI+5mg/MI Qd   |                 | Allergan     |                |
|                                                                                                                                              | Tercian                                                                                                             |                    |                    | S               |                       | 3 Gtt, Unk           |                 | Not Reported |                |
|                                                                                                                                              | Tercian                                                                                                             |                    |                    | S               |                       | 5 Gtt, Tid           |                 | Not Reported |                |
|                                                                                                                                              | Teralhite                                                                                                           |                    |                    | S               |                       | 250 Mg, Unk          |                 | Not Reported |                |
|                                                                                                                                              | Seroplex                                                                                                            |                    |                    | S               |                       | 0.5 Mg, Qd           |                 | Not Reported |                |
|                                                                                                                                              | Seresta                                                                                                             |                    |                    | S               | Oral                  | 40 Mg, Qd            |                 | Not Reported |                |
|                                                                                                                                              | Transipeg (Polyethylene Glycol 3350\Potassium Chloride\Sodium Bicarbonate\Sodium Chloride\Sodium Sulfate Anhydrous) |                    |                    | S               |                       | 11.8 G, Qd           |                 | Not Reported |                |
|                                                                                                                                              | Paracetamol                                                                                                         |                    |                    | S               |                       | 1 G, Tid             |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                    | <u>Case #</u>                                                                                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 05-Dec-2014                                                                                                 | 10635970                                                                                                 | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000072914    |                      | 86 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                       | <u>Product</u>                                                                                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Parathyroid Hormone Increased; Blood Phosphorus Decreased; Electrocardiogram Abnormal; Hypercalcaemia | Escitalopram                                                                                             |                    |                    | S               | Oral                 | 5 Mg                 |                 | Forest       |                |
|                                                                                                             | Teralithe                                                                                                |                    |                    | S               | Oral                 | 750 Mg               |                 | Not Reported |                |
|                                                                                                             | Tercian                                                                                                  |                    |                    | S               | Oral                 | 9 Gtt                |                 | Not Reported |                |
|                                                                                                             | Tercian                                                                                                  |                    |                    | S               | Oral                 | 15 Gtt               |                 | Not Reported |                |
|                                                                                                             | Seresta                                                                                                  |                    |                    | S               | Oral                 | 40 Mg                |                 | Not Reported |                |
|                                                                                                             | Transipeg (Polyethylene Glycol 3350\Potassium Chloride\Sodium Bicarbonate\Sodium Chloride\Sodium Sulfate |                    |                    | S               | Oral                 | 11.8 Mg              |                 | Not Reported |                |
|                                                                                                             |                                                                                                          |                    |                    |                 |                      |                      |                 |              |                |

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|                                                                                                                 |                             |                    |                    |                 |                      |                      |                 |              |                |
|-----------------------------------------------------------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
|                                                                                                                 | Anhydrous)<br>Ganfort       |                    | S                  | Intraocular     | 300 Mg/MI + 5 Mg/MI  |                      |                 | Not Reported |                |
|                                                                                                                 | Paracetamol                 |                    | S                  | Oral            | 3 Gm                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                        | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Dec-2014                                                                                                     | 10640586                    | EXPEDITED (15-DAY) | Y                  | HO, OT          | BE-ZYDUS-005808      |                      | 65 YR           | Male         | BEL            |
| <u>Preferred Term</u>                                                                                           | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Apnoea; Hypokalaemia;<br>Long Qt Syndrome; Loss<br>Of Consciousness; Pallor;<br>Torsade De Pointes;<br>Vomiting | Escitalopram (Escitalopram) |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                 | Omeprazole (Omeprazole)     |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                 | Sotalol (Sotalol)           |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                 | Tacrolimus (Tacrolimus)     |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                 | Bisoprolol                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                        | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Dec-2014                                                                                                     | 10570863                    | EXPEDITED (15-DAY) |                    | HO              | PHHY2014IT142801     |                      | 69 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                                                           | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bradycardia; Hypotension                                                                                        | Lorazepam                   |                    |                    | S               | Oral                 | 1 Mg, Qd             |                 | Novartis     |                |
|                                                                                                                 | Cipralex /Den/              |                    |                    | S               | Oral                 | 10 Mg, Qd            |                 | Not Reported |                |
|                                                                                                                 | Olmesartan Medoxomil        |                    |                    | S               | Oral                 | 10 Mg, Qd            |                 | Not Reported |                |
|                                                                                                                 | Eutirox                     |                    |                    | C               |                      | 125 Mg, Unk          |                 | Not Reported |                |
|                                                                                                                 | Formistin                   |                    |                    | C               |                      | 10 Mg, Unk           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                        | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Dec-2014                                                                                                     | 10637636                    | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000072883    |                      | 76 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                           | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Haematoma Muscle                                                                                                | Escitalopram                |                    |                    | S               | Oral                 | 5 Mg                 |                 | Forest       |                |
|                                                                                                                 | Kardegic                    |                    |                    | S               | Oral                 | 75 Mg                |                 | Not Reported |                |
|                                                                                                                 | Lovenox                     |                    |                    | S               | Unknown              | 2 Df Dosage Form     |                 | Not Reported |                |
|                                                                                                                 | Lovenox                     |                    |                    | S               | Unknown              | 2 Df Dosage Form     |                 | Not Reported |                |

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|  |             |   |         |                       |              |
|--|-------------|---|---------|-----------------------|--------------|
|  | Furosemide  | C | Unknown | 40 Mg                 | Not Reported |
|  | Crestor     | C | Oral    | 10 Mg                 | Not Reported |
|  | Cordarone   | C | Unknown | 0.7143 Df Dosage Form | Not Reported |
|  | Kaleorid    | C | Oral    | 1 Df Dosage Form      | Not Reported |
|  | Tranxene    | C | Oral    | 1 Df Dosage Form      | Not Reported |
|  | Mecir       | C | Oral    | 1 Df Dosage Form      | Not Reported |
|  | Avodart     | C | Oral    | 1 Df Dosage Form      | Not Reported |
|  | Amoxicillin | C | Oral    | 6 Gram                | Not Reported |
|  | Vancomycin  | C | Unknown |                       | Not Reported |

| <u>FDA Received Date</u>             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------------------|----------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 08-Dec-2014                          | 10638446       | EXPEDITED (15-DAY) |                    | OT              | TR-MYLANLABS-2014M1012253 |                      |                 | Unknown    | TUR            |
| <u>Preferred Term</u>                | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Angle Closure Glaucoma; Papilloedema | Escitalopram   |                    |                    | S               | Unknown                   | 20 Mg, Bid           |                 | Mylan      |                |

| <u>FDA Received Date</u>                                                                    | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------|---------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 08-Dec-2014                                                                                 | 10638822            | EXPEDITED (15-DAY) |                    | HO              | CH-FRI-1000072918    |                      | 87 YR           | Female       | CHE            |
| <u>Preferred Term</u>                                                                       | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion; Loss Of Consciousness; Malaise | Escitalopram        |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                                                                             | Iscador             |                    |                    | S               | Subcutaneous         |                      |                 | Not Reported |                |
|                                                                                             | Femara              |                    |                    | S               | Oral                 | 2.5 Mg               |                 | Not Reported |                |
|                                                                                             | Aspirin             |                    |                    | C               | Oral                 | 100 Mg               |                 | Not Reported |                |
|                                                                                             | Importal            |                    |                    | C               | Oral                 | 30 MI                |                 | Not Reported |                |
|                                                                                             | Temesta (Lorazepam) |                    |                    | C               | Oral                 | 1 Mg                 |                 | Not Reported |                |
|                                                                                             | Dafalgan            |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                  | <u>Case #</u>      | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|------------------|--------------------|-----------------|----------------------|------------------------------------|-----------------|--------------|----------------|
| 08-Dec-2014                                                                                                                                                               | 10640133           | DIRECT           |                    | OT              |                      |                                    | 61 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                     | <u>Product</u>     | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Insomnia; Poor Quality Sleep                                                                                                                                              | Lexapro            |                  |                    | S               | Oral                 | 1                                  | 10 YR           | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                  | <u>Case #</u>      | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Dec-2014                                                                                                                                                               | 10640629           | DIRECT           |                    |                 |                      |                                    |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                                                                                                                     | <u>Product</u>     | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Medication Error; Product Dispensing Error; Wrong Product Administered                                                                                                    | Lexapro            |                  |                    | S               |                      |                                    |                 | Not Reported |                |
|                                                                                                                                                                           | Celexa             |                  |                    | S               |                      |                                    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                  | <u>Case #</u>      | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Dec-2014                                                                                                                                                               | 10640637           | DIRECT           |                    |                 |                      |                                    |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                                                                                                                     | <u>Product</u>     | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Intercepted Product Selection Error                                                                                                                                       | Celexa             |                  |                    | S               |                      |                                    |                 | Not Reported |                |
|                                                                                                                                                                           | Lexapro            |                  |                    | S               |                      |                                    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                  | <u>Case #</u>      | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Dec-2014                                                                                                                                                               | 10640927           | DIRECT           |                    | DS, HO          |                      |                                    | 88 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                     | <u>Product</u>     | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Confusional State; Delusion; Depressed Level Of Consciousness; Depression; Disturbance In Attention; Dyspnoea; Fall; Fatigue; Gait Disturbance; Hallucination; | Escitalopram 10 Mg |                  |                    | S               | Oral                 | One Pill Once Daily Taken By Mouth |                 | Not Reported |                |
|                                                                                                                                                                           | Rapaflo            |                  |                    | C               |                      |                                    |                 | Not Reported |                |
|                                                                                                                                                                           | Timolol            |                  |                    | C               |                      |                                    |                 | Not Reported |                |
|                                                                                                                                                                           | Travatan           |                  |                    | C               |                      |                                    |                 | Not Reported |                |
|                                                                                                                                                                           | Multivitamin       | Y                |                    | C               |                      |                                    |                 | Not Reported |                |
|                                                                                                                                                                           | Astaxanthan        |                  |                    | C               |                      |                                    |                 | Not Reported |                |
|                                                                                                                                                                           | Bili Berry         |                  |                    | C               |                      |                                    |                 | Not Reported |                |

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|                          |                  |   |              |
|--------------------------|------------------|---|--------------|
| Hypersomnia; Influenza   | Zeaxanthan       | C | Not Reported |
| Like Illness; Memory     | Co Q10           | C | Not Reported |
| Impairment; Muscular     | Probiotic        | C | Not Reported |
| Weakness; Muscular       | Vitamin D3       | C | Not Reported |
| Weakness; Nightmare;     | Omega 3          | C | Not Reported |
| Speech Disorder;         | Fish Oil         | C | Not Reported |
| Unresponsive To Stimuli; | Vitamin C        | C | Not Reported |
| Urinary Incontinence     | Sam-E            | C | Not Reported |
|                          | Prostate Formula | C | Not Reported |

| <u>FDA Received Date</u>                              | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|-------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|---------------------------------------|-----------------|------------|----------------|
| 08-Dec-2014                                           | 10642424       | DIRECT           |                    |                 |                      |                                       | 54 YR           | Female     | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u> |                |
| Agitation; Anxiety;<br>Headache; Suicidal<br>Ideation | Escitalopram   |                  |                    | S               | Oral                 | 1 Pill, Once Daily, Taken<br>By Mouth |                 | Walmart    |                |

| <u>FDA Received Date</u>                  | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------|----------------------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|-----------------|--------------|----------------|
| 09-Dec-2014                               | 10525092                   | EXPEDITED (15-DAY) |                    | HO              | AT-ASTRAZENECA-<br>2014SE77387 |                      | 47 YR           | Male         | AUT            |
| <u>Preferred Term</u>                     | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Attention                                 | Seroquel Xr                |                    |                    | S               | Oral                           | 400-800 Mg Daily     |                 | Not Reported |                |
| Deficit/Hyperactivity                     | Abilify                    |                    |                    | S               | Oral                           | 5                    |                 | Not Reported |                |
| Disorder; Confusional<br>State; Delirium; | Abilify                    |                    |                    | S               | Oral                           | 10                   |                 | Not Reported |                |
| Disorientation; Gait                      | Substitol (Non Az Product) |                    |                    | S               | Oral                           |                      |                 | Not Reported |                |
| Disturbance; Insomnia;                    | Akineton                   |                    |                    | S               | Oral                           |                      |                 | Not Reported |                |
| Psychomotor                               | Praxiten                   |                    |                    | S               | Oral                           | 150 Max 300          |                 | Not Reported |                |
| Hyperactivity;                            | Cipralext                  |                    |                    | S               | Oral                           | 10-30 Mg/Daily       |                 | Not Reported |                |
| Psychomotor Skills                        | Trittico                   |                    |                    | C               | Oral                           | 150                  |                 | Not Reported |                |
| Impaired; Tremor                          |                            |                    |                    |                 |                                |                      |                 |              |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Dec-2014              | 10576506      | EXPEDITED (15-DAY) |                    | HO              | CH-FRI-1000072209    |                      | 38 YR      | Female     | CHE            |

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| <u>Preferred Term</u>                                    | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anaemia; Hypovolaemic Shock; Intra-Abdominal Haemorrhage | Escitalopram             |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                                          | Marcoumar                |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                          | Sortis                   |              |            | C           | Oral         | 20 Mg              |                 | Not Reported |
|                                                          | Calcitriol Salmon Pharma |              |            | C           | Oral         | 0.5 Mcg            |                 | Not Reported |
|                                                          | Ferrosanol               |              |            | C           | Oral         | 0.5 Df Dosage Form |                 | Not Reported |
|                                                          | Tenormin                 |              |            | C           | Oral         | 50 Mg              |                 | Not Reported |
|                                                          | Amlodipin-Mepha          |              |            | C           | Oral         | 5 Mg               |                 | Not Reported |
|                                                          | Nephrotrans              |              |            | C           | Oral         | 2000 Mg            |                 | Not Reported |
|                                                          | Pantozol (Switzerland)   |              |            | C           | Oral         | 40 Mg              |                 | Not Reported |
|                                                          | Cosaar                   |              |            | C           | Oral         | 50 Mg              |                 | Not Reported |
|                                                          | Vi-De 3                  |              |            | C           | Oral         | 8 Gtt              |                 | Not Reported |
|                                                          | Acidum Folicum Streuli   |              |            | C           | Oral         | 0.7143 Mg          |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Dec-2014              | 10623121      | EXPEDITED (15-DAY) |                    | OT              | CN-FRI-1000072762    |                      | 50 YR      | Female     | CHN            |

| <u>Preferred Term</u>                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Intentional Overdose; Suicide Attempt | Lexapro        |              |            | S           | Oral         | Overdose: 70 Mg    |                 | Forest       |
|                                       | Lexapro        |              |            | S           |              |                    |                 | Forest       |
|                                       | Alprazolam     |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                       | Tandospirone   |              |            | C           | Unknown      | 10 Mg Daily        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Dec-2014              | 10640374      | EXPEDITED (15-DAY) |                    | OT              | US-FRI-1000072794    |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Dental Caries; Dry Mouth; Gingival Disorder; Nerve Injury | Lexapro        |              |            | S           |              | 20 Mg              |                 | Forest     |

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| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Dec-2014              | 10641530      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000072973    |                      | 68 YR      | Female     | FRA            |

| <u>Preferred Term</u>                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction; Post Procedural Haematoma | Escitalopram   |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                             | Pradaxa        |              |            | S           | Oral         | 110 Mg             |                 | Not Reported |
|                                             | Kardegic       |              |            | S           | Oral         | 75 Mg              |                 | Not Reported |
|                                             | Plavix         |              |            | S           | Oral         | 75 Mg              |                 | Not Reported |
|                                             | Insulatard     |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                             | Novonorm       |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                             | Lasilix        |              |            | C           | Unknown      | 40 Mg              |                 | Not Reported |
|                                             | Bisoprolol     |              |            | C           | Unknown      | 5 Mg               |                 | Not Reported |
|                                             | Metformin      |              |            | C           | Unknown      | 850 Mg             |                 | Not Reported |
|                                             | Diffu K        |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                             | Aldactone      |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                             | Perindopril    |              |            | C           | Unknown      | 8 Mg               |                 | Not Reported |
|                                             | Crestor        |              |            | C           | Unknown      | 5 Mg               |                 | Not Reported |
|                                             | Ikorel         |              |            | C           | Unknown      | 10 Mg              |                 | Not Reported |
|                                             | Lovenox        |              |            | C           | Unknown      | 12000 Iu           |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 09-Dec-2014              | 10641925      | EXPEDITED (15-DAY) |                    | HO, LT, OT      | FR-PFIZER INC-2014336460 |                      | 18 YR      | Female     | FRA            |

| <u>Preferred Term</u>                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Coma; Hypotension; Overdose; Poisoning Deliberate | Xanax          |              |            | S           |              | 1.25 Mg, Single    |                 | Pfizer       |
|                                                   | Temerit        |              |            | S           |              | Unk                |                 | Not Reported |
|                                                   | Temerit        |              |            | S           |              | 170 Mg, Single     |                 | Not Reported |
|                                                   | Procoralan     |              |            | S           |              | 85 Mg, Single      |                 | Not Reported |
|                                                   | Tercian        |              |            | S           |              | Unk Unk, As Needed |                 | Not Reported |

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|                                                                                                             | Tercian              |                    | S                  |                 | 625 To 2600 Mg As Single Dose |                      | Not Reported    |              |                |
|-------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|-----------------|--------------|----------------|
|                                                                                                             | Seroplex             |                    | S                  |                 | Unk                           |                      | Not Reported    |              |                |
|                                                                                                             | Seroplex             |                    | S                  |                 | 1100 Mg, Single               |                      | Not Reported    |              |                |
| <u>FDA Received Date</u>                                                                                    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Dec-2014                                                                                                 | 10644220             | EXPEDITED (15-DAY) |                    | DE              | AU-FRI-1000072904             |                      | 62 YR           | Female       | AUS            |
| <u>Preferred Term</u>                                                                                       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyponatraemia                                                                                               | Escitalopram         |                    |                    | S               | Unknown                       |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Dec-2014                                                                                                 | 10648957             | EXPEDITED (15-DAY) | Y                  | HO, OT          | ADR-2014-02298                |                      | 34 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Amnesia; Fall; Head Injury; Infection; Loss Of Consciousness; Periorbital Haemorrhage; Skin Necrosis; Wound | Lioresal (Baclofen)  |                    |                    | S               | Oral                          |                      |                 | Not Reported |                |
|                                                                                                             | Tercian              |                    |                    | S               |                               |                      |                 | Not Reported |                |
|                                                                                                             | Imovane (Zopiclone)  |                    |                    | S               | Oral                          |                      |                 | Not Reported |                |
|                                                                                                             | Atarax (Hydroxyzine) |                    |                    | S               | Oral                          |                      | 107 DAY         | Not Reported |                |
|                                                                                                             | Seroplex             |                    |                    | S               | Oral                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Dec-2014                                                                                                 | 10305485             | EXPEDITED (15-DAY) |                    | HO, LT          | IT-MYLANLABS-2014S1016041     |                      |                 | Unknown      | ITA            |
| <u>Preferred Term</u>                                                                                       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Coma; Drug Interaction                                                                                      | Lorazepam            |                    |                    | S               | Oral                          | 7.5 Mg,Qd            |                 | Not Reported |                |
|                                                                                                             | Venlafaxine          |                    |                    | S               | Oral                          | 150 Mg,Qd            |                 | Not Reported |                |
|                                                                                                             | Invega /05724801/    |                    |                    | S               | Oral                          | 9 Mg,Qd              |                 | Not Reported |                |
|                                                                                                             | Depakin              |                    |                    | S               | Oral                          | 750 Mg,Qd            |                 | Not Reported |                |
|                                                                                                             | Akineton /00079501/  |                    |                    | S               | Oral                          | 4 Mg,Qd              |                 | Not Reported |                |



# FDA Adverse Event Reporting System

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|                                                                       | Tranquirit     | S                  | Oral               | 20 Gtt,Qd       |                            | Not Reported         |                 |              |                |
|-----------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
|                                                                       | Cipralex       | S                  | Oral               | 5 Gtt,Qd        |                            | Not Reported         |                 |              |                |
| <u>FDA Received Date</u>                                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Dec-2014                                                           | 10606854       | EXPEDITED (15-DAY) | CA                 |                 | GB-FRI-1000072622          |                      | 27 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Pregnancy                                                             | Escitalopram   |                    |                    | S               | Oral                       | 20 Mg Daily          |                 | Forest       |                |
|                                                                       | Escitalopram   |                    |                    | S               |                            |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Dec-2014                                                           | 10645620       | EXPEDITED (15-DAY) | HO                 |                 | AT-ASTRAZENECA-2014SE77489 |                      | 47 YR           | Male         | AUT            |
| <u>Preferred Term</u>                                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Delirium; Gait<br>Disturbance; Psychomotor<br>Skills Impaired; Tremor | Seroquel Xr    |                    |                    | S               | Oral                       | 400-800 Mg Daily     |                 | Not Reported |                |
|                                                                       | Abilify        |                    |                    | S               | Unknown                    | 5 Daily              |                 | Not Reported |                |
|                                                                       | Abilify        |                    |                    | S               | Unknown                    | 10 Daily             |                 | Not Reported |                |
|                                                                       | Praxiten       |                    |                    | S               | Unknown                    | Max 300 Mg Daily     |                 | Not Reported |                |
|                                                                       | Praxiten       |                    |                    | S               | Unknown                    |                      |                 | Not Reported |                |
|                                                                       | Praxiten       |                    |                    | S               | Unknown                    |                      |                 | Not Reported |                |
|                                                                       | Praxiten       |                    |                    | S               | Unknown                    |                      |                 | Not Reported |                |
|                                                                       | Praxiten       |                    |                    | S               | Unknown                    | 100-0 Mg, Daily      |                 | Not Reported |                |
|                                                                       | Praxiten       |                    |                    | S               | Unknown                    | 100-0 Mg, Daily      |                 | Not Reported |                |
|                                                                       | Cipralex       |                    |                    | S               | Unknown                    | 10-30mg Daily        |                 | Not Reported |                |
|                                                                       | Substitol Ret  |                    |                    | C               |                            |                      |                 | Not Reported |                |
|                                                                       | Trittico Ret   |                    |                    | C               |                            | 150 Daily            |                 | Not Reported |                |
| Akineton Ret                                                          |                |                    | C                  |                 |                            |                      | Not Reported    |              |                |
| <u>FDA Received Date</u>                                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Dec-2014                                                           | 10645866       | EXPEDITED (15-DAY) | CA                 |                 | GB-FRI-1000072856          |                      |                 | Unknown      | GBR            |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|------------|
| Foetal Exposure During Pregnancy; Ventricular Septal Defect | Escitalopram   |              |            | S           | Transplacental | 20 Mg              |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Dec-2014              | 10646814      | EXPEDITED (15-DAY) |                    | OT              | GXBR2014US002574     |                      | 49 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                   | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                           | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------|-----------------------------|--------------|------------|-------------|--------------|--------------------------------------------------------------|-----------------|--------------|
| Blood Cholesterol Increased; Dry Mouth; Oropharyngeal Pain; Type 2 Diabetes Mellitus; Visual Impairment | Tizanidine Sandoz           |              |            | S           | Unknown      | 8 Mg, Tid                                                    |                 | Novartis     |
|                                                                                                         | Lyrica                      |              |            | S           | Unknown      | 300 Mg, Bid                                                  |                 | Not Reported |
|                                                                                                         | Oxycodone And Acetaminophen |              |            | S           | Unknown      | 10mg Oxycodone And 325 Mg Acetaminophen - 1 Df , Tid         |                 | Not Reported |
|                                                                                                         | Seroquel                    |              |            | S           | Unknown      | 50mg Twice Daily In The Morning And Noon, And 200mg At Night |                 | Not Reported |
|                                                                                                         | Seroquel                    |              |            | S           |              |                                                              |                 | Not Reported |
|                                                                                                         | Venlafaxine                 |              |            | S           | Unknown      | 225 Mg, Qd                                                   |                 | Not Reported |
|                                                                                                         | Lexapro                     |              |            | S           | Unknown      | 20 Mg, Qd                                                    |                 | Not Reported |
|                                                                                                         | Valium                      |              |            | S           | Unknown      | 5 Mg, Tid                                                    |                 | Not Reported |
|                                                                                                         | Demadex                     |              |            | S           | Unknown      | 20 Mg, Qd                                                    |                 | Not Reported |
|                                                                                                         | Aspirin                     |              |            | S           | Unknown      | 162 Mg, Qhs                                                  |                 | Not Reported |
|                                                                                                         | Topamax                     |              |            | S           | Unknown      | 100 Mg, Qd In The Morning                                    |                 | Not Reported |
|                                                                                                         | Ibuprofen                   |              |            | S           | Unknown      | 800 Mg, Unk                                                  |                 | Not Reported |
|                                                                                                         | Fentanyl                    |              |            | S           | Unknown      | 50 Ug, Q48h                                                  |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Dec-2014              | 10647544      | EXPEDITED (15-DAY) |                    | HO              | IT-TEVA-527226ISR    |                      | 23 YR      | Female     | ITA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

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|                                    |                                                  |   |      |              |              |
|------------------------------------|--------------------------------------------------|---|------|--------------|--------------|
| Bradykinesia; Drug Abuse;<br>Sopor | Mirtazapine                                      | S | Oral | 600 Mg Total | Teva         |
|                                    | Periactin - 4 Mg Comprese -<br>Avantgarde S.P.A. | S | Oral | 10 Df Total  | Not Reported |
|                                    | CipraleX - Comprese Rivestite                    | S | Oral | 14 Df Total  | Not Reported |
|                                    | Con Film - H. Lundbeck A/S                       |   |      |              |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Dec-2014              | 10584523      | EXPEDITED (15-DAY) |                    | HO              | IT-WATSON-2014-24184 |                      | 69 YR      | Female     | ITA            |

| <u>Preferred Term</u>                           | <u>Product</u>                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------|--------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Bradycardia; Headache;<br>Hypotension; Overdose | Lorazepam (Unknown)            |              |            | S           | Oral         | 1 Mg, Daily        |                 | Watson       |
|                                                 | Olmesartan Medoxomil (Unknown) |              |            | S           | Oral         | 10 Mg, Daily       |                 | Not Reported |
|                                                 | CipraleX /01588501/            |              |            | S           | Oral         | 10 Mg, Daily       |                 | Not Reported |
|                                                 | Formistin                      |              |            | C           | Unknown      | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 12-Dec-2014              | 10650141      | NON-EXPEDITED    |                    |                 | US-ASTRAZENECA-2014SE95108 |                      | 69 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|---------------------|-----------------|--------------|
| Anxiety; Diarrhoea;<br>Discomfort; Dyspepsia;<br>Feeling Abnormal;<br>Flatulence; Flatulence;<br>Gait Disturbance; Gastric Disorder;<br>Gastrooesophageal Reflux Disease; Hallucination;<br>Intentional Product Misuse; Pain; Panic Attack; Scrotal Swelling; Testicular Pain | Nexium 24hr    |              |            | S           | Oral         |                     |                 | Astrazeneca  |
|                                                                                                                                                                                                                                                                               | Prozac         |              |            | S           | Unknown      |                     |                 | Not Reported |
|                                                                                                                                                                                                                                                                               | Prozac         |              |            | S           | Unknown      | 20 Mg Ultrnate Days |                 | Not Reported |
|                                                                                                                                                                                                                                                                               | Lexapro        |              |            | S           | Unknown      | Generic             |                 | Not Reported |
|                                                                                                                                                                                                                                                                               | Antidepressant |              |            | S           | Unknown      |                     |                 | Not Reported |
|                                                                                                                                                                                                                                                                               | Lisinopril     |              |            | C           |              |                     |                 | Not Reported |
|                                                                                                                                                                                                                                                                               | Atorvastatin   |              |            | C           |              |                     |                 | Not Reported |
|                                                                                                                                                                                                                                                                               | Vitamin B12    |              |            | C           |              |                     |                 | Not Reported |
|                                                                                                                                                                                                                                                                               | Vitamin B6     |              |            | C           |              |                     |                 | Not Reported |
|                                                                                                                                                                                                                                                                               |                |              |            |             |              |                     |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 13-Dec-2014              | 10576106      | EXPEDITED (15-DAY) |                    | HO, OT          | IT-MYLANLABS-2014M1009726 |                      |            | Unknown    | ITA            |

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| <u>Preferred Term</u>                                                                                             | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|-------------------------|----------------------|-----------------|--------------|----------------|
| Bradycardia;<br>Electrocardiogram Qt<br>Interval Abnormal;<br>Headache; Hypotension;<br>Overdose                  | Lorazepam            |                    |                    | S               | Oral                    | 1 Mg, Qd             |                 | Not Reported |                |
|                                                                                                                   | Olmesartan Medoxomil |                    |                    | S               | Oral                    | 10 Mg, Qd            |                 | Not Reported |                |
|                                                                                                                   | Cipralext /01588502/ |                    |                    | S               | Oral                    | 10 Mg, Qd            |                 | Not Reported |                |
|                                                                                                                   | Eutirox              |                    |                    | C               |                         | 125 Mg               |                 | Not Reported |                |
|                                                                                                                   | Formistin            |                    |                    | C               |                         | 10 Mg                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                          | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Dec-2014                                                                                                       | 10578272             | EXPEDITED (15-DAY) |                    | HO              | IT-RANBAXY-2014RR-87839 |                      | 69 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                                                             | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bradycardia; Hypotension                                                                                          | Lorazepam            |                    |                    | S               | Oral                    | 1 Mg, Daily          |                 | Ranbaxy      |                |
|                                                                                                                   | Olmesartan           |                    |                    | S               | Oral                    | 10 Mg, Daily         |                 | Not Reported |                |
|                                                                                                                   | Cipralext            |                    |                    | S               | Oral                    | 10 Mg, Daily         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                          | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Dec-2014                                                                                                       | 10651332             | NON-EXPEDITED      |                    |                 | US-TEVA-506850USA       |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                             | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain Upper;<br>Bradyphrenia; Crying;<br>Depressed Mood;<br>Depression; Drug<br>Ineffective; Tearfulness | Escitalopram         |                    |                    | S               | Unknown                 |                      |                 | Ivax         |                |
| <u>FDA Received Date</u>                                                                                          | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Dec-2014                                                                                                       | 10651334             | NON-EXPEDITED      |                    |                 | US-TEVA-507343USA       |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                             | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Distension;<br>Agitation; Headache;<br>Musculoskeletal Stiffness;                                       | Escitalopram         |                    |                    | S               | Oral                    |                      |                 | Ivax         |                |
|                                                                                                                   | Escitalopram         |                    |                    | S               |                         |                      |                 | Ivax         |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Neck Pain; Nightmare

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Dec-2014              | 10651335      | NON-EXPEDITED    |                    |                 | US-TEVA-520403USA    |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Therapeutic Product Effect Decreased | Escitalopram   |              |            | S           |              |                    |                 | Ivax       |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Dec-2014              | 10652397      | EXPEDITED (15-DAY) |                    | HO, LT          | NL-FRI-1000073081    |                      | 29 YR      | Female     | NLD            |

| <u>Preferred Term</u>                                              | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------|-------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Atrioventricular Block;<br>Drug Interaction;<br>Pulmonary Embolism | Escitalopram      |              |            | S           | Oral         | 10 Mg Daily        |                 | Forest       |
|                                                                    | Lithium Carbonate |              |            | S           |              | 400 Mg Daily       |                 | Not Reported |
|                                                                    | Lithium Carbonate |              |            | S           |              | 100 Mg Daily       |                 | Not Reported |
|                                                                    | Olanzapine        |              |            | C           |              | 2.5 Mg             |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Dec-2014              | 10652621      | EXPEDITED (15-DAY) |                    | HO              | IT-WATSON-2014-26473 |                      | 23 YR      | Female     | ITA            |

| <u>Preferred Term</u>              | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------|-----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Bradykinesia; Drug Abuse;<br>Sopor | Mirtazapine (Unknown) |              |            | S           | Oral         | 600 Mg, Total      |                 | Actavis      |
|                                    | Ciprallex /01588501/  |              |            | S           | Oral         | 14 Df, Total       |                 | Not Reported |
|                                    | Periactin             |              |            | S           | Oral         | 10 Df, Total       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Dec-2014              | 10653048      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000073075    |                      | 79 YR      | Male       | FRA            |

| <u>Preferred Term</u>                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Anaemia; Drug Interaction;<br>Gingival Bleeding | Escitalopram   |              |            | S           | Oral         | 10 Mg              |                 | Forest     |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                 |   |              |               |              |
|---------------------------------|---|--------------|---------------|--------------|
| Arixtra                         | S | Subcutaneous | 7.5 Mg/0.6 MI | Not Reported |
| Arixtra                         | S | Subcutaneous | 7.5 Mg/0.6 MI | Not Reported |
| Uvedose                         | C | Oral         | 0.0111 Df     | Not Reported |
| Ramipril                        | C | Unknown      | 5 Mg          | Not Reported |
| Loxen Lp                        | C | Unknown      | 50 Mg         | Not Reported |
| Alprazolam                      | C | Unknown      | 0.5 Mg        | Not Reported |
| Macrogol Biogaran               | C | Unknown      | 10 G          | Not Reported |
| Oracilline                      | C | Unknown      | 2000000 Iu    | Not Reported |
| Solupred (Prednisolone)         | C | Unknown      | 20 Mg         | Not Reported |
| Bicarbonate De Sodium Lavoisier | C | Unknown      | 1500 MI       | Not Reported |
| Esomeprazole                    | C | Unknown      | 20 Mg         | Not Reported |
| Lasilix                         | C | Unknown      | 60 Mg         | Not Reported |
| Paracetamol                     | C | Unknown      | 4 G           | Not Reported |
| Atrovent                        | C | Unknown      | 0.5 Mg        | Not Reported |
| Bricanyl                        | C | Unknown      | 5 Mg          | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Dec-2014              | 10653058      | EXPEDITED (15-DAY) |                    | HO              | CH-FRI-1000073066    |                      | 90 YR      | Female     | CHE            |

| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cholestatic Liver Injury | Escitalopram   |              |            | S           | Oral         | 15 Mg              |                 | Forest       |
|                          | Escitalopram   |              |            | S           | Oral         | 20 Mg              |                 | Forest       |
|                          | Memantine      |              |            | S           | Oral         | 5 Mg               |                 | Forest       |
|                          | Memantine      |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                          | Trittico       |              |            | S           | Oral         | 50 Mg              |                 | Not Reported |
|                          | Dexamethasone  |              |            | C           | Oral         | 4 Mg               |                 | Not Reported |
|                          | Sintrom        |              |            | C           | Oral         |                    |                 | Not Reported |
|                          | Amlodipine     |              |            | C           | Oral         | 10 Mg              |                 | Not Reported |
|                          | Augmentin      |              |            | C           | Oral         | 500/125 Mg         |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                     |   |      |         |              |
|---------------------|---|------|---------|--------------|
| Distraneurin        | C | Oral | 300 Mg  | Not Reported |
| Nexium              | C | Oral | 20 Mg   | Not Reported |
| Euthyrox            | C | Oral | 50 Mcg  | Not Reported |
| Laxoberon           | C | Oral | 10 Mg   | Not Reported |
| Torem               | C | Oral | 10 Mg   | Not Reported |
| Calcimagon D3       | C | Oral | 2 Df    | Not Reported |
| Zolpidem            | C | Oral | 5 Mg    | Not Reported |
| Temesta (Lorazepam) | C | Oral | 1 Mg    | Not Reported |
| Dafalgan            | C | Oral | 3000 Mg | Not Reported |
| Quetiapine          | C | Oral | 12.5 Mg | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Dec-2014              | 10654435      | DIRECT           | Y                  | OT              |                      |                      | 33 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Homicidal Ideation;   | Escitalopram 20mg Generic |              |            | S           | Oral         |                    |                 | Not Reported |
| Suicidal Ideation     | Prozac                    |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Dec-2014              | 10655237      | DIRECT           |                    |                 |                      |                      | 57 YR      | Female     |                |

| <u>Preferred Term</u>                                                                                                                    | <u>Product</u>  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|------------------------------------------------------------------------------------------------------------------------------------------|-----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Decreased Appetite; Drug Ineffective; Head Discomfort; Insomnia; Negative Thoughts; Nervousness; Product Substitution Issue; Tearfulness | Generic Lexapro |              |            | S           | Oral         |                    |                 | Camber     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Dec-2014              | 10576995      | EXPEDITED (15-DAY) |                    | HO              | DE-FRI-1000072233    |                      | 56 YR      | Female     | DEU            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                       | <u>Product</u>  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------|-----------------|--------------|------------|-------------|--------------|---------------------|-----------------|--------------|
| Heart Rate Irregular;<br>Palpitations; Prescribed<br>Overdose; Restlessness | Escitalopram    |              |            | S           | Oral         | Overdose: 30 Mg/Day |                 | Forest       |
|                                                                             | Risperdal       |              |            | S           | Oral         | 1 Mg                |                 | Not Reported |
|                                                                             | Risperdal       |              |            | S           | Oral         | 2 Mg                |                 | Not Reported |
|                                                                             | Quilonum Retard |              |            | C           | Oral         | 450 Mg              |                 | Not Reported |
|                                                                             | Lyrica          |              |            | C           | Oral         | 100 Mg              |                 | Not Reported |
|                                                                             | Pantozol        |              |            | C           | Oral         | 20 Mg               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Dec-2014              | 10654421      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000073089    |                      | 82 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Haematemesis          | Escitalopram           |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                       | Kardegic               |              |            | S           |              | 75 Mg              |                 | Not Reported |
|                       | Ketoprofene            |              |            | S           |              |                    |                 | Not Reported |
|                       | Previscan (Fluindione) |              |            | S           |              | 10 Or 15 Mg Daily  |                 | Not Reported |
|                       | Rabeprazole            |              |            | C           |              | 20 Mg              |                 | Not Reported |
|                       | Repaglinide            |              |            | C           |              | 2 Mg               |                 | Not Reported |
|                       | Bisoce                 |              |            | C           |              | 25 Mg              |                 | Not Reported |
|                       | Crestor                |              |            | C           |              | 5 Mg               |                 | Not Reported |
|                       | Amlor                  |              |            | C           | Oral         |                    |                 | Not Reported |
|                       | Coaprovel              |              |            | C           | Oral         | 300/25 Mg Daily    |                 | Not Reported |
|                       | Lantus                 |              |            | C           | Subcutaneous |                    |                 | Not Reported |
|                       | Novorapid              |              |            | C           | Subcutaneous | 100 U/MI           |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 16-Dec-2014              | 10654954      | NON-EXPEDITED    |                    |                 | US-PFIZER INC-<br>2014344394 |                      | 72 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                       |           |   |     |              |
|-----------------------|-----------|---|-----|--------------|
| Drug Hypersensitivity | Oxaprozin | S | Unk | Pfizer       |
|                       | Lexapro   | S | Unk | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Dec-2014              | 10655045      | EXPEDITED (15-DAY) |                    | HO, LT          | FR-FRI-1000073006    |                      | 18 YR      | Female     | FRA            |

| <u>Preferred Term</u>                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Coma; Hypotension;<br>Poisoning Deliberate | Nebivolol      |              |            | S           | Oral         |                    |                 | Forest       |
|                                            | Nebivolol      |              |            | S           | Oral         |                    |                 | Not Reported |
|                                            | Escitalopram   |              |            | S           | Oral         |                    |                 | Forest       |
|                                            | Escitalopram   |              |            | S           | Oral         |                    |                 | Not Reported |
|                                            | Procoralan     |              |            | S           |              |                    |                 | Not Reported |
|                                            | Procoralan     |              |            | S           |              |                    |                 | Not Reported |
|                                            | Tercian        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                            | Tercian        |              |            | S           | Oral         | 625 To 2600 Mg     |                 | Not Reported |
|                                            | Xanax          |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Dec-2014              | 10659862      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000073137    |                      | 81 YR      | Female     | FRA            |

| <u>Preferred Term</u>                             | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction;<br>Retroperitoneal<br>Haematoma | Escitalopram           |              |            | S           | Oral         |                    |                 | Forest       |
|                                                   | Innohep                |              |            | S           | Subcutaneous | 1 Df               |                 | Not Reported |
|                                                   | Innohep                |              |            | S           | Subcutaneous | 1 Df               |                 | Not Reported |
|                                                   | Previscan (Fluindione) |              |            | S           | Oral         | 0.5 Df             |                 | Not Reported |
|                                                   | Previscan (Fluindione) |              |            | S           | Oral         | 0.5 Df             |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------|----------------------|------------|------------|----------------|
| 19-Dec-2014              | 8607687       | EXPEDITED (15-DAY) |                    | DE, OT          | AT-RANBAXY-2012R1-56859 |                      | 41 YR      | Female     | AUT            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                            |           |   |         |     |              |
|------------------------------------------------------------|-----------|---|---------|-----|--------------|
| Shock; Toxicity To Various Agents; Unresponsive To Stimuli | Topamax   | S | Unknown | Unk | Not Reported |
|                                                            | Ciprallex | S | Unknown | Unk | Not Reported |
|                                                            | Somnubene | S | Unknown | Unk | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Dec-2014              | 10667639      | EXPEDITED (15-DAY) |                    | OT              | GB-TEVA-529059ISR    |                      | 73 YR      | Female     | GBR            |

| <u>Preferred Term</u>                                                                                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Headache; Influenza Like Illness; Malaise; Nightmare; Pain; Product Substitution Issue; Withdrawal Syndrome | Clomipramine   |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                             | Ciprallex      |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Dec-2014              | 10669020      | EXPEDITED (15-DAY) |                    | DE              | FR-FRI-1000073274    |                      | 72 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cerebral Haemorrhage  | Escitalopram      |              |            | S           |              | 1 Df               |                 | Forest       |
|                       | Kardegic          |              |            | S           | Oral         | 7.5 Mg             |                 | Not Reported |
|                       | Tahor             |              |            | C           |              |                    |                 | Not Reported |
|                       | Coversyl          |              |            | C           |              |                    |                 | Not Reported |
|                       | Lyrica            |              |            | C           |              |                    |                 | Not Reported |
|                       | Topalgic (France) |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Dec-2014              | 10669021      | EXPEDITED (15-DAY) |                    | OT              | GB-FRI-1000073261    |                      | 73 YR      | Female     | GBR            |

| <u>Preferred Term</u>                                                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Headache; Influenza Like Illness; Malaise; Nightmare; Pain; Withdrawal Syndrome | Escitalopram   |              |            | S           | Oral         |                    |                 | Forest       |
|                                                                                 | Clomipramine   |              |            | S           | Unknown      |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                        | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------|----------------------------|--------------------|--------------------|-----------------|---------------------------|--------------------------------|-----------------|--------------|----------------|
| 22-Dec-2014                                                                     | 10669036                   | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000073264         |                                | 75 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                           | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Constipation; Subileus                                                          | Escitalopram               |                    |                    | S               | Oral                      |                                |                 | Forest       |                |
|                                                                                 | Zyprexa                    |                    |                    | S               | Oral                      |                                |                 | Not Reported |                |
|                                                                                 | Risperdal                  |                    |                    | S               | Oral                      |                                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                        | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Dec-2014                                                                     | 10672306                   | DIRECT             |                    | OT              |                           |                                | 63 YR           | Female       |                |
| <u>Preferred Term</u>                                                           | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective; Product Substitution Issue                                    | Escitalopram               |                    |                    | S               |                           | 1 Pill Daily Approx. 2-3 Years | 2-3 YR          | Not Reported |                |
| <u>FDA Received Date</u>                                                        | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Dec-2014                                                                     | 10671402                   | EXPEDITED (15-DAY) |                    | OT              | GB-MYLANLABS-2014M1014313 |                                |                 | Unknown      | GBR            |
| <u>Preferred Term</u>                                                           | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Headache; Influenza Like Illness; Malaise; Nightmare; Pain; Withdrawal Syndrome | Clomipramine               |                    |                    | S               |                           |                                |                 | Not Reported |                |
|                                                                                 | Cipralext                  |                    |                    | S               |                           |                                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                        | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Dec-2014                                                                     | 10671467                   | EXPEDITED (15-DAY) |                    | OT              | CH-FRI-1000073226         |                                | 15 YR           | Male         | CHE            |
| <u>Preferred Term</u>                                                           | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Altered State Of Consciousness; Muscle Spasms; Off Label Use; Tachycardia       | Escitalopram Oral Solution |                    |                    | S               | Oral                      | 5 Gtt                          |                 | Forest       |                |
|                                                                                 | Risperdal                  |                    |                    | S               | Oral                      | 2 Mg                           |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                        | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------|-------------------|--------------------|--------------------|-----------------|----------------------|--------------------------|-----------------|--------------|----------------|
| 23-Dec-2014                                                                                     | 10671469          | EXPEDITED (15-DAY) |                    | OT              | IE-FRI-1000073229    |                          | 30 YR           | Male         | IRL            |
| <u>Preferred Term</u>                                                                           | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Brain Injury; Withdrawal Syndrome                                                               | Lexapro           |                    |                    | S               | Oral                 |                          |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                        | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Dec-2014                                                                                     | 10671496          | EXPEDITED (15-DAY) |                    | OT              | PHFR2014GB008727     |                          | 73 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                                           | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Headache; Influenza Like Illness; Malaise; Nightmare; Pain; Withdrawal Syndrome                 | Clomipramine      |                    |                    | S               | Unknown              |                          |                 | Novartis     |                |
|                                                                                                 | Ciprallex         |                    |                    | S               | Unknown              | Unk                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                        | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Dec-2014                                                                                     | 10671704          | EXPEDITED (15-DAY) |                    | HO, LT          | FR-FRI-1000073289    |                          | 84 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                           | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrial Fibrillation; Electrocardiogram Qt Prolonged; Intentional Overdose; Poisoning Deliberate | Escitalopram      |                    |                    | S               | Oral                 | 1 Df                     |                 | Forest       |                |
|                                                                                                 | Sotalex           |                    |                    | S               | Oral                 |                          |                 | Not Reported |                |
|                                                                                                 | Sotalex           |                    |                    | S               | Oral                 | Overdose Of 1920 Mg Once |                 | Not Reported |                |
|                                                                                                 | Laroxyl           |                    |                    | S               | Oral                 | 50 Df                    |                 | Not Reported |                |
|                                                                                                 | Lexomil           |                    |                    | C               |                      | 1 Df                     |                 | Not Reported |                |
|                                                                                                 | Ceris             |                    |                    | C               |                      | 1 Df                     |                 | Not Reported |                |
|                                                                                                 | Topalgic (France) |                    |                    | C               |                      |                          |                 | Not Reported |                |
|                                                                                                 | Mopral            |                    |                    | C               |                      | 1 Df                     |                 | Not Reported |                |
|                                                                                                 | Insulin           |                    |                    | C               |                      |                          |                 | Not Reported |                |
|                                                                                                 | Lovenox           |                    |                    | C               |                      | 2 Df                     |                 | Not Reported |                |
|                                                                                                 | Inexium           |                    |                    | C               |                      |                          |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| 24-Dec-2014                                               | 10441844                 | EXPEDITED (15-DAY) |                    | DS, HO, LT      | DE-009507513-1409DEU002402 |                      | 58 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                     | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Myoclonus; Pyrexia; Serotonin Syndrome; Sinus Tachycardia | Mirtazapin Stada         |                    |                    | S               | Oral                       | 15 Mg, Qd            |                 | Merck        |                |
|                                                           | Escitalopram             |                    |                    | S               | Oral                       | 10 Mg, Unk           |                 | Not Reported |                |
|                                                           | Amantadine Hydrochloride |                    |                    | S               | Oral                       | 100 Mg, Unk          |                 | Not Reported |                |
|                                                           | Amantadine Hydrochloride |                    |                    | S               |                            |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Dec-2014                                               | 10649630                 | EXPEDITED (15-DAY) |                    | OT              | JP-FRI-1000073009          |                      | 77 YR           | Male         | JPN            |
| <u>Preferred Term</u>                                     | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Activation Syndrome                                       | Escitalopram             |                    |                    | S               | Oral                       | 10 Mg                |                 | Forest       |                |
|                                                           | Rize                     |                    |                    | C               | Oral                       | 10 Mg                |                 | Not Reported |                |
|                                                           | Zolpidem Tartrate        |                    |                    | C               | Oral                       | 5 Mg                 |                 | Not Reported |                |
|                                                           | Brotizolam               |                    |                    | C               | Oral                       | 0.125 Mg             |                 | Not Reported |                |
|                                                           | Brotizolam               |                    |                    | C               | Oral                       | 0.125 Mg             |                 | Not Reported |                |
|                                                           | Argamate                 |                    |                    | C               | Oral                       | 75 Mg                |                 | Not Reported |                |
|                                                           | Bayaspirin               |                    |                    | C               | Oral                       | 100 Mg               |                 | Not Reported |                |
|                                                           | Halfdigoxin              |                    |                    | C               | Oral                       | 0.125 Mg             |                 | Not Reported |                |
|                                                           | Benidipine               |                    |                    | C               | Oral                       | 4 Mg                 |                 | Not Reported |                |
|                                                           | Allopurinol              |                    |                    | C               | Oral                       | 100 Mg               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Dec-2014                                               | 10674610                 | EXPEDITED (15-DAY) |                    | HO, OT          | SI-ACTAVIS-2014-27229      |                      |                 | Male         | SVN            |
| <u>Preferred Term</u>                                     | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Delirium                                                  | Escitalopram (Unknown)   |                    |                    | S               |                            | 10 Mg, Daily         |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                         |   |         |                 |              |
|-------------------------|---|---------|-----------------|--------------|
| Escitalopram (Unknown)  | S | Unknown | 5 Mg, Daily     | Not Reported |
| Lamotrigine (Unknown)   | S |         | 200 Mg, Bid     | Watson       |
| Quetiapine (Unknown)    | S | Unknown | 500 Mg, Daily   | Actavis      |
| Valproic Acid (Unknown) | S | Unknown | 1000 Mg, Bid    | Watson       |
| Acetylsalicylic Acid    | C | Unknown | 100 Mg, Unknown | Not Reported |
| Digoxin                 | C | Unknown | 0.1 Mg, Unknown | Not Reported |
| Carvedilol              | C | Unknown | Unk             | Not Reported |
| Pantoprazole            | C | Unknown | 20 Mg, Unknown  | Not Reported |
| Hydroxyurea             | C | Unknown | 1000 Mg, Bid    | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 24-Dec-2014              | 10675008       | EXPEDITED (15-DAY) |                    | HO              | FR-JNJFOC-20141208555 |                      | 75 YR           | Male         | FRA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Constipation;            | Risperdal      |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
| Haematemesis; Pyrexia;   | Zyprexa        |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
| Subileus                 | Seroplex       |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                           | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>                    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|-----------------------|-----------------------------------------|-----------------|--------------|----------------|
| 26-Dec-2014                                                                                        | 10624688       | NON-EXPEDITED    |                    | OT              | US-JNJFOC-20141119929 |                                         | 49 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                              | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>                      | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Cholesterol Increased; Dry Mouth; Eye Disorder; Oropharyngeal Pain; Type 2 Diabetes Mellitus | Topamax        |                  |                    | S               | Oral                  |                                         |                 | Not Reported |                |
|                                                                                                    | Fentanyl       |                  |                    | S               | Transdermal           |                                         |                 | Not Reported |                |
|                                                                                                    | Oxycodone/Apap |                  |                    | S               | Unknown               | 10/325 Mg                               |                 | Not Reported |                |
|                                                                                                    | Ibuprofen      |                  |                    | S               | Unknown               | 800 Mg In The Morning And 1200 Mg       |                 | Not Reported |                |
|                                                                                                    | Tizanidine     |                  |                    | S               | Unknown               |                                         |                 | Not Reported |                |
|                                                                                                    | Seroquel       |                  |                    | S               | Unknown               | 50 Mg At Morning And Noon And 200 Mg At |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|             |   |         |                                                                |              |
|-------------|---|---------|----------------------------------------------------------------|--------------|
| Seroquel    | S | Unknown | Night.<br>50 Mg At Morning And<br>Noon And 200 Mg At<br>Night. | Not Reported |
| Venlafaxine | S | Oral    | 75 Mg Capsule And A<br>150 Mg Capsule<br>Together              | Not Reported |
| Lexapro     | S | Unknown |                                                                | Not Reported |
| Valium      | S | Unknown |                                                                | Not Reported |
| Demadex     | S | Unknown |                                                                | Not Reported |
| Lyrica      | S | Oral    |                                                                | Not Reported |
| Metformin   | C | Unknown |                                                                | Not Reported |
| Aspirin     | C | Oral    |                                                                | Not Reported |
| Simvastatin | C | Unknown |                                                                | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------------|----------------------|------------|------------|----------------|
| 26-Dec-2014              | 10676293      | EXPEDITED (15-DAY) |                    | HO, OT          | DE-DRREDDYS-<br>GER/GER/14/0045060 |                      | 50 YR      | Female     | DEU            |

| <u>Preferred Term</u>                        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Agitation; Drug Interaction;<br>Restlessness | Venlafaxine    |              |            | S           | Oral         |                    |                 | Not Reported |
|                                              | Venlafaxine    |              |            | S           | Oral         |                    |                 | Not Reported |
|                                              | Cipralext      |              |            | S           | Oral         |                    |                 | Not Reported |
|                                              | Cipralext      |              |            | S           | Oral         |                    |                 | Not Reported |
|                                              | Cipralext      |              |            | S           | Oral         |                    |                 | Not Reported |
|                                              | Cipralext      |              |            | S           | Oral         |                    |                 | Not Reported |
|                                              | Cipralext      |              |            | S           | Oral         |                    |                 | Not Reported |
|                                              | Abilify        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                              | Abilify        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                              | Remergil       |              |            | C           | Oral         |                    |                 | Not Reported |

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| <u>FDA Received Date</u>                                                                                               | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------|------------------------------------|--------------------|--------------------|-----------------|---------------------------------|------------------------------|-----------------|--------------|----------------|
| 27-Dec-2014                                                                                                            | 10163013                           | EXPEDITED (15-DAY) |                    | OT              | PHHY2014US054442                |                              | 67 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                  | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Muscle Spasms; Muscle Spasticity; Pain                                                                                 | Lioresal Intratecal                |                    |                    | S               | Intrathecal                     | 2128 Ot, Qd, (2000 Ug/MI)    |                 | Not Reported |                |
|                                                                                                                        | Lisinopril                         |                    |                    | S               | Oral                            |                              |                 | Novartis     |                |
|                                                                                                                        | Lexapro                            |                    |                    | S               | Oral                            |                              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                               | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Dec-2014                                                                                                            | 10533955                           | EXPEDITED (15-DAY) |                    | HO, LT          | SE-FRI-1000071629               |                              | 23 YR           | Female       | SWE            |
| <u>Preferred Term</u>                                                                                                  | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Depressed Level Of Consciousness; Electrocardiogram Abnormal; Muscle Twitching; Somnolence; Toxicity To Various Agents | Escitalopram                       |                    |                    | S               | Oral                            |                              |                 | Forest       |                |
|                                                                                                                        | Tavegyl                            |                    |                    | S               | Oral                            |                              |                 | Not Reported |                |
|                                                                                                                        | Cetirizine                         |                    |                    | S               | Oral                            |                              |                 | Not Reported |                |
|                                                                                                                        | Postafen (Buclizine Hydrochloride) |                    |                    | S               | Oral                            |                              |                 | Not Reported |                |
|                                                                                                                        | Loratadine                         |                    |                    | S               | Oral                            |                              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                               | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Dec-2014                                                                                                            | 10571984                           | EXPEDITED (15-DAY) |                    | HO              | SE-FRI-1000072215               |                              | 20 YR           | Female       | SWE            |
| <u>Preferred Term</u>                                                                                                  | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Chest Discomfort; Dyspnoea; Overdose; Sinus Tachycardia; Toxicity To Various Agents; Vomiting                          | Escitalopram                       |                    |                    | S               |                                 | Overdose: 14 Tablets (70 Mg) |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                               | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Dec-2014                                                                                                            | 10677628                           | EXPEDITED (15-DAY) |                    | OT              | GB-AUROBINDO-AUR-APL-2014-13279 |                              | 44 YR           | Female       | GBR            |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

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| <u>Preferred Term</u>                                             | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------------------------------------|--------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Blepharospasm; Impaired Driving Ability; Visual Impairment        | Escitalopram 10 Mg |                    |                    | S               | Oral                 | 10 Mg, Unk           |                 | Aurobindo    |                |
| <u>FDA Received Date</u>                                          | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Dec-2014                                                       | 10677859           | EXPEDITED (15-DAY) |                    | OT              | GB-ACCORD-027749     |                      | 44 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                             | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blepharospasm                                                     | Escitalopram       |                    |                    | S               | Oral                 |                      |                 | Accord       |                |
| <u>FDA Received Date</u>                                          | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Dec-2014                                                       | 10679236           | EXPEDITED (15-DAY) |                    | OT              | GB-TEVA-530455ISR    |                      | 44 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                             | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blepharospasm                                                     | Escitalopram       |                    |                    | S               | Oral                 |                      |                 | Ivax         |                |
| <u>FDA Received Date</u>                                          | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Dec-2014                                                       | 10577521           | EXPEDITED (15-DAY) |                    | HO, LT          | SE-FRI-1000072237    |                      | 55 YR           | Female       | SWE            |
| <u>Preferred Term</u>                                             | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Overdose; Suicide Attempt; Toxicity To Various Agents | Escitalopram       |                    |                    | S               | Oral                 | Overdose: 50 Tablets |                 | Forest       |                |
|                                                                   | Citalopram         |                    |                    | S               | Oral                 | Overdose: 50 Tablets |                 | Forest       |                |
|                                                                   | Atarax             |                    |                    | S               | Oral                 | 25 Tabs              |                 | Not Reported |                |
|                                                                   | Mirtazapine        |                    |                    | S               | Oral                 | Ca 50 St             |                 | Not Reported |                |
|                                                                   | Esertia            |                    |                    | C               | Unknown              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                          | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Dec-2014                                                       | 10583333           | EXPEDITED (15-DAY) |                    | OT              | CHPA2014CA014906     |                      | 62 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                             | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                  |                         |   |         |                                              |              |
|------------------------------------------------------------------|-------------------------|---|---------|----------------------------------------------|--------------|
| Alopecia; Arthritis; Breath Sounds Abnormal;                     | Voltaren Emulgel        | S | Topical | 3 Squeezes, Once Or Twice A Day And At Night | Not Reported |
| Bronchitis; Chondropathy; Cough; Depression; Fall;               | Voltaren Emulgel        | S | Topical | 1 Squeeze, Unk                               | Not Reported |
| Fatigue; Feeling Of Body Temperature Change;                     | Voltaren Emulgel        | S |         |                                              | Not Reported |
| Hyperhidrosis;                                                   | Voltaren Emulgel        | S |         |                                              | Not Reported |
| Inappropriate Schedule Of Product Administration;                | Ibuprofen Sandoz        | S | Unknown | 100 Mg, Qd                                   | Novartis     |
| Incorrect Product Administration Duration;                       | Zopiclone               | S | Unknown | 15 Mg, At Night                              | Not Reported |
| Intervertebral Disc Disorder; Lymphoedema;                       | Gabapentin              | S | Unknown | Unk, Tid                                     | Not Reported |
| Lymphoma; Mobility Decreased; Motor Dysfunction; Nausea;         | Gabapentin              | S | Unknown | Unk, Bid                                     | Not Reported |
| Pain; Panic Attack;                                              | Trazodone               | S | Unknown | 50 Mg, Qd At Night                           | Not Reported |
| Peripheral Swelling; Photopsia; Pneumonia;                       | Esomeprazole            | S | Unknown | 40 Mg, Qd                                    | Not Reported |
| Respiratory Arrest;                                              | Clorazepate             | S | Oral    | 15 Mg, Tid                                   | Not Reported |
| Therapeutic Response Decreased; Therapeutic Response Unexpected; | Morphine                | S | Unknown | Unk, Tid                                     | Not Reported |
| Tremor                                                           | Ciprallex//Escitalopram | S | Unknown | 20 Mg, Hs                                    | Not Reported |
|                                                                  | Co Etidrocal            | S | Unknown | 500 Mg, Qd                                   | Not Reported |
|                                                                  | Bupropion Hcl Er        | C | Oral    | 300 Mg, Qd                                   | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Dec-2014              | 10683484      | EXPEDITED (15-DAY) |                    | OT              | CH-FRI-1000073323    |                      | 36 YR      | Female     | CHE            |

| <u>Preferred Term</u>       | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abortion Induced; Pregnancy | Escitalopram        |              |            | S           |              | 20 Mg              |                 | Forest       |
|                             | Zoldorm             |              |            | S           | Unknown      |                    |                 | Not Reported |
|                             | Temesta (Lorazepam) |              |            | S           | Unknown      |                    |                 | Not Reported |
|                             | Tranxilium          |              |            | S           | Unknown      |                    |                 | Not Reported |
|                             | Norlevo             |              |            | S           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Dec-2014              | 10683508      | EXPEDITED (15-DAY) |                    | OT              | US-FRI-1000073348    |                      |            | Female     | USA            |

# FDA Adverse Event Reporting System

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### Detailed Report

| <u>Preferred Term</u>                | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                               | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
|--------------------------------------|----------------|--------------------|--------------------|-----------------|--------------------------------------------|--------------------------|-----------------|--------------|----------------|
| Amnesia; Dementia                    | Lexapro        |                    |                    | S               |                                            |                          |                 | Forest       |                |
| <u>FDA Received Date</u>             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                       | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Dec-2014                          | 10683677       | EXPEDITED (15-DAY) |                    |                 | CA-FRI-1000073405                          |                          | 33 YR           | Female       | CAN            |
| <u>Preferred Term</u>                | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                               | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Headache; Mydriasis; Seizure         | Escitalopram   |                    |                    | S               |                                            | 5 Mg                     |                 | Forest       |                |
|                                      | Keppra         |                    |                    | S               |                                            | Daily Dose Not Reported. |                 | Not Reported |                |
|                                      | Keppra         |                    |                    | S               |                                            | Daily Dose Not Reported. |                 | Not Reported |                |
| <u>FDA Received Date</u>             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                       | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Dec-2014                          | 10684025       | EXPEDITED (15-DAY) |                    | OT              | US-SA-2014SA180072                         |                          |                 | Female       | USA            |
| <u>Preferred Term</u>                | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                               | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective; Psychotic Disorder | Ambien         |                    |                    | S               | Unknown                                    |                          |                 | Not Reported |                |
|                                      | Lexapro        |                    |                    | S               | Unknown                                    |                          |                 | Not Reported |                |
|                                      | Abilify        |                    |                    | S               | Unknown                                    |                          |                 | Not Reported |                |
|                                      | Klonopin       |                    |                    | S               | Unknown                                    |                          |                 | Not Reported |                |
|                                      | Percocet       |                    |                    | C               |                                            |                          |                 | Not Reported |                |
|                                      | Oxy            |                    |                    | C               |                                            |                          |                 | Not Reported |                |
| <u>FDA Received Date</u>             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                       | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Dec-2014                          | 10684053       | EXPEDITED (15-DAY) |                    | OT              | GB-MYLANLABS-2014M1015171                  |                          |                 | Unknown      | GBR            |
| <u>Preferred Term</u>                | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                               | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Blepharospasm                        | Escitalopram   |                    |                    | S               | Oral                                       | 10 Mg, Unk               |                 | Not Reported |                |
| <u>FDA Received Date</u>             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                       | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-Dec-2014                          | 10684508       | EXPEDITED (15-DAY) |                    | HO              | US-LUPIN PHARMACEUTICALS INC.-E2B_00002994 |                          | 88 YR           | Male         | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Agitation; Asthenia;<br>Confusional State; Drug<br>Ineffective; Dysarthria;<br>Dysstasia; Fatigue; Gait<br>Disturbance; Hallucination;<br>Hyperventilation;<br>Incontinence; Intellectual<br>Disability; Malaise;<br>Muscular Weakness;<br>Nightmare; Paranoia;<br>Sleep Disorder;<br>Somnolence; Speech<br>Disorder; Treatment<br>Noncompliance;<br>Unresponsive To Stimuli;<br>Withdrawal Syndrome | Escitalopram Tablets Usp 5mg  |              |            | S           |              |                    |                 | Lupin        |
|                                                                                                                                                                                                                                                                                                                                                                                                      | Escitalopram Tablets Usp 5mg  |              |            | S           |              |                    |                 | Lupin        |
|                                                                                                                                                                                                                                                                                                                                                                                                      | Escitalopram Tablets Usp 10mg |              |            | S           |              |                    |                 | Lupin        |
|                                                                                                                                                                                                                                                                                                                                                                                                      | Travatan                      |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                      | Rapaflo                       |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                      | Same                          |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                      | Timolol                       |              |            | C           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-Dec-2014              | 10686044      | EXPEDITED (15-DAY) |                    | OT              | PHHY2014MX168543     |                      |            | Female     | MEX            |

| <u>Preferred Term</u>                                                                   | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------|--------------------|--------------|------------|-------------|-----------------------------|--------------------|-----------------|--------------|
| Anhedonia; Discomfort;<br>Feeling Abnormal;<br>Nausea; Thanatophobia;<br>Vision Blurred | Ultibro Breezhaler |              |            | S           | Respiratory<br>(inhalation) | 1 Ot, At Morning   |                 | Not Reported |
|                                                                                         | Ultibro Breezhaler |              |            | S           | Respiratory<br>(inhalation) | Unk                |                 | Not Reported |
|                                                                                         | Lexapro            |              |            | S           | Unknown                     |                    |                 | Not Reported |
|                                                                                         | Spiriva            |              |            | C           | Unknown                     | At Morning         |                 | Not Reported |
|                                                                                         | Axis               |              |            | C           | Unknown                     | At Afternoon       |                 | Not Reported |
|                                                                                         | Dilacorran         |              |            | C           | Unknown                     | Unk                |                 | Not Reported |
|                                                                                         | Eutirox            |              |            | C           | Unknown                     | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------|----------------------|------------|------------|----------------|
| 02-Jan-2015              | 10686862      | EXPEDITED (15-DAY) |                    | HO              | FR-AUROBINDO-AUR-<br>APL-2014-13656 |                      |            | Male       | FRA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                 | <u>Product</u>                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
|-----------------------------------------------------------------------|--------------------------------------------|--------------------|--------------------|-----------------|-----------------------|----------------------------------|-----------------|--------------|----------------|
| Drug Ineffective; Drug Withdrawal Syndrome; Feeling Abnormal          | Paroxetine Arrow 20 Mg Film-Coated Tablets |                    |                    | S               | Oral                  | 20 Mg, Daily                     |                 | Aurobindo    |                |
|                                                                       | Seroplex                                   |                    |                    | S               | Oral                  | 20 Mg, Daily                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                              | <u>Case #</u>                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Jan-2015                                                           | 10687184                                   | EXPEDITED (15-DAY) |                    | OT              | TR-ACCORD-027858      |                                  | 76 YR           | Female       | TUR            |
| <u>Preferred Term</u>                                                 | <u>Product</u>                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Depressed Level Of Consciousness; Hyponatraemia; Urinary Incontinence | Escitalopram                               |                    |                    | S               |                       |                                  |                 | Accord       |                |
|                                                                       | Rivastigmine/Rivastigmine Tartrate         |                    |                    | C               |                       |                                  |                 | Not Reported |                |
|                                                                       | Sitagliptin/Sitagliptin Phosphate          |                    |                    | C               |                       |                                  |                 | Not Reported |                |
|                                                                       | Memantine/Memantine Hydrochloride          |                    |                    | C               |                       |                                  |                 | Not Reported |                |
|                                                                       | Losartan                                   |                    |                    | C               |                       |                                  |                 | Not Reported |                |
|                                                                       | Trazodone/Trazodone Hydrochloride          |                    |                    | C               |                       |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                              | <u>Case #</u>                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Jan-2015                                                           | 10687808                                   | EXPEDITED (15-DAY) |                    | OT              | FR-JNJFOC-20141215320 |                                  |                 | Female       | FRA            |
| <u>Preferred Term</u>                                                 | <u>Product</u>                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Exposure During Pregnancy; Pyelonephritis                             | Risperdal                                  |                    |                    | S               | Unknown               |                                  |                 | Not Reported |                |
|                                                                       | Nordaz                                     |                    |                    | S               | Unknown               |                                  |                 | Not Reported |                |
|                                                                       | Seroplex                                   |                    |                    | S               | Unknown               |                                  |                 | Not Reported |                |
|                                                                       | Atarax                                     |                    |                    | S               | Unknown               |                                  |                 | Not Reported |                |
|                                                                       | Imovane                                    |                    |                    | S               | Unknown               |                                  |                 | Not Reported |                |
|                                                                       | Lepticur                                   |                    |                    | S               | Unknown               | Lepticur Was Given A Twice A Day |                 | Not Reported |                |
|                                                                       | Avlocardyl                                 |                    |                    | S               | Unknown               |                                  |                 | Not Reported |                |
| Augmentin                                                             |                                            |                    | S                  | Unknown         |                       |                                  | Not Reported    |              |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------|-------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 02-Jan-2015                                             | 10687809          | EXPEDITED (15-DAY) |                    | HO, OT          | FR-JNJFOC-20141215360 |                      | < 1 DAY         | Female       | FRA            |
| <u>Preferred Term</u>                                   | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Foetal Exposure During Pregnancy; Hypotonia; Somnolence | Risperdal         |                    |                    | S               | Transplacental        |                      |                 | Not Reported |                |
|                                                         | Nordaz            |                    |                    | S               | Transplacental        |                      |                 | Not Reported |                |
|                                                         | Seroplex          |                    |                    | S               | Transplacental        |                      |                 | Not Reported |                |
|                                                         | Atarax            |                    |                    | S               | Transplacental        |                      |                 | Not Reported |                |
|                                                         | Imovane           |                    |                    | S               | Transplacental        |                      |                 | Not Reported |                |
|                                                         | Augmentin         |                    |                    | S               | Transplacental        |                      |                 | Not Reported |                |
|                                                         | Avlocardyl        |                    |                    | S               | Transplacental        |                      |                 | Not Reported |                |
|                                                         | Lepticur          |                    |                    | S               | Transplacental        |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Jan-2015                                             | 10687991          | EXPEDITED (15-DAY) |                    | HO              | DE-FRI-1000073415     |                      | 50 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                   | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Drug Interaction; Restlessness               | Escitalopram      |                    |                    | S               | Oral                  | 10 Mg                |                 | Forest       |                |
|                                                         | Escitalopram      |                    |                    | S               | Oral                  | 20 Mg                |                 | Forest       |                |
|                                                         | Escitalopram      |                    |                    | S               | Oral                  | 10 Mg                |                 | Not Reported |                |
|                                                         | Escitalopram      |                    |                    | S               | Oral                  | 10 Mg                |                 | Not Reported |                |
|                                                         | Escitalopram      |                    |                    | S               | Oral                  | 20 Mg                |                 | Not Reported |                |
|                                                         | Abilify           |                    |                    | S               | Oral                  | 5 Mg                 |                 | Not Reported |                |
|                                                         | Abilify           |                    |                    | S               | Oral                  | 10 Mg                |                 | Not Reported |                |
|                                                         | Venlafaxin Retard |                    |                    | S               | Oral                  | 150 Mg               |                 | Not Reported |                |
|                                                         | Venlafaxin Retard |                    |                    | S               | Oral                  | 75 Mg                |                 | Not Reported |                |
|                                                         | Remergil          |                    |                    | C               | Oral                  |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                      | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|-----------------------------|-----------------|--------------|----------------|
| 02-Jan-2015                                                                   | 10688594               | EXPEDITED (15-DAY) |                    | CA, HO          | FR-FRI-1000073416    |                             | < 1 DAY         | Female       | FRA            |
| <u>Preferred Term</u>                                                         | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Foetal Exposure During Pregnancy; Hypotonia; Somnolence                       | Escitalopram           |                    |                    | S               | Transplacental       | 20 Mg                       |                 | Forest       |                |
|                                                                               | Risperdal              |                    |                    | S               | Transplacental       | 2 Mg                        |                 | Not Reported |                |
|                                                                               | Nordaz                 |                    |                    | S               | Transplacental       | 15 Mg                       |                 | Not Reported |                |
|                                                                               | Atarax                 |                    |                    | S               | Transplacental       | 90 Mg                       |                 | Not Reported |                |
|                                                                               | Imovane                |                    |                    | S               | Transplacental       | Not Specified               |                 | Not Reported |                |
|                                                                               | Lepticur               |                    |                    | C               | Transplacental       |                             |                 | Not Reported |                |
|                                                                               | Avlocardyl             |                    |                    | C               | Transplacental       |                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                      | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Jan-2015                                                                   | 10688595               | EXPEDITED (15-DAY) |                    | OT              | GB-FRI-1000073419    |                             | 44 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                         | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Blepharospasm                                                                 | Escitalopram           |                    |                    | S               | Oral                 | 10 Mg                       |                 | Forest       |                |
| <u>FDA Received Date</u>                                                      | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Jan-2015                                                                   | 10688612               | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000073418    |                             | 71 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                         | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Anaemia; Gingival Bleeding; International Normalised Ratio Increased; Melaena | Escitalopram           |                    |                    | S               | Oral                 | 1 Dosage Forms              |                 | Forest       |                |
|                                                                               | Previscan (Fluindione) |                    |                    | S               | Oral                 | 1 And 3/4 Daily Alternately |                 | Not Reported |                |
|                                                                               | Kardegic               |                    |                    | S               | Oral                 | 1 Dosage Forms              |                 | Not Reported |                |
|                                                                               | Aprovel                |                    |                    | C               | Oral                 | 300 Mg                      |                 | Not Reported |                |
|                                                                               | Amlor                  |                    |                    | C               | Oral                 | 10 Mg                       |                 | Not Reported |                |
|                                                                               | Bisoprolol             |                    |                    | C               | Oral                 | 10 Mg                       |                 | Not Reported |                |
|                                                                               | Lasilix                |                    |                    | C               | Oral                 | 40 Mg                       |                 | Not Reported |                |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                |   |      |                |              |
|--------------------------------|---|------|----------------|--------------|
| Metformine                     | C | Oral | 2550 Mg        | Not Reported |
| Inexium                        | C | Oral | 40 Mg          | Not Reported |
| Doliprane                      | C | Oral | 3000 Mg        | Not Reported |
| Princi B (Pyridoxine\Thiamine) | C | Oral | 6 Dosage Forms | Not Reported |
| Speciafoldine                  | C | Oral | 5 Mg           | Not Reported |
| Diffu K                        | C | Oral | 600 Mg         | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Jan-2015              | 10689400      | DIRECT           | Y                  | HO              |                      |                      | 65 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety               | Escitalopram   |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Jan-2015              | 10442364      | EXPEDITED (15-DAY) |                    | HO              | IT-TEVA-506173ISR    |                      | 72 YR      | Female     | ITA            |

| <u>Preferred Term</u>                                                            | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|-----------------------|-----------------|--------------|
| Acute Kidney Injury;<br>Balance Disorder;<br>Disturbance In Attention;<br>Tremor | Carbolithium 300 Mg  |              |            | S           | Oral         | 450 Milligram Daily;  |                 | Barr         |
|                                                                                  | Entact 10 Mg         |              |            | S           | Oral         | 20 Milligram Daily;   |                 | Not Reported |
|                                                                                  | Eutirox 50 Mcg       |              |            | C           | Oral         | 1 Dosage Forms Daily; |                 | Not Reported |
|                                                                                  | Anafranil 25 Mg      |              |            | C           | Oral         | 2 Dosage Forms Daily; |                 | Not Reported |
|                                                                                  | Cardioapsirin 100 Mg |              |            | C           | Oral         | 1 Dosage Forms Daily; |                 | Not Reported |
|                                                                                  | Torvast              |              |            | C           | Oral         | 10 Milligram Daily;   |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------------------------|----------------------|------------|------------|----------------|
| 05-Jan-2015              | 10689170      | NON-EXPEDITED    |                    | OT              | US-LUPIN<br>PHARMACEUTICALS<br>INC.-2014-01765 |                      |            | Female     | USA            |

| <u>Preferred Term</u>                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Disturbance In Attention;<br>Headache; Insomnia; | Escitalopram   |              |            | S           | Unknown      |                    |                 | Lupin      |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Irritability; Seizure; Vision  
Blurred

| <u>FDA Received Date</u>                  | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------|----------------------|------------------|--------------------|-----------------|------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 05-Jan-2015                               | 10689171             | NON-EXPEDITED    |                    |                 | US-LUPIN<br>PHARMACEUTICALS<br>INC.-2014-01822 |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                     | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Discomfort;<br>Gastric Disorder | Escitalopram Oxalate |                  |                    | S               | Unknown                                        |                      |                 | Not Reported |                |
|                                           | Escitalopram Oxalate |                  |                    | S               | Unknown                                        |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>               | <u>Case #</u>                 | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------|-------------------------------|------------------|--------------------|-----------------|--------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 05-Jan-2015                            | 10689172                      | NON-EXPEDITED    |                    | OT              | US-LUPIN<br>PHARMACEUTICALS<br>INC.-E2B_00002640 |                      | 51 YR           | Female       | USA            |
| <u>Preferred Term</u>                  | <u>Product</u>                | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                     | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Feeling Abnormal; Suicidal<br>Ideation | Escitalopram Tablets Usp 10mg |                  |                    | S               |                                                  |                      |                 | Lupin        |                |
|                                        | Escitalopram Tablets Usp 10mg |                  |                    | S               |                                                  |                      |                 | Lupin        |                |
|                                        | Metoprolol Tartrate           |                  |                    | C               |                                                  |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                               | <u>Case #</u>                | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|------------------------------------------------------------------------|------------------------------|------------------|--------------------|-----------------|--------------------------------------------------|----------------------|-----------------|------------|----------------|
| 05-Jan-2015                                                            | 10689173                     | NON-EXPEDITED    |                    |                 | US-LUPIN<br>PHARMACEUTICALS<br>INC.-E2B_00002803 |                      | 48 YR           | Female     | USA            |
| <u>Preferred Term</u>                                                  | <u>Product</u>               | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                     | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Eye Swelling; Mouth<br>Swelling; Pharyngeal<br>Swelling; Swelling Face | Escitalopram Tablets Usp 5mg |                  |                    | S               |                                                  |                      |                 | Lupin      |                |

| <u>FDA Received Date</u>                        | <u>Case #</u>                 | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|-------------------------------------------------|-------------------------------|------------------|--------------------|-----------------|--------------------------------------------------|----------------------|-----------------|------------|----------------|
| 05-Jan-2015                                     | 10689174                      | NON-EXPEDITED    |                    |                 | US-LUPIN<br>PHARMACEUTICALS<br>INC.-E2B_00002888 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>                           | <u>Product</u>                | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                     | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Anxiety; Drug Ineffective;<br>Feeling Abnormal; | Escitalopram Tablets Usp 5mg  |                  |                    | S               |                                                  |                      |                 | Lupin      |                |
|                                                 | Escitalopram Tablets Usp 10mg |                  |                    | S               |                                                  |                      |                 | Lupin      |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                             |            |   |         |              |
|---------------------------------------------|------------|---|---------|--------------|
| Nephrolithiasis; Product Substitution Issue | Atenolol   | C | Unknown | Not Reported |
|                                             | Lisinopril | C | Unknown | Not Reported |
|                                             | Synthroid  | C | Unknown | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Jan-2015              | 10692623      | DIRECT           |                    |                 |                      |                      | 60 YR      | Female     | USA            |

| <u>Preferred Term</u>                  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|----------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Depression; Product Substitution Issue | Escitalopram   |              |            | S           | Oral         | One                |                 | Torrent    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Jan-2015              | 10670657      | EXPEDITED (15-DAY) | Y                  | DS              | JP2014JPN033508      |                      | 31 YR      | Male       | JPN            |

| <u>Preferred Term</u>                                                    | <u>Product</u>                                              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------|-------------------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Diarrhoea; Ejaculation Delayed; Erectile Dysfunction; Sexual Dysfunction | Paxil Cr                                                    |              |            | S           | Oral         |                    | 12 DAY          | Not Reported |
|                                                                          |                                                             |              |            |             | Oral         |                    | 7 DAY           |              |
|                                                                          |                                                             |              |            |             | Oral         |                    | 174 DAY         |              |
|                                                                          |                                                             |              |            |             | Oral         |                    | 7 DAY           |              |
|                                                                          | Paxil                                                       |              |            | S           | Oral         |                    | 13 DAY          | Not Reported |
|                                                                          |                                                             |              |            |             | Oral         |                    | 7 DAY           |              |
|                                                                          | Lexapro                                                     |              |            | S           | Oral         |                    | 6 DAY           | Not Reported |
|                                                                          |                                                             |              |            |             | Oral         |                    | 216 DAY         |              |
|                                                                          |                                                             |              |            |             | Oral         |                    | 49 DAY          |              |
|                                                                          | Colonel (Polycarbophil Calcium)                             |              |            | C           |              |                    |                 | Not Reported |
|                                                                          | Traditional Chinese Medicine (Traditional Chinese Medicine) |              |            | C           |              |                    |                 | Not Reported |
|                                                                          | Depakene (Valproic Acid) Solution                           |              |            | C           |              |                    |                 | Not Reported |
|                                                                          | Desyrel (Trazodone Hydrochloride)                           |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Jan-2015              | 10694884      | DIRECT           |                    | OT              |                      |                      | 49 YR      | Male       | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                         | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |                |
|-----------------------------------------------------------------------------------------------------------------------------------------------|----------------------|------------------|--------------------|-----------------|------------------------------------------|------------------------------------|-----------------|--------------|----------------|
| Night Sweats; Poor Quality Sleep                                                                                                              | Lexapro              |                  |                    | S               | Oral                                     | 1 Tablet Once Daily Taken By Mouth |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                      | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Jan-2015                                                                                                                                   | 10695683             | DIRECT           |                    | OT              |                                          |                                    | 50 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                         | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Drug Ineffective; Loss Of Personal Independence In Daily Activities; Product Substitution Issue; Suicidal Ideation; Weight Increased | Escitalopram 20 Mg   |                  |                    | S               | Oral                                     | Taken By Mouth                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                      | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Jan-2015                                                                                                                                   | 10694308             | NON-EXPEDITED    |                    |                 | IN-LUPIN PHARMACEUTICALS INC.-2014-01693 |                                    | 20 YR           | Male         | IND            |
| <u>Preferred Term</u>                                                                                                                         | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Somnolence                                                                                                                                    | Aripiprazole         |                  |                    | S               | Unknown                                  |                                    |                 | Not Reported |                |
|                                                                                                                                               | Escitalopram         |                  |                    | S               | Unknown                                  |                                    |                 | Not Reported |                |
|                                                                                                                                               | Mirtazapine          |                  |                    | S               | Unknown                                  |                                    |                 | Not Reported |                |
|                                                                                                                                               | Paliperidone         |                  |                    | C               | Unknown                                  |                                    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                      | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Jan-2015                                                                                                                                   | 9844681              | NON-EXPEDITED    | Y                  | DE              | 2014AP000689                             |                                    | 47 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                         | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardio-Respiratory Arrest; Completed Suicide; Exposure Via Ingestion                                                                          | Amlodipine Besylate  |                  |                    | S               | Oral                                     |                                    |                 | Not Reported |                |
|                                                                                                                                               | Citalopram           |                  |                    | S               | Oral                                     |                                    |                 | Not Reported |                |
|                                                                                                                                               | Escitalopram Oxalate |                  |                    | S               | Oral                                     |                                    |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                 |   |      |              |
|---------------------------------|---|------|--------------|
| Carvedilol Tablets              | S | Oral | Not Reported |
| Bupropion Hydrochloride Tablets | S | Oral | Not Reported |
| Acetaminophen/ Hydrocodone      | S | Oral | Not Reported |
| Alprazolam                      | S | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Jan-2015              | 9858781       | NON-EXPEDITED    | Y                  | DE              | 2014AP000472         |                      | 45 YR      | Female     | USA            |

| <u>Preferred Term</u>                           | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardio-Respiratory Arrest;<br>Completed Suicide | Zolpidem Tartrate    |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                 | Escitalopram Oxalate |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                 | Alprazolam           |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Jan-2015              | 9867119       | NON-EXPEDITED    | Y                  | DE              | 2014AP000420         |                      | 31 YR      | Female     | USA            |

| <u>Preferred Term</u>                           | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardio-Respiratory Arrest;<br>Completed Suicide | Lamotrigine          |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                 | Escitalopram Oxalate |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                 | Meloxicam Tablets    |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Jan-2015              | 10441429      | EXPEDITED (15-DAY) |                    | HO              | IT-FRI-1000070485    |                      | 72 YR      | Female     | ITA            |

| <u>Preferred Term</u>                                                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Acute Kidney Injury;<br>Balance Disorder;<br>Disturbance In Attention;<br>Tremor | Escitalopram   |              |            | S           | Oral         | 20 Mg              |                 | Forest       |
|                                                                                  | Carbolithium   |              |            | S           | Oral         | 600 Mg             |                 | Not Reported |
|                                                                                  | Carbolithium   |              |            | S           | Oral         | 450 Mg             |                 | Not Reported |
|                                                                                  | Euritox        |              |            | C           | Oral         | 50 Ug              |                 | Not Reported |
|                                                                                  | Anafranil      |              |            | C           | Oral         | 50 Mg              |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                      | Cardioaspirin      |                    | C                  | Oral            | 100 Mg                |                                      | Not Reported    |              |                |
|----------------------------------------------------------------------|--------------------|--------------------|--------------------|-----------------|-----------------------|--------------------------------------|-----------------|--------------|----------------|
|                                                                      | Torvast            |                    | C                  |                 | 10 Mg                 |                                      | Not Reported    |              |                |
| <u>FDA Received Date</u>                                             | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Jan-2015                                                          | 10635950           | EXPEDITED (15-DAY) |                    |                 | JP-FRI-1000072891     |                                      | 54 YR           | Male         | JPN            |
| <u>Preferred Term</u>                                                | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Ventricular Extrasystoles                                            | Lexapro            |                    |                    | S               | Oral                  | 20 Mg                                |                 | Forest       |                |
|                                                                      | Wypax              |                    |                    | C               | Oral                  | 1.5 Mg                               |                 | Not Reported |                |
|                                                                      | Wypax              |                    |                    | C               | Oral                  | 3 Mg                                 |                 | Not Reported |                |
|                                                                      | Rohypnol           |                    |                    | C               | Oral                  | 2 Mg                                 |                 | Not Reported |                |
|                                                                      | Doral              |                    |                    | C               | Oral                  | 30 Mg                                |                 | Not Reported |                |
|                                                                      | Loxonin            |                    |                    | C               | Oral                  | 180 Mg                               |                 | Not Reported |                |
|                                                                      | Mucosta            |                    |                    | C               | Oral                  | 300 Mg                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                             | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Jan-2015                                                          | 10697886           | EXPEDITED (15-DAY) |                    | OT              | IT-JNJFOC-20150101734 |                                      | 17 YR           | Male         | ITA            |
| <u>Preferred Term</u>                                                | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Coma; Overdose                                                       | Risperdal          |                    |                    | S               | Oral                  |                                      |                 | Not Reported |                |
|                                                                      | Ciprallex          |                    |                    | S               | Oral                  |                                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                             | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Jan-2015                                                          | 10698207           | EXPEDITED (15-DAY) |                    | OT              | CH-TEVA-527123ISR     |                                      | 69 YR           | Unknown      | CHE            |
| <u>Preferred Term</u>                                                | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective; Merycism; Product Substitution Issue; Restlessness | Escitalopram-Mepha |                    |                    | S               | Unknown               | 10 Mg                                |                 | Ivax         |                |
|                                                                      | Escitalopram-Mepha |                    |                    | S               |                       |                                      |                 | Ivax         |                |
|                                                                      | Zometa             |                    |                    | C               | Unknown               | 10-Aug: Start And End Date Not Known |                 | Not Reported |                |

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|                                                                       | Ponstan                            |                    | C                  | Unknown         |                                          |                      |                 | Not Reported         |                |
|-----------------------------------------------------------------------|------------------------------------|--------------------|--------------------|-----------------|------------------------------------------|----------------------|-----------------|----------------------|----------------|
|                                                                       | Vit D3/Ca                          |                    | C                  |                 |                                          |                      |                 | Not Reported         |                |
|                                                                       | Bisoprolol                         |                    | C                  | Unknown         | 2.5 Milligram Daily;                     |                      |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                              | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 08-Jan-2015                                                           | 10700998                           | DIRECT             |                    | HO              |                                          |                      | 57 YR           | Female               | USA            |
| <u>Preferred Term</u>                                                 | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Dizziness; Product Quality Issue; Product Substitution Issue; Vertigo | Lexapro                            |                    |                    | S               | Oral                                     |                      |                 | Torrent              |                |
| <u>FDA Received Date</u>                                              | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 09-Jan-2015                                                           | 10555755                           | EXPEDITED (15-DAY) |                    | HO, LT          | PHHY2014SE133389                         |                      |                 | Unknown              | SWE            |
| <u>Preferred Term</u>                                                 | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Depressed Level Of Consciousness;                                     | Tavegyl                            |                    |                    | S               | Oral                                     |                      |                 | Not Reported         |                |
| Electrocardiogram Abnormal; Muscle Twitching; Somnolence;             | Cetirizine                         |                    |                    | S               | Oral                                     |                      |                 | Novartis             |                |
| Toxicity To Various Agents                                            | Loratadine                         |                    |                    | S               | Oral                                     |                      |                 | Not Reported         |                |
|                                                                       | Cipralext /Den/                    |                    |                    | S               | Oral                                     |                      |                 | Not Reported         |                |
|                                                                       | Postafen (Meclozine Hydrochloride) |                    |                    | S               | Oral                                     |                      |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                              | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 09-Jan-2015                                                           | 10568790                           | EXPEDITED (15-DAY) |                    | HO              | US-BRISTOL-MYERS SQUIBB COMPANY-21542436 |                      | 12 YR           | Female               | USA            |
| <u>Preferred Term</u>                                                 | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Anger; Cyst; Drug Level Above Therapeutic;                            | Abilify                            |                    |                    | S               | Oral                                     | L In 1 D             |                 | Bristol Myers Squibb |                |
| Headache; Mania; Off Label Use; Unevaluable Event; Weight Increased   | Abilify                            |                    |                    | S               |                                          |                      |                 | Bristol Myers Squibb |                |
|                                                                       | Lexapro                            |                    |                    | S               | Oral                                     | Unk Unk, Qd          |                 | Not Reported         |                |

# FDA Adverse Event Reporting System

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| <u>FDA Received Date</u>                         | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
| 09-Jan-2015                                      | 10700955                  | EXPEDITED (15-DAY) |                    | DE, HO          | US-JNJFOC-20150104515     |                      | 36 YR           | Female       | USA            |
| <u>Preferred Term</u>                            | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Toxicity To Various Agents | Topiramate                |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                                                  | Verapamil                 |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                                                  | Escitalopram              |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                                                  | Codeine                   |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Jan-2015                                      | 10700957                  | EXPEDITED (15-DAY) |                    | DE              | US-JNJFOC-20150104512     |                      | 51 YR           | Female       | USA            |
| <u>Preferred Term</u>                            | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Toxicity To Various Agents                       | Topiramate                |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                                                  | Promethazine              |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                                                  | Verapamil                 |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                                                  | Escitalopram              |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                                                  | Acetaminophen/Hydrocodone |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                                                  | Diazepam                  |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                                                  | Esomeprazole              |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                                                  | Diclofenac                |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Jan-2015                                      | 10701957                  | EXPEDITED (15-DAY) |                    | HO              | FR-MYLANLABS-2014M1000602 |                      |                 | Unknown      | FRA            |
| <u>Preferred Term</u>                            | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Akinesia; Confusional<br>State; Tremor           | Zolpidem 10 Mg            |                    |                    | S               | Oral                      | 10 Mg, Hs            |                 | Mylan        |                |
|                                                  | Seroplex                  |                    |                    | S               | Oral                      | 10 Mg, Qd            |                 | Not Reported |                |
|                                                  | Seroplex                  |                    |                    | S               | Oral                      | 15 Mg, Qd            |                 | Not Reported |                |

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|                                                                        |                      |                    |                    |                 |                              |                      |                 |                              |                |
|------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|------------------------------|----------------|
| Seroplex<br>Seresta                                                    |                      | S<br>S             |                    | Oral            |                              | 20 Mg, Qd            |                 | Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 12-Jan-2015                                                            | 10705216             | EXPEDITED (15-DAY) |                    | DE              | US-PFIZER INC-<br>2015008459 |                      | 43 YR           | Female                       | USA            |
| <u>Preferred Term</u>                                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Death                                                                  | Sertraline Hcl       |                    |                    | S               | Oral                         | Unk                  |                 | Pfizer                       |                |
|                                                                        | Escitalopram         |                    |                    | S               | Oral                         | Unk                  |                 | Not Reported                 |                |
|                                                                        | Atomoxetine          |                    |                    | S               | Oral                         | Unk                  |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 12-Jan-2015                                                            | 10706958             | DIRECT             |                    |                 |                              |                      | 14 YR           | Female                       | USA            |
| <u>Preferred Term</u>                                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Hallucination, Auditory;<br>Therapy Change                             | Escitalopram         |                    |                    | S               |                              |                      |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 12-Jan-2015                                                            | 10706988             | DIRECT             |                    | DS              |                              |                      | 49 YR           | Female                       | USA            |
| <u>Preferred Term</u>                                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Anaemia; Leukopenia                                                    | Lexapro 20 Mg Camber |                    |                    | S               | Oral                         |                      | 7 YR            | Camber                       |                |
| <u>FDA Received Date</u>                                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 12-Jan-2015                                                            | 10707062             | DIRECT             |                    |                 |                              |                      | 64 YR           | Female                       | USA            |
| <u>Preferred Term</u>                                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Product Substitution Issue;<br>Therapeutic Product Effect<br>Decreased | Escitalopram         |                    |                    | S               |                              |                      |                 | Not Reported                 |                |



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| <u>FDA Received Date</u>                                                                                 | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|------------------------------|---------------------------------------------|-----------------|--------------|----------------|
| 12-Jan-2015                                                                                              | 10712901             | DIRECT             |                    |                 |                              |                                             | 49 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective;<br>Gastrointestinal Disorder;<br>Headache; Panic Attack;<br>Product Substitution Issue | Escitalopram Oxalate |                    |                    | S               | Oral                         | One Pill A Day Once Daily<br>Taken By Mouth |                 | Accord       |                |
| <u>FDA Received Date</u>                                                                                 | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Jan-2015                                                                                              | 9943979              | EXPEDITED (15-DAY) |                    | HO, LT, OT      | JP-FRI-1000054770            |                                             | 23 YR           | Female       | JPN            |
| <u>Preferred Term</u>                                                                                    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Ventricular Fibrillation                                                                                 | Lexapro              |                    |                    | S               | Oral                         | 20 Mg                                       |                 | Forest       |                |
|                                                                                                          | Amoxan               |                    |                    | S               | Oral                         | 20 Mg                                       |                 | Not Reported |                |
|                                                                                                          | Seroquel             |                    |                    | S               | Oral                         | 20 Mg                                       |                 | Not Reported |                |
|                                                                                                          | Bibittoace           |                    |                    | S               | Oral                         | 1 Mg                                        |                 | Not Reported |                |
|                                                                                                          | Landsen              |                    |                    | S               | Oral                         | 0.5 Mg                                      |                 | Not Reported |                |
|                                                                                                          | Allelock             |                    |                    | S               | Oral                         | 10 Mg                                       |                 | Not Reported |                |
|                                                                                                          | Kamishoyosan         |                    |                    | C               | Oral                         | 5 Mg                                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                 | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Jan-2015                                                                                              | 10707242             | EXPEDITED (15-DAY) |                    | DE              | US-PFIZER INC-<br>2015006848 |                                             | 28 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Completed<br>Suicide; Respiratory Arrest                                                 | Gabapentin           |                    |                    | S               | Oral                         | Unk                                         |                 | Pfizer       |                |
|                                                                                                          | Alprazolam           |                    |                    | S               | Oral                         | Unk                                         |                 | Pfizer       |                |
|                                                                                                          | Escitalopram         |                    |                    | S               | Oral                         | Unk                                         |                 | Not Reported |                |
|                                                                                                          | Bupropion            |                    |                    | S               | Oral                         | Unk                                         |                 | Not Reported |                |

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| <u>FDA Received Date</u>                              | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|-------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|------------------------------------|----------------------|-----------------|-----------------|----------------|
| 13-Jan-2015                                           | 10707973                  | EXPEDITED (15-DAY) |                    | DE              | US-PFIZER INC-2015007083           |                      | 34 YR           | Female          | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                       | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Cardiac Arrest; Completed Suicide; Respiratory Arrest | Liothyronine Sodium       |                    |                    | S               | Oral                               | Unk                  |                 | Pfizer          |                |
|                                                       | Ondansetron Hcl           |                    |                    | S               | Oral                               | Unk                  |                 | Pfizer          |                |
|                                                       | Sertraline Hcl            |                    |                    | S               | Oral                               | Unk                  |                 | Pfizer          |                |
|                                                       | Gabapentin                |                    |                    | S               | Oral                               | Unk                  |                 | Pfizer          |                |
|                                                       | Amitriptyline             |                    |                    | S               | Oral                               | Unk                  |                 | Not Reported    |                |
|                                                       | Tramadol                  |                    |                    | S               | Oral                               | Unk                  |                 | Not Reported    |                |
|                                                       | Acetaminophen/Hydrocodone |                    |                    | S               | Oral                               | Unk                  |                 | Not Reported    |                |
|                                                       | Linaclotide               |                    |                    | S               | Oral                               | Unk                  |                 | Not Reported    |                |
|                                                       | Diclofenac                |                    |                    | S               | Oral                               | Unk                  |                 | Not Reported    |                |
|                                                       | Lubiprostone              |                    |                    | S               | Oral                               | Unk                  |                 | Not Reported    |                |
|                                                       | Zolpidem                  |                    |                    | S               | Oral                               | Unk                  |                 | Not Reported    |                |
|                                                       | Escitalopram              |                    |                    | S               | Oral                               | Unk                  |                 | Not Reported    |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 13-Jan-2015                                           | 10708638                  | EXPEDITED (15-DAY) |                    | DE, OT          | US-GLAXOSMITHKLINE-US2015GSK002950 |                      | 67 YR           | Male            | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                       | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Completed Suicide                                     | Lamotrigine               |                    |                    | S               | Unknown                            |                      |                 | Glaxosmithkline |                |
|                                                       | Zonisamide                |                    |                    | S               | Unknown                            |                      |                 | Glaxosmithkline |                |
|                                                       | Escitalopram              |                    |                    | S               | Unknown                            |                      |                 | Glaxosmithkline |                |
|                                                       | Lorazepam                 |                    |                    | S               | Unknown                            |                      |                 | Not Reported    |                |
|                                                       | Lovastatin                |                    |                    | S               | Unknown                            |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 14-Jan-2015                                           | 10710602                  | NON-EXPEDITED      |                    |                 | US-ENDO                            |                      | 49 YR           | Female          | USA            |

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PHARMACEUTICALS  
INC.-OXYA20140010

| <u>Preferred Term</u>                                                                                         | <u>Product</u>                        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                               | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------|---------------------------------------|--------------|------------|-------------|--------------|------------------------------------------------------------------|-----------------|--------------|
| Dry Mouth;<br>Hypercholesterolaemia;<br>Oropharyngeal Pain; Type<br>2 Diabetes Mellitus; Visual<br>Impairment | Oxycodone/Acetaminophen<br>10mg/325mg |              |            | S           | Oral         | 30mg/975mg                                                       |                 | Not Reported |
|                                                                                                               | Aspirin Ec                            |              |            | S           | Oral         |                                                                  |                 | Not Reported |
|                                                                                                               | Ibuprofen Tablets                     |              |            | S           | Oral         | 800mg In The Morning<br>And 1200                                 |                 | Not Reported |
|                                                                                                               | Lyrica                                |              |            | S           | Oral         |                                                                  |                 | Not Reported |
|                                                                                                               | Tizanidine                            |              |            | S           | Oral         |                                                                  |                 | Not Reported |
|                                                                                                               | Tizanidine                            |              |            | S           |              |                                                                  |                 | Not Reported |
|                                                                                                               | Seroquel                              |              |            | S           | Oral         | 50 Mg Twice Daily In The<br>Morning And Noon, 200<br>Mg At Night |                 | Not Reported |
|                                                                                                               | Seroquel                              |              |            | S           |              |                                                                  |                 | Not Reported |
|                                                                                                               | Lexapro                               |              |            | S           | Oral         |                                                                  |                 | Not Reported |
|                                                                                                               | Valium                                |              |            | S           | Oral         |                                                                  |                 | Not Reported |
|                                                                                                               | Demadex                               |              |            | S           | Oral         |                                                                  |                 | Not Reported |
|                                                                                                               | Topamax                               |              |            | S           | Oral         |                                                                  |                 | Not Reported |
|                                                                                                               | Fentanyl                              |              |            | S           | Transdermal  |                                                                  |                 | Not Reported |
|                                                                                                               | Effexor                               |              |            | S           | Oral         |                                                                  |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|------------|------------|----------------|
| 14-Jan-2015              | 10710765      | EXPEDITED (15-DAY) |                    | DE              | US-ASTRAZENECA-<br>2015SE01496 |                      | 51 YR      | Female     | USA            |

  

| <u>Preferred Term</u>                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide;<br>Toxicity To Various Agents | Esomeprazole   |              |            | S           | Oral         |                    |                 | Astrazeneca  |
|                                                  | Diazepam       |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Acetaminophen  |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Escitalopram   |              |            | S           | Oral         |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                           |   |      |              |
|---------------------------|---|------|--------------|
| Diclofenac                | S | Oral | Not Reported |
| Acetaminophen/Hydrocodone | S | Oral | Not Reported |
| Promethazine              | S | Oral | Not Reported |
| Topiramate                | S | Oral | Not Reported |
| Verapamil                 | S | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 14-Jan-2015              | 10711233      | EXPEDITED (15-DAY) |                    | DE              | US-PFIZER INC-2015006869 |                      | 48 YR      | Female     | USA            |

| <u>Preferred Term</u>                        | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiac Arrest; Death;<br>Respiratory Arrest | Nitroglycerin       |              |            | S           |              | Unk                |                 | Pfizer       |
|                                              | Ibuprofen           |              |            | S           |              | Unk                |                 | Pfizer       |
|                                              | Azithromycin        |              |            | S           |              | Unk                |                 | Pfizer       |
|                                              | Doxycycline Calcium |              |            | S           |              | Unk                |                 | Pfizer       |
|                                              | Methylprednisolone  |              |            | S           |              | Unk                |                 | Pfizer       |
|                                              | Oxycodone           |              |            | S           |              | Unk                |                 | Not Reported |
|                                              | Cyclobenzaprine     |              |            | S           |              | Unk                |                 | Not Reported |
|                                              | Metoprolol          |              |            | S           |              | Unk                |                 | Not Reported |
|                                              | Clonidine           |              |            | S           |              | Unk                |                 | Not Reported |
|                                              | Lisinopril          |              |            | S           |              | Unk                |                 | Not Reported |
|                                              | Escitalopram        |              |            | S           |              | Unk                |                 | Not Reported |
|                                              | Diclofenac          |              |            | S           |              | Unk                |                 | Not Reported |
|                                              | Cephalexin          |              |            | S           |              | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Jan-2015              | 10711248      | EXPEDITED (15-DAY) |                    | DE, HO          | US-BAYER-2015-004010 |                      | 69 YR      | Male       | USA            |

| <u>Preferred Term</u>                               | <u>Product</u>                  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------|---------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Intentional Overdose;<br>Toxicity To Various Agents | Acetylsalicylic Acid (> 100 Mg) |              | Y          | S           | Oral         |                    |                 | Bayer        |
|                                                     | Digoxin                         |              |            | S           | Oral         |                    |                 | Not Reported |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|              |   |      |              |
|--------------|---|------|--------------|
| Clonazepam   | S | Oral | Not Reported |
| Trazodone    | S | Oral | Not Reported |
| Oxybutynin   | S | Oral | Not Reported |
| Quetiapine   | S | Oral | Not Reported |
| Lamotrigine  | S |      | Not Reported |
| Escitalopram | S | Oral | Not Reported |
| Finasteride  | S | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 14-Jan-2015              | 10711576                               | EXPEDITED (15-DAY) |                    | DE              | US-PFIZER INC-2015008398 |                      | 51 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide        | Verapamil Hcl                          |                    |                    | S               | Oral                     |                      |                 | Pfizer       |                |
|                          | Promethazine                           |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                          | Escitalopram                           |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                          | Acetaminophen W/Hydrocodone Bitartrate |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                          | Diazepam                               |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                          | Topiramate                             |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                          | Esomeprazole                           |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                          | Diclofenac                             |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 14-Jan-2015              | 10711756       | EXPEDITED (15-DAY) |                    | DE              | US-PFIZER INC-2015009066 |                      | 36 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide        | Verapamil Hcl  |                    |                    | S               | Oral                     | Unk                  |                 | Pfizer       |                |
|                          | Escitalopram   |                    |                    | S               | Oral                     | Unk                  |                 | Not Reported |                |
|                          | Codeine        |                    |                    | S               | Oral                     | Unk                  |                 | Not Reported |                |
|                          | Topiramate     |                    |                    | S               | Oral                     | Unk                  |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|--------------------------------------------|----------------------|-----------------|-----------------|----------------|
| 14-Jan-2015                                                                                           | 10712237       | EXPEDITED (15-DAY) |                    | DE, OT          | US-<br>GLAXOSMITHKLINE-<br>US2015GSK002968 |                      | 28 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Cardio-Respiratory Arrest;<br>Completed Suicide                                                       | Bupropion      |                    |                    | S               | Oral                                       |                      |                 | Glaxosmithkline |                |
|                                                                                                       | Escitalopram   |                    |                    | S               | Oral                                       |                      |                 | Glaxosmithkline |                |
|                                                                                                       | Gabapentin     |                    |                    | S               | Oral                                       |                      |                 | Glaxosmithkline |                |
|                                                                                                       | Alprazolam     |                    |                    | S               | Oral                                       |                      |                 | Glaxosmithkline |                |
| <u>FDA Received Date</u>                                                                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 15-Jan-2015                                                                                           | 10366630       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000069661                          |                      | 80 YR           | Male            | FRA            |
| <u>Preferred Term</u>                                                                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Cerebral Haematoma;<br>Drug Interaction;<br>Haemorrhagic Stroke                                       | Escitalopram   |                    |                    | S               | Oral                                       | 1 Df                 |                 | Forest          |                |
|                                                                                                       | Pradaxa        |                    |                    | S               | Oral                                       | 2 Df                 |                 | Not Reported    |                |
|                                                                                                       | Allopurinol    |                    |                    | C               | Unknown                                    | 1 Df                 |                 | Not Reported    |                |
|                                                                                                       | Atorvastatin   |                    |                    | C               | Unknown                                    | 1 Df                 |                 | Not Reported    |                |
|                                                                                                       | Exelon         |                    |                    | C               | Transdermal                                | 1 Df                 |                 | Not Reported    |                |
|                                                                                                       | Loxapac        |                    |                    | C               | Oral                                       | 20 Df                |                 | Not Reported    |                |
|                                                                                                       | Sotalex        |                    |                    | C               | Unknown                                    | 2 Df                 |                 | Not Reported    |                |
|                                                                                                       | Zopiclone      |                    |                    | C               | Unknown                                    | 1 Df                 |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 15-Jan-2015                                                                                           | 10671740       | EXPEDITED (15-DAY) |                    | OT              | SE-FRI-1000073221                          |                      | 38 YR           | Female          | SWE            |
| <u>Preferred Term</u>                                                                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Dizziness; Headache;<br>Hypotension; Muscular<br>Weakness; Tremor; Vision<br>Blurred; Vision Blurred; | Escitalopram   |                    |                    | S               |                                            | 10 Mg                |                 | Forest          |                |
|                                                                                                       | Escitalopram   |                    |                    | S               | Unknown                                    |                      |                 | Forest          |                |
|                                                                                                       | Escitalopram   |                    |                    | S               | Unknown                                    |                      |                 | Not Reported    |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                     |              |   |         |              |
|---------------------|--------------|---|---------|--------------|
| Withdrawal Syndrome | Escitalopram | S | Unknown | Not Reported |
|                     | Escitalopram | S | Unknown | Not Reported |
|                     | Escitalopram | S | Unknown | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 15-Jan-2015              | 10712306      | EXPEDITED (15-DAY) |                    | DE, HO          | US-ASTRAZENECA-2015SE01512 |                      | 69 YR      | Male       | USA            |

| <u>Preferred Term</u>                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide;<br>Toxicity To Various Agents | Quetiapine     |              |            | S           | Oral         |                    |                 | Zeneca       |
|                                                  | Clonazepam     |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Digoxin        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Trazodone      |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Oxybutynin     |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Lamotrigine    |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Escitalopram   |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Finasteride    |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Salicylate     |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------------------------------------|----------------------|------------|------------|----------------|
| 15-Jan-2015              | 10713134      | EXPEDITED (15-DAY) |                    | HO              | US-TARO<br>PHARMACEUTICALS<br>U.S.A., INC-<br>2015SUN00130 |                      | 35 YR      | Female     | USA            |

| <u>Preferred Term</u>                   | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------|-------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction;<br>Serotonin Syndrome | Escitalopram      |              |            | S           | Unknown      | 20 Mg, Unk         |                 | Taro         |
|                                         | Garcinia Cambogia |              |            | S           | Unknown      | 2 Df, Tid          |                 | Not Reported |
|                                         | Sertraline        |              |            | S           | Unknown      | 50 Mg, Daily       |                 | Not Reported |
|                                         | Baclofen          |              |            | C           | Unknown      | Unk                |                 | Not Reported |
|                                         | Gabapentin        |              |            | C           | Unknown      | Unk                |                 | Not Reported |
|                                         | Omeprazole        |              |            | C           | Unknown      | Unk                |                 | Not Reported |
|                                         | Oxycodone         |              |            | C           | Unknown      | Unk                |                 | Not Reported |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                 |   |         |     |              |
|-----------------|---|---------|-----|--------------|
| Silodosin       | C | Unknown | Unk | Not Reported |
| Solifenacin     | C | Unknown | Unk | Not Reported |
| Diphenhydramine | C | Unknown | Unk | Not Reported |
| Cannabinoids    | C |         | Unk | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Jan-2015              | 10713692      | EXPEDITED (15-DAY) | HO                 |                 | FR-FRI-1000073596    |                      | 84 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction; Upper Gastrointestinal Haemorrhage | Escitalopram   |              |            | S           | Oral         |                    |                 | Forest       |
|                                                      | Ketoprofene    |              |            | S           | Cutaneous    |                    |                 | Not Reported |
|                                                      | Aldactazine    |              |            | S           | Oral         | 1 Df               |                 | Not Reported |
|                                                      | Eliquis        |              |            | S           | Oral         | 5 Mg               |                 | Not Reported |
|                                                      | Kardegic       |              |            | S           | Oral         | 75 Mg              |                 | Not Reported |
|                                                      | Temerit        |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                      | Mediatensyl    |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                      | Amiodarone     |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                      | Eptavit        |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                      | Doliprane      |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                      | Esomeprazole   |              |            | C           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Jan-2015              | 10713716      | EXPEDITED (15-DAY) | HO                 |                 | FR-FRI-1000073597    |                      | 32 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Epistaxis; Gingival Bleeding; Haematuria; Rectal Haemorrhage | Escitalopram   |              |            | S           | Oral         | 5mg                |                 | Forest       |
|                                                              | Escitalopram   |              |            | S           | Oral         | 10mg               |                 | Forest       |
|                                                              | Xanax          |              |            | S           | Oral         | 0.25mg             |                 | Not Reported |
|                                                              | Bilaska        |              |            | C           | Oral         | 20 Mg              |                 | Not Reported |
|                                                              | Tardyferon     |              |            | C           | Oral         | 1 Df               |                 | Not Reported |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|--------------------------|-------------------|--------------------|--------------------|-----------------|--------------------------------------------------------|----------------------|-----------------|----------------------|----------------|
| 15-Jan-2015              | 10714860          | EXPEDITED (15-DAY) |                    | DS              | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>BMS-2015-000821 |                      |                 | Female               | USA            |
| <u>Preferred Term</u>    | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Disability               | Abilify           |                    |                    | S               | Unknown                                                | N/A                  |                 | Bristol Myers Squibb |                |
|                          | Lexapro           |                    |                    | S               | Unknown                                                |                      |                 | Not Reported         |                |
| <u>FDA Received Date</u> | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 15-Jan-2015              | 10715091          | EXPEDITED (15-DAY) |                    | DE, OT          | US-<br>GLAXOSMITHKLINE-<br>US2015GSK003131             |                      | 69 YR           | Male                 | USA            |
| <u>Preferred Term</u>    | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Completed Suicide        | Quetiapine        |                    |                    | S               | Oral                                                   |                      |                 | Glaxosmithkline      |                |
|                          | Cardiac Glycoside |                    |                    | S               | Oral                                                   |                      |                 | Not Reported         |                |
|                          | Clonazepam        |                    |                    | S               | Oral                                                   |                      |                 | Glaxosmithkline      |                |
|                          | Trazodone         |                    |                    | S               | Oral                                                   |                      |                 | Not Reported         |                |
|                          | Oxybutynin        |                    |                    | S               |                                                        |                      |                 | Glaxosmithkline      |                |
|                          | Lamotrigine       |                    |                    | S               | Oral                                                   |                      |                 | Glaxosmithkline      |                |
|                          | Escitalopram      |                    |                    | S               | Oral                                                   |                      |                 | Glaxosmithkline      |                |
|                          | Finasteride       |                    |                    | S               | Oral                                                   |                      |                 | Glaxosmithkline      |                |
|                          | Salicylate        |                    |                    | S               | Oral                                                   |                      |                 | Not Reported         |                |
| <u>FDA Received Date</u> | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 15-Jan-2015              | 10715098          | EXPEDITED (15-DAY) |                    | DE, OT          | US-<br>GLAXOSMITHKLINE-<br>US2015GSK003260             |                      | 62 YR           | Male                 | USA            |
| <u>Preferred Term</u>    | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Completed Suicide        | Escitalopram      |                    |                    | S               | Oral                                                   |                      |                 | Glaxosmithkline      |                |
|                          | Lamotrigine       |                    |                    | S               | Oral                                                   |                      |                 | Glaxosmithkline      |                |
|                          | Temazepam         |                    |                    | S               | Oral                                                   |                      |                 | Not Reported         |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                           |   |      |              |
|---------------------------|---|------|--------------|
| Lorazepam                 | S | Oral | Not Reported |
| Primidone                 | S | Oral | Not Reported |
| Benzotropine              | S | Oral | Not Reported |
| Antihyperlipidemics (Nos) | S | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 15-Jan-2015              | 10715158      | EXPEDITED (15-DAY) |                    | DE              | US-JNJFOC-20150107004 |                      | 41 YR      | Male       | USA            |

| <u>Preferred Term</u>                            | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------|-------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide;<br>Toxicity To Various Agents | Acetaminophen/Diphenhydramine | Y            |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Warfarin                      |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Olanzapine                    |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Lisinopril                    |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Escitalopram                  |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Prednisone                    |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 16-Jan-2015              | 10695069      | EXPEDITED (15-DAY) |                    | OT              | US-ABBVIE-15K-163-1329058-00 |                      | 50 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Chills; Gingival Pain;<br>Gingival Swelling;<br>Hyperhidrosis;<br>Pneumonia; Seizure | Humira         |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                      | Lexapro        |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                      | Meloxicam      |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 16-Jan-2015              | 10716258      | EXPEDITED (15-DAY) |                    | HO              | DE-BRISTOL-MYERS SQUIBB COMPANY-BMS-2014-004743 |                      | 50 YR      | Female     | DEU            |

| <u>Preferred Term</u>                        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>           |
|----------------------------------------------|----------------|--------------|------------|-------------|--------------|---------------------------------------------|-----------------|----------------------|
| Agitation; Drug Interaction;<br>Restlessness | Abilify        |              |            | S           | Oral         | 5 Mg/Day, Increased To 10 Mg/Day On 06-Mar- |                 | Bristol Myers Squibb |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                |                                                                                                                        | Cipralex /01588501/<br>Venlafaxin | S<br>S             | Oral<br>Oral               |                                                 | 2013<br>10 Mg/Day<br>150 Mg/Day; 75mg        |                 | Not Reported<br>Not Reported                                                   |                |
|------------------------------------------------|------------------------------------------------------------------------------------------------------------------------|-----------------------------------|--------------------|----------------------------|-------------------------------------------------|----------------------------------------------|-----------------|--------------------------------------------------------------------------------|----------------|
| <u>FDA Received Date</u>                       | <u>Case #</u>                                                                                                          | <u>Case Type</u>                  | <u>Health Prof</u> | <u>Outcomes</u>            | <u>Mfr Control #</u>                            | <u>503B Facility</u>                         | <u>Age</u>      | <u>Sex</u>                                                                     | <u>Country</u> |
| 16-Jan-2015                                    | 10716884                                                                                                               | EXPEDITED (15-DAY)                |                    | OT                         | US-FRI-1000073598                               |                                              |                 | Female                                                                         | USA            |
| <u>Preferred Term</u>                          | <u>Product</u>                                                                                                         | <u>Comp.</u>                      | <u>OTC</u>         | <u>Role</u>                | <u>Route</u>                                    | <u>Dosage Text</u>                           | <u>Duration</u> | <u>Mfr</u>                                                                     |                |
| Deafness; Dizziness;<br>Irritability; Tinnitus | Escitalopram<br>Escitalopram                                                                                           |                                   |                    | S<br>S                     |                                                 | 10 Mg<br>1.25 Mg                             |                 | Forest<br>Forest                                                               |                |
| <u>FDA Received Date</u>                       | <u>Case #</u>                                                                                                          | <u>Case Type</u>                  | <u>Health Prof</u> | <u>Outcomes</u>            | <u>Mfr Control #</u>                            | <u>503B Facility</u>                         | <u>Age</u>      | <u>Sex</u>                                                                     | <u>Country</u> |
| 16-Jan-2015                                    | 10716932                                                                                                               | EXPEDITED (15-DAY)                |                    | HO                         | FR-<br>ELI_LILLY_AND_COMP<br>ANY-FR201501001173 |                                              | 75 YR           | Male                                                                           | FRA            |
| <u>Preferred Term</u>                          | <u>Product</u>                                                                                                         | <u>Comp.</u>                      | <u>OTC</u>         | <u>Role</u>                | <u>Route</u>                                    | <u>Dosage Text</u>                           | <u>Duration</u> | <u>Mfr</u>                                                                     |                |
| Constipation;<br>Haematemesis; Subileus        | Zyprexa<br>Risperdal<br>Seroplex                                                                                       |                                   |                    | S<br>S<br>S                | Oral<br>Unknown<br>Unknown                      | Unk, Unknown<br>Unk, Unknown<br>Unk, Unknown |                 | Eli Lilly And Co<br>Not Reported<br>Not Reported                               |                |
| <u>FDA Received Date</u>                       | <u>Case #</u>                                                                                                          | <u>Case Type</u>                  | <u>Health Prof</u> | <u>Outcomes</u>            | <u>Mfr Control #</u>                            | <u>503B Facility</u>                         | <u>Age</u>      | <u>Sex</u>                                                                     | <u>Country</u> |
| 16-Jan-2015                                    | 10717614                                                                                                               | EXPEDITED (15-DAY)                |                    | DE                         | US-BAYER-2015-<br>005102                        |                                              | 41 YR           | Male                                                                           | USA            |
| <u>Preferred Term</u>                          | <u>Product</u>                                                                                                         | <u>Comp.</u>                      | <u>OTC</u>         | <u>Role</u>                | <u>Route</u>                                    | <u>Dosage Text</u>                           | <u>Duration</u> | <u>Mfr</u>                                                                     |                |
| Toxicity To Various Agents                     | Paracetamol + Diphenhydramine<br>Paracetamol + Diphenhydramine<br>Warfarin<br>Olanzapine<br>Lisinopril<br>Escitalopram | Y<br>Y                            |                    | S<br>S<br>S<br>S<br>S<br>S | Oral<br>Oral<br>Oral<br>Oral<br>Oral<br>Oral    | Unk<br>Unk                                   |                 | Bayer<br>Bayer<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| Prednisone                                                                                      |                             |                    | S                  |                 | Oral                                     |                               |                 | Not Reported    |                |
|-------------------------------------------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|------------------------------------------|-------------------------------|-----------------|-----------------|----------------|
| <u>FDA Received Date</u>                                                                        | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 16-Jan-2015                                                                                     | 10724176                    | DIRECT             |                    |                 |                                          |                               | 40 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                                           | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>      |                |
| Adverse Drug Reaction;<br>Anxiety; Drug Ineffective;<br>Headache; Product<br>Substitution Issue | Escitalopram Oxalate        |                    |                    | S               | Oral                                     |                               |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                        | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 18-Jan-2015                                                                                     | 10718227                    | NON-EXPEDITED      |                    |                 | US-ASTRAZENECA-<br>2014SE95702           |                               |                 | Male            | USA            |
| <u>Preferred Term</u>                                                                           | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>      |                |
| Anxiety; Depression;<br>Erectile Dysfunction;<br>Sexual Dysfunction;<br>Somnolence              | Seroquel Xr                 |                    |                    | S               | Oral                                     |                               |                 | Astrazeneca     |                |
|                                                                                                 | Seroquel Xr                 |                    |                    | S               | Oral                                     |                               |                 | Astrazeneca     |                |
|                                                                                                 | Pristiq (Non Az Product)    |                    |                    | S               | Oral                                     |                               |                 | Not Reported    |                |
|                                                                                                 | Zoloft (Non Az Product)     |                    |                    | S               | Oral                                     |                               |                 | Not Reported    |                |
|                                                                                                 | Wellbutrin (Non Az Product) |                    |                    | S               | Oral                                     |                               |                 | Not Reported    |                |
|                                                                                                 | Lexapro (Non Az Product)    |                    |                    | S               | Oral                                     |                               |                 | Not Reported    |                |
|                                                                                                 | Xanax                       |                    |                    | S               | Oral                                     |                               |                 | Not Reported    |                |
|                                                                                                 | Prozac                      |                    |                    | S               | Unknown                                  |                               |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                        | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 19-Jan-2015                                                                                     | 10354792                    | EXPEDITED (15-DAY) |                    | DS, HO, LT, OT  | US-<br>GLAXOSMITHKLINE-<br>A1083024A     |                               | 40 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                                           | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>      |                |
| Adverse Reaction; Drug<br>Hypersensitivity; Ear<br>Injury; Ear Swelling; Gait<br>Disturbance;   | Benlysta                    |                    |                    | S               | Intravenous (not<br>otherwise specified) | 10 Mg/Kg, 850 Mg Per<br>Month |                 | Glaxosmithkline |                |
|                                                                                                 | Benlysta                    |                    |                    | S               | Unknown                                  | 150mg,25cc In 250ml, Cyc      |                 | Glaxosmithkline |                |

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|                              |                     |   |         |           |                 |
|------------------------------|---------------------|---|---------|-----------|-----------------|
| Hospitalisation; Mobility    | Benlysta            | S |         | 400 Mg, U | Glaxosmithkline |
| Decreased; Otorrhoea;        | Cymbalta            | S |         | 60 Mg, Qd | Glaxosmithkline |
| Pain; Peripheral Swelling;   | Lexapro             | S | Unknown | Unk, U    | Not Reported    |
| Suicidal Ideation; Swelling; | Plaquenil           | C |         |           | Not Reported    |
| Swelling Face                | Triamcinolone Cream | C |         |           | Not Reported    |
|                              | Trazodone           | C |         |           | Not Reported    |
|                              | Gabapentin          | C |         |           | Not Reported    |
|                              | Lasix               | C |         |           | Not Reported    |
|                              | Cyanocobalamin      | C |         |           | Not Reported    |
|                              | Prenatal Vitamins   | C |         |           | Not Reported    |
|                              | Fentanyl Patch      | C |         |           | Not Reported    |
|                              | Solumedrol          | C |         |           | Not Reported    |
|                              | Benadryl            | C |         |           | Glaxosmithkline |
|                              | Trazodone           | C |         |           | Not Reported    |
|                              | Lorazepam           | C |         |           | Not Reported    |
|                              | Ondansetron Hcl     | C |         |           | Glaxosmithkline |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Jan-2015              | 10721283      | EXPEDITED (15-DAY) | HO                 |                 | FR-SA-2015SA005024   |                      | 91 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Fall                  | Lasilix        |              |            | S           | Oral         | 40 Mg              |                 | Not Reported |
|                       | Lexomil        |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Seresta        |              |            | S           | Oral         | 50 Mg; Tab         |                 | Not Reported |
|                       | Seroplex       |              |            | S           | Oral         | 10 Mg; Tab         |                 | Not Reported |
|                       | Preterax       |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Tanganil       |              |            | C           | Oral         |                    |                 | Not Reported |
|                       | Levothyrox     |              |            | C           | Oral         | 125 Mcg            |                 | Not Reported |
|                       | Doliprane      |              |            | C           | Oral         |                    |                 | Not Reported |
|                       | Mopral         |              |            | C           | Oral         |                    |                 | Not Reported |
|                       | Xanax          |              |            | C           |              | Strength: 0.25     |                 | Not Reported |
|                       | Diffu K        |              |            | C           | Oral         | 600 Mg             |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                            | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|---------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|------------------------------------|----------------------|-----------------|-----------------|----------------|
| 19-Jan-2015                                                         | 10722435                | EXPEDITED (15-DAY) |                    | HO              | CA-GLAXOSMITHKLINE-CA2015GSK006578 |                      | 54 YR           | Female          | CAN            |
| <u>Preferred Term</u>                                               | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                       | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Condition Aggravated;<br>Dehydration; Dysphagia;<br>Mental Disorder | Wellbutrin XI           |                    |                    | S               | Oral                               | 150 Mg, Bid          |                 | Glaxosmithkline |                |
|                                                                     | Cipraxel                |                    |                    | S               | Oral                               | 20 Mg, U             |                 | Not Reported    |                |
|                                                                     | Clonazepam              |                    |                    | S               |                                    | 0.5 Mg, Tid          |                 | Not Reported    |                |
|                                                                     | Domperidone             |                    |                    | S               |                                    | 10 Mg, Bid           |                 | Not Reported    |                |
|                                                                     | Ferrous Sulphate        |                    |                    | S               | Oral                               | 300 Mg, Tid          |                 | Not Reported    |                |
|                                                                     | Gabapentin              |                    |                    | S               | Oral                               | 300 Mg, Qd           |                 | Not Reported    |                |
|                                                                     | Gabapentin              |                    |                    | S               |                                    | 600 Mg, Bid          |                 | Not Reported    |                |
|                                                                     | Temazepam               |                    |                    | S               | Oral                               | 30 Mg, 1d            |                 | Not Reported    |                |
|                                                                     | Tylenol With Codeine    |                    |                    | S               | Oral                               | 2 Df, Tid            |                 | Not Reported    |                |
|                                                                     | Vitalux                 |                    |                    | S               | Oral                               | Unk, Bid             |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                            | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 20-Jan-2015                                                         | 10449781                | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2014250872           |                      |                 | Female          | USA            |
| <u>Preferred Term</u>                                               | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                       | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Drug Hypersensitivity                                               | Doxycycline Monohydrate |                    |                    | S               |                                    | Unk                  |                 | Pfizer          |                |
|                                                                     | Bextra                  |                    |                    | S               |                                    | Unk                  |                 | Pfizer          |                |
|                                                                     | Septra                  |                    |                    | S               |                                    | Unk                  |                 | Pfizer          |                |
|                                                                     | Effexor                 |                    |                    | S               |                                    | Unk                  |                 | Pfizer          |                |
|                                                                     | Aspirin                 |                    |                    | S               |                                    | Unk                  |                 | Not Reported    |                |
|                                                                     | Wellbutrin              |                    |                    | S               |                                    | Unk                  |                 | Not Reported    |                |
|                                                                     | Ceclor                  |                    |                    | S               |                                    | Unk                  |                 | Not Reported    |                |
|                                                                     | Cymbalta                |                    |                    | S               |                                    | Unk                  |                 | Not Reported    |                |
|                                                                     | Lexapro                 |                    |                    | S               |                                    | Unk                  |                 | Not Reported    |                |

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|           |   |     |              |
|-----------|---|-----|--------------|
| Symbyax   | S | Unk | Not Reported |
| Lescol    | S | Unk | Not Reported |
| Novocaine | S | Unk | Not Reported |
| Seroquel  | S | Unk | Not Reported |
| Zocor     | S | Unk | Not Reported |
| Topamax   | S | Unk | Not Reported |
| Asa       | S | Unk | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------------------------------------|----------------------|------------|------------|----------------|
| 20-Jan-2015              | 10699229      | NON-EXPEDITED    |                    |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>BMS-2014-001271 |                      |            | Female     | USA            |

| <u>Preferred Term</u>                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>           |
|--------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------|
| Drug Ineffective; Psychotic Disorder | Abilify        |              |            | S           | Unknown      | Unk Mg, Unk        |                 | Bristol Myers Squibb |
|                                      | Abilify        |              |            | S           |              |                    |                 | Bristol Myers Squibb |
|                                      | Abilify        |              |            | S           |              |                    |                 | Bristol Myers Squibb |
|                                      | Lexapro        |              |            | S           | Unknown      | 20 Mg              |                 | Not Reported         |
|                                      | Klonopin       |              |            | S           | Unknown      | Unk                |                 | Not Reported         |
|                                      | Ambien         |              |            | S           | Unknown      | Once Daily         |                 | Not Reported         |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 20-Jan-2015              | 10722672      | EXPEDITED (15-DAY) |                    | HO              | CA-BAUSCH-BL-2015-000732 |                      | 54 YR      | Female     | CAN            |

| <u>Preferred Term</u>                                         | <u>Product</u>   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------|------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Condition Aggravated; Dehydration; Dysphagia; Mental Disorder | Wellbutrin XI    |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                               | Ciprallex        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                               | Clonazepam       |              |            | S           |              |                    |                 | Not Reported |
|                                                               | Domperidone      |              |            | S           |              |                    |                 | Not Reported |
|                                                               | Ferrous Sulphate |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                               | Gabapentin       |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                               | Gabapentin       |              |            | S           | Oral         |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                  |   |      |              |
|----------------------------------|---|------|--------------|
| Temazepam                        | S | Oral | Not Reported |
| Tylenol With Codeine No. 3 - Tab | S | Oral | Not Reported |
| Vitalux                          | S | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|------------|------------|----------------|
| 20-Jan-2015              | 10723046      | EXPEDITED (15-DAY) | HO                 |                 | US-DRREDDYS-USA/USA/15/0045446 |                      | 35 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                           | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hallucination, Visual; Hypertension; Hypokalaemia; Leukocytosis; Serotonin Syndrome; Toxicity To Various Agents | Sertraline Hydrochloride |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                                 | Escitalopram             |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                                 | G. Cambogia              |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                                 | Baclofen                 |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                                                                 | Gabapentin               |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                                                                 | Omeprazole               |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                                                                 | Oxycodone                |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                                                                 | Silodosin                |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                                                                 | Solifenacin              |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                                                                 | Diphenhydramine          |              |            | C           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 20-Jan-2015              | 10724258      | EXPEDITED (15-DAY) | OT                 |                 | FR-ASTRAZENECA-2014SE98632 |                      | 35 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|------------------------|-----------------|--------------|
| Dyslipidaemia; Hyperphagia; Hypothyroidism; Weight Increased | Xeroquel       |              |            | S           | Oral         |                        |                 | Zeneca       |
|                                                              | Xeroquel       |              |            | S           | Oral         |                        |                 | Zeneca       |
|                                                              | Seroplex       |              |            | S           | Oral         |                        |                 | Not Reported |
|                                                              | Alprazolam     |              |            | C           |              |                        |                 | Not Reported |
|                                                              | Atarax         |              |            | C           |              |                        |                 | Not Reported |
|                                                              | Theralene      |              |            | C           |              |                        |                 | Not Reported |
|                                                              | Zopiclone      |              |            | C           |              | 1 To 2 Tablets Per Day |                 | Not Reported |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                                                                       |                          |                    |                    |                 |                                            |                      |                 |              |                              |
|-------------------------------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|--------------------------------------------|----------------------|-----------------|--------------|------------------------------|
| Inhibitor Pump Of Proton<br>Nicotine                                                                  |                          |                    | C<br>C             |                 |                                            |                      |                 |              | Not Reported<br>Not Reported |
| <u>FDA Received Date</u>                                                                              | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u>               |
| 20-Jan-2015                                                                                           | 10724650                 | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000073642                          |                      | 85 YR           | Male         | FRA                          |
| <u>Preferred Term</u>                                                                                 | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                              |
| Carotid Artery Dissection;<br>Cerebral Haemorrhage;<br>Enuresis; Fall;<br>Subarachnoid<br>Haemorrhage | Escitalopram             |                    |                    | S               | Oral                                       | 5mg                  |                 | Forest       |                              |
|                                                                                                       | Xarelto                  |                    |                    | S               | Oral                                       | 15mg                 |                 | Not Reported |                              |
|                                                                                                       | Hemigoxine Nativelle     |                    |                    | C               | Oral                                       | 0.125mg              |                 | Not Reported |                              |
|                                                                                                       | Bisoprolol               |                    |                    | C               | Oral                                       | 5mg                  |                 | Not Reported |                              |
|                                                                                                       | Pantoprazole             |                    |                    | C               | Oral                                       | 20mg                 |                 | Not Reported |                              |
| <u>FDA Received Date</u>                                                                              | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u>               |
| 20-Jan-2015                                                                                           | 10724825                 | EXPEDITED (15-DAY) |                    | DE, HO          | US-JNJFOC-<br>20150105344                  |                      | 69 YR           | Male         | USA                          |
| <u>Preferred Term</u>                                                                                 | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                              |
| Completed Suicide;<br>Toxicity To Various Agents                                                      | Oxybutynin Hydrochloride |                    |                    | S               | Oral                                       |                      |                 | Not Reported |                              |
|                                                                                                       | Digoxin                  |                    |                    | S               | Oral                                       |                      |                 | Not Reported |                              |
|                                                                                                       | Trazodone                |                    |                    | S               | Oral                                       |                      |                 | Not Reported |                              |
|                                                                                                       | Quetiapine               |                    |                    | S               | Oral                                       |                      |                 | Not Reported |                              |
|                                                                                                       | Lamotrigine              |                    |                    | S               | Oral                                       |                      |                 | Not Reported |                              |
|                                                                                                       | Escitalopram             |                    |                    | S               | Oral                                       |                      |                 | Not Reported |                              |
|                                                                                                       | Finasteride              |                    |                    | S               | Oral                                       |                      |                 | Not Reported |                              |
|                                                                                                       | Clonazepam               |                    |                    | S               | Oral                                       |                      |                 | Not Reported |                              |
| <u>FDA Received Date</u>                                                                              | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u>               |
| 20-Jan-2015                                                                                           | 10725180                 | EXPEDITED (15-DAY) |                    | HO, OT          | FR-<br>GLAXOSMITHKLINE-<br>FR2015GSK004487 |                      | 60 YR           | Female       | FRA                          |
| <u>Preferred Term</u>                                                                                 | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                              |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                          |            |   |      |                |                 |
|--------------------------------------------------------------------------|------------|---|------|----------------|-----------------|
| Coma; Electrocardiogram<br>Abnormal; Hypotension;<br>Respiratory Failure | Lamictal   | S | Oral | 3 G, Single    | Glaxosmithkline |
|                                                                          | Tercian    | S | Oral | 375 Mg, Single | Not Reported    |
|                                                                          | Prazepam   | S | Oral | 600 Mg, Single | Not Reported    |
|                                                                          | Seroplex   | S | Oral | 600 Mg, Unk    | Glaxosmithkline |
|                                                                          | Levothyrox | C |      |                | Not Reported    |
|                                                                          | Sulfarlem  | C |      |                | Not Reported    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Jan-2015              | 10727289      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000073762    |                      | 30 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                                                  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Agitation; Coma;<br>Hepatocellular Injury;<br>Hyperhidrosis; Mydriasis;<br>Tachycardia | Escitalopram   |              |            | S           | Oral         | 20 Mg              |                 | Forest       |
|                                                                                        | Depakote       |              |            | C           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Jan-2015              | 10727298      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000073724    |                      | 74 YR      | Female     | FRA            |

| <u>Preferred Term</u>                 | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------|--------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anaemia; Drug Interaction;<br>Melaena | Escitalopram       |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                       | Kardegic           |              |            | S           | Oral         | 75 Mg              |                 | Not Reported |
|                                       | Triatec (Ramipril) |              |            | C           | Oral         | 2.5 Mg             |                 | Not Reported |
|                                       | Eupressyl          |              |            | C           | Oral         | 60 Mg              |                 | Not Reported |
|                                       | Lasilix            |              |            | C           | Oral         | 60 Mg              |                 | Not Reported |
|                                       | Diffu K            |              |            | C           | Oral         | 1800 Mg            |                 | Not Reported |
|                                       | Amlor              |              |            | C           | Oral         | 10 Mg              |                 | Not Reported |
|                                       | Natispray          |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                       | Speciafoldine      |              |            | C           | Oral         | 5 Mg               |                 | Not Reported |
|                                       | Laroscobine        |              |            | C           | Oral         | 1000 Mg            |                 | Not Reported |
|                                       | Seresta            |              |            | C           | Oral         | 60 Mg              |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                      |   |         |        |              |
|------------------------------------------------------|---|---------|--------|--------------|
| Spasfon (Phloroglucinol,<br>Trimethylphloroglucinol) | C | Oral    | 480 Mg | Not Reported |
| Forlax                                               | C | Unknown |        | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Jan-2015              | 10736108      | EXPEDITED (15-DAY) | Y                  | HO              | SE-001614            |                      | 53 YR      | Female     | SWE            |

| <u>Preferred Term</u>                                                                                                                                                                                                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Creatinine Increased; Fluid Intake Reduced; Gastrointestinal Stoma Output Increased; Hypophagia; Ileal Stenosis; Urine Output Decreased | Revestive      |              |            | S           | Subcutaneous |                    |                 | Not Reported |
|                                                                                                                                                                                                                         | Morphine       |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                         | Escitalopram   |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                         | Mirtazapin     |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                         | Codeine        |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                         | Imodium        |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                         | Innohep        |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                         | Imovane        |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Jan-2015              | 10659795      | EXPEDITED (15-DAY) |                    | LT              | JP-FRI-1000073111    |                      | 27 YR      | Male       | JPN            |

| <u>Preferred Term</u>                                                                          | <u>Product</u>                   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------|----------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Altered State Of Consciousness; Electrocardiogram Abnormal; Hypothermia; Myocarditis; Overdose | Lexapro                          |              |            | S           | Oral         | 30 Tablets         |                 | Forest       |
|                                                                                                | Lexapro                          |              |            | S           | Oral         |                    |                 | Forest       |
|                                                                                                | Rohypnol                         |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                | Rohypnol                         |              |            | S           | Oral         | 120 Mg             |                 | Not Reported |
|                                                                                                | Myonal [Eperisone Hydrochloride] |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                | Myonal [Eperisone Hydrochloride] |              |            | S           | Oral         | 4500 Mg            |                 | Not Reported |
|                                                                                                | Celecox                          |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                | Celecox                          |              |            | S           | Oral         | 6000 Mg            |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                     | <u>Case #</u>                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------|--------------------------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 22-Jan-2015                                                  | 10678467                                   | EXPEDITED (15-DAY) |                    | OT              | FR-PFIZER INC-2014356829 |                      | 32 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                        | <u>Product</u>                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Epistaxis; Gingival Bleeding; Haematuria; Rectal Haemorrhage | Xanax                                      |                    |                    | S               | Oral                     | 0.25 Mg, 1x/Day      |                 | Pfizer       |                |
|                                                              | Seroplex                                   |                    |                    | S               | Oral                     | 5 Mg, Unk            |                 | Not Reported |                |
|                                                              | Seroplex                                   |                    |                    | S               | Oral                     | 10 Mg, 1x/Day        |                 | Not Reported |                |
|                                                              | Bilaska                                    |                    |                    | C               |                          | 20 Mg, Daily         |                 | Not Reported |                |
|                                                              | Tardyferon B9 [Ferrous Sulfate;Folic Acid] |                    |                    | C               |                          | 1 Df, Daily          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Jan-2015                                                  | 10695850                                   | EXPEDITED (15-DAY) |                    | HO              | JP-FRI-1000073429        |                      |                 | Male         | JPN            |
| <u>Preferred Term</u>                                        | <u>Product</u>                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Compulsions; Condition Aggravated                            | Lexapro                                    |                    |                    | S               | Oral                     | 20 Mg                |                 | Forest       |                |
|                                                              | Cymbalta                                   |                    |                    | C               | Oral                     | 60 Mg                |                 | Not Reported |                |
|                                                              | Lexotan                                    |                    |                    | C               | Oral                     | 7.5 Mg               |                 | Not Reported |                |
|                                                              | Meilax                                     |                    |                    | C               | Oral                     | 0.5 Mg               |                 | Not Reported |                |
|                                                              | Rohypnol                                   |                    |                    | C               | Oral                     | 1 Mg                 |                 | Not Reported |                |
|                                                              | Mevalotin                                  |                    |                    | C               | Oral                     | 10 Mg                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Jan-2015                                                  | 10728684                                   | EXPEDITED (15-DAY) |                    | DE, HO          | US-ALVOGEN-2015AL000112  |                      | 74 YR           | Male         | USA            |
| <u>Preferred Term</u>                                        | <u>Product</u>                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Toxicity To Various Agents                                   | Atenolol                                   |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                                              | Escitalopram                               |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                                              | Primidone                                  |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                                              | Anxiolytics                                |                    |                    | S               |                          |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| 22-Jan-2015                                                                                               | 10728812             | EXPEDITED (15-DAY) |                    | HO, OT          | FR-ASTRAZENECA-2015SE05270 |                      | 99 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Fall; Hyponatraemia                                                                                       | Inexium              |                    |                    | S               | Oral                       |                      |                 | Astrazeneca  |                |
|                                                                                                           | Seroplex             |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                                                                           | Levothyrox           |                    |                    | C               | Oral                       |                      |                 | Not Reported |                |
|                                                                                                           | Kardegic             |                    |                    | C               | Oral                       |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Jan-2015                                                                                               | 10729394             | EXPEDITED (15-DAY) |                    | HO              | FR-DSJP-DSE-2015-101752    |                      |                 | Unknown      | FRA            |
| <u>Preferred Term</u>                                                                                     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Coma; Miosis                                                                                              | Olmetec 10 Mg        |                    |                    | S               | Oral                       | 10 Mg, Single        |                 | Not Reported |                |
|                                                                                                           | Alprazolam           |                    |                    | S               |                            | 0.5 Mg, Single       |                 | Not Reported |                |
|                                                                                                           | Seroplex             |                    |                    | S               | Oral                       | 1 Df, Single         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Jan-2015                                                                                               | 10729761             | EXPEDITED (15-DAY) |                    | DE, HO, OT      | IS-MYLANLABS-2014M1009534  |                      |                 | Unknown      | ISL            |
| <u>Preferred Term</u>                                                                                     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Pressure Abnormal;<br>Drug Abuse; Drug<br>Dependence; Road Traffic<br>Accident; Weight<br>Decreased | Quetiapine           |                    |                    | S               |                            |                      |                 | Not Reported |                |
|                                                                                                           | Zopiclone            |                    |                    | S               |                            |                      |                 | Not Reported |                |
|                                                                                                           | Ketogan /00129101/   |                    |                    | S               |                            |                      |                 | Not Reported |                |
|                                                                                                           | Esopram              |                    |                    | S               |                            |                      |                 | Not Reported |                |
|                                                                                                           | Phenergan /00033001/ |                    |                    | S               |                            |                      |                 | Not Reported |                |
|                                                                                                           | Sobril               |                    |                    | S               |                            |                      |                 | Not Reported |                |
|                                                                                                           | Oxynorm              |                    |                    | S               |                            |                      |                 | Not Reported |                |
|                                                                                                           | Imovane              |                    |                    | S               |                            |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Jan-2015                                                                                               | 10730780             | EXPEDITED (15-DAY) |                    | DE, OT          | US-UCBSA-2015002076        |                      | 28 YR           | Female       | USA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardio-Respiratory Arrest;<br>Completed Suicide | Alprazolam     |              |            | S           | Oral         |                    |                 | Schwartz     |
|                                                 | Bupropion      |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                 | Escitalopram   |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                 | Gabapentin     |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Jan-2015              | 10736838      | EXPEDITED (15-DAY) | Y                  | DE              | POI0573201500016     |                      | 69 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u>                                                                                              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-------------------------------------------------------------------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Oxybutynin Chloride Extended-Release Tablets Usp 5mg, 10mg And And 15mg (Oxybutynin Hydrochloride) (Tablet) |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Cardiac Glycoside                                                                                           |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Clonazepam                                                                                                  |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Trazodone                                                                                                   |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Quetiapine                                                                                                  |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Lamotrigine                                                                                                 |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Escitalopram                                                                                                |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Finasteride                                                                                                 |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Salicylate                                                                                                  |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Jan-2015              | 10513311      | EXPEDITED (15-DAY) |                    | HO              | IT-ACCORD-026335     |                      | 74 YR      | Female     | ITA            |

| <u>Preferred Term</u>                                                                                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Bradycardia; Bradykinesia;<br>Bradyphrenia;<br>Electrocardiogram Qt<br>Prolonged; Hypotension;<br>Sopor | Quetiapine     |              |            | S           | Oral         |                    |                 | Accord       |
|                                                                                                         | Ciprallex      |              |            | S           | Oral         | 1 Df Daily         |                 | Not Reported |
|                                                                                                         | Paroxetine     |              |            | S           | Oral         | 1.5 Df Daily       |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |         |   |      |            |              |
|--|---------|---|------|------------|--------------|
|  | Prazene | S | Oral | 1 Df Daily | Not Reported |
|  | Stilnox | C |      |            | Not Reported |
|  | Foster  | C |      |            | Not Reported |
|  | Lasix   | C |      |            | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Jan-2015              | 10551850      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000071857    |                      | 90 YR      | Female     | FRA            |

| <u>Preferred Term</u>              | <u>Product</u>                    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------|-----------------------------------|--------------|------------|-------------|--------------|------------------------|-----------------|--------------|
| Drug Interaction;<br>Haemarthrosis | Escitalopram                      |              |            | S           | Oral         | 5mg                    |                 | Forest       |
|                                    | Plavix                            |              |            | S           | Oral         | 1df                    |                 | Not Reported |
|                                    | Xagrid                            |              |            | S           | Oral         | 1 Mg                   |                 | Not Reported |
|                                    | Loxen (Nicardipine Hydrochloride) |              |            | C           |              |                        |                 | Not Reported |
|                                    | Paracetamol                       |              |            | C           |              | 1 To 3/Day (If Needed) |                 | Not Reported |
|                                    | Oxybutynine                       |              |            | C           |              | 0.5 Df                 |                 | Not Reported |
|                                    | Lorazepam                         |              |            | C           |              |                        |                 | Not Reported |
|                                    | Uvedose                           |              |            | C           | Oral         | 0.0333 Df              |                 | Not Reported |
|                                    | Econazole                         |              |            | C           | Transdermal  | 2 Df                   |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 23-Jan-2015              | 10582326      | EXPEDITED (15-DAY) |                    | HO, OT          | US-<br>ELI_LILLY_AND_COMP<br>ANY-US201411000653 |                      | 41 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                          | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>       |
|------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------------|
| Drug Hypersensitivity;<br>Drug Interaction; Ear<br>Injury; Ear Swelling; Off<br>Label Use; Otorrhoea;<br>Peripheral Swelling;<br>Swelling Face | Cymbalta                 |              |            | S           | Unknown      | 60 Mg, Qd          |                 | Eli Lilly And Co |
|                                                                                                                                                | Belimumab                |              |            | S           | Unknown      | 850 Mg, Qd         |                 | Not Reported     |
|                                                                                                                                                | Belimumab                |              |            | S           | Unknown      | 150 Mg, Cyclical   |                 | Not Reported     |
|                                                                                                                                                | Lexapro                  |              |            | S           | Unknown      | Unk, Unknown       |                 | Not Reported     |
|                                                                                                                                                | Triamcinolone /00031902/ |              |            | C           | Unknown      | Unk, Unknown       |                 | Not Reported     |
|                                                                                                                                                | Trazodone                |              |            | C           | Unknown      | Unk, Unknown       |                 | Not Reported     |
|                                                                                                                                                | Gabapentin               |              |            | C           | Unknown      | Unk, Unknown       |                 | Not Reported     |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |                              |   |         |              |              |
|--|------------------------------|---|---------|--------------|--------------|
|  | Lasix /00032601/             | C | Unknown | Unk, Unknown | Not Reported |
|  | Cyanocobalamin               | C | Unknown | Unk, Unknown | Not Reported |
|  | Prenatal Vitamins /01549301/ | C | Unknown | Unk, Unknown | Not Reported |
|  | Fentanyl                     | C | Unknown | Unk, Unknown | Not Reported |
|  | Plaquenil /00072602/         | C | Unknown | Unk, Unknown | Not Reported |
|  | Solumedrol                   | C |         |              | Not Reported |
|  | Lorazepam                    | C |         |              | Not Reported |
|  | Protonix                     | C |         |              | Not Reported |

| <u>FDA Received Date</u>                     | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------|-----------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 23-Jan-2015                                  | 10683261        | EXPEDITED (15-DAY) |                    | HO              | IT-PFIZER INC-2014360168 |                      | 64 YR           | Female       | ITA            |
| <u>Preferred Term</u>                        | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dyspepsia; Insomnia; Malaise; Nausea; Tremor | Zyvoxid         |                    |                    | S               | Oral                     | 1200 Mg, Daily       |                 | Pfizer       |                |
|                                              | Cipraxel        |                    |                    | S               | Oral                     | 20 Mg, Daily         |                 | Not Reported |                |
|                                              | Calcifediol     |                    |                    | C               |                          |                      |                 | Not Reported |                |
|                                              | Alendronic Acid |                    |                    | C               |                          |                      |                 | Not Reported |                |
|                                              | Lansoprazole    |                    |                    | C               |                          |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>          | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------|-------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 23-Jan-2015                       | 10683262                | EXPEDITED (15-DAY) |                    | HO              | IT-PFIZER INC-2014360218 |                      | 55 YR           | Female       | ITA            |
| <u>Preferred Term</u>             | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Malaise; Nausea; Tremor; Vomiting | Zyvoxid                 |                    |                    | S               | Oral                     | 1200 Mg, Daily       |                 | Pfizer       |                |
|                                   | Cipraxel                |                    |                    | S               | Oral                     | 20 Mg, Daily         |                 | Not Reported |                |
|                                   | Lansoprazole            |                    |                    | C               | Oral                     | 30 Mg, Unk           |                 | Not Reported |                |
|                                   | Methylprednisolone      |                    |                    | C               |                          | 8 Mg, Unk            |                 | Not Reported |                |
|                                   | Simvastatin             |                    |                    | C               | Oral                     | 20 Mg, Unk           |                 | Not Reported |                |
|                                   | Metformin Hydrochloride |                    |                    | C               | Oral                     | 1700 Mg, Unk         |                 | Not Reported |                |
|                                   | Cardioaspirin           |                    |                    | C               | Oral                     | 100 Mg, Unk          |                 | Not Reported |                |
|                                   | Eutirox                 |                    |                    | C               | Oral                     | 0.025 Mg, Unk        |                 | Not Reported |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                               |                     |                    |                    |                 |                                                            |                      |                 |              |                |
|---------------------------------------------------------------------------------------------------------------|---------------------|--------------------|--------------------|-----------------|------------------------------------------------------------|----------------------|-----------------|--------------|----------------|
| Oxycontin                                                                                                     |                     |                    | C                  |                 | 40 Mg, Unk                                                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                      | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Jan-2015                                                                                                   | 10718365            | EXPEDITED (15-DAY) |                    | DE, OT          | GB-MACLEODS<br>PHARMACEUTICALS<br>US LTD-<br>MAC2015001568 |                      |                 | Unknown      | GBR            |
| <u>Preferred Term</u>                                                                                         | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Depression; Drug<br>Interaction                                                         | Escitalopram Tablet |                    |                    | S               | Oral                                                       | 10 Mg, Unk           |                 | Macleods     |                |
|                                                                                                               | Escitalopram Tablet |                    |                    | S               | Oral                                                       | 15 Mg, Unk           |                 | Macleods     |                |
|                                                                                                               | Letrozole           |                    |                    | S               | Oral                                                       | Unk                  |                 | Not Reported |                |
|                                                                                                               | Adcal-D3            |                    |                    | C               | Unknown                                                    | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                      | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Jan-2015                                                                                                   | 10731439            | EXPEDITED (15-DAY) |                    | OT              | US-AUROBINDO-AUR-<br>APL-2015-00281                        |                      | 48 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                         | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Adverse Event; Anxiety;<br>Dizziness; Drug<br>Ineffective; Drug<br>Intolerance; Insomnia;<br>Nausea; Vomiting | Citalopram          |                    |                    | S               | Unknown                                                    | Unk                  |                 | Aurobindo    |                |
|                                                                                                               | Citalopram          |                    |                    | S               |                                                            |                      |                 | Aurobindo    |                |
|                                                                                                               | Escitalopram        |                    |                    | S               | Unknown                                                    | 2.5 Mg, Daily        |                 | Aurobindo    |                |
|                                                                                                               | Escitalopram        |                    |                    | S               |                                                            |                      |                 | Aurobindo    |                |
|                                                                                                               | Fluoxetine 10 Mg    |                    |                    | S               | Unknown                                                    | 10 Mg, Daily         |                 | Aurobindo    |                |
|                                                                                                               | Mirtazapine         |                    |                    | S               | Unknown                                                    | 22.5 Mg, Daily       |                 | Aurobindo    |                |
|                                                                                                               | Mirtazapine         |                    |                    | S               |                                                            |                      |                 | Aurobindo    |                |
|                                                                                                               | Paroxetine 10mg     |                    |                    | S               | Unknown                                                    | 10 Mg, Daily         |                 | Aurobindo    |                |
|                                                                                                               | Paroxetine 10mg     |                    |                    | S               |                                                            |                      |                 | Aurobindo    |                |
|                                                                                                               | Sertraline          |                    |                    | S               | Unknown                                                    | 10 Mg, Daily         |                 | Aurobindo    |                |
|                                                                                                               | Sertraline          |                    |                    | S               |                                                            |                      |                 | Aurobindo    |                |
|                                                                                                               | Venlafaxine         |                    |                    | S               | Unknown                                                    | Low Dose             |                 | Aurobindo    |                |
|                                                                                                               | Venlafaxine         |                    |                    | S               |                                                            |                      |                 | Aurobindo    |                |
|                                                                                                               | Diazepam            |                    |                    | S               | Unknown                                                    | 0.5 Mg, Daily        |                 | Not Reported |                |
|                                                                                                               | Doxepin             |                    |                    | S               | Unknown                                                    | Unk                  |                 | Not Reported |                |
|                                                                                                               | Doxepin             |                    |                    | S               |                                                            |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                             | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|----------------------------|-----------------------------------|-----------------|--------------|----------------|
| 25-Jan-2015                                                                                                                                                                                          | 10735143                  | NON-EXPEDITED      |                    |                 | US-ASTRAZENECA-2014SE90536 |                                   | 49 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Back Disorder; Depression; Dry Mouth; Fibromyalgia; Hypercholesterolaemia; Increased Appetite; Muscle Spasms; Oedema; Oropharyngeal Pain; Pain; Type 2 Diabetes Mellitus; Visual Impairment | Seroquel                  |                    |                    | S               | Oral                       |                                   |                 | Zeneca       |                |
|                                                                                                                                                                                                      | Seroquel                  |                    |                    | S               | Oral                       |                                   |                 | Zeneca       |                |
|                                                                                                                                                                                                      | Seroquel                  |                    |                    | S               | Oral                       |                                   |                 | Zeneca       |                |
|                                                                                                                                                                                                      | Seroquel                  |                    |                    | S               | Oral                       |                                   |                 | Zeneca       |                |
|                                                                                                                                                                                                      | Lyrica                    |                    |                    | S               | Oral                       |                                   |                 | Not Reported |                |
|                                                                                                                                                                                                      | Venlafaxine (Effesor)     |                    |                    | S               | Unknown                    |                                   |                 | Not Reported |                |
|                                                                                                                                                                                                      | Valium                    |                    |                    | S               | Unknown                    |                                   |                 | Not Reported |                |
|                                                                                                                                                                                                      | Aspirin                   |                    |                    | S               | Unknown                    |                                   |                 | Not Reported |                |
|                                                                                                                                                                                                      | Ibuprofen                 |                    |                    | S               | Unknown                    | 800 Mg In Morning And 1200        |                 | Not Reported |                |
|                                                                                                                                                                                                      | Fentanyl Patch            |                    |                    | S               | Unknown                    | 50 Mcg Every 48 Hours             |                 | Not Reported |                |
|                                                                                                                                                                                                      | Metformin(Non-Az Product) |                    |                    | S               | Unknown                    |                                   |                 | Not Reported |                |
|                                                                                                                                                                                                      | Tizanidine                |                    |                    | S               | Unknown                    |                                   |                 | Not Reported |                |
|                                                                                                                                                                                                      | Lexapro                   |                    |                    | S               | Unknown                    |                                   |                 | Not Reported |                |
|                                                                                                                                                                                                      | Simvastin                 |                    |                    | S               | Unknown                    |                                   |                 | Not Reported |                |
|                                                                                                                                                                                                      | Topamax                   |                    |                    | S               | Unknown                    |                                   |                 | Not Reported |                |
|                                                                                                                                                                                                      | Demadex                   |                    |                    | S               | Unknown                    |                                   |                 | Not Reported |                |
|                                                                                                                                                                                                      | Oxycodone                 |                    |                    | S               | Unknown                    | 10/325 Mg 1 Of Them 3 Times Daily |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                             | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Jan-2015                                                                                                                                                                                          | 10541372                  | EXPEDITED (15-DAY) |                    | OT              | US-TEVA-516808USA          |                                   |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity; Gastritis Erosive; Hiatus                                                                                                                                                     | Escitalopram              |                    |                    | S               | Oral                       | 10 Milligram Daily;               |                 | Ivax         |                |
|                                                                                                                                                                                                      | Bupropion                 |                    |                    | C               |                            |                                   |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                |               |   |              |
|----------------|---------------|---|--------------|
| Hernia; Nausea | Levothyroxine | C | Not Reported |
|                | Lyrica        | C | Not Reported |
|                | Zyrtec        | C | Not Reported |
|                | Hydrocodone   | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------------------------|----------------------|------------|------------|----------------|
| 26-Jan-2015              | 10725194      | EXPEDITED (15-DAY) |                    | OT              | AU-SYMPMED<br>PHARMACEUTICALS-<br>2015SYM00009 |                      | 67 YR      | Female     | AUS            |

| <u>Preferred Term</u>                                                                                                                                                          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>               |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------------------|
| Atrial Septal Defect; Blood Glucose Increased; Blood Triglycerides Increased; Blood Urea Decreased; Blood Urea                                                                 | Aceon          |              |            | S           |              | Unk                |                 | Symplmed Pharmaceuticals |
| Nitrogen/Creatinine Ratio Decreased; C-Reactive Protein Increased; Cardiac Aneurysm; Globulins                                                                                 | Escitalopram   |              |            | S           |              | Unk                |                 | Not Reported             |
| Decreased; Left Atrial Dilatation; Mitral Valve Disease; Mitral Valve Incompetence; Pericardial Effusion; Pulmonary Valve Incompetence; Sedation; Tricuspid Valve Incompetence | Amisulpride    |              |            | S           |              | Unk                |                 | Not Reported             |
|                                                                                                                                                                                | Atorvastatin   |              |            | S           |              | Unk                |                 | Not Reported             |
|                                                                                                                                                                                | Clozaril       |              |            | S           |              | Unk                |                 | Not Reported             |
|                                                                                                                                                                                | Clozaril       |              |            | S           |              | 75 Mg, Unk         |                 | Not Reported             |
|                                                                                                                                                                                | Fenofibrate    |              |            | S           |              | Unk                |                 | Not Reported             |
|                                                                                                                                                                                | Metformin      |              |            | S           |              | Unk                |                 | Not Reported             |
|                                                                                                                                                                                | Olanzapine     |              |            | S           |              | Unk                |                 | Not Reported             |
|                                                                                                                                                                                | Oxazepam       |              |            | S           |              | Unk                |                 | Not Reported             |
|                                                                                                                                                                                | Thyroxine      |              |            | S           |              | Unk                |                 | Not Reported             |
|                                                                                                                                                                                | Warfarin       |              |            | S           |              | Unk                |                 | Not Reported             |
|                                                                                                                                                                                | Paracetamol    |              |            | C           |              | Unk                |                 | Not Reported             |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 26-Jan-2015              | 10736211      | EXPEDITED (15-DAY) |                    | HO, OT          | US-APOTEX-<br>2015AP005398 |                      | 65 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Delirium; Inappropriate Antidiuretic Hormone Secretion; Mania; Pneumonia Pseudomonal; Toxicity To Various Agents | Olanzapine     |              |            | S           | Unknown      | 10 Mg, Qd          |                 | Apotex     |
|                                                                                                                  | Olanzapine     |              |            | S           | Unknown      | 7.5 Mg, Qd         |                 | Apotex     |
|                                                                                                                  | Alprazolam     |              |            | S           | Unknown      | Unk Unk, Prn       |                 | Apotex     |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                          |   |               |                            |              |
|--------------------------|---|---------------|----------------------------|--------------|
| Sertraline Hydrochloride | S | Unknown       | 50 Mg, Daily               | Apotex       |
| Fluticasone Propionate   | S | Unknown       |                            | Apotex       |
| Escitalopram Oxalate     | S | Unknown       | 10 Mg, Qd                  | Apotex       |
| Escitalopram Oxalate     | S |               | 20 Mg, Qd                  | Apotex       |
| Prednisone               | S | Unknown       | 10 Mg, Daily               | Not Reported |
| Prednisone               | S | Unknown       | 7.5mg Daily, Later Reduced | Not Reported |
| Prednisone               | S | Unknown       | 2.5mg Daily, Later Reduced | Not Reported |
| Prednisone               | S | Unknown       | 2mg Daily                  | Not Reported |
| Prednisone               | S |               | 1 Mg, Qd                   | Not Reported |
| Prednisone               | S |               | 5 Mg, Daily                | Not Reported |
| Prednisone               | S |               | 20 Mg, Daily               | Not Reported |
| Prednisone               | S |               | Unk                        | Not Reported |
| Lorazepam                | S | Intramuscular |                            | Not Reported |
| Esomeprazole             | C | Unknown       |                            | Not Reported |
| Tiotropium Bromide       | C | Unknown       |                            | Not Reported |
| Haloperidol              | C | Intramuscular |                            | Not Reported |
| Buspirone                | C | Unknown       | 15 Mg, Daily               | Not Reported |
| Buspirone                | C | Unknown       | 30 Mg, Daily               | Not Reported |
| Lithium                  | C | Unknown       | 300 Mg, Daily              | Not Reported |
| Lithium                  | C |               | 600 Mg,Daily               | Not Reported |
| Lithium                  | C |               | 300 Mg, Daily              | Not Reported |
| Ipratropium Bromide      | C | Unknown       |                            | Not Reported |
| Risperidone              | C |               | 9 Mg, Qd                   | Not Reported |
| Risperidone              | C | Unknown       | 1.5 Mg, Daily              | Not Reported |
| Quetiapine               | C |               | 6.25 Mg, Qd                | Not Reported |
| Quetiapine               | C |               | 100 Mg, Daily              | Not Reported |
| Quetiapine               | C |               | 300 Mg, Daily              | Not Reported |
| Quetiapine               | C |               | 200 Mg Daily               | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|            |   |         |                |              |
|------------|---|---------|----------------|--------------|
| Quetiapine | C |         | 25 Mg, Daily   | Not Reported |
| Diltiazem  | C | Unknown |                | Not Reported |
| Trazodone  | C | Unknown | 25 Mg, Unknown | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------------------------------|----------------------|------------|------------|----------------|
| 26-Jan-2015              | 10737387      | EXPEDITED (15-DAY) |                    | DE              | US-LEHIGH_VALLEY-<br>USA-<br>POI0580201500027 |                      | 48 YR      | Female     | USA            |

| <u>Preferred Term</u>                                          | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>         |
|----------------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------------|
| Cardiac Arrest; Poisoning<br>Deliberate; Respiratory<br>Arrest | Oxycodone Hcl Capsules |              |            | S           |              |                    |                 | Lehigh Valley Tech |
|                                                                | Cyclobenzaprine        |              |            | S           |              |                    |                 | Not Reported       |
|                                                                | Metoprolol             |              |            | S           |              |                    |                 | Not Reported       |
|                                                                | Clonidine              |              |            | S           |              |                    |                 | Not Reported       |
|                                                                | Nitroglycerin          |              |            | S           |              |                    |                 | Not Reported       |
|                                                                | Lisinopril             |              |            | S           |              |                    |                 | Not Reported       |
|                                                                | Escitalopram           |              |            | S           |              |                    |                 | Not Reported       |
|                                                                | Ibuprofen              |              |            | S           |              |                    |                 | Not Reported       |
|                                                                | Diclofenac             |              |            | S           |              |                    |                 | Not Reported       |
|                                                                | Azithromycin           |              |            | S           |              |                    |                 | Not Reported       |
|                                                                | Cephalexin             |              |            | S           |              |                    |                 | Not Reported       |
|                                                                | Doxycycline            |              |            | S           |              |                    |                 | Not Reported       |
|                                                                | Methylprednisolone     |              |            | S           |              |                    |                 | Not Reported       |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Jan-2015              | 10738787      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000073767    |                      | 60 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                      | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|---------------------------------------------------------|-----------------|--------------|
| Coma; Electrocardiogram<br>Abnormal; Hypotension;<br>Intentional Overdose;<br>Respiratory Failure | Escitalopram   |              |            | S           | Oral         |                                                         |                 | Forest       |
|                                                                                                   | Escitalopram   |              |            | S           | Oral         | Overdose: Estimated Dose<br>Of 150 Mg On<br>04/Dec/2014 |                 | Forest       |
|                                                                                                   | Lamictal       |              |            | S           | Oral         |                                                         |                 | Not Reported |
|                                                                                                   | Lamictal       |              |            | S           | Oral         | Overdose: Estimated Dose<br>Of 3 G On 04/Dec/2014       |                 | Not Reported |
|                                                                                                   | Tercian        |              |            | S           | Oral         |                                                         |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|            |   |      |                                                         |              |
|------------|---|------|---------------------------------------------------------|--------------|
| Tercian    | S | Oral | Overdose: Estimated Dose<br>Of 375 Mg On<br>04/Dec/2014 | Not Reported |
| Prazepam   | S | Oral |                                                         | Not Reported |
| Prazepam   | S | Oral | Overdose: Estimated Dose<br>Of 600 Mg On<br>04/Dec/2014 | Not Reported |
| Levothyrox | C |      |                                                         | Not Reported |
| Sulfarlem  | C |      |                                                         | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|------------|------------|----------------|
| 26-Jan-2015              | 10739325      | EXPEDITED (15-DAY) |                    | DE, OT          | US-009507513-<br>1501USA007584 |                      | 34 YR      | Female     | USA            |

| <u>Preferred Term</u>                            | <u>Product</u>                                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------|-----------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide;<br>Toxicity To Various Agents | Elavil (Made By Merck,<br>Marketed By Zeneca) |              |            | S           | Oral         |                    |                 | Merck        |
|                                                  | Tramadol Hydrochloride                        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Tramadol Hydrochloride                        |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                                                  | Acetaminophen (+)<br>Hydrocodone Bitartrate   |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Ondansetron Hydrochloride                     |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Linaclotide                                   |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Diclofenac                                    |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Lubiprostone                                  |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Zolpidem Tartrate                             |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Liothyronine Sodium                           |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Escitalopram                                  |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Sertraline Hydrochloride                      |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Gabapentin                                    |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------------|----------------------|------------|------------|----------------|
| 27-Jan-2015              | 10725571      | EXPEDITED (15-DAY) |                    | DE, OT          | GB-DRREDDYS-<br>GER/UKI/15/0045450 |                      | 51 YR      | Female     | GBR            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide;<br>Depression; Drug<br>Interaction | Letrozole      |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                       | Escitalopram   |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                       | Escitalopram   |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                       | Adcal-D3       |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 27-Jan-2015              | 10740057      | EXPEDITED (15-DAY) |                    | DE              | US-BAUSCH-BL-2015-001140 |                      | 32 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                    | <u>Product</u>  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------|-----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide;<br>Exposure Via Ingestion;<br>Exposure Via Inhalation | Zolpidem        |              |            | S           |              |                    |                 | Valeant      |
|                                                                          | Ethanol         |              |            | S           |              |                    |                 | Not Reported |
|                                                                          | Methamphetamine |              |            | S           |              |                    |                 | Not Reported |
|                                                                          | Carbon Monoxide |              |            | S           |              |                    |                 | Not Reported |
|                                                                          | Escitaopram     |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Jan-2015              | 10740058      | EXPEDITED (15-DAY) |                    | HO, LT          | CA-ROCHE-1524943     |                      | 52 YR      | Male       | CAN            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|---------------------------------------------|-----------------|--------------|
| Blood Creatine<br>Phosphokinase Increased;<br>Blood Creatinine<br>Increased; Blood<br>Potassium Increased;<br>Blood Pressure<br>Decreased; Bradycardia;<br>Coma; Coma Scale<br>Abnormal; Drug<br>Interaction;<br>Electrocardiogram<br>Abnormal;<br>Electrocardiogram Qt<br>Prolonged; Heart Rate<br>Decreased;<br>Hyperkalaemia; | Diazepam       |              |            | S           | Unknown      |                                             |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                  | Diazepam       |              |            | S           | Oral         | Frequency: Once; Therapy<br>Duration: 1 Day |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                  | Diazepam       |              |            | S           | Oral         | Frequency And Therapy<br>Duration: Once     |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                  | Cipralelex     |              |            | S           | Unknown      |                                             |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                  | Cipralelex     |              |            | S           | Unknown      | Frequency: Once; Therapy<br>Duration: 1 Day |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                  | Cipralelex     |              |            | S           | Oral         | Frequency And Therapy<br>Duration: Once     |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                  | Citalopram     |              |            | S           | Oral         |                                             |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                  | Lorazepam      |              |            | S           | Oral         | Frequency: Once; Therapy<br>Duration: 1 Day |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                  |                |              |            |             |              |                                             |                 |              |
|                                                                                                                                                                                                                                                                                                                                  |                |              |            |             |              |                                             |                 |              |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                               |                         |   |         |                                          |              |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|---|---------|------------------------------------------|--------------|
| Hypotension; Intentional Overdose; Loss Of Consciousness; Mechanical Ventilation; Opiates Positive; Overdose; Oxygen Saturation Decreased; Sinus Tachycardia; Suicide Attempt | Lorazepam               | S | Oral    | Frequency And Therapy Duration: Once     | Not Reported |
|                                                                                                                                                                               | Morphine Sulfate        | S | Oral    |                                          | Not Reported |
|                                                                                                                                                                               | Morphine Sulfate        | S | Unknown |                                          | Not Reported |
|                                                                                                                                                                               | Morphine Sulfate        | S | Unknown |                                          | Not Reported |
|                                                                                                                                                                               | Oxycodone               | S | Oral    | Frequency: Once; Therapy Duration: 1 Day | Not Reported |
|                                                                                                                                                                               | Oxycodone               | S | Oral    |                                          | Not Reported |
|                                                                                                                                                                               | Oxycodone               | S | Unknown |                                          | Not Reported |
|                                                                                                                                                                               | Oxycodone               | S | Unknown |                                          | Not Reported |
|                                                                                                                                                                               | Oxycodone/Acetaminophen | S | Oral    |                                          | Not Reported |
|                                                                                                                                                                               | Zopiclone               | S | Oral    | Frequency: Once; Therapy Duration: 1 Day | Not Reported |
|                                                                                                                                                                               | Zopiclone               | S | Unknown |                                          | Not Reported |
|                                                                                                                                                                               | Zopiclone               | S | Oral    | Frequency And Therapy Duration: Once     | Not Reported |
|                                                                                                                                                                               | Morphine                | S | Oral    |                                          | Not Reported |
|                                                                                                                                                                               | Morphine                | S | Oral    | Frequency: Once; Therapy Duration: 1 Day | Not Reported |
|                                                                                                                                                                               | Morphine                | S | Unknown | Frequency And Therapy Duration: Once     | Not Reported |
|                                                                                                                                                                               | Morphine                | S | Unknown | Frequency And Therapy Duration: Once     | Not Reported |
|                                                                                                                                                                               | Morphine                | S | Unknown | Frequency And Therapy Duration: Once     | Not Reported |
|                                                                                                                                                                               | Altace                  | C |         |                                          | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 27-Jan-2015              | 10740422      | EXPEDITED (15-DAY) |                    | DE, OT          | US-009507513-1501USA007660 |                      | 41 YR      | Male       | USA            |

| <u>Preferred Term</u>                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Completed Suicide; Toxicity To Various Agents | Prinivil       |              |            | S           | Oral         | Unk                |                 | Merck      |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                               |   |      |     |              |
|-------------------------------|---|------|-----|--------------|
| Acetaminophen                 | S | Oral | Unk | Not Reported |
| Diphenhydramine Hydrochloride | S |      | Unk | Not Reported |
| Warfarin                      | S |      | Unk | Not Reported |
| Olanzapine                    | S |      | Unk | Not Reported |
| Escitalopram                  | S |      | Unk | Not Reported |
| Prednisone                    | S | Oral | Unk | Merck        |

| <u>FDA Received Date</u>                                 | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| 27-Jan-2015                                              | 10740530                      | EXPEDITED (15-DAY) | DE                 |                 | US-009507513-1501USA007661 |                      | 48 YR           | Female       | USA            |
| <u>Preferred Term</u>                                    | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Product Administration Error; Toxicity To Various Agents | Prinivil                      |                    |                    | S               | Oral                       | Unk                  |                 | Merck        |                |
|                                                          | Oxycodone                     |                    |                    | S               |                            | Unk                  |                 | Not Reported |                |
|                                                          | Cyclobenzaprine Hydrochloride |                    |                    | S               |                            | Unk                  |                 | Not Reported |                |
|                                                          | Metoprolol                    |                    |                    | S               |                            | Unk                  |                 | Not Reported |                |
|                                                          | Clonidine                     |                    |                    | S               |                            | Unk                  |                 | Not Reported |                |
|                                                          | Nitro-Dur                     |                    |                    | S               | Transdermal                | Unk                  |                 | Merck        |                |
|                                                          | Escitalopram                  |                    |                    | S               |                            | Unk                  |                 | Not Reported |                |
|                                                          | Ibuprofen                     |                    |                    | S               |                            | Unk                  |                 | Not Reported |                |
|                                                          | Diclofenac                    |                    |                    | S               |                            | Unk                  |                 | Not Reported |                |
|                                                          | Azithromycin                  |                    |                    | S               |                            | Unk                  |                 | Not Reported |                |
|                                                          | Cephalexin                    |                    |                    | S               |                            | Unk                  |                 | Not Reported |                |
|                                                          | Doxycycline                   |                    |                    | S               |                            | Unk                  |                 | Not Reported |                |
|                                                          | Methylprednisolone            |                    |                    | S               |                            | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                 | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Jan-2015                                              | 10740620                      | EXPEDITED (15-DAY) | DE, OT             |                 | US-009507513-1501USA007644 |                      | 67 YR           | Male         | USA            |
| <u>Preferred Term</u>                                    | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;                                       | Mevacor Tablet                |                    |                    | S               | Oral                       | Unk                  |                 | Merck        |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                            |              |   |      |              |
|----------------------------|--------------|---|------|--------------|
| Toxicity To Various Agents | Lamotrigine  | S | Oral | Not Reported |
|                            | Zonisamide   | S | Oral | Not Reported |
|                            | Lorazepam    | S | Oral | Not Reported |
|                            | Escitalopram | S | Oral | Not Reported |

| <u>FDA Received Date</u>                         | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| 27-Jan-2015                                      | 10740780                | EXPEDITED (15-DAY) |                    | DE, OT          | US-009507513-1501USA007631 |                      | 69 YR           | Male         | USA            |
| <u>Preferred Term</u>                            | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Toxicity To Various Agents | Oxybutynin              |                    |                    | S               | Oral                       | Unk                  |                 | Merck        |                |
|                                                  | Finasteride             |                    |                    | S               | Oral                       | Unk                  |                 | Merck        |                |
|                                                  | Clonazepam              |                    |                    | S               | Oral                       | Unk                  |                 | Not Reported |                |
|                                                  | Trazodone Hydrochloride |                    |                    | S               | Oral                       | Unk                  |                 | Not Reported |                |
|                                                  | Quetiapine Fumarate     |                    |                    | S               | Oral                       | Unk                  |                 | Not Reported |                |
|                                                  | Lamotrigine             |                    |                    | S               | Oral                       | Unk                  |                 | Not Reported |                |
|                                                  | Escitalopram            |                    |                    | S               | Oral                       | Unk                  |                 | Not Reported |                |
|                                                  | Salicylic Acid          |                    |                    | S               |                            |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 27-Jan-2015                                                                                                                             | 10742821       | EXPEDITED (15-DAY) |                    | HO              | CA-FRI-1000073830    |                      | 93 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                                                                                                   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Depressed<br>Mood; Diarrhoea;<br>Dizziness; Fall;<br>Hyponatraemia;<br>Hypotension;<br>Hypovitaminosis; Poor<br>Quality Sleep | Escitalopram   |                    |                    | S               | Unknown              | 10 Mg Daily.         |                 | Forest       |                |
|                                                                                                                                         | Lorazepam      |                    |                    | S               | Unknown              |                      |                 | Not Reported |                |
|                                                                                                                                         | Metoprolol     |                    |                    | S               | Unknown              | 50 Mg                |                 | Not Reported |                |
|                                                                                                                                         | Metoprolol     |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                         | Pantoprazole   |                    |                    | S               | Unknown              | 80 Mg Daily.         |                 | Not Reported |                |
|                                                                                                                                         | Telmisartan    |                    |                    | S               | Unknown              | 80 Mg Daily.         |                 | Not Reported |                |
|                                                                                                                                         | Telmisartan    |                    |                    | S               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                      | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
| 27-Jan-2015                                                                                                                                                                                                                                                                                   | 10743314           | EXPEDITED (15-DAY) |                    | DE, OT          | GB-MYLANLABS-2015M1001226 |                      |                 | Unknown      | GBR            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                         | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Depression; Drug Interaction                                                                                                                                                                                                                                               | Escitalopram       |                    |                    | S               | Oral                      | 10 Increased To 15mg |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                               | Letrozole          |                    |                    | S               | Oral                      | 2.5 Mg, Unk          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                               | Adcal-D3           |                    |                    | C               |                           | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                      | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Jan-2015                                                                                                                                                                                                                                                                                   | 10745343           | DIRECT             |                    | OT              |                           |                      | 33 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                         | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Drug Ineffective; Product Substitution Issue                                                                                                                                                                                                                                      | Escitalopram 20 Mg |                    |                    | S               | Oral                      |                      | 2 MTH           | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                      | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Jan-2015                                                                                                                                                                                                                                                                                   | 10745675           | DIRECT             |                    | DS, OT          |                           |                      | 56 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                         | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aphasia; Arthralgia; Arthralgia; Back Pain; Bone Pain; Disturbance In Attention; Economic Problem; Emotional Distress; Feelings Of Worthlessness; Incoherent; Insomnia; Loss Of Personal Independence In Daily Activities; Myalgia; Pain In Extremity; Product Substitution Issue; Somnolence | Escitalopram       |                    |                    | S               | Oral                      |                      |                 | Aurobindo    |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                              | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------|--------------------|--------------------|--------------------|-----------------|-------------------------------------|----------------------|-----------------|--------------|----------------|
| 28-Jan-2015                                           | 10723011           | EXPEDITED (15-DAY) |                    | DE, OT          | PHFR2015GB000795                    |                      |                 | Unknown      | GBR            |
| <u>Preferred Term</u>                                 | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Depression; Drug<br>Interaction | Letrozole          |                    |                    | S               | Oral                                | 2.5 Mg, Qd           |                 | Novartis     |                |
|                                                       | Escitalopram       |                    |                    | S               | Oral                                | 10 Mg, Qd            |                 | Not Reported |                |
|                                                       | Escitalopram       |                    |                    | S               | Oral                                | 15 Mg, Qd            |                 | Not Reported |                |
|                                                       | Adcal-D3           |                    |                    | C               | Unknown                             |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Jan-2015                                           | 10731452           | EXPEDITED (15-DAY) |                    | DE, OT          | GB-AUROBINDO-AUR-<br>APL-2015-00326 |                      | 51 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                 | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Depression; Drug<br>Interaction | Escitalopram 10 Mg |                    |                    | S               | Oral                                | 10 Mg, Unk           |                 | Aurobindo    |                |
|                                                       | Escitalopram 10 Mg |                    |                    | S               | Oral                                | 15 Mg, Unk           |                 | Aurobindo    |                |
|                                                       | Letrozole          |                    |                    | S               | Oral                                | 2.5 Mg, Unk          |                 | Not Reported |                |
|                                                       | Adcal D3           |                    |                    | C               | Unknown                             | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Jan-2015                                           | 10743696           | EXPEDITED (15-DAY) |                    | DE, OT          | US-BAUSCH-BL-2015-<br>001156        |                      | 28 YR           | Female       | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardio-Respiratory Arrest;<br>Completed Suicide       | Bupropion          |                    |                    | S               |                                     |                      |                 | Not Reported |                |
|                                                       | Escitalopram       |                    |                    | S               |                                     |                      |                 | Not Reported |                |
|                                                       | Gabapentin         |                    |                    | S               |                                     |                      |                 | Not Reported |                |
|                                                       | Alprazolam         |                    |                    | S               |                                     |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Jan-2015                                           | 10743807           | EXPEDITED (15-DAY) |                    | HO              | IT-AUROBINDO-AUR-<br>APL-2015-00566 |                      | 24 YR           | Male         | ITA            |
| <u>Preferred Term</u>                                 | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

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|                                                                                                                        |                       |                    |                    |                 |                                             |                      |                 |              |                |  |
|------------------------------------------------------------------------------------------------------------------------|-----------------------|--------------------|--------------------|-----------------|---------------------------------------------|----------------------|-----------------|--------------|----------------|--|
| Anxiety; Nausea; Withdrawal Syndrome                                                                                   |                       | Escitalopram 10 Mg |                    | S               | Oral                                        |                      | 10 Mg, Daily    |              | Aurobindo      |  |
| <u>FDA Received Date</u>                                                                                               | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |  |
| 28-Jan-2015                                                                                                            | 10744232              | EXPEDITED (15-DAY) |                    | LT              | SE-AUROBINDO-AUR-APL-2015-00707             |                      | 23 YR           | Female       | SWE            |  |
| <u>Preferred Term</u>                                                                                                  | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |  |
| Depressed Level Of Consciousness; Electrocardiogram Abnormal; Muscle Twitching; Somnolence; Toxicity To Various Agents | Cetirizine            |                    |                    | S               | Unknown                                     |                      |                 | Aurobindo    |                |  |
|                                                                                                                        | Postafen /00060202/   |                    |                    | S               | Unknown                                     |                      |                 | Not Reported |                |  |
|                                                                                                                        | Loratadine            |                    |                    | S               | Unknown                                     |                      |                 | Not Reported |                |  |
|                                                                                                                        | Cipralax /01588501/   |                    |                    | S               | Unknown                                     |                      |                 | Not Reported |                |  |
|                                                                                                                        | Tavegyl               |                    |                    | S               |                                             |                      |                 | Not Reported |                |  |
| <u>FDA Received Date</u>                                                                                               | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |  |
| 28-Jan-2015                                                                                                            | 10746075              | EXPEDITED (15-DAY) |                    | DE              | US-UPSHER-SMITH LABORATORIES, INC.-15000143 |                      | 62 YR           | Male         | USA            |  |
| <u>Preferred Term</u>                                                                                                  | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |  |
| Completed Suicide                                                                                                      | Benzotropine Mesylate |                    |                    | S               | Oral                                        | Unk, Unk             |                 | Upsher-Smith |                |  |
|                                                                                                                        | Temazepam             |                    |                    | S               | Oral                                        | Unk, Unk             |                 | Not Reported |                |  |
|                                                                                                                        | Lorazepam             |                    |                    | S               | Oral                                        | Unk, Unk             |                 | Not Reported |                |  |
|                                                                                                                        | Primidone             |                    |                    | S               | Oral                                        | Unk, Unk             |                 | Not Reported |                |  |
|                                                                                                                        | Lamotrigine           |                    |                    | S               | Oral                                        | Unk, Unk             |                 | Not Reported |                |  |
|                                                                                                                        | Escitalopram          |                    |                    | S               | Oral                                        | Unk, Unk             |                 | Not Reported |                |  |
| <u>FDA Received Date</u>                                                                                               | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |  |
| 28-Jan-2015                                                                                                            | 10746353              | EXPEDITED (15-DAY) |                    | HO              | FR-PFIZER INC-2015029834                    |                      | 39 YR           | Male         | FRA            |  |
| <u>Preferred Term</u>                                                                                                  | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |  |
| Coma; Miosis; Suicide Attempt; Toxicity To Various Agents                                                              | Olmotec               |                    |                    | S               | Oral                                        | 10 Mg, Single        |                 | Not Reported |                |  |
|                                                                                                                        | Alprazolam            |                    |                    | S               | Unknown                                     | 0.5 Mg, Single       |                 | Pfizer       |                |  |

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|                                                                                             |                                  |                    |                    |                 |                          |                                                                  |                 |              |                |  |
|---------------------------------------------------------------------------------------------|----------------------------------|--------------------|--------------------|-----------------|--------------------------|------------------------------------------------------------------|-----------------|--------------|----------------|--|
| Seroplex                                                                                    |                                  |                    | S                  |                 | Oral                     |                                                                  | 1 Df, Single    |              | Not Reported   |  |
| <u>FDA Received Date</u>                                                                    | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                                             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |  |
| 28-Jan-2015                                                                                 | 10748843                         | DIRECT             |                    |                 |                          |                                                                  | 64 YR           | Female       | USA            |  |
| <u>Preferred Term</u>                                                                       | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                                               | <u>Duration</u> | <u>Mfr</u>   |                |  |
| Arthralgia; Libido Decreased; Weight Increased                                              | Escitalopram                     |                    |                    | S               | Oral                     | 10 Mg Once A Day, Once Daily, Taken By Mouth For A Year And Half | 18 MTH          | Accord       |                |  |
| <u>FDA Received Date</u>                                                                    | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                                             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |  |
| 28-Jan-2015                                                                                 | 10932086                         | NON-EXPEDITED      | Y                  | OT              | 2014TUS009803            |                                                                  | 61 YR           | Female       | USA            |  |
| <u>Preferred Term</u>                                                                       | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                                               | <u>Duration</u> | <u>Mfr</u>   |                |  |
| Serotonin Syndrome                                                                          | Brintellix (Vortioxetine) Tablet |                    |                    | S               | Oral                     | 10 Mg (Sample)                                                   |                 | Not Reported |                |  |
|                                                                                             | Lexapro (Escitalopram Oxalate)   |                    |                    | S               |                          | Low Dose                                                         |                 | Not Reported |                |  |
| <u>FDA Received Date</u>                                                                    | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                                             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |  |
| 29-Jan-2015                                                                                 | 10516084                         | EXPEDITED (15-DAY) |                    | HO              | IT-FRI-1000071463        |                                                                  | 74 YR           | Female       | ITA            |  |
| <u>Preferred Term</u>                                                                       | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                                               | <u>Duration</u> | <u>Mfr</u>   |                |  |
| Bradycardia; Bradykinesia; Bradyphrenia; Electrocardiogram Qt Prolonged; Hypotension; Sopor | Escitalopram                     |                    |                    | S               | Oral                     | 10 Mg                                                            |                 | Forest       |                |  |
|                                                                                             | Quetiapine                       |                    |                    | S               | Oral                     | 300 Mg                                                           |                 | Not Reported |                |  |
|                                                                                             | Paroxetine Hydrochloride         |                    |                    | S               | Oral                     | 1.5 Posological Units Daily                                      |                 | Not Reported |                |  |
|                                                                                             | Prazene                          |                    |                    | S               | Oral                     | 20 Mg                                                            |                 | Not Reported |                |  |
|                                                                                             | Lasix                            |                    |                    | C               |                          |                                                                  |                 | Not Reported |                |  |
|                                                                                             | Foster                           |                    |                    | C               | Respiratory (inhalation) |                                                                  |                 | Not Reported |                |  |
|                                                                                             | Stilnox                          |                    |                    | C               | Oral                     |                                                                  |                 | Not Reported |                |  |

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| <u>FDA Received Date</u>                                                                    | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
| 29-Jan-2015                                                                                 | 10527966                 | EXPEDITED (15-DAY) |                    | HO              | IT-MYLANLABS-2014M1006954 |                      |                 | Unknown      | ITA            |
| <u>Preferred Term</u>                                                                       | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bradycardia; Bradykinesia; Bradyphrenia; Electrocardiogram Qt Prolonged; Hypotension; Sopor | Quetiapine               |                    |                    | S               | Oral                      | 300 Mg, Qd           |                 | Not Reported |                |
|                                                                                             | Paroxetine Hydrochloride |                    |                    | S               | Oral                      | 1.5 Df, Qd           |                 | Not Reported |                |
|                                                                                             | Prazene                  |                    |                    | S               | Oral                      | 1 Df, Qd             |                 | Not Reported |                |
|                                                                                             | Cipralext /01588501/     |                    |                    | S               | Oral                      | 1 Df, Qd             |                 | Not Reported |                |
|                                                                                             | Lasix /00032601/         |                    |                    | C               | Unknown                   | Unk                  |                 | Not Reported |                |
|                                                                                             | Foster /06206901/        |                    |                    | C               | Unknown                   | Unk                  |                 | Not Reported |                |
|                                                                                             | Stilnox                  |                    |                    | C               | Unknown                   | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                    | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Jan-2015                                                                                 | 10533958                 | EXPEDITED (15-DAY) |                    | DE              | FR-FRI-1000071671         |                      | 88 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                       | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Peritoneal Haematoma                                                      | Escitalopram             |                    |                    | S               | Oral                      | 5 Mg                 |                 | Forest       |                |
|                                                                                             | Previscan (Fluindione)   |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                                                                                             | Bi-Tildiem               |                    |                    | C               |                           | 2 Dosage Forms       |                 | Not Reported |                |
|                                                                                             | Paracetamol              |                    |                    | C               |                           |                      |                 | Not Reported |                |
|                                                                                             | Uvedose                  |                    |                    | C               | Oral                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                    | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Jan-2015                                                                                 | 10659772                 | EXPEDITED (15-DAY) |                    | HO              | JP-FRI-1000073108         |                      | 84 YR           | Female       | JPN            |
| <u>Preferred Term</u>                                                                       | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Gastrointestinal Haemorrhage; Prothrombin Time Prolonged                  | Lexapro                  |                    |                    | S               | Oral                      | 10 Mg                |                 | Forest       |                |
|                                                                                             | Warfarin                 |                    |                    | S               | Oral                      | 2.25 Mg              |                 | Not Reported |                |
|                                                                                             | Loxonin                  |                    |                    | S               | Transdermal               | 50 Mg                |                 | Not Reported |                |

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|                                                                         |   |             |          |              |
|-------------------------------------------------------------------------|---|-------------|----------|--------------|
| Calonal                                                                 | S | Oral        | 1200 Mg  | Not Reported |
| Millis                                                                  | C | Transdermal | 5 Mg     | Not Reported |
| Halcion                                                                 | C | Oral        | 0.25 Mg  | Not Reported |
| Fosamac 35mg                                                            | C | Oral        |          | Not Reported |
| Maglax                                                                  | C | Oral        | 1000 Mg  | Not Reported |
| Pletaal Od                                                              | C | Oral        | 100 Mg   | Not Reported |
| Methycobal                                                              | C | Oral        | 1000 Mcg | Not Reported |
| Incremin                                                                | C |             | 5 MI     | Not Reported |
| Edirol                                                                  | C | Oral        | 0.75 Mcg | Not Reported |
| Wypax                                                                   | C | Oral        | 1 Mg     | Not Reported |
| Lasix                                                                   | C | Oral        | 20 Mg    | Not Reported |
| Amlodin                                                                 | C | Oral        | 10 Mg    | Not Reported |
| Pariet                                                                  | C | Oral        | 10 Mg    | Not Reported |
| Tsumura<br>Bukuryoingohangekobokuto<br>Extract Granules For Ethical Use | C | Oral        | 5 Gram   | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------------------------|----------------------|------------|------------|----------------|
| 29-Jan-2015              | 10660993      | NON-EXPEDITED    |                    |                 | US-LUPIN<br>PHARMACEUTICALS<br>INC.-2014-01824 |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                                                                                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anger; Crying; Depressed<br>Mood; Dizziness; Feeling<br>Abnormal; Paraesthesia;<br>Restlessness; Withdrawal<br>Syndrome | Escitalopram   |              |            | S           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 29-Jan-2015              | 10747080      | EXPEDITED (15-DAY) |                    | DE              | US-BAUSCH-BL-2015-<br>001331 |                      | 51 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Diazepam       |              |            | S           |              |                    |                 | Not Reported |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                           |   |                 |
|---------------------------|---|-----------------|
| Diclofenac                | S | Bausch And Lomb |
| Promethazine              | S | Not Reported    |
| Verapamil                 | S | Not Reported    |
| Escitalopram              | S | Not Reported    |
| Acetaminophen/Hydrocodone | S | Not Reported    |
| Topiramate                | S | Not Reported    |
| Esomeprazole              | S | Not Reported    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------------------------------|----------------------|------------|------------|----------------|
| 29-Jan-2015              | 10747141      | NON-EXPEDITED    |                    |                 | US-LUPIN<br>PHARMACEUTICALS<br>INC.-E2B_00002976 |                      | 40 YR      | Female     | USA            |

| <u>Preferred Term</u>                                           | <u>Product</u>               | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------------------------------------------------|------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Abdominal Pain Upper;<br>Chills; Diarrhoea;<br>Migraine; Nausea | Escitalopram Tablets Usp 5mg |              |            | S           |              |                    |                 | Lupin      |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                        | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------------------|----------------------|------------|------------|----------------|
| 29-Jan-2015              | 10747773      | EXPEDITED (15-DAY) |                    | DE, OT          | GB-SUN<br>PHARMACEUTICAL<br>INDUSTRIES LTD-<br>2015SUN00251 |                      |            | Unknown    | GBR            |

| <u>Preferred Term</u>                                 | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide;<br>Depression; Drug<br>Interaction | Letrozole Tabs 2.5mg |              |            | S           | Oral         | 2.5mg              |                 | Sun          |
|                                                       | Escitalopram         |              |            | S           | Oral         | 10mg               |                 | Not Reported |
|                                                       | Escitalopram         |              |            | S           | Oral         | 15 Mg, Unk         |                 | Not Reported |
|                                                       | Adcal-D3             |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|------------|------------|----------------|
| 29-Jan-2015              | 10748533      | EXPEDITED (15-DAY) |                    | HO, OT          | US-CIPLA LTD.-<br>2015US00587 |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>                                                                          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Bradykinesia;<br>Cerebral Disorder;<br>Feeding Disorder; Gait<br>Inability; Insomnia; | Donepezil      |              |            | S           |              | Unk                |                 | Cipla        |
|                                                                                                | Donepezil      |              |            | S           |              |                    |                 | Cipla        |
|                                                                                                | Escitalopram   |              |            | S           |              | Unk                |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                |              |   |  |               |  |              |
|--------------------------------|--------------|---|--|---------------|--|--------------|
| Irritability; Muscle Rigidity; | Escitalopram | S |  |               |  | Not Reported |
| Nerve Degeneration;            | Haloperidol  | S |  | 3.5 Mg, Qd    |  | Not Reported |
| Parkinsonian Crisis;           | Haloperidol  | S |  | 17.5 Unk, Unk |  | Not Reported |
| Parkinsonian Gait;             | Amisulpride  | S |  | 50 Mg, Unk    |  | Not Reported |
| Parkinsonian Gait; Tremor      | Amisulpride  | S |  | Unk           |  | Not Reported |
|                                | Mirtazapine  | S |  | 15 Mg, Unk    |  | Not Reported |
|                                | Mirtazapine  | S |  |               |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Jan-2015              | 10748714      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000073970    |                      | 64 YR      | Female     | FRA            |

| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction;       | Escitalopram             |              |            | S           | Oral         | 1 Df               |                 | Forest       |
| Haemoglobin Decreased;  | Kardegic                 |              |            | S           | Oral         | 1 Df               |                 | Not Reported |
| Retroperitoneal         | Plavix                   |              |            | S           | Oral         | 1 Df               |                 | Not Reported |
| Haematoma; Vessel       | Tahor                    |              |            | C           |              | 1 Df               |                 | Not Reported |
| Puncture Site Haematoma | Nebivolol                |              |            | C           |              | 1 Df               |                 | Not Reported |
|                         | Lansoprazole             |              |            | C           |              | 1 Df               |                 | Not Reported |
|                         | Bipreterax               |              |            | C           |              | 5 Mg/1.25 Mg Daily |                 | Not Reported |
|                         | Alprazolam               |              |            | C           |              | 1 Df               |                 | Not Reported |
|                         | Paracetamol              |              |            | C           |              |                    |                 | Not Reported |
|                         | Spasfon (Phloroglucinol, |              |            | C           |              |                    |                 | Not Reported |
|                         | Trimethylphloroglucinol) |              |            |             |              |                    |                 |              |
|                         | Avamys                   |              |            | C           |              | 2 Puffs On Morning |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Jan-2015              | 10748925      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000073893    |                      | 39 YR      | Female     | FRA            |

| <u>Preferred Term</u>             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Coma; Intentional                 | Escitalopram   |              |            | S           | Oral         | 1 Df               |                 | Forest     |
| Overdose; Miosis; Suicide Attempt | Escitalopram   |              |            | S           | Oral         | Overdose Nos.      |                 | Forest     |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|            |   |      |               |              |
|------------|---|------|---------------|--------------|
| Olmotec    | S | Oral | 10 Mg         | Not Reported |
| Olmotec    | S | Oral | Overdose Nos. | Not Reported |
| Alprazolam | S | Oral | 0.5 Mg        | Not Reported |
| Alprazolam | S | Oral | Overdose Nos. | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Jan-2015              | 10750070      | EXPEDITED (15-DAY) |                    | HO, OT          | US-FRI-1000074015    |                      | 61 YR      | Female     | USA            |

| <u>Preferred Term</u>         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------|----------------|--------------|------------|-------------|--------------|--------------------------|-----------------|--------------|
| Abdominal Discomfort;         | Lexapro        |              |            | S           |              | 5 Mg                     |                 | Forest       |
| Abdominal Distension;         | Lexapro        |              |            | S           |              |                          |                 | Forest       |
| Aphonia; Decreased            | Lexapro        |              |            | S           |              |                          |                 | Not Reported |
| Appetite; Depression;         | Celexa         |              |            | S           |              | 5 Mg                     |                 | Forest       |
| Dyspnoea;                     | Norvasc        |              |            | S           |              | 2.5 Mg                   |                 | Not Reported |
| Electrocardiogram Qt          | Levoxyl        |              |            | C           |              | 125 Mcg                  |                 | Not Reported |
| Prolonged; Insomnia;          | Cytomel        |              |            | C           |              | 5 Mcg                    |                 | Not Reported |
| Irritability; Mania; Muscular | Tums           |              |            | C           |              | One In Afternoon And One |                 | Not Reported |
| Weakness; Nasal               |                |              |            |             |              | Later In Day             |                 |              |
| Congestion; Nausea;           | Mylanta        |              |            | C           |              | 1/2 Tsp At Night         |                 | Not Reported |
| Nicotine Dependence;          |                |              |            |             |              |                          |                 |              |
| Thyroid Disorder; Tobacco     |                |              |            |             |              |                          |                 |              |
| User; Urinary Tract           |                |              |            |             |              |                          |                 |              |
| Infection; Weight             |                |              |            |             |              |                          |                 |              |
| Decreased                     |                |              |            |             |              |                          |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 29-Jan-2015              | 10750164      | EXPEDITED (15-DAY) |                    | DE              | US-BAUSCH-BL-2015-001412 |                      | 67 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Lorazepam      |              |            | S           |              |                    |                 | Not Reported |
|                       | Lamotrigine    |              |            | S           |              |                    |                 | Not Reported |
|                       | Zonisamide     |              |            | S           |              |                    |                 | Not Reported |
|                       | Escitalopram   |              |            | S           |              |                    |                 | Not Reported |
|                       | Lovastatin     |              |            | S           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                        | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------|--------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 29-Jan-2015                                     | 10750178           | EXPEDITED (15-DAY) |                    | DE              | US-BAUSCH-BL-2015-001419 |                      | 62 YR           | Male         | USA            |
| <u>Preferred Term</u>                           | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                               | Lorazepam          |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                                 | Primidone          |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                                 | Temazepam          |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                                 | Lamotrigine        |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                                 | Escitalopram       |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                                 | Benzotropine       |                    |                    | S               |                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                        | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Jan-2015                                     | 10750210           | EXPEDITED (15-DAY) |                    | DE, OT          | US-BAUSCH-BL-2015-001357 |                      | 48 YR           | Female       | USA            |
| <u>Preferred Term</u>                           | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardio-Respiratory Arrest;<br>Unevaluable Event | Nitroglycerin      |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                                 | Diclofenac         |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                                 | Doxycycline        |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                                 | Oxycodone          |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                                 | Cyclobenzaprine    |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                                 | Metoprolol         |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                                 | Clonidine          |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                                 | Lisinopril         |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                                 | Escitalopram       |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                                 | Ibuprofen          |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                                 | Azithromycin       |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                                 | Cephalexin         |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                                 | Methylprednisolone |                    |                    | S               |                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                        | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Jan-2015                                     | 10753583           | DIRECT             |                    | OT              |                          |                      | 18 YR           | Female       | USA            |
| <u>Preferred Term</u>                           | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dyskinesia                                      | Lexapro            |                    |                    | S               | Oral                     | 1 Pill Daily         |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------|----------------|--------------------|--------------------|-----------------|---------------------------------------------|----------------------|-----------------|--------------|----------------|
| 30-Jan-2015                                         | 10750445       | EXPEDITED (15-DAY) |                    | DE              | US-BAUSCH-BL-2015-001560                    |                      | 74 YR           | Male         | USA            |
| <u>Preferred Term</u>                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Unevaluable Event                                   | Primidone      |                    |                    | S               |                                             |                      |                 | Not Reported |                |
|                                                     | Atenolol       |                    |                    | S               |                                             |                      |                 | Not Reported |                |
|                                                     | Escitalopram   |                    |                    | S               |                                             |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Jan-2015                                         | 10750455       | EXPEDITED (15-DAY) |                    | DE, OT          | US-BAUSCH-BL-2015-001402                    |                      | 26 YR           | Female       | USA            |
| <u>Preferred Term</u>                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardio-Respiratory Arrest;<br>Drug Abuse            | Lorazepam      |                    |                    | S               |                                             |                      |                 | Not Reported |                |
|                                                     | Ethanol        |                    |                    | S               |                                             |                      |                 | Not Reported |                |
|                                                     | Escitalopram   |                    |                    | S               |                                             |                      |                 | Not Reported |                |
|                                                     | Methocarbamol  |                    |                    | S               |                                             |                      |                 | Not Reported |                |
|                                                     | Oxycodone      |                    |                    | S               |                                             |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Jan-2015                                         | 10751958       | NON-EXPEDITED      |                    |                 | US-ELI_LILLY_AND_COMP<br>ANY-US201501005786 |                      | 15 YR           | Male         | USA            |
| <u>Preferred Term</u>                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Depression; Post-Traumatic Stress Disorder | Prozac         |                    |                    | S               | Unknown                                     |                      |                 | Unknown      |                |
|                                                     | Lexapro        |                    |                    | S               | Unknown                                     |                      |                 | Not Reported |                |
|                                                     | Risperdal      |                    |                    | S               | Unknown                                     |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Jan-2015                                         | 10751959       | EXPEDITED (15-DAY) |                    | HO              | FR-ABBVIE-15P-056-1339280-00                |                      | 12 YR           | Female       | FRA            |
| <u>Preferred Term</u>                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Somnolence; Toxicity To Various Agents; Vomiting    | Depakote       |                    |                    | S               | Oral                                        | Gastro-Resistant     |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |             |   |      |                         |  |              |
|--|-------------|---|------|-------------------------|--|--------------|
|  | Alprazolam  | S | Oral |                         |  | Not Reported |
|  | Tetrazepam  | S | Oral |                         |  | Not Reported |
|  | Venlafaxine | S | Oral |                         |  | Not Reported |
|  | Biprofenid  | S | Oral | Modified-Release Tablet |  | Not Reported |
|  | Surgam      | S | Oral |                         |  | Not Reported |
|  | Seroplex    | S | Oral | Film Coated             |  | Not Reported |
|  | Diclofenac  | S | Oral |                         |  | Not Reported |
|  | Trazepam    | C |      |                         |  | Not Reported |

| <u>FDA Received Date</u>                                                                                      | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>             | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------------------|----------------|
| 30-Jan-2015                                                                                                   | 10754513       | DIRECT           |                    |                 |                      |                      | 62 YR           | Female                 | USA            |
| <u>Preferred Term</u>                                                                                         | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>             |                |
| Anxiety; Product Quality Issue; Product Substitution Issue; Product Substitution Issue; Therapy Non-Responder | Escitalopram   |                  |                    | S               |                      |                      |                 | Bluepoint Laboratories |                |

| <u>FDA Received Date</u>                         | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------------------------------|----------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 02-Feb-2015                                      | 10566245                   | EXPEDITED (15-DAY) |                    | HO              | IT-FRI-1000072061    |                      | 102 DAY         | Female     | ITA            |
| <u>Preferred Term</u>                            | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Somnolence; Vomiting; Wrong Product Administered | Escitalopram Oral Solution |                    |                    | S               | Oral                 | 3 Drops              |                 | Forest     |                |

| <u>FDA Received Date</u>            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|-------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 02-Feb-2015                         | 10722802       | EXPEDITED (15-DAY) |                    | DE, OT          | GB-ACCORD-028098     |                      | 51 YR           | Female     | GBR            |
| <u>Preferred Term</u>               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Completed Suicide; Depression; Drug | Escitalopram   |                    |                    | S               | Oral                 |                      |                 | Accord     |                |
|                                     | Letrozole      |                    |                    | S               | Oral                 |                      |                 | Accord     |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                 |                         |                    |                    |                 |                            |                      |                 |              |                |
|-------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| Interaction                                     |                         | Adcal-D3           |                    | C               |                            | Not Reported         |                 |              |                |
| <u>FDA Received Date</u>                        | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Feb-2015                                     | 10754534                | EXPEDITED (15-DAY) |                    | DE              | US-MALLINCKRODT-T201500503 |                      | 48 YR           | Female       | USA            |
| <u>Preferred Term</u>                           | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardio-Respiratory Arrest                       | Roxicodone              |                    |                    | S               | Unknown                    | Unk                  |                 | Tyco         |                |
|                                                 | Cyclobenzaprine         |                    |                    | S               | Unknown                    | Unk                  |                 | Not Reported |                |
|                                                 | Metoprolol              |                    |                    | S               | Unknown                    | Unk                  |                 | Not Reported |                |
|                                                 | Clonidine               |                    |                    | S               | Unknown                    | Unk                  |                 | Not Reported |                |
|                                                 | Nitroglycerin           |                    |                    | S               | Unknown                    | Unk                  |                 | Not Reported |                |
|                                                 | Lisinopril              |                    |                    | S               | Unknown                    | Unk                  |                 | Not Reported |                |
|                                                 | Escitalopram            |                    |                    | S               | Unknown                    | Unk                  |                 | Not Reported |                |
|                                                 | Ibuprofen               |                    |                    | S               | Unknown                    | Unk                  |                 | Not Reported |                |
|                                                 | Diclofenac              |                    |                    | S               | Unknown                    | Unk                  |                 | Not Reported |                |
|                                                 | Azithromycin            |                    |                    | S               | Unknown                    | Unk                  |                 | Not Reported |                |
|                                                 | Cephalexin              |                    |                    | S               | Unknown                    | Unk                  |                 | Not Reported |                |
|                                                 | Doxycycline             |                    |                    | S               | Unknown                    | Unk                  |                 | Not Reported |                |
|                                                 | Methylprednisolone      |                    |                    | S               | Unknown                    | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                        | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Feb-2015                                     | 10755776                | EXPEDITED (15-DAY) |                    | DE              | US-APOTEX-2015AP005668     |                      | 28 YR           | Female       | USA            |
| <u>Preferred Term</u>                           | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardio-Respiratory Arrest;<br>Completed Suicide | Bupropion Hydrochloride |                    |                    | S               | Oral                       |                      |                 | Apotex       |                |
|                                                 | Escitalopram Oxalate    |                    |                    | S               | Oral                       |                      |                 | Apotex       |                |
|                                                 | Gabapentin              |                    |                    | S               | Oral                       |                      |                 | Apotex       |                |
|                                                 | Alprazolam Tablets Usp  |                    |                    | S               | Oral                       |                      |                 | Apotex       |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                              | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
| 02-Feb-2015                                                                                                                                                                                           | 10758901                   | DIRECT             |                    | DS              |                           |                      | 55 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                 | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Amnesia; Amnesia;<br>Confusional State;<br>Depression; Disturbance<br>In Attention; Female<br>Orgasmic Disorder;<br>Impaired Work Ability;<br>Judgement Impaired;<br>Libido Disorder;<br>Tachyphrenia | Lexapro 10 Mg              |                    |                    | S               |                           | 1 Pill               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                              | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Feb-2015                                                                                                                                                                                           | 10570606                   | EXPEDITED (15-DAY) |                    | HO              | IT-FRI-1000072171         |                      | 91 DAY          | Female       | ITA            |
| <u>Preferred Term</u>                                                                                                                                                                                 | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Somnolence; Vomiting;<br>Wrong Product<br>Administered                                                                                                                                                | Escitalopram Oral Solution |                    |                    | S               | Oral                      |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                                                                                              | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Feb-2015                                                                                                                                                                                           | 10703941                   | EXPEDITED (15-DAY) |                    | DE, HO          | US-JNJFOC-<br>20150105117 |                      | 34 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                 | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Toxicity To Various Agents                                                                                                                                                      | Tramadol                   |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                       | Amitriptyline              |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                       | Acetaminophen/Hydrocodone  |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                       | Ondansetron                |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                       | Diclofenac                 |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                       | Zolpidem                   |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                       | Liothyronine               |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|              |   |      |              |
|--------------|---|------|--------------|
| Escitalopram | S | Oral | Not Reported |
| Sertraline   | S | Oral | Not Reported |
| Gabapentin   | S | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 03-Feb-2015              | 10757326      | EXPEDITED (15-DAY) |                    | OT              | NO-009507513-1501NOR012006 |                      | 36 YR      | Female     | NOR            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                  | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                | <u>Dosage Text</u>                             | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|--------------|------------|-------------|-----------------------------|------------------------------------------------|-----------------|--------------|
| Decreased Appetite;<br>Diarrhoea; Disturbance In<br>Attention; Dizziness;<br>Headache; Heart Rate<br>Irregular; Hyperhidrosis;<br>Hypersomnia; Memory<br>Impairment;<br>Musculoskeletal Pain;<br>Nausea; Paraesthesia;<br>Paraesthesia; Pyrexia;<br>Restlessness;<br>Somnolence; Tinnitus;<br>Vomiting | Montelukast Sodium |              |            | S           | Oral                        | Seasonal                                       |                 | Merck        |
|                                                                                                                                                                                                                                                                                                        | Escitalopram       |              |            | S           | Oral                        | Increased From 10 Mg<br>Daily From 13-Nov-2013 |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                        | Seretide Diskus    |              |            | C           | Respiratory<br>(inhalation) | 1 Df, Bid                                      |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                        | Panodil            |              |            | C           | Oral                        | 1 G, Bid                                       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Feb-2015              | 10759407      | EXPEDITED (15-DAY) |                    | DE              | US-FRI-1000074206    |                      | 34 YR      | Female     | USA            |

| <u>Preferred Term</u>                           | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardio-Respiratory Arrest;<br>Completed Suicide | Linacotide                |              |            | S           |              |                    |                 | Forest       |
|                                                 | Escitalopram              |              |            | S           |              |                    |                 | Forest       |
|                                                 | Amitriptyline             |              |            | S           |              |                    |                 | Not Reported |
|                                                 | Tramadol                  |              |            | S           |              |                    |                 | Not Reported |
|                                                 | Acetaminophen/Hydrocodone |              |            | S           |              |                    |                 | Not Reported |
|                                                 | Ondansetron               |              |            | S           |              |                    |                 | Not Reported |
|                                                 | Diclofenac                |              |            | S           |              |                    |                 | Not Reported |
|                                                 | Lubiprostone              |              |            | S           |              |                    |                 | Not Reported |
|                                                 | Zolpidem                  |              |            | S           |              |                    |                 | Not Reported |
|                                                 | Liothyronine              |              |            | S           |              |                    |                 | Not Reported |
|                                                 | Sertraline                |              |            | S           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                 |                                              |                    |                    |                 |                       |                      |                 |              |                |
|-------------------------------------------------|----------------------------------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| Gabapentin                                      |                                              |                    | S                  |                 |                       | Not Reported         |                 |              |                |
| <u>FDA Received Date</u>                        | <u>Case #</u>                                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Feb-2015                                     | 10759935                                     | EXPEDITED (15-DAY) |                    | DE              | US-PERRIGO-15US000968 |                      | 26 YR           | Female       | USA            |
| <u>Preferred Term</u>                           | <u>Product</u>                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Death                                           | Lorazepam Concentrate Rx 2 Mg/ML 1j9 Ethanol |                    |                    | S               | Oral                  | Unk                  |                 | Perrigo      |                |
|                                                 | Escitalopram                                 |                    |                    | S               | Oral                  | Unk                  |                 | Not Reported |                |
|                                                 | Methocarbamol                                |                    |                    | S               | Oral                  | Unk                  |                 | Not Reported |                |
|                                                 | Oxycodone                                    |                    |                    | S               | Oral                  | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                        | <u>Case #</u>                                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Feb-2015                                     | 10342331                                     | EXPEDITED (15-DAY) |                    | HO              | IT-FRI-1000069028     |                      | 24 YR           | Male         | ITA            |
| <u>Preferred Term</u>                           | <u>Product</u>                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Nausea; Withdrawal Syndrome            | Escitalopram                                 |                    |                    | S               | Oral                  | 10 Unit Dose Per Day |                 | Forest       |                |
|                                                 | Escitalopram                                 |                    |                    | S               |                       | 1/2 Tablet           |                 | Forest       |                |
|                                                 | Escitalopram                                 |                    |                    | S               |                       | 1 Tablet Daily       |                 | Not Reported |                |
| <u>FDA Received Date</u>                        | <u>Case #</u>                                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Feb-2015                                     | 10732592                                     | EXPEDITED (15-DAY) |                    | DE, OT          | GB-TEVA-534889ISR     |                      | 51 YR           | Female       | GBR            |
| <u>Preferred Term</u>                           | <u>Product</u>                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Depression; Drug Interaction | Escitalopram                                 |                    |                    | S               | Oral                  | 10 Increased To 15mg |                 | Ivax         |                |
|                                                 | Escitalopram                                 |                    |                    | S               | Oral                  | 10 Increased To 15mg |                 | Ivax         |                |
|                                                 | Letrozole                                    |                    |                    | S               | Oral                  | 2.5mg                |                 | Teva         |                |
|                                                 | Adcal-D3                                     |                    |                    | C               |                       |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                              | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>     | <u>Country</u> |
|-------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|-------------------------|----------------------|-----------------|----------------|----------------|
| 04-Feb-2015                                           | 10744734                      | EXPEDITED (15-DAY) |                    | DE, OT          | GB-ACTAVIS-2015-00705   |                      | 51 YR           | Female         | GBR            |
| <u>Preferred Term</u>                                 | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>     |                |
| Completed Suicide;<br>Depression; Drug<br>Interaction | Escitalopram (Unknown)        |                    |                    | S               | Oral                    | 10 Mg, Unknown       |                 | Not Reported   |                |
|                                                       | Escitalopram (Unknown)        |                    |                    | S               | Oral                    | 15 Mg, Unk           |                 | Not Reported   |                |
|                                                       | Letrozole (Unknown)           |                    |                    | S               | Oral                    | 2.5 Mg, Unknown      |                 | Actavis Totowa |                |
|                                                       | Adcal D3                      |                    |                    | C               | Unknown                 | Unk, Unknown         |                 | Not Reported   |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>     | <u>Country</u> |
| 04-Feb-2015                                           | 10747758                      | EXPEDITED (15-DAY) | Y                  | DE, OT          | FK201500348             |                      | 51 YR           | Female         | GBR            |
| <u>Preferred Term</u>                                 | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>     |                |
| Completed Suicide;<br>Depression; Drug<br>Interaction | Letrozole                     |                    |                    | S               | Oral                    |                      |                 | Not Reported   |                |
|                                                       | Escitalopram                  |                    |                    | S               | Oral                    |                      |                 | Not Reported   |                |
|                                                       | Adcal-D3 (Lekovit Ca)         |                    |                    | C               | Oral                    |                      |                 | Not Reported   |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>     | <u>Country</u> |
| 04-Feb-2015                                           | 10760444                      | EXPEDITED (15-DAY) |                    | DE              | US-ALVOGEN-2015AL000265 |                      | 41 YR           | Male           | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>     |                |
| Completed Suicide;<br>Toxicity To Various Agents      | Lisinopril                    |                    |                    | S               | Oral                    |                      |                 | Not Reported   |                |
|                                                       | Olanzapine                    |                    |                    | S               | Oral                    |                      |                 | Not Reported   |                |
|                                                       | Escitalopram                  |                    |                    | S               | Oral                    |                      |                 | Not Reported   |                |
|                                                       | Acetaminophen/Diphenhydramine |                    |                    | S               | Oral                    |                      |                 | Not Reported   |                |
|                                                       | Warfarin                      |                    |                    | S               | Oral                    |                      |                 | Not Reported   |                |
|                                                       | Prednisone                    |                    |                    | S               | Oral                    |                      |                 | Not Reported   |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                        | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------------------|----------------------|------------|------------|----------------|
| 04-Feb-2015              | 10760665      | EXPEDITED (15-DAY) |                    | HO              | US-SUN<br>PHARMACEUTICAL<br>INDUSTRIES LTD-<br>2015SUN00282 |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                             | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------|------------|-------------|--------------|---------------------|-----------------|--------------|
| Acute Respiratory Failure;<br>Alpha-1 Anti-Trypsin<br>Deficiency; Delirium;<br>Hypercapnia;<br>Inappropriate Antidiuretic<br>Hormone Secretion;<br>Mania; Pneumonia<br>Pseudomonal; Toxicity To<br>Various Agents | Alprazolam               |              |            | S           | Unknown      |                     |                 | Sun          |
|                                                                                                                                                                                                                   | Alprazolam               |              |            | S           |              |                     |                 | Sun          |
|                                                                                                                                                                                                                   | Olanzapine 10 Mg Tablets |              |            | S           | Unknown      | 10 Mg, Daily        |                 | Sun          |
|                                                                                                                                                                                                                   | Olanzapine 10 Mg Tablets |              |            | S           |              |                     |                 | Sun          |
|                                                                                                                                                                                                                   | Prednisone               |              |            | S           | Unknown      | 10 Mg, Daily        |                 | Not Reported |
|                                                                                                                                                                                                                   | Prednisone               |              |            | S           |              | 7.5 Mg, Daily       |                 | Not Reported |
|                                                                                                                                                                                                                   | Prednisone               |              |            | S           |              | 2.5 Mg, Daily       |                 | Not Reported |
|                                                                                                                                                                                                                   | Prednisone               |              |            | S           |              | 2 Mg, Daily At Home |                 | Not Reported |
|                                                                                                                                                                                                                   | Prednisone               |              |            | S           |              | 1 Mg/Day, Unk       |                 | Not Reported |
|                                                                                                                                                                                                                   | Escitalopram             |              |            | S           | Unknown      |                     |                 | Not Reported |
|                                                                                                                                                                                                                   | Sertraline               |              |            | S           | Unknown      |                     |                 | Not Reported |
|                                                                                                                                                                                                                   | Sertraline               |              |            | S           |              |                     |                 | Not Reported |
|                                                                                                                                                                                                                   | Fluticasone              |              |            | C           | Unknown      |                     |                 | Not Reported |
|                                                                                                                                                                                                                   | Buspirone                |              |            | C           |              |                     |                 | Not Reported |
|                                                                                                                                                                                                                   | Buspirone                |              |            | C           |              |                     |                 | Not Reported |
|                                                                                                                                                                                                                   | Diltiazem                |              |            | C           |              |                     |                 | Not Reported |
|                                                                                                                                                                                                                   | Esomeprazole             |              |            | C           |              |                     |                 | Not Reported |
|                                                                                                                                                                                                                   | Ipratropium              |              |            | C           |              |                     |                 | Not Reported |
|                                                                                                                                                                                                                   | Omeprazole               |              |            | C           |              |                     |                 | Not Reported |

| <u>FDA Received Date</u>                                  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|-----------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|------------------------|----------------------|-----------------|------------|----------------|
| 04-Feb-2015                                               | 10761704             | EXPEDITED (15-DAY) |                    | DE, OT          | US-APOTEX-2015AP005838 |                      | 48 YR           | Female     | USA            |
| <u>Preferred Term</u>                                     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Cardio-Respiratory Arrest | Lisinopril           |                    |                    | S               |                        |                      |                 | Apotex     |                |
|                                                           | Escitalopram Oxalate |                    |                    | S               |                        |                      |                 | Apotex     |                |
|                                                           | Diclofenac Potassium |                    |                    | S               |                        |                      |                 | Apotex     |                |
|                                                           | Azithromycin         |                    |                    | S               |                        |                      |                 | Apotex     |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                       |     |              |
|-----------------------|-----|--------------|
| Oxycodone             | S   | Not Reported |
| Cyclobenzaprine       | S   | Not Reported |
| Metoprolol            | S   | Not Reported |
| Nitroglycerin         | S   | Not Reported |
| Ibuprofen             | S   | Not Reported |
| Cephalexin /00145501/ | S   | Not Reported |
| Doxycycline           | S   | Not Reported |
| Methylprednisolone    | S   | Not Reported |
| Clonidine             | S   | Not Reported |
|                       | Unk |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 04-Feb-2015              | 10762852      | EXPEDITED (15-DAY) |                    | DE, OT          | US-<br>ELI_LILLY_AND_COMP<br>ANY-US201502000707 |                      | 41 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u>                                      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-----------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Olanzapine                                          |              |            | S           | Unknown      |                    |                 | Unknown      |
|                       | Acetaminophen<br>W/Diphenhydramine<br>Hydrochloride |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Warfarin                                            |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Lisinopril                                          |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Escitalopram                                        |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Prednisone                                          |              |            | S           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 04-Feb-2015              | 10762941      | EXPEDITED (15-DAY) |                    | DE              | US-PERRIGO-<br>15US001164 |                      | 37 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>                            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Death                 | Loperamide Hydrochloride 0.2<br>Mg/ML 377 |              |            | S           | Oral         | Unk, Unk           |                 | Perrigo      |
|                       | Escitalopram                              |              |            | S           | Oral         | Unk, Unk           |                 | Not Reported |
|                       | Meloxicam                                 |              |            | S           | Oral         | Unk, Unk           |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                         | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------|--------------------------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 04-Feb-2015                                      | 10763217                             | EXPEDITED (15-DAY) |                    | DE, HO, LT      | FR-FRI-1000074141     |                      | 92 YR           | Female       | FRA            |
| <u>Preferred Term</u>                            | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Haemorrhagic Stroke                              | Escitalopram                         |                    |                    | S               | Oral                  |                      |                 | Forest       |                |
|                                                  | Pentasa                              |                    |                    | S               | Oral                  | 1 Gram               |                 | Not Reported |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Feb-2015                                      | 10763854                             | EXPEDITED (15-DAY) |                    | DE              | US-PERRIGO-15US001193 |                      | 67 YR           | Male         | USA            |
| <u>Preferred Term</u>                            | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Death                                            | Lorazepam Concentrate Rx 2 Mg/MI 1j9 |                    |                    | S               | Oral                  | Unknown, Unknown     |                 | Perrigo      |                |
|                                                  | Lamotrigine                          |                    |                    | S               | Oral                  | Unknown, Unknown     |                 | Not Reported |                |
|                                                  | Zonisamide                           |                    |                    | S               | Oral                  | Unknown, Unknown     |                 | Not Reported |                |
|                                                  | Escitalopram                         |                    |                    | S               | Oral                  | Unknown, Unknown     |                 | Not Reported |                |
|                                                  | Lovastatin                           |                    |                    | S               | Oral                  | Unknown, Unknown     |                 | Not Reported |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Feb-2015                                      | 10489986                             | EXPEDITED (15-DAY) |                    | LT              | IE-FRI-1000071180     |                      | 48 YR           | Female       | IRL            |
| <u>Preferred Term</u>                            | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alcohol Interaction; Psychotic Disorder; Syncope | Escitalopram                         |                    |                    | S               | Oral                  | 10 Mg Daily          |                 | Forest       |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Feb-2015                                      | 10522400                             | EXPEDITED (15-DAY) |                    | HO              | IT-FRI-1000071489     |                      | 91 YR           | Female       | ITA            |
| <u>Preferred Term</u>                            | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Gastric                        | Escitalopram Oral Solution           |                    |                    | S               | Oral                  | 20 Mg                |                 | Forest       |                |

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|             |           |   |      |        |              |
|-------------|-----------|---|------|--------|--------------|
| Haemorrhage | Cardirene | S | Oral | 160 Mg | Not Reported |
|             | Solosa    | C | Oral |        | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Feb-2015              | 10667558      | EXPEDITED (15-DAY) |                    | OT              | AU-FRI-1000073201    |                      |            | Female     | AUS            |

| <u>Preferred Term</u>                                                                    | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| C-Reactive Protein Increased; Pulmonary Valve Incompetence; Tricuspid Valve Incompetence | Escitalopram            |              |            | S           | Unknown      |                    |                 | Forest       |
|                                                                                          | Clozaril                |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                          | Clozaril                |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                          | Clozaril                |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                          | Atorvastatin            |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                          | Amisulpride             |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                          | Fenofibrate             |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                          | Metformin Hydrochloride |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                          | Olanzapine              |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                          | Oxazepam                |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                          | Perindopril             |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                          | Thyroxine               |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                          | Warfarin Sodium         |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                          | Paracetamol             |              |            | C           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 05-Feb-2015              | 10669648      | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2014352780 |                      |            | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Hypersensitivity | Celebrex       |              |            | S           |              | Unk                |                 | Pfizer       |
|                       | Lexapro        |              |            | S           |              | Unk                |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 05-Feb-2015                                                               | 10749404       | EXPEDITED (15-DAY) |                    | DE, OT          | GB-FRI-1000073936    |                      | 51 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Depression; Drug<br>Interaction                     | Escitalopram   |                    |                    | S               | Oral                 | 10 Mg Daily          |                 | Forest       |                |
|                                                                           | Escitalopram   |                    |                    | S               | Oral                 | 15 Mg Daily          |                 | Forest       |                |
|                                                                           | Letrozole      |                    |                    | S               | Oral                 | 2.5 Mg Daily         |                 | Not Reported |                |
|                                                                           | Adcal-D3       |                    |                    | C               | Unknown              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Feb-2015                                                               | 10766240       | EXPEDITED (15-DAY) |                    | LT              | FR-FRI-1000074191    |                      | 87 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bradycardia; Drug<br>Interaction;<br>Electrocardiogram Qt<br>Prolonged    | Escitalopram   |                    |                    | S               | Oral                 | 1 Df                 |                 | Forest       |                |
|                                                                           | Theralene      |                    |                    | S               | Oral                 | 10 Df                |                 | Not Reported |                |
|                                                                           | Imovane        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                           | Mianserine     |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                           | Movicol        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                           | Seresta        |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Feb-2015                                                               | 10766244       | EXPEDITED (15-DAY) |                    | OT              | DE-FRI-1000074138    |                      | 66 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Arthralgia; C-Reactive<br>Protein Increased;<br>Myalgia; Weight Increased | Escitalopram   |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                                                           | Escitalopram   |                    |                    | S               | Oral                 | 5 Mg                 |                 | Forest       |                |
| <u>FDA Received Date</u>                                                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Feb-2015                                                               | 10766246       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000074192    |                      | 12 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |



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|                                                                                                  |              |   |      |                                    |              |
|--------------------------------------------------------------------------------------------------|--------------|---|------|------------------------------------|--------------|
| Intentional Overdose;<br>Somnolence; Suicide<br>Attempt; Toxicity To<br>Various Agents; Vomiting | Escitalopram | S | Oral | Overdose: 140 Mg In One Intake.    | Forest       |
|                                                                                                  | Alprazolam   | S | Oral | Overdose: 12.25 Mg In One Intake.  | Not Reported |
|                                                                                                  | Tetrazepam   | S | Oral | Overdose: 1,000 Mg In One Intake.  | Not Reported |
|                                                                                                  | Venlafaxine  | S | Oral | Overdose: 1,500 Mg In One Intake.  | Not Reported |
|                                                                                                  | Depakote     | S | Oral | Overdose: 2,000 Mg In One Intake.  | Not Reported |
|                                                                                                  | Biprofenid   | S | Oral | Overdose: 3,000 Mg In One Intake.  | Not Reported |
|                                                                                                  | Diclofenac   | S | Oral | Overdose: 3,000 Mg In One Intake.  | Not Reported |
|                                                                                                  | Surgam       | S | Oral | Overdose: 15 Df Nos In One Intake. | Not Reported |
|                                                                                                  | Trazepam     | S | Oral | Overdose: 400 Mg In One Intake.    | Not Reported |

| <u>FDA Received Date</u>                                          | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|-------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|--------------------------------------------------------|----------------------|-----------------|----------------------|----------------|
| 05-Feb-2015                                                       | 10767069       | NON-EXPEDITED    |                    |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>BMS-2015-006843 |                      | 33 YR           | Male                 | USA            |
| <u>Preferred Term</u>                                             | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Blood Testosterone<br>Decreased; Feeling<br>Abnormal; Mood Swings | Abilify        |                  |                    | S               | Unknown                                                | Unk                  |                 | Bristol Myers Squibb |                |
|                                                                   | Lexapro        |                  |                    | S               | Unknown                                                |                      |                 | Not Reported         |                |

| <u>FDA Received Date</u> | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|---------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 05-Feb-2015              | 10767139                  | EXPEDITED (15-DAY) |                    | DE, OT          | US-<br>ELI_LILLY_AND_COMP<br>ANY-US201502000757 |                      | 43 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Death                    | Atomoxetine Hydrochloride |                    |                    | S               | Unknown                                         |                      |                 | Unknown      |                |
|                          | Sertraline                |                    |                    | S               | Unknown                                         |                      |                 | Not Reported |                |

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|                                          |                                       |                    |                    |                 |                        |                      |                 |              |                |
|------------------------------------------|---------------------------------------|--------------------|--------------------|-----------------|------------------------|----------------------|-----------------|--------------|----------------|
| Escitalopram                             |                                       |                    | S                  |                 | Unknown                |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                 | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Feb-2015                              | 10961454                              | EXPEDITED (15-DAY) |                    | DE, HO          | US-APOTEX-2015AP005783 |                      | 69 YR           | Male         | USA            |
| <u>Preferred Term</u>                    | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                        | Clonazepam Tablets Usp                |                    |                    | S               | Oral                   |                      |                 | Apotex       |                |
|                                          | Trazodone Hydrochloride               |                    |                    | S               | Oral                   |                      |                 | Apotex       |                |
|                                          | Quetiapine Fumarate                   |                    |                    | S               | Oral                   |                      |                 | Apotex       |                |
|                                          | Lamotrigine                           |                    |                    | S               | Oral                   |                      |                 | Apotex       |                |
|                                          | Escitalopram Oxalate                  |                    |                    | S               | Oral                   |                      |                 | Apotex       |                |
|                                          | Cardiac Glycosides                    |                    |                    | S               | Oral                   |                      |                 | Not Reported |                |
|                                          | Finasteride                           |                    |                    | S               | Oral                   |                      |                 | Not Reported |                |
|                                          | Salicylates Nos                       |                    |                    | S               |                        |                      |                 | Not Reported |                |
|                                          | Oxybutynin Chloride Oral Solution Usp |                    |                    | S               | Oral                   |                      |                 | Apotex       |                |
| <u>FDA Received Date</u>                 | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Feb-2015                              | 10961493                              | EXPEDITED (15-DAY) |                    | DE              | US-APOTEX-2015AP005834 |                      | 26 YR           | Female       | USA            |
| <u>Preferred Term</u>                    | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardio-Respiratory Arrest;<br>Drug Abuse | Escitalopram Oxalate                  |                    |                    | S               | Oral                   |                      |                 | Apotex       |                |
|                                          | Ethanol                               |                    |                    | S               | Oral                   |                      |                 | Not Reported |                |
|                                          | Methocarbamol                         |                    |                    | S               | Oral                   |                      |                 | Not Reported |                |
|                                          | Oxycodone                             |                    |                    | S               | Oral                   |                      |                 | Not Reported |                |
|                                          | Lorazepam                             |                    |                    | S               | Oral                   |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                 | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Feb-2015                              | 10961506                              | EXPEDITED (15-DAY) |                    | DE              | US-APOTEX-2015AP005836 |                      | 51 YR           | Female       | USA            |
| <u>Preferred Term</u>                    | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                   |                             |   |      |              |
|-------------------|-----------------------------|---|------|--------------|
| Completed Suicide | Escitalopram Oxalate        | S | Oral | Apotex       |
|                   | Verapamil Hydrochloride     | S | Oral | Apotex       |
|                   | Topiramate                  | S | Oral | Apotex       |
|                   | Diclofenac Potassium        | S | Oral | Apotex       |
|                   | Promethazine                | S | Oral | Not Reported |
|                   | Acetaminophen W/Hydrocodone | S | Oral | Not Reported |
|                   | Diazepam                    | S | Oral | Not Reported |
|                   | Esomeprazole                | S | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------|----------------------|------------|------------|----------------|
| 05-Feb-2015              | 10961507      | EXPEDITED (15-DAY) |                    | DE, HO          | US-APOTEX-2015AP005837 |                      | 74 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u>             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Death                 | Escitalopram Oxalate       |              |            | S           | Unknown      |                    |                 | Apotex       |
|                       | Atenolol                   |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Benzodiazepine Derivatives |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Primidone                  |              |            | S           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------|----------------------|------------|------------|----------------|
| 05-Feb-2015              | 10961508      | EXPEDITED (15-DAY) |                    | DE, HO          | US-APOTEX-2015AP005839 |                      | 37 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Escitalopram Oxalate |              |            | S           | Oral         |                    |                 | Apotex       |
|                       | Meloxicam            |              |            | S           | Oral         |                    |                 | Apotex       |
|                       | Loperamide           |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------|----------------------|------------|------------|----------------|
| 05-Feb-2015              | 10961604      | EXPEDITED (15-DAY) |                    | DE              | US-APOTEX-2015AP005943 |                      | 67 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                             |                        |   |     |              |
|-------------------------------------------------------------|------------------------|---|-----|--------------|
| Aspiration; Completed<br>Suicide; Exposure Via<br>Ingestion | Lamotrigine            | S | Unk | Apotex       |
|                                                             | Zonisamide             | S | Unk | Apotex       |
|                                                             | Escitalopram Oxalate   | S |     | Apotex       |
|                                                             | Lovastatin Tablets Usp | S | Unk | Apotex       |
|                                                             | Lorazepam              | S |     | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 05-Feb-2015              | 10962902      | EXPEDITED (15-DAY) |                    | DE, HO, OT      | US-APOTEX-<br>2015AP005947 |                      | 62 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Lamotrigine          |              |            | S           | Oral         |                    |                 | Apotex       |
|                       | Escitalopram Oxalate |              |            | S           | Oral         |                    |                 | Apotex       |
|                       | Temazepam            |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Lorazepam            |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Primidone            |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Benzotropine         |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 05-Feb-2015              | 10962994      | EXPEDITED (15-DAY) |                    | DE              | US-APOTEX-<br>2015AP006006 |                      | 41 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u>                                      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-----------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Olanzapine                                          |              |            | S           | Oral         |                    |                 | Apotex       |
|                       | Acetaminophen<br>W/Diphenhydramine<br>Hydrochloride |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Warfarin                                            |              |            | S           |              |                    |                 | Not Reported |
|                       | Lisinopril                                          |              |            | S           | Oral         |                    |                 | Apotex       |
|                       | Escitalopram Oxalate                                |              |            | S           | Oral         |                    |                 | Apotex       |
|                       | Prednisone                                          |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 05-Feb-2015              | 10963091      | EXPEDITED (15-DAY) |                    | DE              | US-APOTEX-<br>2015AP006080 |                      | 43 YR      | Female     | USA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u> | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Death                 | Sertraline Hydrochloride |              |            | S           | Oral         |                    |                 | Apotex       |
|                       | Escitalopram Oxalate     |              |            | S           | Oral         |                    |                 | Apotex       |
|                       | Atomoxetine              |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------|----------------------|------------|------------|----------------|
| 05-Feb-2015              | 10963160      | EXPEDITED (15-DAY) |                    | DE, HO          | US-APOTEX-2015AP006141 |                      | 34 YR      | Female     | USA            |

| <u>Preferred Term</u>                           | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------|-----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardio-Respiratory Arrest;<br>Completed Suicide | Tramadol Hydrochloride      |              |            | S           |              |                    |                 | Apotex       |
|                                                 | Tramadol Hydrochloride      |              |            | S           |              |                    |                 | Apotex       |
|                                                 | Escitalopram Oxalate        |              |            | S           |              |                    |                 | Apotex       |
|                                                 | Gabapentin                  |              |            | S           |              |                    |                 | Apotex       |
|                                                 | Ondansetron Hydrochloride   |              |            | S           |              |                    |                 | Apotex       |
|                                                 | Sertraline Hydrochloride    |              |            | S           |              |                    |                 | Apotex       |
|                                                 | Zolpidem Tartrate           |              |            | S           |              |                    |                 | Apotex       |
|                                                 | Amitriptyline               |              |            | S           |              |                    |                 | Not Reported |
|                                                 | Acetaminophen W/Hydrocodone |              |            | S           |              |                    |                 | Not Reported |
|                                                 | Linaclotide                 |              |            | S           |              |                    |                 | Not Reported |
|                                                 | Diclofenac                  |              |            | S           |              |                    |                 | Not Reported |
|                                                 | Lubiprostone                |              |            | S           |              |                    |                 | Not Reported |
|                                                 | Liothyronine                |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------|----------------------|------------|------------|----------------|
| 05-Feb-2015              | 10963240      | EXPEDITED (15-DAY) |                    | DE, HO          | US-APOTEX-2015AP006196 |                      | 36 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Verapamil Hydrochloride |              |            | S           | Oral         |                    |                 | Apotex       |
|                       | Escitalopram Oxalate    |              |            | S           | Oral         |                    |                 | Apotex       |
|                       | Topiramate              |              |            | S           | Oral         |                    |                 | Apotex       |
|                       | Codeine                 |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------|----------------------|------------|------------|----------------|
| 05-Feb-2015              | 10963281      | EXPEDITED (15-DAY) |                    | DE              | US-APOTEX-2015AP006235 |                      | 32 YR      | Male       | USA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Zolpidem Tartrate    |              |            | S           | Oral         |                    |                 | Apotex       |
|                       | Escitalopram Oxalate |              |            | S           | Oral         |                    |                 | Apotex       |
|                       | Ethanol              |              |            | S           |              |                    |                 | Not Reported |
|                       | Carbon Monoxide      |              |            | S           |              |                    |                 | Not Reported |
|                       | Methamphetamine      |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 06-Feb-2015              | 10769462      | EXPEDITED (15-DAY) |                    | DE, OT          | US-<br>ELI_LILLY_AND_COMP<br>ANY-US201502000747 |                      | 48 YR      | Female     | USA            |

| <u>Preferred Term</u>     | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardio-Respiratory Arrest | Cephalexin Hydrochloride |              |            | S           | Unknown      |                    |                 | Unknown      |
|                           | Oxycodone                |              |            | S           |              |                    |                 | Not Reported |
|                           | Cyclobenzaprine          |              |            | S           | Unknown      |                    |                 | Not Reported |
|                           | Metoprolol               |              |            | S           | Unknown      |                    |                 | Not Reported |
|                           | Clonidine                |              |            | S           | Unknown      |                    |                 | Not Reported |
|                           | Nitroglycerin            |              |            | S           | Unknown      |                    |                 | Not Reported |
|                           | Lisinopril               |              |            | S           | Unknown      |                    |                 | Not Reported |
|                           | Escitalopram             |              |            | S           | Unknown      |                    |                 | Not Reported |
|                           | Ibuprofen                |              |            | S           | Unknown      |                    |                 | Not Reported |
|                           | Diclofenac               |              |            | S           | Unknown      |                    |                 | Not Reported |
|                           | Azithromycin             |              |            | S           | Unknown      |                    |                 | Not Reported |
|                           | Doxycycline              |              |            | S           | Unknown      |                    |                 | Not Reported |
|                           | Methylprednisolone       |              |            | S           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 06-Feb-2015              | 10769497      | EXPEDITED (15-DAY) |                    | DE              | US-PERRIGO-<br>15US001376 |                      | 62 YR      | Male       | USA            |

| <u>Preferred Term</u>    | <u>Product</u>                          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--------------------------|-----------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Completed Suicide; Death | Lorazepam Concentrate Rx 2<br>Mg/ML 1j9 |              |            | S           | Oral         | Unknown, Unknown   |                 | Perrigo    |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                         |   |      |                  |              |
|-----------------------------------------|---|------|------------------|--------------|
| Temazepam                               | S | Oral | Unknown, Unknown | Not Reported |
| Primidone                               | S | Oral | Unknown, Unknown | Not Reported |
| Lamotrigine                             | S | Oral | Unknown, Unknown | Not Reported |
| Escitalopram                            | S | Oral | Unknown, Unknown | Not Reported |
| Benzotropine                            | S | Oral | Unknown, Unknown | Not Reported |
| Lipid Modifying Agents,<br>Combinations | S | Oral | Unknown, Unknown | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|------------------------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 06-Feb-2015              | 10769876                           | EXPEDITED (15-DAY) |                    | DE              | US-PERRIGO-15US001241 |                      | 48 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Death                    | Ibuprofen 200 Mg 604               |                    |                    | S               | Unknown               | Unknown, Unknown     |                 | Perrigo      |                |
|                          | Nitroglycerin Rx 400 Mcg/Spray 8a5 |                    |                    | S               | Unknown               | Unknown, Unknown     |                 | Perrigo      |                |
|                          | Oxycodone                          |                    |                    | S               | Unknown               | Unknown, Unknown     |                 | Not Reported |                |
|                          | Cyclobenzaprine                    |                    |                    | S               | Unknown               | Unknown, Unknown     |                 | Not Reported |                |
|                          | Metoprolol                         |                    |                    | S               | Unknown               | Unknown, Unknown     |                 | Not Reported |                |
|                          | Clonidine                          |                    |                    | S               | Unknown               |                      |                 | Not Reported |                |
|                          | Lisinopril                         |                    |                    | S               | Unknown               | Unknown, Unknown     |                 | Not Reported |                |
|                          | Escitalopram                       |                    |                    | S               | Unknown               | Unknown, Unknown     |                 | Not Reported |                |
|                          | Diclofenac                         |                    |                    | S               | Unknown               | Unknown, Unknown     |                 | Not Reported |                |
|                          | Azithromycin                       |                    |                    | S               | Unknown               | Unknown, Unknown     |                 | Not Reported |                |
|                          | Cephalexin /00145501/              |                    |                    | S               | Unknown               | Unknown, Unknown     |                 | Not Reported |                |
|                          | Doxycycline                        |                    |                    | S               | Unknown               | Unknown, Unknown     |                 | Not Reported |                |
|                          | Methylprednisolone                 |                    |                    | S               | Unknown               | Unknown, Unknown     |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 06-Feb-2015              | 10771166       | NON-EXPEDITED    |                    |                 | US-ACORDA-ACO_104272_2014 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|          |         |   |         |                 |              |
|----------|---------|---|---------|-----------------|--------------|
| Alopecia | Ampyra  | S | Unknown | 10 Mg, Q 12 Hrs | Acorda       |
|          | Lexapro | S | Unknown |                 | Not Reported |
|          | Zoloft  | C | Unknown | Unk             | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 06-Feb-2015              | 10771526      | EXPEDITED (15-DAY) |                    | OT              | US-ACTAVIS-2015-01217 |                      | 15 YR      | Female     | USA            |

| <u>Preferred Term</u>                                     | <u>Product</u>                                       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------|------------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Acanthosis Nigricans;<br>Amenorrhoea; Weight<br>Increased | Aripiprazole (Unknown)                               |              |            | S           | Unknown      | 20 Mg, Unknown     |                 | Not Reported |
|                                                           | Aripiprazole (Unknown)                               |              |            | S           | Unknown      | 15 Mg, Unknown     |                 | Not Reported |
|                                                           | Bupropion Hydrochloride<br>(Actavis Laboratories FI) |              |            | S           | Unknown      | 100 Mg, Daily      |                 | Actavis      |
|                                                           | Bupropion Hydrochloride<br>(Actavis Laboratories FI) |              |            | S           |              |                    |                 | Actavis      |
|                                                           | Escitalopram (Unknown)                               |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                                                           | Escitalopram (Unknown)                               |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------------------------|----------------------|------------|------------|----------------|
| 07-Feb-2015              | 10772379      | EXPEDITED (15-DAY) |                    | DE              | US-LUPIN<br>PHARMACEUTICALS<br>INC.-2015-00102 |                      | 41 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Acetaminophen/Diphenhydramine |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Warfarin                      |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Olanzapine                    |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Lisinopril                    |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Escitalopram                  |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Prednisone                    |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------------------------|----------------------|------------|------------|----------------|
| 07-Feb-2015              | 10772422      | EXPEDITED (15-DAY) |                    | DE              | US-LUPIN<br>PHARMACEUTICALS<br>INC.-2015-00114 |                      | 48 YR      | Female     | USA            |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u> | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|--------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Death                 | Oxycodone          |              |            | S           |              |                    |                 | Not Reported |
|                       | Cyclobenzaprine    |              |            | S           |              |                    |                 | Not Reported |
|                       | Metoprolol         |              |            | S           |              |                    |                 | Not Reported |
|                       | Clonidine          |              |            | S           |              |                    |                 | Not Reported |
|                       | Nitroglycerin      |              |            | S           |              |                    |                 | Not Reported |
|                       | Lisinopril         |              |            | S           |              |                    |                 | Not Reported |
|                       | Escitalopram       |              |            | S           |              |                    |                 | Not Reported |
|                       | Ibuprofen          |              |            | S           |              |                    |                 | Not Reported |
|                       | Diclofenac         |              |            | S           |              |                    |                 | Not Reported |
|                       | Azithromycin       |              |            | S           |              |                    |                 | Not Reported |
|                       | Cephalexin         |              |            | S           |              |                    |                 | Not Reported |
|                       | Doxycycline        |              |            | S           |              |                    |                 | Not Reported |
|                       | Methylprednisolone |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-------------------------------|----------------------|------------|------------|----------------|
| 07-Feb-2015              | 10772445      | NON-EXPEDITED    |                    |                 | US-ACORDA-<br>ACO_105650_2014 |                      | 58 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Ineffective For<br>Unapproved Indication;<br>Gastrointestinal Disorder | Ampyra         |              |            | S           | Oral         | 10 Mg, Bid         |                 | Acorda       |
|                                                                             | Ampyra         |              |            | S           |              |                    |                 | Acorda       |
|                                                                             | Lexapro        |              |            | S           | Oral         | 20 Mg, Qd          |                 | Not Reported |
|                                                                             | Coq10          |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                                                                             | Concerta       |              |            | S           | Oral         | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 09-Feb-2015              | 10432127      | EXPEDITED (15-DAY) |                    | LT              | FR-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>21343223 |                      | 52 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                                                                                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>           |
|---------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|------------------------|-----------------|----------------------|
| Acute Kidney Injury;<br>Anaemia; Atrial Fibrillation;<br>Bacteraemia;<br>Gastrointestinal<br>Haemorrhage;<br>Hypotension; | Coumadin       |              |            | S           | Oral         | Last Dose On: 11aug14. |                 | Bristol Myers Squibb |
|                                                                                                                           | Seroplex       |              |            | S           | Oral         | Last Dose On: 11aug14. |                 | Not Reported         |
|                                                                                                                           | Efferalgan     |              |            | C           | Unknown      |                        |                 | Bristol Myers Squibb |
|                                                                                                                           | Tramadol       |              |            | C           | Unknown      |                        |                 | Not Reported         |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                             |           |   |         |              |
|---------------------------------------------|-----------|---|---------|--------------|
| Hypothermia; International Normalised Ratio | Nasacor T | C | Unknown | Not Reported |
| Increased; Ischaemic                        | Seresta   | C | Unknown | Not Reported |
| Hepatitis; Muscle                           | Mopral    | C | Unknown | Not Reported |
| Haemorrhage; Oedema                         | Arixtra   | C | Unknown | Not Reported |
| Peripheral                                  |           |   |         |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------------------------|----------------------|------------|------------|----------------|
| 09-Feb-2015              | 10731660      | EXPEDITED (15-DAY) |                    | DE              | US-PAR<br>PHARMACEUTICAL,<br>INC.-2015SCPR010195 |                      | 32 YR      | Male       | USA            |

| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|----------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Completed Suicide; Death | Zolpidem Tartrate Er |              |            | S           |              | Unk, Unknown, Ingst+<br>Inhal |                 | Par          |
|                          | Ethanol              |              |            | S           |              | Unk, Unknown, Ingst+<br>Inhal |                 | Not Reported |
|                          | Methamphetamine      |              |            | S           |              | Unk, Unknown, Ingst+<br>Inhal |                 | Not Reported |
|                          | Carbon Monoxide      |              |            | S           |              | Unk, Unknown, Ingst+<br>Inhal |                 | Not Reported |
|                          | Escitaopram          |              |            | S           |              | Unk, Unknown, Ingst+<br>Inhal |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------------------------|----------------------|------------|------------|----------------|
| 09-Feb-2015              | 10774379      | EXPEDITED (15-DAY) |                    | DE              | US-LUPIN<br>PHARMACEUTICALS<br>INC.-2015-00158 |                      | 67 YR      | Male       | USA            |

| <u>Preferred Term</u>                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide;<br>Toxicity To Various Agents | Lamotrigine    |              |            | S           |              |                    |                 | Not Reported |
|                                                  | Zonisamide     |              |            | S           |              |                    |                 | Not Reported |
|                                                  | Lorazepam      |              |            | S           |              |                    |                 | Not Reported |
|                                                  | Escitalopram   |              |            | S           |              |                    |                 | Not Reported |
|                                                  | Lovastatin     |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>        | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------------|----------------------|------------|------------|----------------|
| 09-Feb-2015              | 10774403      | EXPEDITED (15-DAY) |                    | DE              | US-LUPIN<br>PHARMACEUTICALS |                      | 34 YR      | Female     | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

INC.-2015-00166

| <u>Preferred Term</u> | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Amitriptyline             |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Tramadol                  |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Acetaminophen/Hydrocodone |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Ondansetron               |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Linaclotide               |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Diclofenac                |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Lubiprostone              |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Zolpidem                  |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Liothyronine              |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Escitalopram              |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Sertraline                |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Gabapentin                |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------------------------|----------------------|------------|------------|----------------|
| 09-Feb-2015              | 10774410      | EXPEDITED (15-DAY) |                    | DE              | US-LUPIN<br>PHARMACEUTICALS<br>INC.-2015-00170 |                      | 43 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Death                 | Sertraline     |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Escitalopram   |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Atomoxetine    |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Feb-2015              | 10775790      | EXPEDITED (15-DAY) |                    | OT              | NO-TEVA-538947ISR    |                      | 37 YR      | Female     | NOR            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                          |                         |                           |                             |                          |                               |                               |                          |                     |                         |
|------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Acute Febrile Neutrophilic Dermatitis    |                         | Escitalopram              |                             | S                        |                               | Ivax                          |                          |                     |                         |
| <a href="#">FDA Received Date</a>        | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 09-Feb-2015                              | 10777239                | EXPEDITED (15-DAY)        |                             | DE                       | US-FRI-1000074240             |                               | 26 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>           | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Cardio-Respiratory Arrest;<br>Drug Abuse | Escitalopram            |                           |                             | S                        |                               |                               |                          | Forest              |                         |
|                                          | Ethanol                 |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
|                                          | Metocarbamol            |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
|                                          | Oxycodone               |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
|                                          | Lorazepam               |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>        | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 09-Feb-2015                              | 10777241                | EXPEDITED (15-DAY)        |                             | DE                       | US-FRI-1000074253             |                               | 74 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>           | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Death                                    | Escitalopram            |                           |                             | S                        |                               |                               |                          | Forest              |                         |
|                                          | Atenolol                |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
|                                          | Benzodiazepine          |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
|                                          | Primidone               |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>        | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 09-Feb-2015                              | 10777243                | EXPEDITED (15-DAY)        |                             | DE                       | US-FRI-1000074250             |                               | 43 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>           | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Death                                    | Escitalopram            |                           |                             | S                        |                               |                               |                          | Forest              |                         |
|                                          | Sertraline              |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
|                                          | Atomoxetine             |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>        | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 09-Feb-2015                              | 10777248                | EXPEDITED (15-DAY)        |                             | DE                       | US-FRI-1000074246             |                               | 48 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>           | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Cardio-Respiratory Arrest;               | Escitalopram            |                           |                             | S                        |                               |                               |                          | Forest              |                         |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|       |                    |   |              |
|-------|--------------------|---|--------------|
| Death | Oxycodone          | S | Not Reported |
|       | Cyclobenzaprine    | S | Not Reported |
|       | Metoprolol         | S | Not Reported |
|       | Clonidine          | S | Not Reported |
|       | Nitroglycerin      | S | Not Reported |
|       | Lisinopril         | S | Not Reported |
|       | Ibuprofen          | S | Not Reported |
|       | Diclofenac         | S | Not Reported |
|       | Azithromycin       | S | Not Reported |
|       | Cephalexin         | S | Not Reported |
|       | Doxycycline        | S | Not Reported |
|       | Methylprednisolone | S | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Feb-2015              | 10777251      | EXPEDITED (15-DAY) |                    | DE              | US-FRI-1000074248    |                      | 28 YR      | Female     | USA            |

| <u>Preferred Term</u>                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardio-Respiratory Arrest;<br>Completed Suicide | Escitalopram   |              |            | S           |              |                    |                 | Forest       |
|                                                 | Bupropion      |              |            | S           |              |                    |                 | Not Reported |
|                                                 | Gabapentin     |              |            | S           |              |                    |                 | Not Reported |
|                                                 | Alprazolam     |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Feb-2015              | 10779635      | DIRECT           | Y                  |                 |                      |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                                  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Product Substitution Issue;<br>Therapeutic Product Effect<br>Decreased | Escitalopram   |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Feb-2015              | 10512072      | EXPEDITED (15-DAY) |                    | HO, OT          | CA-FRI-1000071385    |                      |            | Male       | CAN            |

| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|----------------|--------------|------------|-------------|--------------|---------------------------|-----------------|--------------|
| Abdominal Pain;            | Escitalopram   |              |            | S           |              | Overdose: Unknown Dose    |                 | Forest       |
| Accidental Overdose;       | Clobazam       |              |            | S           |              | (Frequency Not Reported.) |                 | Not Reported |
| Anxiety; Asthenia; Balance |                |              |            |             |              |                           |                 |              |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                                                                 |                      |   |                                       |                          |              |
|-------------------------------------------------------------------------------------------------|----------------------|---|---------------------------------------|--------------------------|--------------|
| Disorder; Dizziness;                                                                            | Avastin              | S | Intravenous (not otherwise specified) | Overdose: 680 Mg         | Not Reported |
| Dyspnoea; Faeces Soft;                                                                          | Avastin              | S | Intravenous (not otherwise specified) | Overdose: 800 Mg         | Not Reported |
| Gait Inability; Genital Herpes; Malignant Neoplasm Progression; Mobility Decreased; Oral Herpes | Avastin              | S | Intravenous (not otherwise specified) | Overdose: 850 Mg         | Not Reported |
|                                                                                                 | Rosuvastatin Calcium | S |                                       | Overdose: Unknown Dose   | Not Reported |
|                                                                                                 | Trazodone            | S |                                       | Overdose: Unknown Dose   | Not Reported |
|                                                                                                 | Avodart              | C |                                       |                          | Not Reported |
|                                                                                                 | Dexamethasone        | C |                                       | Daily Dose Not Reported. | Not Reported |
|                                                                                                 | Docusate             | C |                                       | Daily Dose Not Reported. | Not Reported |
|                                                                                                 | Keppra               | C |                                       | Daily Dose Not Reported. | Not Reported |
|                                                                                                 | Pantoprazole         | C |                                       | Daily Dose Not Reported. | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Feb-2015              | 10512205      | EXPEDITED (15-DAY) |                    | HO              | CA-FRI-1000071390    |                      |            | Male       | CAN            |

| <u>Preferred Term</u>                          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Delusion; Qrs Axis Abnormal; Sinus Tachycardia | Escitalopram   |              |            | S           |              | 20 Mg              |                 | Forest       |
|                                                | Apo-Clozapine  |              |            | S           |              | 450 Mg             |                 | Not Reported |
|                                                | Haloperidol    |              |            | S           |              | 5 Mg               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Feb-2015              | 10514654      | EXPEDITED (15-DAY) |                    | DS              | CA-FRI-1000071384    |                      | 41 YR      | Female     | CAN            |

| <u>Preferred Term</u>                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Disturbance In Attention; Off Label Use | Escitalopram   |              |            | S           | Oral         |                    |                 | Forest     |
|                                         | Escitalopram   |              |            | S           |              |                    |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Feb-2015              | 10514656      | EXPEDITED (15-DAY) |                    | LT              | CA-FRI-1000071386    |                      | 67 YR      | Female     | CAN            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|-------------------------|-----------------|--------------|
| Asthenia; Decreased Appetite; Diarrhoea; Muscular Weakness; Nausea; Oxygen Saturation Decreased; Polyuria; Product Use In Unapproved Indication; Tremor; Vomiting | Escitalopram   |              |            | S           | Oral         | 5 Mg                    |                 | Forest       |
|                                                                                                                                                                   | Escitalopram   |              |            | S           |              |                         |                 | Forest       |
|                                                                                                                                                                   | Apo Furosemide |              |            | C           |              | 40 Mg                   |                 | Not Reported |
|                                                                                                                                                                   | Apo Alpraz     |              |            | C           |              | 3 Mg                    |                 | Not Reported |
|                                                                                                                                                                   | Euro K 20      |              |            | C           |              | 1500 Mg                 |                 | Not Reported |
|                                                                                                                                                                   | Pms_Lisinopril |              |            | C           |              | 10 Mg                   |                 | Not Reported |
|                                                                                                                                                                   | Wellbutrin     |              |            | C           |              | 300 Mg                  |                 | Not Reported |
|                                                                                                                                                                   | Lowpin         |              |            | C           |              | 80 Mg                   |                 | Not Reported |
|                                                                                                                                                                   | Apo-Lansopraz  |              |            | C           |              | 30 Mg                   |                 | Not Reported |
|                                                                                                                                                                   | Bricanyl       |              |            | C           |              | Daily Dose Not Reported |                 | Not Reported |
|                                                                                                                                                                   | Symbicort      |              |            | C           |              | Daily Dose Not Reported |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Feb-2015              | 10516407      | EXPEDITED (15-DAY) |                    | OT              | CA-FRI-1000071392    |                      | 19 YR      | Female     | CAN            |

| <u>Preferred Term</u>                                                                                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction; Generalised Tonic-Clonic Seizure; Product Use In Unapproved Indication; Simple Partial Seizures | Escitalopram   |              |            | S           | Oral         | 20 Mg              |                 | Forest       |
|                                                                                                                   | Alysena 28     |              |            | S           | Oral         | 100/20 Mcg         |                 | Not Reported |
|                                                                                                                   | Lamotrigine    |              |            | S           | Oral         | 350 Mg             |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Feb-2015              | 10531795      | EXPEDITED (15-DAY) |                    | OT              | JP-FRI-1000071522    |                      |            | Female     | JPN            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abortion; Pregnancy   | Escitalopram   |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                       | Escitalopram   |              |            | S           | Oral         | 20 Mg              |                 | Forest       |
|                       | Lexotan        |              |            | S           | Oral         | 5 Mg               |                 | Not Reported |
|                       | Solanax        |              |            | S           | Oral         | 0.4 Mg             |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|          |   |      |         |              |
|----------|---|------|---------|--------------|
| Solanax  | S | Oral | 1.2 Mg  | Not Reported |
| Halcion  | C | Oral | 0.25 Mg | Not Reported |
| Seroquel | C | Oral | 100 Mg  | Not Reported |
| Seroquel | C | Oral | 75 Mg   | Not Reported |
| Seroquel | C | Oral | 100 Mg  | Not Reported |
| Silece   | C | Oral | 2 Mg    | Not Reported |
| Landsen  | C | Oral | 3 Mg    | Not Reported |
| Landsen  | C | Oral | 3 Mg    | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------------------------|----------------------|------------|------------|----------------|
| 10-Feb-2015              | 10778570      | EXPEDITED (15-DAY) |                    | DE              | US-LUPIN<br>PHARMACEUTICALS<br>INC.-2015-00259 |                      | 37 YR      | Female     | USA            |

| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Toxicity To Various Agents | Loperamide     |              |            | S           | Oral         |                    |                 | Not Reported |
|                            | Escitalopram   |              |            | S           | Oral         |                    |                 | Not Reported |
|                            | Meloxicam      |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------------------------|----------------------|------------|------------|----------------|
| 10-Feb-2015              | 10778623      | EXPEDITED (15-DAY) |                    | DE              | US-LUPIN<br>PHARMACEUTICALS<br>INC.-2015-00187 |                      | 51 YR      | Female     | USA            |

| <u>Preferred Term</u>      | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Toxicity To Various Agents | Promethazine              |              |            | S           | Oral         |                    |                 | Not Reported |
|                            | Verapamil                 |              |            | S           | Oral         |                    |                 | Not Reported |
|                            | Escitalopram              |              |            | S           | Oral         |                    |                 | Not Reported |
|                            | Acetaminophen/Hydrocodone |              |            | S           | Oral         |                    |                 | Not Reported |
|                            | Diazepam                  |              |            | S           | Oral         |                    |                 | Not Reported |
|                            | Topiramate                |              |            | S           | Oral         |                    |                 | Not Reported |
|                            | Esomeprazole              |              |            | S           | Oral         |                    |                 | Not Reported |
|                            | Diclofenac                |              |            | S           | Oral         |                    |                 | Not Reported |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                    | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|---------------------------------------------------------------------------------------------|-----------------|--------------------|--------------------|-----------------|------------------------------------------------|-------------------------|-----------------|-----------------|----------------|
| 10-Feb-2015                                                                                 | 10778975        | EXPEDITED (15-DAY) |                    | DE              | US-LUPIN<br>PHARMACEUTICALS<br>INC.-2015-00247 |                         | 74 YR           | Male            | USA            |
| <u>Preferred Term</u>                                                                       | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>      |                |
| Death                                                                                       | Atenolol        |                    |                    | S               | Unknown                                        |                         |                 | Not Reported    |                |
|                                                                                             | Benzodiazepine  |                    |                    | S               | Unknown                                        |                         |                 | Not Reported    |                |
|                                                                                             | Escitalopram    |                    |                    | S               | Unknown                                        |                         |                 | Not Reported    |                |
|                                                                                             | Primidone       |                    |                    | S               | Unknown                                        |                         |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                    | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 10-Feb-2015                                                                                 | 10779789        | EXPEDITED (15-DAY) |                    |                 | US-<br>GLAXOSMITHKLINE-<br>A0835418A           |                         | 35 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                                       | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>      |                |
| Chest Discomfort; Chest Pain; Drug Interaction; Fatigue; Feeling Abnormal; Nausea; Vomiting | Treximet Tablet |                    |                    | S               | Oral                                           | 85/500 Mg. Single Dose. | 1 DAY           | Glaxosmithkline |                |
|                                                                                             | Treximet Tablet |                    |                    | S               |                                                |                         |                 | Not Reported    |                |
|                                                                                             | Lexapro         |                    |                    | S               | Unknown                                        |                         |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                    | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 10-Feb-2015                                                                                 | 10782133        | EXPEDITED (15-DAY) |                    | OT              | GB-TEVA-517209ISR                              |                         | 152 DAY         | Female          | GBR            |
| <u>Preferred Term</u>                                                                       | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>      |                |
| Exposure Via Breast Milk; Insomnia                                                          | Escitalopram    |                    |                    | S               | Transmammary                                   |                         |                 | Ivax            |                |
|                                                                                             | Escitalopram    |                    |                    | S               | Transmammary                                   | 20 Milligram Daily;     |                 | Ivax            |                |
| <u>FDA Received Date</u>                                                                    | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 10-Feb-2015                                                                                 | 10782796        | EXPEDITED (15-DAY) |                    | HO, LT          | CA-FRI-1000071387                              |                         | 61 YR           | Female          | CAN            |
| <u>Preferred Term</u>                                                                       | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>      |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                 |              |   |      |                                       |              |
|-----------------------------------------------------------------|--------------|---|------|---------------------------------------|--------------|
| Drug Interaction;<br>Prescribed Overdose;<br>Pulmonary Embolism | Escitalopram | S | Oral | 10 Mg                                 | Forest       |
|                                                                 | Escitalopram | S | Oral | 20 Mg                                 | Forest       |
|                                                                 | Escitalopram | S | Oral | Overdose: Escitalopram<br>30 Mg Daily | Forest       |
|                                                                 | Remeron      | S | Oral | 30 Mg                                 | Not Reported |
|                                                                 | Remeron      | S | Oral | 45 Mg                                 | Not Reported |
|                                                                 | Remeron      | S | Oral | 15 Mg                                 | Not Reported |
|                                                                 | Abilify      | C |      | 5 Mg                                  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|--------------------------|---------------------------------------|--------------------|--------------------|-----------------|--------------------------------------|----------------------|-----------------|-----------------|----------------|
| 10-Feb-2015              | 10782997                              | EXPEDITED (15-DAY) |                    |                 | US-<br>GLAXOSMITHKLINE-<br>A1081750A |                      |                 | Unknown         | USA            |
| <u>Preferred Term</u>    | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Drug Ineffective         | Proventil Inhaler Inhalational Powder |                    |                    | S               | Unknown                              |                      |                 | Glaxosmithkline |                |
|                          | Zoloft                                |                    |                    | S               | Unknown                              |                      |                 | Glaxosmithkline |                |
|                          | Fluoxetine                            |                    |                    | S               | Unknown                              |                      |                 | Glaxosmithkline |                |
|                          | Quetiapine Fumarate                   |                    |                    | S               | Unknown                              |                      |                 | Glaxosmithkline |                |
|                          | Sertraline Hcl Tablet                 |                    |                    | S               | Unknown                              |                      |                 | Glaxosmithkline |                |
|                          | Escitalopram Oxalate                  |                    |                    | S               | Unknown                              |                      |                 | Glaxosmithkline |                |
|                          | Methadone                             |                    |                    | S               | Unknown                              |                      |                 | Glaxosmithkline |                |
|                          | Morphine                              |                    |                    | S               | Unknown                              |                      |                 | Glaxosmithkline |                |
|                          | Lidoderm                              |                    |                    | S               | Unknown                              |                      |                 | Glaxosmithkline |                |
|                          | Spiriva                               |                    |                    | C               |                                      |                      |                 | Not Reported    |                |
|                          | Ventolin                              |                    |                    | C               |                                      |                      |                 | Not Reported    |                |
|                          | Tudorza                               |                    |                    | C               |                                      |                      |                 | Not Reported    |                |
|                          | Lexapro                               |                    |                    | C               |                                      |                      |                 | Not Reported    |                |
|                          | Viibryd                               |                    |                    | C               |                                      |                      |                 | Not Reported    |                |
|                          | Amitriptyline                         |                    |                    | C               |                                      |                      |                 | Not Reported    |                |
|                          | Fentanyl                              |                    |                    | C               |                                      |                      |                 | Not Reported    |                |
|                          | Oxycodone                             |                    |                    | C               |                                      |                      |                 | Not Reported    |                |
|                          | Avinza                                |                    |                    | C               |                                      |                      |                 | Not Reported    |                |
|                          | Trazodone                             |                    |                    | C               |                                      |                      |                 | Not Reported    |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                        |                |                    |                    |                 |                                                 |                               |                 |              |                |
|--------------------------------------------------------|----------------|--------------------|--------------------|-----------------|-------------------------------------------------|-------------------------------|-----------------|--------------|----------------|
| Seroquel                                               |                |                    | C                  |                 |                                                 | Not Reported                  |                 |              |                |
| <u>FDA Received Date</u>                               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Feb-2015                                            | 10783672       | EXPEDITED (15-DAY) |                    | OT              | DE-FRI-1000074405                               |                               | 71 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;<br>Intraocular Pressure<br>Increased | Escitalopram   |                    |                    | S               | Oral                                            |                               |                 | Forest       |                |
|                                                        | Quetiapine     |                    |                    | S               | Unknown                                         |                               |                 | Not Reported |                |
|                                                        | Tebonin        |                    |                    | S               | Unknown                                         | 240 Mg                        |                 | Not Reported |                |
|                                                        | Euthyrox       |                    |                    | C               | Unknown                                         | 100 Mcg                       |                 | Not Reported |                |
|                                                        | Ibuprofen      |                    |                    | C               | Unknown                                         | 1200 Mg                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Feb-2015                                            | 10720029       | EXPEDITED (15-DAY) |                    | DE              | US-PAR<br>PHARMACEUTICAL,<br>INC-2015SCPR009604 |                               | 67 YR           | Male         | USA            |
| <u>Preferred Term</u>                                  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Death                               | Lamotrigine    |                    |                    | S               |                                                 | Unk, Unknown, Ingst+<br>Aspir |                 | Par          |                |
|                                                        | Zonisamide     |                    |                    | S               |                                                 | Unk, Unknown, Ingst+<br>Aspir |                 | Not Reported |                |
|                                                        | Lorazepam      |                    |                    | S               |                                                 | Unk, Unknown, Ingst+<br>Aspir |                 | Not Reported |                |
|                                                        | Escitalopram   |                    |                    | S               |                                                 | Unk, Unknown, Ingst+<br>Aspir |                 | Not Reported |                |
|                                                        | Lovastatin     |                    |                    | S               |                                                 | Unk, Unknown, Ingst+<br>Aspir |                 | Not Reported |                |
| <u>FDA Received Date</u>                               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Feb-2015                                            | 10720441       | EXPEDITED (15-DAY) |                    | DE              | US-PAR<br>PHARMACEUTICAL,<br>INC-2015SCPR009609 |                               | 62 YR           | Male         | USA            |
| <u>Preferred Term</u>                                  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                          |                    |   |      |              |              |
|--------------------------|--------------------|---|------|--------------|--------------|
| Completed Suicide; Death | Lamotrigine        | S | Oral | Unk, Unknown | Par          |
|                          | Temazepam          | S | Oral | Unk, Unknown | Not Reported |
|                          | Lorazepam          | S | Oral | Unk, Unknown | Not Reported |
|                          | Primidone          | S | Oral | Unk, Unknown | Not Reported |
|                          | Escitalopram       | S | Oral | Unk, Unknown | Not Reported |
|                          | Benzotropine       | S | Oral | Unk, Unknown | Not Reported |
|                          | Antihyperlipidemic | S | Oral | Unk, Unknown | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 11-Feb-2015              | 10722282      | EXPEDITED (15-DAY) |                    | DE              | US-PAR<br>PHARMACEUTICAL,<br>INC-2015SCPR009627 |                      | 48 YR      | Female     | USA            |

| <u>Preferred Term</u>                                              | <u>Product</u>  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------|-----------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Cardio-Respiratory Arrest;<br>Death; Toxicity To Various<br>Agents | Clonidine       |              |            | S           |              | Unk, Unknown, Ingst+<br>Inhal |                 | Par          |
|                                                                    | Ibuprofen       |              |            | S           |              | Unk, Unknown, Ingst+<br>Inhal |                 | Par          |
|                                                                    | Doxycycline     |              |            | S           |              | Unk, Unknown, Ingst+<br>Inhal |                 | Par          |
|                                                                    | Oxycodone       |              |            | S           |              | Unk, Unknown, Ingst+<br>Inhal |                 | Not Reported |
|                                                                    | Cyclobenzaprine |              |            | S           |              | Unk, Unknown, Ingst+<br>Inhal |                 | Not Reported |
|                                                                    | Metoprolol      |              |            | S           |              | Unk, Unknown, Ingst+<br>Inhal |                 | Not Reported |
|                                                                    | Nitroglycerin   |              |            | S           |              | Unk, Unknown, Ingst+<br>Inhal |                 | Not Reported |
|                                                                    | Lisinopril      |              |            | S           |              | Unk, Unknown, Ingst+<br>Inhal |                 | Not Reported |
|                                                                    | Escitalopram    |              |            | S           |              | Unk, Unknown, Ingst+<br>Inhal |                 | Not Reported |
|                                                                    | Diclofenac      |              |            | S           |              | Unk, Unknown, Ingst+<br>Inhal |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                       |   |                               |              |
|-----------------------|---|-------------------------------|--------------|
| Azithromycin          | S | Unk, Unknown, Ingst+<br>Inhal | Not Reported |
| Cephalexin /00145501/ | S | Unk, Unknown, Ingst+<br>Inhal | Not Reported |
| Methylprednisolone    | S | Unk, Unknown, Ingst+<br>Inhal | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 11-Feb-2015              | 10770819       | EXPEDITED (15-DAY) |                    | HO              | IT-FRI-1000074099    |                      | 80 YR           | Female       | ITA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Overdose                 | Escitalopram   |                    |                    | S               | Oral                 | 10 Mg Daily          |                 | Forest       |                |
|                          | Xanax          |                    |                    | S               | Oral                 | 10 Drops Daily       |                 | Not Reported |                |
|                          | Metformine     |                    |                    | C               | Unknown              |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>   | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------|-----------------|--------------------|--------------------|-----------------|------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 11-Feb-2015                | 10784144        | EXPEDITED (15-DAY) |                    | DE              | US-LUPIN<br>PHARMACEUTICALS<br>INC.-2015-00295 |                      | 32 YR           | Male         | USA            |
| <u>Preferred Term</u>      | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Toxicity To Various Agents | Zolpidem        |                    |                    | S               | Oral                                           |                      |                 | Not Reported |                |
|                            | Methamphetamine |                    |                    | S               | Oral                                           |                      |                 | Not Reported |                |
|                            | Escitalopram    |                    |                    | S               | Oral                                           |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------|----------------|--------------------|--------------------|-----------------|------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 11-Feb-2015                | 10784203       | EXPEDITED (15-DAY) |                    | DE              | US-LUPIN<br>PHARMACEUTICALS<br>INC.-2015-00316 |                      | 62 YR           | Male         | USA            |
| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Toxicity To Various Agents | Temazepam      |                    |                    | S               | Oral                                           |                      |                 | Not Reported |                |
|                            | Lorazepam      |                    |                    | S               | Oral                                           |                      |                 | Not Reported |                |
|                            | Primidone      |                    |                    | S               | Oral                                           |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|              |   |      |              |
|--------------|---|------|--------------|
| Lamotrigine  | S | Oral | Not Reported |
| Escitalopram | S | Oral | Not Reported |
| Benzotropine | S | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Feb-2015              | 10784263      | EXPEDITED (15-DAY) |                    | HO              | CA-ROCHE-1536061     |                      | 54 YR      | Female     | CAN            |

| <u>Preferred Term</u>                                               | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Condition Aggravated;<br>Dehydration; Dysphagia;<br>Mental Disorder | Clonazepam           |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                     | Cipraxel             |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                     | Domperidone          |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                     | Ferrous Sulphate     |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                     | Gabapentin           |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                     | Gabapentin           |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                     | Temazepam            |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                     | Tylenol With Codeine |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                     | Wellbutrin XL        |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------------------------|----------------------|------------|------------|----------------|
| 11-Feb-2015              | 10784453      | EXPEDITED (15-DAY) |                    | DE              | US-LUPIN<br>PHARMACEUTICALS<br>INC.-2015-00050 |                      | 26 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Abuse            | Escitalopram   |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Methocarbamol  |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Oxycodone      |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Lorazepam      |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|------------|------------|----------------|
| 11-Feb-2015              | 10785752      | EXPEDITED (15-DAY) |                    | OT              | IT-MYLANLABS-<br>2015M1002716 |                      |            | Unknown    | ITA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                    | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|--------------------------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|-----------------|--------------|----------------|
| Drug Ineffective;<br>Restlessness; Sleep<br>Disorder                     | Escitalopram Oxalate          |                    |                    | S               |                                | Unk, Qd              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                 | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Feb-2015                                                              | 10786351                      | EXPEDITED (15-DAY) |                    | HO              | CN-FRI-1000074354              |                      |                 | Female       | CHN            |
| <u>Preferred Term</u>                                                    | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Loss Anaemia;<br>Melaena; Upper<br>Gastrointestinal<br>Haemorrhage | Escitalopram                  |                    |                    | S               | Oral                           | 10 Mg                |                 | Forest       |                |
|                                                                          | Marcoumar                     |                    |                    | S               | Oral                           |                      |                 | Not Reported |                |
|                                                                          | Humalog                       |                    |                    | C               |                                |                      |                 | Not Reported |                |
|                                                                          | Atorvastatin                  |                    |                    | C               |                                |                      |                 | Not Reported |                |
|                                                                          | Beloc-Zok                     |                    |                    | C               |                                |                      |                 | Not Reported |                |
|                                                                          | Spasmo-Canulase               |                    |                    | C               |                                |                      |                 | Not Reported |                |
|                                                                          | Stilnox                       |                    |                    | C               |                                |                      |                 | Not Reported |                |
|                                                                          | Amlodipin                     |                    |                    | C               |                                |                      |                 | Not Reported |                |
|                                                                          | Torem                         |                    |                    | C               |                                |                      |                 | Not Reported |                |
|                                                                          | Esomep                        |                    |                    | C               |                                |                      |                 | Not Reported |                |
|                                                                          | Kinzalplus                    |                    |                    | C               |                                |                      |                 | Not Reported |                |
|                                                                          | Novalgine (Metamizole Sodium) |                    |                    | C               |                                |                      |                 | Not Reported |                |
|                                                                          | Berocca Ca Mg                 |                    |                    | C               |                                |                      |                 | Not Reported |                |
|                                                                          | Vi De3                        |                    |                    | C               |                                |                      |                 | Not Reported |                |
|                                                                          | Paragol N                     |                    |                    | C               |                                |                      |                 | Not Reported |                |
|                                                                          | Palladon                      |                    |                    | C               |                                |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                 | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Feb-2015                                                              | 10786683                      | EXPEDITED (15-DAY) |                    | DE              | US-MALLINCKRODT-<br>T201500700 |                      | 51 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                    | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                                        | Acetaminophen\Hydrocodone     |                    |                    | S               | Oral                           | Unk                  |                 | Mallinckrodt |                |
|                                                                          | Bitartrate                    |                    |                    |                 |                                |                      |                 |              |                |
|                                                                          | Promethazine                  |                    |                    | S               | Oral                           | Unk                  |                 | Not Reported |                |
|                                                                          | Verapamil                     |                    |                    | S               | Oral                           | Unk                  |                 | Not Reported |                |
|                                                                          | Escitalopram                  |                    |                    | S               | Oral                           | Unk                  |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|              |   |      |              |
|--------------|---|------|--------------|
| Diazepam     | S | Oral | Not Reported |
| Topiramate   | S | Oral | Not Reported |
| Esomeprazole | S | Oral | Not Reported |
| Diclofenac   | S | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 12-Feb-2015              | 10723238      | EXPEDITED (15-DAY) |                    | DE              | US-PAR<br>PHARMACEUTICAL,<br>INC-2015SCPR010142 |                      | 41 YR      | Male       | USA            |

| <u>Preferred Term</u>    | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|-----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide; Death | Olanzapine            |              |            | S           | Oral         | Unk, Unknown       |                 | Par          |
|                          | Acetaminophen         |              |            | S           | Oral         | Unk, Unknown       |                 | Not Reported |
|                          | W/Diphenhydramine     |              |            |             |              |                    |                 |              |
|                          | Hydrochloride         |              |            |             |              |                    |                 |              |
|                          | Warfarin              |              |            | S           | Oral         | Unk, Unknown       |                 | Not Reported |
|                          | Lisinopril            |              |            | S           | Oral         | Unk, Unknown       |                 | Not Reported |
|                          | Escitalopram          |              |            | S           | Oral         | Unk, Unknown       |                 | Not Reported |
|                          | Prednisone /00044702/ |              |            | S           | Oral         | Unk, Unknown       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Feb-2015              | 10789564      | EXPEDITED (15-DAY) |                    | OT              | NO-FRI-1000074391    |                      |            | Female     | NOR            |

| <u>Preferred Term</u>                                                                                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Delusion;<br>Depression; Mania;<br>Substance-Induced<br>Psychotic Disorder;<br>Suicidal Ideation | Escitalopram   |              |            | S           | Unknown      |                    |                 | Forest       |
|                                                                                                           | Lamicta        |              |            | S           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Feb-2015              | 9610901       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000049829    |                      | 24 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|             |              |   |      |      |  |              |
|-------------|--------------|---|------|------|--|--------------|
| Neutropenia | Escitalopram | S | Oral |      |  | Forest       |
|             | Zyprexa      | S | Oral | 1 Df |  | Not Reported |
|             | Lorazepam    | C |      |      |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 13-Feb-2015              | 10792064      | EXPEDITED (15-DAY) |                    | DE              | US-MALLINCKRODT-T201500738 |                      | 62 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Temazepam      |              |            | S           | Oral         | Unk                |                 | Tyco         |
|                       | Lorazepam      |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                       | Primidone      |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                       | Lamotrigine    |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                       | Escitalopram   |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Benzotropine   |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Feb-2015              | 10792545      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000074458    |                      | 48 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                 | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------|----------------|--------------|------------|-------------|--------------|----------------------------------------------------|-----------------|--------------|
| Altered State Of Consciousness; Intentional Overdose | Escitalopram   |              |            | S           | Oral         | 10 Mg                                              |                 | Forest       |
|                                                      | Escitalopram   |              |            | S           | Oral         | Overdose 280 Mg Once.                              |                 | Forest       |
|                                                      | Seresta        |              |            | S           | Oral         | 20 To 30 Mg                                        |                 | Not Reported |
|                                                      | Seresta        |              |            | S           | Oral         | Overdose 600 Mg Once.                              |                 | Not Reported |
|                                                      | Ethanol        |              |            | S           | Oral         | Anise-Flavored Spirit, Half Bottle Of Gin And Wine |                 | Not Reported |
|                                                      | Aotal          |              |            | C           | Oral         | 1998 Mg                                            |                 | Not Reported |
|                                                      | Aotal          |              |            | C           | Oral         | Overdose: 6,660 Mg Once.                           |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|------------|------------|----------------|
| 13-Feb-2015              | 10793374      | EXPEDITED (15-DAY) |                    | OT              | GB-AUROBINDO-AUR-APL-2015-01172 |                      | 152 DAY    | Female     | GBR            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                               | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------------------------------------------------------|----------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Exposure Via Breast Milk;<br>Insomnia                                               | Escitalopram Tablets             |                    |                    | S               | Transmammary         | 10 Mg, Once A Day    |                 | Aurobindo    |                |
|                                                                                     | Escitalopram Tablets             |                    |                    | S               | Transmammary         | 20 Mg, Daily         |                 | Aurobindo    |                |
| <u>FDA Received Date</u>                                                            | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Feb-2015                                                                         | 10793491                         | EXPEDITED (15-DAY) |                    | DE              | CHPA2015US001885     |                      | 41 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                               | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                                                   | Acetaminophen,                   |                    | Y                  | S               | Oral                 | Unk                  |                 | Novartis     |                |
|                                                                                     | Diphenhydramine Citrate          |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                     | Warfarin                         |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                     | Olanzapine                       |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                     | Lisinopril                       |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                     | Escitalopram                     |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                     | Prednisone                       |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                            | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Feb-2015                                                                         | 10794882                         | EXPEDITED (15-DAY) |                    | DE              | IT-FRI-1000074548    |                      |                 | Male         | ITA            |
| <u>Preferred Term</u>                                                               | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                                                   | Escitalopram Oral Solution       |                    |                    | S               | Oral                 | 5 Mg                 |                 | Forest       |                |
|                                                                                     | Escitalopram Oral Solution       |                    |                    | S               |                      |                      |                 | Forest       |                |
|                                                                                     | Minias                           |                    |                    | C               | Oral                 | 3 Dosage Forms       |                 | Not Reported |                |
|                                                                                     | Minias                           |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                            | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Feb-2015                                                                         | 10795539                         | EXPEDITED (15-DAY) |                    | DE              | US-WATSON-2015-01981 |                      | 26 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                               | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardio-Respiratory Arrest;<br>Drug Abuse; Drug Abuse;<br>Toxicity To Various Agents | Oxycodone Hydrochloride (Aellic) |                    |                    | S               | Oral                 | Unknown              |                 | Watson       |                |
|                                                                                     | Lorazepam (Watson)               |                    |                    | S               | Oral                 | Unk                  |                 | Watson       |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                     |   |      |         |  |  |  |  |  |              |
|-------------------------------------|---|------|---------|--|--|--|--|--|--------------|
| Laboratories)                       |   |      |         |  |  |  |  |  |              |
| Escitalopram (Unknown)              | S | Oral | Unk     |  |  |  |  |  | Not Reported |
| Methocarbamol (Watson Laboratories) | S | Oral | Unk     |  |  |  |  |  | Watson       |
| Ethanol                             | S | Oral | Unknown |  |  |  |  |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Feb-2015              | 10795724      | EXPEDITED (15-DAY) |                    | DE              | US-WATSON-2015-02654 |                      | 41 YR      | Male       | USA            |

| <u>Preferred Term</u>                            | <u>Product</u>                        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------|---------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide;<br>Toxicity To Various Agents | Warfarin (Unknown)                    |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                                                  | Olanzapine (Unknown)                  |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                                                  | Lisinopril (Watson Laboratories)      |              |            | S           | Oral         | Unk                |                 | Watson       |
|                                                  | Escitalopram (Unknown)                |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                                                  | Prednisone (Watson Laboratories)      |              |            | S           | Oral         | Unk                |                 | Watson       |
|                                                  | Diphenhydramine Citrate W/Paracetamol |              |            | S           | Oral         | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 16-Feb-2015              | 10740509      | EXPEDITED (15-DAY) |                    | DE              | US-PAR<br>PHARMACEUTICAL,<br>INC-2015SCPR009642 |                      | 51 YR      | Female     | USA            |

| <u>Preferred Term</u>    | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide; Death | Verapamil                 |              |            | S           | Oral         | Unk, Unknown       |                 | Par          |
|                          | Diazepam                  |              |            | S           | Oral         | Unk, Unknown       |                 | Par          |
|                          | Promethazine              |              |            | S           | Oral         | Unk, Unknown       |                 | Not Reported |
|                          | Escitalopram              |              |            | S           | Oral         | Unk, Unknown       |                 | Not Reported |
|                          | Acetaminophen/Hydrocodone |              |            | S           | Oral         | Unk, Unknown       |                 | Not Reported |
|                          | Topiramate                |              |            | S           | Oral         | Unk, Unknown       |                 | Not Reported |
|                          | Esomeprazole              |              |            | S           | Oral         | Unk, Unknown       |                 | Not Reported |
|                          | Diclofenac                |              |            | S           | Oral         | Unk, Unknown       |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                               | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 16-Feb-2015                                            | 10740592                  | EXPEDITED (15-DAY) |                    | DE              | US-PAR<br>PHARMACEUTICAL,<br>INC-2015SCPR009652 |                      | 36 YR           | Female       | USA            |
| <u>Preferred Term</u>                                  | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Death                               | Verapamil                 |                    |                    | S               | Oral                                            | Unk, Unknown         |                 | Par          |                |
|                                                        | Escitalopram              |                    |                    | S               | Oral                                            | Unk, Unknown         |                 | Not Reported |                |
|                                                        | Codeine                   |                    |                    | S               | Oral                                            | Unk, Unknown         |                 | Not Reported |                |
|                                                        | Topiramate                |                    |                    | S               | Oral                                            | Unk, Unknown         |                 | Not Reported |                |
| <u>FDA Received Date</u>                               | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Feb-2015                                            | 10743566                  | EXPEDITED (15-DAY) |                    | DE              | US-PAR<br>PHARMACEUTICAL,<br>INC-2015SCPR009684 |                      | 28 YR           | Female       | USA            |
| <u>Preferred Term</u>                                  | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardio-Respiratory Arrest;<br>Completed Suicide; Death | Bupropion Hcl XI          |                    |                    | S               | Oral                                            | Unk, Unknown         |                 | Par          |                |
|                                                        | Alprazolam                |                    |                    | S               | Oral                                            | Unk, Unknown         |                 | Par          |                |
|                                                        | Escitalopram              |                    |                    | S               | Oral                                            | Unk, Unknown         |                 | Not Reported |                |
|                                                        | Gabapentin                |                    |                    | S               | Oral                                            | Unk, Unknown         |                 | Not Reported |                |
| <u>FDA Received Date</u>                               | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Feb-2015                                            | 10750379                  | EXPEDITED (15-DAY) |                    | DE              | US-PAR<br>PHARMACEUTICAL,<br>INC-2015SCPR010075 |                      | 34 YR           | Female       | USA            |
| <u>Preferred Term</u>                                  | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardio-Respiratory Arrest;<br>Completed Suicide; Death | Tramadol                  |                    |                    | S               | Oral                                            | Unk, Unknown         |                 | Par          |                |
|                                                        | Ondansetron               |                    |                    | S               | Oral                                            | Unk, Unknown         |                 | Par          |                |
|                                                        | Zolpidem Tartrate Er      |                    |                    | S               | Oral                                            | Unk, Unknown         |                 | Par          |                |
|                                                        | Amitriptyline             |                    |                    | S               | Oral                                            | Unk, Unknown         |                 | Not Reported |                |
|                                                        | Acetaminophen/Hydrocodone |                    |                    | S               | Oral                                            | Unk, Unknown         |                 | Not Reported |                |
|                                                        | Linaclotide               |                    |                    | S               | Oral                                            | Unk, Unknown         |                 | Not Reported |                |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |              |   |      |              |              |
|--|--------------|---|------|--------------|--------------|
|  | Diclofenac   | S | Oral | Unk, Unknown | Not Reported |
|  | Lubiprostone | S | Oral | Unk, Unknown | Not Reported |
|  | Liothyronine | S | Oral | Unk, Unknown | Not Reported |
|  | Escitalopram | S | Oral | Unk, Unknown | Not Reported |
|  | Sertraline   | S | Oral | Unk, Unknown | Not Reported |
|  | Gabapentin   | S | Oral | Unk, Unknown | Not Reported |

  

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------------------------------------|----------------------|------------|------------|----------------|
| 16-Feb-2015              | 10796137      | EXPEDITED (15-DAY) |                    | OT              | GB-MACLEODS<br>PHARMACEUTICALS<br>US LTD-<br>MAC2015001598 |                      |            | Unknown    | GBR            |

  

| <u>Preferred Term</u>                                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Insomnia; Maternal<br>Exposure During Breast<br>Feeding | Escitalopram   |              |            | S           | Transmammary | 10 Mg, Qd          |                 | Macleods   |
|                                                         | Escitalopram   |              |            | S           |              | 20 Mg, Qd          |                 | Macleods   |

  

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 16-Feb-2015              | 10800694      | EXPEDITED (15-DAY) |                    | DE              | US-WATSON-2015-<br>02937 |                      | 48 YR      | Female     | USA            |

  

| <u>Preferred Term</u>                                                                                                       | <u>Product</u>                                             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>           |
|-----------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------|
| Cardiac Arrest; Exposure<br>Via Ingestion; Exposure<br>Via Inhalation; Respiratory<br>Arrest; Toxicity To Various<br>Agents | Oxycodone Hydrochloride (Aellc)                            |              |            | S           | Unknown      | Unk                |                 | Watson               |
|                                                                                                                             | Cyclobenzaprine Hydrochloride<br>(Actavis Laboratories Fl) |              |            | S           | Unknown      | Unk                |                 | Actavis              |
|                                                                                                                             | Metoprolol (Watson<br>Laboratories)                        |              |            | S           | Unknown      | Unk                |                 | Watson               |
|                                                                                                                             | Clonidine (Watson Laboratories)                            |              |            | S           | Unknown      | Unk                |                 | Watson               |
|                                                                                                                             | Lisinopril (Watson Laboratories)                           |              |            | S           | Unknown      | Unk                |                 | Watson               |
|                                                                                                                             | Escitalopram (Unknown)                                     |              |            | S           | Unknown      | Unk                |                 | Not Reported         |
|                                                                                                                             | Ibuprofen (Amallc)                                         |              |            | S           | Unknown      | Unk                |                 | Actavis Mid Atlantic |
|                                                                                                                             | Diclofenac Sodium (Aellc)                                  |              |            | S           | Unknown      | Unk                |                 | Watson               |
|                                                                                                                             | Azithromycin (Unknown)                                     |              |            | S           | Unknown      | Unk                |                 | Not Reported         |
|                                                                                                                             | Cephalexin (Unknown)                                       |              |            | S           | Unknown      | Unk                |                 | Not Reported         |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |                                          |   |         |     |  |              |
|--|------------------------------------------|---|---------|-----|--|--------------|
|  | Doxycycline (Watson Laboratories)        | S | Unknown | Unk |  | Watson       |
|  | Methylprednisolone (Watson Laboratories) | S | Unknown | Unk |  | Watson       |
|  | Nitroglycerine                           | S | Unknown | Unk |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Feb-2015              | 10801414      | EXPEDITED (15-DAY) | HO                 |                 | CH-ACCORD-028657     |                      | 58 YR      | Male       | CHE            |

| <u>Preferred Term</u>                     | <u>Product</u>                  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>  | <u>Dosage Text</u>                                      | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------|---------------------------------|--------------|------------|-------------|---------------|---------------------------------------------------------|-----------------|--------------|
| Drug Screen Positive; Imprisonment; Mania | Tramadol/Tramadol Hydrochloride |              |            | S           |               | 50 Mg Of Tramadol Twice A Day Was Prescribed            |                 | Accord       |
|                                           | Escitalopram                    |              |            | S           |               |                                                         |                 | Accord       |
|                                           | Alfuzosin                       |              |            | C           |               |                                                         |                 | Not Reported |
|                                           | Metformin                       |              |            | C           |               |                                                         |                 | Not Reported |
|                                           | Zolpidem                        |              |            | C           |               |                                                         |                 | Not Reported |
|                                           | Cannabis Sativa                 |              |            | S           |               |                                                         |                 | Not Reported |
|                                           | Alprazolam                      |              |            | C           |               |                                                         |                 | Not Reported |
|                                           | Triamcinolone                   |              |            | S           | Intramuscular | 2 Im Injections Of 40 Mg Of Triamcinolone 1 Month Apart |                 | Not Reported |
|                                           | Ibuprofen                       |              |            | C           |               |                                                         |                 | Not Reported |
|                                           | Quetiapine/Quetiapine Fumarate  |              |            | C           |               | Increased Progressively Up To 1000 Mg/D                 |                 | Not Reported |
|                                           | Oxazepam                        |              |            | C           |               | Increased Progressively Oxazepam Up To 180 Mg/D         |                 | Not Reported |
|                                           | Paracetamol                     |              |            | C           |               |                                                         |                 | Not Reported |
|                                           | Baclofen                        |              |            | C           |               |                                                         |                 | Not Reported |
|                                           | Atorvastatin                    |              |            | C           |               |                                                         |                 | Not Reported |
|                                           | Trospium/Trospium Chloride      |              |            | C           |               |                                                         |                 | Not Reported |
|                                           | Candesartan                     |              |            | C           |               |                                                         |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 17-Feb-2015              | 10805748      | NON-EXPEDITED    |                    |                 | US-ABBVIE-14K-163-1246266-00 |                      | 55 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                              |           |   |              |
|------------------------------|-----------|---|--------------|
| Depression; Drug Ineffective | Humira    | S | Not Reported |
|                              | Prozac    | S | Not Reported |
|                              | Lexapro   | S | Not Reported |
|                              | Trazodone | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Feb-2015              | 10727279      | EXPEDITED (15-DAY) |                    | DE              | FR-FRI-1000073733    |                      | 85 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                                                                             | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Amnesia; Aphasia; Cerebral Haematoma; Cerebral Haemorrhage; Cerebrovascular Accident; Epilepsy; Language Disorder | Escitalopram             |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                                                                                                   | Kardegic                 |              |            | S           | Oral         | 75 Mg              |                 | Not Reported |
|                                                                                                                   | Previscan (Fluindione)   |              |            | S           | Oral         | 20 Mg              |                 | Not Reported |
|                                                                                                                   | Esomeprazole             |              |            | C           | Oral         | 20 Mg              |                 | Not Reported |
|                                                                                                                   | Cordarone                |              |            | C           | Oral         | 50 Mg              |                 | Not Reported |
|                                                                                                                   | Furosemide               |              |            | C           | Oral         | 20 Mg              |                 | Not Reported |
|                                                                                                                   | Allopurinol              |              |            | C           | Oral         | 1 Dosage Form      |                 | Not Reported |
|                                                                                                                   | Stilnox                  |              |            | C           | Oral         | 10 Mg              |                 | Not Reported |
|                                                                                                                   | Combodart 0.5 Mg/ 0.4 Mg |              |            | C           | Oral         | 1 Dosage Form      |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Feb-2015              | 10792601      | EXPEDITED (15-DAY) |                    | DE, OT          | CHPA2015US002022     |                      | 34 YR      | Female     | USA            |

| <u>Preferred Term</u>                        | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------|-----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardio-Respiratory Arrest; Completed Suicide | Diclofenac                  |              |            | S           | Oral         | Unk                |                 | Novartis     |
|                                              | Amitriptyline               |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                                              | Tramadol                    |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                                              | Acetaminophen W/Hydrocodone |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                                              | Ondansetron                 |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                                              | Linaclotide                 |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                                              | Lubiprostone                |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                                              | Zolpidem                    |              |            | S           | Oral         | Unk                |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|              |   |      |     |              |
|--------------|---|------|-----|--------------|
| Liothyronine | S | Oral | Unk | Not Reported |
| Escitalopram | S | Oral | Unk | Not Reported |
| Sertraline   | S | Oral | Unk | Not Reported |
| Gabapentin   | S | Oral | Unk | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Feb-2015              | 10794257      | EXPEDITED (15-DAY) |                    | DE, OT          | CHPA2015US001920     |                      | 48 YR      | Female     | USA            |

| <u>Preferred Term</u>                                    | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------|--------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardio-Respiratory Arrest;<br>Intentional Product Misuse | Diclofenac         |              |            | S           | Unknown      | Unk                |                 | Novartis     |
|                                                          | Ibuprofen          |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                                                          | Oxycodone          |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                                                          | Cyclobenzaprine    |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                                                          | Metoprolol         |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                                                          | Clonidine          |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                                                          | Nitroglycerin      |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                                                          | Lisinopril         |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                                                          | Escitalopram       |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                                                          | Azithromycin       |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                                                          | Cephalexin         |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                                                          | Doxycycline        |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                                                          | Methylprednisolone |              |            | S           | Unknown      | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|------------|------------|----------------|
| 18-Feb-2015              | 10816406      | EXPEDITED (15-DAY) |                    | DE, OT          | US-009507513-<br>1502USA006421 |                      | 69 YR      | Male       | USA            |

| <u>Preferred Term</u>                   | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide;<br>Product Use Issue | Oxytrol For Women       |              |            | S           | Oral         | Unk, Unknown       |                 | Merck        |
|                                         | Clonazepam              |              |            | S           | Oral         | Unk, Unknown       |                 | Not Reported |
|                                         | Trazodone Hydrochloride |              |            | S           | Oral         | Unk, Unknown       |                 | Not Reported |



## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |                     |   |      |              |              |
|--|---------------------|---|------|--------------|--------------|
|  | Quetiapine Fumarate | S | Oral | Unk, Unknown | Not Reported |
|  | Lamotrigine         | S | Oral | Unk, Unknown | Not Reported |
|  | Escitalopram        | S | Oral | Unk, Unknown | Not Reported |
|  | Finasteride         | S | Oral | Unk, Unknown | Not Reported |

| <u>FDA Received Date</u>           | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 18-Feb-2015                        | 10818509       | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000074581    |                      | 83 YR           | Female       | FRA            |
| <u>Preferred Term</u>              | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;<br>Hyponatraemia | Escitalopram   |                    |                    | S               | Oral                 | 1 Dosage Form        |                 | Forest       |                |
|                                    | Erivedge       |                    |                    | S               | Oral                 | 1 Dosage Form        |                 | Not Reported |                |

| <u>FDA Received Date</u>             | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|---------------------------------|-----------------|--------------|----------------|
| 18-Feb-2015                          | 10838004               | EXPEDITED (15-DAY) | Y                  | OT              | US-TORRENT-00000872  |                                 | 49 YR           | Female       | USA            |
| <u>Preferred Term</u>                | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Impaired<br>Work Ability | Escitalopram           |                    |                    | S               |                      | 10mg Twice Da Day (Am<br>An Pm) |                 | Not Reported |                |
|                                      | Lamictal (Lamotrigine) |                    |                    | C               |                      |                                 |                 | Not Reported |                |
|                                      | Clonazepam             |                    |                    | C               |                      |                                 |                 | Not Reported |                |
|                                      | Furosemide             |                    |                    | C               |                      |                                 |                 | Not Reported |                |
|                                      | Fexofenadine           |                    |                    | C               |                      |                                 |                 | Not Reported |                |
|                                      | Trazodone              |                    |                    | C               |                      |                                 |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 18-Feb-2015              | 10853501                     | EXPEDITED (15-DAY) |                    | DE              | NSR_01854_2015       |                      | 74 YR           | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Poisoning                | Atenolol                     |                    |                    | S               | Oral                 | Df                   |                 | Not Reported |                |
|                          | Benzodiazepine Related Drugs |                    |                    | S               |                      | Df                   |                 | Not Reported |                |
|                          | Escitalopram                 |                    |                    | S               |                      | Df                   |                 | Not Reported |                |
|                          | Primidone                    |                    |                    | S               |                      | (Df)                 |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                                                | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------|----------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 18-Feb-2015                                                                                             | 10855442                   | DIRECT             |                    | OT              |                      |                      | 46 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                   | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Depression;<br>Drug Ineffective; Product<br>Substitution Issue; Self-<br>Injurious Ideation | Lexapro                    |                    |                    | S               | Oral                 | 1 Pill               | 5 YR            | Forest       |                |
| <u>FDA Received Date</u>                                                                                | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Feb-2015                                                                                             | 10855677                   | DIRECT             |                    | LT              |                      |                      | 44 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                   | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anger                                                                                                   | Escitalopram               |                    |                    | S               | Oral                 | 1                    |                 | Camber       |                |
| <u>FDA Received Date</u>                                                                                | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Feb-2015                                                                                             | 10855957                   | DIRECT             |                    | LT              |                      |                      | 68 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                   | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Potassium<br>Increased                                                                            | Lexapro 20mg - Generic     |                    |                    | S               | Oral                 |                      | 9 MTH           | Not Reported |                |
|                                                                                                         | Xanax                      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                         | Percocet                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                         | Adderall                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                         | Effexor                    |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                         | Vitamin C-B-D              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                         | Citrucel                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                         | Oscal                      |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Feb-2015                                                                                             | 10562974                   | EXPEDITED (15-DAY) |                    | HO              | IT-FRI-1000071982    |                      | 36 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                                                   | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Abuse; Mydriasis;                                                                                  | Escitalopram Oral Solution |                    |                    | S               | Oral                 |                      |                 | Forest       |                |

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|                                          |                                                                    |                           |                             |                          |                               |                               |                          |                     |                         |
|------------------------------------------|--------------------------------------------------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Sopor                                    | En                                                                 |                           | S                           | Oral                     |                               | Form Strength 1mg/ML          |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>        | <a href="#">Case #</a>                                             | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 19-Feb-2015                              | 10591588                                                           | EXPEDITED (15-DAY)        |                             | DS                       | FR-FRI-1000072493             |                               | 56 YR                    | Female              | FRA                     |
| <a href="#">Preferred Term</a>           | <a href="#">Product</a>                                            | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Eye Haemorrhage; Retinal Vein Thrombosis | Escitalopram                                                       |                           |                             | S                        | Oral                          | 5 Mg                          |                          | Forest              |                         |
|                                          | Escitalopram                                                       |                           |                             | S                        | Oral                          | 10 Mg                         |                          | Forest              |                         |
|                                          | Lexomil                                                            |                           |                             | C                        | Oral                          |                               |                          | Not Reported        |                         |
|                                          | Xanax                                                              |                           |                             | C                        | Oral                          |                               |                          | Not Reported        |                         |
|                                          | Esberiven Fort                                                     |                           |                             | C                        | Oral                          |                               |                          | Not Reported        |                         |
|                                          | Nurofenflash                                                       |                           |                             | C                        | Oral                          |                               |                          | Not Reported        |                         |
|                                          | Doliprane                                                          |                           |                             | C                        | Oral                          | 1 Gram                        |                          | Not Reported        |                         |
|                                          | Actifed (Pseudoephedrine Hydrochloride)\Tripolidine Hydrochloride) |                           |                             | C                        | Oral                          |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>        | <a href="#">Case #</a>                                             | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 19-Feb-2015                              | 10627562                                                           | EXPEDITED (15-DAY)        |                             | HO                       | IT-MERCK-1412ITA001286        |                               | 23 YR                    | Female              | ITA                     |
| <a href="#">Preferred Term</a>           | <a href="#">Product</a>                                            | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Bradykinesia; Drug Abuse; Sopor          | Mirtazapine                                                        |                           |                             | S                        | Oral                          | 600 Mg, Frequency Total       |                          | Merck               |                         |
|                                          | Periactin Tablets                                                  |                           |                             | S                        | Oral                          | 10 Df, Frequency Total        |                          | Not Reported        |                         |
|                                          | Cipralext                                                          |                           |                             | S                        | Oral                          | 14 Df, Frequency Total        |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>        | <a href="#">Case #</a>                                             | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 19-Feb-2015                              | 10792597                                                           | EXPEDITED (15-DAY)        |                             | DE                       | CHPA2015US002063              |                               | 51 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>           | <a href="#">Product</a>                                            | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Completed Suicide                        | Diclofenac                                                         |                           |                             | S                        | Oral                          | Unk                           |                          | Novartis            |                         |
|                                          | Promethazine                                                       |                           |                             | S                        | Oral                          |                               |                          | Not Reported        |                         |

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|                  |   |      |              |
|------------------|---|------|--------------|
| Verapamil        | S | Oral | Not Reported |
| Escitalopram     | S | Oral | Not Reported |
| Hydrocodone/Apap | S | Oral | Not Reported |
| Diazepam         | S | Oral | Not Reported |
| Topiramate       | S | Oral | Not Reported |
| Esomeprazole     | S | Oral | Not Reported |

| <u>FDA Received Date</u>                     | <u>Case #</u>              | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|----------------------------------------------|----------------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 19-Feb-2015                                  | 10828646                   | NON-EXPEDITED    |                    |                 | US-TARO-2015TAR00064 |                      | 8 YR            | Male       | USA            |
| <u>Preferred Term</u>                        | <u>Product</u>             | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective; Product Substitution Issue | Escitalopram Oral Solution |                  |                    | S               | Oral                 | 2 MI, 1x/Day         |                 | Taro       |                |
|                                              | Escitalopram Oral Solution |                  |                    | S               |                      |                      |                 | Taro       |                |

| <u>FDA Received Date</u> | <u>Case #</u>              | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 19-Feb-2015              | 10828650                   | NON-EXPEDITED    |                    |                 | US-TARO-2015TAR00100 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>    | <u>Product</u>             | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective         | Escitalopram Oral Solution |                  |                    | S               |                      |                      |                 | Taro       |                |

| <u>FDA Received Date</u>          | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------|----------------|------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| 19-Feb-2015                       | 10831755       | NON-EXPEDITED    |                    |                 | US-ABBVIE-14P-163-1195142-00 |                      | 71 YR           | Female       | USA            |
| <u>Preferred Term</u>             | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Pruritus; Rash Papular | Humira         |                  |                    | S               |                              |                      |                 | Not Reported |                |
|                                   | Lexapro        |                  |                    | S               |                              |                      |                 | Not Reported |                |
|                                   | Lexapro        |                  |                    | S               |                              |                      |                 | Not Reported |                |
|                                   | Unknown Lotion |                  |                    | C               |                              |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 19-Feb-2015              | 10832054      | EXPEDITED (15-DAY) |                    | HO              | US-GLAXOSMITHKLINE INC.- |                      | 48 YR      | Female     | USA            |

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US2015GSK020027

| <u>Preferred Term</u>                                                                                                | <u>Product</u>                     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|----------------------------------------------------------------------------------------------------------------------|------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Asthenia; Dysarthria;<br>Headache; Hypertension;<br>Hypokalaemia; Mental<br>Status Changes; Multiple<br>Drug Therapy | Fluticasone                        |              |            | S           | Nasal        | 2 Df, Qd           |                 | Glaxosmithkline |
|                                                                                                                      | Desvenlafaxine Extended<br>Release |              |            | S           | Oral         | Unk, Qd            |                 | Not Reported    |
|                                                                                                                      | Lyrica                             |              |            | S           |              | 75 Mg, Qd          |                 | Not Reported    |
|                                                                                                                      | Ibuprofen                          |              |            | S           | Oral         | 800 Mg, Tid        |                 | Not Reported    |
|                                                                                                                      | Loratadine                         |              |            | S           | Oral         | 10 Mg, Qd          |                 | Not Reported    |
|                                                                                                                      | Robaxin                            |              |            | S           | Oral         | 750 Mg, Tid        |                 | Not Reported    |
|                                                                                                                      | Clonazepam                         |              |            | S           | Oral         | 1 Mg, Bid          |                 | Not Reported    |
|                                                                                                                      | Lexapro                            |              |            | S           | Oral         | 20 Mg, Qd          |                 | Not Reported    |
|                                                                                                                      | Abilify                            |              |            | S           | Oral         | 15 Mg, Unk         |                 | Not Reported    |
|                                                                                                                      | Vicodin                            |              |            | S           | Oral         | Unk, Prn           |                 | Not Reported    |
|                                                                                                                      | Zestoretic                         |              |            | S           | Oral         | Unk, Qd            |                 | Not Reported    |
|                                                                                                                      | Ambien                             |              |            | S           | Oral         | Unk                |                 | Not Reported    |
|                                                                                                                      | Vivelle                            |              |            | S           | Transdermal  | 0.1 Mg, Unk        |                 | Not Reported    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------------------|----------------------|------------|------------|----------------|
| 19-Feb-2015              | 10832695      | NON-EXPEDITED    |                    | OT              | US-ABBVIE-14P-163-<br>1196138-00 |                      | 75 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                           | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anaphylactic Reaction;<br>Depressed Mood; Drug<br>Ineffective; Drug<br>Ineffective; Frequent<br>Bowel Movements | Humira              |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                 | Humira              |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                 | Humira              |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                 | Humira              |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                 | Lexapro             |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                 | Lipitor             |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                 | Toprol XL           |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                 | Microzide           |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                 | Hydrochlorothiazide |              |            | C           |              |                    |                 | Not Reported |

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| Imodium                                                                               |                |                    | C                  |                 | 4-6 Tabs Qd          |                      |                 | Not Reported |                |
|---------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| <u>FDA Received Date</u>                                                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Feb-2015                                                                           | 10833531       | EXPEDITED (15-DAY) |                    | HO              | US-FRI-1000074413    |                      | 48 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dysarthria; Hypertension;<br>Hypokalaemia; Mental<br>Status Changes; Off Label<br>Use | Lexapro        |                    |                    | S               | Oral                 | 20 Mg                |                 | Forest       |                |
|                                                                                       | Lexapro        |                    |                    | S               |                      |                      |                 | Forest       |                |
|                                                                                       | Ibuprofen      |                    |                    | S               | Oral                 | 2400 Mg              |                 | Not Reported |                |
|                                                                                       | Ambien         |                    |                    | S               | Oral                 | 10 Mg                |                 | Not Reported |                |
|                                                                                       | Vicodin        |                    |                    | S               | Oral                 | 5/500 Prn            |                 | Not Reported |                |
|                                                                                       | Abilify        |                    |                    | S               | Oral                 | 30 Mg                |                 | Not Reported |                |
|                                                                                       | Abilify        |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                       | Abilify        |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                       | Lyrica         |                    |                    | S               | Oral                 | 75 Mg                |                 | Not Reported |                |
|                                                                                       | Lyrica         |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                       | Clonazepam     |                    |                    | S               | Oral                 | 2 Mg                 |                 | Not Reported |                |
|                                                                                       | Clonazepam     |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                       | Robaxin        |                    |                    | S               | Oral                 | 2250 Mg              |                 | Not Reported |                |
|                                                                                       | Robaxin        |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                       | Robaxin        |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                       | Zestoretic     |                    |                    | S               | Oral                 | 20/12.5              |                 | Not Reported |                |
|                                                                                       | Fluticasone    |                    |                    | S               | Nasal                | 2 Df                 |                 | Not Reported |                |
|                                                                                       | Loratadine     |                    |                    | S               | Oral                 | 10 Mg                |                 | Not Reported |                |
|                                                                                       | Desvenlafaxine |                    |                    | S               | Oral                 | 50 Mg                |                 | Not Reported |                |
|                                                                                       | Desvenlafaxine |                    |                    | S               | Oral                 | 100 Mg               |                 | Not Reported |                |
|                                                                                       | Desvenlafaxine |                    |                    | S               | Oral                 | 100 Mg               |                 | Not Reported |                |
|                                                                                       | Desvenlafaxine |                    |                    | S               | Oral                 | 50 Mg                |                 | Not Reported |                |
|                                                                                       | Desvenlafaxine |                    |                    | S               | Oral                 | 25 Mg                |                 | Not Reported |                |
|                                                                                       | Vivelle        |                    |                    | S               | Transdermal          |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|--------------------|--------------------|-----------------|----------------------|----------------------------|-----------------|--------------|----------------|
| 19-Feb-2015                                                                                                                                             | 10834058           | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000074609    |                            | 50 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                                   | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypokalaemia; Intentional Overdose; Malaise; Seizure; Suicide Attempt; Tetany; Torsade De Pointes; Toxicity To Various Agents; Ventricular Fibrillation | Escitalopram       |                    |                    | S               | Oral                 | 10 Mg                      |                 | Forest       |                |
|                                                                                                                                                         | Escitalopram       |                    |                    | S               | Oral                 | Escitalopram Overdose Nos. |                 | Forest       |                |
|                                                                                                                                                         | Xanax              |                    |                    | S               | Oral                 | 0.25 Mg                    |                 | Not Reported |                |
|                                                                                                                                                         | Xanax              |                    |                    | S               | Oral                 | Alprazolam Overdose Nos.   |                 | Not Reported |                |
|                                                                                                                                                         | Imovane            |                    |                    | C               |                      | 7.5 Mg                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Feb-2015                                                                                                                                             | 10834060           | EXPEDITED (15-DAY) |                    | HO              | TW-FRI-1000074612    |                            | 68 YR           | Female       | TWN            |
| <u>Preferred Term</u>                                                                                                                                   | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyponatraemia; Mania; Therapeutic Product Effect Incomplete                                                                                             | Escitalopram       |                    |                    | S               | Oral                 | 10 Mg                      |                 | Forest       |                |
|                                                                                                                                                         | Estazolam          |                    |                    | C               | Unknown              | 2 Mg                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Feb-2015                                                                                                                                             | 10861526           | EXPEDITED (15-DAY) | Y                  | DE              | DEP_02506_2015       |                            | 51 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                   | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Exposure Via Ingestion                                                                                                               | Diclofenac         |                    |                    | S               | Oral                 |                            |                 | Not Reported |                |
|                                                                                                                                                         | Promethazine       |                    |                    | S               | Oral                 |                            |                 | Not Reported |                |
|                                                                                                                                                         | Verapamil          |                    |                    | S               | Oral                 |                            |                 | Not Reported |                |
|                                                                                                                                                         | Escitalopram       |                    |                    | S               | Oral                 |                            |                 | Not Reported |                |
|                                                                                                                                                         | Apap W/Hydrocodone |                    |                    | S               | Oral                 |                            |                 | Not Reported |                |
|                                                                                                                                                         | Diazepam           |                    |                    | S               | Oral                 |                            |                 | Not Reported |                |
|                                                                                                                                                         | Topiramate         |                    |                    | S               | Oral                 |                            |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Esomeprazole

S

Oral

Not Reported

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Feb-2015              | 10861538      | EXPEDITED (15-DAY) | Y                  | DE              | DEP_02505_2015       |                      | 34 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                       | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------|-----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiac Arrest; Completed Suicide; Poisoning Deliberate; Respiratory Arrest | Diclofenac                  |              |            | S           | Oral         | Df Oral            |                 | Not Reported |
|                                                                             | Gabapentin                  |              |            | S           | Oral         | Df Oral            |                 | Not Reported |
|                                                                             | Amitriptyline               |              |            | S           | Oral         | Df Oral            |                 | Not Reported |
|                                                                             | Tramadol                    |              |            | S           | Oral         | Df Oral            |                 | Not Reported |
|                                                                             | Acetaminophen W/Hydrocodone |              |            | S           | Oral         | Df Oral            |                 | Not Reported |
|                                                                             | Ondansetron                 |              |            | S           | Oral         | Df Oral            |                 | Not Reported |
|                                                                             | Linacotide                  |              |            | S           | Oral         | Df Oral            |                 | Not Reported |
|                                                                             | Lubiprostone                |              |            | S           | Oral         | Df Oral            |                 | Not Reported |
|                                                                             | Zolpidem                    |              |            | S           | Oral         | Df Oral            |                 | Not Reported |
|                                                                             | Liothyronine                |              |            | S           | Oral         | Df Oral            |                 | Not Reported |
|                                                                             | Escitalopram                |              |            | S           | Oral         | Df Oral            |                 | Not Reported |
|                                                                             | Sertraline                  |              |            | S           | Oral         | Df Oral            |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Feb-2015              | 10861543      | EXPEDITED (15-DAY) | Y                  | DE              | DEP_02504_2015       |                      | 48 YR      | Female     | USA            |

| <u>Preferred Term</u>                         | <u>Product</u>  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------|-----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiac Arrest; Poisoning; Respiratory Arrest | Diclofenac      |              |            | S           |              | Df                 |                 | Not Reported |
|                                               | Oxycodone       |              |            | S           |              | Df                 |                 | Not Reported |
|                                               | Cyclobenzaprine |              |            | S           |              | Df                 |                 | Not Reported |
|                                               | Metoprolol      |              |            | S           |              | Df                 |                 | Not Reported |
|                                               | Clonidine       |              |            | S           |              | Df                 |                 | Not Reported |
|                                               | Nitroglycerin   |              |            | S           |              | Df                 |                 | Not Reported |
|                                               | Lisinopril      |              |            | S           |              | Df                 |                 | Not Reported |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                       |   |    |              |
|-----------------------|---|----|--------------|
| Escitalopram          | S | Df | Not Reported |
| Ibuprofen             | S | Df | Not Reported |
| Azithromycin          | S | Df | Not Reported |
| Cephalexin /00145501/ | S | Df | Not Reported |
| Doxycycline           | S | Df | Not Reported |
| Methylprednisolone    | S | Df | Not Reported |

| <u>FDA Received Date</u>                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 19-Feb-2015                                           | 10861719       | EXPEDITED (15-DAY) | Y                  | DE              | DEP_02522_2015       |                      | 28 YR           | Female       | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Completed Suicide; Respiratory Arrest | Gabapentin     |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                       | Bupropion      |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                       | Escitalopram   |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                       | Alprazolam     |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                               | <u>Case #</u>     | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------|-------------------|------------------|--------------------|-----------------|----------------------|----------------------------------------|-----------------|--------------|----------------|
| 19-Feb-2015                                                            | 10866377          | DIRECT           |                    | DS              |                      |                                        | 64 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                  | <u>Product</u>    | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective; Dyspnoea; Dyspnoea Exertional; Myocardial Infarction | Escitalopram 20mg |                  |                    | S               | Oral                 | 1 Pill Daily Once Daily Taken By Mouth | 10 YR           | Not Reported |                |

| <u>FDA Received Date</u>                                      | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 20-Feb-2015                                                   | 10838583                 | EXPEDITED (15-DAY) |                    | HO, OT          | PHHY2015US017395     |                      | 48 YR           | Female       | USA            |
| <u>Preferred Term</u>                                         | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Confusional State; Dysarthria; Electrocardiogram St | Vivelle                  |                    |                    | S               | Transdermal          | 0.1 Mg, Unk          |                 | Not Reported |                |
|                                                               | Desvenlafaxine Succinate |                    |                    | S               | Oral                 | 50 Mg, Qd            |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                         |                          |   |                             |                      |              |
|-------------------------|--------------------------|---|-----------------------------|----------------------|--------------|
| Segment Abnormal;       | Desvenlafaxine Succinate | S | Oral                        | 100 Mg, Qd           | Not Reported |
| Haemoglobin Increased;  | Desvenlafaxine Succinate | S | Unknown                     | 50 Mg, Qd            | Not Reported |
| Headache; Hypertension; | Desvenlafaxine Succinate | S | Unknown                     | Unk                  | Not Reported |
| Hypokalaemia; Mental    | Desvenlafaxine Succinate | S | Oral                        | 25 Mg, Qd            | Not Reported |
| Status Changes; White   | Clonazepam               | S | Oral                        | 1 Mg, Bid            | Not Reported |
| Blood Cell Count        | Loratadine               | S | Oral                        | 10 Mg, Qd            | Not Reported |
| Increased               | Lyrica                   | S | Oral                        | 75 Mg, Qd            | Not Reported |
|                         | Ibuprofen Sandoz         | S | Oral                        | 800 Mg, Tid          | Novartis     |
|                         | Robaxin                  | S | Oral                        | 750 Mg, Tid          | Not Reported |
|                         | Lexapro                  | S | Oral                        | 20 Mg, Qd            | Not Reported |
|                         | Lexapro                  | S |                             |                      | Not Reported |
|                         | Abilify                  | S | Oral                        | 15 Mg, Bid           | Not Reported |
|                         | Fluticasone              | S | Respiratory<br>(inhalation) | 2 Df, Qd             | Not Reported |
|                         | Vicodin                  | S | Oral                        | 5 Ot, Prn (5/500)    | Not Reported |
|                         | Zestoretic               | S | Oral                        | 20 Mg, Unk (20/12.5) | Not Reported |
|                         | Ambien                   | S | Oral                        | 10 Mg, Qd            | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------------------|----------------------|------------|------------|----------------|
| 20-Feb-2015              | 10839280      | NON-EXPEDITED    |                    |                 | US-ABBVIE-14P-163-<br>1232895-00 |                      | 31 YR      | Female     | USA            |

| <u>Preferred Term</u>      | <u>Product</u>  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|-----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Adverse Event; Anxiety;    | Humira          |              |            | S           | Unknown      |                    |                 | Not Reported |
| Anxiety; Arthralgia;       | Humira          |              |            | S           | Unknown      |                    |                 | Not Reported |
| Bronchitis; Condition      | Humira          |              |            | S           | Unknown      |                    |                 | Not Reported |
| Aggravated; Depression;    | Lexapro         |              |            | S           | Unknown      |                    |                 | Not Reported |
| Depression; Drug           | Iud Nos         |              |            | S           | Unknown      |                    |                 | Not Reported |
| Ineffective; Fear Of       | Leflunomide     |              |            | S           | Unknown      |                    |                 | Not Reported |
| Injection; Fibromyalgia;   | Naproxen Sodium |              |            | C           | Oral         | By Mouth As Needed |                 | Not Reported |
| Headache; Inappropriate    |                 |              |            |             |              |                    |                 | Not Reported |
| Schedule Of Product        |                 |              |            |             |              |                    |                 | Not Reported |
| Administration; Infection; |                 |              |            |             |              |                    |                 | Not Reported |
| Inflammation;              |                 |              |            |             |              |                    |                 | Not Reported |
| Inflammation; Influenza;   |                 |              |            |             |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Injection Site Discomfort;  
 Injection Site Pain;  
 Musculoskeletal Stiffness;  
 Nasopharyngitis; Pain;  
 Pain In Extremity; Pain In  
 Extremity; Pain In  
 Extremity; Pain In  
 Extremity; Psoriasis;  
 Psoriasis; Sinus  
 Congestion; Therapeutic  
 Product Effect Incomplete;  
 Thinking Abnormal; White  
 Blood Cell Count  
 Increased; Wrong  
 Technique In Product  
 Usage Process

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 20-Feb-2015              | 10843650      | EXPEDITED (15-DAY) |                    | DE              | US-MALLINCKRODT-T201500679 |                      | 34 YR      | Female     | USA            |

  

| <u>Preferred Term</u>                                 | <u>Product</u>                       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------|--------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiac Arrest; Completed Suicide; Respiratory Arrest | Acetaminophen\Hydrocodone Bitartrate |              |            | S           | Oral         | Unk                |                 | Mallinckrodt |
|                                                       | Amitriptyline                        |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                                                       | Tramadol                             |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                                                       | Ondansetron                          |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                                                       | Linaclotide                          |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                                                       | Diclofenac                           |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                                                       | Lubiprostone                         |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                                                       | Zolpidem                             |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                                                       | Liothyronine                         |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                                                       | Escitalopram                         |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                                                       | Sertraline                           |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                                                       | Gabapentin                           |              |            | S           | Oral         | Unk                |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <a href="#">FDA Received Date</a>                                                                                                                                                | <a href="#">Case #</a>            | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 20-Feb-2015                                                                                                                                                                      | 10844857                          | EXPEDITED (15-DAY)        |                             | OT                       | MY-FRI-1000074588             |                               | 35 YR                    | Female              | MYS                     |
| <a href="#">Preferred Term</a>                                                                                                                                                   | <a href="#">Product</a>           | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Dyspepsia                                                                                                                                                                        | Lexapro                           |                           |                             | S                        | Oral                          | 10 Mg                         |                          | Forest              |                         |
| <a href="#">FDA Received Date</a>                                                                                                                                                | <a href="#">Case #</a>            | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 20-Feb-2015                                                                                                                                                                      | 10866544                          | DIRECT                    |                             | OT                       |                               |                               | 40 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>                                                                                                                                                   | <a href="#">Product</a>           | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Anxiety; Blood Pressure Increased; Dizziness; Drug Withdrawal Syndrome; Gastrointestinal Disorder; Haematochezia; Headache; Panic Attack; Product Substitution Issue; Somnolence | Escitalopram 10mg Aurobindo Pharm |                           |                             | S                        | Oral                          | 1                             |                          | Aurobindo           |                         |
| <a href="#">FDA Received Date</a>                                                                                                                                                | <a href="#">Case #</a>            | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 20-Feb-2015                                                                                                                                                                      | 10868505                          | DIRECT                    | Y                           | OT                       |                               |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                                                                                                                   | <a href="#">Product</a>           | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Agitation; Migraine                                                                                                                                                              | Escitalopram                      |                           |                             | S                        | Oral                          |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                                                                                | <a href="#">Case #</a>            | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 20-Feb-2015                                                                                                                                                                      | 10868667                          | DIRECT                    |                             |                          |                               |                               |                          | Male                | USA                     |
| <a href="#">Preferred Term</a>                                                                                                                                                   | <a href="#">Product</a>           | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Ineffective; Product Substitution Issue                                                                                                                                     | Generic Lexapro                   |                           |                             | S                        | Oral                          |                               |                          | Not Reported        |                         |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                           | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------|-----------------------------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|-----------------|--------------|----------------|
| 21-Feb-2015                                                        | 10624919                          | EXPEDITED (15-DAY) |                    | HO              | IT-AUROBINDO-AUR-APL-2014-12751 |                      | 23 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                              | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bradykinesia; Drug Abuse; Sopor                                    | Mirtazapine                       |                    |                    | S               | Oral                            | 600 Mg, Total        |                 | Aurobindo    |                |
|                                                                    | Periactin                         |                    |                    | S               | Oral                            | 10 Df, Total         |                 | Not Reported |                |
|                                                                    | Cipralex /01588501/               |                    |                    | S               | Oral                            | 14 Df, Total         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                           | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Feb-2015                                                        | 10850118                          | EXPEDITED (15-DAY) |                    | DE              | US-BANPHARM-20153483            |                      | 37 YR           | Female       | USA            |
| <u>Preferred Term</u>                                              | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Exposure Via Ingestion                          | Loperamide Unknown Product        |                    |                    | S               | Oral                            |                      |                 | Not Reported |                |
|                                                                    | Escitalopram                      |                    |                    | S               |                                 |                      |                 | Not Reported |                |
|                                                                    | Meloxicam                         |                    |                    | S               |                                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                           | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Feb-2015                                                        | 10850130                          | EXPEDITED (15-DAY) |                    | OT              | GB-TEVA-540958ACC               |                      | 60 YR           | Male         | GBR            |
| <u>Preferred Term</u>                                              | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Product Substitution Issue                                | Escitalopram Oxalate              |                    |                    | S               | Oral                            | 5 Milligram Daily;   |                 | Ivax         |                |
| <u>FDA Received Date</u>                                           | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Feb-2015                                                        | 10850334                          | EXPEDITED (15-DAY) |                    | DE              | US-WATSON-2015-03602            |                      | 67 YR           | Male         | USA            |
| <u>Preferred Term</u>                                              | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Exposure Via Ingestion; Foreign Body Aspiration | Lamotrigine (Watson Laboratories) |                    |                    | S               | Unknown                         | Unk                  |                 | Watson       |                |
|                                                                    | Zonisamide (Watson Laboratories)  |                    |                    | S               | Unknown                         | Unk                  |                 | Watson       |                |
|                                                                    | Lorazepam (Watson)                |                    |                    | S               | Unknown                         | Unk                  |                 | Watson       |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                        |   |         |     |  |  |  |  |                   |  |
|------------------------|---|---------|-----|--|--|--|--|-------------------|--|
| Laboratories)          |   |         |     |  |  |  |  |                   |  |
| Escitalopram (Unknown) | S | Unknown | Unk |  |  |  |  | Not Reported      |  |
| Lovastatin (Aellc)     | S | Oral    | Unk |  |  |  |  | Actavis Elizabeth |  |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Feb-2015              | 9815686       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000052812    |                      | 91 YR      | Female     | FRA            |

| <u>Preferred Term</u>                               | <u>Product</u>                                                                                                      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------|---------------------------------------------------------------------------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anaemia; Drug Interaction;<br>Ecchymosis; Haematoma | Escitalopram                                                                                                        |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                                     | Plavix                                                                                                              |              |            | S           | Oral         | 75 Mg              |                 | Not Reported |
|                                                     | Arixtra                                                                                                             |              |            | S           | Subcutaneous | 5 Mg               |                 | Not Reported |
|                                                     | Celluvisc                                                                                                           |              |            | C           | Ophthalmic   | 4 Mg/0.4 MI        |                 | Not Reported |
|                                                     | Cordarone                                                                                                           |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                     | Tardyferon                                                                                                          |              |            | C           |              |                    |                 | Not Reported |
|                                                     | Alprazolam                                                                                                          |              |            | C           |              |                    |                 | Not Reported |
|                                                     | Amlor                                                                                                               |              |            | C           |              |                    |                 | Not Reported |
|                                                     | Dichlorhydrate De Cetirizine                                                                                        |              |            | C           |              |                    |                 | Not Reported |
|                                                     | Mestinon                                                                                                            |              |            | C           |              |                    |                 | Not Reported |
|                                                     | Ebixa                                                                                                               |              |            | C           |              |                    |                 | Not Reported |
|                                                     | Furadantine                                                                                                         |              |            | C           |              |                    |                 | Not Reported |
|                                                     | Dafalgan                                                                                                            |              |            | C           |              |                    |                 | Not Reported |
|                                                     | Transipeg (Polyethylene Glycol 3350\Potassium Chloride\Sodium Bicarbonate\Sodium Chloride\Sodium Sulfate Anhydrous) |              |            | C           |              |                    |                 | Not Reported |
|                                                     | Inexium                                                                                                             |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 23-Feb-2015              | 10562977      | EXPEDITED (15-DAY) |                    | HO              | IT-MYLANLABS-2014M1008807 |                      |            | Unknown    | ITA            |

| <u>Preferred Term</u>                  | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Somnolence; Vomiting;<br>Wrong Product | Escitalopram Oxalate |              |            | S           | Oral         | 3 Gtt, Total       |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Administered

| <u>FDA Received Date</u>                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------|----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
| 23-Feb-2015                                      | 10574634             | EXPEDITED (15-DAY) |                    | HO              | IT-MYLANLABS-2014M1009525 |                      |                 | Unknown      | ITA            |
| <u>Preferred Term</u>                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Somnolence; Vomiting; Wrong Product Administered | Escitalopram Oxalate |                    |                    | S               | Oral                      | 3 Gtt, Total         |                 | Not Reported |                |

| <u>FDA Received Date</u>                            | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| 23-Feb-2015                                         | 10864413                      | EXPEDITED (15-DAY) |                    | OT              | IN-ABBVIE-15P-078-1351193-00 |                      |                 | Unknown      | IND            |
| <u>Preferred Term</u>                               | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Akathisia;                               | Divalproex Sodium             |                    |                    | S               | Unknown                      |                      |                 | Not Reported |                |
| Anxiety; Constipation;                              | Olanzapine                    |                    |                    | S               | Unknown                      |                      |                 | Not Reported |                |
| Diarrhoea; Dizziness; Dry Mouth; Dystonia; Fatigue; | Risperidone                   |                    |                    | S               | Unknown                      |                      |                 | Not Reported |                |
| Gynaecomastia;                                      | Clozapine                     |                    |                    | S               | Unknown                      |                      |                 | Not Reported |                |
| Headache; Hypotension;                              | Amisulpride                   |                    |                    | S               | Unknown                      |                      |                 | Not Reported |                |
| Increased Appetite;                                 | Quetiapine Fumarate           |                    |                    | S               | Unknown                      |                      |                 | Not Reported |                |
| Insomnia; Nausea;                                   | Chlorpromazine                |                    |                    | S               | Unknown                      |                      |                 | Not Reported |                |
| Orthostatic Hypotension;                            | Haloperidol                   |                    |                    | S               | Unknown                      |                      |                 | Not Reported |                |
| Parkinsonism; Pyrexia;                              | Fluphenazine Decanoate        |                    |                    | S               | Unknown                      |                      |                 | Not Reported |                |
| Salivary Hypersecretion;                            | Escitalopram                  |                    |                    | S               | Unknown                      |                      |                 | Not Reported |                |
| Sedation; Seizure;                                  | Lorazepam                     |                    |                    | S               | Unknown                      |                      |                 | Not Reported |                |
| Somnolence; Tachycardia;                            | Trihexyphenidyl Hydrochloride |                    |                    | S               | Unknown                      |                      |                 | Not Reported |                |
| Tardive Dyskinesia;                                 | Zuclopenthixol Decanoate      |                    |                    | S               | Unknown                      |                      |                 | Not Reported |                |
| Tremor; Vision Blurred;                             | Aripiprazole                  |                    |                    | S               | Unknown                      |                      |                 | Not Reported |                |
| Vomiting; Weight Increased                          | Trifluoperazine               |                    |                    | S               | Unknown                      |                      |                 | Not Reported |                |
|                                                     | Asenapine                     |                    |                    | S               | Unknown                      |                      |                 | Not Reported |                |
|                                                     | Imipramine                    |                    |                    | S               | Unknown                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>   | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------|--------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 23-Feb-2015                | 10870013                       | EXPEDITED (15-DAY) | Y                  | CA              | UCM201502-000125     |                      |                 | Female       | USA            |
| <u>Preferred Term</u>      | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrial Septal Defect;      | Topiramate (Topiramate)        |                    |                    | S               | Transplacental       |                      |                 | Not Reported |                |
| Cardiac Malposition;       | (Topiramate)                   |                    |                    |                 |                      |                      |                 |              |                |
| Congenital Diaphragmatic   | Tramadol (Tramadol) (Tramadol) |                    |                    | S               | Transplacental       |                      |                 | Not Reported |                |
| Eventration; Deformity     | Escitalopram                   |                    |                    | S               | Transplacental       |                      |                 | Not Reported |                |
| Thorax; Maternal Drugs     | Oxycodone/Acetaminophen        |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Affecting Foetus; Nipple   |                                |                    |                    |                 |                      |                      |                 |              |                |
| Disorder; Patent Ductus    |                                |                    |                    |                 |                      |                      |                 |              |                |
| Arteriosus; Rib Hypoplasia |                                |                    |                    |                 |                      |                      |                 |              |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Feb-2015                | 10871494                       | DIRECT             |                    | OT              |                      |                      | 42 YR           | Female       | USA            |
| <u>Preferred Term</u>      | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective; Product  | Escitalopram 10mg Camber       |                    |                    | S               | Oral                 | 1                    |                 | Camber       |                |
| Quality Issue; Product     | Escitalopram 10mg Teva         |                    |                    | S               | Oral                 | 1                    |                 | Teva         |                |
| Substitution Issue;        | Vitamins - B Complex           |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Suicidal Ideation          | Calcium                        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                            | Glucosamine/Msm                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                            | Escitalopram                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Feb-2015                | 10874145                       | DIRECT             | Y                  | DS              |                      |                      | 56 YR           | Female       | USA            |
| <u>Preferred Term</u>      | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Arthralgia; Bone Pain;     | Escitalopram 20mg              |                    |                    | S               | Oral                 | 20mg, 1 Qd, Po       |                 | Aurobindo    |                |
| Depression; Disturbance    | Dextroamphetamine Er           |                    |                    | C               |                      |                      |                 | Not Reported |                |
| In Attention; Feelings Of  |                                |                    |                    |                 |                      |                      |                 |              |                |
| Worthlessness; Insomnia;   |                                |                    |                    |                 |                      |                      |                 |              |                |
| Loss Of Personal           |                                |                    |                    |                 |                      |                      |                 |              |                |
| Independence In Daily      |                                |                    |                    |                 |                      |                      |                 |              |                |
| Activities; Myalgia;       |                                |                    |                    |                 |                      |                      |                 |              |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Product Substitution Issue

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Feb-2015              | 10874295      | DIRECT           | Y                  |                 |                      |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------|----------------|--------------|------------|-------------|--------------|-------------------------------------|-----------------|--------------|
| Drug Ineffective; Migraine;<br>Product Substitution Issue | Escitalopram   |              |            | S           | Oral         | 1-2 Months 2013 20 Mg<br>Daily Oral |                 | Not Reported |
|                                                           | Escitalopram   |              |            | S           | Oral         | 1/2 Months 2014 20 Mg<br>Daily Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Feb-2015              | 10598183      | EXPEDITED (15-DAY) |                    | OT              | CH-FRI-1000072554    |                      | 28 YR      | Female     | CHE            |

| <u>Preferred Term</u>                        | <u>Product</u>                        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------|---------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Metrorrhagia; Pregnancy;<br>Premature Labour | Escitalopram                          |              |            | S           | Oral         | 20 Mg              |                 | Forest       |
|                                              | Escitalopram                          |              |            | S           |              |                    |                 | Forest       |
|                                              | Seropram (Citalopram<br>Hydrobromide) |              |            | S           |              | 20 Mg              |                 | Not Reported |
|                                              | Abilify                               |              |            | S           | Oral         | 10 Mg              |                 | Not Reported |
|                                              | Abilify                               |              |            | S           |              |                    |                 | Not Reported |
|                                              | Edronax                               |              |            | S           | Oral         | 4 Mg               |                 | Not Reported |
|                                              | Edronax<br>Latuda                     |              |            | S           |              | 40 Mg              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------------------------------|----------------------|------------|------------|----------------|
| 24-Feb-2015              | 10722809      | EXPEDITED (15-DAY) |                    | LT, OT          | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>BMS-2015-001902 |                      | 15 YR      | Male       | USA            |

| <u>Preferred Term</u>            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>           |
|----------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------|
| Aggression; Suicidal<br>Ideation | Abilify        |              |            | S           | Oral         | 7.5 Mg, Qd         |                 | Bristol Myers Squibb |
|                                  | Abilify        |              |            | S           | Oral         | 15 Mg, Unk         |                 | Bristol Myers Squibb |
|                                  | Wellbutrin     |              |            | S           | Unknown      | 300 Mg, Qd         |                 | Not Reported         |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                       |   |         |           |  |              |
|---------------------------------------|---|---------|-----------|--|--------------|
| Wellbutrin                            | S |         |           |  | Not Reported |
| Lexapro                               | S | Unknown | 5 Mg, Unk |  | Not Reported |
| Prozac                                | C | Unknown | Unk       |  | Not Reported |
| Montelukast                           | C | Unknown |           |  | Not Reported |
| Zyrtec                                | C | Unknown |           |  | Not Reported |
| Vitamin C /00008001/                  | C | Unknown |           |  | Not Reported |
| Fish Oil                              | C | Unknown |           |  | Not Reported |
| Multivitamin /00097801/               | C | Unknown |           |  | Not Reported |
| Minocycline\Minocycline Hydrochloride | C | Unknown |           |  | Not Reported |

| <u>FDA Received Date</u>                  | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 24-Feb-2015                               | 10857240       | NON-EXPEDITED    |                    | HO              | FR-FRI-1000074646    |                      | 88 YR           | Female       | FRA            |
| <u>Preferred Term</u>                     | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Ear Haemorrhage; Fall; Subdural Haematoma | Escitalopram   |                  |                    | S               | Oral                 | 5 Mg                 |                 | Forest       |                |
|                                           | Kardegic       |                  |                    | S               | Oral                 | 75 Mg                |                 | Not Reported |                |
|                                           | Atenolol       |                  |                    | S               | Oral                 | 100 Mg               |                 | Not Reported |                |
|                                           | Tahor          |                  |                    | C               | Oral                 | 10 Mg                |                 | Not Reported |                |
|                                           | Paracetamol    |                  |                    | C               | Oral                 | 2 Gram               |                 | Not Reported |                |

| <u>FDA Received Date</u>                      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------|----------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
| 24-Feb-2015                                   | 10857878       | EXPEDITED (15-DAY) |                    | HO              | FR-MYLANLABS-2015M1005398 |                      |                 | Unknown      | FRA            |
| <u>Preferred Term</u>                         | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anaemia; Ecchymosis; Haematoma; Off Label Use | Fondaparinux   |                    |                    | S               | Subcutaneous              | 5 Mg/04.Ml, Qd       |                 | Not Reported |                |
|                                               | Fondaparinux   |                    |                    | S               |                           | Unk                  |                 | Not Reported |                |
|                                               | Fondaparinux   |                    |                    | S               | Subcutaneous              | Unk                  |                 | Not Reported |                |
|                                               | Plavix         |                    |                    | S               | Oral                      | 75 Mg, Qd            |                 | Not Reported |                |
|                                               | Seroplex       |                    |                    | S               | Oral                      | 10 Mg, Qd            |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                      |   |             |              |
|----------------------|---|-------------|--------------|
| Celluvisc /00007002/ | C | 4 Mg, Unk   | Not Reported |
| Cordarone            | C | 200 Mg, Unk | Not Reported |
| Tardyferon           | C | Unk         | Not Reported |
| Alprazolam           | C | Unk         | Not Reported |
| Amlor                | C | Unk         | Not Reported |
| Cetirizine           | C | Unk         | Not Reported |
| Mestinon             | C | Unk         | Not Reported |
| Ebixa                | C | Unk         | Not Reported |
| Furadantine          | C | Unk         | Not Reported |
| Dafalgan             | C | Unk         | Not Reported |
| Transipeg /00754501/ | C | Unk         | Not Reported |
| Inexium /01479302/   | C | Unk         | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 24-Feb-2015              | 10858250      | EXPEDITED (15-DAY) |                    | OT              | GB-MYLANLABS-2015M1004187 |                      |            | Unknown    | GBR            |

| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|----------------|--------------|------------|-------------|--------------|---------------------|-----------------|--------------|
| Exposure Via Breast Milk; | Escitalopram   |              |            | S           | Transmammary | 10 Mg, Qd           |                 | Not Reported |
| Insomnia                  | Escitalopram   |              |            | S           | Transmammary | 20 Milligram Daily; |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Feb-2015              | 10861268      | EXPEDITED (15-DAY) |                    | DE              | US-BANPHARM-20153480 |                      | 67 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u>             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Zonisamide Unknown Product |              |            | S           |              |                    |                 | Not Reported |
|                       | Lamotrigine                |              |            | S           |              |                    |                 | Not Reported |
|                       | Lorazepam                  |              |            | S           |              |                    |                 | Not Reported |
|                       | Escitalopram               |              |            | S           |              |                    |                 | Not Reported |
|                       | Lovastatin                 |              |            | S           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                    | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------|---------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 24-Feb-2015                                 | 10861322                  | EXPEDITED (15-DAY) |                    | HO              | FR-JNJFOC-20150213608    |                      | 94 YR           | Male         | FRA            |
| <u>Preferred Term</u>                       | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Fall                                        | Ixprim                    |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                                             | Seroplex                  |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                                             | Temesta (Lorazepam)       |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                                             | Paracetamol               |                    |                    | C               | Oral                     |                      |                 | Not Reported |                |
|                                             | Permixon                  |                    |                    | C               | Oral                     |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                    | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Feb-2015                                 | 10861845                  | EXPEDITED (15-DAY) |                    | DE              | US-BANPHARM-20153503     |                      | 48 YR           | Female       | USA            |
| <u>Preferred Term</u>                       | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Death                                       | Ibuprofen Unknown Product |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                             | Oxycodone                 |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                             | Cyclobenzaprine           |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                             | Metoprolol                |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                             | Clonidine                 |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                             | Nitroglycerin             |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                             | Lisinopril                |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                             | Escitalopram              |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                             | Diclofenac                |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                             | Azithromycin              |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                             | Cephalexin                |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                             | Doxycycline               |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                             | Methylprednisolone        |                    |                    | S               |                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                    | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Feb-2015                                 | 10863810                  | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-2015065264 |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                       | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Autism Spectrum Disorder; Bipolar Disorder; | Zoloft                    |                    |                    | S               |                          | Unk                  |                 | Pfizer       |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                          |         |   |     |              |
|----------------------------------------------------------|---------|---|-----|--------------|
| Obsessive-Compulsive Disorder; Psychomotor Hyperactivity | Lexapro | S | Unk | Not Reported |
|----------------------------------------------------------|---------|---|-----|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Feb-2015              | 10864411      | EXPEDITED (15-DAY) |                    | OT              | PHHY2015FR020823     |                      |            | Unknown    | FRA            |

| <u>Preferred Term</u>                            | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------|-------------------------|--------------|------------|-------------|----------------|---------------------------|-----------------|--------------|
| Foetal Exposure During Pregnancy; Premature Baby | Dihydroergotamine       |              |            | S           | Transplacental |                           |                 | Not Reported |
|                                                  | Aripiprazole            |              |            | S           | Transplacental | Maternal Dose (10 Mg/Day) |                 | Not Reported |
|                                                  | Escitalopram            |              |            | S           | Transplacental |                           |                 | Not Reported |
|                                                  | Oxazepam                |              |            | S           | Transplacental |                           |                 | Novartis     |
|                                                  | Pipamperone             |              |            | S           | Transplacental |                           |                 | Not Reported |
|                                                  | Loprazolam              |              |            | S           | Transplacental |                           |                 | Not Reported |
|                                                  | Dipotassium Clorazepate |              |            | S           | Transplacental |                           |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Feb-2015              | 10865536      | EXPEDITED (15-DAY) |                    | DE, HO          | 2015SP000111         |                      | 37 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Meloxicam      |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Loperamide     |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Escitalopram   |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Feb-2015              | 10599532      | EXPEDITED (15-DAY) |                    | CA, DE          | US-FRI-1000072579    |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiac Septal Defect; Congenital Pulmonary Valve Disorder | Lexapro        |              |            | S           | Other        | 10 Mg              |                 | Forest       |
|                                                            | Prenatal Plus  |              |            | C           |              |                    |                 | Not Reported |

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## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                       | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 25-Feb-2015                                                                                                                                                                    | 10867498               | EXPEDITED (15-DAY) |                    | OT              | SE-FRI-1000074684     |                      |                 | Male         | SWE            |
| <u>Preferred Term</u>                                                                                                                                                          | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypoacusis; Tinnitus                                                                                                                                                           | Escitalopram           |                    |                    | S               | Oral                  | 10 Mg                |                 | Forest       |                |
|                                                                                                                                                                                | Escitalopram           |                    |                    | S               | Oral                  | 5 Mg                 |                 | Forest       |                |
|                                                                                                                                                                                | Quetiapine             |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |
|                                                                                                                                                                                | Lamictal               |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |
|                                                                                                                                                                                | Concerta               |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |
|                                                                                                                                                                                | Zopiclone              |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                       | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Feb-2015                                                                                                                                                                    | 10867500               | EXPEDITED (15-DAY) |                    | CA, OT          | US-JNJFOC-20150213245 |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                          | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrial Septal Defect; Congenital Anomaly; Congenital Diaphragmatic Eventration; Dextrocardia; Foetal Exposure During Pregnancy; Patent Ductus Arteriosus; Supernumerary Nipple | Tramadol Hydrochloride |                    |                    | S               | Transplacental        |                      |                 | Not Reported |                |
|                                                                                                                                                                                | Topiramate             |                    |                    | S               | Transplacental        |                      |                 | Not Reported |                |
|                                                                                                                                                                                | Oxycodone/Paracetamol  |                    |                    | S               | Transplacental        |                      |                 | Not Reported |                |
|                                                                                                                                                                                | Escitalopram           |                    |                    | S               | Transplacental        |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                       | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Feb-2015                                                                                                                                                                    | 10867516               | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000074658     |                      | 8 YR            | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                                                          | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Autism Spectrum Disorder; Exposure During Pregnancy                                                                                                                            | Escitalopram           |                    |                    | S               | Transplacental        |                      |                 | Forest       |                |
|                                                                                                                                                                                | Alprazolam             |                    |                    | S               | Transplacental        |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                      | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------|-------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 25-Feb-2015                                                   | 10868503          | EXPEDITED (15-DAY) |                    | HO, LT          | ES-JNJFOC-20150209712    |                      | 53 YR           | Male         | ESP            |
| <u>Preferred Term</u>                                         | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bradycardia; Drug Interaction; Electrocardiogram Qt Prolonged | Risperdal         |                    |                    | S               | Unknown                  |                      |                 | Not Reported |                |
|                                                               | Escitalopram      |                    |                    | S               | Unknown                  |                      |                 | Not Reported |                |
|                                                               | Lormetazepam      |                    |                    | C               | Unknown                  |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Feb-2015                                                   | 10881865          | DIRECT             |                    |                 |                          |                      | 57 YR           | Male         | USA            |
| <u>Preferred Term</u>                                         | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State; Dizziness; Mental Disorder                 | Escitalopram      |                    |                    | S               | Oral                     |                      |                 | Teva         |                |
|                                                               | Vitamin C         |                    |                    | C               |                          |                      |                 | Not Reported |                |
|                                                               | Vitamin B Complex |                    |                    | C               |                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Feb-2015                                                   | 10813515          | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2015061007 |                      | 64 YR           | Unknown      | USA            |
| <u>Preferred Term</u>                                         | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity; Rash; Rubber Sensitivity               | Etanercept        |                    |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                                                               | Enbrel            |                    |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                                                               | Celecoxib         |                    |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                                                               | Celebrex          |                    |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                                                               | Naproxen Sodium   |                    |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                                                               | Voltaren          |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                                                               | Diclofenac Sodium |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                                                               | Imuran            |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                                                               | Azathioprine      |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                                                               | Arava             |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |

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|                        |   |     |              |
|------------------------|---|-----|--------------|
| Leflunomide            | S | Unk | Not Reported |
| Anaprox                | S | Unk | Not Reported |
| Myochrysine            | S | Unk | Not Reported |
| Gold Sodium Thiomalate | S | Unk | Not Reported |
| Lexapro                | S | Unk | Not Reported |
| Escitalopram Oxalate   | S | Unk | Not Reported |
| Sulindac               | S | Unk | Not Reported |
| Clinoril               | S | Unk | Not Reported |
| Hydrocodone            | S | Unk | Not Reported |
| Vicodin                | S | Unk | Not Reported |
| Fluoxetine Hcl         | S | Unk | Not Reported |
| Prozac                 | S | Unk | Not Reported |
| Acetaminophen          | S | Unk | Not Reported |
| Etodolac               | S | Unk | Not Reported |
| Lodine                 | S | Unk | Not Reported |
| Nabumetone             | S | Unk | Not Reported |
| Relafen                | S | Unk | Not Reported |
| Rofecoxib              | S | Unk | Not Reported |
| Vioxx                  | S | Unk | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 26-Feb-2015              | 10869980      | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2015070729 |                      |            | Male       | USA            |

| <u>Preferred Term</u>                                                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Ineffective;<br>Dyskinesia; Dystonia;<br>Extrapyramidal Disorder | Geodon         |              |            | S           |              | Unk                |                 | Pfizer       |
|                                                                       | Cymbalta       |              |            | S           |              | Unk                |                 | Not Reported |
|                                                                       | Lexapro        |              |            | S           |              | Unk                |                 | Not Reported |
|                                                                       | Cogentin       |              |            | S           |              | Unk                |                 | Not Reported |



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| <u>FDA Received Date</u>                                   | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------|--------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 26-Feb-2015                                                | 10881901           | EXPEDITED (15-DAY) | Y                  | DE              | ABR_02027_2015       |                      | 67 YR           | Male         | USA            |
| <u>Preferred Term</u>                                      | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Poisoning                            | Lamotrigine        |                    |                    | S               |                      | Df                   |                 | Not Reported |                |
|                                                            | Zonisamide         |                    |                    | S               |                      | Df                   |                 | Not Reported |                |
|                                                            | Lorazepam          |                    |                    | S               |                      | Df                   |                 | Not Reported |                |
|                                                            | Escitalopram       |                    |                    | S               |                      | Df                   |                 | Not Reported |                |
|                                                            | Lovastatin         |                    |                    | S               |                      | Df                   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                   | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Feb-2015                                                | 10881960           | EXPEDITED (15-DAY) | Y                  | DE              | ABR_02033_2015       |                      | 69 YR           | Male         | USA            |
| <u>Preferred Term</u>                                      | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Exposure Via Ingestion;<br>Poisoning | Lamotrigine        |                    |                    | S               | Oral                 | Df                   |                 | Not Reported |                |
|                                                            | Cardiac Glycosides |                    |                    | S               | Oral                 | Df                   |                 | Not Reported |                |
|                                                            | Clonazepam         |                    |                    | S               | Oral                 | Df                   |                 | Not Reported |                |
|                                                            | Trazodone          |                    |                    | S               | Oral                 | Df                   |                 | Not Reported |                |
|                                                            | Oxybutynin         |                    |                    | S               | Oral                 | Df                   |                 | Not Reported |                |
|                                                            | Quetiapine         |                    |                    | S               | Oral                 | Df                   |                 | Not Reported |                |
|                                                            | Escitalopram       |                    |                    | S               | Oral                 | Df                   |                 | Not Reported |                |
|                                                            | Finasteride        |                    |                    | S               | Oral                 | Df                   |                 | Not Reported |                |
|                                                            | Salicylates Nos    |                    |                    | S               | Oral                 | Df                   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                   | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Feb-2015                                                | 10882045           | EXPEDITED (15-DAY) | Y                  | DE              | ABR_02039_2015       |                      | 62 YR           | Male         | USA            |
| <u>Preferred Term</u>                                      | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Exposure Via Ingestion;              | Lamotrigine        |                    |                    | S               | Oral                 | Df                   |                 | Not Reported |                |

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|           |                                      |   |      |    |              |
|-----------|--------------------------------------|---|------|----|--------------|
| Poisoning | Temazepam                            | S | Oral | Df | Not Reported |
|           | Lorazepam                            | S | Oral | Df | Not Reported |
|           | Primidone                            | S | Oral | Df | Not Reported |
|           | Escitalopram                         | S | Oral | Df | Not Reported |
|           | Benzotropine                         | S | Oral | Df | Not Reported |
|           | Lipid Modifying Agents, Combinations | S | Oral | Df | Not Reported |

| <u>FDA Received Date</u>                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
|------------------------------------------------|----------------------|--------------------|--------------------|-----------------|---------------------------------------------|----------------------|-----------------|------------------|----------------|
| 27-Feb-2015                                    | 10768978             | EXPEDITED (15-DAY) |                    | HO              | AT-ELI_LILLY_AND_COMP<br>ANY-AT201502000978 |                      | 33 YR           | Male             | AUT            |
| <u>Preferred Term</u>                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |
| Generalised Anxiety Disorder; Major Depression | Cymbalta             |                    |                    | S               | Unknown                                     | Unk                  |                 | Eli Lilly And Co |                |
|                                                | Cipralext /01588501/ |                    |                    | S               | Oral                                        | 10 Mg, Unknown       |                 | Not Reported     |                |
|                                                | Trittico             |                    |                    | C               |                                             |                      |                 | Not Reported     |                |
|                                                | Mogadon              |                    |                    | C               |                                             | Unk                  |                 | Not Reported     |                |
|                                                | Nozinan /00038601/   |                    |                    | C               |                                             | Unk                  |                 | Not Reported     |                |

| <u>FDA Received Date</u>                                                                                                                      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 27-Feb-2015                                                                                                                                   | 10794575       | EXPEDITED (15-DAY) |                    | HO              | FR-PFIZER INC-2015051201 |                      | 50 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                         | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Arrhythmia; Hypokalaemia; Malaise; Seizure; Suicide Attempt; Tetany; Torsade De Pointes; Toxicity To Various Agents; Ventricular Fibrillation | Xanax          |                    |                    | S               | Oral                     | 0.25 Mg, Daily       |                 | Pfizer       |                |
|                                                                                                                                               | Seroplex       |                    |                    | S               | Oral                     | 10 Mg, Daily         |                 | Not Reported |                |
|                                                                                                                                               | Imovane        |                    |                    | C               |                          | 7.5 Mg, Daily        |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 27-Feb-2015              | 10872567      | EXPEDITED (15-DAY) |                    | OT              | TW-CIPLA LTD.-2015TW01332 |                      |            | Unknown    | TWN            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                 | <u>Product</u>                                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
|-----------------------------------------------------------------------|---------------------------------------------------|--------------------|--------------------|-----------------|-----------------------|-------------------------------|-----------------|--------------|----------------|
| Gastrointestinal Disorder;<br>Merycism                                | Sertraline                                        |                    |                    | S               |                       | 150 Mg, Per Day For 6 Months  |                 | Cipla        |                |
|                                                                       | Bupropion                                         |                    |                    | S               |                       | 300 Mg, Per Day For 3 Months  |                 | Not Reported |                |
|                                                                       | Duloxetine                                        |                    |                    | S               |                       | 120 Mg, Per Day, For 6 Months |                 | Not Reported |                |
|                                                                       | Escitalopram                                      |                    |                    | S               |                       | 20 Mg, Per Day For 3 Months   |                 | Not Reported |                |
|                                                                       | Venlafaxine                                       |                    |                    | S               |                       | 225 Mg, Per Day, For 6 Months |                 | Not Reported |                |
| <u>FDA Received Date</u>                                              | <u>Case #</u>                                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Feb-2015                                                           | 10875217                                          | EXPEDITED (15-DAY) |                    | DE              | US-ACTAVIS-2015-03951 |                               | 28 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                 | <u>Product</u>                                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Toxicity To Various Agents                      | Bupropion Hydrochloride (Actavis Laboratories FI) |                    |                    | S               | Oral                  | Unknown                       |                 | Actavis      |                |
|                                                                       | Escitalopram (Unknown)                            |                    |                    | S               | Oral                  | Unknown                       |                 | Not Reported |                |
|                                                                       | Gabapentin (Aellc)                                |                    |                    | S               | Oral                  | Unknown                       |                 | Watson       |                |
|                                                                       | Alprazolam (Aellc)                                |                    |                    | S               | Oral                  | Unknown                       |                 | Watson       |                |
| <u>FDA Received Date</u>                                              | <u>Case #</u>                                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Mar-2015                                                           | 10641498                                          | EXPEDITED (15-DAY) |                    | HO              | IT-FRI-1000072956     |                               | 23 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                 | <u>Product</u>                                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Bradykinesia; Drug Abuse;<br>Intentional Overdose;<br>Overdose; Sopor | Escitalopram                                      |                    |                    | S               | Oral                  | Overdose: 140 Mg Daily        |                 | Forest       |                |
|                                                                       | Mirtazapine                                       |                    |                    | S               | Oral                  | 600 Mg Daily                  |                 | Not Reported |                |
|                                                                       | Periactin                                         |                    |                    | S               | Oral                  | 40 Mg Daily                   |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                        | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|---------------------------------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|------------------------------------------|----------------------|-----------------|----------------------|----------------|
| 02-Mar-2015                                                                     | 10652902                      | EXPEDITED (15-DAY) |                    | HO              | IT-MYLANLABS-2014M1013411                |                      |                 | Unknown              | ITA            |
| <u>Preferred Term</u>                                                           | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Bradykinesia; Drug Abuse; Overdose; Sopor                                       | Mirtazapine                   |                    |                    | S               | Oral                                     | 600 Mg, Total        |                 | Not Reported         |                |
|                                                                                 | Periactin                     |                    |                    | S               | Oral                                     | 10 Df, Total         |                 | Not Reported         |                |
|                                                                                 | Cipraxel /01588502/           |                    |                    | S               | Oral                                     | 14 Df, Total         |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                        | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 02-Mar-2015                                                                     | 10904086                      | DIRECT             |                    | OT              |                                          |                      | 28 YR           | Female               | USA            |
| <u>Preferred Term</u>                                                           | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Serotonin Syndrome; Vomiting                                                    | Rizatriptan                   |                    |                    | S               | Oral                                     | 1 Pill               |                 | Not Reported         |                |
|                                                                                 | Escitalopram Oxalate          |                    |                    | S               | Oral                                     | 1 Pill               |                 | Not Reported         |                |
|                                                                                 | Yaz Birth Control Green Bayer |                    |                    | C               |                                          |                      |                 | Not Reported         |                |
|                                                                                 | Humira Syringe 40mg Abbvie    |                    |                    | C               |                                          |                      |                 | Not Reported         |                |
|                                                                                 | Lexapro                       |                    |                    | C               |                                          |                      |                 | Not Reported         |                |
|                                                                                 | Provigil                      |                    |                    | C               |                                          |                      |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                        | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 03-Mar-2015                                                                     | 9777944                       | EXPEDITED (15-DAY) |                    | HO              | IT-BRISTOL-MYERS SQUIBB COMPANY-19923440 |                      | 86 YR           | Female               | ITA            |
| <u>Preferred Term</u>                                                           | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Bradycardia; Drug Abuse; Intentional Overdose; Psychomotor Hyperactivity; Sopor | Metformin Hydrochloride       |                    |                    | S               | Oral                                     | 1500 Mg, Unk         |                 | Bristol Myers Squibb |                |
|                                                                                 | Tavor (Lorazepam)             |                    |                    | S               | Oral                                     | 6 Df, Unk            |                 | Not Reported         |                |
|                                                                                 | Cipraxel                      |                    |                    | S               | Oral                                     | 3 Df, Unk            |                 | Not Reported         |                |
|                                                                                 | Diamicron                     |                    |                    | S               | Oral                                     | 30 Mg, Unk           |                 | Not Reported         |                |
|                                                                                 | Tachipirina                   |                    |                    | S               | Oral                                     | 3 Df, Unk            |                 | Not Reported         |                |
|                                                                                 | Serenase (Haloperidol)        |                    |                    | S               | Oral                                     | 2 Df, Unk            |                 | Not Reported         |                |
|                                                                                 | Bisoprolol Hemifumarate       |                    |                    | S               | Oral                                     | 3 Df, Unk            |                 | Not Reported         |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                 |   |               |                    |                      |
|-----------------|---|---------------|--------------------|----------------------|
| Macrogol        | C | Unknown       | 1 Df, Unk          | Not Reported         |
| Coumadin        | C | Unknown       | 5 Mg, Unk          | Bristol Myers Squibb |
| Cholecalciferol | C | Intramuscular | 1 Df, Qmo          | Not Reported         |
| Nexium          | C | Unknown       |                    | Not Reported         |
| Isoptin         | C | Unknown       | Film-Coated Tablet | Not Reported         |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Mar-2015              | 10727677      | EXPEDITED (15-DAY) |                    | OT              | PHHY2015FR006478     |                      | 89 YR      | Female     | FRA            |

| <u>Preferred Term</u>                   | <u>Product</u>                       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                         | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------|--------------------------------------|--------------|------------|-------------|--------------|------------------------------------------------------------|-----------------|--------------|
| Orthostatic Hypotension;<br>Tachycardia | Cotareg                              |              |            | S           | Oral         | 1 Df (Valsartan 80mg,<br>Hydrochlorothiazide<br>12.5mg) Qd |                 | Novartis     |
|                                         | Loxen (Nicardipine<br>Hydrochloride) |              |            | S           | Oral         | 20 Mg, Prn                                                 |                 | Not Reported |
|                                         | Loxen (Nicardipine<br>Hydrochloride) |              |            | S           | Oral         | 20 Mg, Prn (If Bp Greater<br>Than 17/9)                    |                 | Not Reported |
|                                         | Norfloxacin                          |              |            | S           | Oral         | 2 Df, Qd                                                   |                 | Not Reported |
|                                         | Seroplex                             |              |            | S           | Oral         | 20 Mg, Qd                                                  |                 | Not Reported |
|                                         | Seroplex                             |              |            | S           | Oral         | 10 Mg, Qd                                                  |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Mar-2015              | 10885135      | EXPEDITED (15-DAY) |                    | HO              | CH-FRI-1000074919    |                      | 74 YR      | Male       | CHE            |

| <u>Preferred Term</u>                                                                                                                              | <u>Product</u>             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                             | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|--------------|------------|-------------|------------------------------------------|--------------------|-----------------|--------------|
| Hiccups; Laboratory Test<br>Interference; Polymyalgia<br>Rheumatica; Pyrexia;<br>Respiratory Syncytial<br>Virus Test Positive;<br>Thrombocytopenia | Escitalopram               |              |            | S           | Oral                                     | 5 Mg               |                 | Forest       |
|                                                                                                                                                    | Escitalopram Oral Solution |              |            | S           | Oral                                     | 10 Mg              |                 | Forest       |
|                                                                                                                                                    | Tolvon                     |              |            | S           | Oral                                     | 15 Mg              |                 | Not Reported |
|                                                                                                                                                    | Augmentin                  |              |            | C           | Intravenous (not<br>otherwise specified) | 3.6 Gram           |                 | Not Reported |
|                                                                                                                                                    | Tazobac                    |              |            | C           | Intravenous (not<br>otherwise specified) | 13.5 Gram          |                 | Not Reported |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                    |   |              |          |              |
|--------------------|---|--------------|----------|--------------|
| Tavanic            | C | Oral         | 500 Mg   | Not Reported |
| Tienam             | C | Unknown      | 2000 Mg  | Not Reported |
| Dalfalgan          | C | Oral         | 3 Gram   | Not Reported |
| Prednisone Labatec | C | Oral         | 20 Mg    | Not Reported |
| Enalapril Actavis  | C | Oral         | 20 Mg    | Not Reported |
| Nexium             | C | Oral         | 40 Mg    | Not Reported |
| Clexane            | C | Oral         | 40 Mg    | Not Reported |
| Morphine           | C | Subcutaneous | 8 Mg     | Not Reported |
| Co-Amoxicillin     | C | Unknown      | 3.9 Gram | Not Reported |
| Paracetamol        | C |              | 3 Gram   | Not Reported |
| Paracetamol        | C |              | 1 Gram   | Not Reported |
| Tienam             | C | Unknown      |          | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Mar-2015              | 10885899      | EXPEDITED (15-DAY) |                    | DE              | US-BANPHARM-20153551 |                      | 41 YR      | Male       | USA            |

| <u>Preferred Term</u>                        | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide;<br>Exposure Via Ingestion | Diphenhydramine Unknown |              |            | S           |              |                    |                 | Not Reported |
|                                              | Product/Acetaminophen   |              |            |             |              |                    |                 |              |
|                                              | Warfarin                |              |            | S           |              |                    |                 | Not Reported |
|                                              | Olanzapine              |              |            | S           |              |                    |                 | Not Reported |
|                                              | Lisinopril              |              |            | S           |              |                    |                 | Not Reported |
|                                              | Escitalopram            |              |            | S           |              |                    |                 | Not Reported |
|                                              | Prednisone              |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 04-Mar-2015              | 10886328      | EXPEDITED (15-DAY) |                    | DE              | US-ACTAVIS-2015-03966 |                      | 34 YR      | Female     | USA            |

| <u>Preferred Term</u>                            | <u>Product</u>                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>        |
|--------------------------------------------------|--------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|-------------------|
| Completed Suicide;<br>Toxicity To Various Agents | Amitriptyline                  |              |            | S           | Oral         | Unknown            |                 | Not Reported      |
|                                                  | Tramadol Hydrochloride (Aellc) |              |            | S           | Oral         | Unknown            |                 | Actavis Elizabeth |
|                                                  | Hydrocodone-Acetaminophen      |              |            | S           | Oral         | Unknown            |                 | Watson            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                |   |      |         |  |  |  |  |  |              |
|------------------------------------------------|---|------|---------|--|--|--|--|--|--------------|
| (Watson Laboratories)                          |   |      |         |  |  |  |  |  |              |
| Ondansetron (Unknown)                          | S | Oral | Unknown |  |  |  |  |  | Not Reported |
| Diclofenac Sodium (Aellc)                      | S | Oral | Unknown |  |  |  |  |  | Watson       |
| Zolpidem Tartrate (Watson Laboratories)        | S | Oral | Unknown |  |  |  |  |  | Watson       |
| Escitalopram (Unknown)                         | S | Oral | Unknown |  |  |  |  |  | Not Reported |
| Sertraline Hydrochloride (Watson Laboratories) | S | Oral | Unknown |  |  |  |  |  | Watson       |
| Gabapentin (Aellc)                             | S | Oral | Unknown |  |  |  |  |  | Watson       |
| Lubiprostone                                   | S | Oral | Unknown |  |  |  |  |  | Not Reported |
| Linaclotide                                    | S | Oral | Unknown |  |  |  |  |  | Not Reported |
| Liothyronine                                   | S | Oral | Unknown |  |  |  |  |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Mar-2015              | 10886337      | EXPEDITED (15-DAY) |                    | DE              | US-WATSON-2015-03982 |                      | 43 YR      | Female     | USA            |

| <u>Preferred Term</u>      | <u>Product</u>                                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Toxicity To Various Agents | Sertraline Hydrochloride (Watson Laboratories) |              |            | S           | Oral         | Unknown            |                 | Watson       |
|                            | Escitalopram (Unknown)                         |              |            | S           | Oral         | Unknown            |                 | Not Reported |
|                            | Atomoxetine                                    |              |            | S           | Oral         | Unknown            |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Mar-2015              | 10888964      | EXPEDITED (15-DAY) |                    | DE              | US-WATSON-2015-04064 |                      | 51 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                       | <u>Product</u>                                  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------|-------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide;<br>Exposure Via Ingestion;<br>Toxicity To Various Agents | Promethazine (Watson Laboratories)              |              |            | S           | Oral         | Unknown            |                 | Watson       |
|                                                                             | Verapamil Hydrochloride (Watson Laboratories)   |              |            | S           | Oral         | Unknown            |                 | Watson       |
|                                                                             | Escitalopram (Unknown)                          |              |            | S           | Oral         | Unknown            |                 | Not Reported |
|                                                                             | Hydrocodone-Acetaminophen (Watson Laboratories) |              |            | S           | Oral         | Unknown            |                 | Watson       |
|                                                                             | Diazepam (Watson)                               |              |            | S           | Oral         | Unknown            |                 | Watson       |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                       |             |                      |                               |                                  |
|-----------------------------------------------------------------------------------------------------------------------|-------------|----------------------|-------------------------------|----------------------------------|
| Laboratories)<br>Topiramate (Watson<br>Laboratories)<br>Diclofenac (Watson<br>Laboratories)<br>Esomeprazole (Unknown) | S<br>S<br>S | Oral<br>Oral<br>Oral | Unknown<br>Unknown<br>Unknown | Watson<br>Watson<br>Not Reported |
|-----------------------------------------------------------------------------------------------------------------------|-------------|----------------------|-------------------------------|----------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|------------|------------|----------------|
| 05-Mar-2015              | 10889272      | EXPEDITED (15-DAY) |                    | OT              | GB-MYLANLABS-<br>2015M1006720 |                      |            | Unknown    | GBR            |

| <u>Preferred Term</u>                                                                                                                                              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Aggression; Agitation;<br>Alcohol Abuse; Anxiety;<br>Decreased Appetite;<br>Impulsive Behaviour;<br>Insomnia; Paranoia;<br>Sexual Inhibition;<br>Unevaluable Event | Escitalopram   |              |            | S           | Unknown      | 10-20mg            |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|------------|------------|----------------|
| 05-Mar-2015              | 10889276      | EXPEDITED (15-DAY) |                    | OT              | GB-MYLANLABS-<br>2015M1006719 |                      |            | Unknown    | GBR            |

| <u>Preferred Term</u>                                                                                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Alcohol Abuse;<br>Alcoholism; Imprisonment;<br>Mania; Suicidal Behaviour;<br>Tremor; Unevaluable<br>Event | Escitalopram   |              |            | S           | Unknown      | 10mg               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|------------|------------|----------------|
| 05-Mar-2015              | 10889281      | EXPEDITED (15-DAY) |                    | OT              | GB-MYLANLABS-<br>2015M1006718 |                      |            | Unknown    | GBR            |

| <u>Preferred Term</u>                                                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Aggression; Alcoholism;<br>Behaviour Disorder;<br>Decreased Interest; | Escitalopram   |              |            | S           | Unknown      | 10mg               |                 | Not Reported |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Emotional Disorder;  
Unevaluable Event;  
Unevaluable Event

| <u>FDA Received Date</u>                              | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------|---------------------|--------------------|--------------------|-----------------|----------------------------|------------------------|-----------------|--------------|----------------|
| 05-Mar-2015                                           | 10890264            | EXPEDITED (15-DAY) |                    | HO              | CH-009507513-1502CHE010796 |                        | 20 YR           | Male         | CHE            |
| <u>Preferred Term</u>                                 | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug-Induced Liver Injury;<br>Transaminases Increased | Remeron             |                    |                    | S               | Oral                       | 15 Mg, Qd              |                 | Merck        |                |
|                                                       | Quetiapine Fumarate |                    |                    | S               | Oral                       | 25 Mg, Qod             |                 | Not Reported |                |
|                                                       | Quetiapine Fumarate |                    |                    | S               | Oral                       | 50 Mg, Qd              |                 | Not Reported |                |
|                                                       | Quetiapine Fumarate |                    |                    | S               | Oral                       | 75 Mg, Qd              |                 | Not Reported |                |
|                                                       | Ciprallex           |                    |                    | S               | Oral                       | 10 Mg, Qd              |                 | Not Reported |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Mar-2015                                           | 10891885            | EXPEDITED (15-DAY) |                    | HO              | CH-FRI-1000075013          |                        |                 | Male         | CHE            |
| <u>Preferred Term</u>                                 | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug-Induced Liver Injury;<br>Transaminases Increased | Escitalopram        |                    |                    | S               | Oral                       | 10 Mg Daily            |                 | Forest       |                |
|                                                       | Sequase             |                    |                    | S               | Oral                       | 25 Mg Every Second Day |                 | Not Reported |                |
|                                                       | Sequase             |                    |                    | S               | Oral                       | 50 Mg Daily            |                 | Not Reported |                |
|                                                       | Sequase             |                    |                    | S               | Oral                       | 75 Mg Daily            |                 | Not Reported |                |
|                                                       | Remeron             |                    |                    | S               | Oral                       | 15 Mg Daily            |                 | Not Reported |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Mar-2015                                           | 10892524            | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000074907          |                        |                 | Male         | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Coarctation Of The Aorta;<br>Congenital Anomaly       | Lexapro             |                    |                    | S               |                            |                        |                 | Forest       |                |
|                                                       | Sertraline          |                    |                    | S               |                            |                        |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                            | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|---------------------------------------------------------------------|--------------------|--------------------|--------------------|-----------------|--------------------------------------------------------|--------------------------------|-----------------|----------------------|----------------|
| 09-Mar-2015                                                         | 10869461           | EXPEDITED (15-DAY) |                    | HO              | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>BMS-2015-010390 |                                | 48 YR           | Female               | USA            |
| <u>Preferred Term</u>                                               | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                           | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>           |                |
| Dysarthria; Hypertension;<br>Hypokalaemia; Mental<br>Status Changes | Abilify            |                    |                    | S               | Oral                                                   | 15 Mg, Bid                     |                 | Bristol Myers Squibb |                |
|                                                                     | Ibuprofen          |                    |                    | S               | Oral                                                   | 800 Mg, Tid                    |                 | Bristol Myers Squibb |                |
|                                                                     | Desvenlafaxine     |                    |                    | S               | Oral                                                   | 50 Mg, Qd                      |                 | Not Reported         |                |
|                                                                     | Lexapro            |                    |                    | S               | Oral                                                   | 20 Mg, Unk                     |                 | Not Reported         |                |
|                                                                     | Fluticasone        |                    |                    | S               | Unknown                                                | 1 Df= 2 Sprays, Qd             |                 | Not Reported         |                |
|                                                                     | Vicodin            |                    |                    | S               | Oral                                                   | 1 Df= 5/500 Units Nos, Prn     |                 | Not Reported         |                |
|                                                                     | Zestoretic         |                    |                    | S               | Oral                                                   | 1 Df= 20/12.5 Units Nos,<br>Qd |                 | Not Reported         |                |
|                                                                     | Ambien             |                    |                    | S               | Oral                                                   | 10 Mg, Qd                      |                 | Not Reported         |                |
|                                                                     | Vivelle /00045401/ |                    |                    | S               | Transdermal                                            | 0.1 Mg, Unk                    |                 | Not Reported         |                |
|                                                                     | Lyrica             |                    |                    | S               | Oral                                                   | 75 Mg, Qd                      |                 | Not Reported         |                |
|                                                                     | Loratadine         |                    |                    | S               | Oral                                                   | 10 Mg, Qd                      |                 | Not Reported         |                |
|                                                                     | Robaxin            |                    |                    | S               | Oral                                                   | 750 Mg, Tid                    |                 | Not Reported         |                |
|                                                                     | Clonazepam         |                    |                    | S               | Oral                                                   | 1 Mg, Bid                      |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                            | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 09-Mar-2015                                                         | 10896590           | EXPEDITED (15-DAY) |                    | OT              | US-LUPIN<br>PHARMACEUTICALS<br>INC.-E2B_00003236       |                                |                 | Female               | USA            |
| <u>Preferred Term</u>                                               | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                           | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>           |                |
| Coeliac Disease                                                     | Escitalopram       |                    |                    | S               | Unknown                                                |                                |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                            | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 09-Mar-2015                                                         | 10896746           | EXPEDITED (15-DAY) |                    | HO              | ES-JNJFOC-<br>20150220454                              |                                | 49 YR           | Female               | ESP            |
| <u>Preferred Term</u>                                               | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                           | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>           |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|           |                         |   |      |              |
|-----------|-------------------------|---|------|--------------|
| Catatonia | Risperdal               | S | Oral | Not Reported |
|           | Trazodone Hydrochloride | S | Oral | Not Reported |
|           | Cipralext               | S | Oral | Not Reported |
|           | Etumina                 | S | Oral | Not Reported |
|           | Orfidal                 | S | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Mar-2015              | 10899129      | EXPEDITED (15-DAY) | LT                 |                 | IE-TEVA-545414ISR    |                      | 41 YR      | Female     | IRL            |

| <u>Preferred Term</u>                                           | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                           | <u>Duration</u> | <u>Mfr</u> |
|-----------------------------------------------------------------|-------------------------------|--------------|------------|-------------|--------------|----------------------------------------------|-----------------|------------|
| Chills; Diarrhoea;<br>Hyperhidrosis; Pyrexia;<br>Tremor; Tremor | Escitalopram Teva             |              |            | S           | Oral         | 10 Milligram Daily;                          |                 | Ivax       |
|                                                                 | Lansoprazole Teva Sante 15 Mg |              |            | S           | Oral         | 30 Milligram Daily; Gastro-Resistant Capsule |                 | Teva       |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------------------------------------|----------------------|------------|------------|----------------|
| 09-Mar-2015              | 10899754      | EXPEDITED (15-DAY) |                    | OT              | GB-MACLEODS<br>PHARMACEUTICALS<br>US LTD-<br>MAC2015001628 |                      |            | Unknown    | GBR            |

| <u>Preferred Term</u>                                  | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--------------------------------------------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Anxiety; Depressed Mood;<br>Product Substitution Issue | Escitalopram 10mg Tablet |              |            | S           | Oral         | 10 Mg, Unk         |                 | Macleods   |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Mar-2015              | 10899759      | EXPEDITED (15-DAY) |                    | HO              | CH-FRI-1000075094    |                      |            | Male       | CHE            |

| <u>Preferred Term</u>                                                                                                                                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Loss Anaemia;<br>Duodenal Ulcer;<br>Haematemesis;<br>International Normalised<br>Ratio Increased; Melaena;<br>Upper Gastrointestinal<br>Haemorrhage | Escitalopram   |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                                                                                                                                           | Marcoumar      |              |            | S           | Oral         | 1 Df Dosage Form   |                 | Not Reported |
|                                                                                                                                                           | Algifor        |              |            | S           | Oral         | 1600 Mg Daily      |                 | Not Reported |
|                                                                                                                                                           | Benerva        |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                                           | Becozym        |              |            | C           | Unknown      |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                |   |         |              |
|----------------|---|---------|--------------|
| Atorvastatin   | C | Unknown | Not Reported |
| Acidum Folicum | C | Unknown | Not Reported |
| Amlodipin      | C | Unknown | Not Reported |
| Co Diovan      | C | Unknown | Not Reported |
| Remeron        | C | Unknown | Not Reported |
| Nizoral Creme  | C | Unknown | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Mar-2015              | 10899760      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000075003    |                      | 49 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|----------------------|-----------------|--------------|
| Drug Interaction;<br>International Normalised<br>Ratio Increased; Subdural<br>Haematoma | Escitalopram   |              |            | S           | Oral         | 10 Mg                |                 | Forest       |
|                                                                                         | Coumadine      |              |            | S           | Oral         | 7 Mg                 |                 | Not Reported |
|                                                                                         | Procoralan     |              |            | C           | Unknown      | 5 Mg                 |                 | Not Reported |
|                                                                                         | Crestor        |              |            | C           | Unknown      | 10 Mg                |                 | Not Reported |
|                                                                                         | Levothyrox     |              |            | C           | Unknown      | 175 Mcg              |                 | Not Reported |
|                                                                                         | Bromazepam     |              |            | C           | Unknown      | 6 Mg                 |                 | Not Reported |
|                                                                                         | Spifen         |              |            | C           | Oral         | 1 Tablet If Headache |                 | Not Reported |
|                                                                                         | Dafalgan       |              |            | C           | Unknown      |                      |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Mar-2015              | 10905274      | DIRECT           |                    | OT              |                      |                      | 14 YR      | Female     | USA            |

| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Panic Attack; Screaming | Escitalopram   |              |            | S           |              | 0.5                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Mar-2015              | 10906848      | DIRECT           |                    |                 |                      |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|          |                    |   |      |                                       |              |
|----------|--------------------|---|------|---------------------------------------|--------------|
| Tinnitus | Escitalopram 10 Mg | S | Oral | 1 Tablet Once Daily Taken<br>By Mouth | Not Reported |
|          | Clonzapam          | C |      |                                       | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Mar-2015              | 10906935      | DIRECT           |                    |                 |                      |                      | 58 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                          | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blister; Erythema; Pruritus;<br>Rash; Skin Exfoliation;<br>Swelling; Urticaria | Lexapro                   |              |            | S           | Oral         | 1 Pill             |                 | Camber       |
|                                                                                | Atenolol                  |              |            | C           |              |                    |                 | Not Reported |
|                                                                                | Lovastatin                |              |            | C           |              |                    |                 | Not Reported |
|                                                                                | Acetaminophen\Hydrocodone |              |            | C           |              |                    |                 | Not Reported |
|                                                                                | Bitartrate                |              |            |             |              |                    |                 |              |
|                                                                                | Daily Multiple Vitamin    |              |            | C           |              |                    |                 | Not Reported |
|                                                                                | Policosanol               |              |            | C           |              |                    |                 | Not Reported |
|                                                                                | Vitamin D-3               |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Mar-2015              | 10693270      | EXPEDITED (15-DAY) |                    | OT              | JP-FRI-1000073458    |                      | 73 YR      | Female     | JPN            |

| <u>Preferred Term</u>                                                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Bradycardia; Cardiac<br>Arrest; Electrocardiogram<br>Qt Prolonged; Sinus Arrest | Escitalopram   |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                                                                 | Rize           |              |            | C           | Oral         | 10 Mg              |                 | Not Reported |
|                                                                                 | Spironolactone |              |            | C           | Oral         | 25 Mg              |                 | Not Reported |
|                                                                                 | Lasix          |              |            | C           | Oral         | 20 Mg              |                 | Not Reported |
|                                                                                 | Allopurinol    |              |            | C           | Oral         | 100 Mg             |                 | Not Reported |
|                                                                                 | Blopress       |              |            | C           | Oral         | 2 Mg               |                 | Not Reported |
|                                                                                 | Warfarin       |              |            | C           | Oral         | 2.5 Mg             |                 | Not Reported |
|                                                                                 | Berasus La     |              |            | C           | Oral         | 120 Mg             |                 | Not Reported |
|                                                                                 | Aspenon        |              |            | C           | Oral         | 40 Mg              |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                             | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------|--------------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|-----------------|--------------|----------------|
| 10-Mar-2015                                                          | 10900183           | EXPEDITED (15-DAY) |                    | DS, OT          | GB-AUROBINDO-AUR-APL-2015-01853 |                      | 20 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Depression; Insomnia; Mood Altered                          | Escitalopram       |                    |                    | S               | Oral                            | 5 Mg, Unk            |                 | Aurobindo    |                |
|                                                                      | Diphenhydramine    |                    |                    | C               | Unknown                         | Unk                  |                 | Not Reported |                |
|                                                                      | Propranolol        |                    |                    | C               | Unknown                         | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                             | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Mar-2015                                                          | 10900243           | EXPEDITED (15-DAY) |                    | OT              | GB-ACCORD-029067                |                      | 40 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Depressed Mood; Product Substitution Issue                  | Escitalopram       |                    |                    | S               | Oral                            |                      |                 | Accord       |                |
| <u>FDA Received Date</u>                                             | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Mar-2015                                                          | 10900452           | EXPEDITED (15-DAY) |                    | OT              | GB-AUROBINDO-AUR-APL-2015-01876 |                      | 40 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Depressed Mood; Product Substitution Issue                  | Escitalopram 10 Mg |                    |                    | S               | Oral                            | 10 Mg, Unk           |                 | Aurobindo    |                |
| <u>FDA Received Date</u>                                             | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Mar-2015                                                          | 10902971           | EXPEDITED (15-DAY) |                    | OT              | GB-FRI-1000075129               |                      | 40 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Depressed Mood; Mental Disorder; Product Substitution Issue | Escitalopram       |                    |                    | S               | Oral                            | 10 Mg Daily          |                 | Forest       |                |
|                                                                      | Escitalopram       |                    |                    | S               | Oral                            | 10 Mg Daily          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                             | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Mar-2015                                                          | 10651333           | NON-EXPEDITED      |                    | OT              | US-TEVA-514401USA               |                      |                 | Female       | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <a href="#">Preferred Term</a>                                                                                                                                                                                                                                | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Agitation; Anxiety;<br>Depressed Mood;<br>Depression; Disturbance<br>In Attention; Disturbance<br>In Attention; Drug<br>Ineffective; Dyskinesia;<br>Insomnia; Product<br>Substitution Issue;<br>Restless Legs Syndrome;<br>Restlessness; Suicidal<br>Ideation | Escitalopram            |                           |                             | S                        |                               | 40 Milligram Daily;           |                          | Ivax                |                         |
|                                                                                                                                                                                                                                                               | Nexium                  |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
|                                                                                                                                                                                                                                                               | Dyazide                 |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                                                                                                                                                             | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 11-Mar-2015                                                                                                                                                                                                                                                   | 10692687                | EXPEDITED (15-DAY)        |                             | OT                       | CH-TEVA-527122ISR             |                               | 37 YR                    | Male                | CHE                     |
| <a href="#">Preferred Term</a>                                                                                                                                                                                                                                | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Decreased Activity;<br>Fatigue; Malaise; Night<br>Sweats; Product<br>Substitution Issue;<br>Sedation; Sexual<br>Dysfunction; Therapeutic<br>Product Effect Decreased                                                                                          | Escitalopram-Mepha      |                           |                             | S                        | Unknown                       |                               |                          | Ivax                |                         |
|                                                                                                                                                                                                                                                               | Ass 100mg               |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                                                                                                                                                             | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 11-Mar-2015                                                                                                                                                                                                                                                   | 10903155                | NON-EXPEDITED             |                             |                          | US-TEVA-533916USA             |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                                                                                                                                                                                                | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Rash; Urticaria                                                                                                                                                                                                                                               | Escitalopram            |                           |                             | S                        | Unknown                       |                               |                          | Ivax                |                         |
| <a href="#">FDA Received Date</a>                                                                                                                                                                                                                             | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 11-Mar-2015                                                                                                                                                                                                                                                   | 10903156                | NON-EXPEDITED             |                             |                          | US-TEVA-529529USA             |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                                                                                                                                                                                                | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                    |                            |                  |                    |                 |                      |                      |                 |              |                |
|----------------------------------------------------------------------------------------------------|----------------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Depressed Mood; Drug Ineffective; Listless; Malaise; Malaise; Therapeutic Response Changed; Tremor | Escitalopram               |                  |                    | S               |                      |                      |                 |              | Ivax           |
| <u>FDA Received Date</u>                                                                           | <u>Case #</u>              | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Mar-2015                                                                                        | 10903157                   | NON-EXPEDITED    |                    |                 | US-TEVA-541122USA    |                      |                 | Male         | USA            |
| <u>Preferred Term</u>                                                                              | <u>Product</u>             | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Diarrhoea; Dry Mouth                                                                               | Escitalopram               |                  |                    | S               |                      |                      |                 | Ivax         |                |
| <u>FDA Received Date</u>                                                                           | <u>Case #</u>              | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Mar-2015                                                                                        | 10903158                   | NON-EXPEDITED    |                    | OT              | US-TEVA-544459USA    |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                              | <u>Product</u>             | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Migraine; Suicidal Ideation                                                                        | Escitalopram               |                  |                    | S               |                      |                      |                 | Ivax         |                |
| <u>FDA Received Date</u>                                                                           | <u>Case #</u>              | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Mar-2015                                                                                        | 10903159                   | NON-EXPEDITED    |                    |                 | US-TEVA-530442USA    |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                              | <u>Product</u>             | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective                                                                                   | Escitalopram               |                  |                    | S               | Unknown              |                      |                 | Ivax         |                |
| <u>FDA Received Date</u>                                                                           | <u>Case #</u>              | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Mar-2015                                                                                        | 10903160                   | NON-EXPEDITED    |                    |                 | US-TEVA-533598USA    |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                              | <u>Product</u>             | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Dry Mouth; Muscular Weakness; Muscular Weakness; Thirst                                 | Escitalopram               |                  |                    | S               | Oral                 | 40 Milligram Daily;  |                 | Ivax         |                |
|                                                                                                    | Hydroxychloroquine Sulfate |                  |                    | S               | Oral                 | 400 Milligram Daily; |                 | Not Reported |                |
|                                                                                                    | Aciphex                    |                  |                    | C               | Oral                 | 40 Milligram Daily;  |                 | Not Reported |                |



# FDA Adverse Event Reporting System

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| <u>FDA Received Date</u>    | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------|----------------|--------------------|--------------------|-----------------|------------------------------------|------------------------|-----------------|--------------|----------------|
| 11-Mar-2015                 | 10903162       | NON-EXPEDITED      |                    |                 | US-TEVA-534526USA                  |                        | 68 YR           | Male         | USA            |
| <u>Preferred Term</u>       | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                       | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Back Pain;       | Escitalopram   |                    |                    | S               |                                    |                        |                 | Ivax         |                |
| Bladder Disorder; Dysuria;  | Escitalopram   |                    |                    | S               |                                    |                        |                 | Ivax         |                |
| Dysuria; Feeling            |                |                    |                    |                 |                                    |                        |                 |              |                |
| Abnormal; Muscle            |                |                    |                    |                 |                                    |                        |                 |              |                |
| Spasms; Penis Disorder;     |                |                    |                    |                 |                                    |                        |                 |              |                |
| Pruritus                    |                |                    |                    |                 |                                    |                        |                 |              |                |
| <u>FDA Received Date</u>    | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Mar-2015                 | 10904659       | NON-EXPEDITED      |                    |                 | US-TEVA-530225USA                  |                        |                 | Male         | USA            |
| <u>Preferred Term</u>       | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                       | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Crying; Decreased           | Escitalopram   |                    |                    | S               |                                    |                        |                 | Ivax         |                |
| Activity; Drug Ineffective; | Escitalopram   |                    |                    | S               |                                    |                        |                 | Ivax         |                |
| Hypersomnia; Product        | Lexapro        |                    |                    | S               |                                    |                        |                 | Not Reported |                |
| Substitution Issue;         | Lexapro        |                    |                    | S               |                                    |                        |                 | Not Reported |                |
| Psychiatric Symptom         |                |                    |                    |                 |                                    |                        |                 |              |                |
| <u>FDA Received Date</u>    | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Mar-2015                 | 10905212       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000075088                  |                        | 22 YR           | Female       | FRA            |
| <u>Preferred Term</u>       | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                       | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Overdose;         | Escitalopram   |                    |                    | S               |                                    | Overdose Of 15 Tablets |                 | Forest       |                |
| Suicide Attempt; Toxicity   |                |                    |                    |                 |                                    | Nos                    |                 |              |                |
| To Various Agents           |                |                    |                    |                 |                                    |                        |                 |              |                |
| <u>FDA Received Date</u>    | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Mar-2015                 | 10906110       | EXPEDITED (15-DAY) |                    | HO, OT          | US-GLAXOSMITHKLINE-US2015GSK028046 |                        |                 | Female       | USA            |
| <u>Preferred Term</u>       | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                       | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System

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### Detailed Report

|                            |                |   |         |            |                 |
|----------------------------|----------------|---|---------|------------|-----------------|
| Abnormal Behaviour;        | Wellbutrin Sr  | S | Oral    | 100 Mg, 1d | Glaxosmithkline |
| Aggression;                | Wellbutrin Sr  | S | Unknown | 150 Mg, Qd | Glaxosmithkline |
| Cerebrovascular Accident;  | Bupropion      | S |         | Unk, U     | Glaxosmithkline |
| Drug Ineffective; Fatigue; | Lexapro        | S | Unknown | 10 Mg, U   | Not Reported    |
| Hallucination, Auditory;   | Cartia Xt      | C |         |            | Not Reported    |
| Hip Fracture; Insomnia;    | Lovaza         | C |         |            | Not Reported    |
| Weight Decreased           | Plavix         | C |         |            | Not Reported    |
|                            | Protonix       | C |         |            | Not Reported    |
|                            | Aspirin (Baby) | C |         |            | Not Reported    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 12-Mar-2015              | 10654817      | NON-EXPEDITED    |                    | OT              | US-PFIZER INC-2014343239 |                      | 73 YR      | Female     | USA            |

| <u>Preferred Term</u>      | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Pressure Increased;  | Effexor Xr           |              |            | S           |              | 150 Mg, 1x/Day     |                 | Pfizer       |
| Confusional State; Feeling | Effexor Xr           |              |            | S           |              |                    |                 | Pfizer       |
| Abnormal; Headache;        | Effexor              |              |            | S           |              | 150 Mg, 1x/Day     |                 | Pfizer       |
| Paraesthesia               | Effexor              |              |            | S           |              |                    |                 | Pfizer       |
|                            | Venlafaxine Hcl      |              |            | S           |              | 150 Mg, 1x/Day     |                 | Pfizer       |
|                            | Venlafaxine Hcl      |              |            | S           |              |                    |                 | Pfizer       |
|                            | Escitalopram Oxalate |              |            | S           |              | 10 Mg, 1x/Day      |                 | Not Reported |
|                            | Vesicare             |              |            | S           |              | Unk Unk, 1x/Day    |                 | Not Reported |
|                            | Celebrex             |              |            | C           |              | 200 Mg, 1x/Day     |                 | Not Reported |
|                            | Azathioprine         |              |            | C           |              | 50, Unk            |                 | Not Reported |
|                            | Hydroxychloroquine   |              |            | C           |              | 200, Unk           |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------------------|----------------------|------------|------------|----------------|
| 13-Mar-2015              | 9721536       | EXPEDITED (15-DAY) |                    |                 | JP-BRISTOL-MYERS SQUIBB COMPANY-19862523 |                      |            | Unknown    | JPN            |

| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>           |
|------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------|
| Drug Interaction; Drug | Abilify              |              |            | S           | Oral         | Unk                |                 | Bristol Myers Squibb |
| Level Increased        | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg, Qd          |                 | Not Reported         |

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### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 13-Mar-2015              | 10747658      | EXPEDITED (15-DAY) |                    | HO, LT          | FR-JNJFOC-20150112509 |                      | 58 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                                                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Atrioventricular Block First Degree; Coma; Electrocardiogram Qt Prolonged; Sinus Bradycardia; Suicide Attempt | Ixprim         |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                               | Domperidone    |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                               | Loperamide     |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                               | Paracetamol    |              | Y          | S           | Oral         |                    |                 | Not Reported |
|                                                                                                               | Paracetamol    |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                               | Theralene      |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                               | Zopiclone      |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                               | Escitalopram   |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                               | Lexomil        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                               | Seroplex       |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                               | Imovane        |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                               | Utrogestan     |              |            | C           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|------------|------------|----------------|
| 13-Mar-2015              | 10911591      | EXPEDITED (15-DAY) |                    | OT              | IT-AUROBINDO-AUR-APL-2015-02049 |                      |            | Female     | ITA            |

| <u>Preferred Term</u>                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Abortion Spontaneous; Maternal Exposure Timing Unspecified | Escitalopram   |              |            | S           | Oral         | Unk                |                 | Aurobindo  |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Mar-2015              | 10803904      | EXPEDITED (15-DAY) |                    | OT              | IE-FRI-1000074529    |                      | 41 YR      | Female     | IRL            |

| <u>Preferred Term</u>                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Cold Sweat; Dizziness; Dyskinesia; Hallucination, | Lexapro        |              |            | S           | Unknown      |                    |                 | Forest     |

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|                           |             |   |         |       |              |
|---------------------------|-------------|---|---------|-------|--------------|
| Visual; Hiccups;          | Lexapro     | S | Unknown | 10 Mg | Forest       |
| Palpitations; Product Use | Fucithalmic | S | Unknown |       | Not Reported |
| In Unapproved Indication; | Seretide    | C | Unknown |       | Not Reported |
| Seizure; Wheezing;        | Antibiotics | C | Unknown |       | Not Reported |
| Withdrawal Syndrome       |             |   |         |       |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Mar-2015              | 10915912      | EXPEDITED (15-DAY) |                    | HO              | IT-TEVA-546890ACC    |                      | 55 YR      | Female     | ITA            |

| <u>Preferred Term</u>    | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|---------------------------|--------------|------------|-------------|--------------|-------------------------|-----------------|--------------|
| Bradycardia; Drug Abuse; | Escitalopram              |              |            | S           | Oral         | 400 Mg Total            |                 | Ivax         |
| Oxygen Saturation        | Cardioaspirin - 100 Mg    |              |            | C           |              | Gastro-Resistant Tablet |                 | Not Reported |
| Decreased                | Comprese Gastroresistenti |              |            | C           |              | Oral Drops, Solution    |                 | Not Reported |
|                          | En - 1 Mg/MI Gocce Orali, |              |            |             |              |                         |                 |              |
|                          | Soluzione 20 MI           |              |            |             |              |                         |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 16-Mar-2015              | 10915972      | EXPEDITED (15-DAY) |                    | OT              | GB-MYLANLABS-2015M1006667 |                      |            | Unknown    | GBR            |

| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Depressed Mood;   | Escitalopram   |              |            | S           | Oral         | 10 Mg, Unk         |                 | Not Reported |
| Product Substitution Issue |                |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Mar-2015              | 10916246      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000075266    |                      | 64 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------------------------|-----------------|--------------|
| Somnolence; Suicide   | Escitalopram   |              |            | S           | Oral         | 1 Df                                 |                 | Forest       |
| Attempt; Toxicity To  | Escitalopram   |              |            | S           | Oral         | Overdose Of 1 Intake Of Unknown Dose |                 | Forest       |
| Various Agents        | Lexomil Roche  |              |            | S           | Oral         | Overdose Of 1 Intake Of Unknown Dose |                 | Not Reported |
|                       | Mopral         |              |            | C           |              | 1 Df                                 |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------|---------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 16-Mar-2015                                                                                                             | 10916259                              | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000075214    |                      | 25 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                   | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Ecchymosis;<br>Musculoskeletal Pain                                                                                     | Escitalopram                          |                    |                    | S               | Oral                 | 1 Df                 |                 | Forest       |                |
|                                                                                                                         | Stilnox                               |                    |                    | C               | Oral                 | 1 Df                 |                 | Not Reported |                |
|                                                                                                                         | Victan                                |                    |                    | C               | Oral                 | 1 Df                 |                 | Not Reported |                |
|                                                                                                                         | Hept A Myl                            |                    |                    | C               | Oral                 | 30 Gtt               |                 | Not Reported |                |
|                                                                                                                         | Tardyferon                            |                    |                    | C               |                      | 2 Df                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Mar-2015                                                                                                             | 10925060                              | DIRECT             |                    | HO              |                      |                      | 30 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                   | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Alcohol Use;<br>Intentional Self-Injury;<br>Loss Of Consciousness;<br>Memory Impairment; Skin<br>Laceration | Bupropion Hcl                         |                    |                    | S               | Oral                 | 1 Pill               | 4 MTH           | Mylan        |                |
|                                                                                                                         | Escitalopram                          |                    |                    | S               | Oral                 | 1 Pills              | 9 MTH           | Accord       |                |
|                                                                                                                         | Zyrtec                                |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Mar-2015                                                                                                             | 10926532                              | EXPEDITED (15-DAY) | Y                  | OT              | 2015JUB00058         |                      | 50 YR           | Male         | IND            |
| <u>Preferred Term</u>                                                                                                   | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypochloraemia;<br>Hypokalaemia;<br>Hyponatraemic<br>Encephalopathy;<br>Inappropriate Antidiuretic<br>Hormone Secretion | Escitalopram (Escitalopram)           |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                         | Unknown                               |                    |                    |                 |                      |                      |                 |              |                |
|                                                                                                                         | Telmisartan (Telmisartan)             |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                         | Acetyl Salicylate (Acetyl Salicylate) |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Mar-2015                                                                                                             | 10919987                              | EXPEDITED (15-DAY) |                    | HO, OT          | PHHY2015ES027626     |                      | 81 YR           | Female       | ESP            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                  | <u>Product</u>                                                                                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|--------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|--------------------|--------------------|-----------------|------------------------------------------------|----------------------|-----------------|--------------|----------------|
| Aphasia; Blood Pressure Increased; Drug Interaction; Gamma-Glutamyltransferase Increased; Hemianopia                                                   | Escitalopram                                                                                       |                    |                    | S               | Unknown                                        | 1 Df, Qd             |                 | Not Reported |                |
|                                                                                                                                                        | Etoricoxib                                                                                         |                    |                    | S               | Unknown                                        | 1 Df, Qd             |                 | Not Reported |                |
|                                                                                                                                                        | Tramadol                                                                                           |                    |                    | S               | Unknown                                        | 1 Df, Qd             |                 | Not Reported |                |
|                                                                                                                                                        | Tramadol+Paracetamol                                                                               |                    |                    | S               | Unknown                                        | 1 Df, Tid            |                 | Not Reported |                |
|                                                                                                                                                        | Deflazacort                                                                                        |                    |                    | C               | Unknown                                        | 1 Df, Qd             |                 | Not Reported |                |
|                                                                                                                                                        | Salbutamol                                                                                         |                    |                    | C               | Unknown                                        | 1 Df, Prn            |                 | Not Reported |                |
|                                                                                                                                                        | Montelukast                                                                                        |                    |                    | C               | Unknown                                        |                      |                 | Not Reported |                |
|                                                                                                                                                        | Atorvastatin                                                                                       |                    |                    | C               | Unknown                                        | 1 Df, Qd             |                 | Not Reported |                |
|                                                                                                                                                        | Omeprazole                                                                                         |                    |                    | C               | Unknown                                        | 1 Df, Qd             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                               | <u>Case #</u>                                                                                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Mar-2015                                                                                                                                            | 10920228                                                                                           | NON-EXPEDITED      |                    | DE              | US-LUPIN<br>PHARMACEUTICALS<br>INC.-2015-00418 |                      | 36 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                  | <u>Product</u>                                                                                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                                                                                                                      | Verapamil                                                                                          |                    |                    | S               | Oral                                           |                      |                 | Not Reported |                |
|                                                                                                                                                        | Escitalopram                                                                                       |                    |                    | S               | Oral                                           |                      |                 | Not Reported |                |
|                                                                                                                                                        | Codeine                                                                                            |                    |                    | S               | Oral                                           |                      |                 | Not Reported |                |
|                                                                                                                                                        | Topiramate                                                                                         |                    |                    | S               | Oral                                           |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                               | <u>Case #</u>                                                                                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Mar-2015                                                                                                                                            | 10922470                                                                                           | EXPEDITED (15-DAY) |                    | HO, OT          | US-BAUSCH-BL-2015-009455                       |                      | 90 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                  | <u>Product</u>                                                                                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Behaviour; Aggression; Cerebrovascular Accident; Drug Ineffective; Fatigue; Fatigue; Hallucination, Auditory; Hip Fracture; Insomnia; Product | Bupropion                                                                                          |                    |                    | S               | Unknown                                        |                      |                 | Not Reported |                |
|                                                                                                                                                        | Wellbutrin Sr 150mg (Bupropion Hydrochloride) (Prolonged Release Tablet) (Bupropion Hydrochloride) |                    |                    | S               | Oral                                           |                      |                 | Not Reported |                |
|                                                                                                                                                        | Wellbutrin Sr 150mg (Bupropion Hydrochloride) (Prolonged                                           |                    |                    | S               | Unknown                                        |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| Substitution Issue;<br>Psychomotor<br>Hyperactivity; Weight<br>Decreased | Release Tablet) (Bupropion<br>Hydrochloride) |                    |                    |                 |                      |                      |                 |              |                |
|--------------------------------------------------------------------------|----------------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
|                                                                          | Lexapro                                      |                    | S                  |                 | Unknown              |                      |                 |              | Not Reported   |
|                                                                          | Cartia Xt                                    |                    | C                  |                 |                      |                      |                 |              | Not Reported   |
|                                                                          | Lovaza                                       |                    | C                  |                 |                      |                      |                 |              | Not Reported   |
|                                                                          | Plavix                                       |                    | C                  |                 |                      |                      |                 |              | Not Reported   |
|                                                                          | Protonix                                     |                    | C                  |                 |                      |                      |                 |              | Not Reported   |
|                                                                          | Adult Low Dose Aspirin                       |                    | C                  |                 |                      |                      |                 |              | Not Reported   |
| <u>FDA Received Date</u>                                                 | <u>Case #</u>                                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Mar-2015                                                              | 10927922                                     | DIRECT             |                    | DS              |                      |                      | 44 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                    | <u>Product</u>                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective; Product<br>Substitution Issue                          | Escitalopram                                 |                    |                    | S               | Oral                 | 1 Pill               | 1 MTH           | Lupin        |                |
|                                                                          | Omega 3                                      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                          | Magnesium                                    |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                          | Vitamin D Nos                                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                          | Multi Vitamin                                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                          | Calcium                                      |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                 | <u>Case #</u>                                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Mar-2015                                                              | 10929250                                     | EXPEDITED (15-DAY) | Y                  | OT              | 2015HINLIT0252       |                      | 41 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                    | <u>Product</u>                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alcohol Abuse;<br>Alcoholism; Mania;<br>Suicidal Behaviour;<br>Tremor    | Escitalopram (Escitalopram)                  |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                          | Unknown                                      |                    |                    |                 |                      |                      |                 |              |                |
| <u>FDA Received Date</u>                                                 | <u>Case #</u>                                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Mar-2015                                                              | 10930638                                     | EXPEDITED (15-DAY) | Y                  | OT              | 2015HINLIT0251       |                      | 48 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                    | <u>Product</u>                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Behaviour;<br>Aggression; Alcoholism;<br>Decreased Interest;    | Escitalopram (Escitalopram)                  |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                          | Unknown                                      |                    |                    |                 |                      |                      |                 |              |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Feeling Abnormal; Partner Stress

| <u>FDA Received Date</u>                              | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 17-Mar-2015                                           | 10930679                    | EXPEDITED (15-DAY) | Y                  | OT              | 2015HINLIT0253       |                      | 42 YR           | Male         | GBR            |
| <u>Preferred Term</u>                                 | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alcohol Abuse; Anxiety; Impulsive Behaviour; Paranoia | Escitalopram (Escitalopram) |                    |                    | S               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                            | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 17-Mar-2015                                         | 10930690                    | EXPEDITED (15-DAY) | Y                  | OT              | 2015HINLIT0254       |                      |                 | Unknown      | GBR            |
| <u>Preferred Term</u>                               | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Alcoholism; Decreased Appetite; Insomnia | Escitalopram (Escitalopram) |                    |                    | S               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                            | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------|--------------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|-----------------|------------|----------------|
| 18-Mar-2015                                                                                         | 10923722           | EXPEDITED (15-DAY) |                    | OT              | GB-AUROBINDO-AUR-APL-2015-02173 |                      | 41 YR           | Female     | GBR            |
| <u>Preferred Term</u>                                                                               | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Alcohol Abuse; Alcoholism; Impaired Driving Ability; Imprisonment; Mania; Suicidal Ideation; Tremor | Escitalopram 10 Mg |                    |                    | S               | Unknown                         | 10 Mg, Unk           |                 | Aurobindo  |                |

| <u>FDA Received Date</u>                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------------------------|----------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|-----------------|------------|----------------|
| 18-Mar-2015                                | 10923913       | EXPEDITED (15-DAY) |                    | OT              | GB-AUROBINDO-AUR-APL-2015-02174 |                      | 42 YR           | Male       | GBR            |
| <u>Preferred Term</u>                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Abnormal Behaviour; Aggression; Agitation; | Escitalopram   |                    |                    | S               | Unknown                         | 10-20 Mg             |                 | Aurobindo  |                |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Alcohol Abuse; Anxiety;  
Decreased Appetite;  
Depressed Mood;  
Impulsive Behaviour;  
Insomnia; Paranoia;  
Psychiatric Symptom;  
Sexual Inhibition

| <u>FDA Received Date</u>                                                                                                                  | <u>Case #</u>                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u>                | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>                                                   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|--------------------|--------------------|------------------|-------------------------------------|--------------------------------|-----------------|--------------------------------------------------------------|----------------|
| 18-Mar-2015                                                                                                                               | 10924208                                    | EXPEDITED (15-DAY) |                    | OT               | GB-AUROBINDO-AUR-<br>APL-2015-02172 |                                | 48 YR           | Female                                                       | GBR            |
| <u>Preferred Term</u>                                                                                                                     | <u>Product</u>                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>                        | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>                                                   |                |
| Aggression; Alcoholism;<br>Behaviour Disorder;<br>Decreased Interest;<br>Emotional Distress;<br>Partner Stress                            | Escitalopram 10 Mg                          |                    |                    | S                | Unknown                             | 10 Mg, Unk                     |                 | Aurobindo                                                    |                |
| <u>FDA Received Date</u>                                                                                                                  | <u>Case #</u>                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u>                | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>                                                   | <u>Country</u> |
| 18-Mar-2015                                                                                                                               | 10929337                                    | DIRECT             |                    |                  |                                     |                                | 78 YR           | Female                                                       | USA            |
| <u>Preferred Term</u>                                                                                                                     | <u>Product</u>                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>                        | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>                                                   |                |
| Anxiety; Depression;<br>Gastrointestinal Disorder;<br>Product Substitution Issue                                                          | Escitalopram 20 Mg Accord<br>Healthca       |                    |                    | S                | Oral                                | 1 Once Daily Taken By<br>Mouth |                 | Accord                                                       |                |
| <u>FDA Received Date</u>                                                                                                                  | <u>Case #</u>                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u>                | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>                                                   | <u>Country</u> |
| 18-Mar-2015                                                                                                                               | 10930691                                    | DIRECT             | Y                  |                  |                                     |                                | 23 YR           | Female                                                       |                |
| <u>Preferred Term</u>                                                                                                                     | <u>Product</u>                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>                        | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>                                                   |                |
| Altered Visual Depth<br>Perception; Balance<br>Disorder; Diarrhoea;<br>Disturbance In Attention;<br>Feeling Hot; Loss Of<br>Consciousness | Lexapro<br>Propranolol<br>Vyvance<br>Yasmin |                    |                    | S<br>C<br>C<br>C |                                     |                                |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 18-Mar-2015                              | 10944137       | EXPEDITED (15-DAY) | Y                  | OT              | ES-ZYDUS-007190      |                      | 81 YR           | Female       | ESP            |
| <u>Preferred Term</u>                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aphasia; Drug Interaction;<br>Hemianopia | Escitalopram   |                    |                    | S               |                      | 10.00 Dosage         |                 | Not Reported |                |
|                                          | Etoricoxiib    |                    |                    | S               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                                     | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|--------------------------------------------------------|----------------------|-----------------|----------------------|----------------|
| 19-Mar-2015                                                                                                                                                  | 10694075               | EXPEDITED (15-DAY) |                    | HO, OT          | FR-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>BMS-2014-004150 |                      | 84 YR           | Female               | FRA            |
| <u>Preferred Term</u>                                                                                                                                        | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Anaemia; Drug Interaction;<br>Gastric Ulcer; Prerenal<br>Failure; Rectal<br>Haemorrhage; Upper<br>Gastrointestinal<br>Haemorrhage; Vitamin<br>B12 Deficiency | Eliquis                |                    |                    | S               | Oral                                                   | 2.5 Mg, Bid          |                 | Bristol Myers Squibb |                |
|                                                                                                                                                              | Kardegic               |                    |                    | S               | Oral                                                   | 75 Mg, Unk           |                 | Not Reported         |                |
|                                                                                                                                                              | Ketoprofene /00032001/ |                    |                    | S               | Cutaneous                                              | Unk                  |                 | Not Reported         |                |
|                                                                                                                                                              | Aldactazine            |                    |                    | S               | Oral                                                   | 1 Df, Qd             |                 | Not Reported         |                |
|                                                                                                                                                              | Seroplex               |                    |                    | S               | Oral                                                   | Unk                  |                 | Not Reported         |                |
|                                                                                                                                                              | Temerit                |                    |                    | C               | Unknown                                                | Unk                  |                 | Not Reported         |                |
|                                                                                                                                                              | Mediatensyl /00631801/ |                    |                    | C               | Unknown                                                |                      |                 | Not Reported         |                |
|                                                                                                                                                              | Amiodarone             |                    |                    | C               | Unknown                                                | Unk                  |                 | Not Reported         |                |
|                                                                                                                                                              | Eptavit                |                    |                    | C               | Unknown                                                |                      |                 | Not Reported         |                |
|                                                                                                                                                              | Doliprane              |                    |                    | C               | Unknown                                                | Unk                  |                 | Not Reported         |                |
|                                                                                                                                                              | Lansoprazole           |                    |                    | C               | Unknown                                                |                      |                 | Not Reported         |                |
|                                                                                                                                                              | Inexium /01479302/     |                    |                    | C               | Unknown                                                |                      |                 | Not Reported         |                |

| <u>FDA Received Date</u>                     | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|----------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 19-Mar-2015                                  | 10888702                | EXPEDITED (15-DAY) |                    | OT              | CH-TEVA-539615ISR    |                      | 17 YR           | Female     | CHE            |
| <u>Preferred Term</u>                        | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Euphoric Mood; Fatigue;<br>Feeling Abnormal; | Escitalopram Mepha 5 Mg |                    |                    | S               | Oral                 | 5 Milligram Daily;   |                 | Ivax       |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Inappropriate Affect;  
Insomnia; Logorrhoea;  
Mania; Memory  
Impairment; Tension;  
Tremor

Escitalopram Mepha Was  
Discontinued After About 1  
Week

| <u>FDA Received Date</u>                                                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|------------------------------|-----------------------------------------------|-----------------|--------------|----------------|
| 19-Mar-2015                                                                              | 10921099       | EXPEDITED (15-DAY) |                    | HO              | IT-FRI-1000075276            |                                               | 55 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u>   |                |
| Bradycardia; Drug Abuse;<br>Overdose; Oxygen<br>Saturation Decreased                     | Escitalopram   |                    |                    | S               | Oral                         | Escitalopram 400 Mg<br>Once                   |                 | Forest       |                |
|                                                                                          | Cardioaspirin  |                    |                    | C               | Oral                         |                                               |                 | Not Reported |                |
|                                                                                          | En             |                    |                    | C               | Oral                         |                                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Mar-2015                                                                              | 10930205       | NON-EXPEDITED      |                    |                 | US-PFIZER INC-<br>2015093348 |                                               | 67 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity;<br>Drug Ineffective                                               | Zoloft         |                    |                    | S               |                              | Unk                                           |                 | Pfizer       |                |
|                                                                                          | Lexapro        |                    |                    | S               |                              | Unk                                           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Mar-2015                                                                              | 10932045       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000075344            |                                               | 34 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u>   |                |
| Coma; Intentional<br>Overdose; Miosis; Suicide<br>Attempt; Toxicity To<br>Various Agents | Escitalopram   |                    |                    | S               | Oral                         | Overdose: 280 Mg.                             |                 | Forest       |                |
|                                                                                          | Theralene      |                    |                    | S               | Oral                         | Overdose: 1 Bottle Of<br>Alimemazine 4 % Nos. |                 | Not Reported |                |
|                                                                                          | Zopiclone      |                    |                    | S               | Oral                         | Overdose: 105 Mg.                             |                 | Not Reported |                |
|                                                                                          | Tetrazepam     |                    |                    | S               | Oral                         | Overdose: 950 Mg.                             |                 | Not Reported |                |
|                                                                                          | Diazepam       |                    |                    | S               | Oral                         | 100 Mg                                        |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                   | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------|-------------------|--------------------|--------------------|-----------------|------------------------------------------|----------------------|-----------------|--------------|----------------|
| 19-Mar-2015                                                                                                                                | 10932046          | EXPEDITED (15-DAY) |                    | DE              | FR-FRI-1000075347                        |                      | 58 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                      | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Tamponade;<br>Dyspnoea; Pericardial<br>Effusion                                                                                    | Escitalopram      |                    |                    | S               | Oral                                     |                      |                 | Forest       |                |
|                                                                                                                                            | Laroxyl           |                    |                    | S               | Intravenous (not<br>otherwise specified) | 50 Mg/2 MI           |                 | Not Reported |                |
|                                                                                                                                            | Foziretic         |                    |                    | C               | Oral                                     | 20 Mg/12.5 Mg        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                   | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Mar-2015                                                                                                                                | 10932566          | DIRECT             | Y                  |                 |                                          |                      | 26 YR           | Male         |                |
| <u>Preferred Term</u>                                                                                                                      | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Urinary Retention                                                                                                                          | Lexapro           |                    |                    | S               |                                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                   | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Mar-2015                                                                                                                                | 10932708          | DIRECT             |                    | DS              |                                          |                      | 62 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                      | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Depression<br>Suicidal; Dizziness; Drug<br>Ineffective; Drug<br>Withdrawal Syndrome;<br>Fall; Insomnia; Irritability;<br>Tremor | Escitalopram Teva |                    |                    | S               | Oral                                     |                      |                 | Teva         |                |
|                                                                                                                                            | Liothyronine      |                    |                    | C               |                                          |                      |                 | Not Reported |                |
|                                                                                                                                            | Levothyroxine     |                    |                    | C               |                                          |                      |                 | Not Reported |                |
|                                                                                                                                            | Alprazolam        |                    |                    | C               |                                          |                      |                 | Not Reported |                |
|                                                                                                                                            | Vitamin D Nos     |                    |                    | C               |                                          |                      |                 | Not Reported |                |
|                                                                                                                                            | B12               |                    |                    | C               |                                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                   | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Mar-2015                                                                                                                                | 10854202          | EXPEDITED (15-DAY) |                    | DE, HO          | FR-ABBVIE-15P-056-<br>1350738-00         |                      | 76 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                                                      | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Thrombocytopenia                                                                                                                           | Creon 25000 Iu    |                    |                    | S               | Oral                                     |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                |   |              |                                                       |
|----------------|---|--------------|-------------------------------------------------------|
| Kardegic       | S | Oral         | Not Reported                                          |
| Atorvastatine  | S | Oral         | Not Reported                                          |
| Klipal Codeine | S | Oral         | Not Reported                                          |
| Insulatard     | S | Subcutaneous | 22 lu At Morning And 10 lu At Evening<br>Not Reported |
| Seroplex       | S | Oral         | Not Reported                                          |
| Ramipril       | S | Oral         | Not Reported                                          |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Mar-2015              | 10874806      | EXPEDITED (15-DAY) | CA                 |                 | US-FRI-1000074713    |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                      | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------|-------------------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Atrial Septal Defect;                                      | Escitalopram            |              |            | S           | Transplacental |                    |                 | Forest       |
| Congenital Anomaly;                                        | Topiramate              |              |            | S           | Transplacental |                    |                 | Not Reported |
| Congenital Diaphragmatic Eventration; Dextrocardia;        | Oxycodone/Acetaminophen |              |            | S           | Unknown        |                    |                 | Not Reported |
| Foetal Exposure During Pregnancy; Patent Ductus Arteriosus | Prenatal Multivitamins  |              |            | S           | Transplacental |                    |                 | Not Reported |
|                                                            | Tramadol                |              |            | S           | Transplacental |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 20-Mar-2015              | 10932953      | EXPEDITED (15-DAY) | HO                 |                 | BR-PFIZER INC-2015092288 |                      | 73 YR      | Female     | BRA            |

| <u>Preferred Term</u>       | <u>Product</u>               | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                               | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------|------------------------------|--------------|------------|-------------|--------------|--------------------------------------------------|-----------------|--------------|
| Blood Pressure Fluctuation; | Atorvastatin Calcium         |              |            | S           | Oral         | 20 Mg, At Night                                  |                 | Pfizer       |
| Cerebrovascular Accident;   | Seroquel                     |              |            | S           |              | Unk                                              |                 | Not Reported |
| Headache; Nausea;           | Exodus//Escitalopram Oxalate |              |            | S           |              | Unk                                              |                 | Not Reported |
| Somnolence                  | Vasopril [Enalapril Maleate] |              |            | C           | Oral         | 25 Mg, Every Morning                             |                 | Not Reported |
|                             | Citoneurin                   |              |            | C           |              |                                                  |                 | Not Reported |
|                             | Aas                          |              |            | C           |              | 2 "Cp" (Unspecified Formulation) Of 100mg, Daily |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                      | <u>Case #</u>                                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------|-----------------------------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
| 20-Mar-2015                                                   | 10933774                                      | EXPEDITED (15-DAY) |                    | HO              | IT-MYLANLABS-2015M1007825 |                      |                 | Unknown      | ITA            |
| <u>Preferred Term</u>                                         | <u>Product</u>                                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bradycardia; Drug Abuse; Overdose; Oxygen Saturation Abnormal | Escitalopram Oxalate                          |                    |                    | S               | Oral                      | 400 Mg, Total        |                 | Not Reported |                |
|                                                               | Cardioaspirin                                 |                    |                    | C               |                           |                      |                 | Not Reported |                |
|                                                               | En                                            |                    |                    | C               | Oral                      | Unk MI, Unk          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>                                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Mar-2015                                                   | 10936076                                      | EXPEDITED (15-DAY) |                    | DE              | US-WATSON-2015-04472      |                      | 36 YR           | Female       | USA            |
| <u>Preferred Term</u>                                         | <u>Product</u>                                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Toxicity To Various Agents                 | Verapamil Hydrochloride (Watson Laboratories) |                    |                    | S               | Oral                      | Unknown              |                 | Watson       |                |
|                                                               | Escitalopram (Unknown)                        |                    |                    | S               | Oral                      | Unknown              |                 | Not Reported |                |
|                                                               | Codeine (Unknown)                             |                    |                    | S               | Oral                      | Unknown              |                 | Not Reported |                |
|                                                               | Topiramate (Watson Laboratories)              |                    |                    | S               | Oral                      | Unknown              |                 | Watson       |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>                                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Mar-2015                                                   | 10941775                                      | EXPEDITED (15-DAY) |                    | DE              | US-ACTAVIS-2015-06119     |                      | 62 YR           | Male         | USA            |
| <u>Preferred Term</u>                                         | <u>Product</u>                                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Toxicity To Various Agents                 | Temazepam (Aellc)                             |                    |                    | S               | Oral                      | Unk                  |                 | Watson       |                |
|                                                               | Lorazepam (Watson Laboratories)               |                    |                    | S               | Oral                      | Unk                  |                 | Watson       |                |
|                                                               | Primidone (Watson Laboratories)               |                    |                    | S               | Oral                      | Unk                  |                 | Watson       |                |
|                                                               | Lamotrigine (Watson Laboratories)             |                    |                    | S               | Oral                      | Unk                  |                 | Watson       |                |
|                                                               | Escitalopram (Unknown)                        |                    |                    | S               | Oral                      | Unk                  |                 | Not Reported |                |
|                                                               | Benzotropine                                  |                    |                    | S               | Oral                      | Unk                  |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                    | <u>Case #</u>                                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>     | <u>Country</u> |
|-----------------------------------------------------------------------------|-----------------------------------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|----------------|----------------|
| 22-Mar-2015                                                                 | 10943336                                      | EXPEDITED (15-DAY) |                    | DE              | US-WATSON-2015-05352  |                      | 74 YR           | Male           | USA            |
| <u>Preferred Term</u>                                                       | <u>Product</u>                                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>     |                |
| Toxicity To Various Agents                                                  | Atenolol (Watson Laboratories)                |                    |                    | S               | Unknown               | Unknown              |                 | Watson         |                |
|                                                                             | Primidone (Watson Laboratories)               |                    |                    | S               | Unknown               | Unknown              |                 | Watson         |                |
|                                                                             | Escitalopram (Unknown)                        |                    |                    | S               | Unknown               | Unknown              |                 | Not Reported   |                |
| <u>FDA Received Date</u>                                                    | <u>Case #</u>                                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>     | <u>Country</u> |
| 22-Mar-2015                                                                 | 10943341                                      | EXPEDITED (15-DAY) |                    | DE              | US-ACTAVIS-2015-05346 |                      | 69 YR           | Male           | USA            |
| <u>Preferred Term</u>                                                       | <u>Product</u>                                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>     |                |
| Completed Suicide;<br>Exposure Via Ingestion;<br>Toxicity To Various Agents | Clonazepam (Aellc)                            |                    |                    | S               | Oral                  | Unknown              |                 | Watson         |                |
|                                                                             | Trazodone Hydrochloride (Watson Laboratories) |                    |                    | S               | Oral                  | Unknown              |                 | Watson         |                |
|                                                                             | Oxybutynin Core                               |                    |                    | S               | Oral                  | Unknown              |                 | Watson         |                |
|                                                                             | Quetiapine (Agptc)                            |                    |                    | S               | Oral                  | Unknown              |                 | Actavis        |                |
|                                                                             | Lamotrigine (Watson Laboratories)             |                    |                    | S               | Oral                  | Unknown              |                 | Watson         |                |
|                                                                             | Finasteride (Atllc)                           |                    |                    | S               | Oral                  | Unknown              |                 | Actavis Totowa |                |
|                                                                             | Acetylsalicylic Acid (Unknown)                |                    |                    | S               | Oral                  | Unknown              |                 | Not Reported   |                |
|                                                                             | Escitalopram (Unknown)                        |                    |                    | S               | Oral                  | Unknown              |                 | Not Reported   |                |
|                                                                             | Digoxin (Unknown)                             |                    |                    | S               | Oral                  | Unknown              |                 | Not Reported   |                |
| <u>FDA Received Date</u>                                                    | <u>Case #</u>                                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>     | <u>Country</u> |
| 22-Mar-2015                                                                 | 10943421                                      | EXPEDITED (15-DAY) |                    | DE              | US-WATSON-2015-05712  |                      | 32 YR           | Male           | USA            |
| <u>Preferred Term</u>                                                       | <u>Product</u>                                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>     |                |
| Completed Suicide                                                           | Zolpidem Tartrate (Watson Laboratories)       |                    |                    | S               | Unknown               | Unk                  |                 | Watson         |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                           |                                        | Escitalopram (Unknown) | S                  | Unknown         | Unk                                                        |                      |                 | Not Reported      |                |
|---------------------------------------------------------------------------|----------------------------------------|------------------------|--------------------|-----------------|------------------------------------------------------------|----------------------|-----------------|-------------------|----------------|
|                                                                           |                                        | Methamphetamine        | S                  | Unknown         | Unk                                                        |                      |                 | Not Reported      |                |
|                                                                           |                                        | Ethanol                | S                  | Unknown         | Unk                                                        |                      |                 | Not Reported      |                |
| <u>FDA Received Date</u>                                                  | <u>Case #</u>                          | <u>Case Type</u>       | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>        | <u>Country</u> |
| 23-Mar-2015                                                               | 10943961                               | EXPEDITED (15-DAY)     |                    | OT              | GB-MACLEODS<br>PHARMACEUTICALS<br>US LTD-<br>MAC2015001656 |                      |                 | Unknown           | GBR            |
| <u>Preferred Term</u>                                                     | <u>Product</u>                         | <u>Comp.</u>           | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>        |                |
| Cough; Micturition<br>Urgency; Pollakiuria; Rash<br>Generalised; Wheezing | Escitalopram 20mg Tablet               |                        |                    | S               | Oral                                                       | 20 Mg, Unk           |                 | Macleods          |                |
|                                                                           | Nortriptyline                          |                        |                    | S               | Oral                                                       | 50 Mg, Tid           |                 | Not Reported      |                |
|                                                                           | Crestor                                |                        |                    | C               | Unknown                                                    | Unk                  |                 | Not Reported      |                |
| <u>FDA Received Date</u>                                                  | <u>Case #</u>                          | <u>Case Type</u>       | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>        | <u>Country</u> |
| 23-Mar-2015                                                               | 10949296                               | DIRECT                 |                    |                 |                                                            |                      | 51 YR           | Unknown           | USA            |
| <u>Preferred Term</u>                                                     | <u>Product</u>                         | <u>Comp.</u>           | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>        |                |
| Drug Interaction;<br>Hyperhidrosis                                        | Mucinex                                |                        | Y                  | S               | Oral                                                       |                      |                 | Reckitt Benckiser |                |
|                                                                           | Lexapro                                |                        |                    | S               | Oral                                                       |                      |                 | Not Reported      |                |
|                                                                           | Lisinopril                             |                        |                    | C               |                                                            |                      |                 | Not Reported      |                |
|                                                                           | Lunesta                                |                        |                    | C               |                                                            |                      |                 | Not Reported      |                |
|                                                                           | Tizandine (Tizandine<br>Hydrochloride) |                        |                    | C               |                                                            |                      |                 | Not Reported      |                |
|                                                                           | Calcium                                |                        |                    | C               |                                                            |                      |                 | Not Reported      |                |
|                                                                           | Omega 3                                |                        |                    | C               |                                                            |                      |                 | Not Reported      |                |
|                                                                           | Vitamin B 12                           |                        |                    | C               |                                                            |                      |                 | Not Reported      |                |
|                                                                           | Pesudoephedrine                        |                        |                    | C               |                                                            |                      |                 | Not Reported      |                |
|                                                                           | Diphenhydramine                        |                        |                    | C               |                                                            |                      |                 | Not Reported      |                |
|                                                                           | Flonase Nasal Spray                    |                        |                    | C               |                                                            |                      |                 | Not Reported      |                |
|                                                                           | Acetaminophen                          |                        |                    | C               |                                                            |                      |                 | Not Reported      |                |
| <u>FDA Received Date</u>                                                  | <u>Case #</u>                          | <u>Case Type</u>       | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>        | <u>Country</u> |
| 23-Mar-2015                                                               | 10952894                               | EXPEDITED (15-DAY)     | Y                  | OT              | ADR-2015-00559                                             |                      | 30 YR           | Female            | SAU            |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                                                                                                                                                                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Anxiety; Clonus; Condition Aggravated; Drug Eruption; Drug-Induced Liver Injury; Hyperreflexia; Hypertonia; Hyporeflexia; Muscle Rigidity; Muscle Spasms; Muscle Tightness; Musculoskeletal Stiffness; Pain In Extremity | Baclofen       |                    | N                  | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                          | Pregabalin     |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                          | Carbamazepine  |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                          | Escitalopram   |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                          | Phenytoin      |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Mar-2015                                                                                                                                                                                                              | 10611809       | EXPEDITED (15-DAY) |                    | HO, LT          | JP-FRI-1000072705    |                      | 59 YR           | Female       | JPN            |
| <u>Preferred Term</u>                                                                                                                                                                                                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anal Incontinence; Loss Of Consciousness; Nausea; Urinary Incontinence; Vomiting                                                                                                                                         | Lexapro        |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                                                                                                                                                                                                          | Gasmotin       |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                          | Frاندول S      |                    |                    | C               | Transdermal          | 1 Mg                 |                 | Not Reported |                |
|                                                                                                                                                                                                                          | Livalo Od      |                    |                    | C               | Oral                 | 1 Mg                 |                 | Not Reported |                |
|                                                                                                                                                                                                                          | Nifedipine Cr  |                    |                    | C               | Oral                 | 40 Mg                |                 | Not Reported |                |
|                                                                                                                                                                                                                          | Nicorandil     |                    |                    | C               | Oral                 | 15 Mg                |                 | Not Reported |                |
|                                                                                                                                                                                                                          | Rozerem        |                    |                    | C               | Oral                 | 8 Mg                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Mar-2015                                                                                                                                                                                                              | 10905215       | EXPEDITED (15-DAY) |                    | HO              | IT-FRI-1000075117    |                      | 40 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                                                                                                                                                                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Diplegia; Paralysis; Withdrawal Syndrome                                                                                                                                                                                 | Escitalopram   |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                                                                                                                                                                                                          | Escitalopram   |                    |                    | S               | Oral                 | 20 Mg                |                 | Forest       |                |
|                                                                                                                                                                                                                          | Seroquel Rp    |                    |                    | S               | Oral                 | 50 Mg                |                 | Not Reported |                |
|                                                                                                                                                                                                                          | Seroquel Rp    |                    |                    | S               | Oral                 | 150 Mg               |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                  | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|---------------------------------|--------------------------|-----------------|--------------|----------------|
| 24-Mar-2015                                                                               | 10947959                | EXPEDITED (15-DAY) |                    | HO              | FR-AUROBINDO-AUR-APL-2015-02478 |                          | 70 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                     | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain; Asthenia; Burning Sensation; Decreased Appetite; Hyperthermia; Pyrexia    | Mirtazapine Arrow 15mg  |                    |                    | S               | Oral                            | 15 Mg, Daily             |                 | Aurobindo    |                |
|                                                                                           | Noctamide               |                    |                    | S               | Oral                            | 2 Mg, Daily              |                 | Not Reported |                |
|                                                                                           | Seroplex                |                    |                    | S               | Unknown                         | 20 Mg, Daily             |                 | Not Reported |                |
|                                                                                           | Tercian /00759301/      |                    |                    | S               | Oral                            | 60 Gtt, Daily            |                 | Not Reported |                |
|                                                                                           | Theralene               |                    |                    | S               | Unknown                         | Unk                      |                 | Not Reported |                |
|                                                                                           | Diazepam                |                    |                    | S               | Unknown                         | Unk                      |                 | Not Reported |                |
|                                                                                           | Lamaline /00764901/     |                    |                    | C               | Unknown                         | Unk                      |                 | Not Reported |                |
|                                                                                           | Ibuprofene              |                    |                    | C               | Unknown                         | Unk                      |                 | Not Reported |                |
|                                                                                           | Trimebutine Almus       |                    |                    | C               | Unknown                         | Unk                      |                 | Not Reported |                |
|                                                                                           | Meteospasmyl /01017401/ |                    |                    | C               | Unknown                         | Unk                      |                 | Not Reported |                |
|                                                                                           | Isoptine                |                    |                    | C               | Unknown                         | Unk                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                  | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Mar-2015                                                                               | 10948040                | EXPEDITED (15-DAY) |                    | OT              | GB-ACCORD-029486                |                          | 61 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                                     | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Cough; Micturition Urgency; Pollakiuria; Rash Generalised; Urinary Incontinence; Wheezing | Escitalopram            |                    |                    | S               | Oral                            |                          |                 | Accord       |                |
|                                                                                           | Nortriptyline           |                    |                    | S               | Oral                            |                          |                 | Not Reported |                |
|                                                                                           | Crestor                 |                    |                    | C               |                                 |                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                  | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Mar-2015                                                                               | 10950740                | EXPEDITED (15-DAY) |                    | DE              | NL-PFIZER INC-2015101655        |                          | 56 YR           | Male         | NLD            |
| <u>Preferred Term</u>                                                                     | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Death                                                                                     | Alprazolam              |                    |                    | S               |                                 | 0.5 Mg, 3x/Day As Needed |                 | Pfizer       |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|           |   |                          |              |
|-----------|---|--------------------------|--------------|
| Trazolan  | S | 100 Mg, 1x/Day As Needed | Unknown      |
| Medikinet | S | 20 Mg, 1x/Day            | Not Reported |
| Medikinet | S | 40 Mg, 1x/Day            | Not Reported |
| Medikinet | S | 50 Mg, 1x/Day            | Not Reported |
| Lexapro   | S | 15 Mg, 1x/Day            | Not Reported |
| Zopiclon  | S | 15 Mg, 2x/Day As Needed  | Not Reported |
| Omeprazol | C | 20 Mg, 1x/Day            | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|------------------|----------------|
| 25-Mar-2015              | 9631713        | EXPEDITED (15-DAY) |                    | HO              | FR-<br>ELI_LILLY_AND_COMP<br>ANY-FR201310003041 |                      | 24 YR           | Female           | FRA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |
| Neutropenia              | Zyprexa        |                    |                    | S               | Oral                                            | 5 Mg, Qd             |                 | Eli Lilly And Co |                |
|                          | Seroplex       |                    |                    | S               | Oral                                            | 1 Df, Unknown        |                 | Not Reported     |                |
|                          | Lorazepam      |                    |                    | C               | Oral                                            | 1 Df, Unknown        |                 | Not Reported     |                |

| <u>FDA Received Date</u>                    | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------|--------------------|--------------------|--------------------|-----------------|-------------------------------------|----------------------|-----------------|--------------|----------------|
| 25-Mar-2015                                 | 10952121           | EXPEDITED (15-DAY) |                    | OT              | GB-AUROBINDO-AUR-<br>APL-2015-02494 |                      | 61 YR           | Female       | GBR            |
| <u>Preferred Term</u>                       | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cough; Micturition                          | Escitalopram 20 Mg |                    |                    | S               | Oral                                | 20 Mg, Unk           |                 | Aurobindo    |                |
| Urgency; Pollakiuria; Rash                  | Nortriptyline      |                    |                    | S               | Oral                                | 50 Mg, 3 Times A Day |                 | Not Reported |                |
| Generalised; Urinary Incontinence; Wheezing | Crestor            |                    |                    | C               | Unknown                             | Unk                  |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|-----------------|------------|----------------|
| 25-Mar-2015              | 10953073       | EXPEDITED (15-DAY) |                    | DE              | US-CIPLA LTD.-<br>2015US02280 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Completed Suicide        | Lamotrigine    |                    |                    | S               |                               |                      |                 | Cipla      |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|              |   |              |
|--------------|---|--------------|
| Escitalopram | S | Teva         |
| Zonisamide   | S | Not Reported |
| Lorazepam    | S | Not Reported |
| Lovastatin   | S | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 25-Mar-2015              | 10953253      | NON-EXPEDITED    |                    |                 | US-PFIZER INC-<br>2015092606 |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Hypersensitivity | Norvasc        |              |            | S           |              | Unk                |                 | Pfizer       |
|                       | Bactrim        |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Lexapro        |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Albuterol      |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Advair         |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Mobic          |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Pravachol      |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Dyazide        |              |            | S           |              | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|------------|------------|----------------|
| 25-Mar-2015              | 10953676      | EXPEDITED (15-DAY) |                    | DE              | US-CIPLA LTD.-<br>2015US02392 |                      |            | Unknown    | USA            |

| <u>Preferred Term</u> | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|--------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Zolpidem Tartarate |              |            | S           |              |                    |                 | Cipla        |
|                       | Ethanol            |              |            | S           |              |                    |                 | Not Reported |
|                       | Methamphetamine    |              |            | S           |              |                    |                 | Not Reported |
|                       | Escitaopram        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Mar-2015              | 10956620      | DIRECT           | Y                  | OT              |                      |                      | 42 YR      | Male       | USA            |

| <u>Preferred Term</u>                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Diarrhoea; Product Substitution Issue | Escitalopram   |              |            | S           | Oral         | 1                  |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Mar-2015              | 10573727      | EXPEDITED (15-DAY) |                    | HO              | JP-FRI-1000072173    |                      | 76 YR      | Male       | JPN            |

| <u>Preferred Term</u>             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Loss Of Consciousness;<br>Seizure | Lexapro        |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                   | Bayaspirin     |              |            | C           | Oral         | 100 Mg             |                 | Not Reported |
|                                   | Zetia          |              |            | C           | Oral         | 10 Mg              |                 | Not Reported |
|                                   | Crestor        |              |            | C           | Oral         | 2.5 Mg             |                 | Not Reported |
|                                   | Fluitran       |              |            | C           | Oral         | 2 Mg               |                 | Not Reported |
|                                   | Farom          |              |            | C           | Oral         | 100 Mg             |                 | Not Reported |
|                                   | Artist         |              |            | C           | Oral         | 5 Mg               |                 | Not Reported |
|                                   | Prazaxa        |              |            | C           | Oral         | 220 Mg             |                 | Not Reported |
|                                   | Nexium         |              |            | C           | Oral         | 20 Mg              |                 | Not Reported |
|                                   | Halcion        |              |            | C           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 26-Mar-2015              | 10707412      | EXPEDITED (15-DAY) |                    | OT              | US-ASTELLAS-2015US000304 |                      | 73 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|--------------|------------|-------------|--------------|------------------------|-----------------|--------------|
| Condition Aggravated;<br>Confusional State;<br>Decreased Appetite;<br>Feeling Abnormal;<br>Headache; Herpes Virus<br>Infection; Hypertension;<br>Insomnia; Memory<br>Impairment; Myalgia;<br>Paraesthesia;<br>Unevaluable Event;<br>Weight Decreased | Vesicare           |              |            | S           | Unknown      | Unk Unk, Once Daily    |                 | Astellas     |
|                                                                                                                                                                                                                                                      | Effexor            |              |            | S           | Unknown      |                        |                 | Not Reported |
|                                                                                                                                                                                                                                                      | Effexor            |              |            | S           | Unknown      |                        |                 | Not Reported |
|                                                                                                                                                                                                                                                      | Escitalopram       |              |            | S           | Unknown      |                        |                 | Not Reported |
|                                                                                                                                                                                                                                                      | Celebrex           |              |            | C           | Unknown      | 200 Unk, Unknown Freq. |                 | Not Reported |
|                                                                                                                                                                                                                                                      | Azathioprin        |              |            | C           | Unknown      | 50 Unk, Unknown Freq.  |                 | Not Reported |
|                                                                                                                                                                                                                                                      | Hydroxychloroquine |              |            | C           | Unknown      | 200 Unk, Unknown Freq. |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                           | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|-----------------------|------------------------|-----------------|--------------|----------------|
| 26-Mar-2015                                                        | 10750143             | EXPEDITED (15-DAY) |                    | HO, OT          | PHHY2015ES009237      |                        | 24 YR           | Male         | ESP            |
| <u>Preferred Term</u>                                              | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Overdose;<br>Suicide Attempt                           | Gilenya              |                    |                    | S               | Unknown               |                        |                 | Novartis     |                |
|                                                                    | Gilenya              |                    |                    | S               | Oral                  | 56 Tablets At One Time |                 | Novartis     |                |
|                                                                    | Escitalopram         |                    |                    | S               | Oral                  | 24 Tablets At One Time |                 | Not Reported |                |
| <u>FDA Received Date</u>                                           | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Mar-2015                                                        | 10934637             | NON-EXPEDITED      |                    | HO              | ES-JNJFOC-20150307838 |                        | 59 YR           | Male         | ESP            |
| <u>Preferred Term</u>                                              | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Behaviour Disorder; Drug<br>Interaction; Transplant<br>Dysfunction | Simeprevir           |                    |                    | S               | Oral                  |                        |                 | Not Reported |                |
|                                                                    | Sofosbuvir           |                    |                    | S               | Unknown               |                        |                 | Not Reported |                |
|                                                                    | Escitalopram         |                    |                    | S               | Unknown               |                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                           | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Mar-2015                                                        | 10955497             | EXPEDITED (15-DAY) |                    | OT              | US-ACCORD-029559      |                        | 72 YR           | Male         | USA            |
| <u>Preferred Term</u>                                              | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Exfoliative Rash;<br>Subacute Cutaneous<br>Lupus Erythematosus     | Escitalopram         |                    |                    | S               |                       |                        |                 | Accord       |                |
|                                                                    | Metoprolol           |                    |                    | S               |                       |                        |                 | Not Reported |                |
|                                                                    | Acetylsalicylic Acid |                    |                    | S               |                       |                        |                 | Not Reported |                |
|                                                                    | Dipyridamole         |                    |                    | S               |                       |                        |                 | Not Reported |                |
|                                                                    | Levothyroxine        |                    |                    | S               |                       |                        |                 | Not Reported |                |
|                                                                    | Pravastatin          |                    |                    | S               |                       |                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                           | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Mar-2015                                                        | 10956131             | EXPEDITED (15-DAY) |                    | OT              | GB-TEVA-549142ACC     |                        | 61 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                              | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                            |               |   |      |                      |              |
|----------------------------|---------------|---|------|----------------------|--------------|
| Cough; Micturition         | Escitalopram  | S | Oral |                      | Ivax         |
| Urgency; Pollakiuria; Rash | Nortriptyline | S | Oral | 150 Milligram Daily; | Not Reported |
| Generalised; Wheezing      | Crestor       | C |      |                      | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 26-Mar-2015              | 10957556      | EXPEDITED (15-DAY) | HO                 |                 | CH-JNJFOC-20150318732 |                      | 58 YR      | Male       | CHE            |

| <u>Preferred Term</u> | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>  | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|------------------------|--------------|------------|-------------|---------------|--------------------|-----------------|--------------|
| Mania                 | Tramadol Hydrochloride |              |            | S           | Unknown       |                    |                 | Not Reported |
|                       | Escitalopram           |              |            | S           | Unknown       |                    |                 | Not Reported |
|                       | Triamcinolone          |              |            | S           | Intramuscular |                    |                 | Not Reported |
|                       | Triamcinolone          |              |            | S           | Intramuscular |                    |                 | Not Reported |
|                       | Triamcinolone          |              |            | S           | Intramuscular |                    |                 | Not Reported |
|                       | Triamcinolone          |              |            | S           | Intramuscular |                    |                 | Not Reported |
|                       | Baclofen               |              |            | C           | Unknown       |                    |                 | Not Reported |
|                       | Ibuprofen              |              |            | C           | Unknown       |                    |                 | Not Reported |
|                       | Paracetamol            |              |            | C           | Unknown       |                    |                 | Not Reported |
|                       | Oxazepam               |              |            | C           | Unknown       |                    |                 | Not Reported |
|                       | Oxazepam               |              |            | C           | Unknown       |                    |                 | Not Reported |
|                       | Candesartan            |              |            | C           | Unknown       |                    |                 | Not Reported |
|                       | Metformin              |              |            | C           | Unknown       |                    |                 | Not Reported |
|                       | Alprazolam             |              |            | C           | Unknown       |                    |                 | Not Reported |
|                       | Alfuzosin              |              |            | C           | Unknown       |                    |                 | Not Reported |
|                       | Trospium               |              |            | C           | Unknown       |                    |                 | Not Reported |
|                       | Quetiapine             |              |            | C           | Unknown       |                    |                 | Not Reported |
|                       | Quetiapine             |              |            | C           | Unknown       |                    |                 | Not Reported |
|                       | Quetiapine             |              |            | C           | Unknown       |                    |                 | Not Reported |
|                       | Zolpidem               |              |            | C           | Unknown       |                    |                 | Not Reported |
|                       | Atorvastatin           |              |            | C           | Unknown       |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                 | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|-----------------|--------------|----------------|
| 27-Mar-2015                                              | 10959295                  | EXPEDITED (15-DAY) |                    | DE              | US-CIPLA LTD.-<br>2015US02401 |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                    | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                        | Lamotrigine               |                    |                    | S               |                               |                      |                 | Cipla        |                |
|                                                          | Temazepam                 |                    |                    | S               |                               |                      |                 | Not Reported |                |
|                                                          | Lorazepam                 |                    |                    | S               |                               |                      |                 | Not Reported |                |
|                                                          | Primidone                 |                    |                    | S               |                               |                      |                 | Not Reported |                |
|                                                          | Escitalopram              |                    |                    | S               |                               |                      |                 | Not Reported |                |
|                                                          | Benzotropine              |                    |                    | S               |                               |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                 | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Mar-2015                                              | 10959317                  | EXPEDITED (15-DAY) |                    | DE              | US-CIPLA LTD.-<br>2015US02439 |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                    | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                        | Meloxicam                 |                    |                    | S               |                               |                      |                 | Cipla        |                |
|                                                          | Escitalopram              |                    |                    | S               |                               |                      |                 | Not Reported |                |
|                                                          | Loperamide                |                    |                    | S               |                               |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                 | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Mar-2015                                              | 10959338                  | EXPEDITED (15-DAY) |                    | DE, OT          | US-CIPLA LTD.-<br>2015US02291 |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                    | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Completed<br>Suicide; Respiratory Arrest | Zolpidem Tartarate        |                    |                    | S               |                               |                      |                 | Cipla        |                |
|                                                          | Sertraline                |                    |                    | S               |                               |                      |                 | Cipla        |                |
|                                                          | Amitriptyline             |                    |                    | S               |                               |                      |                 | Not Reported |                |
|                                                          | Tramadol                  |                    |                    | S               |                               |                      |                 | Not Reported |                |
|                                                          | Acetaminophen/Hydrocodone |                    |                    | S               |                               |                      |                 | Not Reported |                |
|                                                          | Ondansetron               |                    |                    | S               |                               |                      |                 | Not Reported |                |
|                                                          | Linaclotide               |                    |                    | S               |                               |                      |                 | Not Reported |                |
|                                                          | Diclofenac                |                    |                    | S               |                               |                      |                 | Not Reported |                |
|                                                          | Lubiprostone              |                    |                    | S               |                               |                      |                 | Not Reported |                |
|                                                          | Liothyronine              |                    |                    | S               |                               |                      |                 | Not Reported |                |
|                                                          | Escitalopram              |                    |                    | S               |                               |                      |                 | Not Reported |                |
|                                                          | Gabapentin                |                    |                    | S               |                               |                      |                 | Not Reported |                |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u>                                                                                                                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>                      | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                                                                                    | <u>Country</u> |
|--------------------------|--------------------------------------------------------------------------------------------------------------------------------|--------------------|--------------------|--------------------------------------|-------------------------------|----------------------|-----------------|---------------------------------------------------------------------------------------------------------------|----------------|
| 27-Mar-2015              | 10959341                                                                                                                       | EXPEDITED (15-DAY) |                    | DE                                   | US-CIPLA LTD.-<br>2015US02296 |                      |                 | Unknown                                                                                                       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>                                                                                                                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                          | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                                                                                    |                |
| Death                    | Sertraline<br>Atomoxetine<br>Escitalopram                                                                                      |                    |                    | S<br>S<br>S                          |                               |                      |                 | Cipla<br>Not Reported<br>Not Reported                                                                         |                |
| <u>FDA Received Date</u> | <u>Case #</u>                                                                                                                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>                      | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                                                                                    | <u>Country</u> |
| 27-Mar-2015              | 10959863                                                                                                                       | EXPEDITED (15-DAY) |                    | OT                                   | US-ACCORD-029591              |                      |                 | Unknown                                                                                                       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>                                                                                                                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                          | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                                                                                    |                |
| Nephrolithiasis          | Escitalopram Oxalate Accord                                                                                                    |                    |                    | S                                    |                               |                      |                 | Accord                                                                                                        |                |
| <u>FDA Received Date</u> | <u>Case #</u>                                                                                                                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>                      | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                                                                                    | <u>Country</u> |
| 27-Mar-2015              | 10961059                                                                                                                       | EXPEDITED (15-DAY) |                    | DE                                   | US-CIPLA LTD.-<br>2015US02315 |                      |                 | Unknown                                                                                                       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>                                                                                                                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                          | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                                                                                    |                |
| Completed Suicide        | Escitalopram<br>Topiramate<br>Promethazine<br>Verapamil<br>Acetaminophen/Hydrocodone<br>Diazepam<br>Esomeprazole<br>Diclofenac |                    |                    | S<br>S<br>S<br>S<br>S<br>S<br>S<br>S |                               |                      |                 | Teva<br>Cipla<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>                                                                                                                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>                      | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                                                                                    | <u>Country</u> |
| 27-Mar-2015              | 10961129                                                                                                                       | EXPEDITED (15-DAY) |                    | DE                                   | US-CIPLA LTD.-<br>2015US02328 |                      |                 | Unknown                                                                                                       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>                                                                                                                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                          | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                                                                                    |                |
| Completed Suicide        | Topiramate<br>Verapamil<br>Escitalopram                                                                                        |                    |                    | S<br>S<br>S                          |                               |                      |                 | Cipla<br>Not Reported<br>Not Reported                                                                         |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                                                                                                                                    |                |                    |                    |                 |                          |                            |                 |            |                    |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|--------------------------|----------------------------|-----------------|------------|--------------------|
| Codeine                                                                                                                                                                                                                                                                                                            |                |                    | S                  |                 |                          | Not Reported               |                 |            |                    |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                           | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u> | <u>Country</u>     |
| 27-Mar-2015                                                                                                                                                                                                                                                                                                        | 10963484       | DIRECT             |                    |                 |                          |                            | 63 YR           | Male       | USA                |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                              | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u> |                    |
| Agitation; Anger; Drug Ineffective; Impaired Driving Ability; Insomnia; Memory Impairment                                                                                                                                                                                                                          | Gilenya        |                    |                    | S               | Oral                     |                            |                 |            | Not Reported       |
|                                                                                                                                                                                                                                                                                                                    | Lexapro        |                    |                    | S               | Oral                     |                            |                 |            | Not Reported       |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                           | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u> | <u>Country</u>     |
| 27-Mar-2015                                                                                                                                                                                                                                                                                                        | 10966280       | DIRECT             |                    |                 |                          |                            | 36 YR           | Male       | USA                |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                              | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u> |                    |
| Hallucination, Auditory                                                                                                                                                                                                                                                                                            | Escitalopram   |                    |                    | S               | Oral                     | 1 Pill                     | 3 DAY           |            | International Labs |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                           | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u> | <u>Country</u>     |
| 30-Mar-2015                                                                                                                                                                                                                                                                                                        | 10557289       | EXPEDITED (15-DAY) |                    | HO, OT          | US-PFIZER INC-2014300572 |                            | 35 YR           | Male       | USA                |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                              | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u> |                    |
| Adjustment Disorder; Agitation; Anhedonia; Anxiety; Apathy; Depressed Mood; Derealisation; Disturbance In Attention; Eating Disorder; Feelings Of Worthlessness; Haematemesis; Headache; Impaired Work Ability; Insomnia; Lethargy; Mania; Mental Disorder; Mental Impairment; Nausea; Palpitations; Panic Attack; | Zoloft         |                    |                    | S               | Oral                     | 25 Mg, 1x/Day              |                 |            | Pfizer             |
|                                                                                                                                                                                                                                                                                                                    | Zoloft         |                    |                    | S               |                          |                            |                 |            | Pfizer             |
|                                                                                                                                                                                                                                                                                                                    | Zoloft         |                    |                    | S               |                          |                            |                 |            | Pfizer             |
|                                                                                                                                                                                                                                                                                                                    | Zoloft         |                    |                    | S               |                          |                            |                 |            | Pfizer             |
|                                                                                                                                                                                                                                                                                                                    | Celexa         |                    |                    | S               | Oral                     | 10 Mg, 1x/Day              |                 |            | Not Reported       |
|                                                                                                                                                                                                                                                                                                                    | Celexa         |                    |                    | S               |                          |                            |                 |            | Not Reported       |
|                                                                                                                                                                                                                                                                                                                    | Lexapro        |                    |                    | S               | Oral                     | 5 Mg, Daily                |                 |            | Not Reported       |
|                                                                                                                                                                                                                                                                                                                    | Lexapro        |                    |                    | S               |                          | 10mg, Unk                  |                 |            | Not Reported       |
|                                                                                                                                                                                                                                                                                                                    | Ambien         |                    |                    | S               | Oral                     | 5 Mg, Unk                  |                 |            | Not Reported       |
|                                                                                                                                                                                                                                                                                                                    | Ambien         |                    |                    | S               | Oral                     | 10 Mg, 1x/Day Before Sleep |                 |            | Not Reported       |
|                                                                                                                                                                                                                                                                                                                    | Multivitamins  |                    |                    | C               |                          | Unk                        |                 |            | Not Reported       |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Paranoia; Suicidal  
Ideation; Tachyphrenia;  
Tremor; Vomiting; Weight  
Decreased; Withdrawal  
Syndrome

| <u>FDA Received Date</u>                                                                                                                                      | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|-------------------------------|----------------------------|-----------------|--------------|----------------|
| 30-Mar-2015                                                                                                                                                   | 10920518                    | EXPEDITED (15-DAY) |                    | OT              | PHHY2015BR030111              |                            |                 | Female       | BRA            |
| <u>Preferred Term</u>                                                                                                                                         | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain Upper;<br>Condition Aggravated;<br>Depression; Disturbance<br>In Attention; Feeling<br>Abnormal; Headache;<br>Nephrolithiasis;<br>Osteoporosis | Deserila                    |                    |                    | S               | Oral                          | 1 Df, Qd                   |                 | Not Reported |                |
|                                                                                                                                                               | Diclofenac                  |                    |                    | S               | Unknown                       |                            |                 | Novartis     |                |
|                                                                                                                                                               | Citalopram                  |                    |                    | S               | Unknown                       |                            |                 | Not Reported |                |
|                                                                                                                                                               | Olcadil                     |                    |                    | S               | Oral                          | 1 Df, Qd                   |                 | Not Reported |                |
|                                                                                                                                                               | Neosaldina                  |                    |                    | S               | Unknown                       |                            |                 | Not Reported |                |
|                                                                                                                                                               | Escitalopram                |                    |                    | S               | Unknown                       |                            |                 | Not Reported |                |
|                                                                                                                                                               | Buscopan                    |                    |                    | S               | Unknown                       |                            |                 | Not Reported |                |
|                                                                                                                                                               | Venlafaxine                 |                    |                    | C               | Oral                          | 1 Df, Qd                   |                 | Not Reported |                |
|                                                                                                                                                               | Venlafaxine                 |                    |                    | C               |                               |                            |                 | Not Reported |                |
|                                                                                                                                                               | Depakote                    |                    |                    | C               | Oral                          | 1 Df, Qd                   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                      | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Mar-2015                                                                                                                                                   | 10966082                    | NON-EXPEDITED      |                    |                 | US-MYLANLABS-<br>2014M1012235 |                            | 49 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                         | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>   |                |
| Dry Mouth; Oropharyngeal<br>Pain                                                                                                                              | Fentanyl                    |                    |                    | S               | Transdermal                   | 50 Mg, Qh, Changed<br>Q48h |                 | Not Reported |                |
|                                                                                                                                                               | Lyrica                      |                    |                    | S               |                               | 300 Mg, Bid                |                 | Not Reported |                |
|                                                                                                                                                               | Tizanidine                  |                    |                    | S               |                               | 8 Mg, Tid                  |                 | Not Reported |                |
|                                                                                                                                                               | Tizanidine                  |                    |                    | S               |                               |                            |                 | Not Reported |                |
|                                                                                                                                                               | Tizanidine                  |                    |                    | S               |                               |                            |                 | Not Reported |                |
|                                                                                                                                                               | Oxycodone And Acetaminophen |                    |                    | S               |                               | 10 Mg, Tid                 |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                    |   |             |              |
|--------------------|---|-------------|--------------|
| Seroquel           | S | 300 Mg, Qd  | Not Reported |
| Seroquel           | S |             | Not Reported |
| Seroquel           | S |             | Not Reported |
| Metformin          | S | 1000 Mg, Qd | Not Reported |
| Venlafaxine        | S | 150 Mg, Qd  | Not Reported |
| Venlafaxine        | S | 75 Mg, Qd   | Not Reported |
| Lexapro            | S | 20 Mg, Qd   | Not Reported |
| Valium             | S | 5 Mg, Tid   | Not Reported |
| Aspirin /00002701/ | S | 162 Mg, Hs  | Not Reported |
| Simvastatin        | S | 40 Mg, Unk  | Not Reported |
| Topamax            | S | 100 Mg, Am  | Not Reported |
| Ibuprofen          | S | 800 Mg, Am  | Not Reported |
| Demdex /01036501/  | S | 20 Mg, Qd   | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Mar-2015              | 10968354      | EXPEDITED (15-DAY) |                    | HO, OT          | PHHY2015US035699     |                      | 27 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                                               | <u>Product</u>                         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------|------------|-------------|--------------|--------------------------|-----------------|--------------|
| Agitation; Body Temperature Increased; Clonus; Hyperhidrosis; Hyperreflexia; Hypotonia; Muscle Rigidity; Mydriasis; Overdose; Serotonin Syndrome; Sinus Tachycardia | Metaxalone                             |              |            | S           | Unknown      | 800 Mg, Qid              |                 | Novartis     |
|                                                                                                                                                                     | Escitalopram                           |              |            | S           | Unknown      | 30 Mg, Qd                |                 | Not Reported |
|                                                                                                                                                                     | Alpon//Alprazolam                      |              |            | C           | Unknown      | 1 Mg, Qhs                |                 | Not Reported |
|                                                                                                                                                                     | Clonazepam                             |              |            | C           | Unknown      | 1 Mg, Tid                |                 | Not Reported |
|                                                                                                                                                                     | Prazosin                               |              |            | C           | Unknown      | 2 Mg, Qhs                |                 | Not Reported |
|                                                                                                                                                                     | Propranolol                            |              |            | C           | Unknown      | 80 Mg, Qd                |                 | Not Reported |
|                                                                                                                                                                     | Quetiapine                             |              |            | C           | Unknown      | 200 Mg, Qhs              |                 | Not Reported |
|                                                                                                                                                                     | Butalbital, Acetaminophen And Caffeine |              |            | C           | Unknown      | 415 Mg, Bid              |                 | Not Reported |
|                                                                                                                                                                     | Mometasone                             |              |            | C           | Nasal        | 50mcg/Act 2 Sprays Daily |                 | Not Reported |
|                                                                                                                                                                     | Apo Prednison                          |              |            | C           | Oral         | 40 Mg, Qd                |                 | Not Reported |
|                                                                                                                                                                     | Triamcinolone                          |              |            | C           | Topical      | 0.1 %, Bid               |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                               | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|--------------------|--------------------|-----------------|--------------------------------------------------|-------------------------|-----------------|------------|----------------|
| 30-Mar-2015                                                                                                                                                                                                                                                                                                                                            | 10968725                       | NON-EXPEDITED      |                    |                 | US-LUPIN<br>PHARMACEUTICALS<br>INC.-E2B_00003049 |                         |                 | Female     | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                  | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                     | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u> |                |
| Alopecia                                                                                                                                                                                                                                                                                                                                               | Escitalopram Tablets Usp 10mg  |                    |                    | S               |                                                  |                         |                 | Lupin      |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                               | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 30-Mar-2015                                                                                                                                                                                                                                                                                                                                            | 10970407                       | DIRECT             |                    |                 |                                                  |                         | 52 YR           | Male       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                  | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                     | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u> |                |
| Abnormal Dreams;<br>Disturbance In Attention;<br>Panic Reaction;<br>Paraesthesia; Product<br>Substitution Issue                                                                                                                                                                                                                                        | Escitalopram Tab 10 Mg Torrent |                    |                    | S               | Oral                                             | 1 Tablet Taken By Mouth |                 | Torrent    |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                               | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 31-Mar-2015                                                                                                                                                                                                                                                                                                                                            | 10257880                       | EXPEDITED (15-DAY) |                    | HO, LT          | AT-FRI-1000068460                                |                         | 43 YR           | Female     | AUT            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                  | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                     | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u> |                |
| Abdominal Pain Upper;<br>Anxiety; Brain Oedema;<br>Coma; Constipation;<br>Demyelination; Dysarthria;<br>Extensor Plantar<br>Response; Fatigue; Gait<br>Disturbance;<br>Gastrooesophageal Reflux<br>Disease; Headache;<br>Hiatus Hernia;<br>Hyponatraemia;<br>Inappropriate Antidiuretic<br>Hormone Secretion;<br>Laryngospasm;<br>Leukoencephalopathy; | Escitalopram                   |                    |                    | S               | Oral                                             | 10 Mg                   |                 | Forest     |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Mouth Swelling; Myopia;  
Nasal Congestion;  
Nystagmus; Seizure;  
Syncope; Vocal Cord  
Paralysis

| <u>FDA Received Date</u>                 | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------|----------------------|------------------|--------------------|-----------------|------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 31-Mar-2015                              | 10970075             | NON-EXPEDITED    |                    |                 | US-LUPIN<br>PHARMACEUTICALS<br>INC.-2015-00343 |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                    | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Coeliac Disease;<br>Condition Aggravated | Escitalopram Oxalate |                  |                    | S               | Unknown                                        |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                 | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-Mar-2015                              | 10970136             | NON-EXPEDITED    |                    | DE              | US-LUPIN<br>PHARMACEUTICALS<br>INC.-2015-00407 |                      | 28 YR           | Female       | USA            |
| <u>Preferred Term</u>                    | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                        | Bupropion            |                  |                    | S               | Oral                                           |                      |                 | Not Reported |                |
|                                          | Escitalopram         |                  |                    | S               | Oral                                           |                      |                 | Not Reported |                |
|                                          | Gabapentin           |                  |                    | S               | Oral                                           |                      |                 | Not Reported |                |
|                                          | Alprazolam           |                  |                    | S               | Oral                                           |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                 | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-Mar-2015                              | 10970146             | NON-EXPEDITED    |                    | DE              | US-LUPIN<br>PHARMACEUTICALS<br>INC.-2015-00421 |                      | 69 YR           | Male         | USA            |
| <u>Preferred Term</u>                    | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                        | Digoxin              |                  |                    | S               | Oral                                           |                      |                 | Not Reported |                |
|                                          | Clonazepam           |                  |                    | S               | Oral                                           |                      |                 | Not Reported |                |
|                                          | Trazodone            |                  |                    | S               | Oral                                           |                      |                 | Not Reported |                |
|                                          | Oxybutynin           |                  |                    | S               | Oral                                           |                      |                 | Not Reported |                |
|                                          | Quetiapine           |                  |                    | S               | Oral                                           |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|              |   |      |              |
|--------------|---|------|--------------|
| Lamotrigine  | S | Oral | Not Reported |
| Escitalopram | S | Oral | Not Reported |
| Finasteride  | S | Oral | Not Reported |
| Salicylate   | S | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-Mar-2015              | 10971357      | NON-EXPEDITED    |                    |                 | US-TEVA-550299USA    |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                             | <u>Product</u>             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>              |
|-------------------------------------------------------------------|----------------------------|--------------|------------|-------------|--------------|----------------------|-----------------|-------------------------|
| Dizziness; Exposure Via Breast Milk; Nausea; Suppressed Lactation | Plan B One-Step<br>Lexapro |              |            | S<br>S      | Oral         | 1.5 Milligram Daily; |                 | Duramed<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 31-Mar-2015              | 10972699      | EXPEDITED (15-DAY) |                    | OT              | GB-MYLANLABS-2015M1008946 |                      |            | Unknown    | GBR            |

| <u>Preferred Term</u>                                               | <u>Product</u>                           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>                                   |
|---------------------------------------------------------------------|------------------------------------------|--------------|------------|-------------|--------------|---------------------------------|-----------------|----------------------------------------------|
| Cough; Micturition Urgency; Pollakiuria; Rash Generalised; Wheezing | Escitalopram<br>Nortriptyline<br>Crestor |              |            | S<br>S<br>C | Oral<br>Oral | 20 Mg, Unk<br>50 Mg, Tid<br>Unk |                 | Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-Mar-2015              | 10973764      | DIRECT           |                    | OT              |                      |                      | 90 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                             | <u>Product</u>                                                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>      | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                                             |
|-----------------------------------------------------------------------------------|---------------------------------------------------------------|--------------|------------|------------------|--------------|--------------------|-----------------|--------------------------------------------------------|
| Balance Disorder; Depression; Dissociation; Gait Inability; Hallucinations, Mixed | Escitalopram 10mg Camber<br>Nexum<br>Lipator<br>Prostate Drug |              |            | S<br>C<br>C<br>C | Oral         | 1 Tab              |                 | Camber<br>Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-Mar-2015              | 10990648      | NON-EXPEDITED    | Y                  | HO              | 2014000047           |                      | 54 YR      | Male       | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                       | <u>Product</u>                                        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------|-------------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Product Dose Omission;<br>Suicidal Ideation | Trazodone (Trazodone) Tablet                          |              |            | S           | Oral         |                    |                 | Not Reported |
|                                             | Atorvastatin Calcium<br>(Atorvastatin Calcium) Tablet |              |            | S           | Oral         |                    |                 | Not Reported |
|                                             | Escitalopram Oxalate<br>(Escitalopram Oxalate)        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                             | Invega (Paliperidone Palmitate)                       |              |            | C           |              |                    |                 | Not Reported |
|                                             | Bumetanide                                            |              |            | C           |              |                    |                 | Not Reported |
|                                             | Isosorbide Mononitrate                                |              |            | C           |              |                    |                 | Not Reported |
|                                             | Lantus (Insulin Glargine)                             |              |            | C           |              |                    |                 | Not Reported |
|                                             | Labetalol                                             |              |            | C           |              |                    |                 | Not Reported |
|                                             | Losartan                                              |              |            | C           |              |                    |                 | Not Reported |
|                                             | Simvastatin                                           |              |            | C           |              |                    |                 | Not Reported |
|                                             | Aspirin (Acetylsalicylic Acid)                        |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 01-Apr-2015              | 10862628      | EXPEDITED (15-DAY) |                    | DE, HO, OT      | FR-PFIZER INC-<br>2015062451 |                      | 76 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                                                                                                  | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                            | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|---------------------------------------------------------------|-----------------|--------------|
| Decreased Appetite;<br>Diarrhoea; Dyspnoea;<br>Haemoglobin Decreased;<br>Neoplasm Malignant;<br>Oedema Peripheral;<br>Thrombocytopenia | Ramipril             |              |            | S           | Oral         | 10 Mg, Daily                                                  |                 | Pfizer       |
|                                                                                                                                        | Atorvastatin Calcium |              |            | S           | Oral         | 10 Mg, Daily                                                  |                 | Pfizer       |
|                                                                                                                                        | Kardegic             |              |            | S           | Oral         | 1 Df, Daily                                                   |                 | Not Reported |
|                                                                                                                                        | Seroplex             |              |            | S           | Oral         | 1 Df, Daily                                                   |                 | Not Reported |
|                                                                                                                                        | Klipal Codeine       |              |            | S           | Oral         | 2 Df, Daily                                                   |                 | Not Reported |
|                                                                                                                                        | Creon                |              |            | S           | Oral         | Unk                                                           |                 | Not Reported |
|                                                                                                                                        | Insulatard           |              |            | S           | Subcutaneous | Unk, 2x/Day (22 Iu In<br>Morning And 10 Iu In The<br>Evening) |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Apr-2015              | 10863848      | EXPEDITED (15-DAY) |                    | DS              | PT-TEVA-542519ISR    |                      | 57 YR      | Female     | PRT            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                               |                         |   |      |              |
|---------------------------------------------------------------|-------------------------|---|------|--------------|
| Dysgeusia; Fatigue;<br>Headache; Malaise;<br>Tinnitus; Tremor | Escitalopram Ratiopharm | S | Oral | Ivax         |
|                                                               | Surmontil 25            | C | Oral | Not Reported |
|                                                               | Unilan                  | C | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Apr-2015              | 10975279      | EXPEDITED (15-DAY) |                    | OT              | GB-FRI-1000075553    |                      | 61 YR      | Female     | GBR            |

| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cough; Micturition         | Escitalopram   |              |            | S           | Oral         | 20 Mg              |                 | Forest       |
| Urgency; Pollakiuria; Rash | Nortriptyline  |              |            | S           | Oral         | 150 Mg             |                 | Not Reported |
| Generalised; Wheezing      | Crestor        |              |            | C           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Apr-2015              | 10975281      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000075531    |                      | 70 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u>                              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|---------------------------------------------|--------------|------------|-------------|--------------|----------------------|-----------------|--------------|
| Hyperthermia          | Escitalopram                                |              |            | S           |              | 20 Mg                |                 | Forest       |
|                       | Mirtazapine Arrow                           |              |            | S           | Oral         | 15 Mg                |                 | Arrow        |
|                       | Noctamide                                   |              |            | S           | Oral         | 2 Mg                 |                 | Not Reported |
|                       | Tercian                                     |              |            | S           |              | 60 Df                |                 | Not Reported |
|                       | Theralene                                   |              |            | S           | Oral         | 30 Drops At Bed Time |                 | Not Reported |
|                       | Diazepam Choay                              |              |            | S           |              | 1 Df                 |                 | Not Reported |
|                       | Lamaline                                    |              |            | C           |              |                      |                 | Not Reported |
|                       | (Acetaminophen\Caffeine\Opium )             |              |            |             |              |                      |                 |              |
|                       | Ibuprofen Agi Pharma                        |              |            | C           |              |                      |                 | Not Reported |
|                       | Trimebutine Almus                           |              |            | C           |              |                      |                 | Not Reported |
|                       | Meteospasmyl (Alverine Citrate\Dimethicone) |              |            | C           |              |                      |                 | Not Reported |
|                       | Isoptine                                    |              |            | C           |              |                      |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 01-Apr-2015                                                                                                                                                                                                                                                                                      | 10975282       | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000075579    |                      | 70 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Anxiety; Morbid Thoughts                                                                                                                                                                                                                                                              | Escitalopram   |                    |                    | S               | Oral                 | 1 Df                 |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Apr-2015                                                                                                                                                                                                                                                                                      | 10052902       | EXPEDITED (15-DAY) |                    | HO              | DK-TEVA-471831ISR    |                      |                 | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depressed Level Of Consciousness; Fatigue; Gait Disturbance; Hepatic Encephalopathy; Hepatic Failure; Hypoaesthesia; Lethargy; Motor Dysfunction; Muscle Contractions Involuntary; Muscle Spasms; Muscle Tightness; Musculoskeletal Stiffness; Myalgia; Restlessness; Serotonin Syndrome; Tremor | Modiodal       |                    |                    | S               | Unknown              |                      |                 | Cephalon     |                |
|                                                                                                                                                                                                                                                                                                  | Ciprallex      |                    |                    | S               | Unknown              |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                  | Cymbalta       |                    |                    | S               | Unknown              |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                  | Alopam         |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Apr-2015                                                                                                                                                                                                                                                                                      | 10055775       | EXPEDITED (15-DAY) |                    | HO              | DK-TEVA-472509ISR    |                      | 54 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depressed Level Of Consciousness; Fatigue; Hepatic Encephalopathy; Hepatic Failure; Hypoaesthesia; Hypokinesia; Hypokinesia;                                                                                                                                                                     | Modiodal       |                    |                    | S               | Oral                 |                      |                 | Cephalon     |                |
|                                                                                                                                                                                                                                                                                                  | Ciprallex      |                    |                    | S               | Oral                 | 30 Milligram Daily;  |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                  | Cymbalta       |                    |                    | S               | Oral                 | 120 Milligram Daily; |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                  | Alopam         |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Lethargy; Motor  
Dysfunction; Muscle  
Contractions Involuntary;  
Muscle Spasms; Muscle  
Tightness;  
Musculoskeletal Stiffness;  
Myalgia; Restlessness;  
Serotonin Syndrome;  
Tremor

| <u>FDA Received Date</u>   | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|----------------------------|----------------------------------|--------------------|--------------------|-----------------|-----------------------------------------|----------------------|-----------------|-----------------|----------------|
| 02-Apr-2015                | 10954463                         | EXPEDITED (15-DAY) |                    | OT              | CH-<br>GLAXOSMITHKLINE-<br>CH2015035840 |                      | 41 YR           | Female          | CHE            |
| <u>Preferred Term</u>      | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                            | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Hypothyroidism             | Lamictal                         |                    |                    | S               | Oral                                    | Unk                  |                 | Glaxosmithkline |                |
|                            | Lamictal                         |                    |                    | S               | Oral                                    | 200 Mg, Bid          |                 | Glaxosmithkline |                |
|                            | Tecfidera                        |                    |                    | S               | Oral                                    | 240 Mg, Bid          |                 | Not Reported    |                |
|                            | Escitalopram                     |                    |                    | S               | Oral                                    | 10 Mg, Qod           |                 | Not Reported    |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 02-Apr-2015                | 10978658                         | EXPEDITED (15-DAY) |                    | OT              | GB-WATSON-2015-<br>06935                |                      | 61 YR           | Female          | GBR            |
| <u>Preferred Term</u>      | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                            | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Cough; Micturition         | Escitalopram (Unknown)           |                    |                    | S               | Oral                                    | 20 Mg, Unk           |                 | Not Reported    |                |
| Urgency; Pollakiuria; Rash | Nortriptyline Hydrochloride      |                    |                    | S               | Oral                                    | 50 Mg, Tid           |                 | Watson          |                |
| Generalised; Wheezing      | (Watson Laboratories)<br>Crestor |                    |                    | C               | Unknown                                 | Unk                  |                 | Not Reported    |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 02-Apr-2015                | 10981853                         | EXPEDITED (15-DAY) |                    | CA, DE          | US-FRI-1000075516                       |                      | < 1 DAY         | Female          | USA            |
| <u>Preferred Term</u>      | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                            | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Coarctation Of The Aorta;  | Lexapro                          |                    |                    | S               | Transplacental                          |                      |                 | Forest          |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Congenital Anomaly;  
Foetal Exposure During  
Pregnancy

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 03-Apr-2015              | 10215854      | NON-EXPEDITED    |                    | HO, OT          | CA-JNJFOC-20140517961 |                      | 23 YR      | Female     | CAN            |

| <u>Preferred Term</u>                                                                                                | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                          | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------|-------------------|--------------|------------|-------------|---------------------------------------|--------------------------------|-----------------|--------------|
| Cholelithiasis; Exposure During Pregnancy; Fall; Hidradenitis; Product Use In Unapproved Indication; Skin Laceration | Remicade          |              |            | S           | Intravenous (not otherwise specified) | 15th Infusion                  |                 | Not Reported |
|                                                                                                                      | Remicade          |              |            | S           | Intravenous (not otherwise specified) | Infusion Number 14             |                 | Not Reported |
|                                                                                                                      | Remicade          |              |            | S           | Intravenous (not otherwise specified) | 5 Vials                        |                 | Not Reported |
|                                                                                                                      | Remicade          |              |            | S           | Intravenous (not otherwise specified) |                                |                 | Not Reported |
|                                                                                                                      | Remicade          |              |            | S           | Intravenous (not otherwise specified) |                                |                 | Not Reported |
|                                                                                                                      | Metformin         |              |            | S           | Unknown                               |                                |                 | Not Reported |
|                                                                                                                      | Morphine          |              |            | S           | Unknown                               |                                |                 | Not Reported |
|                                                                                                                      | Gravol            |              |            | S           | Unknown                               |                                |                 | Not Reported |
|                                                                                                                      | Metamucil         |              |            | S           | Unknown                               |                                |                 | Not Reported |
|                                                                                                                      | Ativan            |              |            | S           | Unknown                               |                                |                 | Not Reported |
|                                                                                                                      | Ciprallex         |              |            | S           | Unknown                               |                                |                 | Not Reported |
|                                                                                                                      | Baclofen          |              |            | S           | Unknown                               |                                |                 | Not Reported |
|                                                                                                                      | Diclectin         |              |            | S           | Unknown                               | Started In Pregnancy With This |                 | Not Reported |
|                                                                                                                      | Rabeprazole       |              |            | S           | Unknown                               |                                |                 | Not Reported |
|                                                                                                                      | Prenatal Vitamins |              |            | C           | Unknown                               |                                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Apr-2015              | 10985118      | EXPEDITED (15-DAY) |                    | HO              | PHHY2015CH037482     |                      | 58 YR      | Male       | CHE            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                         | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>  | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|--------------|------------|-------------|---------------|--------------------|-----------------|--------------|
| Abnormal Behaviour;<br>Affect Lability; Aggression;<br>Disinhibition; Drug<br>Interaction; Energy<br>Increased; Euphoric<br>Mood; Euphoric Mood;<br>Flight Of Ideas;<br>Grandiosity; Impulsive<br>Behaviour; Irritability;<br>Logorrhoea; Mania;<br>Psychomotor<br>Hyperactivity; Serotonin<br>Syndrome; Sleep<br>Disorder; Tachyphrenia;<br>Weight Decreased | Escitalopram      |              |            | S           | Unknown       | 20 Mg, Qd          |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                               | Tramadol          |              |            | S           | Unknown       | 50 Mg, Bid         |                 | Novartis     |
|                                                                                                                                                                                                                                                                                                                                                               | Triamcinolone     |              |            | S           | Intramuscular | 40 Mg, Unk         |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                               | Cannabis          |              |            | S           | Unknown       |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                               | Quetiapine        |              |            | C           | Unknown       | 300 Mg, Qd         |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                               | Quetiapine        |              |            | C           | Unknown       | 1000 Mg, Qd        |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                               | Quetiapine        |              |            | C           | Unknown       | 800 Mg, Qd         |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                               | Oxazepam          |              |            | C           | Unknown       | 60 Mg, Qd          |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                               | Oxazepam          |              |            | C           | Unknown       | 180 Mg, Qd         |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                               | Alprazolam        |              |            | C           | Unknown       | 2 Mg, Qd           |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                               | Zolpidem          |              |            | C           | Unknown       | 12.5 Mg, Qd        |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                               | Baclofen          |              |            | C           | Unknown       | 150 Mg, Qd         |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                               | Candesartan       |              |            | C           | Unknown       | 8 Mg, Qd           |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                               | Metformin         |              |            | C           | Unknown       | 500 Mg, Unk        |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                               | Atorvastatin      |              |            | C           | Unknown       | 20 Mg, Qd          |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                               | Alfuzosin         |              |            | C           | Unknown       | 10 Mg, Qd          |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                               | Trospium Chloride |              |            | C           | Unknown       | 20 Mg, Qd          |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                               | Acetaminophen     |              |            | C           | Unknown       | 4 G, Qd            |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                               | Ibuprofen         |              |            | C           | Unknown       | 1800 Mg, Qd        |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                               | Alcohol           |              |            | C           | Unknown       |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Apr-2015              | 10054066      | EXPEDITED (15-DAY) |                    | HO              | DK-FRI-1000066025    |                      | 54 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                                                        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Depressed Level Of<br>Consciousness; Fatigue;<br>Hepatic Encephalopathy;<br>Hepatic Failure; | Escitalopram   |              |            | S           | Oral         | 30 Mg              |                 | Forest       |
|                                                                                              | Modiodal       |              |            | S           | Oral         | Styrke: 100 Mg.    |                 | Not Reported |
|                                                                                              | Cymbalta       |              |            | S           | Oral         | 120 Mg             |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                                                    |        |   |      |              |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|---|------|--------------|
| Hypoaesthesia;<br>Hypokinesia; Lethargy;<br>Motor Dysfunction; Muscle<br>Contractions Involuntary;<br>Muscle Spasms; Muscle<br>Tightness;<br>Musculoskeletal Stiffness;<br>Myalgia; Restlessness;<br>Serotonin Syndrome;<br>Tremor | Alopan | C | Oral | Not Reported |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|---|------|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Apr-2015              | 10576332      | EXPEDITED (15-DAY) |                    | HO, OT          | US-SA-2014SA153437   |                      | 35 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                   | <u>Product</u>                                                                                                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Agitation; Anhedonia;                                                                                   | Ambien                                                                                                        |              |            | S           | Oral         |                    |                 | Not Reported |
| Anxiety; Apathy; Crying;                                                                                | Ambien                                                                                                        |              |            | S           | Oral         |                    |                 | Not Reported |
| Daydreaming; Decreased<br>Appetite; Depressed                                                           | Zoloft                                                                                                        |              |            | S           | Oral         |                    |                 | Not Reported |
| Mood; Disturbance In<br>Attention; Fear; Feeding<br>Disorder; Feeling Of                                | Zoloft                                                                                                        |              |            | S           | Oral         |                    |                 | Not Reported |
| Despair; Haematemesis;                                                                                  | Celexa                                                                                                        |              |            | S           | Oral         |                    |                 | Not Reported |
| Hallucination; Headache;                                                                                | Celexa                                                                                                        |              |            | S           | Oral         |                    |                 | Not Reported |
| Impaired Work Ability;                                                                                  | Lexapro                                                                                                       |              |            | S           | Unknown      |                    |                 | Not Reported |
| Insomnia; Lethargy; Major<br>Depression; Mania; Mental<br>Impairment; Nausea;                           | Lexapro                                                                                                       |              |            | S           | Unknown      |                    |                 | Not Reported |
| Palpitations; Palpitations;<br>Paranoia; Suicidal<br>Ideation; Tremor;<br>Vomiting; Weight<br>Decreased | Panthenol/Retinol/Thiamine<br>Hydrochloride/Ascorbic<br>Acid/Ergocalciferol/Folic<br>Acid/Riboflavin/Nicotina |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Apr-2015              | 10683516      | EXPEDITED (15-DAY) |                    | HO              | IT-FRI-1000073378    |                      | 30 YR      | Female     | ITA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                         |              |   |      |                                       |        |
|-----------------------------------------|--------------|---|------|---------------------------------------|--------|
| Intentional Overdose;<br>Nausea; Tremor | Escitalopram | S | Oral | Overdose:60 Mg Total In<br>Single Day | Forest |
|                                         | Escitalopram | S |      | 5 Mg                                  | Forest |

| <u>FDA Received Date</u>                                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| 06-Apr-2015                                                                         | 10990453       | EXPEDITED (15-DAY) |                    | OT              | JP-PFIZER INC-<br>2015114085 |                      | 59 YR           | Female       | JPN            |
| <u>Preferred Term</u>                                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dementia With Lewy<br>Bodies; Depression; Drug<br>Hypersensitivity;<br>Parkinsonism | Jzoloft        |                    |                    | S               | Oral                         | 25 Mg, Daily         |                 | Pfizer       |                |
|                                                                                     | Risperidone    |                    |                    | S               |                              | 1 Mg, Daily          |                 | Not Reported |                |
|                                                                                     | Risperidone    |                    |                    | S               |                              | 2 Mg, Daily          |                 | Not Reported |                |
|                                                                                     | Flunitrazepam  |                    |                    | S               |                              | 1 Mg, Daily          |                 | Not Reported |                |
|                                                                                     | Escitalopram   |                    |                    | S               |                              | 10 Mg, Daily         |                 | Not Reported |                |
|                                                                                     | Mirtazapine    |                    |                    | S               |                              | 15 Mg, Daily         |                 | Not Reported |                |
|                                                                                     | Olanzapine     |                    |                    | S               |                              | 5 Mg, Daily          |                 | Not Reported |                |
|                                                                                     | Olanzapine     |                    |                    | S               |                              | 10 Mg, Daily         |                 | Not Reported |                |
|                                                                                     | Aripiprazole   |                    |                    | S               |                              | 6 Mg, Daily          |                 | Not Reported |                |

| <u>FDA Received Date</u>                      | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------|--------------------------------|--------------------|--------------------|-----------------|------------------------------------------|----------------------|-----------------|--------------|----------------|
| 06-Apr-2015                                   | 10991704                       | EXPEDITED (15-DAY) |                    | HO              | PHHY2015CA037404                         |                      | 31 YR           | Female       | CAN            |
| <u>Preferred Term</u>                         | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bradycardia; Neutropenia;<br>Pleural Effusion | Piperacillin+Tazobactam Sandoz |                    |                    | S               | Unknown                                  |                      |                 | Novartis     |                |
|                                               | Ciprofloxacin                  |                    |                    | S               | Oral                                     | 1000 Mg, Unk         |                 | Not Reported |                |
|                                               | Ciprofloxacin                  |                    |                    | S               | Intravenous (not<br>otherwise specified) |                      |                 | Not Reported |                |
|                                               | Morphine                       |                    |                    | S               | Unknown                                  | 2.5 Mg, Q4h          |                 | Not Reported |                |
|                                               | Avastin                        |                    |                    | S               | Intravenous (not<br>otherwise specified) | 15 Mg/Kg, Unk        |                 | Not Reported |                |
|                                               | Trastuzumab                    |                    |                    | S               | Intravenous (not<br>otherwise specified) | 8 Mg/Kg, Unk         |                 | Not Reported |                |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                    |   |                                                     |              |
|--------------------|---|-----------------------------------------------------|--------------|
| Tylenol No.1 Forte | S | Unknown                                             | Not Reported |
| Tylenol            | S | Unknown                                             | Not Reported |
| Carboplatin        | S | Intravenous (not otherwise specified)               | Not Reported |
| Cipralex           | S | Unknown 10 Mg, Qd                                   | Not Reported |
| Docetaxel          | S | Intravenous (not otherwise specified) 75 Mg/M2, Unk | Not Reported |
| Docetaxel          | S | Intravenous (not otherwise specified) 75 Mg/M2, Unk | Not Reported |
| Docusate           | C | Unknown                                             | Not Reported |
| Gravol             | C | Unknown                                             | Not Reported |
| Lactulose          | C | Unknown                                             | Not Reported |
| Codeine            | C | Unknown                                             | Not Reported |
| Senna              | C | Unknown                                             | Not Reported |
| Trazodone          | C | Unknown                                             | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Apr-2015              | 10994222      | DIRECT           | Y                  | OT              |                      |                      | 49 YR      | Female     | USA            |

| <u>Preferred Term</u>                                               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Decreased Activity; Depression; Product Substitution Issue | Escitalopram   |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Apr-2015              | 10994825      | DIRECT           |                    | OT              |                      |                      | 62 YR      | Female     | USA            |

| <u>Preferred Term</u>        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------|----------------|--------------|------------|-------------|--------------|------------------------|-----------------|--------------|
| Headache; Serotonin Syndrome | Lexapro        |              |            | S           | Oral         | 1 Pill, Taken By Mouth | 8 YR            | Not Reported |
|                              | Clonazepam     |              |            | C           |              |                        |                 | Not Reported |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 06-Apr-2015              | 10997629             | EXPEDITED (15-DAY) | Y                  | HO              | US-TORRENT-00000918  |                      |                 | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Panic Attack             | Escitalopram Tablets |                    |                    | S               |                      |                      | 2 WEEK          | Not Reported |                |

| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
|----------------------------|----------------------|--------------------|--------------------|-----------------|---------------------------------------------|----------------------|-----------------|------------------|----------------|
| 07-Apr-2015                | 10050122             | EXPEDITED (15-DAY) |                    | HO, OT          | DK-ELI_LILLY_AND_COMP<br>ANY-DK201403008928 |                      | 54 YR           | Male             | DNK            |
| <u>Preferred Term</u>      | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |
| Anxiety; Coma Hepatic;     | Cymbalta             |                    |                    | S               | Oral                                        | 120 Mg, Unknown      |                 | Eli Lilly And Co |                |
| Depressed Level Of         | Modiodal             |                    |                    | S               | Oral                                        | 200 Mg, Qd           |                 | Not Reported     |                |
| Consciousness; Drug        | Modiodal             |                    |                    | S               | Oral                                        | 400 Mg, Qd           |                 | Not Reported     |                |
| Interaction; Fatigue;      | Ciprallex /01588502/ |                    |                    | S               | Oral                                        | 20 Mg, Unknown       |                 | Not Reported     |                |
| Hepatic Cirrhosis; Hepatic | Ciprallex /01588502/ |                    |                    | S               | Oral                                        | 30 Mg, Unknown       |                 | Not Reported     |                |
| Encephalopathy; Hepatic    | Ciprallex /01588502/ |                    |                    | S               | Oral                                        | 120 Mg, Unknown      |                 | Not Reported     |                |
| Failure; Hypoaesthesia;    | Alopan               |                    |                    | C               | Oral                                        | Unk Unk, Prn         |                 | Not Reported     |                |
| Hypokinesia; Incoherent;   |                      |                    |                    |                 |                                             |                      |                 |                  |                |
| Lethargy; Motor            |                      |                    |                    |                 |                                             |                      |                 |                  |                |
| Dysfunction; Muscle        |                      |                    |                    |                 |                                             |                      |                 |                  |                |
| Contractions Involuntary;  |                      |                    |                    |                 |                                             |                      |                 |                  |                |
| Muscle Spasms; Muscle      |                      |                    |                    |                 |                                             |                      |                 |                  |                |
| Tightness; Muscle          |                      |                    |                    |                 |                                             |                      |                 |                  |                |
| Twitching; Musculoskeletal |                      |                    |                    |                 |                                             |                      |                 |                  |                |
| Stiffness; Myalgia;        |                      |                    |                    |                 |                                             |                      |                 |                  |                |
| Serotonin Syndrome;        |                      |                    |                    |                 |                                             |                      |                 |                  |                |
| Tremor                     |                      |                    |                    |                 |                                             |                      |                 |                  |                |

| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 07-Apr-2015               | 10732731       | EXPEDITED (15-DAY) |                    | OT              | CZ-FRI-1000073718    |                      | 4 DAY           | Unknown      | CZE            |
| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Exposure Via Breast Milk; | Escitalopram   |                    |                    | S               | Transmammary         |                      |                 | Forest       |                |
| Neonatal Seizure          | Fluvoxamin     |                    |                    | S               | Transmammary         |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

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| <u>FDA Received Date</u>                                  | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                       | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|--------------------------------------------|------------------------------------|-----------------|--------------|----------------|
| 07-Apr-2015                                               | 10732733                | EXPEDITED (15-DAY) |                    | OT              | CZ-FRI-1000073720                          |                                    | 4 DAY           | Unknown      | CZE            |
| <u>Preferred Term</u>                                     | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                               | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Maternal Exposure During Breast Feeding; Neonatal Seizure | Escitalopram            |                    |                    | S               | Transmammary                               |                                    |                 | Forest       |                |
|                                                           | Fluvoxamin              |                    |                    | S               | Transmammary                               |                                    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                  | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                       | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Apr-2015                                               | 10953873                | EXPEDITED (15-DAY) |                    | OT              | CH-TEVA-549212ISR                          |                                    | 42 YR           | Female       | CHE            |
| <u>Preferred Term</u>                                     | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                               | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypothyroidism; Serum Ferritin Decreased                  | Escitalopram Mepha 5 Mg |                    |                    | S               | Oral                                       | Continuing, 1 Tablet Every 2 Days  |                 | Ivax         |                |
|                                                           | Tecfidera               |                    |                    | S               | Oral                                       | 480 Milligram Daily; Continuing    |                 | Not Reported |                |
|                                                           | Lamictal                |                    |                    | S               | Oral                                       |                                    |                 | Not Reported |                |
|                                                           | Lamictal                |                    |                    | S               | Oral                                       | 350 Milligram Daily; 150mg-0-200mg |                 | Not Reported |                |
| <u>FDA Received Date</u>                                  | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                       | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Apr-2015                                               | 10993184                | NON-EXPEDITED      |                    |                 | IN-LUPIN PHARMACEUTICALS INC.-E2B_00003193 |                                    | 24 YR           | Male         | IND            |
| <u>Preferred Term</u>                                     | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                               | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Rash; Toxicity To Various Agents        | Stalopam                |                    |                    | S               | Oral                                       |                                    |                 | Not Reported |                |
|                                                           | Lithium                 |                    |                    | S               | Oral                                       |                                    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                  | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                       | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Apr-2015                                               | 10995746                | EXPEDITED (15-DAY) |                    | OT              | GB-FRI-1000075626                          |                                    | 20 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                     | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                               | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                                      |              |   |      |       |  |        |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|---|------|-------|--|--------|
| Abnormal Dreams;<br>Abnormal Dreams;<br>Anorgasmia; Anxiety;<br>Confusional State;<br>Derealisation;<br>Dissociation; Flatulence;<br>Genital Hypoaesthesia;<br>Menorrhagia; Nausea;<br>Paraesthesia;<br>Restlessness | Escitalopram | S | Oral | 20 Mg |  | Forest |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|---|------|-------|--|--------|

| <u>FDA Received Date</u> | <u>Case #</u>    | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|------------------|------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 07-Apr-2015              | 10995748         | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2015119331 |                      |                 | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>   | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity    | Tetracycline Hcl |                  |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                          | Lexapro          |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                          | Bleph-10         |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|-----------------------|--------------------|--------------------|-----------------|---------------------------|-----------------------|-----------------|--------------|----------------|
| 07-Apr-2015              | 10996178              | EXPEDITED (15-DAY) |                    | HO, OT          | CH-MYLANLABS-2015M1011175 |                       |                 | Unknown      | CHE            |
| <u>Preferred Term</u>    | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Abuse; Mania        | Tramadol              |                    |                    | S               | Unknown                   |                       |                 | Mylan        |                |
|                          | Escitalopram          |                    |                    | S               | Unknown                   | 20/Mg/Day             |                 | Mylan        |                |
|                          | Triamcinolone         |                    |                    | S               | Intramuscular             | 40 Mg One Month Apart |                 | Not Reported |                |
|                          | Quetiapine            |                    |                    | C               | Unknown                   | 300 Mg/Day            |                 | Not Reported |                |
|                          | Oxazepam              |                    |                    | C               | Unknown                   | 60 Mg/Day             |                 | Not Reported |                |
|                          | Alprazolam            |                    |                    | C               | Unknown                   | 2 Mg/Day              |                 | Not Reported |                |
|                          | Zolpidem              |                    |                    | C               | Unknown                   | 12.5 Mg/Day           |                 | Not Reported |                |
|                          | Baclofen              |                    |                    | C               | Unknown                   | 150 Mg/Day            |                 | Not Reported |                |
|                          | Candesartan Cilexetil |                    |                    | C               | Unknown                   | 8 Mg/Day              |                 | Not Reported |                |
|                          | Metformin             |                    |                    | C               | Unknown                   | 500 Mg/Day            |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                   |   |         |             |              |
|-------------------|---|---------|-------------|--------------|
| Atorvastatin      | C | Unknown | 20 Mg/Day   | Not Reported |
| Alfuzosin         | C | Unknown | 10 Mg/Day   | Not Reported |
| Trospium Chloride | C | Unknown | 20 Mg/Day   | Not Reported |
| Ibuprofen         | C | Unknown | 1800 Mg/Day | Not Reported |
| Paracetamol       | C | Unknown | 4 Gm/Day    | Not Reported |

| <u>FDA Received Date</u>                                                                               | <u>Case #</u>               | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------|-----------------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 07-Apr-2015                                                                                            | 10998089                    | DIRECT           |                    | OT              |                      |                      | 34 YR           | Female     | USA            |
| <u>Preferred Term</u>                                                                                  | <u>Product</u>              | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Anxiety; Drug Ineffective;<br>Mental Disorder; Product<br>Quality Issue; Product<br>Substitution Issue | Escitalopram 10mg Walgreens |                  |                    | S               | Oral                 |                      |                 | Walgreen   |                |

| <u>FDA Received Date</u>                                                | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|-----------------|--------------|----------------|
| 08-Apr-2015                                                             | 10999059       | EXPEDITED (15-DAY) |                    | HO              | CH-FRI-1000075675               |                      | 78 YR           | Male         | CHE            |
| <u>Preferred Term</u>                                                   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cholestasis; Pruritus;<br>Rash Erythematous;<br>Transaminases Increased | Escitalopram   |                    |                    | S               | Oral                            | 20 Mg                |                 | Forest       |                |
|                                                                         | Irifen Lactab  |                    |                    | S               | Oral                            | 800 Mg               |                 | Not Reported |                |
|                                                                         | Dafalgan       |                    |                    | C               | Occlusive dressing<br>technique | 3000 Mg              |                 | Not Reported |                |
|                                                                         | Anxiolit       |                    |                    | C               | Oral                            | 7.5 Mg               |                 | Not Reported |                |
|                                                                         | Clexane        |                    |                    | C               | Subcutaneous                    | 40 Mg                |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|--------------------------|-------------------------|--------------------|--------------------|-----------------|--------------------------------------------------------|----------------------|-----------------|----------------------|----------------|
| 08-Apr-2015              | 11002052                | EXPEDITED (15-DAY) |                    | OT              | CH-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>BMS-2015-022277 |                      | 58 YR           | Male                 | CHE            |
| <u>Preferred Term</u>    | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Mania                    | Triamcinolone Acetonide |                    |                    | S               | Intramuscular                                          | 40 Mg, Qmo           |                 | Bristol Myers Squibb |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                         |   |         |             |  |                      |
|-------------------------|---|---------|-------------|--|----------------------|
| Triamcinolone Acetonide | S |         |             |  | Bristol Myers Squibb |
| Tramadol                | S | Unknown | 50 Mg, Bid  |  | Not Reported         |
| Escitalopram            | S | Unknown | 20 Mg, Qd   |  | Not Reported         |
| Paracetamol             | C | Unknown | 4 G, Qd     |  | Bristol Myers Squibb |
| Paracetamol             | C |         |             |  | Bristol Myers Squibb |
| Ibuprofen               | C | Unknown | 1800 Mg, Qd |  | Not Reported         |
| Ibuprofen               | C |         |             |  | Not Reported         |
| Quetiapine              | C | Unknown | 300 Mg, Qd  |  | Not Reported         |
| Oxazepam                | C | Unknown | 60 Mg, Qd   |  | Not Reported         |
| Alprazolam              | C | Unknown | 2 Mg, Qd    |  | Not Reported         |
| Zolpidem                | C | Unknown | 12.5 Mg, Qd |  | Not Reported         |
| Baclofen                | C | Unknown | 150 Mg, Qd  |  | Not Reported         |
| Candesartan             | C | Unknown | 8 Mg, Qd    |  | Not Reported         |
| Metformin               | C | Unknown | 500 Mg, Qd  |  | Not Reported         |
| Atorvastatin            | C | Unknown | 20 Mg, Qd   |  | Not Reported         |
| Alfuzosin               | C | Unknown | 10 Mg, Qd   |  | Not Reported         |
| Trospium                | C | Unknown | 20 Mg, Qd   |  | Not Reported         |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Apr-2015              | 11003289      | DIRECT           |                    | DE              |                      |                      | 27 YR      | Male       | USA            |

| <u>Preferred Term</u>                      | <u>Product</u>  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                              | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------|-----------------|--------------|------------|-------------|--------------|-------------------------------------------------|-----------------|--------------|
| Fall; Headache;<br>Hyperhidrosis; Insomnia | Escitalopram    |              |            | S           | Oral         | 1 1/2 To 2 Years, Once<br>Daily, Taken By Mouth | 2 YR            | Cvs Caremark |
|                                            | Synthroid       |              |            | C           |              |                                                 |                 | Not Reported |
|                                            | Multi Vitamins  |              |            | C           |              |                                                 |                 | Not Reported |
|                                            | Herbal Remedies |              |            | C           |              |                                                 |                 | Not Reported |
|                                            | Lexapro         |              |            | S           |              |                                                 |                 | Not Reported |
|                                            | Citalopram      |              |            | S           |              |                                                 |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Apr-2015              | 10870056      | EXPEDITED (15-DAY) | Y                  | OT              | ADR-2015-00365       |                      | 61 YR      | Male       | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                  | <u>Product</u>                                                | <u>Comp.</u>                  | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------|-------------------------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Condition Aggravated;<br>Diastolic Dysfunction;<br>Dyspnoea; Mitral Valve<br>Stenosis; Supraventricular<br>Tachycardia | Baclofen                                                      |                               |            | S           | Intrathecal  |                    |                 | Not Reported |
|                                                                                                                        |                                                               |                               |            |             | Intrathecal  |                    |                 |              |
|                                                                                                                        |                                                               |                               |            |             | Intrathecal  |                    |                 |              |
|                                                                                                                        |                                                               |                               |            |             | Intrathecal  |                    |                 |              |
|                                                                                                                        |                                                               |                               |            |             | Intrathecal  |                    |                 |              |
|                                                                                                                        |                                                               |                               |            |             | Intrathecal  |                    |                 |              |
|                                                                                                                        |                                                               |                               |            |             | Intrathecal  |                    |                 |              |
|                                                                                                                        |                                                               |                               |            |             | Intrathecal  |                    |                 |              |
|                                                                                                                        |                                                               |                               |            |             | Intrathecal  |                    |                 |              |
|                                                                                                                        |                                                               |                               |            |             | Intrathecal  |                    |                 |              |
|                                                                                                                        |                                                               |                               |            |             | Intrathecal  |                    |                 |              |
|                                                                                                                        |                                                               |                               |            |             | Intrathecal  |                    |                 |              |
|                                                                                                                        |                                                               |                               |            |             | Intrathecal  |                    |                 |              |
|                                                                                                                        |                                                               |                               |            |             | Intrathecal  |                    |                 |              |
|                                                                                                                        |                                                               |                               |            |             | Intrathecal  |                    |                 |              |
|                                                                                                                        |                                                               |                               |            |             | Intrathecal  |                    |                 |              |
|                                                                                                                        |                                                               |                               |            |             | Intrathecal  |                    |                 |              |
|                                                                                                                        |                                                               |                               |            |             | Intrathecal  |                    |                 |              |
|                                                                                                                        |                                                               |                               |            |             | Intrathecal  |                    |                 |              |
|                                                                                                                        |                                                               |                               |            |             | Intrathecal  |                    |                 |              |
|                                                                                                                        |                                                               |                               |            |             | Intrathecal  |                    |                 |              |
|                                                                                                                        |                                                               |                               |            |             | Intrathecal  |                    |                 |              |
|                                                                                                                        |                                                               |                               |            |             | Intrathecal  |                    |                 |              |
|                                                                                                                        |                                                               |                               |            |             | Intrathecal  |                    |                 |              |
|                                                                                                                        |                                                               |                               |            |             | Intrathecal  |                    |                 |              |
|                                                                                                                        |                                                               | Norvasc (Amlodipine Besilate) |            |             | S            |                    |                 |              |
|                                                                                                                        | Actos (Pioglitazone Hydrochloride)                            |                               |            | S           |              |                    |                 | Not Reported |
|                                                                                                                        | Escitalopram Oxalate                                          |                               |            | S           |              |                    |                 | Not Reported |
|                                                                                                                        | Diovan (Valsartan)                                            |                               |            | S           |              |                    |                 | Not Reported |
|                                                                                                                        | Senna S                                                       |                               |            | S           |              |                    |                 | Not Reported |
|                                                                                                                        | Centrum Silver                                                | Y                             |            | S           |              |                    |                 | Not Reported |
|                                                                                                                        | Crestor (Rosuvastatin Calcium)                                |                               |            | S           |              |                    |                 | Not Reported |
|                                                                                                                        | Metformin Hydrochloride                                       |                               |            | S           |              |                    |                 | Not Reported |
|                                                                                                                        | Aggrenox                                                      |                               |            | S           |              |                    |                 | Not Reported |
|                                                                                                                        | Foltx                                                         |                               |            | S           |              |                    |                 | Not Reported |
|                                                                                                                        | Folbee (Cyanocobalamin, Folic Acid, Pyridoxine Hydrochloride) |                               |            | S           |              |                    |                 | Not Reported |
|                                                                                                                        | Fish Oil                                                      |                               |            | S           |              |                    |                 | Not Reported |
|                                                                                                                        | Metoprolol Succinate                                          |                               |            | S           |              |                    |                 | Not Reported |
|                                                                                                                        | Acetylsalicylic Acid (Acetylsalicylic Acid)                   |                               |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Apr-2015              | 11009463      | EXPEDITED (15-DAY) |                    | HO              | FR-SA-2015SA042798   |                      | 89 YR      | Female     | FRA            |

| <u>Preferred Term</u>            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Fall; Orthostatic<br>Hypotension | Lasilix        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                  | Bisoce         |              |            | S           | Unknown      |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                        |   |                   |              |
|------------------------|---|-------------------|--------------|
| Epinitril              | S | Transdermal       | Not Reported |
| Seroplex               | S | Unknown           | Not Reported |
| Levothyrox             | C | Strength: 100mcg  | Not Reported |
| Hemigoxine Nativelle   | C | Strength: 0.125mg | Not Reported |
| Inexium                | C |                   | Not Reported |
| Previscan (Fluindione) | C | Strength: 20mg    | Not Reported |
| Valsartan              | C |                   | Not Reported |
| Temesta (Lorazepam)    | C |                   | Not Reported |
| Atorvastatin           | C |                   | Not Reported |
| Digoxine Nativelle     | C | Strength: 0.25 Mg | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 10-Apr-2015              | 11010748      | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2015124654 |                      | 38 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Hypersensitivity | Effexor Xr     |              |            | S           |              | Unk                |                 | Pfizer       |
|                       | Celexa         |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Lexapro        |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Wellbutrin     |              |            | S           |              | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Apr-2015              | 11011085      | EXPEDITED (15-DAY) |                    | HO              | FR-SA-2015SA045137   |                      | 59 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hyponatraemia         | Stilnox        |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Seroplex       |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Seresta        |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 10-Apr-2015              | 11011578      | EXPEDITED (15-DAY) |                    | HO              | IT-ASTRAZENECA-2015SE32689 |                      | 40 YR      | Female     | ITA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                          |           |   |      |              |
|------------------------------------------|-----------|---|------|--------------|
| Mania; Paralysis;<br>Withdrawal Syndrome | Seroquel  | S | Oral | Astrazeneca  |
|                                          | Seroquel  | S | Oral | Astrazeneca  |
|                                          | Seroquel  | S | Oral | Astrazeneca  |
|                                          | Ciprallex | S | Oral | Not Reported |
|                                          | Ciprallex | S | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Apr-2015              | 10791811      | EXPEDITED (15-DAY) |                    | OT              | FR-ROCHE-1533897     |                      | 83 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cholestasis; Drug<br>Interaction; Eosinophilia;<br>Hepatocellular Injury;<br>Hyponatraemia | Erivedge       |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                            | Seroplex       |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Apr-2015              | 10995745      | EXPEDITED (15-DAY) |                    | HO              | NL-FRI-1000075633    |                      | 50 YR      | Male       | NLD            |

| <u>Preferred Term</u>                                                                                                                                                          | <u>Product</u>             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiac Disorder; Chest<br>Pain; Chills; Dry Mouth;<br>Hypertension; Malaise;<br>Memory Impairment;<br>Palpitations; Rash;<br>Restlessness; Therapeutic<br>Response Unexpected | Escitalopram Oral Solution |              |            | S           | Oral         |                    |                 | Forest       |
|                                                                                                                                                                                | Lexapro                    |              |            | S           | Oral         | 15 Mg              |                 | Forest       |
|                                                                                                                                                                                | Lexapro                    |              |            | S           | Unknown      |                    |                 | Forest       |
|                                                                                                                                                                                | Escitalopram               |              |            | S           | Oral         | 15 Mg              |                 | Forest       |
|                                                                                                                                                                                | Seroplex                   |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                                                | Diazepam                   |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                                                                | Omeprazol                  |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                                                                | Diclofenac                 |              |            | C           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Apr-2015              | 11021097      | EXPEDITED (15-DAY) |                    | HO              | CH-TEVA-554600ISR    |                      | 58 YR      | Male       | CHE            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|



## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                   |                       |   |               |                       |              |
|-------------------|-----------------------|---|---------------|-----------------------|--------------|
| Drug Abuse; Mania | Escitalopram          | S | Unknown       |                       | Ivax         |
|                   | Tramadol              | S | Unknown       | 100 Milligram Daily;  | Teva         |
|                   | Triamcinolone         | S | Intramuscular | 40 Mg One Month Apart | Not Reported |
|                   | Quetiapine            | C | Unknown       | 300 Milligram Daily;  | Not Reported |
|                   | Oxazepam              | C | Unknown       | 60 Milligram Daily;   | Not Reported |
|                   | Alprazolam            | C | Unknown       | 2 Milligram Daily;    | Not Reported |
|                   | Zolpidem              | C | Unknown       | 12.5 Milligram Daily; | Not Reported |
|                   | Baclofen              | C | Unknown       | 150 Milligram Daily;  | Not Reported |
|                   | Candesartan Cilexetil | C | Unknown       | 8 Milligram Daily;    | Not Reported |
|                   | Metformin             | C | Unknown       |                       | Not Reported |
|                   | Atorvastatin          | C | Unknown       | 20 Milligram Daily;   | Not Reported |
|                   | Alfuzosin             | C | Unknown       | 10 Milligram Daily;   | Not Reported |
|                   | Trospium Chloride     | C | Unknown       | 20 Milligram Daily;   | Not Reported |
|                   | Ibuprofen             | C | Unknown       | 1800 Milligram Daily; | Not Reported |
|                   | Paracetamol           | C | Unknown       | 4 Milligram Daily;    | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Apr-2015              | 11024103      | EXPEDITED (15-DAY) |                    | HO              | BE-FRI-1000075831    |                      |            | Female     | BEL            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                               | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|------------------------------------------------------------------|-----------------|--------------|
| Eye Pain; Face Oedema | Escitalopram   |              |            | S           | Oral         |                                                                  |                 | Forest       |
|                       | Zaldiar        |              |            | C           | Unknown      | Zaldiar/Tramadol,<br>Thydrochloride 37,5mg,<br>Paracetamol 325mg |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Apr-2015              | 11025729      | DIRECT           |                    | HO              |                      |                      | 89 YR      | Female     | USA            |

| <u>Preferred Term</u>             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Fall; Gait Disturbance;<br>Tremor | Lexapro        |              |            | S           | Oral         |                    |                 | Mylan      |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                |   |              |
|----------------|---|--------------|
| Wellbutrin     | C | Not Reported |
| Pravastatin    | C | Not Reported |
| Tyenol         | C | Not Reported |
| Calcium        | C | Not Reported |
| B-12           | C | Not Reported |
| Magnesium      | C | Not Reported |
| D3             | C | Not Reported |
| Centrum Silver | C | Not Reported |
| Aspirin        | C | Not Reported |
| Lorazepam      | C | Not Reported |
| Ambien         | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Apr-2015              | 11026348      | DIRECT           |                    | OT              |                      |                      | 43 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                 | <u>Product</u>                                                       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>           | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                                                                   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------|--------------|------------|-----------------------|--------------|--------------------|-----------------|------------------------------------------------------------------------------|
| Agitation; Cardiac Flutter;<br>Chest Discomfort; Dry<br>Mouth; Fatigue; Feeling<br>Abnormal; Feeling<br>Abnormal; Heart Rate<br>Increased; Hyperhidrosis;<br>Mydriasis; Nausea; Ocular<br>Hyperaemia; Palpitations;<br>Vision Blurred | Lexapro<br>Flonase<br>Retina A (Topical)<br>Omega 3'S<br>Vitamin B,D |              |            | S<br>C<br>C<br>C<br>C | Oral         | 1 Pill             |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 14-Apr-2015              | 11024502      | EXPEDITED (15-DAY) |                    | OT              | CH-JNJFOC-20131210845 |                      | 55 YR      | Male       | CHE            |

| <u>Preferred Term</u>                  | <u>Product</u>                                                                         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>                | <u>Route</u>                                                   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                                                                                   |
|----------------------------------------|----------------------------------------------------------------------------------------|--------------|------------|----------------------------|----------------------------------------------------------------|--------------------|-----------------|----------------------------------------------------------------------------------------------|
| Hypomagnesaemia;<br>Torsade De Pointes | Ibuprofen<br>Acetaminophen<br>Acetaminophen<br>Methadone<br>Escitalopram<br>Olanzapine |              | Y          | S<br>S<br>S<br>S<br>S<br>S | Unknown<br>Unknown<br>Unknown<br>Unknown<br>Unknown<br>Unknown |                    |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                      | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>             | <u>Country</u> |
|-----------------------------------------------------------------------------------------------|-----------------------------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|------------------------|----------------|
| 14-Apr-2015                                                                                   | 11025956                          | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000075833          |                      | 78 YR           | Male                   | FRA            |
| <u>Preferred Term</u>                                                                         | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>             |                |
| Cerebral Haemorrhage;<br>Hemianopia                                                           | Escitalopram                      |                    |                    | S               | Oral                       | 5 Mg                 |                 | Forest                 |                |
| Homonymous; Neurologic<br>Neglect Syndrome                                                    | Aspegic [Acetylsalicylate Lysine] |                    |                    | S               | Oral                       | 1 Df                 |                 | Not Reported           |                |
| <u>FDA Received Date</u>                                                                      | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>             | <u>Country</u> |
| 14-Apr-2015                                                                                   | 11026002                          | EXPEDITED (15-DAY) |                    | OT              | BE-FRI-1000075852          |                      |                 | Female                 | BEL            |
| <u>Preferred Term</u>                                                                         | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>             |                |
| Incision Site<br>Haemorrhage; Post<br>Procedural Haemorrhage                                  | Escitalopram<br>Nsaids            |                    |                    | S<br>C          |                            |                      |                 | Forest<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                      | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>             | <u>Country</u> |
| 14-Apr-2015                                                                                   | 11026383                          | EXPEDITED (15-DAY) |                    | HO, LT, OT      | FR-APOTEX-<br>2015AP008206 |                      | 86 YR           | Female                 | FRA            |
| <u>Preferred Term</u>                                                                         | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>             |                |
| Coma; Confusional State;<br>Hyponatraemia;<br>Inappropriate Antidiuretic<br>Hormone Secretion | Paxil Tablets                     |                    |                    | S               | Unknown                    | 20 Mg, Daily         |                 | Apotex                 |                |
|                                                                                               | Seroplex                          |                    |                    | S               | Oral                       | 10 Mg, Daily         |                 | Not Reported           |                |
|                                                                                               | Aldactazine                       |                    |                    | S               | Oral                       | Unk                  |                 | Not Reported           |                |
|                                                                                               | Zopiclone                         |                    |                    | C               | Unknown                    | Unk                  |                 | Not Reported           |                |
|                                                                                               | Cortancyl                         |                    |                    | C               | Unknown                    | Unk                  |                 | Not Reported           |                |
|                                                                                               | Paracetamol+Codein                |                    |                    | C               | Unknown                    |                      |                 | Not Reported           |                |
| <u>FDA Received Date</u>                                                                      | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>             | <u>Country</u> |
| 14-Apr-2015                                                                                   | 11030896                          | DIRECT             | Y                  |                 |                            |                      | 61 YR           | Male                   | USA            |
| <u>Preferred Term</u>                                                                         | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>             |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                   |              |   |      |       |
|---------------------------------------------------|--------------|---|------|-------|
| Agitation; Drug Ineffective;<br>Suicidal Ideation | Escitalopram | S | Oral | Mylan |
|---------------------------------------------------|--------------|---|------|-------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Apr-2015              | 11037038      | EXPEDITED (15-DAY) | HO                 |                 | 2816258              |                      | 31 YR      | Female     | CAN            |

| <u>Preferred Term</u>                         | <u>Product</u>                          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                          | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------|-----------------------------------------|--------------|------------|-------------|---------------------------------------|------------------------------------------|-----------------|--------------|
| Bradycardia; Neutropenia;<br>Pleural Effusion | Morphine Sulphate                       |              |            | S           |                                       | 2.5 Mg Milligram(S), 1 Hour              |                 | Not Reported |
|                                               | Carboplatin                             |              |            | S           | Intravenous (not otherwise specified) | 1 Week Intravenous                       |                 | Not Reported |
|                                               | Ciprofloxacin                           |              |            | S           | Intravenous (not otherwise specified) | 1 Week Intravenous                       |                 | Not Reported |
|                                               | Docetaxel                               |              |            | S           | Intravenous (not otherwise specified) |                                          |                 | Not Reported |
|                                               |                                         |              |            |             | Intravenous (not otherwise specified) | 75 Mg/M 2 Milligram(S)/Sq.Meter (1 Week) |                 |              |
|                                               | Avastin /00848101/                      |              |            | S           | Intravenous (not otherwise specified) | 15 Mg/Kg Milligram(S), 1 Week            |                 | Not Reported |
|                                               | Cipralext /01588501/                    |              |            | S           |                                       | 10 Mg Milligram(S), 1 Day                |                 | Not Reported |
|                                               | Ciprofloxacin                           |              |            | S           | Oral                                  |                                          |                 | Not Reported |
|                                               | Piperacillin Sodium W/Tazobactam Sodium |              |            | S           |                                       |                                          |                 | Not Reported |
|                                               | Trastuzumab                             |              |            | S           | Intravenous (not otherwise specified) | 8 Mg/Kg Milligram(S)/Kilogram, 1 Week    |                 | Not Reported |
|                                               | Tylenol /00020001/                      |              |            | S           |                                       |                                          |                 | Not Reported |
|                                               | Tylenol No. 1                           |              |            | S           |                                       |                                          |                 | Not Reported |
|                                               | Codeine                                 |              |            | C           |                                       |                                          |                 | Not Reported |
|                                               | Docusate                                |              |            | C           |                                       |                                          |                 | Not Reported |
|                                               | Gravol                                  |              |            | C           |                                       |                                          |                 | Not Reported |
|                                               | Lactulose                               |              |            | C           |                                       |                                          |                 | Not Reported |
|                                               | Senna                                   |              |            | C           |                                       |                                          |                 | Not Reported |
|                                               | Trazodone                               |              |            | C           |                                       |                                          |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>  | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------|-----------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
| 15-Apr-2015               | 10532723        | EXPEDITED (15-DAY) |                    | HO              | DE-MYLANLABS-2014M1007047 |                      |                 | Unknown      | DEU            |
| <u>Preferred Term</u>     | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Blood Pressure | Lamotrigin Dura |                    |                    | S               | Oral                      | 950 Mg, Total        |                 | Mylan        |                |
| Systolic Decreased;       | Escitalopram    |                    |                    | S               | Oral                      | 500 Mg, Total        |                 | Not Reported |                |
| Bundle Branch Block       | Anafranil       |                    |                    | S               | Oral                      | 7500 Mg, Total       |                 | Not Reported |                |
| Right; Gastrointestinal   |                 |                    |                    |                 |                           |                      |                 |              |                |
| Sounds Abnormal; Renal    |                 |                    |                    |                 |                           |                      |                 |              |                |
| Failure; Rhabdomyolysis;  |                 |                    |                    |                 |                           |                      |                 |              |                |
| Suicidal Behaviour;       |                 |                    |                    |                 |                           |                      |                 |              |                |
| Tachycardia; Vomiting     |                 |                    |                    |                 |                           |                      |                 |              |                |
| <u>FDA Received Date</u>  | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Apr-2015               | 10585403        | EXPEDITED (15-DAY) |                    | OT              | US-FRI-1000072263         |                      | 35 YR           | Male         | USA            |
| <u>Preferred Term</u>     | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Anhedonia;     | Celexa          |                    |                    | S               | Oral                      | 10 Mg                |                 | Forest       |                |
| Anxiety; Apathy; Crying;  | Celexa          |                    |                    | S               |                           |                      |                 | Forest       |                |
| Depressed Mood;           | Lexapro         |                    |                    | S               | Oral                      | 5 Mg                 |                 | Forest       |                |
| Disorientation; Fear;     | Lexapro         |                    |                    | S               | Oral                      | 10 Mg                |                 | Forest       |                |
| Feeding Disorder;         | Ambien          |                    |                    | S               | Oral                      | 10 Mg                |                 | Not Reported |                |
| Feelings Of               | Ambien          |                    |                    | S               |                           |                      |                 | Not Reported |                |
| Worthlessness;            | Zoloft          |                    |                    | S               | Oral                      | 25 Mg                |                 | Not Reported |                |
| Haematemesis;             | Zoloft          |                    |                    | S               |                           |                      |                 | Not Reported |                |
| Headache; Insomnia;       | Zoloft          |                    |                    | S               |                           |                      |                 | Not Reported |                |
| Lethargy; Mania; Mental   | Multivitamin    |                    |                    | C               |                           |                      |                 | Not Reported |                |
| Impairment; Nausea;       |                 |                    |                    |                 |                           |                      |                 | Not Reported |                |
| Palpitations; Paranoia;   |                 |                    |                    |                 |                           |                      |                 | Not Reported |                |
| Suicidal Ideation;        |                 |                    |                    |                 |                           |                      |                 | Not Reported |                |
| Tachyphrenia; Thought     |                 |                    |                    |                 |                           |                      |                 |              |                |
| Blocking; Tremor; Tremor; |                 |                    |                    |                 |                           |                      |                 |              |                |
| Unevaluable Event;        |                 |                    |                    |                 |                           |                      |                 |              |                |
| Vomiting; Weight          |                 |                    |                    |                 |                           |                      |                 |              |                |
| Decreased                 |                 |                    |                    |                 |                           |                      |                 |              |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                      | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
|-----------------------------------------------------------------------------------------------|---------------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|------------------|----------------|
| 15-Apr-2015                                                                                   | 11030874            | EXPEDITED (15-DAY) |                    | HO, LT          | FR-FRI-1000075866                               |                      | 86 YR           | Female           | FRA            |
| <u>Preferred Term</u>                                                                         | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |
| Coma; Confusional State;<br>Hyponatraemia;<br>Inappropriate Antidiuretic<br>Hormone Secretion | Escitalopram        |                    |                    | S               | Oral                                            | 10 Mg                |                 | Forest           |                |
|                                                                                               | Deroxat             |                    |                    | S               |                                                 | 20 Mg                |                 | Not Reported     |                |
|                                                                                               | Aldactazine         |                    |                    | S               | Oral                                            |                      |                 | Not Reported     |                |
|                                                                                               | Zopiclone           |                    |                    | C               | Unknown                                         |                      |                 | Not Reported     |                |
|                                                                                               | Oxazepam            |                    |                    | C               | Unknown                                         |                      |                 | Not Reported     |                |
|                                                                                               | Cortancyl           |                    |                    | C               | Unknown                                         | 4 Mg                 |                 | Not Reported     |                |
|                                                                                               | Paracetamol+Codeine |                    |                    | C               | Unknown                                         |                      |                 | Not Reported     |                |
| <u>FDA Received Date</u>                                                                      | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 16-Apr-2015                                                                                   | 11038442            | EXPEDITED (15-DAY) |                    | HO              | TR-<br>ELI_LILLY_AND_COMP<br>ANY-TR201504004276 |                      | 21 YR           | Male             | TUR            |
| <u>Preferred Term</u>                                                                         | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |
| Delirium; Drug Interaction                                                                    | Olanzapine          |                    |                    | S               |                                                 | 5 Mg, Qd             |                 | Eli Lilly And Co |                |
|                                                                                               | Olanzapine          |                    |                    | S               |                                                 |                      |                 | Eli Lilly And Co |                |
|                                                                                               | Escitalopram        |                    |                    | S               |                                                 | 20 Mg, Qd            |                 | Not Reported     |                |
|                                                                                               | Escitalopram        |                    |                    | S               |                                                 |                      |                 | Not Reported     |                |
|                                                                                               | Cannabis            |                    |                    | S               | Unknown                                         |                      |                 | Not Reported     |                |
| <u>FDA Received Date</u>                                                                      | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 16-Apr-2015                                                                                   | 11038520            | EXPEDITED (15-DAY) |                    | OT              | GXKR2015DE002012                                |                      |                 | Unknown          | DEU            |
| <u>Preferred Term</u>                                                                         | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |
| Abortion Missed                                                                               | Mirtazapine         |                    |                    | S               | Oral                                            | 7.5 Mg, Unk          |                 | Novartis         |                |
|                                                                                               | Cipralext /Den/     |                    |                    | S               | Oral                                            | 10 - 20 Mg, Unk      |                 | Not Reported     |                |

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| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------------------------------------|----------------------|------------|------------|----------------|
| 16-Apr-2015              | 11042456      | EXPEDITED (15-DAY) |                    | HO, OT          | CA-B.I.<br>PHARMACEUTICALS,I<br>NC./RIDGEFIELD-2015-<br>BI-19 |                      | 63 YR      | Female     | CAN            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                            | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------|------------|-------------|-----------------------------|--------------------|-----------------|----------------------|
| Asthenia; Bone Disorder;<br>Chest Discomfort; Cough;<br>Cyanosis; Decreased<br>Appetite; Depression;<br>Diarrhoea; Dizziness;<br>Drug Ineffective;<br>Dyspnoea Exertional;<br>Emphysema; Fall; Fatigue;<br>Headache; Hiatus Hernia;<br>Hypoaesthesia; Insomnia;<br>Malaise; Overdose; Pain;<br>Panic Reaction;<br>Pneumonia; Pruritus;<br>Pulmonary Mass; Tremor | Atrovent               |              |            | S           | Unknown                     |                    |                 | Boehringer Ingelheim |
|                                                                                                                                                                                                                                                                                                                                                                  | Clarithromycin         |              |            | S           | Unknown                     |                    |                 | Not Reported         |
|                                                                                                                                                                                                                                                                                                                                                                  | Escitalopram           |              |            | S           | Unknown                     |                    |                 | Not Reported         |
|                                                                                                                                                                                                                                                                                                                                                                  | Fluticasone Propionate |              |            | S           | Respiratory<br>(inhalation) |                    |                 | Not Reported         |
|                                                                                                                                                                                                                                                                                                                                                                  | Fluticasone Propionate |              |            | S           | Respiratory<br>(inhalation) |                    |                 | Not Reported         |
|                                                                                                                                                                                                                                                                                                                                                                  | Glycopyrronium Bromide |              |            | S           | Unknown                     |                    |                 | Not Reported         |
|                                                                                                                                                                                                                                                                                                                                                                  | Prednisone             |              |            | S           | Unknown                     |                    |                 | Not Reported         |
|                                                                                                                                                                                                                                                                                                                                                                  | Salbutamol Sulfate     |              |            | S           | Unknown                     |                    |                 | Not Reported         |
|                                                                                                                                                                                                                                                                                                                                                                  | Tiotropium             |              |            | S           | Unknown                     |                    |                 | Not Reported         |
|                                                                                                                                                                                                                                                                                                                                                                  | Clonazepam             |              |            | C           | Unknown                     |                    |                 | Not Reported         |
|                                                                                                                                                                                                                                                                                                                                                                  | Meloxicam              |              |            | C           | Unknown                     |                    |                 | Not Reported         |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|------------|------------|----------------|
| 17-Apr-2015              | 10725008      | EXPEDITED (15-DAY) |                    | LT, OT          | SE-009507513-<br>1501SWE005841 |                      | 55 YR      | Female     | SWE            |

| <u>Preferred Term</u>                          | <u>Product</u>                        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------|---------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Suicide Attempt; Toxicity<br>To Various Agents | Mirtazapine                           |              |            | S           | Oral         |                    |                 | Merck        |
|                                                | Atarax (Hydroxyzine<br>Hydrochloride) |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                                                | Citalopram                            |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                | Ciprallex                             |              |            | S           | Oral         |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

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### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Apr-2015              | 11007885      | EXPEDITED (15-DAY) |                    | OT              | CA-FRI-1000075772    |                      | 30 YR      | Female     | CAN            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Abdominal Discomfort;<br>Agitation; Asthenia; Blood<br>Pressure Increased;<br>Headache;<br>Hypoaesthesia;<br>Hypoaesthesia Oral;<br>Insomnia; Loss Of<br>Personal Independence In<br>Daily Activities; Malaise;<br>Palpitations; Paraesthesia;<br>Paraesthesia Oral;<br>Pruritus; Respiratory Rate<br>Increased; Shock<br>Symptom; Tinnitus | Escitalopram   |              |            | S           | Oral         | 5 Mg               |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Apr-2015              | 11044483      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000075965    |                      | 83 YR      | Male       | FRA            |

| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Behaviour Disorder; Fall | Escitalopram   |              |            | S           | Unknown      | 10 Mg              |                 | Forest       |
|                          | Ditropan       |              |            | S           | Unknown      | 7.5 Mg             |                 | Not Reported |
|                          | Tiapridal      |              |            | S           | Oral         | 40 Gtt             |                 | Not Reported |
|                          | Alprazolam     |              |            | S           | Unknown      | 0.75 Mg            |                 | Not Reported |
|                          | Bisoce         |              |            | C           | Unknown      | 10 Mg              |                 | Not Reported |
|                          | Tamsulosine Lp |              |            | C           | Unknown      | 0.4 Mg             |                 | Not Reported |
|                          | Seresta        |              |            | C           | Unknown      | 10 Mg              |                 | Not Reported |
|                          | Galantamine Lp |              |            | C           | Unknown      | 8 Mg               |                 | Not Reported |
|                          | Kardegic       |              |            | C           | Unknown      | 75 Mg              |                 | Not Reported |
|                          | Levothyrox     |              |            | C           | Unknown      | 12.5 Mcg           |                 | Not Reported |



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|                                                                                                                                                                                                          | Movicol        |                    | C                  | Unknown         | 1 Df                          |                      |                 | Not Reported |                |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|-----------------|--------------|----------------|
|                                                                                                                                                                                                          | Zopiclone      |                    | C                  | Unknown         | 3.75 Mg                       |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Apr-2015                                                                                                                                                                                              | 11045889       | EXPEDITED (15-DAY) |                    | HO              | PHHY2015TR045315              |                      | 21 YR           | Male         | TUR            |
| <u>Preferred Term</u>                                                                                                                                                                                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Behaviour;<br>Agitation; Altered State Of<br>Consciousness; Amnesia;<br>Delirium; Drug Interaction;<br>Hyperaesthesia;<br>Somnolence; Toxicity To<br>Various Agents;<br>Unresponsive To Stimuli | Escitalopram   |                    |                    | S               | Unknown                       | 20 Mg, Qd            |                 | Not Reported |                |
|                                                                                                                                                                                                          | Escitalopram   |                    |                    | S               |                               |                      |                 | Not Reported |                |
|                                                                                                                                                                                                          | Olanzapine     |                    |                    | S               | Unknown                       | 5 Mg, Qd             |                 | Novartis     |                |
|                                                                                                                                                                                                          | Olanzapine     |                    |                    | S               |                               |                      |                 | Novartis     |                |
|                                                                                                                                                                                                          | Cannabis       |                    |                    | S               | Unknown                       |                      |                 | Not Reported |                |
|                                                                                                                                                                                                          | Cannabis       |                    |                    | S               |                               |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Apr-2015                                                                                                                                                                                              | 11047106       | EXPEDITED (15-DAY) |                    | OT              | IN-CIPLA LTD.-<br>2015IN02951 |                      |                 | Unknown      | IND            |
| <u>Preferred Term</u>                                                                                                                                                                                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated;<br>Drug Ineffective; Psychotic<br>Disorder                                                                                                                                         | Sertraline     |                    |                    | S               |                               | Unk                  |                 | Cipla        |                |
|                                                                                                                                                                                                          | Escitalopram   |                    |                    | S               |                               |                      |                 | Not Reported |                |
|                                                                                                                                                                                                          | Fluoxetine     |                    |                    | S               |                               | Unk                  |                 | Not Reported |                |
|                                                                                                                                                                                                          | Fluvoxamine    |                    |                    | S               |                               |                      |                 | Not Reported |                |
|                                                                                                                                                                                                          | Clomipramine   |                    |                    | S               |                               |                      |                 | Not Reported |                |
|                                                                                                                                                                                                          | Paroxetine     |                    |                    | S               |                               |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Apr-2015                                                                                                                                                                                              | 11048656       | EXPEDITED (15-DAY) |                    | OT              | AU-CIPLA LTD.-<br>2015AU02934 |                      |                 | Unknown      | AUS            |
| <u>Preferred Term</u>                                                                                                                                                                                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hallucination, Tactile;<br>Hypomania                                                                                                                                                                     | Lamotrigine    |                    |                    | S               | Unknown                       | 100 Mg, Bid          |                 | Cipla        |                |
|                                                                                                                                                                                                          | Lamotrigine    |                    |                    | S               | Unknown                       | 50 Mg, Bid           |                 | Cipla        |                |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                  |   |         |                             |              |
|------------------|---|---------|-----------------------------|--------------|
| Lamotrigine      | S | Unknown | 25 Mg, Qd On Alternate Days | Cipla        |
| Lamotrigine      | S | Unknown | 50 Mg, Bid                  | Cipla        |
| Sertraline       | S | Unknown |                             | Cipla        |
| Citalopram       | S | Unknown |                             | Cipla        |
| Escitalopram     | S |         | 20 Mg, Qd                   | Not Reported |
| Paroxetine       | S | Unknown |                             | Not Reported |
| Sodium Valproate | S | Unknown | 400 Mg, Bid                 | Not Reported |
| Sodium Valproate | S | Unknown | 500 Mg, Qd                  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Apr-2015              | 11048913      | EXPEDITED (15-DAY) |                    | HO, OT          | PHHY2015US045760     |                      | 48 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Catatonia; Corneal Reflex Decreased; Embolic Stroke; Mental Disorder; Muscle Rigidity; Negativism; Pyrexia; Seizure; Verbigeration | Clozapin Hexal |              |            | S           | Unknown      | Unk                |                 | Novartis     |
|                                                                                                                                    | Clozapin Hexal |              |            | S           |              |                    |                 | Novartis     |
|                                                                                                                                    | Escitalopram   |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                    | Escitalopram   |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                    | Quetiapine     |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                    | Quetiapine     |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Apr-2015              | 11050707      | DIRECT           |                    |                 |                      |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                                                     | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------|-------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Accidental Overdose; Dizziness; International Normalised Ratio Increased; Malaise; Tremor | Coumadin Warfarin |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                           | Lexapro Lexapro   |              |            | S           | Oral         |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Apr-2015              | 11051597      | DIRECT           |                    | DS, LT, OT      |                      |                      | 55 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                             | <u>Product</u>   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------|------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Constipation; Drug Ineffective; Hyperhidrosis; Nausea; Product Substitution Issue | Lexapro          |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                   | Alprazolam       |              |            | C           |              |                    |                 | Not Reported |
|                                                                                   | Bupropion        |              |            | C           |              |                    |                 | Not Reported |
|                                                                                   | Lexapro          |              |            | C           |              |                    |                 | Not Reported |
|                                                                                   | Atenolol         |              |            | C           |              |                    |                 | Not Reported |
|                                                                                   | Lisinopril       |              |            | C           |              |                    |                 | Not Reported |
|                                                                                   | Vit. D           |              |            | C           |              |                    |                 | Not Reported |
|                                                                                   | Metformin        |              |            | C           |              |                    |                 | Not Reported |
|                                                                                   | Temazepam        |              |            | C           |              |                    |                 | Not Reported |
|                                                                                   | Tylenol          |              |            | C           |              |                    |                 | Not Reported |
|                                                                                   | Aleve            |              |            | C           |              |                    |                 | Not Reported |
|                                                                                   | Benadryl/Mucinex |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Apr-2015              | 9744533       | EXPEDITED (15-DAY) |                    | DS              | IE-FRI-1000052119    |                      |            | Male       | IRL            |

| <u>Preferred Term</u>                                                                                                                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Agitation; Anxiety; Depressed Mood; Drug Ineffective; Paranoia; Psychomotor Hyperactivity; Somnolence; Suicidal Ideation; Withdrawal Syndrome | Lexapro        |              |            | S           | Oral         |                    |                 | Forest       |
|                                                                                                                                               | Quetiapine     |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                               | Librium        |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------------|----------------------|------------|------------|----------------|
| 21-Apr-2015              | 10700814      | EXPEDITED (15-DAY) |                    | OT              | CA-RB<br>PHARMACEUTICALS<br>LIMITED-RB-74673-<br>2014 |                      | 3 DAY      | Male       | CAN            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                      |                   |   |                |                      |                   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|---|----------------|----------------------|-------------------|
| Agitation Neonatal; Drug Withdrawal Syndrome                                                                                                                                         | Suboxone          | S | Transplacental | 10 Mg, Daily         | Reckitt Benckiser |
| Neonatal; Exposure Via Breast Milk; Facial Asymmetry; Foetal Exposure During Pregnancy;                                                                                              | Suboxone          | S | Transmammary   | 12 Mg, Daily         | Reckitt Benckiser |
| Hyperbilirubinaemia Neonatal; Hypoglycaemia Neonatal; Jaundice Neonatal; Knee Deformity; Neonatal Respiratory Distress; Selective Eating Disorder; Talipes; Weight Decrease Neonatal | Subutex           | S | Transplacental | 10 Mg, Daily         | Reckitt Benckiser |
|                                                                                                                                                                                      | Subutex           | S | Transplacental | 12 Mg, Daily         | Reckitt Benckiser |
|                                                                                                                                                                                      | Nicotine          | S | Transplacental | 2-5 Cigarettes Daily | Not Reported      |
|                                                                                                                                                                                      | Ciprallex         | S | Transplacental | 30 Mg Dialy          | Not Reported      |
|                                                                                                                                                                                      | Ciprallex         | S |                |                      | Not Reported      |
|                                                                                                                                                                                      | Calcium           | S | Transplacental | 1000 Mg              | Not Reported      |
|                                                                                                                                                                                      | Vitamin D3        | S | Transplacental | 1000 Iu Daily        | Not Reported      |
|                                                                                                                                                                                      | Folic Acid        | S | Transplacental | 1000 Mg, Qd          | Not Reported      |
|                                                                                                                                                                                      | Prenatal Vitamins | C | Transplacental | Unk                  | Not Reported      |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|------------|------------|----------------|
| 21-Apr-2015              | 10741218      | EXPEDITED (15-DAY) | LT                 |                 | SE-AUROBINDO-AUR-APL-2015-00628 |                      | 55 YR      | Female     | SWE            |

| <u>Preferred Term</u>                       | <u>Product</u>               | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------|------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Suicide Attempt; Toxicity To Various Agents | Mirtazapine Od Tablets 30 Mg |              |            | S           | Oral         | 30 Mg, Daily       |                 | Aurobindo    |
|                                             | Atarax /00058401/            |              |            | S           | Oral         | 25 Mg, Daily       |                 | Not Reported |
|                                             | Citalopram                   |              |            | S           | Oral         | 20 Mg, Daily       |                 | Not Reported |
|                                             | Ciprallex /01588501/         |              |            | S           | Oral         | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 21-Apr-2015              | 10785976      | EXPEDITED (15-DAY) | OT                 |                 | IT-JNJFOC-20150119966 |                      | 74 YR      | Female     | ITA            |

| <u>Preferred Term</u>                        | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Abuse; Muscle Rigidity; Overdose; Sopor | Serenase (Haloperidol) |              |            | S           | Oral         |                    |                 | Not Reported |
|                                              | Serenase (Haloperidol) |              |            | S           | Oral         |                    |                 | Not Reported |
|                                              | Serenase (Haloperidol) |              |            | S           | Oral         |                    |                 | Not Reported |
|                                              | Tavor (Lorazepam)      |              |            | S           | Oral         |                    |                 | Not Reported |
|                                              | Tavor (Lorazepam)      |              |            | S           | Oral         |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                    |   |         |              |
|--------------------|---|---------|--------------|
| Cipralelex         | S | Oral    | Not Reported |
| Cipralelex         | S | Oral    | Not Reported |
| Akineton           | C | Unknown | Not Reported |
| Triatec (Ramipril) | C | Oral    | Not Reported |
| Sequacor           | C | Oral    | Not Reported |
| Cardioaspirin      | C | Oral    | Not Reported |
| Pantopan           | C | Oral    | Not Reported |
| Atorvastatin       | C | Oral    | Not Reported |
| Nootropil          | C |         | Not Reported |
| Nootropil          | C |         | Not Reported |
| Citicolin          | C |         | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Apr-2015              | 11047786      | NON-EXPEDITED    |                    |                 | CN-FRI-1000075915    |                      |            | Female     | CHN            |

| <u>Preferred Term</u>                                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Erythema; Herpes Virus Infection; Pruritus; Swelling Face | Escitalopram   |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                                           | Clonazepam     |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                           | Seroquel       |              |            | C           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Apr-2015              | 11052067      | EXPEDITED (15-DAY) |                    | DS, OT          | SE-TEVA-555036ISR    |                      | 25 YR      | Male       | SWE            |

| <u>Preferred Term</u>                                                                                                                                    | <u>Product</u>                              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|--------------|------------|-------------|--------------|---------------------|-----------------|--------------|
| Anxiety; Gait Disturbance; Product Quality Issue; Product Substitution Issue; Product Substitution Issue; Product Substitution Issue; Somnolence; Stress | Escitalopram Teva 10 Mg Filmragerad Tablett |              |            | S           | Oral         | 10 Milligram Daily; |                 | Ivax         |
|                                                                                                                                                          | Propavan 25 Mg Tablett                      |              |            | C           |              |                     |                 | Not Reported |
|                                                                                                                                                          | Concerta                                    |              |            | C           |              |                     |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                   | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 21-Apr-2015                                                                | 11053929               | EXPEDITED (15-DAY) |                    | OT              | CA-FRI-1000075989     |                      | 69 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                                      | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Iron Decreased;<br>Intestinal Haemorrhage                            | Escitalopram           |                    |                    | S               | Oral                  | 20 Mg                |                 | Forest       |                |
|                                                                            | Escitalopram           |                    |                    | S               | Oral                  | 10 Mg                |                 | Forest       |                |
|                                                                            | Escitalopram           |                    |                    | S               | Oral                  | 5 Mg                 |                 | Not Reported |                |
|                                                                            | Iron                   |                    |                    | C               |                       |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                   | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Apr-2015                                                                | 9397437                | EXPEDITED (15-DAY) |                    | HO              | IT-JNJFOC-20130705029 |                      | 86 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                      | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Electrocardiogram Qt<br>Prolonged;<br>Hyponatraemia;<br>Hypotension; Sopor | Serenase (Haloperidol) |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                            | Serenase (Haloperidol) |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                            | Serenase (Haloperidol) |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                            | Cipralelex             |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                            | Cipralelex             |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                            | Cipralelex             |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                            | Bisoprolol Fumarate    |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |
|                                                                            | Metformine             |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |
|                                                                            | Isoptin                |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |
|                                                                            | Coumadin               |                    |                    | C               | Oral                  |                      |                 | Not Reported |                |
|                                                                            | Dibase                 |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |
|                                                                            | Tavor (Lorazepam)      |                    |                    | C               | Oral                  |                      |                 | Not Reported |                |
|                                                                            | Nexium                 |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |
|                                                                            | Diamicron              |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                               | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------|------------------------------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|-----------------|--------------|----------------|
| 22-Apr-2015                                            | 11054863                           | EXPEDITED (15-DAY) |                    | HO              | US-CIPLA LTD.-<br>2015US03274  |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                  | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrioventricular Block Complete; Hypotension; Overdose | Amlodipine                         |                    |                    | S               | Unknown                        | 5 Mg, Unk            |                 | Cipla        |                |
|                                                        | Hydrochlorothiazide                |                    |                    | S               | Unknown                        | Unk                  |                 | Not Reported |                |
|                                                        | Buspiron [Buspirone Hydrochloride] |                    |                    | S               | Unknown                        | Unk                  |                 | Not Reported |                |
|                                                        | Dexamfetamine                      |                    |                    | S               | Unknown                        | Unk                  |                 | Not Reported |                |
|                                                        | Lexapro                            |                    |                    | S               | Unknown                        | Unk                  |                 | Not Reported |                |
|                                                        | Venlafexine                        |                    |                    | S               | Unknown                        | Unk                  |                 | Not Reported |                |
|                                                        | Prozac                             |                    |                    | S               | Unknown                        | Unk                  |                 | Not Reported |                |
|                                                        | Clonazepam                         |                    |                    | S               |                                | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                               | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Apr-2015                                            | 11056074                           | EXPEDITED (15-DAY) |                    | OT              | CH-ASTRAZENECA-<br>2015SE35217 |                      | 26 YR           | Male         | CHE            |
| <u>Preferred Term</u>                                  | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Obesity; Weight Increased            | Seroquel Xr                        |                    |                    | S               | Oral                           |                      |                 | Astrazeneca  |                |
|                                                        | Seroquel Xr                        |                    |                    | S               | Oral                           |                      |                 | Astrazeneca  |                |
|                                                        | Abilify                            |                    |                    | S               | Oral                           |                      |                 | Not Reported |                |
|                                                        | Abilify                            |                    |                    | S               | Oral                           |                      |                 | Not Reported |                |
|                                                        | Cipralex                           |                    |                    | S               | Oral                           |                      |                 | Not Reported |                |
|                                                        | Simvastatin                        |                    |                    | C               | Oral                           |                      |                 | Not Reported |                |
|                                                        | Valium                             |                    |                    | C               | Oral                           |                      |                 | Not Reported |                |
|                                                        | Temesta (Lorazepam)                |                    |                    | C               | Oral                           |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                               | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Apr-2015                                            | 11056100                           | EXPEDITED (15-DAY) |                    | HO              | CA-ASTRAZENECA-<br>2015SE35955 |                      |                 | Female       | CAN            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                              | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
|----------------------------------------------------|----------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------------------|-----------------|--------------|----------------|
| Intentional Overdose;<br>Suicide Attempt           | Seroquel                   |                    |                    | S               | Oral                      |                                  |                 | Zeneca       |                |
|                                                    | Ativan                     |                    |                    | S               | Oral                      |                                  |                 | Not Reported |                |
|                                                    | Humalog                    |                    |                    | S               | Subcutaneous              |                                  |                 | Not Reported |                |
|                                                    | Humalog                    |                    |                    | S               | Oral                      |                                  |                 | Not Reported |                |
|                                                    | Cipralex                   |                    |                    | S               | Oral                      |                                  |                 | Not Reported |                |
|                                                    | Cipralex                   |                    |                    | S               | Oral                      |                                  |                 | Not Reported |                |
|                                                    | Cipralex                   |                    |                    | S               | Oral                      |                                  |                 | Not Reported |                |
|                                                    | Topiramate                 |                    |                    | C               |                           |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                           | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Apr-2015                                        | 11056313                   | EXPEDITED (15-DAY) |                    | HO              | TR-MYLANLABS-2015M1013332 |                                  |                 | Unknown      | TUR            |
| <u>Preferred Term</u>                              | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Delirium                                           | Olanzapine                 |                    |                    | S               | Oral                      | 5mg/Day                          |                 | Mylan        |                |
|                                                    | Escitalopram               |                    |                    | S               | Unknown                   | 20 Mg/Day                        |                 | Mylan        |                |
| <u>FDA Received Date</u>                           | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Apr-2015                                        | 11058625                   | DIRECT             |                    |                 |                           |                                  | 51 YR           | Male         | USA            |
| <u>Preferred Term</u>                              | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Withdrawal<br>Syndrome; Serotonin<br>Syndrome | Deplin                     |                    |                    | S               | Oral                      | 1 Pill Once Daily Taken By Mouth |                 | Pamlab       |                |
|                                                    | Lexapro                    |                    |                    | S               | Oral                      |                                  |                 | Forest       |                |
| <u>FDA Received Date</u>                           | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Apr-2015                                        | 9402687                    | EXPEDITED (15-DAY) |                    | HO              | IT-FRI-1000046681         |                                  | 86 YR           | Female       | ITA            |
| <u>Preferred Term</u>                              | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Electrocardiogram Qt<br>Prolonged;                 | Escitalopram Oral Solution |                    |                    | S               | Oral                      | 17 Drops Daily                   |                 | Forest       |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                      |                        |   |         |      |              |
|--------------------------------------|------------------------|---|---------|------|--------------|
| Hyponatraemia;<br>Hypotension; Sopor | Serenase 1mg Compresse | S | Oral    | 1 Mg | Not Reported |
|                                      | Bisprolol Fumarate     | C | Unknown |      | Not Reported |
|                                      | Metformin              | C | Unknown |      | Not Reported |
|                                      | Isoptin                | C | Unknown |      | Not Reported |
|                                      | Coumadin 5mg Compresse | C | Oral    |      | Not Reported |
|                                      | Dibase                 | C | Unknown |      | Not Reported |
|                                      | Tavor (Lorazepam)      | C | Oral    |      | Not Reported |
|                                      | Nexium                 | C | Unknown |      | Not Reported |

| <u>FDA Received Date</u>                                | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------|----------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 23-Apr-2015                                             | 10025169                   | EXPEDITED (15-DAY) |                    | HO              | IT-FRI-1000064769    |                      | 36 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                   | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Abuse; Intentional<br>Overdose; Sopor;<br>Vomiting | Escitalopram Oral Solution |                    |                    | S               | Oral                 | 10-15 Drops Daily    |                 | Forest       |                |
|                                                         | Escitalopram Oral Solution |                    |                    | S               | Oral                 | Overdose: 15 MI      |                 | Forest       |                |
|                                                         | Tachifludec                |                    |                    | S               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|-----------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|-------------------------------------|-----------------|------------|----------------|
| 23-Apr-2015                                   | 11046685       | EXPEDITED (15-DAY) |                    | OT              | ES-ACCORD-030137     |                                     | 73 YR           | Female     | ESP            |
| <u>Preferred Term</u>                         | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u> |                |
| Angle Closure Glaucoma;<br>Choroidal Effusion | Escitalopram   |                    |                    | S               |                      | Double The Drug Dose 20<br>Mg A Day |                 | Accord     |                |

| <u>FDA Received Date</u>                                                                    | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|-----------------|--------------|----------------|
| 23-Apr-2015                                                                                 | 11057877       | EXPEDITED (15-DAY) |                    | DS              | CA-ASTRAZENECA-<br>2015SE35976 |                      | 51 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                                                       | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anger; Anxiety; Blood<br>Pressure Increased;<br>Depression; Heart Rate<br>Increased; Mental | Seroquel       |                    |                    | S               | Oral                           |                      |                 | Zeneca       |                |
|                                                                                             | Abilify        |                    |                    | S               | Oral                           |                      |                 | Not Reported |                |

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|                                                    |                    |                    |                    |                 |                                                             |                      |                 |              |                |
|----------------------------------------------------|--------------------|--------------------|--------------------|-----------------|-------------------------------------------------------------|----------------------|-----------------|--------------|----------------|
| Impairment                                         | Ciprallex          |                    | S                  |                 | Unknown                                                     |                      | Not Reported    |              |                |
| <u>FDA Received Date</u>                           | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                        | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Apr-2015                                        | 11057936           | EXPEDITED (15-DAY) |                    | OT              | TR-SUN<br>PHARMACEUTICAL<br>INDUSTRIES LTD-<br>2015RR-95946 |                      | 21 YR           | Male         | TUR            |
| <u>Preferred Term</u>                              | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anterograde Amnesia;<br>Delirium; Drug Interaction | Olanzapine         |                    |                    | S               | Oral                                                        | 5 Mg, Daily          |                 | Sun          |                |
|                                                    | Olanzapine         |                    |                    | S               |                                                             |                      |                 | Sun          |                |
|                                                    | Escitalopram       |                    |                    | S               | Unknown                                                     | 20 Mg, Daily         |                 | Not Reported |                |
|                                                    | Escitalopram       |                    |                    | S               |                                                             |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                           | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                        | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Apr-2015                                        | 11058664           | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000075968                                           |                      | 91 YR           | Male         | FRA            |
| <u>Preferred Term</u>                              | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;<br>Haematoma Muscle              | Escitalopram       |                    |                    | S               | Oral                                                        | 5 Mg                 |                 | Forest       |                |
|                                                    | Plavix             |                    |                    | S               | Oral                                                        | 75 Mg                |                 | Not Reported |                |
|                                                    | Azilect            |                    |                    | C               | Unknown                                                     | 1 Mg                 |                 | Not Reported |                |
|                                                    | Pravastatine       |                    |                    | C               | Unknown                                                     | 40 Mg                |                 | Not Reported |                |
|                                                    | Movicol            |                    |                    | C               | Oral                                                        | 1 Df                 |                 | Not Reported |                |
|                                                    | Modopar            |                    |                    | C               | Unknown                                                     | 125 Mg               |                 | Not Reported |                |
|                                                    | Modopar            |                    |                    | C               | Unknown                                                     | 187.5 Mg             |                 | Not Reported |                |
|                                                    | Modopar Lp         |                    |                    | C               | Unknown                                                     | 125 Mg               |                 | Not Reported |                |
|                                                    | Tardyferon         |                    |                    | C               | Unknown                                                     | 160 Mg               |                 | Not Reported |                |
|                                                    | Speciafoldine      |                    |                    | C               | Unknown                                                     | 5 Mg                 |                 | Not Reported |                |
|                                                    | Pantoprazole       |                    |                    | C               | Unknown                                                     | 40 Mg                |                 | Not Reported |                |
|                                                    | Efferalgan Codeine |                    |                    | C               | Unknown                                                     | 3 Df                 |                 | Not Reported |                |
|                                                    | Xolaam             |                    |                    | C               | Unknown                                                     | 3 Df                 |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u>                                            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|--------------------------------|-----------------------------------------------------------------|-----------------|--------------|----------------|
| 23-Apr-2015                                                                                                    | 11059167       | EXPEDITED (15-DAY) |                    | OT              | PHHY2015BR006746               |                                                                 |                 | Male         | BRA            |
| <u>Preferred Term</u>                                                                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>                                              | <u>Duration</u> | <u>Mfr</u>   |                |
| Apathy; Balance Disorder;<br>Decreased Activity; Fall;<br>Hydrocephalus;<br>Incontinence; Pain In<br>Extremity | Galvus Met     |                    |                    | S               | Unknown                        | 1 Df, Qd 1 Df (Tablet), Bid<br>(In The Morning And At<br>Night) |                 | Not Reported |                |
|                                                                                                                | Exelon Patch   |                    |                    | S               | Transdermal                    | 18 Mg/ 10 Cm2 (9.5 Mg),<br>Qd                                   |                 | Novartis     |                |
|                                                                                                                | Reconter       |                    |                    | S               | Unknown                        | 1 Df, Qd                                                        |                 | Not Reported |                |
|                                                                                                                | Reconter       |                    |                    | S               |                                |                                                                 |                 | Not Reported |                |
|                                                                                                                | Glifage        |                    |                    | S               | Unknown                        | 2 Df, Qhs                                                       |                 | Not Reported |                |
|                                                                                                                | Aradois        |                    |                    | C               | Unknown                        | 1 Df, Bid (In The Morning<br>And At Night)                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u>                                            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Apr-2015                                                                                                    | 11060779       | EXPEDITED (15-DAY) |                    | OT              | DE-009507513-<br>1504DEU014216 |                                                                 | 43 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                                                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>                                              | <u>Duration</u> | <u>Mfr</u>   |                |
| Abortion Missed                                                                                                | Mirtazapine    |                    |                    | S               | Oral                           | 7.5 Mg, Qd                                                      |                 | Merck        |                |
|                                                                                                                | Ciprallex      |                    |                    | S               | Oral                           | 10 Mg, Qd                                                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u>                                            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Apr-2015                                                                                                    | 10525818       | EXPEDITED (15-DAY) |                    |                 | PHHY2014BR129288               |                                                                 | 91 YR           | Female       | BRA            |
| <u>Preferred Term</u>                                                                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>                                              | <u>Duration</u> | <u>Mfr</u>   |                |
| Anaemia; Off Label Use;<br>Renal Failure; Urinary<br>Tract Infection                                           | Exelon Patch   |                    |                    | S               | Transdermal                    | 13.3 Mg, Qd<br>(27mg/15cm2)                                     |                 | Not Reported |                |
|                                                                                                                | Leponex        |                    |                    | S               | Unknown                        | 15 Mg, Qd                                                       |                 | Novartis     |                |
|                                                                                                                | Leponex        |                    |                    | S               | Unknown                        | 50 Mg, Qd                                                       |                 | Novartis     |                |
|                                                                                                                | Leponex        |                    |                    | S               | Unknown                        | 75 Mg, Qd                                                       |                 | Novartis     |                |

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|                              |   |         |             |              |
|------------------------------|---|---------|-------------|--------------|
| Leponex                      | S | Unknown | 100 Mg, Qd  | Novartis     |
| Zider                        | S | Unknown | 2 Df, Daily | Not Reported |
| Exodus//Escitalopram Oxalate | S | Unknown | 1 Df, Qd    | Not Reported |
| Vonau                        | S | Unknown | 1 Df, Prn   | Not Reported |
| Donaren                      | C | Oral    | 1 Df, Qd    | Not Reported |
| Citalopram                   | C | Oral    | 1 Df, Qd    | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 24-Apr-2015              | 11061092         | EXPEDITED (15-DAY) |                    | HO              | FR-ROCHE-1567870     |                      | 56 YR           | Female       | FRA            |
| <u>Preferred Term</u>    | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cholestasis              | Valium           |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                          | Tegretol         |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                          | Alepsal (France) |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                          | Seroplex         |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                          | Difclir          |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|--------------------------|---------------------------|-----------------|--------------|----------------|
| 24-Apr-2015                                                   | 11062485       | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-2015141106 |                           | 49 YR           | Female       | USA            |
| <u>Preferred Term</u>                                         | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |                |
| Bipolar Disorder; Product Dispensing Error; Suicidal Ideation | Alprazolam     |                    |                    | S               |                          | 1 Mg, Qid As Needed (Prn) |                 | Pfizer       |                |
|                                                               | Alprazolam     |                    |                    | S               |                          |                           |                 | Pfizer       |                |
|                                                               | Alprazolam     |                    |                    | S               |                          |                           |                 | Pfizer       |                |
|                                                               | Lamotrigine    |                    |                    | S               |                          | 350 Mg, Daily (Qhs)       |                 | Not Reported |                |
|                                                               | Lamotrigine    |                    |                    | S               |                          |                           |                 | Not Reported |                |
|                                                               | Lamotrigine    |                    |                    | S               |                          |                           |                 | Not Reported |                |
|                                                               | Escitalopram   |                    |                    | S               |                          | 25 Mg, 1x/Day             |                 | Not Reported |                |
|                                                               | Escitalopram   |                    |                    | S               |                          |                           |                 | Not Reported |                |
|                                                               |                |                    |                    |                 |                          |                           |                 |              |                |

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|  |               |   |  |  |                |  |  |              |
|--|---------------|---|--|--|----------------|--|--|--------------|
|  | Escitalopram  | S |  |  |                |  |  | Not Reported |
|  | Escitalopram  | S |  |  |                |  |  | Not Reported |
|  | Oxcarbazepine | S |  |  | 300 Mg, 2x/Day |  |  | Not Reported |
|  | Oxcarbazepine | S |  |  |                |  |  | Not Reported |
|  | Oxcarbazepine | S |  |  |                |  |  | Not Reported |
|  | Oxcarbazepine | S |  |  |                |  |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 24-Apr-2015              | 11062545       | EXPEDITED (15-DAY) |                    | OT              | DE-TEVA-555246GER    |                      | 43 YR           | Female       | DEU            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abortion Missed          | Mirtazapin     |                    |                    | S               | Oral                 |                      |                 | Teva         |                |
|                          | Cipralex       |                    |                    | S               | Oral                 | 10-20mg              |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                          | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u>                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------|--------------------|--------------------|--------------------|-----------------|-------------------------------|--------------------------------------|-----------------|--------------|----------------|
| 25-Apr-2015                                                                       | 11065745           | EXPEDITED (15-DAY) |                    | HO              | TR-CIPLA LTD.-<br>2015TR03365 |                                      |                 | Unknown      | TUR            |
| <u>Preferred Term</u>                                                             | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Extrapyramidal Disorder;<br>Incontinence; Major<br>Depression; Muscle<br>Rigidity | Risperidone        |                    |                    | S               | Oral                          | 3 Mg, Unk                            |                 | Cipla        |                |
|                                                                                   | Lamivudine         |                    |                    | S               | Unknown                       | 100 Mg, Unk                          |                 | Cipla        |                |
|                                                                                   | Interferon Alfa 2b |                    |                    | S               | Unknown                       | 30 Million Iu, Three Times<br>A Week |                 | Not Reported |                |
|                                                                                   | Escitalopram       |                    |                    | S               | Unknown                       | 10 Mg, Unk                           |                 | Not Reported |                |
|                                                                                   | Escitalopram       |                    |                    | S               | Unknown                       | 15 Unk, Unk                          |                 | Not Reported |                |
|                                                                                   | Escitalopram       |                    |                    | S               | Unknown                       | 20 Unk, Unk                          |                 | Not Reported |                |
|                                                                                   | Biperiden          |                    |                    | S               | Unknown                       |                                      |                 | Not Reported |                |
|                                                                                   | Lorazepam          |                    |                    | S               | Unknown                       |                                      |                 | Not Reported |                |
|                                                                                   | Olanzapine         |                    |                    | S               | Unknown                       | 5 Mg, Unk                            |                 | Not Reported |                |
|                                                                                   | Aripiprazole       |                    |                    | S               | Unknown                       | 5 Mg, Unk                            |                 | Not Reported |                |
|                                                                                   | Aripiprazole       |                    |                    | S               | Unknown                       | 10 Mg, Unk                           |                 | Not Reported |                |

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| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 27-Apr-2015              | 11068648      | NON-EXPEDITED    |                    |                 | US-PFIZER INC-<br>2015141073 |                      | 67 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Hypersensitivity | Neurontin      |              |            | S           |              | Unk                |                 | Pfizer       |
|                       | Xanax          |              |            | S           |              | Unk                |                 | Pfizer       |
|                       | Lisinopril     |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Codeine        |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Celexa         |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Lexapro        |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Lovastatin     |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Amitriptyline  |              |            | S           |              | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|------------|------------|----------------|
| 27-Apr-2015              | 11069296      | EXPEDITED (15-DAY) |                    | OT              | US-CIPLA LTD.-<br>2015US03366 |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Aggression; Anger;           | Citalopram     |              |            | S           |              | 10 Mg              |                 | Cipla        |
| Anxiety; Blood               | Citalopram     |              |            | S           |              | 15 Mg              |                 | Cipla        |
| Testosterone Decreased;      | Citalopram     |              |            | S           |              | 10 Mg              |                 | Cipla        |
| Bone Development             | Citalopram     |              |            | S           |              | 7.5 Mg             |                 | Cipla        |
| Abnormal; Decreased          | Citalopram     |              |            | S           |              | 175 Mg             |                 | Cipla        |
| Appetite; Depressive         | Lamotrigine    |              |            | S           |              | 75 Mg              |                 | Not Reported |
| Symptom; Disturbance In      | Fluvoxamine    |              |            | S           |              | 0.5 Mg             |                 | Cipla        |
| Attention; Drug Ineffective; | Risperidone    |              |            | S           |              | 5-10 Mg            |                 | Not Reported |
| Formication; Insomnia;       | Aripiprazole   |              |            | S           |              | 2 Mg               |                 | Not Reported |
| Irritability; Loss Of        | Aripiprazole   |              |            | S           |              | 1 Mg               |                 | Not Reported |
| Personal Independence In     | Atomoxetine    |              |            | S           |              | 18 Mg              |                 | Not Reported |
| Daily Activities; Nail       | Dexamfetamine  |              |            | S           |              | 30-60 Mg           |                 | Not Reported |
| Picking; Panic Attack;       |                |              |            |             |              |                    |                 |              |
| Psychomotor                  |                |              |            |             |              |                    |                 |              |
| Hyperactivity; Sensory       |                |              |            |             |              |                    |                 |              |
| Disturbance; Sinusitis;      |                |              |            |             |              |                    |                 |              |
| Stress                       |                |              |            |             |              |                    |                 |              |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                        |   |              |              |
|------------------------|---|--------------|--------------|
| Dextroamphetamine      | S | 15 Mg        | Not Reported |
| Testosterone Cypionate | S | 200 Mg/ML    | Not Reported |
| Escitalopram           | S | 5 Mg         | Not Reported |
| Escitalopram           | S | 10 Mg        | Not Reported |
| Escitalopram           | S | 20 Mg        | Not Reported |
| Oxcarbazepine          | S | Total 375 Mg | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Apr-2015              | 11070413      | EXPEDITED (15-DAY) |                    | HO              | PHHY2015FR048960     |                      | 59 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>     | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|------------------|--------------------|-----------------|--------------|
| Gamma-Glutamyltransferase Increased; Leukopenia; Thrombocytopenia; Transaminases Increased | Exjade         |              |            | S           | Oral             | 1 Df, Qw3          |                 | Novartis     |
|                                                                                            | Seroplex       |              |            | S           | Oral             | 1 Df, Qd           |                 | Not Reported |
|                                                                                            | Aranesp        |              |            | C           | Subcutaneous     | 1 Df, Qw           |                 | Not Reported |
|                                                                                            | Glucidion      |              |            | C           | Intravenous drip |                    |                 | Not Reported |
|                                                                                            | Bromazepam     |              |            | C           |                  |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Apr-2015              | 11071339      | DIRECT           |                    |                 |                      |                      | 44 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                          | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|------------------------------------|-----------------|--------------|
| Abnormal Dreams; Dizziness; Headache; Insomnia; Irritability; Migraine; Nausea; Poor Quality Sleep; Product Substitution Issue | Escitalopram           |              |            | S           | Oral         | 1 Pill, Once Daily, Taken By Mouth |                 | Lupin        |
|                                                                                                                                | Multivitamin For Women |              |            | C           |              |                                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Apr-2015              | 10732732      | EXPEDITED (15-DAY) |                    | HO              | CH-FRI-1000073773    |                      | 81 YR      | Female     | CHE            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                  |              |   |              |               |              |
|------------------------------------------------------------------|--------------|---|--------------|---------------|--------------|
| Anaemia; Anaemia;<br>Ecchymosis; Haematoma;<br>Mouth Haemorrhage | Escitalopram | S | Oral         | 10 Mg Daily   | Forest       |
|                                                                  | Sintrom      | S | Oral         |               | Not Reported |
|                                                                  | Fraxiforte   | S | Subcutaneous | 1 Df          | Not Reported |
|                                                                  | Atacand      | C | Oral         | 16 Mg Daily   | Not Reported |
|                                                                  | Dalacin C    | C | Oral         | 3 Other Daily | Not Reported |
|                                                                  | Nitroderm    | C | Topical      |               | Not Reported |
|                                                                  | Tenormin     | C | Oral         | 12.5 Mg       | Not Reported |
|                                                                  | Inegy        | C | Oral         | 1 Other Daily | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Apr-2015              | 10793045      | EXPEDITED (15-DAY) |                    | HO, OT          | IT-FRI-1000074396    |                      | 74 YR      | Female     | ITA            |

| <u>Preferred Term</u>                                                             | <u>Product</u>             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------|----------------------------|--------------|------------|-------------|--------------|-------------------------|-----------------|--------------|
| Cerebrovascular Disorder;<br>Muscle Rigidity; Overdose;<br>Sopor; Speech Disorder | Escitalopram Oral Solution |              |            | S           | Oral         | 20 Drops                |                 | Forest       |
|                                                                                   | Escitalopram Oral Solution |              |            | S           |              |                         |                 | Forest       |
|                                                                                   | Serenase (Haloperidol)     |              |            | S           | Oral         |                         |                 | Not Reported |
|                                                                                   | Serenase (Haloperidol)     |              |            | S           | Oral         |                         |                 | Not Reported |
|                                                                                   | Serenase (Haloperidol)     |              |            | S           | Oral         | 25 Drops In The Evening |                 | Not Reported |
|                                                                                   | Tavor (Lorazepam)          |              |            | S           | Oral         |                         |                 | Not Reported |
|                                                                                   | Tavor (Lorazepam)          |              |            | S           | Oral         | 2 Mg                    |                 | Not Reported |
|                                                                                   | Tavor (Lorazepam)          |              |            | S           | Oral         | Overdose: 4 Mg          |                 | Not Reported |
|                                                                                   | Sequacor                   |              |            | C           | Oral         | 5 Mg                    |                 | Not Reported |
|                                                                                   | Cardioaspirin              |              |            | C           | Oral         | 100 Mg                  |                 | Not Reported |
|                                                                                   | Triatec (Ramipril)         |              |            | C           | Oral         | 10 Mg                   |                 | Not Reported |
|                                                                                   | Pantopan                   |              |            | C           | Oral         | 20 Mg                   |                 | Not Reported |
|                                                                                   | Nootropil                  |              |            | C           | Oral         | 3000 Mg                 |                 | Not Reported |
|                                                                                   | Atorvastatina              |              |            | C           | Oral         | 20 Mg                   |                 | Not Reported |
|                                                                                   | Psycoton                   |              |            | C           | Oral         | 3 G                     |                 | Not Reported |
|                                                                                   | Citicolin                  |              |            | C           | Oral         | 4000 Mg                 |                 | Not Reported |
|                                                                                   | Hibiscus Sabdariffa        |              |            | C           |              |                         |                 | Not Reported |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Apr-2015              | 10920576      | EXPEDITED (15-DAY) |                    | HO, LT, OT      | PHHY2015CH030129     |                      |            | Female     | CHE            |

| <u>Preferred Term</u>     | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|-------------------------|--------------|------------|-------------|--------------|---------------------------|-----------------|--------------|
| Agitation; Bradypnoea;    | Ritalin                 |              |            | S           | Unknown      |                           |                 | Not Reported |
| Delusion; Depression;     | Ritalin                 |              |            | S           | Unknown      | 80 Mg, Qd                 |                 | Not Reported |
| Drug Interaction;         | Ritalin                 |              |            | S           | Unknown      | 10 Mg, Qd                 |                 | Not Reported |
| Electrocardiogram Qt      | Ritalin La              |              |            | S           | Unknown      | 10 Mg, Qd                 |                 | Not Reported |
| Prolonged; Fear;          | Ritalin La              |              |            | S           | Unknown      | 30 Mg, Qd                 |                 | Not Reported |
| Hallucination; Herpes     | Ritalin-Sr              |              |            | S           | Unknown      | 20 Mg, Qd                 |                 | Not Reported |
| Simplex Test Positive;    | Cetirizine              |              |            | S           | Unknown      | 200 Mg, Unk               |                 | Novartis     |
| Impulsive Behaviour; Loss | Cipraxel//Escitalopram  |              |            | S           | Oral         | 10 Mg, Qd                 |                 | Not Reported |
| Of Consciousness;         | Cipraxel//Escitalopram  |              |            | S           | Unknown      | 300 Mg, Unk               |                 | Not Reported |
| Maternal Exposure During  | Bilaxten                |              |            | S           | Oral         |                           |                 | Not Reported |
| Pregnancy; Overdose;      | Bilaxten                |              |            | S           | Unknown      | 400 Mg, Unk               |                 | Not Reported |
| Prurigo; Psychotic        | Seroquel                |              |            | S           | Unknown      | 2.5 G, Unk                |                 | Not Reported |
| Disorder; Restlessness;   | Rocuronium              |              |            | C           | Unknown      | 50 Mg, Unk                |                 | Not Reported |
| Somatic Delusion;         | Zyprexa                 |              |            | C           | Oral         | 2.5 Ot, Qd                |                 | Not Reported |
| Somnolence; Suicide       | Sequase                 |              |            | C           | Oral         | 25 Mg, Qd                 |                 | Not Reported |
| Attempt; Toxicity To      | Sequase                 |              |            | C           | Unknown      | 50 Mg, Unk                |                 | Not Reported |
| Various Agents            | Concerta                |              |            | C           | Unknown      |                           |                 | Not Reported |
|                           | Surmontil//Trimipramine |              |            | C           | Unknown      | 100 Mg, (In The Evening)  |                 | Not Reported |
|                           | Relaxan                 |              |            | C           | Unknown      | 3 Df, Bid                 |                 | Not Reported |
|                           | Trittico                |              |            | C           | Unknown      | 50 Mg, (Night Medication) |                 | Not Reported |
|                           | Mianserin               |              |            | C           | Unknown      |                           |                 | Not Reported |
|                           | Mianserin               |              |            | C           | Unknown      | 60 M, Unk                 |                 | Not Reported |
|                           | Redormin//Remifentanil  |              |            | C           | Unknown      | 1 G, Unk                  |                 | Not Reported |
|                           | Hydrochloride           |              |            | C           | Unknown      | 2 Df, Qd (500 Mg)         |                 | Not Reported |
|                           | Redormin//Remifentanil  |              |            | C           | Unknown      |                           |                 | Not Reported |
|                           | Hydrochloride           |              |            | C           | Unknown      |                           |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                        |   |         |            |              |
|------------------------|---|---------|------------|--------------|
| Valdoxan               | C | Unknown | 25 Mg, Qd  | Not Reported |
| Valdoxan               | C |         |            | Not Reported |
| Passiflora             | C | Unknown |            | Not Reported |
| Passiflora             | C |         |            | Not Reported |
| Bactrim Forte          | C | Unknown |            | Not Reported |
| Pantozol (Switzerland) | C | Unknown | 20 Mg, Qd  | Not Reported |
| Etomidate              | C | Unknown | 12 Mg, Unk | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 28-Apr-2015              | 10925717       | EXPEDITED (15-DAY) |                    | HO              | SE-FRI-1000075321    |                      | 30 YR           | Female       | SWE            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Breast Enlargement       | Escitalopram   |                    |                    | S               | Oral                 | 20 Mg                |                 | Forest       |                |
|                          | Imovane        |                    |                    | C               | Unknown              |                      |                 | Not Reported |                |
|                          | Zolpidem       |                    |                    | C               | Unknown              |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                  | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 28-Apr-2015                                                               | 11071096                  | EXPEDITED (15-DAY) |                    | HO              | US-ACCORD-030299     |                      | 50 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                     | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cerebrovascular Accident;<br>Drooling; Dysarthria;<br>Hypoaesthesia; Pain | Escitalopram              |                    |                    | S               | Oral                 |                      |                 | Accord       |                |
|                                                                           | Hydrocodone               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                           | Oxycodone/Oxycodone       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                           | Hydrochloride/Oxycodone   |                    |                    |                 |                      |                      |                 |              |                |
|                                                                           | Pectinate/Oxycodone       |                    |                    |                 |                      |                      |                 |              |                |
|                                                                           | Terephthalate             |                    |                    |                 |                      |                      |                 |              |                |
|                                                                           | Topiramate                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                           | Aciclovir                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                           | Chlorhexidine             |                    |                    | C               |                      | Mouth Rinse          |                 | Not Reported |                |
|                                                                           | Clindamycin               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                           | Betamethasone             |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                           | Dipropionate/Clotrimazole |                    |                    |                 |                      |                      |                 |              |                |
|                                                                           | Sumatriptan               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                           | Prednisone                |                    |                    | C               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|             |   |              |
|-------------|---|--------------|
| Rizatriptan | C | Not Reported |
| Xanax       | C | Not Reported |
| Wellbutrin  | C | Not Reported |
| Valium      | C | Not Reported |
| Diltiazem   | C | Not Reported |
| Lantus      | C | Not Reported |
| Omeprazole  | C | Not Reported |
| Prazosin    | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                        | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------------------|----------------------|------------|------------|----------------|
| 28-Apr-2015              | 11071653      | EXPEDITED (15-DAY) |                    | OT              | DE-SUN<br>PHARMACEUTICAL<br>INDUSTRIES LTD-<br>2015RR-96247 |                      | 43 YR      | Female     | DEU            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abortion Missed       | Mirtazapin     |              |            | S           | Oral         | 7.5 Mg             |                 | Sun          |
|                       | Ciprallex      |              |            | S           | Oral         | 10 Mg, Daily       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Apr-2015              | 11072196      | EXPEDITED (15-DAY) |                    | OT              | CH-FRI-1000076058    |                      | 27 YR      | Male       | CHE            |

| <u>Preferred Term</u>     | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Obesity; Weight Increased | Escitalopram        |              |            | S           | Oral         | 20 Mg              |                 | Forest       |
|                           | Seroquel Xr         |              |            | S           | Oral         | 800 Mg             |                 | Not Reported |
|                           | Abilify             |              |            | S           | Oral         | 10 Mg              |                 | Not Reported |
|                           | Abilify             |              |            | S           | Oral         | 15 Mg              |                 | Not Reported |
|                           | Simvastatin         |              |            | C           | Oral         | 20 Mg              |                 | Not Reported |
|                           | Valium              |              |            | C           | Oral         | 5 Mg               |                 | Not Reported |
|                           | Temesta (Lorazepam) |              |            | C           | Oral         | 5 Mg               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 28-Apr-2015              | 11072703      | EXPEDITED (15-DAY) |                    | OT              | DE-WATSON-2015-<br>08834 |                      | 43 YR      | Female     | DEU            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                           |                       |   |      |                 |              |
|---------------------------|-----------------------|---|------|-----------------|--------------|
| Abortion Missed;          | Mirtazapine (Unknown) | S | Oral | 7.5 Mg, Unknown | Actavis      |
| Exposure During Pregnancy | Cipralex /01588501/   | S | Oral | 10 Mg, Unknown  | Not Reported |

| <u>FDA Received Date</u>     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------|----------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| 28-Apr-2015                  | 11073027       | EXPEDITED (15-DAY) |                    | OT              | CA-ASTRAZENECA-2015SE37371 |                      | 56 YR           | Female       | CAN            |
| <u>Preferred Term</u>        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Gastric Ulcer; Off Label Use | Crestor        |                    |                    | S               | Oral                       |                      |                 | Astrazeneca  |                |
|                              | Cipralex       |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                              | Metformin      |                    |                    | C               |                            |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|-------------------------------------------------|-----------------|--------------|----------------|
| 28-Apr-2015                            | 11079170       | EXPEDITED (15-DAY) | Y                  | HO              | IPC201504-000225     |                                                 | 58 YR           | Male         | CHE            |
| <u>Preferred Term</u>                  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                              | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Abuse; Imprisonment; Mania; Theft | Tramadol       |                    |                    | S               |                      |                                                 |                 | Not Reported |                |
|                                        | Escitalopram   |                    |                    | S               |                      |                                                 |                 | Not Reported |                |
|                                        | Triamcinolone  |                    |                    | S               | Intramuscular        | 40 Mg, 2 Intramuscular Injection, Intramuscular |                 | Not Reported |                |
|                                        | Oxazepam       |                    |                    | C               |                      |                                                 |                 | Not Reported |                |
|                                        | Alprazolam     |                    |                    | C               |                      |                                                 |                 | Not Reported |                |
|                                        | Zolpidem       |                    |                    | C               |                      |                                                 |                 | Not Reported |                |
|                                        | Baclofen       |                    |                    | C               |                      |                                                 |                 | Not Reported |                |
|                                        | Candesartan    |                    |                    | C               |                      |                                                 |                 | Not Reported |                |
|                                        | Metformin      |                    |                    | C               |                      |                                                 |                 | Not Reported |                |
|                                        | Atorvastatin   |                    |                    | C               |                      |                                                 |                 | Not Reported |                |
|                                        | Alfuzosin      |                    |                    | C               |                      |                                                 |                 | Not Reported |                |
|                                        | Trospium       |                    |                    | S               |                      |                                                 |                 | Not Reported |                |
|                                        | Acetaminophen  |                    |                    | C               |                      |                                                 |                 | Not Reported |                |
|                                        | Ibuprofen      |                    |                    | C               |                      |                                                 |                 | Not Reported |                |
|                                        | Quetiapine     |                    |                    | C               |                      |                                                 |                 | Not Reported |                |
|                                        | Trospium       |                    |                    | C               |                      |                                                 |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------------|----------------------|------------|------------|----------------|
| 29-Apr-2015              | 11047264      | EXPEDITED (15-DAY) |                    | HO              | JP-BRISTOL-MYERS SQUIBB COMPANY- |                      | 57 YR      | Male       | JPN            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

BMS-2015-023996

| <u>Preferred Term</u>                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>           |
|---------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------|
| Haemorrhage; Mania;<br>Tooth Fracture | Aripiprazole   |              |            | S           | Oral         | 3 Mg, Qd           |                 | Bristol Myers Squibb |
|                                       | Aripiprazole   |              |            | S           | Oral         | 6 Mg, Qd           |                 | Bristol Myers Squibb |
|                                       | Lexapro        |              |            | S           | Oral         | 10 Mg, Qd          |                 | Not Reported         |
|                                       | Lexapro        |              |            | S           | Oral         | 5 Mg, Qd           |                 | Not Reported         |
|                                       | Lexapro        |              |            | S           | Oral         | 15 Mg, Qd          |                 | Not Reported         |
|                                       | Lexapro        |              |            | S           | Oral         | 10 Mg, Qd          |                 | Not Reported         |
|                                       | Cymbalta       |              |            | S           | Oral         | 20 Mg, Qd          |                 | Not Reported         |
|                                       | Cymbalta       |              |            | S           | Oral         | 40 Mg, Qd          |                 | Not Reported         |
|                                       | Cymbalta       |              |            | S           | Oral         | 20 Mg, Qd          |                 | Not Reported         |
|                                       | Cymbalta       |              |            | S           | Oral         | 40 Mg, Qd          |                 | Not Reported         |
|                                       | Cymbalta       |              |            | S           | Oral         | 20 Mg, Qd          |                 | Not Reported         |
|                                       | Lunesta        |              |            | C           | Unknown      | Unk                |                 | Not Reported         |
|                                       | Estazolam      |              |            | C           | Unknown      | Unk                |                 | Not Reported         |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 29-Apr-2015              | 11074478      | EXPEDITED (15-DAY) |                    | OT              | DE-MYLANLABS-2015M1012853 |                      |            | Unknown    | DEU            |

| <u>Preferred Term</u>                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abortion Missed;<br>Exposure During<br>Pregnancy | Cipralext      |              |            | S           | Oral         | 10 Mg, Unk         |                 | Not Reported |
|                                                  | Mirtazapin     |              |            | S           | Oral         | 7.5 Mg, Unk        |                 | Mylan        |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 29-Apr-2015              | 11075572      | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2015144489 |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                       |                 |   |            |              |
|-----------------------|-----------------|---|------------|--------------|
| Drug Hypersensitivity | Vancomycin      | S | Unk        | Unknown      |
|                       | Clindamycin Hcl | S | Unk        | Pfizer       |
|                       | Clarithromycin  | S | Unk        | Pfizer       |
|                       | Zinacef         | S | Unk        | Not Reported |
|                       | Daptomycin      | S | Unk        | Not Reported |
|                       | Lexapro         | S | 10 Mg, Unk | Not Reported |
|                       | Nortriptyline   | S | Unk        | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Apr-2015              | 11075768      | EXPEDITED (15-DAY) |                    | HO, LT          | FR-FRI-1000076073    |                      | 52 YR      | Female     | FRA            |

| <u>Preferred Term</u>       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------|----------------|--------------|------------|-------------|--------------|-----------------------|-----------------|--------------|
| Overdose; Suicidal Ideation | Escitalopram   |              |            | S           | Oral         | 1 Df                  |                 | Forest       |
|                             | Escitalopram   |              |            | S           | Oral         | Overdose: 140 Mg Once |                 | Forest       |
|                             | Zolpidem       |              |            | S           | Oral         | 1 Df                  |                 | Not Reported |
|                             | Zolpidem       |              |            | S           | Oral         | Overdose: 140 Mg Once |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 29-Apr-2015              | 11076307      | EXPEDITED (15-DAY) |                    | OT              | CH-ASTRAZENECA-2015SE25417 |                      | 34 YR      | Male       | CHE            |

| <u>Preferred Term</u>                                                                                                                                                | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                           | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|--------------|------------|-------------|--------------|------------------------------------------------------------------------------|-----------------|--------------|
| Adjustment Disorder With Depressed Mood; Aggression; Attention Deficit/Hyperactivity Disorder; Drug Abuse; Drug Interaction; Rash; Suicide Attempt; Weight Decreased | Seroquel            |              |            | S           | Oral         |                                                                              |                 | Not Reported |
|                                                                                                                                                                      | Seroquel            |              |            | S           | Oral         |                                                                              |                 | Not Reported |
|                                                                                                                                                                      | Ritalin             |              |            | S           | Unknown      |                                                                              |                 | Not Reported |
|                                                                                                                                                                      | Escitalopram        |              |            | S           | Unknown      |                                                                              |                 | Not Reported |
|                                                                                                                                                                      | Temesta (Lorazepam) |              |            | C           |              | 1mg Temesta With Each Sequase, 2.5mg For Severe Panic And 2.5mg For Sleeping |                 | Not Reported |
|                                                                                                                                                                      | Temesta             |              |            | C           |              | 1mg Temesta With Each Sequase, 2.5mg For                                     |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|              |   |                                       |                                        |              |
|--------------|---|---------------------------------------|----------------------------------------|--------------|
|              |   |                                       | Severe Panic And 2.5mg<br>For Sleeping |              |
| Stilnox      | C |                                       |                                        | Not Reported |
| Sirdalud     | C | 1-2x /4 Mg                            |                                        | Not Reported |
| Dafalgan     | C | 1-2 G                                 |                                        | Not Reported |
| Centrum      | C |                                       |                                        | Not Reported |
| Lutein       | C |                                       |                                        | Not Reported |
| Calcimagon   | C |                                       |                                        | Not Reported |
| Magnesium    | C |                                       |                                        | Not Reported |
| Buscopan     | C | Several Doses                         |                                        | Not Reported |
| Tramal Drops | C | 500 Mg Combined With 30<br>Mg Codeine |                                        | Not Reported |
| Kreon        | C | 1000                                  |                                        | Not Reported |
| Vit B12      | C |                                       |                                        | Not Reported |
| Vit D3       | C |                                       |                                        | Not Reported |
| Ferritin     | C |                                       |                                        | Not Reported |
| Collusanol   | C |                                       |                                        | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Apr-2015              | 11082020      | EXPEDITED (15-DAY) | Y                  | HO              | NSR_02056_2015       |                      | 58 YR      | Male       | CHE            |

| <u>Preferred Term</u>                                                                                                                                                                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Aggression; Alcohol Use;<br>Disinhibition; Family<br>Stress; Irritability; Mania;<br>Psychomotor<br>Hyperactivity; Psychotic<br>Disorder; Serotonin<br>Syndrome; Substance<br>Use; Theft | Tramadol       |              |            | S           |              | (Df)               | 1 MTH           | Not Reported |
|                                                                                                                                                                                          | Escitalopram   |              |            | S           |              |                    | 6 MTH           | Not Reported |
|                                                                                                                                                                                          | Quetiapine     |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                          | Oxazepam       |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                          | Alprazolam     |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                          | Zolpidem       |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                          | Metformin      |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                          | Atorvastatin   |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                          | Alfuzosin      |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                          | Trospium       |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                          | Acetaminophen  |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                          | Ibuprofen      |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                          | Triamcinolone  |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|----------------------------|--------------------------|--------------------|--------------------|-----------------|--------------------------------------------|----------------------|-----------------|-----------------|----------------|
| 30-Apr-2015                | 10656709                 | EXPEDITED (15-DAY) |                    | OT              | US-AMGEN-<br>USASL2014096700               |                      | 77 YR           | Female          | USA            |
| <u>Preferred Term</u>      | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Arthralgia; Chills;        | Enbrel                   |                    |                    | S               | Unknown                                    | 50 Mg, Qwk           |                 | Amgen           |                |
| Condition Aggravated;      | Lexapro                  |                    |                    | S               | Unknown                                    | Unk                  |                 | Not Reported    |                |
| Dizziness; Fall; Fatigue;  | Methotrexate             |                    |                    | C               |                                            | #4 2.5mg Pills Once  |                 | Not Reported    |                |
| Hyperhidrosis; Injection   |                          |                    |                    |                 |                                            | Weekly               |                 |                 |                |
| Site Bruising; Joint       | Oxycodone                |                    |                    | C               |                                            | Unk, Bid             |                 | Not Reported    |                |
| Swelling; Limb Injury;     |                          |                    |                    |                 |                                            |                      |                 |                 |                |
| Mobility Decreased; Pain;  |                          |                    |                    |                 |                                            |                      |                 |                 |                |
| Pain In Extremity; Rash    |                          |                    |                    |                 |                                            |                      |                 |                 |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 30-Apr-2015                | 10728743                 | EXPEDITED (15-DAY) |                    | LT              | SE-009507513-<br>1501SWE005439             |                      | 23 YR           | Female          | SWE            |
| <u>Preferred Term</u>      | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Depressed Level Of         | Loratadine               |                    |                    | S               | Oral                                       |                      |                 | Merck           |                |
| Consciousness;             | Cipralax                 |                    |                    | S               | Oral                                       |                      |                 | Not Reported    |                |
| Electrocardiogram          | Tavegyl                  |                    |                    | S               | Oral                                       |                      |                 | Not Reported    |                |
| Abnormal; Muscle           | Postafen (Meclozine      |                    |                    | S               | Oral                                       |                      |                 | Not Reported    |                |
| Twitching; Somnolence;     | Hydrochloride)           |                    |                    |                 |                                            |                      |                 |                 |                |
| Toxicity To Various Agents | Cetirizine Hydrochloride |                    |                    | S               | Oral                                       |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 30-Apr-2015                | 11053111                 | EXPEDITED (15-DAY) |                    |                 | US-<br>GLAXOSMITHKLINE-<br>US2015GSK046104 |                      |                 | Male            | USA            |
| <u>Preferred Term</u>      | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Balance Disorder           | Wellbutrin XI Tablet     |                    |                    | S               | Oral                                       | 450 Mg, Qd           |                 | Glaxosmithkline |                |
|                            | Lexapro                  |                    |                    | S               | Oral                                       | Unk, U               |                 | Not Reported    |                |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                   | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------|-------------------------------------|--------------------|--------------------|-----------------|---------------------------------------|----------------------|-----------------|--------------|----------------|
| 30-Apr-2015                                                                                | 11080019                            | EXPEDITED (15-DAY) |                    | HO, OT          | US-APOTEX-2015AP008855                |                      | 17 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                      | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrioventricular Block Complete; Hypotension; Overdose; Shock                              | Amlodipine Besylate                 |                    |                    | S               | Unknown                               | 20-25 Tablets        |                 | Apotex       |                |
|                                                                                            | Hydrochlorothiazide                 |                    |                    | S               | Unknown                               |                      |                 | Apotex       |                |
|                                                                                            | Buspirone Hydrochloride Tablets Usp |                    |                    | S               | Unknown                               |                      |                 | Apotex       |                |
|                                                                                            | Clonazepam Tablets Usp              |                    |                    | S               | Unknown                               |                      |                 | Apotex       |                |
|                                                                                            | Dexamfetamine                       |                    |                    | S               | Unknown                               |                      |                 | Not Reported |                |
|                                                                                            | Lexapro                             |                    |                    | S               | Unknown                               |                      |                 | Not Reported |                |
|                                                                                            | Venlafaxine                         |                    |                    | S               | Unknown                               |                      |                 | Not Reported |                |
|                                                                                            | Prozac                              |                    |                    | S               | Unknown                               |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                   | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Apr-2015                                                                                | 11080152                            | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000076236                     |                      | 59 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                      | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Gamma-Glutamyltransferase Increased; Leukopenia; Thrombocytopenia; Transaminases Increased | Escitalopram                        |                    |                    | S               | Oral                                  | 1 Df                 |                 | Forest       |                |
|                                                                                            | Exjade                              |                    |                    | S               | Oral                                  | 0.4286 Df            |                 | Not Reported |                |
|                                                                                            | Aranesp                             |                    |                    | C               | Subcutaneous                          | 0.1429 Df            |                 | Not Reported |                |
|                                                                                            | Glucidion                           |                    |                    | C               | Intravenous (not otherwise specified) |                      |                 | Not Reported |                |
|                                                                                            | Bromazepam                          |                    |                    | C               |                                       |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                   | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Apr-2015                                                                                | 11080153                            | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000076209                     |                      | 85 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                      | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anaemia; Drug Interaction; Epistaxis; International                                        | Escitalopram                        |                    |                    | S               | Oral                                  | 5 Mg                 |                 | Forest       |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                            |                        |   |         |           |              |
|----------------------------|------------------------|---|---------|-----------|--------------|
| Normalised Ratio Increased | Previscan (Fluindione) | S | Oral    | 10 Mg     | Not Reported |
|                            | Ramipril               | C | Unknown | 2.5 Mg    | Not Reported |
|                            | Cardensiel             | C | Unknown | 2.5 Mg    | Not Reported |
|                            | Furosemide             | C | Unknown | 40 Mg     | Not Reported |
|                            | Levothyrox             | C | Unknown | 25 Mcg    | Not Reported |
|                            | Dafalgan               | C | Unknown | If Needed | Not Reported |
|                            | Oxybutynine            | C | Unknown | 1 Df      | Not Reported |
|                            | Arestal                | C | Unknown | 1 Mg      | Not Reported |
|                            | Noctamide              | C | Unknown | 1 Mg      | Not Reported |
|                            | Uvedose                | C | Unknown |           | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Apr-2015              | 11080992      | DIRECT           |                    |                 |                      |                      | 68 YR      | Female     | USA            |

| <u>Preferred Term</u>                                               | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Ineffective; Product Quality Issue; Product Substitution Issue | Escitalopram        |              |            | S           | Oral         | One                |                 | Aurobindo    |
|                                                                     | Lexapro             |              |            | C           |              |                    |                 | Not Reported |
|                                                                     | Telmisartan         |              |            | C           |              |                    |                 | Not Reported |
|                                                                     | Hydrochlorothiazide |              |            | C           |              |                    |                 | Not Reported |
|                                                                     | Atenolol            |              |            | C           |              |                    |                 | Not Reported |
|                                                                     | Celebrex            |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Apr-2015              | 11081430      | DIRECT           | Y                  |                 |                      |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                      | <u>Product</u>  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------|-----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Product Substitution Issue; Therapeutic Response Decreased | Generic Lexapro |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-May-2015              | 11075733      | EXPEDITED (15-DAY) |                    | OT              | PHHY2015US048685     |                      | 49 YR      | Female     | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                               | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
|-----------------------------------------------------------------------------------------------------|-----------------------|--------------------|--------------------|-----------------|---------------------------|---------------------------------|-----------------|--------------|----------------|
| Bipolar Disorder; Product Dispensing Error; Product Use In Unapproved Indication; Suicidal Ideation | Oxcarbazepine         |                    |                    | S               | Unknown                   | 300 Mg, Bid                     |                 | Not Reported |                |
|                                                                                                     | Lamotrigine           |                    |                    | S               | Unknown                   | 350 Mg, Qhs                     |                 | Novartis     |                |
|                                                                                                     | Escitalopram          |                    |                    | S               | Unknown                   | 25 Mg, Qd                       |                 | Not Reported |                |
|                                                                                                     | Alprazolam            |                    |                    | S               | Unknown                   | 1 Mg, Qd As Needed.             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                            | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-May-2015                                                                                         | 11087577              | DIRECT             |                    |                 |                           |                                 | 28 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                               | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Fatigue; Headache; Nausea; Tremor                                                                   | Lexapro               |                    |                    | S               | Oral                      | 5mg, Once Daily, Taken By Mouth |                 | Lupin        |                |
| <u>FDA Received Date</u>                                                                            | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-May-2015                                                                                         | 11086278              | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2015M1014178 |                                 |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                                               | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Staphylococcal Infection                                                                   | Cytarabine            |                    |                    | S               |                           | Unk                             |                 | Mylan        |                |
|                                                                                                     | Nardil                |                    |                    | S               |                           | 15 Mg, Qid                      |                 | Not Reported |                |
|                                                                                                     | Nardil                |                    |                    | S               |                           | 15 Mg, Qd                       |                 | Not Reported |                |
|                                                                                                     | Nardil                |                    |                    | S               |                           | 30 Mg, Qd                       |                 | Not Reported |                |
|                                                                                                     | Nardil                |                    |                    | S               |                           | 45 Mg, Qd                       |                 | Not Reported |                |
|                                                                                                     | Xanax                 |                    |                    | S               |                           | 0.5 Mg, Tid                     |                 | Not Reported |                |
|                                                                                                     | Xanax                 |                    |                    | S               |                           | 1 Mg, Tid                       |                 | Not Reported |                |
|                                                                                                     | Klonopin              |                    |                    | S               |                           | Unk                             |                 | Not Reported |                |
|                                                                                                     | Klonopin              |                    |                    | S               |                           |                                 |                 | Not Reported |                |
|                                                                                                     | Escitalopram          |                    |                    | S               |                           | 10 Mg, Bid                      |                 | Not Reported |                |
|                                                                                                     | Escitalopram          |                    |                    | S               |                           |                                 |                 | Not Reported |                |
|                                                                                                     | Antibiotic /00011701/ |                    |                    | C               |                           | Unk                             |                 | Not Reported |                |
| Fluconazole                                                                                         |                       |                    | C                  |                 | Unk                       |                                 | Not Reported    |              |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                      |   |     |              |
|----------------------|---|-----|--------------|
| Pepcid /00305201/    | C | Unk | Not Reported |
| Compazine /00013302/ | C | Unk | Not Reported |
| Acyclovir /00587301/ | C | Unk | Not Reported |
| Rituxan              | S | Unk | Not Reported |
| Bendamustine         | S | Unk | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-May-2015              | 10646815      | EXPEDITED (15-DAY) |                    | OT              | DE-FRI-1000073038    |                      | 59 YR      | Female     | DEU            |

| <u>Preferred Term</u>                                                     | <u>Product</u>             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>  | <u>Dosage Text</u>                                                                | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------|----------------------------|--------------|------------|-------------|---------------|-----------------------------------------------------------------------------------|-----------------|--------------|
| Condition Aggravated;<br>Electrocardiogram Qt<br>Prolonged; Extrasystoles | Escitalopram Oral Solution |              |            | S           | Oral          | Started With 1 Mg/Day,<br>Increased By 1 Mg Every<br>Three Days Up To 6<br>Mg/Day |                 | Forest       |
|                                                                           | Diltahexal                 |              |            | C           | Oral          | 180 Mg                                                                            |                 | Not Reported |
|                                                                           | Imap                       |              |            | C           | Intramuscular |                                                                                   |                 | Not Reported |
|                                                                           | Imap                       |              |            | C           | Intramuscular |                                                                                   |                 | Not Reported |
|                                                                           | Alprazolam                 |              |            | C           | Unknown       | As Needed 0.5 To 1<br>Mg/Day                                                      |                 | Not Reported |
|                                                                           | Thyroxin                   |              |            | C           | Oral          | 100 Micrograms                                                                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 04-May-2015              | 10908164      | EXPEDITED (15-DAY) |                    | HO, LT          | US-MERCK-<br>1503USA003903 |                      | 47 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>     | <u>Dosage Text</u>                                                                     | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|------------------|----------------------------------------------------------------------------------------|-----------------|--------------|
| Diarrhoea;<br>Electrocardiogram Qt<br>Prolonged; Hypokalaemia;<br>Lung Infection; Nausea | Vorinostat     |              |            | S           | Oral             | 500mg, Tid, On Days 1-3,<br>Cycle 1                                                    |                 | Merck        |
|                                                                                          | Vorinostat     |              |            | S           | Oral             | 500mg, Tid, Total Dose<br>Administered This Course<br>4500 Mg, On Days 1-3,<br>Cycle 4 |                 | Merck        |
|                                                                                          | Idarubicin     |              |            | S           | Intravenous (not | 12 Mg/M2, Qd On Days 4-                                                                |                 | Not Reported |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                         |   |                                       |                                                                                |              |
|-------------------------|---|---------------------------------------|--------------------------------------------------------------------------------|--------------|
| Idarubicin              | S | otherwise specified)                  | 6, Cycle 1                                                                     | Not Reported |
|                         |   | Intravenous (not otherwise specified) | 8 Mg/M2, Qd On Days 4-5, Cycle 4, Total Dose Administered This Course 192.3 Mg |              |
| Cytarabine              | S | Intravenous (not otherwise specified) | 1500 Mg/M2/Day On Days 4-7, Cycle 1                                            | Not Reported |
| Cytarabine              | S | Intravenous (not otherwise specified) | 750 Mg/M2/Day, On Days 4-6, Cycle 4                                            | Not Reported |
| Compazine               | S |                                       | Unk                                                                            | Not Reported |
| Posaconazole            | S | Oral                                  | Unk                                                                            | Merck        |
| Zofran                  | S |                                       | Unk                                                                            | Not Reported |
| Acyclovir               | S |                                       | Unk                                                                            | Not Reported |
| Amlodipine              | S |                                       | Unk                                                                            | Not Reported |
| Ciprofloxacin           | S |                                       | Unk                                                                            | Not Reported |
| Fluconazole             | S |                                       | Unk                                                                            | Not Reported |
| Lexapro                 | S |                                       | Unk                                                                            | Not Reported |
| Tramadol Hydrochloride  | S |                                       | Unk                                                                            | Not Reported |
| Bupropion Hydrochloride | C |                                       | Unk                                                                            | Not Reported |

|                          |               |                    |                    |                 |                                                             |                      |            |            |                |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------------------|----------------------|------------|------------|----------------|
| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                        | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
| 04-May-2015              | 11046214      | EXPEDITED (15-DAY) |                    | HO, OT          | CH-SUN<br>PHARMACEUTICAL<br>INDUSTRIES LTD-<br>2015RR-94738 |                      | 58 YR      | Male       | CHE            |

| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>  | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|----------------|--------------|------------|-------------|---------------|-----------------------------------------------|-----------------|--------------|
| Mania; Serotonin Syndrome | Tramadol       |              |            | S           | Unknown       | Exact Dose Not Known, 50mg Bid Was Prescribed |                 | Sun          |
|                           | Escitalopram   |              |            | S           | Unknown       | 20 Mg, Daily                                  |                 | Not Reported |
|                           | Triamcinolone  |              |            | S           | Intramuscular | 2 X 40 Mg, 1 Month Apart                      |                 | Ranbaxy      |
|                           | Cannabis       |              |            | S           | Unknown       | Unk                                           |                 | Not Reported |
|                           | Quetiapine     |              |            | C           | Unknown       | 300 Mg, Daily                                 |                 | Not Reported |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|               |   |         |                                                  |              |
|---------------|---|---------|--------------------------------------------------|--------------|
| Quetiapine    | C | Unknown | Increased Progressively<br>Up To1000 Mg, Daily   | Not Reported |
| Quetiapine    | C | Unknown | 800 Mg, Daily                                    | Not Reported |
| Alprazolam    | C | Unknown | 2 Mg, Daily                                      | Not Reported |
| Zolpidem      | C | Unknown | 12.5 Mg, Daily                                   | Not Reported |
| Baclofen      | C | Unknown | 150 Mg, Daily                                    | Not Reported |
| Oxazepam      | C | Unknown | 60 Mg, Daily                                     | Not Reported |
| Oxazepam      | C | Unknown | Progressiveley Increased<br>Tup To 180 Mg, Daily | Not Reported |
| Candesartan   | C | Unknown | 8 Mg, Daily                                      | Not Reported |
| Metformin     | C | Unknown | 500 Mg, Daily                                    | Not Reported |
| Alfuzosin     | C | Unknown | 10 Mg, Daily                                     | Not Reported |
| Trospium      | C | Unknown | 20 Mg, Daily                                     | Not Reported |
| Acetaminophen | C | Unknown | 4 G, Daily                                       | Not Reported |
| Ibuprofen     | C | Unknown | 1800 Mg, Daily                                   | Not Reported |
| Atorvastatin  | C | Unknown | 20 Mg, Daily                                     | Not Reported |

| <u>FDA Received Date</u>                                                                                                                | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|------------------------------------|----------------------|-----------------|--------------|----------------|
| 04-May-2015                                                                                                                             | 11086718                    | EXPEDITED (15-DAY) |                    | HO, OT          | US-DRREDDYS-<br>USA/USA/15/0047720 |                      | 48 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                   | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                       | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Acute Kidney Injury;<br>Catatonia; Compartment<br>Syndrome; Hypotension;<br>Pyrexia; Respiratory<br>Failure; Rhabdomyolysis;<br>Seizure | Quetiapine Fumarate Tablets |                    |                    | S               | Unknown                            |                      |                 | Not Reported |                |
|                                                                                                                                         | Quetiapine Fumarate Tablets |                    |                    | S               |                                    |                      |                 | Not Reported |                |
|                                                                                                                                         | Clozapine                   |                    |                    | S               | Unknown                            |                      |                 | Not Reported |                |
|                                                                                                                                         | Clozapine                   |                    |                    | S               |                                    |                      |                 | Not Reported |                |
|                                                                                                                                         | Escitalopram                |                    |                    | S               | Unknown                            |                      |                 | Not Reported |                |
|                                                                                                                                         | Escitalopram                |                    |                    | S               |                                    |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|-------------------------------------|----------------------|-----------------|------------|----------------|
| 04-May-2015              | 11087450       | EXPEDITED (15-DAY) |                    | OT              | IN-AUROBINDO-AUR-<br>APL-2015-03898 |                      | 21 YR           | Male       | IND            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                             |                    |   |         |              |              |
|-----------------------------|--------------------|---|---------|--------------|--------------|
| Consciousness               | Escitalopram 20 Mg | S | Unknown | 20 Mg, Daily | Aurobindo    |
| Fluctuating; Delirium; Drug | Escitalopram 20 Mg | S |         |              | Aurobindo    |
| Interaction; Dyskinesia;    | Olanzapine         | S | Unknown | 5 Mg, Daily  | Not Reported |
| Hyperaesthesia;             | Olanzapine         | S |         |              | Not Reported |
| Poisoning; Soliloquy;       | Cannabis           | S | Unknown |              | Not Reported |
| Somnolence                  |                    |   |         |              |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------|----------------------|------------|------------|----------------|
| 04-May-2015              | 11087480      | EXPEDITED (15-DAY) | HO                 |                 | IN-AUROBINDO-AUR-<br>APL-2015-03952 |                      | 71 YR      | Female     | IND            |

| <u>Preferred Term</u>                | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--------------------------------------|--------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Joint Swelling; Oedema<br>Peripheral | Escitalopram 10 Mg |              |            | S           | Unknown      | 10 Mg, Daily       |                 | Aurobindo  |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-May-2015              | 11087512      | EXPEDITED (15-DAY) | HO                 |                 | FR-FRI-1000076258    |                      | 56 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cholestasis           | Escitalopram            |              |            | S           | Oral         | 15 Mg              |                 | Forest       |
|                       | Tegretol                |              |            | S           | Oral         | 2 Df               |                 | Not Reported |
|                       | Alepsal (Phenobarbital) |              |            | S           | Unknown      | 100 Mg             |                 | Not Reported |
|                       | Alepsal (Phenobarbital) |              |            | S           | Unknown      | 250 Mg             |                 | Not Reported |
|                       | Valium Roche            |              |            | S           | Oral         | 3 Df               |                 | Not Reported |
|                       | Difclir                 |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-May-2015              | 10834062      | EXPEDITED (15-DAY) | OT                 |                 | CA-FRI-1000074585    |                      | 42 YR      | Female     | CAN            |

| <u>Preferred Term</u>                                                                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u> |
|-------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------------|-----------------|------------|
| Loss Of Personal<br>Independence In Daily<br>Activities; Transient<br>Ischaemic Attack; Vertigo | Escitalopram   |              |            | S           | Oral         | Daily Dose Not Reported. |                 | Forest     |
|                                                                                                 | Escitalopram   |              |            | S           |              |                          |                 | Forest     |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------|----------------|--------------------|--------------------|-----------------|------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 05-May-2015                | 11089298       | EXPEDITED (15-DAY) |                    | HO              | TR-LUPIN<br>PHARMACEUTICALS<br>INC.-2015-01072 |                      | 21 YR           | Male         | TUR            |
| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Delirium; Drug Interaction | Escitalopram   |                    |                    | S               | Unknown                                        | 20 Mg/Day            |                 | Not Reported |                |
|                            | Escitalopram   |                    |                    | S               |                                                |                      |                 | Not Reported |                |
|                            | Olanzapine     |                    |                    | S               |                                                | 5 Mg/Day             |                 | Not Reported |                |
|                            | Olanzapine     |                    |                    | S               |                                                |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                                                                                                                                              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|------------------|----------------|
| 05-May-2015                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 11089968             | EXPEDITED (15-DAY) |                    | HO, OT          | CH-<br>ELI_LILLY_AND_COMP<br>ANY-CH201504008853 |                      | 82 YR           | Female           | CHE            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |
| Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Biliary Dilatation; Blood Alkaline Phosphatase Increased; Blood Urea Increased; C-Reactive Protein Increased; Clavicle Fracture; Cogwheel Rigidity; Depressed Level Of Consciousness; Fall; Gallbladder Disorder; Gamma-Glutamyltransferase Increased; Hepatitis; Hyperammonaemia; Hyperbilirubinaemia; Lethargy; Psychomotor Retardation; Pyrexia; Somnolence; Ultrasound Abdomen Abnormal | Zyprexa              |                    |                    | S               | Oral                                            | 2.5 Mg, Bid          |                 | Eli Lilly And Co |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Zyprexa              |                    |                    | S               | Oral                                            | 2.5 Mg, Bid          |                 | Eli Lilly And Co |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Cipralext /01588501/ |                    |                    | S               | Oral                                            | 5 Mg, Qd             |                 | Not Reported     |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Atorvastatin         |                    |                    | S               | Unknown                                         |                      |                 | Not Reported     |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Prolia               |                    |                    | C               | Subcutaneous                                    | 60 Mg, Unk           |                 | Not Reported     |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Prednisone           |                    |                    | C               | Oral                                            | 15 Mg, Qd            |                 | Not Reported     |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Euthyrox             |                    |                    | C               | Oral                                            | 100 Ug, Qd           |                 | Not Reported     |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Atacand              |                    |                    | C               | Oral                                            | 8 Mg, Qd             |                 | Not Reported     |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Simcora              |                    |                    | C               | Oral                                            | 40 Mg, Qd            |                 | Not Reported     |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Enoxaparin Sodium    |                    |                    | C               | Subcutaneous                                    | 40 Mg, Qd            |                 | Not Reported     |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Tramadol             |                    |                    | C               | Oral                                            | 12.5 Mg, Tid         |                 | Not Reported     |                |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                   | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------|------------------------------------|--------------------|--------------------|-----------------|----------------------|------------------------------------------------|-----------------|--------------|----------------|
| 05-May-2015                                                                                                                | 11092043                           | EXPEDITED (15-DAY) |                    | OT              | BR-FRI-1000076344    |                                                | 95 YR           | Female       | BRA            |
| <u>Preferred Term</u>                                                                                                      | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                             | <u>Duration</u> | <u>Mfr</u>   |                |
| Deafness; Hallucination                                                                                                    | Escitalopram Oral Solution         |                    |                    | S               | Oral                 |                                                |                 | Forest       |                |
|                                                                                                                            | Escitalopram Oral Solution         |                    |                    | S               | Oral                 |                                                |                 | Forest       |                |
|                                                                                                                            | Synthroid                          |                    |                    | C               | Oral                 |                                                |                 | Not Reported |                |
|                                                                                                                            | Aspirin Prevent                    |                    |                    | C               | Oral                 | 100 Mg                                         |                 | Not Reported |                |
|                                                                                                                            | Ictus                              |                    |                    | C               | Oral                 | 12 Mg                                          |                 | Not Reported |                |
|                                                                                                                            | Lasix                              |                    |                    | C               | Oral                 |                                                |                 | Not Reported |                |
|                                                                                                                            | Vasopril [Enalapril Maleate]       |                    |                    | C               | Oral                 | 10 Mg                                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                   | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-May-2015                                                                                                                | 11096132                           | EXPEDITED (15-DAY) |                    | HO              | INS201504-000147     |                                                | 42 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                      | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                             | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Off Label Use; Serotonin Syndrome                                                                        | Subsys Sublingual Spray (Fentanyl) |                    |                    | S               |                      | Up To 4 Doses A Day                            |                 | Not Reported |                |
|                                                                                                                            | Escitalopram (Escitalopram)        |                    |                    | S               |                      | 20 Mg, 1.5 Tablet Total<br>Atleast 8 Years Ago |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                   | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-May-2015                                                                                                                | 11094735                           | EXPEDITED (15-DAY) |                    | OT              | CN-FRI-1000076287    |                                                | 30 YR           | Male         | CHN            |
| <u>Preferred Term</u>                                                                                                      | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                             | <u>Duration</u> | <u>Mfr</u>   |                |
| Chest Discomfort; Depressed Mood; Heart Rate Increased; Hypoaesthesia Oral; Incorrect Dose Administered; Mental Impairment | Lexapro                            |                    |                    | S               | Oral                 |                                                |                 | Forest       |                |
|                                                                                                                            | Olanzapine                         |                    |                    | C               | Oral                 |                                                |                 | Not Reported |                |
|                                                                                                                            | Baishike                           |                    |                    | C               | Oral                 |                                                |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                           | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 06-May-2015                                                                                                                        | 11095964       | DIRECT           |                    | LT              |                      |                      | 8 YR            | Female       | USA            |
| <u>Preferred Term</u>                                                                                                              | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Behaviour;<br>Aggression; Aggression;<br>Intentional Self-Injury;<br>Product Quality Issue;<br>Product Substitution Issue | Escitalopram   |                  |                    | S               | Oral                 | 1 Pill               |                 | Camber       |                |
|                                                                                                                                    | Escitalopram   |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                    | Melatonin      |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                    |                |                  |                    |                 |                      |                      |                 |              |                |

| <u>FDA Received Date</u>                                                                                                                                                                                                                                                             | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|--------------------|--------------------|-----------------|-------------------------------------|------------------------------------|-----------------|--------------|----------------|
| 07-May-2015                                                                                                                                                                                                                                                                          | 10853827                                | EXPEDITED (15-DAY) |                    | HO              | US-AUROBINDO-AUR-<br>APL-2015-01440 |                                    | 27 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                        | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Blood Pressure<br>Abnormal; Clonus;<br>Confusional State; Drug<br>Level Above Therapeutic;<br>Hyperhidrosis;<br>Hyperreflexia; Hypotonia;<br>Mental Status Changes;<br>Muscle Rigidity;<br>Myoclonus; Overdose;<br>Serotonin Syndrome;<br>Sinus Tachycardia; Skin<br>Warm | Alprazolam 1mg                          |                    |                    | S               | Unknown                             | 1 Mg, At Bed Time                  |                 | Aurobindo    |                |
|                                                                                                                                                                                                                                                                                      | Escitalopram                            |                    |                    | S               | Unknown                             | 30 Mg, Daily                       |                 | Aurobindo    |                |
|                                                                                                                                                                                                                                                                                      | Quetiapine 200mg                        |                    |                    | S               | Unknown                             | 200 Mg, At Bed Time                |                 | Aurobindo    |                |
|                                                                                                                                                                                                                                                                                      | Butalbital, Acetaminophen &<br>Caffeine |                    |                    | S               | Unknown                             | 50/325/40 Mg, Two Times<br>A Day   |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                      | Clonazepam                              |                    |                    | S               | Unknown                             | 1 Mg, 3 Times A Day                |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                      | Metaxalone                              |                    |                    | S               | Unknown                             | Three Extra Tablets 7 H<br>Earlier |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                      | Mometasone                              |                    |                    | S               | Unknown                             | 50 Mcg/Act 2 Sprays Daily          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                      | Prazosin                                |                    |                    | S               | Unknown                             | 2 Mg, At Bed Time                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                      | Prednisone                              |                    |                    | S               | Oral                                | 40 Mg, Daily                       |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                      | Propranolol                             |                    |                    | S               | Unknown                             | 80 Mg, Daily                       |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                      | Triamcinolone                           |                    |                    | S               | Unknown                             | 0.1 %, Two Times A Day             |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 07-May-2015              | 11069826       | EXPEDITED (15-DAY) |                    | HO, OT          | US-UCBSA-2015012258  |                      | 26 YR           | Female     | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                                                                                                                                    |                                                                                |                                 |      |                                                                                                  |                                                                                                     |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------|---------------------------------|------|--------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Abortion Spontaneous;<br>Decreased Appetite;<br>Dysphemia; Ectopic<br>Pregnancy; Generalised<br>Anxiety Disorder;<br>Hypoaesthesia; Post-<br>Traumatic Stress Disorder;<br>Pregnancy; Pregnancy<br>With Contraceptive<br>Device; Sinus<br>Tachycardia; Tremor;<br>Vaginal Haemorrhage;<br>Vision Blurred; Vomiting | Keppra Xr<br>Lexapro<br>Nuvaring<br>Buspar<br>Vitamins Nos<br>Jolessa<br>Xanax | S<br>S<br>S<br>S<br>C<br>C<br>C | Oral | 1000 Mg, Once Daily (Qd)<br>5 Mg/2 Daily<br>Unk<br>Unk<br>Unk<br>Unk<br>0.25 Mg, Once Daily (Qd) | Ucb<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------|---------------------------------|------|--------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-May-2015              | 11098384      | EXPEDITED (15-DAY) |                    | DE              | PHHY2015FR054613     |                      | 91 YR      | Female     | FRA            |

| <u>Preferred Term</u>                     | <u>Product</u>                       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------|--------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Serotonin Syndrome;<br>Torsade De Pointes | Rasilez                              |              |            | S           | Oral         | 300 Mg, Qd         |                 | Novartis     |
|                                           | Nisis                                |              |            | S           | Oral         | 160 Mg, Bid        |                 | Not Reported |
|                                           | Atarax//Hydroxyzine<br>Hydrochloride |              |            | S           | Oral         | 2 Df, Qd           |                 | Not Reported |
|                                           | Oflocet                              |              |            | S           | Oral         | 200 Mg, Bid        |                 | Not Reported |
|                                           | Seroplex                             |              |            | S           | Oral         | 10 Mg, Qd          |                 | Not Reported |
|                                           | Seroplex                             |              |            | S           | Oral         | 15 Mg, Qd          |                 | Not Reported |
|                                           | Lexomil                              |              |            | S           | Oral         | 0.5 Df, Tid        |                 | Not Reported |
|                                           | Hyperium                             |              |            | S           | Oral         | 1 Mg, Bid          |                 | Not Reported |
|                                           | Hyperium                             |              |            | S           | Oral         | 1 Mg, Qd           |                 | Not Reported |
|                                           | Inexium//Esomeprazole Sodium         |              |            | S           | Oral         | 40 Mg, Qd          |                 | Not Reported |
|                                           | Dafalgan                             |              |            | C           | Oral         | 1 G, Tid           |                 | Not Reported |
|                                           | Tardyferon                           |              |            | C           | Oral         | 80 Mg, Bid         |                 | Not Reported |
|                                           | Fumafer                              |              |            | C           | Unknown      |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                               | <u>Case #</u>                                                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|-----------------------------------------------------------------|-----------------|--------------|----------------|
| 07-May-2015                                                                                                                            | 11102244                                                                   | EXPEDITED (15-DAY) | Y                  | HO, RI          | US-H14001-15-00648   |                                                                 | 17 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                  | <u>Product</u>                                                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                              | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrioventricular Block Complete; Ejection Fraction Decreased; Heart Rate Decreased; Hypotension; Intentional Overdose; Lethargy; Shock | Amlodipine (Amlodipine) (5 Milligram, Tablets) (Amlodipine)                |                    |                    | S               |                      | Unknown, 20-25 Tablets Of 5 Mg                                  |                 | Not Reported |                |
|                                                                                                                                        | Hydrochlorothiazide (Hydrochlorothiazide) (Unknown)                        |                    |                    | S               |                      |                                                                 |                 | Not Reported |                |
|                                                                                                                                        | Buspiron (Buspiron) (Hyoscine Butylbromide, Metamizole Sodium Monohydrate) |                    |                    | S               |                      |                                                                 |                 | Not Reported |                |
|                                                                                                                                        | Dexamfetamine (Dexamfetamine) (Unknown)                                    |                    |                    | S               |                      |                                                                 |                 | Not Reported |                |
|                                                                                                                                        | Lexapro (Escitalopram Oxalate) (Escitalopram Oxalate)                      |                    |                    | S               |                      |                                                                 |                 | Not Reported |                |
|                                                                                                                                        | Venlafaxine (Venlafaxine)                                                  |                    |                    | S               |                      |                                                                 |                 | Not Reported |                |
|                                                                                                                                        | Prozac (Fluoxetine Hydrochloride) (Fluoxetine Hydrochloride)               |                    |                    | S               |                      |                                                                 |                 | Not Reported |                |
|                                                                                                                                        | Clonazepam (Clonazepam)                                                    |                    |                    | S               |                      |                                                                 |                 | Not Reported |                |
|                                                                                                                                        | (Clonazepam)                                                               |                    |                    |                 |                      |                                                                 |                 |              |                |
|                                                                                                                                        |                                                                            |                    |                    |                 |                      |                                                                 |                 |              |                |
| <u>FDA Received Date</u>                                                                                                               | <u>Case #</u>                                                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-May-2015                                                                                                                            | 11115108                                                                   | NON-EXPEDITED      | Y                  | HO, OT          | 2015AP005135         |                                                                 | 35 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                  | <u>Product</u>                                                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                              | <u>Duration</u> | <u>Mfr</u>   |                |
| Serotonin Syndrome                                                                                                                     | Sertraline Hydrochloride (Sertraline) Tablet                               |                    |                    | S               |                      |                                                                 |                 | Not Reported |                |
|                                                                                                                                        | Escitalopram Oxalate (Escitalopram) Tablet                                 |                    |                    | S               |                      |                                                                 | 1 YR            | Not Reported |                |
|                                                                                                                                        | Garcinia Cambogia                                                          |                    |                    | S               |                      | 1000 Mg; Two Capsules Three Times A Day For The Previous 2-3 Mo | 2-3 MTH         | Not Reported |                |
|                                                                                                                                        | Baclofen                                                                   |                    |                    | C               |                      |                                                                 |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |                 |   |              |
|--|-----------------|---|--------------|
|  | Gabapentin      | C | Not Reported |
|  | Omeprazole      | C | Not Reported |
|  | Oxycodone       | C | Not Reported |
|  | Sildenafil      | C | Not Reported |
|  | Sildenafil      | C | Not Reported |
|  | Diphenhydramine | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 08-May-2015              | 10877848      | EXPEDITED (15-DAY) |                    | CA, OT          | US-PFIZER INC-2015073679 |                      |            | Male       | USA            |

| <u>Preferred Term</u>                                        | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------|-------------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Coarctation Of The Aorta; Maternal Exposure During Pregnancy | Zoloft            |              |            | S           | Transplacental | Unk                |                 | Pfizer       |
|                                                              | Sertraline Hcl    |              |            | S           | Transplacental | Unk                |                 | Pfizer       |
|                                                              | Lexapro           |              |            | S           | Transplacental | Unk                |                 | Not Reported |
|                                                              | Prenatal Vitamins |              |            | C           | Transplacental | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                               | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------------------------------|----------------------|------------|------------|----------------|
| 08-May-2015              | 11098898      | EXPEDITED (15-DAY) |                    | OT              | US-GLENMARK PHARMACEUTICALS EUROPE LIMITED-2015GMK |                      | 49 YR      | Female     | USA            |

| <u>Preferred Term</u>                                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|-------------------------|-----------------|--------------|
| Bipolar Disorder; Product Dispensing Error; Suicidal Ideation | Lamotrigine    |              |            | S           |              | 350 Mg, Qhs             |                 | Glenmark     |
|                                                               | Oxcarbazepine  |              |            | S           |              | 300 Mg, Bid             |                 | Glenmark     |
|                                                               | Escitalopram   |              |            | S           |              | 25 Mg, Qd               |                 | Not Reported |
|                                                               | Alprazolam     |              |            | S           |              | 1 Mg, Qid, As Necessary |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 09-May-2015              | 11101828      | EXPEDITED (15-DAY) |                    | DE, HO          | US-JNJFOC-20150502122 |                      | 75 YR      | Female     | USA            |

| <u>Preferred Term</u>                          | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------|------------------------|--------------|------------|-------------|--------------|-----------------------------------|-----------------|--------------|
| Drug Ineffective; Dysphagia; Pneumonia; Sepsis | Tylenol Extra Strength |              | Y          | S           | Unknown      | 2 Tabs In The Morning And At Noon |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                         |   |   |              |                                       |              |
|-------------------------|---|---|--------------|---------------------------------------|--------------|
| Tylenol Extra Strength  |   | S | Unknown      | 2 Tabs In The Morning<br>And At Noon  | Not Reported |
| Tylenol                 |   | S | Unknown      | 1 To 2 Tabs As Needed<br>Twice Daily) | Not Reported |
| Tylenol                 |   | S | Unknown      |                                       | Not Reported |
| Tylenol                 | Y | S | Unknown      |                                       | Not Reported |
| Tylenol                 |   | S | Unknown      | 1 To 2 Tabs As Needed<br>Twice Daily) | Not Reported |
| Acetylsalicylic Acid    | Y | S | Unknown      |                                       | Not Reported |
| Amlodipine              |   | S | Unknown      |                                       | Not Reported |
| Levothyroxine           |   | S | Unknown      |                                       | Not Reported |
| Furosemide              |   | S | Unknown      |                                       | Not Reported |
| Lansoprazole            |   | S | Unknown      |                                       | Not Reported |
| Meloxicam               |   | S | Unknown      |                                       | Not Reported |
| Senokot                 |   | S | Unknown      | At Bedtime                            | Not Reported |
| Quinapril               |   | S | Unknown      |                                       | Not Reported |
| Atenolol                |   | S | Unknown      |                                       | Not Reported |
| Docusate Sodium         |   | S | Unknown      |                                       | Not Reported |
| Nitro-Dur               |   | S | Unknown      | Daily                                 | Not Reported |
| Potassium Chloride      |   | S | Unknown      | Daily                                 | Not Reported |
| Humalog                 |   | S | Subcutaneous |                                       | Not Reported |
| Escitalopram            |   | S | Unknown      |                                       | Not Reported |
| Temazepam               |   | S | Unknown      | At Bedtime                            | Not Reported |
| Morphine                |   | S | Oral         |                                       | Not Reported |
| Vitamin                 |   | S | Unknown      | Daily                                 | Not Reported |
| Oxycodone-Acetaminophen |   | S | Unknown      |                                       | Not Reported |
| Oxycodone-Acetaminophen |   | S | Unknown      | 5/325 Mg At Bed Time                  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 11-May-2015              | 10748021      | EXPEDITED (15-DAY) | HO                 |                 | FR-JNJFOC-20150112085 |                      | < 1 DAY    | Male       | FRA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                             | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|-----------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| Agitation Neonatal; Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Respiratory Distress; Somnolence; Tremor | Risperdal      |                    |                    | S               | Transplacental           |                      |                 | Not Reported |                |
|                                                                                                                                   | Seroplex       |                    |                    | S               | Transplacental           |                      |                 | Not Reported |                |
|                                                                                                                                   | Theralene      |                    |                    | S               | Transplacental           |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                          | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-May-2015                                                                                                                       | 10873667       | EXPEDITED (15-DAY) |                    | HO, LT          | FR-JNJFOC-20150209628    |                      | 20 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                                             | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cholecystitis Infective; Colitis Ischaemic; Colitis Ulcerative; Lactic Acidosis; Metabolic Acidosis                               | Risperdal      |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                                                                                                                                   | Risperdal      |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                                                                                                                                   | Loxapac        |                    |                    | S               | Unknown                  |                      |                 | Not Reported |                |
|                                                                                                                                   | Loxapac        |                    |                    | S               | Unknown                  |                      |                 | Not Reported |                |
|                                                                                                                                   | Loxapac        |                    |                    | S               | Unknown                  |                      |                 | Not Reported |                |
|                                                                                                                                   | Loxapac        |                    |                    | S               | Unknown                  |                      |                 | Not Reported |                |
|                                                                                                                                   | Lepticur       |                    |                    | S               | Unknown                  |                      |                 | Not Reported |                |
|                                                                                                                                   | Lepticur       |                    |                    | S               | Unknown                  |                      |                 | Not Reported |                |
|                                                                                                                                   | Seroplex       |                    |                    | S               | Unknown                  |                      |                 | Not Reported |                |
|                                                                                                                                   | Seroplex       |                    |                    | S               | Unknown                  |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                          | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-May-2015                                                                                                                       | 10913761       | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2015087070 |                      | 74 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                             | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Potassium Decreased; Decreased Appetite; Drug Interaction; Electric Shock; Memory Impairment; Mental Disorder; Weight       | Effexor Xr     |                    |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                                                                                                                                   | Effexor Xr     |                    |                    | S               |                          | Unk, Alternate Day   |                 | Pfizer       |                |
|                                                                                                                                   | Tramadol       |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                                                                                                                                   | Tramadol       |                    |                    | S               |                          |                      |                 | Not Reported |                |

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|           |         |   |              |              |
|-----------|---------|---|--------------|--------------|
| Decreased | Lexapro | S | 10 Mg, Daily | Not Reported |
|           | Imuran  | S | Unk          | Not Reported |
|           | Asa     | C | Unk          | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------------------------------------|----------------------|------------|------------|----------------|
| 11-May-2015              | 11102689      | EXPEDITED (15-DAY) |                    | OT              | US-TARO<br>PHARMACEUTICALS<br>U.S.A., INC-<br>2015SUN01160 |                      | 49 YR      | Female     | USA            |

| <u>Preferred Term</u>                                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|---------------------|-----------------|--------------|
| Bipolar I Disorder; Product Dispensing Error; Suicidal Ideation | Lamotrigine    |              |            | S           | Unknown      | 350 Mg, At Bed Time |                 | Taro         |
|                                                                 | Escitalopram   |              |            | S           | Unknown      | 25 Mg, Qd           |                 | Taro         |
|                                                                 | Oxcarbazepine  |              |            | S           | Unknown      | 300 Mg, Bid         |                 | Not Reported |
|                                                                 | Alprazolam     |              |            | S           | Unknown      | 1 Mg, Qid, Prn      |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|------------|------------|----------------|
| 11-May-2015              | 11104312      | EXPEDITED (15-DAY) |                    | OT              | IT-CIPLA LTD.-<br>2015IT03616 |                      |            | Unknown    | ITA            |

| <u>Preferred Term</u>                                                                                                                                                                              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Binge Eating; Depressed Mood; Drug Ineffective; Food Craving; Frustration Tolerance Decreased; Gastrointestinal Disorder; Headache; Hyperhidrosis; Irritability; Tremor; Weight Loss Poor | Citalopram     |              |            | S           |              |                    |                 | Cipla        |
|                                                                                                                                                                                                    | Sertraline     |              |            | S           |              | 100 Mg, Qd         |                 | Cipla        |
|                                                                                                                                                                                                    | Topiramate     |              |            | S           |              | 50 Mg, Qd          |                 | Cipla        |
|                                                                                                                                                                                                    | Topiramate     |              |            | S           |              | 400 Mg, Qd         |                 | Cipla        |
|                                                                                                                                                                                                    | Fluoxetine     |              |            | S           |              | 20 Mg, Qd          |                 | Not Reported |
|                                                                                                                                                                                                    | Venlafaxine    |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                    | Escitalopram   |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                    | Bupropion XI   |              |            | S           |              | 150 Mg Daily       |                 | Not Reported |
|                                                                                                                                                                                                    | Bupropion XI   |              |            | S           |              | 300 Mg Daily       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 11-May-2015              | 11104352      | EXPEDITED (15-DAY) |                    | OT              | JP-APOTEX-<br>2015AP008495 |                      |            | Unknown    | JPN            |



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| <u>Preferred Term</u>                                                                   | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
|-----------------------------------------------------------------------------------------|------------------------------|--------------------|--------------------|-----------------|---------------------------------|-------------------------|-----------------|--------------|----------------|
| Myoclonus; Paralysis                                                                    | Paxil Cr Tablets             |                    |                    | S               | Oral                            | 50 Mg, Qd               |                 | Apotex       |                |
|                                                                                         | Lexapro                      |                    |                    | S               | Unknown                         | Unk                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-May-2015                                                                             | 11105857                     | DIRECT             | Y                  | OT              |                                 |                         | 30 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                   | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective; Product Quality Issue; Product Substitution Issue                     | Escitalopram                 |                    |                    | S               | Oral                            |                         |                 | Camber       |                |
| <u>FDA Received Date</u>                                                                | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-May-2015                                                                             | 11029779                     | EXPEDITED (15-DAY) |                    | OT              | NL-AUROBINDO-AUR-APL-2015-03224 |                         |                 | Female       | NLD            |
| <u>Preferred Term</u>                                                                   | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Constipation; Depressed Mood; Flatulence; Product Substitution Issue; Suicidal Ideation | Escitalopram Aurobindo 20 Mg |                    |                    | S               | Unknown                         | Unk                     |                 | Aurobindo    |                |
|                                                                                         | Microgynon 30                |                    |                    | C               | Unknown                         | Unk                     |                 | Not Reported |                |
|                                                                                         | Valaciclovir                 |                    |                    | C               | Unknown                         | 500 M                   |                 | Not Reported |                |
|                                                                                         | Quetiapine                   |                    |                    | S               | Unknown                         | 25 Mg, Unk Now And Then |                 | Not Reported |                |
|                                                                                         | L-Lysine /00919901/          |                    |                    | C               | Unknown                         | Unk                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-May-2015                                                                             | 11059057                     | EXPEDITED (15-DAY) |                    | HO              | TR-APOTEX-2015AP008472          |                         | 21 YR           | Male         | TUR            |
| <u>Preferred Term</u>                                                                   | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Delirium; Drug Interaction                                                              | Olanzapine                   |                    |                    | S               | Oral                            | 5 Mg, Daily             |                 | Apotex       |                |
|                                                                                         | Escitalopram                 |                    |                    | S               | Unknown                         | 20 Mg, Daily            |                 | Not Reported |                |
|                                                                                         | Cannabis                     |                    |                    | S               |                                 |                         |                 | Not Reported |                |

# FDA Adverse Event Reporting System

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| <u>FDA Received Date</u>                                                                                                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u>                                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|--------------------------------|-----------------------------------------------------|-----------------|--------------|----------------|
| 12-May-2015                                                                                                                              | 11106856       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000076461              |                                                     | 87 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>                                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State;<br>Disturbance In Attention;<br>Fall; Haematoma                                                                       | Escitalopram   |                    |                    | S               | Oral                           | 1 Df                                                |                 | Forest       |                |
|                                                                                                                                          | Seresta        |                    |                    | S               | Oral                           | 1 Df                                                |                 | Not Reported |                |
|                                                                                                                                          | Theralene      |                    |                    | S               | Oral                           | 0.5 Df                                              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u>                                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-May-2015                                                                                                                              | 11106919       | EXPEDITED (15-DAY) |                    | OT              | GB-FRI-1000076345              |                                                     | 51 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                                                                                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>                                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Chest Pain; Headache;<br>Joint Stiffness                                                                                                 | Escitalopram   |                    |                    | S               | Oral                           | 10 Mg                                               |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u>                                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-May-2015                                                                                                                              | 11107409       | EXPEDITED (15-DAY) |                    | DE, HO, OT      | FR-ASTRAZENECA-<br>2015SE43144 |                                                     | 91 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>                                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Adrenomegaly;<br>Hepatosplenomegaly;<br>Phaeochromocytoma;<br>Sedation; Serotonin<br>Syndrome; Spleen<br>Disorder; Torsade De<br>Pointes | Inexium        |                    |                    | S               | Oral                           |                                                     |                 | Astrazeneca  |                |
|                                                                                                                                          | Lexomil Roche  |                    |                    | S               | Oral                           | Non Astrazeneca Product,<br>3 Mg, Three Times A Day |                 | Not Reported |                |
|                                                                                                                                          | Lexomil Roche  |                    |                    | S               | Oral                           | Non Astrazeneca Product,<br>1.5 Mg, At Night        |                 | Not Reported |                |
|                                                                                                                                          | Seroplex       |                    |                    | S               | Oral                           |                                                     |                 | Not Reported |                |
|                                                                                                                                          | Seroplex       |                    |                    | S               | Oral                           |                                                     |                 | Not Reported |                |
|                                                                                                                                          | Atarax         |                    |                    | S               | Oral                           |                                                     |                 | Not Reported |                |
|                                                                                                                                          | Oflocet        |                    |                    | S               | Oral                           |                                                     |                 | Not Reported |                |
|                                                                                                                                          | Rasilez        |                    |                    | S               | Oral                           |                                                     |                 | Not Reported |                |
|                                                                                                                                          | Nisis          |                    |                    | S               | Oral                           |                                                     |                 | Not Reported |                |

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|  |            |   |      |  |  |  |  |              |
|--|------------|---|------|--|--|--|--|--------------|
|  | Hyperium   | S | Oral |  |  |  |  | Not Reported |
|  | Hyperium   | S |      |  |  |  |  | Not Reported |
|  | Dafalgan   | C | Oral |  |  |  |  | Not Reported |
|  | Tardyferon | C | Oral |  |  |  |  | Not Reported |
|  | Fumafer    | C |      |  |  |  |  | Not Reported |

| <u>FDA Received Date</u>                                        | <u>Case #</u>   | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------|-----------------|------------------|--------------------|-----------------|----------------------|----------------------------------------------|-----------------|--------------|----------------|
| 12-May-2015                                                     | 11111787        | DIRECT           |                    | HO, LT          |                      |                                              | 22 YR           | Female       | USA            |
| <u>Preferred Term</u>                                           | <u>Product</u>  | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                           | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Behaviour;<br>Intentional Overdose;<br>Suicide Attempt | Escitalopram    |                  |                    | S               | Oral                 | 1 Pill, 10 Mg, Once Daily,<br>Taken By Mouth |                 | Not Reported |                |
|                                                                 | Lexapro-Generic |                  |                    | C               |                      |                                              |                 | Not Reported |                |
|                                                                 | Multi-Vitamin   |                  |                    | C               |                      |                                              |                 | Not Reported |                |

| <u>FDA Received Date</u>                 | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 12-May-2015                              | 11111987                      | EXPEDITED (15-DAY) | Y                  | OT              | US-H14001-15-00687   |                      | 49 YR           | Female       | USA            |
| <u>Preferred Term</u>                    | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bipolar I Disorder; Suicidal<br>Ideation | Lamotrigine (Lamotrigine)     |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                          | Escitalopram (Escitalopram)   |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                          | Oxcarbazepine (Oxcarbazepine) |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                          | Alprazolam (Alprazolam)       |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                          | (Alprazolam)                  |                    |                    |                 |                      |                      |                 |              |                |

| <u>FDA Received Date</u>                                                                     | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|----------------------------------------------------------------------------------------------|--------------------|--------------------|--------------------|-----------------|-------------------------------------|----------------------|-----------------|------------|----------------|
| 13-May-2015                                                                                  | 11108822           | EXPEDITED (15-DAY) |                    | OT              | US-AUROBINDO-AUR-<br>APL-2015-04070 |                      | 49 YR           | Female     | USA            |
| <u>Preferred Term</u>                                                                        | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Bipolar Disorder; Drug<br>Ineffective; Expired<br>Product Administered;<br>Suicidal Ideation | Alprazolam 1mg     |                    |                    | S               | Unknown                             | 1 Mg, Four Times/Day |                 | Aurobindo  |                |
|                                                                                              | Escitalopram       |                    |                    | S               | Unknown                             | 25 Mg, Once A Day    |                 | Aurobindo  |                |
|                                                                                              | Lamotrigine Tablet |                    |                    | S               | Oral                                | 25, Mg               |                 | Aurobindo  |                |

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|                                                                                            |                                    |                    |                    |                 |                                |                      |                 |              |                |
|--------------------------------------------------------------------------------------------|------------------------------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|-----------------|--------------|----------------|
| Oxcarbazepine                                                                              |                                    |                    | S                  | Unknown         | 300 Mg, Two Times A Day        |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                   | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-May-2015                                                                                | 11109167                           | EXPEDITED (15-DAY) |                    | HO              | US-DRREDDYS-USA/USA/15/0047921 |                      | 17 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                      | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrioventricular Block Complete; Ejection Fraction Decreased; Hypotension; Overdose; Shock | Amlodipine Besylate                |                    |                    | S               | Unknown                        |                      |                 | Not Reported |                |
|                                                                                            | Venlafaxine Hydrochloride          |                    |                    | S               | Unknown                        |                      |                 | Not Reported |                |
|                                                                                            | Hydrochlorothiazide                |                    |                    | S               | Unknown                        |                      |                 | Not Reported |                |
|                                                                                            | Buspiron [Buspirone Hydrochloride] |                    |                    | S               | Unknown                        |                      |                 | Not Reported |                |
|                                                                                            | Dexamfetamine                      |                    |                    | S               | Unknown                        |                      |                 | Not Reported |                |
|                                                                                            | Lexapro                            |                    |                    | S               | Unknown                        |                      |                 | Not Reported |                |
|                                                                                            | Prozac                             |                    |                    | S               | Unknown                        |                      |                 | Not Reported |                |
|                                                                                            | Clonazepam                         |                    |                    | S               | Unknown                        |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                   | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-May-2015                                                                                | 11109619                           | EXPEDITED (15-DAY) |                    | CA              | NL-FRI-1000076448              |                      | < 1 DAY         | Female       | NLD            |
| <u>Preferred Term</u>                                                                      | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dextrocardia; Foetal Exposure During Pregnancy; Hypoplastic Left Heart Syndrome            | Escitalopram                       |                    |                    | S               | Transplacental                 |                      |                 | Forest       |                |
|                                                                                            | Escitalopram                       |                    |                    | S               | Oral                           |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                   | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-May-2015                                                                                | 9773550                            | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000052353              |                      | 83 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                      | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Pruritus                                                                                   | Escitalopram                       |                    |                    | S               | Oral                           | 1 Df                 |                 | Forest       |                |
|                                                                                            | Cacit Vitamin D3                   |                    |                    | S               | Oral                           | 500 Mg/440 Iu Daily  |                 | Not Reported |                |
|                                                                                            | Speciafoldine                      |                    |                    | S               | Oral                           | 2 Df                 |                 | Not Reported |                |

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|                                                                         | Aprovel        |                    | S                  | Oral            | 1 Df                                                        |                                        |                 | Not Reported |                |
|-------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|-------------------------------------------------------------|----------------------------------------|-----------------|--------------|----------------|
|                                                                         | Doliprane      |                    | S                  |                 | 3 Df                                                        |                                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                        | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-May-2015                                                             | 11056346       | EXPEDITED (15-DAY) |                    | HO              | TR-FRI-1000075967                                           |                                        | 64 YR           | Female       | TUR            |
| <u>Preferred Term</u>                                                   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Embolism Venous;<br>Pulmonary Embolism                                  | Escitalopram   |                    |                    | S               |                                                             | 5 Mg                                   |                 | Forest       |                |
|                                                                         | Escitalopram   |                    |                    | S               |                                                             | 10 Mg                                  |                 | Forest       |                |
|                                                                         | Escitalopram   |                    |                    | S               |                                                             | 15 Mg                                  |                 | Not Reported |                |
|                                                                         | Haloperidol    |                    |                    | C               |                                                             | 1 Mg                                   |                 | Not Reported |                |
|                                                                         | Haloperidol    |                    |                    | C               | Unknown                                                     | 3.5 Mg                                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                        | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-May-2015                                                             | 11112029       | EXPEDITED (15-DAY) |                    | OT              | US-SUN<br>PHARMACEUTICAL<br>INDUSTRIES LTD-<br>2015US-97235 |                                        | 49 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Bipolar I Disorder; Product<br>Substitution Issue;<br>Suicidal Ideation | Lamotrigine    |                    |                    | S               | Unknown                                                     | 350 Mg, Qd (Every Night<br>At Bedtime) |                 | Taro         |                |
|                                                                         | Oxcarbazepine  |                    |                    | S               | Unknown                                                     | 300 Mg, Bid                            |                 | Ranbaxy      |                |
|                                                                         | Escitalopram   |                    |                    | S               | Unknown                                                     | 25 Mg, Qd                              |                 | Not Reported |                |
|                                                                         | Alprazolam     |                    |                    | S               | Unknown                                                     | 1 Mg, Qid                              |                 | Sun          |                |
| <u>FDA Received Date</u>                                                | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                        | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-May-2015                                                             | 11113689       | EXPEDITED (15-DAY) |                    | DE, HO          | FR-FRI-1000076600                                           |                                        | 91 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Off Label Use; Serotonin<br>Syndrome; Torsade De<br>Pointes             | Escitalopram   |                    |                    | S               | Oral                                                        | 10 Mg                                  |                 | Forest       |                |
|                                                                         | Escitalopram   |                    |                    | S               | Oral                                                        | 15 Mg                                  |                 | Forest       |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|            |   |         |         |              |
|------------|---|---------|---------|--------------|
| Atarax     | S | Oral    | 2 Df    | Not Reported |
| Oflocet    | S | Oral    | 2 Df    | Not Reported |
| Lexomil    | S | Oral    | 0.25 Df | Not Reported |
| Lexomil    | S | Oral    | 1.5 Df  | Not Reported |
| Rasilez    | S | Oral    | 1 Df    | Not Reported |
| Nisis      | S | Oral    | 2 Df    | Not Reported |
| Hyperium   | S | Oral    | 2 Df    | Not Reported |
| Hyperium   | S | Oral    | 1 Df    | Not Reported |
| Inexium    | S | Unknown | 1 Df    | Not Reported |
| Dafalgan   | C | Oral    | 3 Df    | Not Reported |
| Tardyferon | C | Oral    | 1 Df    | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-May-2015              | 11116062      | DIRECT           |                    | OT              |                      |                      | 61 YR      | Female     | USA            |

  

| <u>Preferred Term</u>                                                                                          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Depression; Disease Recurrence;<br>Gastrointestinal Disorder;<br>Product Substitution Issue;<br>Sleep Disorder | Escitalopram   |              |            | S           |              | 1 20 Mg And 10 Mg  |                 | Accord       |
|                                                                                                                | Synthroid      |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                | Klonopin       |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                | Turmeric       |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                | B Complete     |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                | Vit C          |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                | Vit D3         |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                | Zinc           |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                | Omegas         |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                | Probiotics     |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                | Magnesium      |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                | Escitalopram   |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-May-2015              | 11158166      | NON-EXPEDITED    | Y                  | DE              | 2015010067           |                      | 34 YR      | Female     | USA            |

  

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                 |                                                             |   |              |
|-------------------------------------------------|-------------------------------------------------------------|---|--------------|
| Cardio-Respiratory Arrest;<br>Completed Suicide | Zolpidem (Zolpidem)                                         | S | Not Reported |
|                                                 | Amitriptyline (Amitriptyline)                               | S | Not Reported |
|                                                 | Tramadol (Tramadol)                                         | S | Not Reported |
|                                                 | Hydrocodone W/Acetaminophen<br>(Hydrocodone, Acetaminophen) | S | Not Reported |
|                                                 | Ondansetron (Ondansetron)                                   | S | Not Reported |
|                                                 | Linaclotide (Linaclotide)                                   | S | Not Reported |
|                                                 | Diclofenac (Diclofenac)                                     | S | Not Reported |
|                                                 | Lubiprostone (Lubiprostone)                                 | S | Not Reported |
|                                                 | Liothyronine (Liothyronine)                                 | S | Not Reported |
|                                                 | Escitalopram (Escitalopram)                                 | S | Not Reported |
|                                                 | Sertraline (Sertraline)                                     | S | Not Reported |
|                                                 | Gabapentin (Gabapentin)                                     | S | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------|----------------------|------------|------------|----------------|
| 15-May-2015              | 11008908      | EXPEDITED (15-DAY) |                    | OT              | ES-AUROBINDO-AUR-<br>APL-2015-03091 |                      | 73 YR      | Female     | ESP            |

| <u>Preferred Term</u>                                                                                                                        | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------|--------------------|--------------|------------|-------------|--------------|------------------------|-----------------|------------|
| Angle Closure Glaucoma;<br>Choroidal Detachment;<br>Choroidal Effusion;<br>Headache; Intraocular<br>Pressure Increased;<br>Visual Impairment | Escitalopram 20 Mg |              |            | S           | Unknown      | 20 Mg, Daily           |                 | Aurobindo  |
|                                                                                                                                              | Escitalopram 20 Mg |              |            | S           | Unknown      | 20 Mg, Two Times A Day |                 | Aurobindo  |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------------------------------------|----------------------|------------|------------|----------------|
| 15-May-2015              | 11114407      | EXPEDITED (15-DAY) |                    | HO, LT          | GB-MACLEODS<br>PHARMACEUTICALS<br>US LTD-<br>MAC2015001747 |                      |            | Unknown    | GBR            |

| <u>Preferred Term</u> | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| B-Cell Lymphoma       | Escitalopram Tablet |              |            | S           | Oral         | 15 Mg, Qd          |                 | Macleods     |
|                       | Escitalopram Tablet |              |            | S           |              | Unk                |                 | Macleods     |
|                       | Amisulpride         |              |            | S           | Oral         | 400 Mg, Qd         |                 | Not Reported |
|                       | Clozapine           |              |            | S           | Oral         | 700 Mg,Per Day     |                 | Not Reported |
|                       | Aspirin             |              |            | C           | Unknown      |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|              |   |         |              |
|--------------|---|---------|--------------|
| Atorvastatin | C | Unknown | Not Reported |
| Esomeprazole | C | Unknown | Not Reported |
| Isotard XI   | C | Unknown | Not Reported |
| Metformin    | C | Unknown | Not Reported |
| Paracetamol  | C | Unknown | Not Reported |
| Procyclidine | C | Unknown | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------|----------------------|------------|------------|----------------|
| 15-May-2015              | 11116296      | EXPEDITED (15-DAY) |                    | OT              | US-TAKEDA-2015TUS006437 |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Suicidal Ideation     | Brintellix     |              |            | S           | Oral         | 5 Mg, Qd           |                 | Takeda       |
|                       | Brintellix     |              |            | S           | Oral         | Unk                |                 | Takeda       |
|                       | Brintellix     |              |            | S           | Oral         | 20 Mg, Qd          |                 | Takeda       |
|                       | Lexapro        |              |            | S           | Oral         | 20 Mg, Unk         |                 | Not Reported |
|                       | Lexapro        |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                       | Lexapro        |              |            | S           | Oral         | 5 Mg, Unk          |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 15-May-2015              | 11117203      | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2015164804 |                      | 82 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|-----------------------------------|-----------------|--------------|
| Condition Aggravated;<br>Condition Aggravated;<br>Dizziness; Drug<br>Ineffective; Tremor | Xeljanz        |              |            | S           |              | 5 Mg, 2x/Day                      |                 | Pfizer       |
|                                                                                          | Xeljanz        |              |            | S           |              |                                   |                 | Pfizer       |
|                                                                                          | Tramadol       |              |            | S           |              | Unk, As Needed (4 Times<br>A Day) |                 | Not Reported |
|                                                                                          | Lexapro        |              |            | S           |              | Unk                               |                 | Not Reported |
|                                                                                          | Lexapro        |              |            | S           |              |                                   |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-May-2015              | 11117311      | EXPEDITED (15-DAY) |                    | HO, LT          | PHFR2015GB003741     |                      | 52 YR      | Male       | GBR            |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|---------------------------------------------|-----------------|--------------|
| B-Cell Lymphoma       | Clozapine      |              |            | S           | Oral         | 200 Mg In The Morning<br>And 500mg At Night |                 | Novartis     |
|                       | Amisulpride    |              |            | S           | Oral         | 400 Mg, Qhs                                 |                 | Not Reported |
|                       | Escitalopram   |              |            | S           | Oral         | In The Morning                              |                 | Not Reported |
|                       | Aspirin        |              |            | C           | Unknown      |                                             |                 | Not Reported |
|                       | Atorvastatin   |              |            | C           | Unknown      |                                             |                 | Not Reported |
|                       | Esomeprazole   |              |            | C           | Unknown      |                                             |                 | Not Reported |
|                       | Isotard XI     |              |            | C           | Unknown      |                                             |                 | Not Reported |
|                       | Metformin      |              |            | C           | Unknown      |                                             |                 | Not Reported |
|                       | Paracetamol    |              |            | C           | Unknown      |                                             |                 | Not Reported |
|                       | Procyclidine   |              |            | C           | Unknown      |                                             |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-May-2015              | 11119346      | DIRECT           |                    |                 |                      |                      | 61 YR      | Male       |                |

| <u>Preferred Term</u>                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Headache; Headache;<br>Product Substitution Issue | Escitalopram   |              |            | S           | Oral         |                    |                 | Mylan      |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------|----------------------|------------|------------|----------------|
| 18-May-2015              | 11118031      | EXPEDITED (15-DAY) |                    | HO, LT          | GB-AUROBINDO-AUR-<br>APL-2015-04380 |                      | 52 YR      | Male       | GBR            |

| <u>Preferred Term</u> | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                            | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|--------------------|--------------|------------|-------------|--------------|---------------------------------------------------------------|-----------------|--------------|
| B-Cell Lymphoma       | Amisulpride 400 Mg |              |            | S           | Oral         | 400 Mg, Once A Day At<br>Night                                |                 | Not Reported |
|                       | Escitalopram       |              |            | S           | Oral         | 15 Mg, Every Morning                                          |                 | Aurobindo    |
|                       | Clozapine          |              |            | S           | Oral         | 700 Mg, Daily(200 Mg In<br>The Morning And 500mg<br>At Night) |                 | Not Reported |
|                       | Aspirin            |              |            | C           | Unknown      | Unk                                                           |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|              |   |         |     |              |
|--------------|---|---------|-----|--------------|
| Atorvastatin | C | Unknown | Unk | Not Reported |
| Esomeprazole | C | Unknown | Unk | Not Reported |
| Isotard XI   | C | Unknown | Unk | Not Reported |
| Metformin    | C | Unknown | Unk | Not Reported |
| Paracetamol  | C | Unknown | Unk | Not Reported |
| Procyclidine | C | Unknown | Unk | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-May-2015              | 11119638      | EXPEDITED (15-DAY) |                    | OT              | DE-FRI-1000076637    |                      | 43 YR      | Female     | DEU            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Head Titubation       | Escitalopram   |              |            | S           | Oral         | 5 Mg               |                 | Forest       |
|                       | Escitalopram   |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                       | Escitalopram   |              |            | S           | Oral         | 15 Mg              |                 | Not Reported |
|                       | Escitalopram   |              |            | S           | Oral         | 20 Mg              |                 | Not Reported |
|                       | Escitalopram   |              |            | S           | Oral         | 15 Mg              |                 | Not Reported |
|                       | Amisulpride    |              |            | S           | Oral         | 400 Mg             |                 | Not Reported |
|                       | Amisulpride    |              |            | S           | Oral         | 500 Mg             |                 | Not Reported |
|                       | Amisulpride    |              |            | S           | Oral         | 600 Mg             |                 | Not Reported |
|                       | Amisulpride    |              |            | S           | Oral         | 450 Mg             |                 | Not Reported |
|                       | Amisulpride    |              |            | S           | Oral         | 300 Mg             |                 | Not Reported |
|                       | Amisulpride    |              |            | S           | Oral         | 150 Mg             |                 | Not Reported |
|                       | Amisulpride    |              |            | S           | Oral         | Unknown            |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-May-2015              | 11119701      | EXPEDITED (15-DAY) |                    | OT              | DE-FRI-1000076601    |                      | 35 YR      | Female     | DEU            |

| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Contusion; Metrorrhagia | Escitalopram   |              |            | S           | Oral         | 20 Mg              |                 | Forest     |
|                         | Escitalopram   |              |            | S           | Oral         | 10 Mg              |                 | Forest     |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                   |                | Gabapentin         | C                  | Oral            | 1200 Mg              |                                          |                 | Not Reported |                |
|-------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|------------------------------------------|-----------------|--------------|----------------|
|                                                                                                                   |                | Beloc-Zok          | C                  | Oral            | 95 Mg                |                                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                          | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-May-2015                                                                                                       | 10758404       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000074134    |                                          | < 1 DAY         | Male         | FRA            |
| <u>Preferred Term</u>                                                                                             | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Drug Withdrawal Syndrome Neonatal; Exposure During Pregnancy; Respiratory Distress; Somnolence; Tremor | Escitalopram   |                    |                    | S               | Transplacental       | 15 Mg                                    |                 | Forest       |                |
|                                                                                                                   | Theralene      |                    |                    | S               | Transplacental       | 10 Mg                                    |                 | Not Reported |                |
|                                                                                                                   | Risperdal      |                    |                    | S               | Transplacental       | 0.5 Mg                                   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                          | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-May-2015                                                                                                       | 10867476       | EXPEDITED (15-DAY) |                    | HO, LT          | FR-FRI-1000074726    |                                          | 20 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                             | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>   |                |
| Colitis Ischaemic; Colitis Ulcerative                                                                             | Escitalopram   |                    |                    | S               | Oral                 | 1 Df                                     |                 | Forest       |                |
|                                                                                                                   | Risperdal      |                    |                    | S               | Oral                 |                                          |                 | Not Reported |                |
|                                                                                                                   | Loxapac        |                    |                    | S               | Oral                 | 4 Df                                     |                 | Not Reported |                |
|                                                                                                                   | Lepticur       |                    |                    | S               | Oral                 | 2 Df                                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                          | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-May-2015                                                                                                       | 11121648       | EXPEDITED (15-DAY) |                    | HO, LT          | GB-TEVA-562768ACC    |                                          | 52 YR           | Male         | GBR            |
| <u>Preferred Term</u>                                                                                             | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>   |                |
| B-Cell Lymphoma                                                                                                   | Escitalopram   |                    |                    | S               | Oral                 | 15 Milligram Daily; In The Morning       |                 | Ivax         |                |
|                                                                                                                   | Amisulpride    |                    |                    | S               | Oral                 | 400 Milligram Daily; At Night            |                 | Not Reported |                |
|                                                                                                                   | Clozapine      |                    |                    | S               | Oral                 | 200 Mg In The Morning And 500mg At Night |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|              |   |              |
|--------------|---|--------------|
| Aspirin      | C | Not Reported |
| Atorvastatin | C | Not Reported |
| Esomeprazole | C | Not Reported |
| Isotard XI   | C | Not Reported |
| Metformin    | C | Not Reported |
| Paracetamol  | C | Not Reported |
| Procyclidine | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 19-May-2015              | 11122048      | EXPEDITED (15-DAY) |                    | HO, OT          | FR-JNJFOC-20150504306 |                      | 72 YR      | Male       | FRA            |

| <u>Preferred Term</u>                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Acute Kidney Injury;                              | Stelara        |              |            | S           | Subcutaneous |                    |                 | Not Reported |
| Agitation; Atrophy;                               | Stelara        |              |            | S           | Subcutaneous |                    |                 | Not Reported |
| Behaviour Disorder;                               | Seroplex       |              |            | S           | Unknown      |                    |                 | Not Reported |
| Benign Prostatic Hyperplasia;                     | Insulin        |              |            | C           |              |                    |                 | Not Reported |
| Extrapyrimaldal Disorder;                         | Lithium        |              |            | C           | Unknown      |                    |                 | Not Reported |
| General Physical Condition Abnormal;              |                |              |            |             |              |                    |                 |              |
| Hypercalcaemia;                                   |                |              |            |             |              |                    |                 |              |
| Hyperhidrosis;                                    |                |              |            |             |              |                    |                 |              |
| Hypertension;                                     |                |              |            |             |              |                    |                 |              |
| Inappropriate Schedule Of Product Administration; |                |              |            |             |              |                    |                 |              |
| Insomnia; Myalgia;                                |                |              |            |             |              |                    |                 |              |
| Pyrexia; Urinary Retention                        |                |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-May-2015              | 11122235      | EXPEDITED (15-DAY) |                    | HO              | CH-FRI-1000076597    |                      | 72 YR      | Female     | CHE            |

| <u>Preferred Term</u>                                               | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Fall; Hyponatraemia;                                                | Escitalopram           |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
| Inappropriate Antidiuretic Hormone Secretion; Loss Of Consciousness | Comilorid Mite         |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                     | Meto Zerok             |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                     | Pantozol (Switzerland) |              |            | C           | Unknown      |                    |                 | Not Reported |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |                               |   |         |              |
|--|-------------------------------|---|---------|--------------|
|  | Calcimagon D3                 | C | Unknown | Not Reported |
|  | Symbicort                     | C | Unknown | Not Reported |
|  | Spiriva                       | C | Unknown | Not Reported |
|  | Dafalgan                      | C | Unknown | Not Reported |
|  | Zolpidem                      | C | Unknown | Not Reported |
|  | Travatan                      | C | Unknown | Not Reported |
|  | Novalgine (Metamizole Sodium) | C | Unknown | Not Reported |

| <u>FDA Received Date</u>                                             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|-----------------|--------------|----------------|
| 19-May-2015                                                          | 11122346       | EXPEDITED (15-DAY) |                    | OT              | NL-CIPLA LTD.-<br>2015NL03866 |                      |                 | Unknown      | NLD            |
| <u>Preferred Term</u>                                                | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Resistance;<br>Intellectual Disability;<br>Neutropenia; Seizure | Risperidone    |                    |                    | S               | Unknown                       |                      |                 | Cipla        |                |
|                                                                      | Haloperidol    |                    |                    | S               | Unknown                       |                      |                 | Not Reported |                |
|                                                                      | Flupentixol    |                    |                    | S               | Unknown                       |                      |                 | Not Reported |                |
|                                                                      | Olanzapine     |                    |                    | S               | Unknown                       |                      |                 | Not Reported |                |
|                                                                      | Escitalopram   |                    |                    | S               | Unknown                       |                      |                 | Not Reported |                |
|                                                                      | Valproic Acid  |                    |                    | S               | Unknown                       |                      |                 | Not Reported |                |
|                                                                      | Clozapine      |                    |                    | S               | Unknown                       |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u>                                                                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------------------------|--------------------|--------------------|-----------------|--------------------------------|--------------------------------------------------------------------------------------------|-----------------|--------------|----------------|
| 19-May-2015              | 11123564                         | EXPEDITED (15-DAY) |                    | HO              | FR-009507513-<br>1505FRA001318 |                                                                                            | 56 YR           | Female       | FRA            |
| <u>Preferred Term</u>    | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>                                                                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Cholestasis              | Fidaxomicin                      |                    |                    | S               | Oral                           | 200 Mg, Unk                                                                                |                 | Merck        |                |
|                          | Tegretol                         |                    |                    | S               | Oral                           | 400 Mg, Bid                                                                                |                 | Not Reported |                |
|                          | Alepsal (Caffeine\Phenobarbital) |                    |                    | S               |                                | 250 Mg, Daily (50 Mg In<br>The Morning And 100 Mg<br>On Noon And 100 Mg In<br>The Evening) |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|          |   |      |                       |              |
|----------|---|------|-----------------------|--------------|
| Valium   | S | Oral | 5 Mg, Tid             | Not Reported |
| Seroplex | S | Oral | 15 Mg, In The Morning | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-May-2015              | 11124252      | DIRECT           |                    | DS, OT          |                      |                      | 29 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                | <u>Product</u>                                                                                                                      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>                     | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>                                                                                                   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|--------------|------------|---------------------------------|--------------|----------------------------------|-----------------|--------------------------------------------------------------------------------------------------------------|
| Agoraphobia; Amnesia;<br>Anxiety; Aphasia; Bruxism;<br>Confusional State; Crying;<br>Dyspepsia; Dyspnoea;<br>Dysstasia; Heart Rate<br>Abnormal; Hyperhidrosis;<br>Insomnia; Mental<br>Impairment; Migraine;<br>Mood Swings; Nausea;<br>Negative Thoughts;<br>Orthostatic Hypotension;<br>Suicidal Ideation;<br>Syncope; Vertigo; Weight<br>Increased | Escitalopram<br>Junel<br>Multivitamin<br>B Complex<br>B12 Methylcobalamin<br>Phosphatidyl Serine<br>Ionic Magnesium<br>Milk Thistle |              |            | S<br>C<br>C<br>C<br>C<br>C<br>C | Oral         | 1, Once Daily, Taken By<br>Mouth |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-May-2015              | 11124498      | DIRECT           |                    |                 |                      |                      | 29 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                       | <u>Product</u>                                                                              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>           | <u>Route</u> | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>                                                            |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------|--------------|------------|-----------------------|--------------|-------------------------------------|-----------------|-----------------------------------------------------------------------|
| Abnormal Dreams;<br>Fatigue; Feeling Cold;<br>Hypersomnia; Movement<br>Disorder; Nausea;<br>Nightmare; Product<br>Quality Issue; Product<br>Substitution Issue;<br>Retching | Escitalopram<br>Generic Lexapro<br>Generic Adderal Xr<br>Generic Ambien Cr<br>Vitamin D Nos |              |            | S<br>C<br>C<br>C<br>C | Oral         | 1 Pill Once Daily Taken By<br>Mouth |                 | Lupin<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------|----------------------|------------|------------|----------------|
| 20-May-2015              | 10637506      | EXPEDITED (15-DAY) |                    | HO, OT          | CA-GSKJP-DK201416122002 |                      |            | Unknown    | CAN            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>             | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------|------------|-------------|--------------------------|--------------------|-----------------|-----------------|
| Anxiety; Arterial Disorder; Asthenia; Biopsy Lung; Bone Disorder; Chest Discomfort; Cough; Cyanosis; Decreased Appetite; Depression; Diarrhoea; Dizziness; Drug Ineffective; Dyspnoea; Dyspnoea Exertional; Emphysema; Fall; Fatigue; Gait Disturbance; Headache; Hiatus Hernia; Hypoaesthesia; Infection; Insomnia; Limb Discomfort; Lung Infection; Malaise; Movement Disorder; Overdose; Pain; Panic Reaction; Pneumonia; Pruritus; Pulmonary Mass; Restlessness; Scar; Thinking Abnormal; Tremor | Advair Diskus            |              |            | S           | Respiratory (inhalation) | 1 Df, Bid          |                 | Glaxosmithkline |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Ventolin                 |              |            | S           | Unknown                  |                    |                 | Glaxosmithkline |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Spiriva                  |              |            | S           | Unknown                  |                    |                 | Not Reported    |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Clarithromycin           |              |            | S           | Unknown                  |                    |                 | Glaxosmithkline |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Atrovent                 |              |            | S           | Unknown                  |                    |                 | Glaxosmithkline |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Seebri Breezhaler        |              |            | S           | Unknown                  |                    |                 | Glaxosmithkline |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Unknown Drug For Anxiety |              |            | S           | Unknown                  | 2 To 4 Tablets Die |                 | Not Reported    |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Prednisone               |              |            | S           | Unknown                  |                    |                 | Not Reported    |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Ciprallex                |              |            | S           |                          |                    |                 | Glaxosmithkline |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Antihypertensive         |              |            | C           | Unknown                  |                    |                 | Not Reported    |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Gaba                     |              |            | C           | Unknown                  |                    |                 | Not Reported    |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Unknown Medication       |              |            | C           | Unknown                  |                    |                 | Not Reported    |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Clonazepam               |              |            | C           |                          |                    |                 | Not Reported    |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Meloxicam                |              |            | C           |                          |                    |                 | Not Reported    |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 20-May-2015              | 10868726       | EXPEDITED (15-DAY) |                    | HO              | IT-FRI-1000074712    |                      | 63 YR           | Female       | ITA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Urticaria                | Escitalopram   |                    |                    | S               | Unknown              |                      |                 | Forest       |                |
|                          | Norvasc        |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                          | Blopress       |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |                                    |   |         |              |
|--|------------------------------------|---|---------|--------------|
|  | Lantanon (Mianserin Hydrochloride) | S | Unknown | Not Reported |
|  | Cardioaspirin                      | C | Oral    | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>               | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|-----------------------------|------------------|--------------------|-----------------|--------------------------|----------------------------------------|-----------------|--------------|----------------|
| 20-May-2015              | 11125511                    | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2015167782 |                                        |                 | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>              | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity    | Diflucan                    |                  |                    | S               | Oral                     | 150 Mg, Weekly (1 Df Weekly As Needed) |                 | Pfizer       |                |
|                          | Oxycodone                   |                  |                    | S               |                          | Unk                                    |                 | Pfizer       |                |
|                          | Amoxil                      |                  |                    | S               |                          | Unk                                    |                 | Not Reported |                |
|                          | Benadryl Allergy /01454801/ |                  |                    | S               |                          | Unk                                    |                 | Not Reported |                |
|                          | Lexapro                     |                  |                    | S               |                          | Unk                                    |                 | Not Reported |                |
|                          | Cymbalta                    |                  |                    | S               |                          | Unk                                    |                 | Not Reported |                |
|                          | Ambien                      |                  |                    | S               |                          | Unk                                    |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                               | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|-------------------------------------------|-----------------|--------------|----------------|
| 20-May-2015                                                                                                                            | 11126442       | NON-EXPEDITED    |                    |                 | US-TEVA-562053USA    |                                           | 69 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                        | <u>Duration</u> | <u>Mfr</u>   |                |
| Constipation; Drug Interaction; Feeling Abnormal; Feeling Abnormal; Fungal Infection; Insomnia; Rash; Restlessness; Somnolence; Tremor | Azilect        |                  |                    | S               | Unknown              | 4 Days A Week (Mon, Tues, Wed, And Thurs) |                 | Teva         |                |
|                                                                                                                                        | Azilect        |                  |                    | S               | Unknown              | 1 Milligram Daily;                        |                 | Teva         |                |
|                                                                                                                                        | Amantadine     |                  |                    | S               | Unknown              |                                           |                 | Not Reported |                |
|                                                                                                                                        | Lexapro        |                  |                    | S               | Unknown              | 20 Milligram Daily;                       |                 | Not Reported |                |
|                                                                                                                                        | Invokana       |                  |                    | C               |                      |                                           |                 | Not Reported |                |
|                                                                                                                                        | Mirapex Er     |                  |                    | C               |                      |                                           |                 | Not Reported |                |
|                                                                                                                                        | Sinemet        |                  |                    | C               |                      |                                           |                 | Not Reported |                |
|                                                                                                                                        | Metformin      |                  |                    | C               |                      |                                           |                 | Not Reported |                |
|                                                                                                                                        | Victoza        |                  |                    | C               |                      |                                           |                 | Not Reported |                |
|                                                                                                                                        | Lantus         |                  |                    | C               |                      |                                           |                 | Not Reported |                |
|                                                                                                                                        | Plavix         |                  |                    | C               |                      |                                           |                 | Not Reported |                |



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|                            |                               | Diovan               |                    | C               |                          |                      |                 |              | Not Reported   |
|----------------------------|-------------------------------|----------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
|                            |                               | Crestor              |                    | C               |                          |                      |                 |              | Not Reported   |
|                            |                               | Dexamethasone Elixir |                    | C               |                          |                      |                 |              | Not Reported   |
| <u>FDA Received Date</u>   | <u>Case #</u>                 | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-May-2015                | 11128147                      | DIRECT               |                    |                 |                          |                      | 6 YR            | Female       | USA            |
| <u>Preferred Term</u>      | <u>Product</u>                | <u>Comp.</u>         | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Contusion                  | Escitalopram 5mg Amneal       |                      |                    | S               | Oral                     | Liquid               |                 | Amneal       |                |
|                            | Albuterol Puffer              |                      |                    | C               |                          |                      |                 | Not Reported |                |
|                            | Singulair                     |                      |                    | C               |                          |                      |                 | Not Reported |                |
|                            | Loratidine                    |                      |                    | C               |                          |                      |                 | Not Reported |                |
|                            | Vitamins                      |                      |                    | C               |                          |                      |                 | Not Reported |                |
|                            | Melatonin                     |                      |                    | C               |                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                 | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-May-2015                | 10607240                      | EXPEDITED (15-DAY)   |                    | DS, HO, LT, OT  | DE-FRI-1000072654        |                      | 42 YR           | Female       | DEU            |
| <u>Preferred Term</u>      | <u>Product</u>                | <u>Comp.</u>         | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Acne; Agranulocytosis;     | Escitalopram                  |                      |                    | S               | Oral                     | 10 Mg                |                 | Forest       |                |
| Ascites; Drug-Induced      | Spironolactone                |                      |                    | S               | Unknown                  | 50 Mg                |                 | Not Reported |                |
| Liver Injury; Hepatic      | Spironolactone                |                      |                    | S               |                          |                      |                 | Not Reported |                |
| Cirrhosis; Splenomegaly;   | Torsemide                     |                      |                    | S               | Unknown                  | 10 Mg                |                 | Not Reported |                |
| Thrombocytopenia;          | Torsemide                     |                      |                    | S               |                          |                      |                 | Not Reported |                |
| Urinary Tract Infection    | Novalgine (Metamizole Sodium) |                      |                    | S               | Oral                     | 20 Drops As Needed   |                 | Not Reported |                |
|                            | Sertralin                     |                      |                    | C               | Oral                     | 50 Mg                |                 | Not Reported |                |
|                            | Mirtazapin                    |                      |                    | C               | Oral                     | 30 Mg                |                 | Not Reported |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                 | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-May-2015                | 11109357                      | EXPEDITED (15-DAY)   |                    | HO              | ES-PFIZER INC-2015162074 |                      | 94 YR           | Female       | ESP            |
| <u>Preferred Term</u>      | <u>Product</u>                | <u>Comp.</u>         | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anaemia; Drug Interaction; | Trangorex                     |                      |                    | S               | Oral                     | 200 Mg, Daily        |                 | Pfizer       |                |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                      |                             |   |                                       |              |              |
|----------------------|-----------------------------|---|---------------------------------------|--------------|--------------|
| Hypocoagulable State | Amoxicillin/Clavulanic Acid | S | Intravenous (not otherwise specified) | 1 G, 3x/Day  | Not Reported |
|                      | Sintrom                     | S | Oral                                  | Unk          | Not Reported |
|                      | Esertia                     | S | Oral                                  | 15 Mg, Daily | Not Reported |
|                      | Enalapril                   | C |                                       | Unk          | Not Reported |
|                      | Furosemide                  | C |                                       | Unk          | Not Reported |
|                      | Paracetamol                 | C |                                       | Unk          | Not Reported |
|                      | Omeprazole                  | C |                                       | Unk          | Not Reported |
|                      | Eutirox                     | C |                                       | Unk          | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-May-2015              | 11127164      | EXPEDITED (15-DAY) |                    | HO, LT          | GB-ACCORD-030786     |                      | 52 YR      | Male       | GBR            |

| <u>Preferred Term</u>          | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------|---------------------------|--------------|------------|-------------|--------------|------------------------------------------|-----------------|--------------|
| B-Cell Lymphoma; Off Label Use | Escitalopram              |              |            | S           | Oral         | In The Morning                           |                 | Accord       |
|                                | Amisulpride               |              |            | S           | Oral         | At Night                                 |                 | Not Reported |
|                                | Clozapine                 |              |            | S           | Oral         | 200 Mg In The Morning And 500mg At Night |                 | Not Reported |
|                                | Aspirin                   |              |            | C           |              |                                          |                 | Not Reported |
|                                | Atorvastatin              |              |            | C           |              |                                          |                 | Not Reported |
|                                | Esomeprazole/Esomeprazole |              |            | C           |              |                                          |                 | Not Reported |
|                                | Magnesium/Esomeprazole    |              |            |             |              |                                          |                 |              |
|                                | Sodium Isotard XI         |              |            | C           |              |                                          |                 | Not Reported |
|                                | Metformin                 |              |            | C           |              |                                          |                 | Not Reported |
|                                | Paracetamol               |              |            | C           |              |                                          |                 | Not Reported |
|                                | Procyclidine              |              |            | C           |              |                                          |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-May-2015              | 11128237      | EXPEDITED (15-DAY) |                    | CA              | DK-FRI-1000076816    |                      |            | Unknown    | DNK            |

| <u>Preferred Term</u>                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|------------|
| Foetal Exposure During Pregnancy; Heart Disease | Escitalopram   |              |            | S           | Transplacental |                    |                 | Forest     |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Congenital

| <u>FDA Received Date</u>                          | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| 21-May-2015                                       | 11128624       | EXPEDITED (15-DAY) |                    | OT              | CH-ASTRAZENECA-2015SE44954 |                      | < 1 DAY         | Male         | CHE            |
| <u>Preferred Term</u>                             | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Murmur; Drug Withdrawal Syndrome Neonatal | Seroquel       |                    |                    | S               | Transplacental             |                      |                 | Zeneca       |                |
|                                                   | Cipraxel       |                    |                    | S               | Transplacental             |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>          | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                                                         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|------------------------|------------------|--------------------|-----------------|--------------------------|------------------------------------------------------------------------------|-----------------|--------------|----------------|
| 21-May-2015              | 11129284               | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2015169291 |                                                                              | 59 YR           | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u>         | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                                                           | <u>Duration</u> | <u>Mfr</u>   |                |
| Nausea; Pain             | Lyrice                 |                  |                    | S               | Oral                     | 300 Mg, 2x/Day , Daily                                                       |                 | Pfizer       |                |
|                          | Lidocaine Hcl          |                  |                    | S               | Topical                  | Unk (Apply Up To 3 Patches, Only Once For Up To 12 Hr Within A 24 Hr Period) |                 | Pfizer       |                |
|                          | Mirtazapine            |                  |                    | S               | Oral                     | Unk, 1x/Day (Take 1 Tab By Mouth At Dinnertime)                              |                 | Not Reported |                |
|                          | Pantoprazole           |                  |                    | S               | Oral                     | 40 Mg, Daily                                                                 |                 | Pfizer       |                |
|                          | Escitalopram Oxalate   |                  |                    | S               | Oral                     | 10 Mg, Daily                                                                 |                 | Not Reported |                |
|                          | Ranitidine Hcl         |                  |                    | S               |                          | 150 Mg, 2x/Day                                                               |                 | Not Reported |                |
|                          | Hydrocortisone Acetate |                  |                    | S               |                          | Apply Small Amount To Rash Twice A Day                                       |                 | Pfizer       |                |
|                          | Diltiazem Hcl          |                  |                    | S               | Oral                     | 30 Mg, 2x/Day                                                                |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|------------|----------------|
| 22-May-2015              | 9255725        | NON-EXPEDITED    |                    |                 | US-009507513-1304USA014622 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Anogenital Warts;        | Propecia       |                  |                    | S               | Oral                       | 1 Mg, Qd             |                 | Merck      |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                  |          |   |      |           |              |
|----------------------------------------------------------------------------------------------------------------------------------|----------|---|------|-----------|--------------|
| Depression; Erectile Dysfunction; Joint Dislocation; Libido Decreased; Road Traffic Accident; Sexual Dysfunction; Skin Papilloma | Propecia | S | Oral | 1 Mg, Qd  | Merck        |
|                                                                                                                                  | Lexapro  | S | Oral | 10 Mg, Qd | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-May-2015              | 9683959       | EXPEDITED (15-DAY) |                    | DE, HO          | PHHY2013US125116     |                      | 29 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Areflexia; Brain Injury; Cardiac Arrest; Circulatory Collapse; Corneal Reflex Decreased; Dry Skin; Gastrointestinal Sounds Abnormal; Hypotension; Overdose; Peripheral Coldness; Pulseless Electrical Activity; Pupil Fixed; Sinus Tachycardia; Unresponsive To Stimuli | Ibuprofen      |              |            | S           | Unknown      |                    |                 | Novartis     |
|                                                                                                                                                                                                                                                                         | Bupropion      |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                         | Escitalopram   |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                         | Quetiapine     |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                         | Desvenlafaxine |              |            | S           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 22-May-2015              | 10815174      | EXPEDITED (15-DAY) |                    | HO              | US-ASTRAZENECA-2015SE15149 |                      | 64 YR      | Female     | ITA            |

| <u>Preferred Term</u> | <u>Product</u>                     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Urticaria             | Blopress                           |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                       | Norvasc                            |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                       | Lantanon (Mianserin Hydrochloride) |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                       | Entact                             |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                       | Cardioaspirin                      |              |            | S           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                              | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------|----------------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 22-May-2015                                                                                                           | 11131450                         | EXPEDITED (15-DAY) |                    | DS              | NL-FRI-1000076846        |                      | 37 YR           | Male         | NLD            |
| <u>Preferred Term</u>                                                                                                 | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anorgasmia; Erectile Dysfunction; Genital Hypoaesthesia; Listless; Loss Of Libido; Partner Stress; Sexual Dysfunction | Lexapro                          |                    |                    | S               | Oral                     | 10 Mg                |                 | Forest       |                |
|                                                                                                                       | Lamictal Dispersible Chew Tablet |                    |                    | C               | Oral                     | 400 Mg               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                              | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-May-2015                                                                                                           | 11131662                         | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-2015169516 |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                 | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Fatigue; Major Depression; Post-Traumatic Stress Disorder                                                             | Doxepin Hcl                      |                    |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                                                                                                                       | Pristiq                          |                    |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                                                                                                                       | Effexor                          |                    |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                                                                                                                       | Geodon                           |                    |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                                                                                                                       | Cymbalta                         |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                                                                                                                       | Lexapro                          |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                                                                                                                       | Thorazine                        |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                                                                                                                       | Zyprexa                          |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                              | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-May-2015                                                                                                           | 11132712                         | EXPEDITED (15-DAY) |                    | OT              | AU-FRI-1000076826        |                      |                 | Female       | AUS            |
| <u>Preferred Term</u>                                                                                                 | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Memory Impairment                                                                                                     | Escitalopram                     |                    |                    | S               | Oral                     |                      |                 | Forest       |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-May-2015              | 11132757      | EXPEDITED (15-DAY) |                    | HO              | ES-FRI-1000076841    |                      | 94 YR      | Female     | ESP            |

| <u>Preferred Term</u>                              | <u>Product</u>                                        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                          | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------|-------------------------------------------------------|--------------|------------|-------------|---------------------------------------|--------------------|-----------------|--------------|
| Anaemia; Drug Interaction;<br>Hypocoagulable State | Escitalopram                                          |              |            | S           | Oral                                  | 15 Mg              |                 | Forest       |
|                                                    | Sintrom 4 Mg Comprimidos , 20 Comprimidos             |              |            | S           | Oral                                  |                    |                 | Not Reported |
|                                                    | Amoxicilina + Clavulanico                             |              |            | S           | Intravenous (not otherwise specified) | 3 G                |                 | Not Reported |
|                                                    | Trangorex 200 Mg Comprimidos , 30 Comprimidos         |              |            | S           | Oral                                  | 200 Mg             |                 | Not Reported |
|                                                    | Enalapril                                             |              |            | C           | Oral                                  | 5 Mg               |                 | Not Reported |
|                                                    | Furosemida                                            |              |            | C           | Oral                                  | 40 Mg              |                 | Not Reported |
|                                                    | Paracetamol                                           |              |            | C           | Intravenous (not otherwise specified) | 3 G                |                 | Not Reported |
|                                                    | Omeprazol                                             |              |            | C           | Oral                                  | 20 Mg              |                 | Not Reported |
|                                                    | Eutirox 112 Microgramos Comprimidos , 100 Comprimidos |              |            | C           | Oral                                  | 112 Mcg            |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 24-May-2015              | 10928772      | NON-EXPEDITED    |                    |                 | US-JNJFOC-20140514835 |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Adverse Drug Reaction;<br>Drug Ineffective; Product Use In Unapproved Indication | Concerta       |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                  | Fetzima        |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                  | Lexapro        |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                  | Viibryd        |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                  | Prozac         |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                  | Abilify        |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                  | Zyprexa        |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                  | Seroquel       |              |            | S           | Unknown      |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                        | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------|----------------|------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 24-May-2015                                                     | 10928779       | NON-EXPEDITED    |                    |                 | US-JNJFOC-20140911403 |                      | 58 YR           | Male         | USA            |
| <u>Preferred Term</u>                                           | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Gastrointestinal Disorder                                       | Concerta       |                  |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                 | Fampridine     |                  |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                 | Fampridine     |                  |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                 | Lexapro        |                  |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                 | Ubidecarenone  |                  |                    | S               | Oral                  |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                        | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-May-2015                                                     | 9255219        | NON-EXPEDITED    |                    | HO              | US-JNJFOC-20130310450 |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                           | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Emotional Disorder; Exposure During Pregnancy; Premature Labour | Topamax        |                  |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                 | Miralax        |                  |                    | S               | Unknown               |                      |                 | Not Reported |                |
|                                                                 | Dulcolax       |                  |                    | S               | Unknown               |                      |                 | Not Reported |                |
|                                                                 | Lexapro        |                  |                    | S               | Unknown               |                      |                 | Not Reported |                |
|                                                                 | Reglan         |                  |                    | S               | Unknown               |                      |                 | Not Reported |                |
|                                                                 | Zofran         |                  |                    | S               | Unknown               |                      |                 | Not Reported |                |
|                                                                 | Zofran         |                  |                    | S               | Unknown               |                      |                 | Not Reported |                |
|                                                                 | Methadone      |                  |                    | S               | Unknown               |                      |                 | Not Reported |                |
|                                                                 | Percocet       |                  |                    | S               | Unknown               |                      |                 | Not Reported |                |
|                                                                 | Lortab         |                  |                    | S               | Unknown               |                      |                 | Not Reported |                |
|                                                                 | Cymbalta       |                  |                    | S               | Unknown               |                      |                 | Not Reported |                |
|                                                                 | Stadol         |                  |                    | S               | Unknown               |                      |                 | Not Reported |                |
|                                                                 | Dilaudid       |                  |                    | S               | Unknown               |                      |                 | Not Reported |                |
|                                                                 | Neurontin      |                  |                    | S               | Unknown               |                      |                 | Not Reported |                |
|                                                                 | Protonix       |                  |                    | S               | Unknown               |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                   |   |         |              |
|-------------------|---|---------|--------------|
| Bentyl            | S | Unknown | Not Reported |
| Prenatal Vitamins | C | Unknown | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 25-May-2015              | 9661130       | NON-EXPEDITED    |                    | OT              | US-JNJFOC-20130606595 |                      |            | Male       | USA            |

| <u>Preferred Term</u>                                                         | <u>Product</u>   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>  | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------|------------------|--------------|------------|-------------|---------------|--------------------|-----------------|--------------|
| Breast Mass; Breast Pain; Emotional Distress; Gynaecomastia; Weight Increased | Risperdal Consta |              |            | S           | Intramuscular |                    |                 | Not Reported |
|                                                                               | Risperdal        |              |            | S           | Oral          |                    |                 | Not Reported |
|                                                                               | Wellbutrin       |              |            | S           | Unknown       |                    |                 | Not Reported |
|                                                                               | Wellbutrin       |              |            | S           | Unknown       |                    |                 | Not Reported |
|                                                                               | Lexapro          |              |            | S           | Unknown       |                    |                 | Not Reported |
|                                                                               | Lipitor          |              |            | C           | Unknown       |                    |                 | Not Reported |
|                                                                               | Tegretol         |              |            | C           | Unknown       |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 25-May-2015              | 10589297      | NON-EXPEDITED    |                    | OT              | US-JNJFOC-20141108501 |                      | 49 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                   | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------|-----------------------|--------------|------------|-------------|--------------|---------------------------------------------------|-----------------|--------------|
| Blood Cholesterol Increased; Dry Mouth; Oropharyngeal Pain; Type 2 Diabetes Mellitus; Visual Impairment | Ibuprofen             |              |            | S           | Unknown      | 800 Mg In The Morning And 1200                    |                 | Not Reported |
|                                                                                                         | Fentanyl              |              |            | S           | Unknown      | 50 Microgram, Every 48 Hours                      |                 | Not Reported |
|                                                                                                         | Oxycodone Paracetamol |              |            | S           | Unknown      | 10/325 Mg, 1 Of Them 3 Times Daily, As Needed     |                 | Not Reported |
|                                                                                                         | Topamax               |              |            | S           | Unknown      | 100 Mg, Daily (Daily In The Morning)              |                 | Not Reported |
|                                                                                                         | Aspirin               |              |            | S           | Unknown      | 162 Mg, 1 Time Per Day (81mg, 2 Tablets At Night) |                 | Not Reported |
|                                                                                                         | Lyrica                |              |            | S           | Unknown      |                                                   |                 | Not Reported |
|                                                                                                         | Seroquel              |              |            | S           | Unknown      | 50 Mg Twice Daily In The                          |                 | Not Reported |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|               |   |         |                                                                   |              |
|---------------|---|---------|-------------------------------------------------------------------|--------------|
| Seroquel      | S | Unknown | Morning And Noon<br>200 Mg At Night, Unk,<br>Unk, 3 Times Per Day | Not Reported |
| Seroquel      | S | Unknown | 200 Mg At Night, Unk,<br>Unk, 3 Times Per Day                     | Not Reported |
| Seroquel      | S | Unknown | 50 Mg Twice Daily In The<br>Morning And Noon                      | Not Reported |
| Lexapro       | S | Unknown |                                                                   | Not Reported |
| Demadex       | S | Unknown |                                                                   | Not Reported |
| Valium        | S | Unknown |                                                                   | Not Reported |
| Metformin Hcl | S | Unknown |                                                                   | Not Reported |
| Effexor Xr    | S | Unknown | 225 Mg, Daily (75mg<br>Capsule And A 150mg<br>Capsule Together)   | Not Reported |
| Tizanidine    | S | Unknown |                                                                   | Not Reported |
| Simvastatin   | S | Unknown | 40 Mg, Unk                                                        | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 25-May-2015              | 10937081      | NON-EXPEDITED    |                    |                 | US-JNJFOC-<br>20130417562 |                      | 22 YR      | Female     | USA            |

| <u>Preferred Term</u>                               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Emotional Disorder;<br>Exposure During<br>Pregnancy | Topamax        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                     | Topamax        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                     | Topamax        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                     | Phenobarbital  |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                     | Depakote       |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                     | Neurontin      |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                     | Lexapro        |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                     | Lexapro        |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                     | Lorazepam      |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                     | Promethazine   |              |            | S           | Oral         |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                |   |         |              |
|----------------|---|---------|--------------|
| Nitrofurantoin | S | Unknown | Not Reported |
| Cefaclor       | S | Unknown | Not Reported |
| Fluconazole    | S | Unknown | Not Reported |
| Fluoxetine     | S | Oral    | Not Reported |
| Vitamin B2     | C | Unknown | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 25-May-2015              | 10937181      | NON-EXPEDITED    |                    |                 | US-JNJFOC-20130315736 |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Ineffective      | Topamax        |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Depakote       |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Seroquel       |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Zoloft         |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Prozac         |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Lamictal       |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Wellbutrin     |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Lexapro        |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Klonopin       |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Valium         |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Paxil          |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Celexa         |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Cymbalta       |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Anafranil      |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Imipramine     |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Tegretol       |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Luvox          |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Pristiq        |              |            | C           | Unknown      |                    |                 | Not Reported |
|                       | Lithium        |              |            | C           | Unknown      |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|             |   |         |              |
|-------------|---|---------|--------------|
| Seroquel Xr | C | Unknown | Not Reported |
| Xanax       | C | Unknown | Not Reported |
| Adderall    | C | Unknown | Not Reported |
| Abilify     | C | Unknown | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 25-May-2015              | 10938290      | NON-EXPEDITED    |                    |                 | US-JNJFOC-20120706407 |                      |            | Female     | USA            |

| <u>Preferred Term</u>              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Ineffective; Drug Interaction | Stelara        |              |            | S           | Subcutaneous | 12th Week          |                 | Not Reported |
|                                    | Topamax        |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                    | Lexapro        |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                    | Lexapro        |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                    | Klonopin       |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                    | Klonopin       |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                    | Trazodone      |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                    | Trazodone      |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                    | Abilify        |              |            | S           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 25-May-2015              | 10972837      | NON-EXPEDITED    |                    |                 | US-JNJFOC-20140117180 |                      | 16 YR      | Female     | USA            |

| <u>Preferred Term</u>     | <u>Product</u>   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>  | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|------------------|--------------|------------|-------------|---------------|--------------------|-----------------|--------------|
| Blood Prolactin Increased | Risperdal Consta |              |            | S           | Intramuscular |                    |                 | Not Reported |
|                           | Abilify          |              |            | S           | Unknown       |                    |                 | Not Reported |
|                           | Lexapro          |              |            | S           | Unknown       |                    |                 | Not Reported |
|                           | Clonidine        |              |            | S           | Unknown       |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 25-May-2015              | 11014917      | NON-EXPEDITED    |                    | OT              | US-JNJFOC-20140111142 |                      | 48 YR      | Female     | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>            | <u>Product</u>                       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------|--------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Generalised Tonic-Clonic Seizure | Tramadol Hydrochloride               |              |            | S           | Unknown      | Patients 2, 5      |                 | Not Reported |
|                                  | Ceftriaxone                          |              |            | S           | Unknown      | Patient 2          |                 | Not Reported |
|                                  | Escitalopram                         |              |            | S           | Unknown      | Patient 2          |                 | Not Reported |
|                                  | Oxygen                               |              |            | S           | Unknown      | Patients 2, 5      |                 | Not Reported |
|                                  | Metronidazole                        |              |            | C           | Unknown      | Patient 2          |                 | Not Reported |
|                                  | Zolpidem                             |              |            | C           | Unknown      | Patient 2          |                 | Not Reported |
|                                  | Acetaminophen\Hydrocodone Bitartrate |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                  | Hydromorphone                        |              |            | C           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 25-May-2015              | 11020446      | NON-EXPEDITED    |                    |                 | US-JNJFOC-20140803303 |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>                     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Hypersensitivity | Levofloxacin                       |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Effexor                            |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Lamotrigine                        |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Elavil                             |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Vancomycin                         |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Amoxicillin Clavulanic Acid Sandoz |              |            | S           |              |                    |                 | Not Reported |
|                       | Lexapro                            |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Celebrex                           |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Dilantin                           |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Meloxicam                          |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Tioconazole                        |              |            | S           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 25-May-2015              | 11036478      | NON-EXPEDITED    |                    |                 | US-JNJFOC-20140518737 |                      |            | Female     | USA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Arthralgia; Drug Interaction; Headache | Xarelto        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                        | Lexapro        |              |            | S           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 25-May-2015              | 11065063      | NON-EXPEDITED    |                    |                 | US-JNJFOC-20111104649 |                      |            | Female     | USA            |

| <u>Preferred Term</u>                      | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------|-------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Exposure During Pregnancy; Stress | Topamax           |              |            | S           | Oral         |                    |                 | Not Reported |
|                                            | Topamax           |              |            | S           | Oral         |                    |                 | Not Reported |
|                                            | Topamax           |              |            | S           | Oral         |                    |                 | Not Reported |
|                                            | Topamax           |              |            | S           | Oral         |                    |                 | Not Reported |
|                                            | Topamax           |              |            | S           | Oral         |                    |                 | Not Reported |
|                                            | Zantac            |              |            | S           | Oral         |                    |                 | Not Reported |
|                                            | Keppra            |              |            | S           | Oral         |                    |                 | Not Reported |
|                                            | Lexapro           |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                            | Azithromycin      |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                            | Sulphacetamide    |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                            | Phenergan         |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                            | Acebutolol        |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                            | Ferrous Sulfate   |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                            | Folic Acid        |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                            | Prenatal Vitamins |              |            | C           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-May-2015              | 11096234      | EXPEDITED (15-DAY) |                    | OT              | BR-ROCHE-1574283     |                      | 75 YR      | Male       | BRA            |

| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Pressure Increased | Rivotril       |              |            | S           | Oral         |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                          |                |                    |                    |                 |                          |                           |                 |              |                |
|--------------------------|----------------|--------------------|--------------------|-----------------|--------------------------|---------------------------|-----------------|--------------|----------------|
| Escitalopram             |                |                    | S                  |                 | Unknown                  |                           |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-May-2015              | 11141487       | NON-EXPEDITED      |                    |                 | US-JNJFOC-20120611062    |                           | 30 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |                |
| Diarrhoea                | Risperdal      |                    |                    | S               | Oral                     | 3 X/Morning And 4 X/Night |                 | Not Reported |                |
|                          | Topamax        |                    |                    | S               | Oral                     |                           |                 | Not Reported |                |
|                          | Lexapro        |                    |                    | S               | Unknown                  |                           |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-May-2015              | 10700592       | EXPEDITED (15-DAY) |                    | CA, OT          | CH-PFIZER INC-2015004043 |                           |                 | Female       | CHE            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrial Septal Defect;    | Xanax          |                    |                    | S               | Transplacental           | 0.5 Mg, Daily             |                 | Pfizer       |                |
| Maternal Exposure During | Xanax          |                    |                    | S               | Transplacental           | 1.5 Mg, Daily             |                 | Pfizer       |                |
| Pregnancy; Premature     | Xanax          |                    |                    | S               | Transplacental           | 0.125 Mg At Noon And      |                 | Pfizer       |                |
| Baby; Psychomotor Skills |                |                    |                    |                 |                          | 0.25 Mg In The Evening    |                 |              |                |
| Impaired; Pulmonary      | Ciprallex      |                    |                    | S               | Transplacental           | 10 Mg, 1x/Day             |                 | Not Reported |                |
| Valve Stenosis           |                |                    |                    |                 |                          |                           |                 |              |                |
| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-May-2015              | 10923628       | NON-EXPEDITED      |                    |                 | US-JNJFOC-20141001642    |                           | 19 YR           | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Paranoia      | Risperidone    |                    |                    | S               | Unknown                  |                           |                 | Not Reported |                |
|                          | Haloperidol    |                    |                    | S               | Unknown                  |                           |                 | Not Reported |                |
|                          | Escitalopram   |                    |                    | S               | Unknown                  |                           |                 | Not Reported |                |
|                          | Citalopram     |                    |                    | S               | Unknown                  |                           |                 | Not Reported |                |
|                          | Fluphenazine   |                    |                    | S               | Unknown                  |                           |                 | Not Reported |                |
|                          | Lorazepam      |                    |                    | S               | Unknown                  |                           |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                      |                    |                    |                    |                 |                                            |                                                            |                 |                 |                |
|--------------------------------------|--------------------|--------------------|--------------------|-----------------|--------------------------------------------|------------------------------------------------------------|-----------------|-----------------|----------------|
| Quetiapine                           |                    |                    | S                  |                 | Unknown                                    |                                                            |                 | Not Reported    |                |
| <u>FDA Received Date</u>             | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                       | <u>503B Facility</u>                                       | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 26-May-2015                          | 11137071           | EXPEDITED (15-DAY) |                    | OT              | US-<br>GLAXOSMITHKLINE-<br>US2015GSK071572 |                                                            | 70 YR           | Female          | USA            |
| <u>Preferred Term</u>                | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                               | <u>Dosage Text</u>                                         | <u>Duration</u> | <u>Mfr</u>      |                |
| Confusional State; Drug Interaction; | Bupropion          |                    |                    | S               |                                            |                                                            |                 | Glaxosmithkline |                |
| Hyponatraemia;                       | Escitalopram       |                    |                    | S               |                                            | 3 Mg, 1d                                                   |                 | Glaxosmithkline |                |
| Inappropriate Antidiuretic           | Quetiapine         |                    |                    | S               |                                            | 400 Mg, 1d, At Night                                       |                 | Glaxosmithkline |                |
| Hormone Secretion                    | Lamotrigine        |                    |                    | S               |                                            | 75 Mg, Bid                                                 |                 | Glaxosmithkline |                |
| <u>FDA Received Date</u>             | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                       | <u>503B Facility</u>                                       | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 26-May-2015                          | 11137623           | EXPEDITED (15-DAY) |                    | HO, LT          | GB-MYLANLABS-<br>2015M1016329              |                                                            |                 | Unknown         | GBR            |
| <u>Preferred Term</u>                | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                               | <u>Dosage Text</u>                                         | <u>Duration</u> | <u>Mfr</u>      |                |
| B-Cell Lymphoma                      | Escitalopram       |                    |                    | S               | Oral                                       | 15 Mg, Qd (In The Morning)                                 |                 | Not Reported    |                |
|                                      | Amisulpride        |                    |                    | S               | Oral                                       | 400 Mg, Qd (At Night)                                      |                 | Not Reported    |                |
|                                      | Clozapine          |                    |                    | S               | Oral                                       | 700 Mg Per Day, (200 Mg In The Morning And 500mg At Night) |                 | Not Reported    |                |
|                                      | Aspirin /00002701/ |                    |                    | C               |                                            | Unk                                                        |                 | Not Reported    |                |
|                                      | Atorvastatin       |                    |                    | C               |                                            | Unk                                                        |                 | Not Reported    |                |
|                                      | Esomeprazole       |                    |                    | C               |                                            | Unk                                                        |                 | Not Reported    |                |
|                                      | Isotard XI         |                    |                    | C               |                                            | Unk                                                        |                 | Not Reported    |                |
|                                      | Metformin          |                    |                    | C               |                                            | Unk                                                        |                 | Not Reported    |                |
|                                      | Paracetamol        |                    |                    | C               |                                            | Unk                                                        |                 | Not Reported    |                |
|                                      | Procyclidine       |                    |                    | C               |                                            | Unk                                                        |                 | Not Reported    |                |
| <u>FDA Received Date</u>             | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                       | <u>503B Facility</u>                                       | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 27-May-2015                          | 9833071            | EXPEDITED (15-DAY) |                    | LT, OT          | PHHY2013CH155164                           |                                                            | 31 YR           | Male            | CHE            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|------------------------------------------------|----------------------|-----------------|--------------|----------------|
| Abdominal Pain Upper;<br>Choking; Drug Interaction;<br>Drug Withdrawal<br>Syndrome;<br>Electrocardiogram Qt<br>Prolonged;<br>Electrocardiogram<br>Repolarisation<br>Abnormality; Generalised<br>Tonic-Clonic Seizure;<br>Hypokalaemia;<br>Hypomagnesaemia; Loss<br>Of Consciousness;<br>Nausea; Product<br>Administration Error; Pulse<br>Absent; Respiration<br>Abnormal; Stress<br>Cardiomyopathy; Torsade<br>De Pointes; Unresponsive<br>To Stimuli; Ventricular<br>Tachyarrhythmia;<br>Ventricular Tachycardia | Escitalopram   |                    |                    | S               | Unknown                                        |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Methadone      |                    |                    | S               | Oral                                           | 50-60 Mg, Daily      |                 | Novartis     |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Ondansetron    |                    |                    | S               | Unknown                                        |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-May-2015                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 10891883       | EXPEDITED (15-DAY) |                    | HO              | IT-FRI-1000075007                              |                      | 37 YR           | Male         | ITA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Accidental Overdose;<br>Product Administration<br>Error; Sopor                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Escitalopram   |                    |                    | S               | Oral                                           |                      |                 | Forest       |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Escitalopram   |                    |                    | S               | Oral                                           |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-May-2015                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 11138465       | NON-EXPEDITED      |                    |                 | AU-LUPIN<br>PHARMACEUTICALS<br>INC.-2015-01030 |                      |                 | Female       | AUS            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|           |                                            |   |         |              |
|-----------|--------------------------------------------|---|---------|--------------|
| Dizziness | Escitalopram Generic Health<br>20mg Tablet | S | Unknown | Not Reported |
|-----------|--------------------------------------------|---|---------|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------------------------|----------------------|------------|------------|----------------|
| 27-May-2015              | 11138466      | NON-EXPEDITED    |                    |                 | US-LUPIN<br>PHARMACEUTICALS<br>INC.-2015-01034 |                      |            | Female     | USA            |

| <u>Preferred Term</u>                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Drug Ineffective;<br>Panic Attack | Escitalopram   |              |            | S           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-May-2015              | 11142199      | EXPEDITED (15-DAY) |                    | LT              | FR-FRI-1000076943    |                      | 85 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                             | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-------------------------|--------------|------------|-------------|------------------------------------------|------------------------------------------|-----------------|--------------|
| Encephalopathy        | Escitalopram            |              |            | S           | Oral                                     | 5 Mg                                     |                 | Forest       |
|                       | Tienam                  |              |            | S           | Intravenous (not<br>otherwise specified) | 2 G                                      |                 | Not Reported |
|                       | Flagyl                  |              |            | C           | Oral                                     | 1500 Mg                                  |                 | Not Reported |
|                       | Kardegic                |              |            | C           | Oral                                     | 75 Mg                                    |                 | Not Reported |
|                       | Chlorhydrate De Sotalol |              |            | C           | Oral                                     | 160 Mg                                   |                 | Not Reported |
|                       | Oxycontin Lp            |              |            | C           |                                          | 20 Mg On Morning And 30<br>Mg On Evening |                 | Not Reported |
|                       | Oxynorm                 |              |            | C           | Oral                                     | 40 Mg                                    |                 | Not Reported |
|                       | Amlor                   |              |            | C           | Oral                                     | 5 Mg                                     |                 | Not Reported |
|                       | Xanax                   |              |            | C           | Oral                                     | 0.25 Mg                                  |                 | Not Reported |
|                       | Eupantol                |              |            | C           | Oral                                     | 40 Mg                                    |                 | Not Reported |
|                       | Vancomycine             |              |            | C           | Intravenous (not<br>otherwise specified) | 2250 Mg                                  |                 | Not Reported |
|                       | Calciparine             |              |            | C           | Subcutaneous                             | 0.4 MI                                   |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                                                                                               | <u>Case #</u>                                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 27-May-2015                                                                                                                                                                                                                                                                            | 11142202                                     | EXPEDITED (15-DAY) |                    | LT              | FR-FRI-1000076952    |                      | 56 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                  | <u>Product</u>                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardio-Respiratory Arrest;<br>Electrocardiogram Qt<br>Prolonged; Torsade De<br>Pointes                                                                                                                                                                                                 | Escitalopram                                 |                    |                    | S               | Oral                 | 5 Mg                 |                 | Forest       |                |
|                                                                                                                                                                                                                                                                                        | Plaquenil                                    |                    |                    | S               | Oral                 | 400 Mg               |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                        | Procoralan                                   |                    |                    | S               | Oral                 | 10 Mg                |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                        | Atacand                                      |                    |                    | C               | Oral                 | 4 Mg                 |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                        | Aldactone                                    |                    |                    | C               | Oral                 | 12.5 Mg              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                               | <u>Case #</u>                                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-May-2015                                                                                                                                                                                                                                                                            | 11144938                                     | DIRECT             | Y                  | OT              |                      |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                  | <u>Product</u>                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective                                                                                                                                                                                                                                                                       | Lexapro 20 Mg Camber                         |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                        | Lexapro 5 Mg                                 |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                               | <u>Case #</u>                                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-May-2015                                                                                                                                                                                                                                                                            | 11148905                                     | EXPEDITED (15-DAY) | Y                  | HO, LT, OT      | 2015COV00106         |                      | 56 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                  | <u>Product</u>                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardio-Respiratory Arrest;<br>Chest Pain; Diarrhoea;<br>Drug Ineffective;<br>Dyspnoea Exertional;<br>Electrocardiogram Qt<br>Prolonged;<br>Hyperlactacidaemia;<br>Hypokalaemia; Loss Of<br>Consciousness; Malaise;<br>Metabolic Acidosis;<br>Mydriasis; Nausea;<br>Torsade De Pointes; | Plaquenil Tablet                             |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                        | (Hydroxychloroquine) Tablet                  |                    |                    |                 |                      |                      |                 |              |                |
|                                                                                                                                                                                                                                                                                        | Seroplex (Escitalopram Oxalate)              |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                        | Procoralan (Ivabradine Hydrochloride) Tablet |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                        | Atacand (Candesartan Cilexetil)              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                        | Aldactone (Spironolactone)                   |                    |                    | C               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Vertigo

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 28-May-2015              | 7319573       | EXPEDITED (15-DAY) |                    | OT              | ES-ASTRAZENECA-2010SE10022 |                      | 67 YR      | Female     | ESP            |

| <u>Preferred Term</u> | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-------------------------------|--------------|------------|-------------|--------------|---------------------------|-----------------|--------------|
| Blindness; Glaucoma   | Seroquel                      |              |            | S           | Oral         |                           |                 | Not Reported |
|                       | Cipralex                      |              |            | S           | Oral         |                           |                 | Not Reported |
|                       | Coaprovel                     |              |            | S           | Oral         | 150/12.5 Mg 1 Df Daily    |                 | Not Reported |
|                       | Pantoprazole Alter            |              |            | S           | Oral         |                           |                 | Not Reported |
|                       | Trialmin                      |              |            | S           | Oral         |                           |                 | Not Reported |
|                       | Alendronate (Alendronic Acid) |              |            | C           | Oral         |                           |                 | Not Reported |
|                       | Adartrel                      |              |            | C           | Oral         |                           |                 | Not Reported |
|                       | Bonesil D Flas                |              |            | C           | Oral         | 1500 Mg/400 lu 1 Df Daily |                 | Not Reported |
|                       | Simvastatin                   |              |            | C           | Oral         |                           |                 | Not Reported |
|                       | Toraseamide                   |              |            | C           | Oral         |                           |                 | Not Reported |
|                       | Zolpidem                      |              |            | C           | Oral         |                           |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------------------|----------------------|------------|------------|----------------|
| 28-May-2015              | 11142972      | EXPEDITED (15-DAY) |                    | OT              | US-LUPIN PHARMACEUTICALS INC.-2015-01472 |                      | 49 YR      | Female     | USA            |

| <u>Preferred Term</u>               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Bipolar Disorder; Suicidal Ideation | Lamotrigine    |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                     | Oxcarbazepine  |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                     | Escitalopram   |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                     | Alprazolam     |              |            | S           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|------------|------------|----------------|
| 28-May-2015              | 11144071      | EXPEDITED (15-DAY) |                    | DE, HO          | GR-SANOFI-AVENTIS-2012SA094260 |                      | 72 YR      | Female     | GRC            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Acute Kidney Injury; Acute Respiratory Distress Syndrome; Alanine Aminotransferase Increased; Antipsychotic Drug Level Increased; Aspartate Aminotransferase Increased; Blood Creatine Phosphokinase Increased; Blood Creatinine Increased; Blood Pressure Decreased; Blood Sodium Increased; Blood Urea Increased; Blood Uric Acid Increased; Cardio-Respiratory Arrest; Depressed Level Of Consciousness; Drug Interaction; Hyperpyrexia; Leukocytosis; Muscle Rigidity; Myoglobinuria; Neuroleptic Malignant Syndrome; Rhabdomyolysis; Stupor; Tachypnoea | Lithium Carbonate       |                    |                    | S               | Unknown              |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Escitalopram Oxalate    |                    |                    | S               | Unknown              |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Irbesartan              |                    |                    | S               | Unknown              |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Amlodipine Besilate     |                    |                    | S               | Unknown              |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Buspirone Hydrochloride |                    |                    | S               | Unknown              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-May-2015                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 11144707                | EXPEDITED (15-DAY) |                    | HO, LT          | GB-FRI-1000076918    |                      | 52 YR           | Male         | GBR            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| B-Cell Lymphoma; Product Use In Unapproved Indication                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Escitalopram            |                    |                    | S               | Oral                 | 15 Mg                |                 | Forest       |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Amisulpride             |                    |                    | S               | Oral                 | 400 Mg               |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Clozapine               |                    |                    | S               | Oral                 | 700 Mg               |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Aspirin                 |                    |                    | C               | Unknown              |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Atorvastatin            |                    |                    | C               | Unknown              |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |              |   |         |              |
|--|--------------|---|---------|--------------|
|  | Esomeprazole | C | Unknown | Not Reported |
|  | Isotard XI   | C | Unknown | Not Reported |
|  | Metformin    | C | Unknown | Not Reported |
|  | Paracetamol  | C | Unknown | Not Reported |
|  | Procyclidine | C | Unknown | Not Reported |

| <u>FDA Received Date</u>                                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 28-May-2015                                                                         | 11144955       | EXPEDITED (15-DAY) |                    | OT              | CH-FRI-1000076945    |                      | < 1 DAY         | Male         | CHE            |
| <u>Preferred Term</u>                                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Murmur; Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy | Escitalopram   |                    |                    | S               | Transplacental       |                      |                 | Forest       |                |
|                                                                                     | Seroquel       |                    |                    | S               | Transplacental       |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|--------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|------------------------------------|----------------------|-----------------|-----------------|----------------|
| 28-May-2015                                                                          | 11146015       | EXPEDITED (15-DAY) |                    | OT              | CH-GLAXOSMITHKLINE-CH2015GSK072869 |                      | 34 YR           | Female          | CHE            |
| <u>Preferred Term</u>                                                                | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                       | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Maternal Exposure During Pregnancy; Premature Labour; Premature Rupture Of Membranes | Xenical        |                    |                    | S               | Unknown                            | Unk                  |                 | Glaxosmithkline |                |
|                                                                                      | Ciprallex      |                    |                    | S               | Unknown                            |                      |                 | Glaxosmithkline |                |
|                                                                                      | Topamax        |                    |                    | S               | Oral                               | Unk                  |                 | Glaxosmithkline |                |

| <u>FDA Received Date</u>                                                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|------------------------------------|----------------------|-----------------|-----------------|----------------|
| 28-May-2015                                                                              | 11146020       | EXPEDITED (15-DAY) |                    | OT              | GB-GLAXOSMITHKLINE-GB2015GSK072855 |                      |                 | Female          | GBR            |
| <u>Preferred Term</u>                                                                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                       | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Back Pain; Burning Sensation; Drug Ineffective; Muscle Spasms; Muscle Twitching; Swollen | Xenical        |                    |                    | S               | Unknown                            | 120 Mg, Unk          |                 | Glaxosmithkline |                |
|                                                                                          | Lyrica         |                    |                    | S               | Unknown                            | 300 Mg, Tid          |                 | Not Reported    |                |
|                                                                                          | Simvastatin    |                    |                    | S               | Unknown                            | 40 Mg, Unk           |                 | Glaxosmithkline |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|        |                     |   |             |                    |                 |
|--------|---------------------|---|-------------|--------------------|-----------------|
| Tongue | Celebrex            | S | Unknown     | 200 Mg, Unk        | Glaxosmithkline |
|        | Omeprazole          | S |             | 20 Mg, Unk         | Glaxosmithkline |
|        | Dexamphetamine      | S | Unknown     | 5 Mg, Unk          | Glaxosmithkline |
|        | Cipralext           | S | Unknown     | 20 Mg, Unk         | Glaxosmithkline |
|        | Tramadol            | S | Oral        | 100 Mg, Unk        | Glaxosmithkline |
|        | Butrans             | S | Transdermal | 10 Ug, Unk Per Hr. | Not Reported    |
|        | Oxybutynin Chloride | S | Unknown     | Unk                | Glaxosmithkline |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|--------------------------------------------|----------------------|-----------------|-----------------|----------------|
| 28-May-2015              | 11146028       | EXPEDITED (15-DAY) |                    | OT              | CH-<br>GLAXOSMITHKLINE-<br>CH2015GSK072870 |                      | 1 DAY           | Female          | CHE            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Premature Baby           | Xenical        |                    |                    | S               | Transplacental                             | Unk                  |                 | Glaxosmithkline |                |
|                          | Cipralext      |                    |                    | S               | Transplacental                             | Unk                  |                 | Glaxosmithkline |                |
|                          | Topamax        |                    |                    | S               | Transplacental                             | Unk                  |                 | Glaxosmithkline |                |

| <u>FDA Received Date</u> | <u>Case #</u>    | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 28-May-2015              | 11148197         | DIRECT           |                    |                 |                      |                      | 37 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>   | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression               | Escitalopram 20g |                  |                    | S               | Oral                 |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                    | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
| 29-May-2015                                                 | 8574627        | EXPEDITED (15-DAY) |                    | HO, LT          | ES-JNJFOC-<br>20120513188 |                      | 71 YR           | Male         | ESP            |
| <u>Preferred Term</u>                                       | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;<br>Epistaxis; Hypotension;<br>Tachycardia | Risperdal Flas |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                                                             | Escitalopram   |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                                                             | Quetiapine     |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                                                                                                                                                                                   |                |                    |                    |                 |                                 |                      |                 |              |                |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|-----------------|--------------|----------------|
| Simvastatin                                                                                                                                                                                                       |                |                    | C                  |                 | Oral                            |                      | Not Reported    |              |                |
| <u>FDA Received Date</u>                                                                                                                                                                                          | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-May-2015                                                                                                                                                                                                       | 11095904       | EXPEDITED (15-DAY) |                    | HO              | US-AUROBINDO-AUR-APL-2015-04005 |                      | 48 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                             | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Acute Kidney Injury; Catatonia; Condition Aggravated; Corneal Reflex Decreased; Hypokinesia; Hypotension; Mental Status Changes; Negativism; Pyrexia; Respiratory Failure; Rhabdomyolysis; Seizure; Verbigeration | Escitalopram   |                    |                    | S               | Unknown                         | Unk                  |                 | Aurobindo    |                |
|                                                                                                                                                                                                                   | Escitalopram   |                    |                    | S               |                                 |                      |                 | Aurobindo    |                |
|                                                                                                                                                                                                                   | Quetiapine     |                    |                    | S               | Unknown                         | Unk                  |                 | Aurobindo    |                |
|                                                                                                                                                                                                                   | Quetiapine     |                    |                    | S               |                                 |                      |                 | Aurobindo    |                |
|                                                                                                                                                                                                                   | Clozapine      |                    |                    | S               | Unknown                         | Unk                  |                 | Not Reported |                |
|                                                                                                                                                                                                                   | Clozapine      |                    |                    | S               |                                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                          | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-May-2015                                                                                                                                                                                                       | 11148230       | EXPEDITED (15-DAY) |                    | HO              | FR-JNJFOC-20150517740           |                      | 88 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                                             | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyponatraemia                                                                                                                                                                                                     | Xarelto        |                    |                    | S               | Oral                            | Unknown              |                 | Not Reported |                |
|                                                                                                                                                                                                                   | Xarelto        |                    |                    | S               | Oral                            | Unknown              |                 | Not Reported |                |
|                                                                                                                                                                                                                   | Seroplex       |                    |                    | S               | Oral                            | Unknown              |                 | Not Reported |                |
|                                                                                                                                                                                                                   | Lasilix        |                    |                    | S               | Oral                            | Unknown              |                 | Not Reported |                |
|                                                                                                                                                                                                                   | Crestor        |                    |                    | S               | Oral                            | Unknown              |                 | Not Reported |                |
|                                                                                                                                                                                                                   | Cardensiel     |                    |                    | S               | Oral                            | Unknown              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                          | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-May-2015                                                                                                                                                                                                       | 11148321       | EXPEDITED (15-DAY) |                    | OT              | KP-CIPLA LTD.-2015KP04140       |                      |                 | Unknown      | PRK            |
| <u>Preferred Term</u>                                                                                                                                                                                             | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Mood Altered                                                                                                                                                                                                      | Lamotrigine    |                    |                    | S               | Unknown                         |                      |                 | Cipla        |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|              |   |         |              |
|--------------|---|---------|--------------|
| Sertraline   | S | Unknown | Cipla        |
| Escitalopram | S |         | Not Reported |
| Fluoxetine   | S | Unknown | Not Reported |
| Paroxetine   | S | Unknown | Not Reported |

| <u>FDA Received Date</u>                               | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
|--------------------------------------------------------|-------------------|--------------------|--------------------|-----------------|---------------------------------------------|----------------------|-----------------|------------------|----------------|
| 29-May-2015                                            | 11149412          | EXPEDITED (15-DAY) |                    | HO              | FR-ASTRAZENECA-2015SE51969                  |                      | 88 YR           | Female           | FRA            |
| <u>Preferred Term</u>                                  | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |
| Hyponatraemia                                          | Crestor           |                    |                    | S               | Oral                                        |                      |                 | Astrazeneca      |                |
|                                                        | Seroplex          |                    |                    | S               | Oral                                        |                      |                 | Not Reported     |                |
|                                                        | Lasilix           |                    |                    | S               | Oral                                        |                      |                 | Not Reported     |                |
|                                                        | Cardensiel        |                    |                    | S               | Oral                                        |                      |                 | Not Reported     |                |
|                                                        | Xarelto           |                    |                    | S               | Oral                                        |                      |                 | Not Reported     |                |
| <u>FDA Received Date</u>                               | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 31-May-2015                                            | 11150420          | EXPEDITED (15-DAY) |                    | DE              | GR-SA-BMS17442690                           |                      | 72 YR           | Female           | GRC            |
| <u>Preferred Term</u>                                  | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |
| Drug Interaction;<br>Neuroleptic Malignant<br>Syndrome | Irbesartan        |                    |                    | S               |                                             |                      |                 | Not Reported     |                |
|                                                        | Buspirone         |                    |                    | S               |                                             |                      |                 | Not Reported     |                |
|                                                        | Lithium           |                    |                    | S               |                                             |                      |                 | Not Reported     |                |
|                                                        | Amlodipine        |                    |                    | S               |                                             |                      |                 | Not Reported     |                |
|                                                        | Escitalopram      |                    |                    | S               |                                             |                      |                 | Not Reported     |                |
| <u>FDA Received Date</u>                               | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 01-Jun-2015                                            | 8820028           | EXPEDITED (15-DAY) |                    | HO, OT          | ES-ELI_LILLY_AND_COMP<br>ANY-ES201209006034 |                      | 71 YR           | Male             | ESP            |
| <u>Preferred Term</u>                                  | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |
| Acute Psychosis; Drug<br>Interaction                   | Zyprexa           |                    |                    | S               | Oral                                        | 10 Mg, Unknown       |                 | Eli Lilly And Co |                |
|                                                        | Deprax /00447702/ |                    |                    | S               | Oral                                        | 20 Mg, Qd            |                 | Not Reported     |                |



## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                      |   |      |               |              |
|----------------------|---|------|---------------|--------------|
| Escitalopram         | S | Oral | 10 Mg, Qd     | Not Reported |
| Sinemet-Plus         | S | Oral | 100 Mg, Qd    | Not Reported |
| Omeprazol /00661201/ | C | Oral | 20 Mg, Qd     | Not Reported |
| Stelara              | C |      | 1 Df, Unknown | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Jun-2015              | 10717256      | EXPEDITED (15-DAY) | CA                 |                 | CH-FRI-1000073679    |                      |            | Female     | CHE            |

| <u>Preferred Term</u>                                                                                                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Atrial Septal Defect; Foetal Exposure During Pregnancy; Premature Baby; Psychomotor Skills Impaired; Pulmonary Valve Stenosis | Escitalopram   |              |            | S           | Transplacental | 10 Mg              |                 | Forest       |
|                                                                                                                               | Xanax          |              |            | S           | Transplacental |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Jun-2015              | 10975277      | EXPEDITED (15-DAY) | DE                 |                 | NL-FRI-1000075554    |                      | 56 YR      | Male       | NLD            |

| <u>Preferred Term</u> | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Sudden Death          | Lexapro           |              |            | S           | Oral         | 15 Mg Daily        |                 | Forest       |
|                       | Medikinet         |              |            | S           | Unknown      | 20 Mg Daily        |                 | Not Reported |
|                       | Medikinet         |              |            | S           | Unknown      | 40 Mg Daily        |                 | Not Reported |
|                       | Medikinet         |              |            | S           | Unknown      | 50 Mg              |                 | Not Reported |
|                       | Trazolan          |              |            | S           | Unknown      | 100 Mg Daily       |                 | Not Reported |
|                       | Zopiclon          |              |            | S           | Unknown      | 15 Mg Daily        |                 | Not Reported |
|                       | Alprazolam        |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Omeprazol Actavis |              |            | C           | Unknown      | 20 Mg Daily        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 01-Jun-2015              | 11076174      | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2015138562 |                      | 63 YR      | Male       | USA            |

# FDA Adverse Event Reporting System

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### Detailed Report

| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|--------------------------|----------------------|--------------------|--------------------|-----------------|-------------------------------------|----------------------|-----------------|--------------|----------------|
| Drug Ineffective         | Xanax                |                    |                    | S               | Oral                                | 0.5 Mg, 3x/Day       |                 | Pfizer       |                |
|                          | Xanax                |                    |                    | S               |                                     |                      |                 | Pfizer       |                |
|                          | Nardil               |                    |                    | S               | Oral                                | 15 Mg, 1x/Day        |                 | Pfizer       |                |
|                          | Nardil               |                    |                    | S               | Oral                                | 15 Mg, 2x/Day        |                 | Pfizer       |                |
|                          | Nardil               |                    |                    | S               | Oral                                | 15 Mg, 3x/Day        |                 | Pfizer       |                |
|                          | Nardil               |                    |                    | S               | Oral                                | 15 Mg, 4x/Day        |                 | Pfizer       |                |
|                          | Escitalopram         |                    |                    | S               | Oral                                | 10 Mg, 2x/Day        |                 | Not Reported |                |
|                          | Escitalopram         |                    |                    | S               |                                     |                      |                 | Not Reported |                |
|                          | Klonopin             |                    |                    | S               | Oral                                | Unk                  |                 | Not Reported |                |
| Klonopin                 |                      |                    | S                  |                 |                                     |                      | Not Reported    |              |                |
| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Jun-2015              | 11150679             | EXPEDITED (15-DAY) |                    | OT              | GB-AUROBINDO-AUR-<br>APL-2015-04742 |                      | 49 YR           | Female       | GBR            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Muscle Spasms; Pain      | Escitalopram 20 Mg   |                    |                    | S               | Oral                                | 20 Mg, Unk           |                 | Aurobindo    |                |
|                          | Cetirizine           |                    |                    | C               | Unknown                             | Unk                  |                 | Not Reported |                |
|                          | Desogestrel          |                    |                    | C               | Unknown                             | Unk                  |                 | Not Reported |                |
|                          | Omeprazol /00661201/ |                    |                    | C               | Unknown                             | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Jun-2015              | 11151887             | NON-EXPEDITED      |                    |                 | US-PFIZER INC-<br>2015181908        |                      | 50 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity    | Zoloft               |                    |                    | S               |                                     | Unk                  |                 | Pfizer       |                |
|                          | Lexapro              |                    |                    | S               |                                     | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Jun-2015              | 9656903              | EXPEDITED (15-DAY) |                    | OT              | PHHY2013ES113758                    |                      | 57 YR           | Female       | ESP            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>                                                        | <u>Duration</u> | <u>Mfr</u>   |                |
|----------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|------------------------------------------------|---------------------------------------------------------------------------|-----------------|--------------|----------------|
| Hyponatraemia                                                                    | Olanzapine     |                    |                    | S               | Unknown                                        |                                                                           |                 | Novartis     |                |
|                                                                                  | Enalapril      |                    |                    | S               | Unknown                                        |                                                                           |                 | Not Reported |                |
|                                                                                  | Citalopram     |                    |                    | S               | Unknown                                        |                                                                           |                 | Not Reported |                |
|                                                                                  | Escitalopram   |                    |                    | S               | Unknown                                        |                                                                           |                 | Not Reported |                |
|                                                                                  | Venlafaxine    |                    |                    | S               | Unknown                                        |                                                                           |                 | Not Reported |                |
|                                                                                  | Haloperidol    |                    |                    | S               | Unknown                                        |                                                                           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u>                                                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Jun-2015                                                                      | 11155470       | EXPEDITED (15-DAY) |                    | HO              | FR-PFIZER INC-2015180829                       |                                                                           | 82 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>                                                        | <u>Duration</u> | <u>Mfr</u>   |                |
| Anaemia; Fall;<br>Hyponatraemia;<br>Hypotension; Loss Of<br>Consciousness; Wound | Xanax          |                    |                    | S               | Oral                                           | 0.25 Mg, 1x/Day                                                           |                 | Pfizer       |                |
|                                                                                  | Seroplex       |                    |                    | S               | Oral                                           | 5 Mg, 1x/Day                                                              |                 | Not Reported |                |
|                                                                                  | Coveram        |                    |                    | S               | Oral                                           | Perindopril Arginine: 5 Mg/<br>Amlodipine Besylate: 5<br>Mg; 1 Df, 1x/Day |                 | Not Reported |                |
|                                                                                  | Novatrex       |                    |                    | C               |                                                | 2.5 Mg, Unk                                                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u>                                                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Jun-2015                                                                      | 11157321       | EXPEDITED (15-DAY) |                    | OT              | GB-LUPIN<br>PHARMACEUTICALS<br>INC.-2015-01556 |                                                                           | 41 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>                                                        | <u>Duration</u> | <u>Mfr</u>   |                |
| Alcohol Abuse;<br>Alcoholism; Mania;<br>Suicidal Ideation; Tremor                | Escitalopram   |                    |                    | S               | Unknown                                        |                                                                           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u>                                                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Jun-2015                                                                      | 11163665       | DIRECT             |                    | OT              |                                                |                                                                           |                 | Female       | USA            |
| <u>Preferred Term</u>                                                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>                                                        | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                |                 |   |      |        |              |
|--------------------------------|-----------------|---|------|--------|--------------|
| Therapy Cessation;<br>Tinnitus | Lexapro         | S | Oral | 2 WEEK | Not Reported |
|                                | Simvastatin     | C |      |        | Not Reported |
|                                | Levothyroxine   | C |      |        | Not Reported |
|                                | Allopurinol     | C |      |        | Not Reported |
|                                | Wellbutrin      | C |      |        | Not Reported |
|                                | Topamax         | C |      |        | Not Reported |
|                                | Remeron         | C |      |        | Not Reported |
|                                | Clonazepam      | C |      |        | Not Reported |
|                                | Losartan        | C |      |        | Not Reported |
|                                | Potassium       | C |      |        | Not Reported |
|                                | Flexeril        | C |      |        | Not Reported |
|                                | Hydrocodone     | C |      |        | Not Reported |
|                                | Naproxen        | C |      |        | Not Reported |
|                                | Vitamin D3      | C |      |        | Not Reported |
|                                | Loratadine      | C |      |        | Not Reported |
|                                | Magnesium       | C |      |        | Not Reported |
|                                | Zinc            | C |      |        | Not Reported |
|                                | Multivitamin    | C |      |        | Not Reported |
|                                | Iron            | C |      |        | Not Reported |
|                                | Orphenadrine Er | C |      |        | Not Reported |
|                                | Nora-Be         | C |      |        | Not Reported |

| <u>FDA Received Date</u>                                                                                                                                 | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|-----------------------------------------|-----------------|--------------|----------------|
| 03-Jun-2015                                                                                                                                              | 11163903       | DIRECT           |                    |                 |                      |                                         | 47 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                      | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Dizziness;<br>Headache; Incorrect Dose<br>Administered; Product<br>Dispensing Error; Product<br>Quality Issue; Product<br>Substitution Issue | Escitalopram   |                  |                    | S               | Oral                 | 1/2 A Pill Once Daily<br>Taken By Mouth |                 | Mylan        |                |
|                                                                                                                                                          | Trazadone      |                  |                    | C               |                      |                                         |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------------|-----------------|------------|----------------|
| 03-Jun-2015              | 11164243       | DIRECT           |                    |                 |                      |                            | 53 YR           | Female     | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u> |                |
| Dry Eye; Dry Mouth;      | Escitalopram   |                  |                    | S               | Oral                 | 1 Pill Once Daily Taken By |                 | Camber     |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Headache; Insomnia;  
Product Substitution Issue;  
Suicidal Ideation

Mouth

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Jun-2015              | 11057637      | EXPEDITED (15-DAY) |                    | DS              | PHEH2015US006748     |                      |            | Female     | USA            |

| <u>Preferred Term</u>          | <u>Product</u>                   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------|----------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Constipation; Recurrent Cancer | Sandostatin (Octreotide Acetate) |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                | Sandostatin (Octreotide Acetate) |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                                | Metolazone                       |              |            | S           | Unknown      |                    |                 | Novartis     |
|                                | Cymbalta                         |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                | Lexapro                          |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                | Lasix                            |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                | Potassium                        |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                | Magnesium                        |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                | Zyrtec                           |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                | Zantac                           |              |            | S           | Unknown      |                    |                 | Not Reported |
| Fentanyl                       |                                  |              | C          | Unknown     |              |                    | Not Reported    |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Jun-2015              | 11163223      | EXPEDITED (15-DAY) |                    | OT              | CA-FRI-1000077154    |                      | 43 YR      | Male       | CAN            |

| <u>Preferred Term</u>                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------|----------------|--------------|------------|-------------|--------------|------------------------------------|-----------------|--------------|
| Angioedema; Prescribed Overdose; Rash; Vasculitis | Escitalopram   |              |            | S           | Oral         | Overdose: Escitalopram 30 Mg Daily |                 | Forest       |
|                                                   | Escitalopram   |              |            | S           |              |                                    |                 | Forest       |
|                                                   | Trintellix     |              |            | S           | Oral         | 10 Mg                              |                 | Not Reported |
|                                                   | Trintellix     |              |            | S           |              |                                    |                 | Not Reported |
|                                                   | Terbinafine    |              |            | S           | Oral         | 250 Mg                             |                 | Not Reported |
|                                                   | Amitriptyline  |              |            | C           | Oral         | 100 Mg                             |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|             |   |              |              |              |
|-------------|---|--------------|--------------|--------------|
| Clonazepam  | C | Oral         | 3 Mg         | Not Reported |
| Clonazepam  | C |              |              | Not Reported |
| Nozinan     | C | Oral         | 37.5 Mg      | Not Reported |
| Nph Insulin | C | Subcutaneous | As Directed. | Not Reported |
| Crestor     | C | Oral         | 5 Mg         | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 04-Jun-2015              | 11164001       | EXPEDITED (15-DAY) |                    | OT              | GB-ACCORD-031147     |                      | 49 YR           | Female       | GBR            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Muscle Spasms; Pain      | Escitalopram   |                    |                    | S               | Oral                 |                      |                 | Accord       |                |
|                          | Cetirizine     |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Desogestrel    |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Omeprazole     |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                      | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------|--------------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 04-Jun-2015                                                                                                                                   | 11165739           | EXPEDITED (15-DAY) |                    | HO, LT, OT      | CH-<br>ELI_LILLY_AND_COMP<br>ANY-CH201506001053 |                      | 48 YR           | Female       | CHE            |
| <u>Preferred Term</u>                                                                                                                         | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardio-Respiratory Arrest;<br>Electrocardiogram Qt<br>Prolonged; Electrolyte<br>Imbalance; Torsade De<br>Pointes; Ventricular<br>Fibrillation | Fluoxetine         |                    |                    | S               | Oral                                            | Unk Unk, Unknown     |                 | Unknown      |                |
|                                                                                                                                               | Escitalopram       |                    |                    | S               | Oral                                            | 10 Mg, Bid           |                 | Not Reported |                |
|                                                                                                                                               | Atacand            |                    |                    | C               | Oral                                            | 16 Mg, Bid           |                 | Not Reported |                |
|                                                                                                                                               | Tranxilium         |                    |                    | C               |                                                 | Unk Unk, Unknown     |                 | Not Reported |                |
|                                                                                                                                               | Temesta /00273201/ |                    |                    | C               |                                                 | Unk Unk, Unknown     |                 | Not Reported |                |

| <u>FDA Received Date</u>                                          | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|-----------------------------------------------------|-----------------|--------------|----------------|
| 04-Jun-2015                                                       | 11170753       | DIRECT           |                    | OT              |                      |                                                     | 47 YR           | Male         | USA            |
| <u>Preferred Term</u>                                             | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Dreams;<br>Anorgasmia; Ejaculation<br>Failure; Emotional | Escitalopram   |                  |                    | S               | Oral                 | 1/2 Pill 5 Days -1 Pill 2<br>Days Twice Daily Taken | 9 DAY           | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                      |                     |   |          |              |
|--------------------------------------------------------------------------------------|---------------------|---|----------|--------------|
| Disorder; Genital Hypoaesthesia; Mental Impairment; Nightmare; Premature Ejaculation | Amlodipine Besylate | C | By Mouth | Not Reported |
|                                                                                      | Levothyroxine       | C |          | Not Reported |
|                                                                                      | Micardis            | C |          | Not Reported |
|                                                                                      | Pravastatin         | C |          | Not Reported |
|                                                                                      | Low Dose Aspirin    | C |          | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Jun-2015              | 11020319      | EXPEDITED (15-DAY) | HO                 |                 | JP-TEVA-554172USA    |                      | 58 YR      | Male       | JPN            |

| <u>Preferred Term</u> | <u>Product</u>             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                          | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------------|--------------|------------|-------------|---------------------------------------|------------------------|-----------------|--------------|
| Bipolar Disorder      | Bendamustine Hydrochloride |              |            | S           | Intravenous (not otherwise specified) | Unk, Cyclic            |                 | Cephalon     |
|                       | Bendamustine Hydrochloride |              |            | S           | Intravenous (not otherwise specified) | Unk, Cyclic            |                 | Cephalon     |
|                       | Placebo                    |              |            | S           | Oral                                  | Unk Unk, Unknown Freq. |                 | Not Reported |
|                       | Placebo                    |              |            | S           |                                       | Unk, Unknown Freq.     |                 | Not Reported |
|                       | Rituximab                  |              |            | S           | Intravenous (not otherwise specified) | Unk, Unknown Freq.     |                 | Not Reported |
|                       | Lithium Carbonate          |              |            | S           | Oral                                  |                        |                 | Not Reported |
|                       | Lexapro /01588502/         |              |            | S           | Oral                                  |                        |                 | Not Reported |
|                       | Cercine                    |              |            | S           | Oral                                  |                        |                 | Not Reported |
|                       | Feburic                    |              |            | C           | Oral                                  |                        |                 | Not Reported |
|                       | Takepron                   |              |            | C           | Oral                                  |                        |                 | Not Reported |
|                       | Baktar                     |              |            | C           | Unknown                               |                        |                 | Not Reported |
|                       | Myonal /00287502/          |              |            | C           | Unknown                               |                        |                 | Not Reported |
|                       | Hirudoid /00723701/        |              |            | C           | Topical                               |                        |                 | Not Reported |
|                       | Miya Bm                    |              |            | C           | Oral                                  | Unk Unk, Thrice Daily  |                 | Not Reported |
|                       | Lulicon                    |              |            | C           | Topical                               |                        |                 | Not Reported |
|                       | Antebate                   |              |            | C           | Topical                               |                        |                 | Not Reported |
|                       | Zefnart                    |              |            | C           | Topical                               |                        |                 | Not Reported |
|                       | Allegra                    |              |            | C           | Oral                                  |                        |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                    |   |         |              |
|--------------------|---|---------|--------------|
| Lamisil /00992601/ | C | Topical | Not Reported |
| Astat /01368101/   | C | Topical | Not Reported |
| Loperamide         | C | Oral    | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Jun-2015              | 11166890      | EXPEDITED (15-DAY) |                    | OT              | GB-TEVA-566648ACC    |                      | 49 YR      | Female     | GBR            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Muscle Spasms; Pain   | Escitalopram   |              |            | S           | Oral         |                    |                 | Ivax         |
|                       | Cetirizine     |              |            | C           |              |                    |                 | Not Reported |
|                       | Desogestrel    |              |            | C           |              |                    |                 | Not Reported |
|                       | Omeprazol      |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 05-Jun-2015              | 11169437      | EXPEDITED (15-DAY) |                    | HO, OT          | CA-<br>ELI_LILLY_AND_COMP<br>ANY-CA201506000752 |                      |            | Female     | CAN            |

| <u>Preferred Term</u>                    | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>       |
|------------------------------------------|-----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------------|
| Intentional Overdose;<br>Suicide Attempt | Humalog Lispro        |              |            | S           | Subcutaneous |                    |                 | Eli Lilly And Co |
|                                          | Humalog Lispro        |              |            | S           | Oral         | 10 Df, Unk         |                 | Eli Lilly And Co |
|                                          | Ativan                |              |            | S           | Oral         | 80 Df, Unk         |                 | Not Reported     |
|                                          | Cipralelex /01588501/ |              |            | S           | Oral         | 20 Mg, Qd          |                 | Not Reported     |
|                                          | Cipralelex /01588501/ |              |            | S           | Oral         | 10 Mg, Qd          |                 | Not Reported     |
|                                          | Cipralelex /01588501/ |              |            | S           | Oral         |                    |                 | Not Reported     |
|                                          | Seroquel              |              |            | S           | Oral         |                    |                 | Not Reported     |
|                                          | Topiramate            |              |            | C           |              |                    |                 | Not Reported     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Jun-2015              | 11171994      | DIRECT           |                    | DS, LT          |                      |                      | 50 YR      | Female     | USA            |

| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|----------------|--------------|------------|-------------|--------------|-------------------------|-----------------|--------------|
| Anxiety; Arthralgia; Back | Amitriptyline  |              |            | S           | Oral         | 2-4 At Bedtime Taken By |                 | Not Reported |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                                                                                                                    |                     |   |      |                                           |              |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|---|------|-------------------------------------------|--------------|
| Pain; Chest Pain;<br>Cognitive Disorder;<br>Confusional State;<br>Dementia; Dizziness<br>Postural; Drug Monitoring<br>Procedure Not Performed;<br>Impaired Work Ability;<br>Memory Impairment;<br>Myalgia; Panic Reaction;<br>Product Prescribing Error;<br>Stress; Tachycardia;<br>Vision Blurred | Escitalopram        | S | Oral | M Outh<br>2 Twice Daily Taken By<br>Mouth | Not Reported |
|                                                                                                                                                                                                                                                                                                    | High Blood Pressure | C |      |                                           | Not Reported |
|                                                                                                                                                                                                                                                                                                    | Heart Rate Medicine | C |      |                                           | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Jun-2015              | 11110941      | EXPEDITED (15-DAY) |                    | HO              | PL-FRI-1000076141    |                      | 43 YR      | Male       | POL            |

| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|----------------|--------------|------------|-------------|--------------|-----------------------|-----------------|--------------|
| Gastrointestinal Disorder; | Escitalopram   |              |            | S           | Unknown      | Overdose: 40 Mg Daily |                 | Forest       |
| Prescribed Overdose;       | Divalproex     |              |            | C           | Unknown      | 1000 Mg               |                 | Not Reported |
| Sexual Dysfunction         | Lithium        |              |            | C           | Unknown      | 750 Mg                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>        | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------------|----------------------|------------|------------|----------------|
| 08-Jun-2015              | 11134417      | EXPEDITED (15-DAY) |                    | OT              | CA-TAKEDA-<br>2015TJP008784 |                      |            | Male       | CAN            |

| <u>Preferred Term</u>                                   | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------|-------------------|--------------|------------|-------------|--------------|-------------------------------------|-----------------|--------------|
| Angioedema; Prescribed<br>Overdose; Rash;<br>Vasculitis | Trintellix        |              |            | S           | Oral         | 10 Mg, Qd                           |                 | Takeda       |
|                                                         | Trintellix        |              |            | S           |              |                                     |                 | Takeda       |
|                                                         | Terbinafine       |              |            | S           | Oral         | 250 Mg, Qd                          |                 | Not Reported |
|                                                         | Cipralext Tablets |              |            | S           | Oral         | Overdose: Escitalopram<br>30 Mg, Qd |                 | Not Reported |
|                                                         | Cipralext Tablets |              |            | S           |              |                                     |                 | Not Reported |
|                                                         | Amitriptyline     |              |            | C           | Oral         | 100 Mg, Qd                          |                 | Not Reported |
|                                                         | Clonazepam        |              |            | C           | Oral         | 1 Mg, Tid                           |                 | Not Reported |
|                                                         | Clonazepam        |              |            | C           |              |                                     |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                  | Nozinan /00038601/ | C                  | Oral               | 37.5 Mg, Qd     |                      | Not Reported                                |                 |              |                |
|----------------------------------------------------------------------------------|--------------------|--------------------|--------------------|-----------------|----------------------|---------------------------------------------|-----------------|--------------|----------------|
|                                                                                  | Nph Insulin        | C                  | Subcutaneous       | As Directed.    |                      | Not Reported                                |                 |              |                |
|                                                                                  | Crestor            | C                  | Oral               | 5 Mg, Qd        |                      | Not Reported                                |                 |              |                |
| <u>FDA Received Date</u>                                                         | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Jun-2015                                                                      | 11170510           | EXPEDITED (15-DAY) |                    | OT              | FR-TEVA-568381ISR    |                                             | 20 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                            | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Rhabdomyolysis; Sedation                                                         | Escitalopram       |                    |                    | S               | Unknown              | Titrated From 5 To 20 Mg/D, Then Given 30mg |                 | Ivax         |                |
|                                                                                  | Escitalopram       |                    |                    | S               | Unknown              | 30 Mg                                       |                 | Ivax         |                |
|                                                                                  | Aripiprazole       |                    |                    | S               | Unknown              | 10 Mg                                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                         | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Jun-2015                                                                      | 11172183           | EXPEDITED (15-DAY) |                    | OT              | GB-FRI-1000077097    |                                             | 49 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                            | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Muscle Spasms; Pain                                                              | Escitalopram       |                    |                    | S               | Oral                 | 20 Mg Daily                                 |                 | Forest       |                |
|                                                                                  | Escitalopram       |                    |                    | S               |                      |                                             |                 | Forest       |                |
|                                                                                  | Cetirizine         |                    |                    | C               | Unknown              |                                             |                 | Not Reported |                |
|                                                                                  | Desogestrel        |                    |                    | C               | Unknown              |                                             |                 | Not Reported |                |
|                                                                                  | Omeprazole         |                    |                    | C               | Unknown              |                                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                         | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Jun-2015                                                                      | 11172184           | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000077099    |                                             | 82 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                            | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Anaemia; Fall;<br>Hyponatraemia;<br>Hypotension; Loss Of<br>Consciousness; Wound | Escitalopram       |                    |                    | S               | Oral                 | 1 Df                                        |                 | Forest       |                |
|                                                                                  | Coveram            |                    |                    | S               | Oral                 | 5 Mg/5 Mg                                   |                 | Not Reported |                |
|                                                                                  | Xanax              |                    |                    | S               | Oral                 | 1 Df                                        |                 | Not Reported |                |

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| Novatrex                                                                                               |                      |                    | C                  |                 | Unknown                                                 |                              |                 | Not Reported |                |
|--------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|---------------------------------------------------------|------------------------------|-----------------|--------------|----------------|
| <u>FDA Received Date</u>                                                                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                    | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Jun-2015                                                                                            | 11172233             | EXPEDITED (15-DAY) |                    | HO              | FR-SYMLMED<br>PHARMACEUTICALS-<br>2015SYMLMED00001<br>9 |                              |                 | Unknown      | FRA            |
| <u>Preferred Term</u>                                                                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                            | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Anaemia; Fall;<br>Hyponatraemia;<br>Hypotension; Loss Of<br>Consciousness; Wound;<br>Wound Haemorrhage | Coveram              |                    |                    | S               | Oral                                                    | 5mg/5mg Tablet Once<br>Daily |                 | Unknown      |                |
|                                                                                                        | Seroplex             |                    |                    | S               | Oral                                                    | 5 Mg, Qd                     |                 | Not Reported |                |
|                                                                                                        | Xanax                |                    |                    | S               | Oral                                                    | 0.25 Mg, Qd                  |                 | Not Reported |                |
|                                                                                                        | Novatrex /00113801/  |                    |                    | C               |                                                         |                              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                    | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Jun-2015                                                                                            | 10609022             | EXPEDITED (15-DAY) |                    | OT              | PHHY2014US146215                                        |                              |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                            | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Muscle Spasms; Pain;<br>Sensory Disturbance;<br>Therapeutic Response<br>Decreased                      | Baclofen Intrathecal |                    |                    | S               | Intrathecal                                             | 83 Ug, Per Day               |                 | Not Reported |                |
|                                                                                                        | Baclofen Intrathecal |                    |                    | S               |                                                         |                              |                 | Not Reported |                |
|                                                                                                        | Clonidine            |                    |                    | S               | Oral                                                    |                              |                 | Not Reported | Novartis       |
|                                                                                                        | Clonidine            |                    |                    | S               | Intrathecal                                             | 83 Ug, Per Day               |                 | Not Reported |                |
|                                                                                                        | Lexapro              |                    |                    | S               | Oral                                                    |                              |                 | Not Reported |                |
|                                                                                                        | Flexeril             |                    |                    | S               | Oral                                                    |                              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                    | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Jun-2015                                                                                            | 11151277             | EXPEDITED (15-DAY) |                    | DE, HO          | GR-PFIZER INC-<br>2015181860                            |                              | 72 YR           | Female       | GRC            |
| <u>Preferred Term</u>                                                                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                            | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Acute Kidney Injury; Acute<br>Respiratory Distress<br>Syndrome; Cardio-<br>Respiratory Arrest; Drug    | Amlodipine Besilate  |                    |                    | S               |                                                         | 5 Mg, 1x/Day                 |                 | Pfizer       |                |
|                                                                                                        | Lithium Carbonate    |                    |                    | S               |                                                         | 300 Mg, 3x/Day               |                 | Not Reported |                |
|                                                                                                        | Escitalopram Oxalate |                    |                    | S               |                                                         | 20 Mg, 1x/Day                |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                                                                                                   |                                                      |                    |                    |                 |                                          |                                   |                 |            |                |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------|--------------------|--------------------|-----------------|------------------------------------------|-----------------------------------|-----------------|------------|----------------|
| Interaction; Neuroleptic Malignant Syndrome; Rhabdomyolysis                                                                                                                                                                                                                       | Irbesartan                                           | S                  |                    |                 |                                          | 150 Mg, 1x/Day                    |                 |            | Not Reported   |
|                                                                                                                                                                                                                                                                                   | Buspirone Hydrochloride                              | S                  |                    |                 |                                          | 10 Mg, 1x/Day                     |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                          | <u>Case #</u>                                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 09-Jun-2015                                                                                                                                                                                                                                                                       | 11174091                                             | NON-EXPEDITED      |                    |                 | US-LUPIN PHARMACEUTICALS INC.-2015-01026 |                                   |                 | Female     | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                             | <u>Product</u>                                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u> |                |
| Fatigue; Insomnia                                                                                                                                                                                                                                                                 | Escitalopram                                         |                    |                    | S               | Unknown                                  |                                   |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                          | <u>Case #</u>                                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 09-Jun-2015                                                                                                                                                                                                                                                                       | 11177690                                             | DIRECT             |                    | DE              |                                          |                                   | 54 YR           | Male       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                             | <u>Product</u>                                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u> |                |
| Abnormal Behaviour; Completed Suicide; Headache; Social Avoidant Behaviour; Vision Blurred                                                                                                                                                                                        | Escitalopram 10 Mg                                   |                    |                    | S               |                                          |                                   | 2 MTH           |            | Not Reported   |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                          | <u>Case #</u>                                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 10-Jun-2015                                                                                                                                                                                                                                                                       | 11169808                                             | EXPEDITED (15-DAY) | Y                  | HO, OT          | ADR-2015-01025                           |                                   | 22 YR           | Female     | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                             | <u>Product</u>                                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u> |                |
| Agitation; Altered State Of Consciousness; Condition Aggravated; Confusional State; Constipation; Drug Withdrawal Syndrome; Hyperhidrosis; Hypertonia; Initial Insomnia; Muscle Spasticity; Musculoskeletal Stiffness; Pneumonia; Respiratory Tract Congestion; Screaming; Speech | Lioresal Intrathecal(Baclofen Injection) 2000 Mcg/MI |                    |                    | S               |                                          |                                   |                 |            | Not Reported   |
|                                                                                                                                                                                                                                                                                   | Ellura                                               |                    |                    | S               |                                          |                                   |                 |            | Not Reported   |
|                                                                                                                                                                                                                                                                                   | Microgestin 1.5/30                                   |                    |                    | S               |                                          |                                   |                 |            | Not Reported   |
|                                                                                                                                                                                                                                                                                   | Oxytrol                                              |                    |                    | S               | Topical                                  | 24 Hr Patch                       |                 |            | Not Reported   |
|                                                                                                                                                                                                                                                                                   | Lexapro                                              |                    |                    | S               |                                          |                                   |                 |            | Not Reported   |
|                                                                                                                                                                                                                                                                                   | Trazadone                                            |                    |                    | S               |                                          | 50 Mg Tab 1-2 Tabs At Bedtime Prn |                 |            | Not Reported   |
|                                                                                                                                                                                                                                                                                   | Valium                                               |                    |                    | S               |                                          | 5 Mg 1-2 Tab Prn                  |                 |            | Not Reported   |

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Disorder; Therapeutic  
Response Changed;  
Tooth Disorder

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
| 10-Jun-2015              | 11178934       | EXPEDITED (15-DAY) |                    | OT              | GB-MYLANLABS-2015M1017659 |                      |                 | Unknown      | GBR            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Muscle Spasms; Pain      | Escitalopram   |                    |                    | S               | Oral                      | 20 Mg, Unk           |                 | Not Reported |                |
|                          | Cetirizine     |                    |                    | C               |                           | Unk                  |                 | Not Reported |                |
|                          | Desogestrel    |                    |                    | C               |                           | Unk                  |                 | Not Reported |                |
|                          | Omeprazol      |                    |                    | C               |                           | Unk                  |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------------------|-----------------|--------------|----------------|
| 10-Jun-2015                                                                                | 11183630       | DIRECT           |                    |                 |                      |                                  | 49 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                      | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Fatigue; Feeling Abnormal; Insomnia; Mental Impairment; Product Substitution Issue; Tremor | Lexapro        |                  |                    | S               | Oral                 | 1 /Day Once Daily Taken By Mouth |                 | Accord       |                |
|                                                                                            | Cpap           |                  |                    | C               |                      |                                  |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                                               | <u>Case #</u>                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 10-Jun-2015                                                                                                                                                            | 11184305                                 | EXPEDITED (15-DAY) | Y                  | OT              | 2015HINLIT0479       |                      | 44 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                                                                                                                  | <u>Product</u>                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bruxism; Depression; Disease Recurrence; Drug Ineffective; Headache; Hypomania; Migraine; Musculoskeletal Pain; Neck Pain; Pain In Jaw; Therapy Change; Therapy Change | Escitalopram (Escitalopram)              |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                        | Unknown                                  |                    |                    |                 |                      |                      |                 |              |                |
|                                                                                                                                                                        | Lithium (Lithium)                        |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                        | Valproate (Valproate)                    |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                        | Indomethacin+Caffeine+Prochlorperazine   |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                        | (Indomethacin+Caffeine+Prochlorperazine) |                    |                    |                 |                      |                      |                 |              |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                 | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| 10-Jun-2015                              | 11184322                    | EXPEDITED (15-DAY) | Y                  | OT              | 2015HINLIT0476               |                      | 54 YR           | Male         | ITA            |
| <u>Preferred Term</u>                    | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bruxism; Hypomania;<br>Tongue Biting     | Escitalopram (Escitalopram) |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                                          | Lithium (Lithium)           |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                                          | Valproate (Valproate)       |                    |                    | C               |                              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                 | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Jun-2015                              | 11184496                    | EXPEDITED (15-DAY) | Y                  | OT              | 2015HINLIT0477               |                      | 35 YR           | Male         | IND            |
| <u>Preferred Term</u>                    | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Rabbit Syndrome                          | Escitalopram (Escitalopram) |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                                          | Unknown                     |                    |                    |                 |                              |                      |                 |              |                |
|                                          | Clonazepam                  |                    |                    | C               |                              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                 | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Jun-2015                              | 11189519                    | EXPEDITED (15-DAY) | Y                  | HO              | NSR_02133_2015               |                      | 81 YR           | Female       | ESP            |
| <u>Preferred Term</u>                    | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aphasia; Drug Interaction;<br>Hemianopia | Tramadol (Tramadol)         |                    |                    | S               |                              | Df                   |                 | Not Reported |                |
|                                          | Tramadol And Acetaminophen  |                    |                    | S               |                              | (1/1/1)              |                 | Not Reported |                |
|                                          | Escitalopram (Escitalopram) |                    |                    | S               |                              | (10; 1/0/0)          |                 | Not Reported |                |
|                                          | Etoricoxib (Etoricoxib)     |                    |                    | S               |                              | (90; 1/0/0)          |                 | Not Reported |                |
|                                          | Deflazacort                 |                    |                    | C               |                              |                      |                 | Not Reported |                |
|                                          | Salbutamol                  |                    |                    | C               |                              |                      |                 | Not Reported |                |
|                                          | Montelukast                 |                    |                    | C               |                              |                      |                 | Not Reported |                |
|                                          | Atorvastatin                |                    |                    | C               |                              |                      |                 | Not Reported |                |
|                                          | Omeprazole                  |                    |                    | C               |                              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                 | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Jun-2015                              | 11184226                    | NON-EXPEDITED      |                    |                 | US-PFIZER INC-<br>2015193932 |                      |                 | Unknown      | USA            |

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| <u>Preferred Term</u>                    | <u>Product</u>                                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|------------------------------------------|--------------------------------------------------------------|--------------------|--------------------|-----------------|-----------------------------------------------------|----------------------|-----------------|--------------|----------------|
| Dyspareunia                              | Duavee                                                       |                    |                    | S               |                                                     | Unk                  |                 | Pfizer       |                |
|                                          | Wellbutrin                                                   |                    |                    | S               |                                                     | Unk                  |                 | Not Reported |                |
|                                          | Lexapro                                                      |                    |                    | S               |                                                     | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                 | <u>Case #</u>                                                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Jun-2015                              | 11185070                                                     | EXPEDITED (15-DAY) |                    | OT              | US-ROXANE<br>LABORATORIES, INC.-<br>2015-RO-00946RO |                      | 49 YR           | Female       | USA            |
| <u>Preferred Term</u>                    | <u>Product</u>                                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bipolar I Disorder; Suicidal<br>Ideation | Oxcarbazepine                                                |                    |                    | S               | Unknown                                             | 600 Mg               |                 | Roxane       |                |
|                                          | Alprazolam Intensol [Oral<br>Solution (Concentrate)] 1 Mg/ML |                    |                    | S               | Unknown                                             |                      |                 | Roxane       |                |
|                                          | Lamotrigine                                                  |                    |                    | S               | Unknown                                             | 350 Mg               |                 | Not Reported |                |
|                                          | Escitalopram                                                 |                    |                    | S               | Unknown                                             | 25 Mg                |                 | Not Reported |                |
| <u>FDA Received Date</u>                 | <u>Case #</u>                                                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Jun-2015                              | 11188630                                                     | DIRECT             |                    | OT              |                                                     |                      | 53 YR           | Female       | USA            |
| <u>Preferred Term</u>                    | <u>Product</u>                                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Nausea;<br>Somnolence         | Escitalopram                                                 |                    |                    | S               | Oral                                                |                      |                 | Unknown      |                |
| <u>FDA Received Date</u>                 | <u>Case #</u>                                                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Jun-2015                              | 11191265                                                     | EXPEDITED (15-DAY) |                    | OT              | KR-ROCHE-1593361                                    |                      | 69 YR           | Female       | KOR            |
| <u>Preferred Term</u>                    | <u>Product</u>                                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Parkinsonism                             | Clonazepam                                                   |                    |                    | S               | Unknown                                             |                      |                 | Not Reported |                |
|                                          | Clonazepam                                                   |                    |                    | S               |                                                     |                      |                 | Not Reported |                |
|                                          | Haloperidol                                                  |                    |                    | S               | Unknown                                             |                      |                 | Not Reported |                |
|                                          | Buspirone                                                    |                    |                    | S               | Unknown                                             |                      |                 | Not Reported |                |
|                                          | Escitalopram                                                 |                    |                    | S               | Unknown                                             |                      |                 | Not Reported |                |

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| Escitalopram               |                                  |                    | S                  |                 |                      |                      | Not Reported    |              |                |
|----------------------------|----------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| <u>FDA Received Date</u>   | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Jun-2015                | 11195086                         | EXPEDITED (15-DAY) | Y                  | OT              | ADR-2015-01121       |                      |                 | Female       | USA            |
| <u>Preferred Term</u>      | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Arthralgia; Arthralgia;    | Baclofen                         |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Atrophy; Back Pain;        | Dilaudid (Hydromorphone)         |                    |                    | S               | Intrathecal          |                      |                 | Not Reported |                |
| Burning Sensation;         | Bupivacaine Intrathecal          |                    |                    | S               | Intrathecal          |                      |                 | Not Reported |                |
| Bursitis; Complex          |                                  |                    |                    |                 |                      |                      |                 |              |                |
| Regional Pain Syndrome;    | Lorazepam                        |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Depression; Diarrhoea;     | Baclofen                         |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Fall; Fractured Sacrum;    | Tramadol                         |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Haemangioma;               | Mobic                            |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Hallucination;             | Zantac                           |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Hyperaesthesia;            | Zanaflex                         |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Hypoaesthesia; Insomnia;   | Valium                           |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Joint Effusion; Mobility   | Amitriptyline                    |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Decreased; Mood Swings;    | Naltrexone                       |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Muscle Spasms; Muscle      | Hydroxyzine                      |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Spasms; Muscular           | Lidocaine                        |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Weakness;                  | Lithium                          |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Musculoskeletal Stiffness; | Mathocarbamol                    |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Myofascial Pain            | Melatonin                        |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Syndrome; Neuralgia;       | Diclofenac                       |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Osteoarthritis;            | Miralax                          |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Osteoporosis; Pain In      | Ranitidine                       |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Extremity; Panic Reaction; | Senna                            |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Paraesthesia; Paralysis;   | Docusate                         |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Physical Deconditioning;   | Vitamin B Complex With Vitamin C |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Post Laminectomy           |                                  |                    |                    |                 |                      |                      |                 |              |                |
| Syndrome; Sacroiliitis;    | Multivitamin                     |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Scoliosis; Skin            | Vitamin D3                       |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Discolouration; Social     | Acetaminophen                    |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Avoidant Behaviour;        | Topamax                          |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Somatic Symptom            | Heparin                          |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Disorder; Stress Fracture; | Topiramate                       |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Substance-Induced          | Lorazepam                        |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Psychotic Disorder;        | Tramadol                         |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Therapy Non-Responder;     | Meloxicam                        |                    |                    | S               |                      |                      |                 | Not Reported |                |



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|                                            |                             |   |         |              |
|--------------------------------------------|-----------------------------|---|---------|--------------|
| Urinary Incontinence;<br>Urinary Retention | Diazepam                    | S | Topical | Not Reported |
|                                            | Lidocaine                   | S |         | Not Reported |
|                                            | Nortipyline                 | S |         | Not Reported |
|                                            | Olanzapine                  | S |         | Not Reported |
|                                            | Hydroxyzine                 | S |         | Not Reported |
|                                            | Fortco                      | S |         | Not Reported |
|                                            | Savella                     | S |         | Not Reported |
|                                            | Tizanidine                  | S |         | Not Reported |
|                                            | Ketorolac                   | S |         | Not Reported |
|                                            | Effexor                     | S |         | Not Reported |
|                                            | Flexeril                    | S |         | Not Reported |
|                                            | Lorazepam                   | S |         | Not Reported |
|                                            | Vicodin                     | S |         | Not Reported |
|                                            | Neuropathic Pain Compound 1 | S |         | Not Reported |
|                                            | Horizant                    | S |         | Not Reported |
|                                            | Savella                     | S |         | Not Reported |
|                                            | Medrol                      | S |         | Not Reported |
|                                            | Celebrex                    | S |         | Not Reported |
|                                            | Celexa                      | S |         | Not Reported |
|                                            | Cymbalta                    | S |         | Not Reported |
|                                            | Lodine                      | S |         | Not Reported |
|                                            | Nexium                      | S |         | Not Reported |
|                                            | Nucynta                     | S |         | Not Reported |
|                                            | Pristiq                     | S |         | Not Reported |
|                                            | Seroquel                    | S |         | Not Reported |
|                                            | Skelaxin                    | S |         | Not Reported |
|                                            | Vallium                     | S |         | Not Reported |
|                                            | Piroxicam                   | S |         | Not Reported |
|                                            | Hyoscyamine                 | S |         | Not Reported |
|                                            | Librax                      | S |         | Not Reported |
|                                            | Bextra                      | S |         | Not Reported |
|                                            | Actonel                     | S |         | Not Reported |
|                                            | Xanax                       | S |         | Not Reported |
|                                            | Zoloft                      | S |         | Not Reported |
|                                            | Lamictal                    | S |         | Not Reported |
|                                            | Mobic                       | S |         | Not Reported |
|                                            | Percocet                    | S |         | Not Reported |
|                                            | Ultracet                    | S |         | Not Reported |
|                                            | Butrans                     | S |         | Not Reported |
|                                            | Toradol                     | S |         | Not Reported |
|                                            | Depakote                    | S |         | Not Reported |
|                                            | Ativan                      | S |         | Not Reported |

**FDA Adverse Event Reporting System  
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|                       |   |              |
|-----------------------|---|--------------|
| Gabapentin            | S | Not Reported |
| Abilify               | S | Not Reported |
| Gabapentin            | S | Not Reported |
| Osteoporosis Infusion | S | Not Reported |
| Hydromorphone         | S | Not Reported |
| Toprol XL             | S | Not Reported |
| Plaquenil             | S | Not Reported |
| Aspirin               | S | Not Reported |
| Clonazepam            | S | Not Reported |
| Venlafaxine           | S | Not Reported |
| Naproxen              | S | Not Reported |
| Ondansetron           | S | Not Reported |
| Tylenol               | S | Not Reported |
| Roxicodone            | S | Not Reported |
| Bisacodyl             | S | Not Reported |
| Ketorolac             | S | Not Reported |
| Carbamazepine         | S | Not Reported |
| Cholecalciferol       | S | Not Reported |
| Diclofenac Sodium     | S | Not Reported |
| Enoxaparin            | S | Not Reported |
| Nortriptyline         | S | Not Reported |
| Olanzapine            | S | Not Reported |
| Methocarbamol         | S | Not Reported |
| Tranlycypromine       | S | Not Reported |
| Divalproex            | S | Not Reported |
| Ferrous Sulphate      | S | Not Reported |
| Pantoprazole          | S | Not Reported |
| Lactated Ringers      | S | Not Reported |
| Magnesium Citrate     | S | Not Reported |
| Pantoprazole          | S | Not Reported |
| Milk Of Magnesia      | S | Not Reported |
| Amitriptyline         | S | Not Reported |
| Fluphenazine          | S | Not Reported |
| Soma                  | S | Not Reported |
| Lithium               | S | Not Reported |
| Phenergan             | S | Not Reported |
| Benzoazepine          | S | Not Reported |
| Amitriptyline         | S | Not Reported |
| Prolixin              | S | Not Reported |
| Bactrim               | S | Not Reported |
| Macrobid              | S | Not Reported |
| Melatonin             | S | Not Reported |

**FDA Adverse Event Reporting System  
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|                           |   |              |
|---------------------------|---|--------------|
| Ranitidine                | S | Not Reported |
| Senna                     | S | Not Reported |
| Docusate                  | S | Not Reported |
| Prolixin                  | S | Not Reported |
| Pantoprazole              | S | Not Reported |
| Naltrexone Hcl            | S | Not Reported |
| Acetaminophen\Hydrocodone | S | Not Reported |
| Bitartrate                |   |              |
| Biaxin                    | S | Not Reported |
| Amoxicillin               | S | Not Reported |
| Cyclobenzaprine           | S | Not Reported |
| Alprazolam                | S | Not Reported |
| Sertraline Hcl            | S | Not Reported |
| Arthrotec                 | S | Not Reported |
| Methylprednisolone        | S | Not Reported |
| Levaquin                  | S | Not Reported |
| Ibuprofen                 | S | Not Reported |
| Sulfamethoxazole          | S | Not Reported |
| Ambien                    | S | Not Reported |
| Oxycodone                 | S | Not Reported |
| Propoxy-N/Apap            | S | Not Reported |
| Lexapro                   | S | Not Reported |
| Metaxalone                | S | Not Reported |
| Ciprofloxacin Hcl         | S | Not Reported |
| Cephalexin                | S | Not Reported |
| Limbrel                   | S | Not Reported |
| Alendronate Sodium        | S | Not Reported |
| Valacyclovir              | S | Not Reported |
| Nitrostat                 | S | Not Reported |
| Prednisone                | S | Not Reported |
| Doxycycline Hyclate       | S | Not Reported |
| Quetiapine Fumarate       | S | Not Reported |
| Promethazine              | S | Not Reported |
| Duloxetine Hcl            | S | Not Reported |
| Namenda                   | S | Not Reported |
| Risperidone               | S | Not Reported |
| Orphenadrine              | S | Not Reported |
| Cimetidine                | S | Not Reported |
| Mexiletine                | S | Not Reported |
| Nuvigil                   | S | Not Reported |
| Trazodone                 | S | Not Reported |
| Zoloft                    | S | Not Reported |

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| Lidoderm Patch                                                                                                     |                             |                    | S                  |                 | Not Reported               |                            |                 |              |                |
|--------------------------------------------------------------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|----------------------------|----------------------------|-----------------|--------------|----------------|
| Fentora                                                                                                            |                             |                    | S                  |                 | Not Reported               |                            |                 |              |                |
| <u>FDA Received Date</u>                                                                                           | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Jun-2015                                                                                                        | 11190477                    | EXPEDITED (15-DAY) |                    | OT              | US-BAYER-2015-316953       |                            | 70 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                              | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Iron Increased; Expired Product Administered; Intestinal Ulcer; Off Label Use; Red Blood Cell Count Abnormal | Bayer Aspirin Regimen Adult |                    |                    | S               | Oral                       | 1 Df, Qd                   |                 | Bayer        |                |
|                                                                                                                    | Low Strength                |                    |                    |                 |                            |                            |                 |              |                |
|                                                                                                                    | Plavix                      |                    |                    | C               |                            | Unk                        |                 | Not Reported |                |
|                                                                                                                    | Lipitor                     |                    |                    | C               |                            |                            |                 | Not Reported |                |
|                                                                                                                    | Ambien                      |                    |                    | C               |                            |                            |                 | Not Reported |                |
|                                                                                                                    | Seroquel                    |                    |                    | C               |                            |                            |                 | Not Reported |                |
|                                                                                                                    | Lexapro                     |                    |                    | S               |                            | Unk                        |                 | Not Reported |                |
|                                                                                                                    | Vitamin D Nos               |                    |                    | C               |                            |                            |                 | Not Reported |                |
|                                                                                                                    | Magnesium [Magnesium Oxide] |                    |                    | C               |                            | Unk                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                           | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Jun-2015                                                                                                        | 11192055                    | EXPEDITED (15-DAY) |                    | HO              | FR-PFIZER INC-2015195948   |                            | 13 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                              | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>   |                |
| Malaise; Somnolence                                                                                                | Xanax                       |                    |                    | S               | Oral                       | 5 Mg (20-0.25 Mg, Tablets) |                 | Pfizer       |                |
|                                                                                                                    | Doliprane                   |                    |                    | S               | Oral                       | 2000 Mg (4-500mg Tablets)  |                 | Not Reported |                |
|                                                                                                                    | Paracetamol                 |                    |                    | S               | Oral                       | 4000 Mg, (8-500mg) Single  |                 | Not Reported |                |
|                                                                                                                    | Seroplex                    |                    |                    | S               | Oral                       | 90mg (18- 5mg Tablets)     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                           | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Jun-2015                                                                                                        | 11193456                    | EXPEDITED (15-DAY) |                    | HO, LT          | FR-ASTRAZENECA-2015SE59233 |                            | 55 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                              | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>   |                |

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|                           |                                                    |   |      |              |
|---------------------------|----------------------------------------------------|---|------|--------------|
| Coma; Electrocardiogram   | Xeroquel                                           | S | Oral | Astrazeneca  |
| Qrs Complex Prolonged;    | Zolmitriptan                                       | S | Oral | Not Reported |
| Shock; Status Epilepticus | Escitalopram                                       | S | Oral | Not Reported |
|                           | Esperal                                            | S | Oral | Not Reported |
|                           | Zyban                                              | C |      | Not Reported |
|                           | Atarax                                             | C |      | Not Reported |
|                           | Princi B                                           | C |      | Not Reported |
|                           | (Cyanocobalamin\Pyridoxine Hydrochloride\Thiamine) |   |      |              |
|                           | Cernevit                                           | C |      | Not Reported |
|                           | Decan (Minerals)                                   | C |      | Not Reported |
|                           | Vitamin C                                          | C |      | Not Reported |
|                           | Lovenox                                            | C |      | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Jun-2015              | 11193884      | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000077320    |                      |            | Male       | FRA            |

| <u>Preferred Term</u>                                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|------------|
| Foetal Exposure During Pregnancy; Neurodevelopmental Disorder | Escitalopram   |              |            | S           | Transplacental |                    |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Jun-2015              | 11199720      | DIRECT           |                    |                 |                      |                      | 27 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                              | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------|--------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Headache; Product Quality Issue; Product Quality Issue; Product Substitution Issue | Escitalopram 10 Mg |              |            | S           | Oral         | 1 Pill             |                 | Accord       |
|                                                                                    | Albuterol          |              |            | C           |              |                    |                 | Not Reported |
|                                                                                    | Allegra            |              |            | C           |              |                    |                 | Not Reported |
|                                                                                    | Flonase            |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Jun-2015              | 11199792      | DIRECT           |                    | OT              |                      |                      | 37 YR      | Female     | USA            |

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| <u>Preferred Term</u> | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Alopecia              | Escitalopram           |              |            | S           | Oral         |                    |                 | Torrent      |
|                       | Zegerid                |              |            | C           |              |                    |                 | Not Reported |
|                       | Melatonin              |              |            | C           |              |                    |                 | Not Reported |
|                       | Allegra                |              |            | C           |              |                    |                 | Not Reported |
|                       | Ibuprofen              |              |            | C           |              |                    |                 | Not Reported |
|                       | Benadryl               |              |            | C           |              |                    |                 | Not Reported |
|                       | Epiduo Gel             |              |            | C           |              |                    |                 | Not Reported |
|                       | Triamcinolone Ointment |              |            | C           |              |                    |                 | Not Reported |
|                       | Ketoconazole           |              |            | C           |              |                    |                 | Not Reported |
|                       | Seborrheic Dermatitis  |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Jun-2015              | 11175143      | EXPEDITED (15-DAY) |                    | HO              | JP-FRI-1000077171    |                      | 24 YR      | Female     | JPN            |

| <u>Preferred Term</u>  | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Off Label Use; Seizure | Lexapro                |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                        | Amoxan                 |              |            | S           |              | 50 Mg              |                 | Not Reported |
|                        | Meilax                 |              |            | C           |              |                    |                 | Not Reported |
|                        | Saikokaryukotsuboreito |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Jun-2015              | 11182082      | EXPEDITED (15-DAY) |                    | HO              | PHHY2015ES066883     |                      | 88 YR      | Female     | ESP            |

| <u>Preferred Term</u>                          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Bradyphrenia;<br>Hyponatraemia; Slow<br>Speech | Escitalopram   |              |            | S           | Oral         | 10 Mg, Qd          |                 | Not Reported |
|                                                | Esidrex        |              |            | S           |              | 25 Mg, Qd          |                 | Novartis     |
|                                                | Enalapril      |              |            | C           | Oral         | 20 Mg, Qd          |                 | Not Reported |
|                                                | Coropres       |              |            | C           |              | 25 Mg, Bid         |                 | Not Reported |
|                                                | Eucreas        |              |            | C           | Oral         | 10 Mg, Qd          |                 | Not Reported |
|                                                | Lantus         |              |            | C           |              | 11 lu, Qd          |                 | Not Reported |
|                                                | Optivite       |              |            | C           | Oral         |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                      |                           |                    |                    |                 |                                    |                                             |                 |              |                |
|------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|------------------------------------|---------------------------------------------|-----------------|--------------|----------------|
| Zaldiar                                              |                           |                    | C                  |                 | Oral                               |                                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                             | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u>                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Jun-2015                                          | 11195884                  | NON-EXPEDITED      |                    |                 | US-DRREDDYS-<br>USA/USA/15/0045394 |                                             | 48 YR           | Female       | USA            |
| <u>Preferred Term</u>                                | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                       | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Adverse Event; Vomiting                              | Sertraline Hydrochloride  |                    |                    | S               | Unknown                            |                                             |                 | Not Reported |                |
|                                                      | Venlafaxine Hydrochloride |                    |                    | S               | Unknown                            | Low Dose                                    |                 | Not Reported |                |
|                                                      | Escitalopram              |                    |                    | S               | Unknown                            |                                             |                 | Not Reported |                |
|                                                      | Paroxetine                |                    |                    | S               |                                    |                                             |                 | Not Reported |                |
|                                                      | Mirtazapine               |                    |                    | S               | Unknown                            |                                             |                 | Not Reported |                |
|                                                      | Fluoxetine Tablets        |                    |                    | C               | Unknown                            |                                             |                 | Not Reported |                |
|                                                      | Diazepam                  |                    |                    | C               | Unknown                            |                                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                             | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u>                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Jun-2015                                          | 11197407                  | EXPEDITED (15-DAY) |                    | HO              | CH-FRI-1000077441                  |                                             | 48 YR           | Female       | CHE            |
| <u>Preferred Term</u>                                | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                       | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest;<br>Electrocardiogram Qt<br>Prolonged | Escitalopram              |                    |                    | S               | Oral                               | 20 Mg                                       |                 | Forest       |                |
|                                                      | Fluoxetin                 |                    |                    | S               | Oral                               | Treated For 12 Years With<br>Unknown Dosage |                 | Not Reported |                |
|                                                      | Atacand                   |                    |                    | C               | Oral                               | 32 Mg                                       |                 | Not Reported |                |
|                                                      | Tranxilium                |                    |                    | C               | Oral                               |                                             |                 | Not Reported |                |
|                                                      | Temesta (Lorazepam)       |                    |                    | C               | Oral                               |                                             |                 | Not Reported |                |
|                                                      |                           |                    |                    |                 |                                    |                                             |                 |              |                |
| <u>FDA Received Date</u>                             | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u>                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Jun-2015                                          | 11197408                  | EXPEDITED (15-DAY) |                    | OT              | JP-FRI-1000077437                  |                                             |                 | Male         | JPN            |
| <u>Preferred Term</u>                                | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                       | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Creatine<br>Phosphokinase Increased;           | Lexapro                   |                    |                    | S               | Oral                               |                                             |                 | Forest       |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                           |                                                             |                    |                    |                 |                                                     |                         |                 |                      |                |
|-------------------------------------------|-------------------------------------------------------------|--------------------|--------------------|-----------------|-----------------------------------------------------|-------------------------|-----------------|----------------------|----------------|
| Hepatic Function Abnormal                 |                                                             | Depas (Etizolam)   |                    | C               | Oral                                                |                         | Not Reported    |                      |                |
| <u>FDA Received Date</u>                  | <u>Case #</u>                                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 17-Jun-2015                               | 11197409                                                    | EXPEDITED (15-DAY) |                    | HO              | US-FRI-1000076071                                   |                         | 56 YR           | Female               | USA            |
| <u>Preferred Term</u>                     | <u>Product</u>                                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                        | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>           |                |
| Kidney Infection; Urinary Tract Infection | Escitalopram                                                |                    |                    | S               | Oral                                                | 20 Mg Milligram(S), Unk |                 | Forest               |                |
|                                           | Blinded Investigational Medicinal Product (Imp) Non-Partner |                    |                    | S               | Oral                                                | Unk                     |                 | Not Reported         |                |
|                                           | Lisinopril                                                  |                    |                    | C               | Oral                                                | 10 Mg Milligram(S), Unk |                 | Not Reported         |                |
|                                           | Levothyroxine                                               |                    |                    | C               | Oral                                                | 100 Mcg, Unk            |                 | Not Reported         |                |
|                                           | Azelastine                                                  |                    |                    | C               | Ophthalmic                                          | 1 Gtt Drop(S), Unk      |                 | Not Reported         |                |
|                                           | Benadryl                                                    |                    |                    | C               | Oral                                                | 25 Mcg, Unk             |                 | Not Reported         |                |
| <u>FDA Received Date</u>                  | <u>Case #</u>                                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 18-Jun-2015                               | 11143373                                                    | EXPEDITED (15-DAY) |                    | OT              | ES-UCBSA-2015016384                                 |                         |                 | Male                 | ESP            |
| <u>Preferred Term</u>                     | <u>Product</u>                                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                        | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>           |                |
| Neutropenia                               | Vimpat                                                      |                    |                    | S               |                                                     | 200 Mg, 2x/Day (Bid)    |                 | Ucb                  |                |
|                                           | Omeprazole                                                  |                    |                    | S               |                                                     | Unk                     |                 | Not Reported         |                |
|                                           | Escitalopram                                                |                    |                    | S               |                                                     | Unk                     |                 | Not Reported         |                |
|                                           | Phenobarbital                                               |                    |                    | C               |                                                     | Unk                     |                 | Not Reported         |                |
|                                           | Phenytoin                                                   |                    |                    | C               |                                                     | Unk                     |                 | Not Reported         |                |
| <u>FDA Received Date</u>                  | <u>Case #</u>                                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 18-Jun-2015                               | 11156885                                                    | EXPEDITED (15-DAY) |                    | HO              | ES-B.I. PHARMACEUTICALS,I NC./RIDGEFIELD-2015-BI-28 |                         | 81 YR           | Female               | ESP            |
| <u>Preferred Term</u>                     | <u>Product</u>                                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                        | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>           |                |
| Hyponatraemia                             | Micardisplus                                                |                    |                    | S               | Oral                                                | 1 Anz                   |                 | Boehringer Ingelheim |                |



## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                |   |         |                                                                     |              |
|----------------|---|---------|---------------------------------------------------------------------|--------------|
| Escitalopram   | S | Oral    | 10 Mg                                                               | Not Reported |
| Tryptizol      | S | Oral    | 25 Mg                                                               | Not Reported |
| Metformina     | C | Unknown | Dose Per Application:<br>50mg /850 Mg; Daily<br>Dose: 100mg/1700 Mg | Not Reported |
| Glimepirida    | C | Unknown | 4 Mg                                                                | Not Reported |
| Paracetamol    | C | Unknown | 1000 Mg                                                             | Not Reported |
| Zarator        | C | Unknown | 10 Mg                                                               | Not Reported |
| Adiro          | C | Unknown | 100 Mg                                                              | Not Reported |
| Atenolol Alter | C | Unknown | 25 Mg                                                               | Not Reported |
| Omeprazol      | C | Unknown | 40 Mg                                                               | Not Reported |
| Sintrom        | C | Unknown | 4 Mg                                                                | Not Reported |
| Xumadol        | C | Unknown | 2 G                                                                 | Not Reported |
| Plusvent       | C | Unknown | 100 Mcg                                                             | Not Reported |

| <u>FDA Received Date</u>            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>        | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------|----------------------|--------------------|--------------------|-----------------|-----------------------------|----------------------|-----------------|--------------|----------------|
| 18-Jun-2015                         | 11169927             | EXPEDITED (15-DAY) |                    | DE, OT          | CA-TAKEDA-<br>2015TJP010080 |                      | 46 YR           | Male         | CAN            |
| <u>Preferred Term</u>               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Drug Ineffective | Trintellix           |                    |                    | S               | Oral                        | 5 Mg, Qd             |                 | Takeda       |                |
|                                     | Ciprallex /01588501/ |                    |                    | S               | Oral                        | 10 Mg, Qd            |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|---------------------------------------|--------------------|--------------------|-----------------|------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 18-Jun-2015              | 11198315                              | EXPEDITED (15-DAY) |                    |                 | US-STRIDES ARCOLAB<br>LIMITED-<br>2014SP004427 |                      |                 | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity    | Levofloxacin                          |                    |                    | S               |                                                | Unk                  |                 | Not Reported |                |
|                          | Vancomycin                            |                    |                    | S               |                                                | Unk                  |                 | Strides      |                |
|                          | Amoxicillin And Clavulanate Potassium |                    |                    | S               |                                                | Unk                  |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|               |   |     |              |
|---------------|---|-----|--------------|
| Meloxicam     | S | Unk | Strides      |
| Effexor       | S | Unk | Not Reported |
| Lamotrigine   | S | Unk | Not Reported |
| Lexapro       | S | Unk | Not Reported |
| Sulfonamide   | S | Unk | Not Reported |
| Celebrex      | S | Unk | Not Reported |
| Phenytoin     | S | Unk | Not Reported |
| Amitriptyline | S | Unk | Not Reported |
| Tioconazole   | S | Unk | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|---------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 18-Jun-2015              | 11200493            | EXPEDITED (15-DAY) |                    | DE              | FR-FRI-1000077500    |                      | 87 YR           | Female       | FRA            |
| <u>Preferred Term</u>    | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cerebral Haematoma       | Escitalopram        |                    |                    | S               | Oral                 |                      |                 | Forest       |                |
|                          | Plavix              |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                          | Hyperium            |                    |                    | C               | Unknown              |                      |                 | Not Reported |                |
|                          | Lercan              |                    |                    | C               | Unknown              |                      |                 | Not Reported |                |
|                          | Insulin Basal Bolus |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Simvastatine        |                    |                    | C               | Unknown              |                      |                 | Not Reported |                |
|                          | Lasilix             |                    |                    | C               | Unknown              |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 18-Jun-2015               | 11200906       | EXPEDITED (15-DAY) |                    | LT              | FR-FRI-1000077463    |                      | 39 YR           | Male         | FRA            |
| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alcoholism; Condition     | Escitalopram   |                    |                    | S               | Oral                 |                      |                 | Forest       |                |
| Aggravated; Suicidal      | Selincro       |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
| Ideation; Suicide Attempt | Naltrexone     |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                           | Venlafaxine    |                    |                    | S               | Oral                 | 225 Mg               |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                     |   |         |        |              |
|---------------------|---|---------|--------|--------------|
| Atarax              | C | Oral    |        | Not Reported |
| Temesta (Lorazepam) | C | Oral    | 2.5 Mg | Not Reported |
| Inexium             | C | Oral    |        | Not Reported |
| Seresta             | C | Unknown |        | Not Reported |
| Bevitine            | C | Unknown |        | Not Reported |
| Lansoprazole        | C | Unknown |        | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Jun-2015              | 11200931      | EXPEDITED (15-DAY) | CA                 |                 | US-FRI-1000077480    |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Heart Disease Congenital | Lexapro        |              |            | S           |              |                    |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Jun-2015              | 11200934      | EXPEDITED (15-DAY) | CA                 |                 | US-FRI-1000077531    |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Heart Disease Congenital | Lexapro        |              |            | S           |              |                    |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Jun-2015              | 11200935      | EXPEDITED (15-DAY) | CA                 |                 | US-FRI-1000077455    |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Heart Disease Congenital | Lexapro        |              |            | S           |              |                    |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Jun-2015              | 11206424      | DIRECT           |                    | HO              |                      |                      | 16 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Suicidal Ideation     | Lexapro 20 Mg Camber |              |            | S           | Oral         | 1 Pill             |                 | Not Reported |
|                       | Buspar               |              |            | C           |              |                    |                 | Not Reported |
|                       | Deplin               |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                 |                |                    |                    |                 |                      |                      |                    |                 |                |
|---------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|--------------------|-----------------|----------------|
| Ativan                          |                |                    | C                  |                 |                      | Not Reported         |                    |                 |                |
| <u>FDA Received Date</u>        | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |
| 19-Jun-2015                     | 11203271       | EXPEDITED (15-DAY) |                    | CA, DE          | US-FRI-1000077459    |                      | < 1 DAY            | Female          | USA            |
| <u>Preferred Term</u>           | <u>Product</u> |                    | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>          | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>     |
| Atrioventricular Septal Defect  | Lexapro        |                    |                    |                 | S                    |                      |                    |                 | Forest         |
| <u>FDA Received Date</u>        | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |
| 19-Jun-2015                     | 11203322       | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000077523    |                      |                    | Unknown         | USA            |
| <u>Preferred Term</u>           | <u>Product</u> |                    | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>          | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>     |
| Heart Disease Congenital        | Lexapro        |                    |                    |                 | S                    |                      |                    |                 | Forest         |
| <u>FDA Received Date</u>        | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |
| 19-Jun-2015                     | 11203468       | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000077528    |                      |                    | Unknown         | USA            |
| <u>Preferred Term</u>           | <u>Product</u> |                    | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>          | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>     |
| Heart Disease Congenital        | Lexapro        |                    |                    |                 | S                    |                      |                    |                 | Forest         |
| <u>FDA Received Date</u>        | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |
| 19-Jun-2015                     | 11203536       | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000077526    |                      |                    | Unknown         | USA            |
| <u>Preferred Term</u>           | <u>Product</u> |                    | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>          | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>     |
| Heart Disease Congenital        | Lexapro        |                    |                    |                 | S                    |                      |                    |                 | Forest         |
| <u>FDA Received Date</u>        | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |
| 19-Jun-2015                     | 11203577       | EXPEDITED (15-DAY) |                    | CA, DE, OT      | US-FRI-1000077461    |                      |                    | Unknown         | USA            |
| <u>Preferred Term</u>           | <u>Product</u> |                    | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>          | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>     |
| Hypoplastic Left Heart Syndrome | Lexapro        |                    |                    |                 | S                    | Transplacental       |                    |                 | Forest         |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>               | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|---------------------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 19-Jun-2015                         | 11203662                | EXPEDITED (15-DAY)        |                             | CA                       | US-FRI-1000077510                           |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>      | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                       | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Heart Disease Congenital            | Lexapro                 |                           |                             | S                        |                                             |                               |                          | Forest              |                         |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>               | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 19-Jun-2015                         | 11203686                | EXPEDITED (15-DAY)        |                             | CA                       | US-FRI-1000077514                           |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>      | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                       | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Heart Disease Congenital            | Lexapro                 |                           |                             | S                        |                                             |                               |                          | Forest              |                         |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>               | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 19-Jun-2015                         | 11211333                | DIRECT                    |                             | DS                       |                                             |                               | 60 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>      | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                       | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Aggression; Fear                    | Lexapro                 |                           |                             | S                        | Oral                                        | 1 Once Daily Taken By Mouth   |                          | Walmart             |                         |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>               | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 22-Jun-2015                         | 11178866                | EXPEDITED (15-DAY)        |                             | DE, OT                   | CA-FRI-1000077199                           |                               | 46 YR                    | Male                | CAN                     |
| <a href="#">Preferred Term</a>      | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                       | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Completed Suicide; Drug Ineffective | Escitalopram            |                           |                             | S                        | Oral                                        | 10 Mg                         |                          | Forest              |                         |
|                                     | Trintellix              |                           |                             | S                        | Oral                                        | 5 Mg                          |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>               | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 22-Jun-2015                         | 11204764                | EXPEDITED (15-DAY)        |                             | OT                       | ES-JUBILANT<br>GENERICs LIMITED-<br>1040095 |                               | 71 YR                    | Male                | ESP                     |
| <a href="#">Preferred Term</a>      | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                       | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                 |                        |   |      |              |
|-----------------|------------------------|---|------|--------------|
| Acute Psychosis | Olanzapine             | S | Oral | Jubilant     |
|                 | Escitalopram           | S |      | Not Reported |
|                 | Trazodone              | S |      | Not Reported |
|                 | Carbidopa And Levodopa | S |      | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Jun-2015              | 11205850      | EXPEDITED (15-DAY) |                    | OT              | ES-SA-2015SA084359   |                      | 67 YR      | Female     | ESP            |

| <u>Preferred Term</u> | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blindness; Glaucoma   | Quetiapine Fumarate |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Escitalopram        |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Gemfibrozil         |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Pantoprazole        |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Irbesartan          |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Hydrochlorothiazide |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Ropinirole          |              |            | C           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Jun-2015              | 11206620      | EXPEDITED (15-DAY) | Y                  | OT              | PHHY2014US174191     |                      | 54 YR      | Female     | USA            |

| <u>Preferred Term</u>     | <u>Product</u>             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety Disorder;         | Baclofen Intrathecal       |              |            | S           | Intrathecal  | 10 Mg, Tid Prn     |                 | Not Reported |
| Arthralgia; Asthenia;     | Baclofen                   |              |            | S           | Oral         | 10 Mg, Tid Prn     |                 | Not Reported |
| Atrophy; Back Pain;       | Nortriptyline              |              |            | S           | Unknown      | Unk                |                 | Not Reported |
| Bursitis; Contusion;      | Paracetamol                |              |            | S           | Unknown      | Unk                |                 | Not Reported |
| Depression; Fall;         | Clonazepam                 |              |            | S           | Unknown      | 0.5 Mg, Bid        |                 | Not Reported |
| Insomnia; Joint Effusion; | Carbamazepine              |              |            | S           | Unknown      | Unk                |                 | Novartis     |
| Muscle Spasms;            | Ibuprofen                  |              |            | S           | Unknown      | Unk                |                 | Not Reported |
| Myofascial Pain           | Pantoprazole               |              |            | S           | Unknown      | Unk                |                 | Not Reported |
| Syndrome; Osteoporosis;   | Methylprednisolone Acetate |              |            | S           | Unknown      | Unk                |                 | Not Reported |
| Panic Reaction; Social    |                            |              |            |             |              |                    |                 |              |
| Avoidant Behaviour;       |                            |              |            |             |              |                    |                 |              |
| Somatic Symptom           |                            |              |            |             |              |                    |                 |              |
| Disorder; Substance-      |                            |              |            |             |              |                    |                 |              |
| Induced Psychotic         |                            |              |            |             |              |                    |                 |              |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                 |                             |   |         |     |              |
|---------------------------------|-----------------------------|---|---------|-----|--------------|
| Disorder; Therapy Non-Responder | Tramadol                    | S | Unknown | Unk | Not Reported |
|                                 | Amitriptyline               | S | Unknown | Unk | Not Reported |
|                                 | Naltrexon Hcl               | S | Unknown | Unk | Not Reported |
|                                 | Hydroxyzine                 | S | Unknown | Unk | Not Reported |
|                                 | Lidocaine                   | S | Unknown | Unk | Not Reported |
|                                 | Ranitidine                  | S | Unknown | Unk | Not Reported |
|                                 | Heparin                     | S | Unknown | Unk | Not Reported |
|                                 | Topiramate                  | S | Unknown | Unk | Not Reported |
|                                 | Lorazepam                   | S | Unknown | Unk | Not Reported |
|                                 | Meloxicam                   | S | Unknown | Unk | Not Reported |
|                                 | Olanzapine                  | S | Unknown | Unk | Not Reported |
|                                 | Tizanidine                  | S | Unknown | Unk | Not Reported |
|                                 | Ketorolac                   | S | Unknown | Unk | Not Reported |
|                                 | Naproxen                    | S | Unknown | Unk | Not Reported |
|                                 | Enoxaparin Sodium           | S | Unknown | Unk | Not Reported |
|                                 | Fluphenazine                | S | Unknown | Unk | Not Reported |
|                                 | Ondansetron                 | S | Unknown | Unk | Not Reported |
|                                 | Trazodone                   | S | Unknown | Unk | Not Reported |
|                                 | Amoxicillin                 | S | Unknown | Unk | Not Reported |
|                                 | Alprazolam                  | S | Unknown | Unk | Not Reported |
|                                 | Cyclobenzaprine             | S | Unknown | Unk | Not Reported |
|                                 | Sulfamethoxazole            | S | Unknown | Unk | Not Reported |
|                                 | Sertraline Hydrochloride    | S | Unknown | Unk | Not Reported |
|                                 | Ciprofloxacin Hydrochloride | S | Unknown | Unk | Not Reported |
|                                 | Valaciclovir                | S | Unknown | Unk | Not Reported |
|                                 | Metaxalone                  | S | Unknown | Unk | Not Reported |
|                                 | Quetiapine                  | S | Unknown | Unk | Not Reported |
|                                 | Prednisone                  | S | Unknown | Unk | Not Reported |
|                                 | Promethazine                | S | Unknown | Unk | Not Reported |

**FDA Adverse Event Reporting System  
Freedom of Information Act (FOIA)  
Detailed Report**

|                                             |   |              |            |              |
|---------------------------------------------|---|--------------|------------|--------------|
| Risperidone                                 | S | Unknown      | Unk        | Not Reported |
| Orphenadrine                                | S | Unknown      | Unk        | Not Reported |
| Cimetidine                                  | S | Unknown      | Unk        | Not Reported |
| Gabapentin                                  | S | Unknown      | Unk        | Not Reported |
| Alendronate Sodium                          | S | Unknown      | Unk        | Not Reported |
| Effexor                                     | S | Unknown      | 150 Mg, Qd | Not Reported |
| Zantac                                      | S | Unknown      | Unk        | Not Reported |
| Flexeril                                    | S | Endocervical | Unk        | Not Reported |
| Vicodin                                     | S | Unknown      | Unk        | Not Reported |
| Horizant                                    | S | Unknown      | Unk        | Not Reported |
| Medrol                                      | S | Unknown      | Unk        | Not Reported |
| Celebrex                                    | S | Unknown      | Unk        | Not Reported |
| Lithium                                     | S | Unknown      | Unk        | Not Reported |
| Celexa                                      | S | Unknown      | Unk        | Not Reported |
| Valium                                      | S | Unknown      | Unk        | Not Reported |
| Cymbalta                                    | S | Unknown      | Unk        | Not Reported |
| Lodine                                      | S | Unknown      | Unk        | Not Reported |
| Nexium//Esomeprazole                        | S | Unknown      | Unk        | Not Reported |
| Magnesium                                   |   |              |            |              |
| Nucynta                                     | S | Unknown      | Unk        | Not Reported |
| Seroquel                                    | S | Unknown      | Unk        | Not Reported |
| Skelaxin                                    | S | Unknown      | Unk        | Not Reported |
| Piroxicam                                   | S | Unknown      | Unk        | Not Reported |
| Vitamin B Complex With Vitamin C /02146701/ | S | Unknown      | Unk        | Not Reported |
| Hyoscyamine                                 | S | Unknown      | Unk        | Not Reported |
| Melatonin                                   | S | Unknown      | Unk        | Not Reported |
| Vitamin B3                                  | S | Unknown      | Unk        | Not Reported |
| Savella                                     | S | Unknown      | Unk        | Not Reported |
| Diclofenac Sodium                           | S | Unknown      | Unk        | Not Reported |



**FDA Adverse Event Reporting System  
Freedom of Information Act (FOIA)  
Detailed Report**

|               |   |              |                                                                    |              |
|---------------|---|--------------|--------------------------------------------------------------------|--------------|
| Librax        | S | Unknown      | Unk                                                                | Not Reported |
| Senna         | S | Unknown      | Unk                                                                | Not Reported |
| Docusate      | S | Unknown      | Unk                                                                | Not Reported |
| Topamax       | S | Unknown      | Unk                                                                | Not Reported |
| Miralax       | S | Unknown      | Unk                                                                | Not Reported |
| Multi Vitamin | S | Unknown      | Unk                                                                | Not Reported |
| Dilaudid      | S | Intrathecal  |                                                                    | Not Reported |
| Dilaudid      | S | Intrathecal  | 5.996 Mg, 20.0 Mg/MI<br>(Dose Was Decreased 14<br>Percent) Per Day | Not Reported |
| Dilaudid      | S |              | Unk, 10 Mg/MI Minimum<br>Rate                                      | Not Reported |
| Zanaflex      | S | Unknown      | Unk                                                                | Not Reported |
| Mobic         | S | Unknown      | Unk                                                                | Not Reported |
| Methocarbamol | S | Unknown      | Unk                                                                | Not Reported |
| Bextra        | S | Unknown      | Unk                                                                | Not Reported |
| Actonel       | S | Endocervical | Unk                                                                | Not Reported |
| Xanax         | S | Unknown      | Unk                                                                | Not Reported |
| Zoloft        | S | Unknown      | Unk                                                                | Not Reported |
| Lamictal      | S | Unknown      | Unk                                                                | Not Reported |
| Percocet      | S | Unknown      | Unk                                                                | Not Reported |
| Ultracet      | S | Unknown      | Unk                                                                | Not Reported |
| Butrans       | S | Unknown      | Unk                                                                | Not Reported |
| Toradol       | S | Unknown      | Unk                                                                | Not Reported |
| Depakote      | S | Unknown      | Unk                                                                | Not Reported |
| Ativan        | S | Unknown      | Unk                                                                | Not Reported |
| Namenda       | S | Unknown      | Unk                                                                | Not Reported |
| Abilify       | S | Unknown      | Unk                                                                | Not Reported |
| Hydromorphone | S | Unknown      | Unk                                                                | Not Reported |
| Toprol XL     | S | Unknown      | Unk                                                                | Not Reported |

**FDA Adverse Event Reporting System  
Freedom of Information Act (FOIA)  
Detailed Report**

|                           |   |              |     |              |
|---------------------------|---|--------------|-----|--------------|
| Plaquenil                 | S | Unknown      | Unk | Not Reported |
| Aspirin                   | S | Unknown      | Unk | Not Reported |
| Venlafaxin                | S | Unknown      | Unk | Not Reported |
| Tylenol                   | S | Unknown      | Unk | Not Reported |
| Roxicodone                | S | Unknown      | Unk | Not Reported |
| Bisacodyl                 | S | Unknown      | Unk | Not Reported |
| Tranlycypromine           | S | Unknown      | Unk | Not Reported |
| Divalproex                | S | Unknown      | Unk | Not Reported |
| Ferrous Sulphate          | S | Unknown      | Unk | Not Reported |
| Lactated Ringers          | S | Unknown      | Unk | Not Reported |
| Magnesium Citrate Enteral | S | Unknown      | Unk | Not Reported |
| Milk Of Magnesia          | S | Unknown      | Unk | Not Reported |
| Sona                      | S | Unknown      | Unk | Not Reported |
| Phenergan /00488301/      | S | Unknown      | Unk | Not Reported |
| Benzodiazepines           | S | Unknown      | Unk | Not Reported |
| Prolixin                  | S | Unknown      | Unk | Not Reported |
| Bactrim                   | S | Unknown      | Unk | Not Reported |
| Macrobid                  | S |              |     | Not Reported |
| Acetaminophen\Hydrocodone | S | Unknown      | Unk | Not Reported |
| Bitartrate                |   |              |     |              |
| Biaxin                    | S | Unknown      | Unk | Not Reported |
| Arthrotec                 | S | Endocervical | Unk | Not Reported |
| Levaquin                  | S | Unknown      | Unk | Not Reported |
| Ambien                    | S | Unknown      | Unk | Not Reported |
| Oxycodone                 | S | Unknown      | Unk | Not Reported |
| Propoxyphene N/Apap       | S | Unknown      | Unk | Not Reported |
| Lexapro                   | S | Unknown      | Unk | Not Reported |
| Cephalexin                | S | Unknown      | Unk | Not Reported |
| Limbrel                   | S | Unknown      | Unk | Not Reported |
| Nitrostat                 | S | Unknown      | Unk | Not Reported |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |                     |   |             |            |  |              |
|--|---------------------|---|-------------|------------|--|--------------|
|  | Doxycycline Hyclate | S | Unknown     | Unk        |  | Not Reported |
|  | Duloxetine Hcl      | S | Unknown     | Unk        |  | Not Reported |
|  | Mexiletine          | S | Unknown     | Unk        |  | Not Reported |
|  | Nuvigil             | S | Unknown     | 150 Mg, Qd |  | Not Reported |
|  | Lidoderm            | S | Unknown     | Unk        |  | Not Reported |
|  | Bupivacaine         | S | Intrathecal | Unk        |  | Not Reported |
|  | Fentora             | S | Unknown     | Unk        |  | Not Reported |

| <u>FDA Received Date</u>                                                                                                                                                                | <u>Case #</u>     | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|------------------|--------------------|-----------------|----------------------|------------------------------------------------|-----------------|--------------|----------------|
| 22-Jun-2015                                                                                                                                                                             | 11212785          | DIRECT           |                    |                 |                      |                                                | 46 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                   | <u>Product</u>    | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                             | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Bruxism;<br>Diarrhoea; Incorrect Dose<br>Administered; Malaise;<br>Muscle Spasms;<br>Musculoskeletal Stiffness;<br>Mydriasis; Nausea;<br>Toxicity To Various<br>Agents; Tremor | Escitalopram 10mg |                  |                    | S               | Oral                 | Half A Pill (5mg) Once<br>Daily Taken By Mouth |                 | Not Reported |                |
|                                                                                                                                                                                         | Bisoprolol        |                  |                    | C               |                      |                                                |                 | Not Reported |                |
|                                                                                                                                                                                         | B Complex         |                  |                    | C               |                      |                                                |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                | <u>Case #</u>       | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------|---------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 22-Jun-2015                                                             | 11214907            | DIRECT           |                    | LT              |                      |                      | 28 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                   | <u>Product</u>      | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Personality Change;<br>Product Substitution Issue;<br>Suicidal Ideation | Escitalopram 20mg   |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                         | Synthroid           |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                         | Folic Acid Vitamins |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                         | Vitamin D Nos       |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                         | Biotin Vitamins     |                  |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Jun-2015              | 11214961      | DIRECT           |                    | DS              |                      |                      | 38 YR      | Male       | USA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                             | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|----------------------------|-------------------------|-----------------|--------------|----------------|
| Drug Ineffective; Product Substitution Issue; Withdrawal Syndrome | Escitalopram 20 Mg Mylan |                    |                    | S               | Oral                       |                         |                 | Mylan        |                |
|                                                                   | Daily Multi-Vitamin B12  |                    |                    | C               |                            |                         |                 | Not Reported |                |
|                                                                   |                          |                    |                    | C               |                            |                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                          | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Jun-2015                                                       | 11173165                 | EXPEDITED (15-DAY) |                    | OT              | US-FRI-1000077222          |                         | 90 YR           | Male         | USA            |
| <u>Preferred Term</u>                                             | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrioventricular Block Second Degree; Dizziness; Presyncope       | Escitalopram             |                    |                    | S               |                            | 10 Mg                   |                 | Forest       |                |
|                                                                   | Memantine                |                    |                    | S               |                            | 10 Mg                   |                 | Forest       |                |
|                                                                   | Aspirin                  |                    |                    | C               |                            | 81 Mg                   |                 | Not Reported |                |
|                                                                   | Clopidogrel              |                    |                    | C               |                            | 37.5 Mg                 |                 | Not Reported |                |
|                                                                   | Seroquel                 |                    |                    | C               |                            | 25 Mg                   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                          | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Jun-2015                                                       | 11211165                 | EXPEDITED (15-DAY) | Y                  | HO, OT          | IT-ASTRAZENECA-2015SE60008 |                         | 41 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                             | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Coma; Drug Abuse; Intentional Self-Injury                         | Seroquel                 |                    |                    | S               | Oral                       |                         |                 | Zeneca       |                |
|                                                                   | Entact                   |                    |                    | S               | Oral                       |                         |                 | Not Reported |                |
|                                                                   | Gestodiol                |                    |                    | S               | Oral                       | 30 Mcg +75 Mcg, Unknown |                 | Not Reported |                |
|                                                                   | Depakin Chrono           |                    |                    | C               |                            |                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                          | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Jun-2015                                                       | 11211475                 | EXPEDITED (15-DAY) |                    | OT              | PHHY2015BR031566           |                         |                 | Female       | BRA            |
| <u>Preferred Term</u>                                             | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Emotional Disorder; Headache; Hip Fracture; Memory    | Exelon Patch             |                    |                    | S               | Transdermal                | 1 Df, Qd (After Dinner) |                 | Novartis     |                |
|                                                                   | Meloxicam                |                    |                    | S               | Unknown                    | 15 Mg, Qd (After Lunch) |                 | Not Reported |                |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                              |              |   |         |                            |              |
|--------------------------------------------------------------|--------------|---|---------|----------------------------|--------------|
| Impairment; Off Label Use; Rib Fracture; Upper Limb Fracture | Escitalopram | S | Unknown | 1 Df, Qd (After Breakfast) | Not Reported |
|                                                              | Assert       | S | Unknown | 1 Df, Qhs (At Night)       | Not Reported |
|                                                              | Assert       | S |         |                            | Not Reported |
|                                                              | Assert       | S |         |                            | Not Reported |
|                                                              | Prebictal    | C | Oral    | 1 Df, Qd                   | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|------------|------------|----------------|
| 23-Jun-2015              | 11211657      | EXPEDITED (15-DAY) |                    | OT              | US-AUROBINDO-AUR-APL-2015-05333 |                      |            | Male       | USA            |

| <u>Preferred Term</u>                                           | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------|---------------------|--------------|------------|-------------|--------------|-------------------------|-----------------|--------------|
| Breath Sounds Abnormal; Cardiac Failure                         | Metformin 500mg     |              |            | S           | Unknown      | 500 Mg, Two Times A Day |                 | Aurobindo    |
| Congestive; Cough;                                              | Abilify             |              |            | S           | Unknown      | 2 Mg, Once A Day        |                 | Not Reported |
| Disorientation; Dyspnoea;                                       | Aspirin             |              |            | S           | Unknown      | 81 Mg, Once A Day       |                 | Not Reported |
| Dyspnoea Exertional;                                            | Cymbalta            |              |            | S           | Unknown      | 60 Mg, Once A Day       |                 | Not Reported |
| Malaise; Obesity;                                               | Digoxin             |              |            | S           | Oral         | 250 Mcg, Unk            |                 | Not Reported |
| Pulmonary Arterial Hypertension; Pulmonary Hypertension; Rales; | Flomax /00889901/   |              |            | S           | Unknown      | 0.4 Mg, Once A Day      |                 | Not Reported |
| Sleep Apnoea Syndrome;                                          | Furosemide          |              |            | S           | Unknown      | 40 Mg, Once A Day       |                 | Not Reported |
| Weight Decreased;                                               | Lexapro             |              |            | S           | Unknown      | 10 Mg, Once A Day       |                 | Not Reported |
| Wheezing                                                        | Potassium Chloride  |              |            | S           | Unknown      | 10 Meq, Two Times A Day |                 | Not Reported |
|                                                                 | Revatio             |              |            | S           | Unknown      | 20 Mg, 3 Times A Day    |                 | Not Reported |
|                                                                 | Tracleer /01587701/ |              |            | S           | Unknown      | 125 Mg, Unk             |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Jun-2015              | 11212571      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000077627    |                      |            | Female     | FRA            |

| <u>Preferred Term</u>                                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Affective Disorder; Bipolar I Disorder; Irritability; Logorrhoea | Escitalopram   |              |            | S           |              | 10 Mg              |                 | Forest       |
|                                                                  | Tercian        |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                  | Inexium        |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                  | Augmentin      |              |            | C           | Unknown      |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| Kardegic                                                                              |                        |                    | C                  |                 | Unknown                       |                      |                 | Not Reported |                |
|---------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|-----------------|--------------|----------------|
| <u>FDA Received Date</u>                                                              | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Jun-2015                                                                           | 10459479               | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000070707             |                      | 91 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                 | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;<br>Haematoma Muscle;<br>International Normalised<br>Ratio Increased | Escitalopram           |                    |                    | S               | Oral                          |                      |                 | Forest       |                |
|                                                                                       | Previscan (Fluindione) |                    |                    | S               | Oral                          |                      |                 | Not Reported |                |
|                                                                                       | Tavanic                |                    |                    | S               | Oral                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                              | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Jun-2015                                                                           | 11214261               | EXPEDITED (15-DAY) |                    | HO              | PHHY2015IT072832              |                      | 51 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                                 | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Electrocardiogram Qt<br>Prolonged;<br>Electrocardiogram St<br>Segment Elevation       | Lorazepam              |                    |                    | S               | Oral                          | 20 Mg, Once/Single   |                 | Novartis     |                |
|                                                                                       | Cipralext 10 Mg        |                    |                    | S               | Oral                          | 280 Mg, Once/Single  |                 | Not Reported |                |
|                                                                                       | Benexol                |                    |                    | S               | Oral                          | 6 Df, Once/Single    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                              | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Jun-2015                                                                           | 11215669               | EXPEDITED (15-DAY) |                    | OT              | AU-MYLANLABS-<br>2015M1021301 |                      |                 | Unknown      | AUS            |
| <u>Preferred Term</u>                                                                 | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Headache; Nausea;<br>Product Substitution Issue;<br>Withdrawal Syndrome               | Loxalate               |                    |                    | S               |                               | 1 Df, Qd             |                 | Mylan        |                |
| <u>FDA Received Date</u>                                                              | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Jun-2015                                                                           | 11216874               | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000077704             |                      |                 | Unknown      | FRA            |
| <u>Preferred Term</u>                                                                 | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Constipation; Decreased<br>Appetite; Eye Swelling;                                    | Escitalopram           |                    |                    | S               | Oral                          | 10 Mg                |                 | Forest       |                |

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|                                                                      |            |   |      |       |              |
|----------------------------------------------------------------------|------------|---|------|-------|--------------|
| Malaise; Nausea; Ocular<br>Hyperaemia; Urinary<br>Retention; Vertigo | Omeprazole | S | Oral | 10 Mg | Not Reported |
|----------------------------------------------------------------------|------------|---|------|-------|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Jun-2015              | 10369476      | EXPEDITED (15-DAY) |                    | LT              | FR-FRI-1000069719    |                      | 84 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Toxic Encephalopathy  | Escitalopram                |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                       | Renitec [Enalapril Maleate] |              |            | C           |              |                    |                 | Not Reported |
|                       | Dafalgan                    |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Jun-2015              | 10867558      | EXPEDITED (15-DAY) |                    | OT              | IT-FRI-1000074744    |                      | 67 YR      | Female     | ITA            |

| <u>Preferred Term</u>                                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Disorientation; Drug<br>Abuse; Electrocardiogram<br>Qt Prolonged; Overdose | Escitalopram   |              |            | S           | Oral         |                    |                 | Forest       |
|                                                                            | Escitalopram   |              |            | S           | Oral         | Overdose: 10 Units |                 | Forest       |
|                                                                            | Talofen        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                            | Talofen        |              |            | S           | Oral         | Overdose: 30 Ml.   |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>        | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------------|----------------------|------------|------------|----------------|
| 25-Jun-2015              | 11217343      | EXPEDITED (15-DAY) |                    | OT              | DE-TAKEDA-<br>2015TJP011331 |                      | 48 YR      | Male       | DEU            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Scleral Haemorrhage   | Brintellix     |              |            | S           | Oral         | 5 Mg, Qd           |                 | Takeda       |
|                       | Escitalopram   |              |            | S           | Oral         | 5 Mg, Qd           |                 | Not Reported |
|                       | Mirtazapin     |              |            | C           | Oral         | 7.5 Mg, Qd         |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Jun-2015              | 11218295      | EXPEDITED (15-DAY) |                    | HO, LT          | FR-FRI-1000077670    |                      | 55 YR      | Female     | FRA            |

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| <u>Preferred Term</u>                                                                                   | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                           | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|--------------------------------------------------------------|-----------------|--------------|----------------|
| Coma; Electrocardiogram<br>Qrs Complex Prolonged;<br>Intentional Overdose;<br>Shock; Status Epilepticus | Escitalopram            |                    |                    | S               | Unknown              |                                                              |                 | Forest       |                |
|                                                                                                         | Escitalopram            |                    |                    | S               | Oral                 | Overdose: 1,800 Mg                                           |                 | Forest       |                |
|                                                                                                         | Esperal                 |                    |                    | S               | Unknown              |                                                              |                 | Not Reported |                |
|                                                                                                         | Esperal                 |                    |                    | S               | Oral                 | Overdose: 30 Grams                                           |                 | Not Reported |                |
|                                                                                                         | Xeroquel                |                    |                    | S               | Oral                 |                                                              |                 | Not Reported |                |
|                                                                                                         | Xeroquel                |                    |                    | S               |                      | Overdose: 48 Grams                                           |                 | Not Reported |                |
|                                                                                                         | Zolmitriptan            |                    |                    | S               | Oral                 | Overdose: 45 Mg                                              |                 | Not Reported |                |
|                                                                                                         | Zyban                   |                    |                    | C               | Unknown              |                                                              |                 | Not Reported |                |
|                                                                                                         | Atarax                  |                    |                    | C               | Unknown              |                                                              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Jun-2015                                                                                             | 11218300                | EXPEDITED (15-DAY) |                    | OT              | CN-FRI-1000077660    |                                                              | 45 YR           | Female       | CHN            |
| <u>Preferred Term</u>                                                                                   | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                           | <u>Duration</u> | <u>Mfr</u>   |                |
| Dysphoria; Intracranial<br>Aneurysm                                                                     | Escitalopram            |                    |                    | S               | Unknown              | In The Morning                                               |                 | Forest       |                |
|                                                                                                         | Trazodone Hydrochloride |                    |                    | C               | Oral                 | 0.5 - 1 Tablet Per Day<br>Before Sleeping,<br>Intermittently |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Jun-2015                                                                                             | 11218771                | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000077672    |                                                              | 78 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                   | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                           | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;<br>Hyponatraemia                                                                      | Escitalopram            |                    |                    | S               | Oral                 |                                                              |                 | Forest       |                |
|                                                                                                         | Escitalopram            |                    |                    | S               | Oral                 |                                                              |                 | Forest       |                |
|                                                                                                         | Indapamide              |                    |                    | S               | Oral                 |                                                              |                 | Not Reported |                |
|                                                                                                         | Stilnox                 |                    |                    | C               |                      |                                                              |                 | Not Reported |                |
|                                                                                                         | Alprazolam              |                    |                    | C               |                      |                                                              |                 | Not Reported |                |
|                                                                                                         | Dafalgan                |                    |                    | C               |                      |                                                              |                 | Not Reported |                |
|                                                                                                         | Uvedose                 |                    |                    | C               |                      |                                                              |                 | Not Reported |                |



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| Euphytose                                                                                                                                                                                                                                                                                                                                                           |                | C                  |                    | Not Reported    |                                            |                      |                 |                 |                |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|--------------------------------------------|----------------------|-----------------|-----------------|----------------|
| Clinutren                                                                                                                                                                                                                                                                                                                                                           |                | C                  |                    | Not Reported    |                                            |                      |                 |                 |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 25-Jun-2015                                                                                                                                                                                                                                                                                                                                                         | 11218786       | EXPEDITED (15-DAY) |                    | HO              | FR-<br>GLAXOSMITHKLINE-<br>FR2015GSK090062 |                      | 61 YR           | Male            | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Disorganised Speech;<br>Echolalia; Logorrhoea;<br>Reduced Facial<br>Expression; Staring                                                                                                                                                                                                                                                                             | Lamictal       |                    |                    | S               | Oral                                       | 25 Mg, Bid           |                 | Glaxosmithkline |                |
|                                                                                                                                                                                                                                                                                                                                                                     | Imovane        |                    |                    | S               | Oral                                       | Unk                  |                 | Glaxosmithkline |                |
|                                                                                                                                                                                                                                                                                                                                                                     | Artane         |                    |                    | S               | Oral                                       | 2 Mg, Tid            |                 | Not Reported    |                |
|                                                                                                                                                                                                                                                                                                                                                                     | Seroplex       |                    |                    | S               | Oral                                       | 10 Mg, Qd            |                 | Glaxosmithkline |                |
|                                                                                                                                                                                                                                                                                                                                                                     | Risperdal      |                    |                    | C               | Oral                                       | 2 Mg, Bid            |                 | Glaxosmithkline |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 25-Jun-2015                                                                                                                                                                                                                                                                                                                                                         | 11218823       | EXPEDITED (15-DAY) |                    | OT              | JP-SA-2015SA089352                         |                      | 55 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Anxiety Disorder;<br>Arthralgia; Asthenia;<br>Atrophy; Back Pain;<br>Bursitis; Contusion;<br>Depression; Fall;<br>Insomnia; Joint Effusion;<br>Muscle Spasms;<br>Myofascial Pain<br>Syndrome; Osteoporosis;<br>Panic Reaction; Social<br>Avoidant Behaviour;<br>Somatic Symptom<br>Disorder; Substance-<br>Induced Psychotic<br>Disorder; Therapy Non-<br>Responder | Levaquin       |                    |                    | S               | Unknown                                    |                      |                 | Not Reported    |                |
|                                                                                                                                                                                                                                                                                                                                                                     | Ambien         |                    |                    | S               | Unknown                                    |                      |                 | Not Reported    |                |
|                                                                                                                                                                                                                                                                                                                                                                     | Baclofen       |                    |                    | S               | Intrathecal                                |                      |                 | Not Reported    |                |
|                                                                                                                                                                                                                                                                                                                                                                     | Baclofen       |                    |                    | S               | Oral                                       |                      |                 | Not Reported    |                |
|                                                                                                                                                                                                                                                                                                                                                                     | Dilaudid       |                    |                    | S               | Unknown                                    |                      |                 | Not Reported    |                |
|                                                                                                                                                                                                                                                                                                                                                                     | Dilaudid       |                    |                    | S               | Unknown                                    |                      |                 | Not Reported    |                |
|                                                                                                                                                                                                                                                                                                                                                                     | Bupivacaine    |                    |                    | S               | Intrathecal                                |                      |                 | Not Reported    |                |
|                                                                                                                                                                                                                                                                                                                                                                     | Lorazepam      |                    |                    | S               | Unknown                                    |                      |                 | Not Reported    |                |
|                                                                                                                                                                                                                                                                                                                                                                     | Tramadol       |                    |                    | S               | Unknown                                    |                      |                 | Not Reported    |                |
|                                                                                                                                                                                                                                                                                                                                                                     | Mobic          |                    |                    | S               | Unknown                                    |                      |                 | Not Reported    |                |
|                                                                                                                                                                                                                                                                                                                                                                     | Zantac         |                    |                    | S               | Unknown                                    |                      |                 | Not Reported    |                |
|                                                                                                                                                                                                                                                                                                                                                                     | Zanaflex       |                    |                    | S               | Unknown                                    |                      |                 | Not Reported    |                |
|                                                                                                                                                                                                                                                                                                                                                                     | Zanaflex       |                    |                    | S               | Unknown                                    |                      |                 | Not Reported    |                |

**FDA Adverse Event Reporting System  
Freedom of Information Act (FOIA)  
Detailed Report**

|                                                                                                                             |   |         |             |              |
|-----------------------------------------------------------------------------------------------------------------------------|---|---------|-------------|--------------|
| Valium                                                                                                                      | S | Unknown |             | Not Reported |
| Amitriptyline                                                                                                               | S | Unknown |             | Not Reported |
| Hydroxyzine                                                                                                                 | S | Unknown |             | Not Reported |
| Lidocaine                                                                                                                   | S | Topical | Form-Patch  | Not Reported |
| Lithium                                                                                                                     | S | Unknown |             | Not Reported |
| Methocarbamol                                                                                                               | S | Unknown |             | Not Reported |
| Melatonin                                                                                                                   | S | Unknown |             | Not Reported |
| Diclofenac                                                                                                                  | S | Unknown |             | Not Reported |
| Miralax                                                                                                                     | S | Unknown | Form-Powder | Not Reported |
| Ranitidine                                                                                                                  | S | Unknown |             | Not Reported |
| Senna                                                                                                                       | S | Unknown |             | Not Reported |
| Docusate                                                                                                                    | S | Unknown |             | Not Reported |
| Panthenol/Retinol/Thiamine<br>Hydrochloride/Ascorbic<br>Acid/Ergocalciferol/Folic<br>Acid/Riboflavin/Nicotina<br>Vitamin D3 | S | Unknown |             | Not Reported |
| Acetaminophen                                                                                                               | S | Unknown |             | Not Reported |
| Topamax                                                                                                                     | S | Unknown |             | Not Reported |
| Heparin                                                                                                                     | S | Unknown |             | Not Reported |
| Topiramate                                                                                                                  | S | Unknown |             | Not Reported |
| Meloxicam                                                                                                                   | S | Unknown |             | Not Reported |
| Diazepam                                                                                                                    | S | Unknown |             | Not Reported |
| Nortriptyline                                                                                                               | S | Unknown |             | Not Reported |
| Olanzapine                                                                                                                  | S | Unknown |             | Not Reported |
| Savella                                                                                                                     | S | Unknown |             | Not Reported |
| Tizanidine                                                                                                                  | S | Unknown |             | Not Reported |
| Ketorolac                                                                                                                   | S | Unknown |             | Not Reported |
| Effexor                                                                                                                     | S | Unknown |             | Not Reported |
| Flexeril                                                                                                                    | S | Unknown |             | Not Reported |

**FDA Adverse Event Reporting System  
Freedom of Information Act (FOIA)  
Detailed Report**

|               |   |         |              |
|---------------|---|---------|--------------|
| Vicodin       | S | Unknown | Not Reported |
| Medrol        | S | Unknown | Not Reported |
| Celebrex      | S | Unknown | Not Reported |
| Celexa        | S | Unknown | Not Reported |
| Cymbalta      | S | Unknown | Not Reported |
| Lodine        | S | Unknown | Not Reported |
| Nexium        | S | Unknown | Not Reported |
| Nucynta       | S | Unknown | Not Reported |
| Pristiq       | S | Unknown | Not Reported |
| Seroquel      | S | Unknown | Not Reported |
| Skelaxin      | S | Unknown | Not Reported |
| Piroxicam     | S | Unknown | Not Reported |
| Hyoscyamine   | S | Unknown | Not Reported |
| Librax        | S | Unknown | Not Reported |
| Bextra        | S | Unknown | Not Reported |
| Actonel       | S | Unknown | Not Reported |
| Xanax         | S | Unknown | Not Reported |
| Zoloft        | S | Unknown | Not Reported |
| Zoloft        | S | Unknown | Not Reported |
| Lamictal      | S | Unknown | Not Reported |
| Mobic         | S | Unknown | Not Reported |
| Percocet      | S | Unknown | Not Reported |
| Ultracet      | S | Unknown | Not Reported |
| Toradol       | S | Unknown | Not Reported |
| Depakote      | S | Unknown | Not Reported |
| Ativan        | S | Unknown | Not Reported |
| Abilify       | S | Unknown | Not Reported |
| Gabapentin    | S | Unknown | Not Reported |
| Hydromorphone | S | Unknown | Not Reported |

**FDA Adverse Event Reporting System  
Freedom of Information Act (FOIA)  
Detailed Report**

|                                      |   |         |              |
|--------------------------------------|---|---------|--------------|
| Toprol XL                            | S | Unknown | Not Reported |
| Plaquenil                            | S | Unknown | Not Reported |
| Aspirin                              | S | Unknown | Not Reported |
| Clonazepam                           | S | Unknown | Not Reported |
| Naproxen                             | S | Unknown | Not Reported |
| Ondansetron                          | S | Unknown | Not Reported |
| Tylenol                              | S | Unknown | Not Reported |
| Roxicodone                           | S | Unknown | Not Reported |
| Bisacodyl                            | S | Oral    | Not Reported |
| Enoxaparin                           | S | Unknown | Not Reported |
| Methocarbamol                        | S | Unknown | Not Reported |
| Tranylcypromine                      | S | Unknown | Not Reported |
| Divalproex Sodium                    | S | Unknown | Not Reported |
| Ferrous Sulphate                     | S | Unknown | Not Reported |
| Pantoprazole                         | S | Unknown | Not Reported |
| Magnesium Citrate                    | S | Oral    | Not Reported |
| Milk Of Magnesia                     | S | Unknown | Not Reported |
| Fluphenazine                         | S | Unknown | Not Reported |
| Phenergan                            | S | Unknown | Not Reported |
| Prolixin                             | S | Unknown | Not Reported |
| Bactrim                              | S | Unknown | Not Reported |
| Macrobid                             | S | Unknown | Not Reported |
| Acetaminophen\Hydrocodone Bitartrate | S | Unknown | Not Reported |
| Biaxin                               | S | Unknown | Not Reported |
| Amoxicillin                          | S | Unknown | Not Reported |
| Cyclobenzaprine                      | S | Unknown | Not Reported |
| Alprazolam                           | S | Unknown | Not Reported |
| Sertraline                           | S | Unknown | Not Reported |
| Arthrotec                            | S | Unknown | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                             |   |         |              |
|-----------------------------|---|---------|--------------|
| Methylprednisolone          | S | Unknown | Not Reported |
| Ibuprofen                   | S | Unknown | Not Reported |
| Sulfamethoxazole            | S | Unknown | Not Reported |
| Oxycodone                   | S | Unknown | Not Reported |
| Lexapro                     | S | Unknown | Not Reported |
| Metaxalone                  | S | Unknown | Not Reported |
| Ciprofloxacin Hydrochloride | S | Unknown | Not Reported |
| Cephalexin                  | S | Unknown | Not Reported |
| Alendronate Sodium          | S | Unknown | Not Reported |
| Valaciclovir                | S | Unknown | Not Reported |
| Nitrostat                   | S | Unknown | Not Reported |
| Prednisone                  | S | Unknown | Not Reported |
| Doxycycline Hyclate         | S | Unknown | Not Reported |
| Quetiapine Fumarate         | S | Unknown | Not Reported |
| Promethazine                | S | Unknown | Not Reported |
| Duloxetine                  | S | Unknown | Not Reported |
| Namenda                     | S | Unknown | Not Reported |
| Risperidone                 | S | Unknown | Not Reported |
| Orphenadrine                | S | Unknown | Not Reported |
| Cimetidine                  | S | Unknown | Not Reported |
| Mexiletine                  | S | Unknown | Not Reported |
| Nuvigil                     | S | Unknown | Not Reported |
| Trazodone                   | S | Unknown | Not Reported |
| Lidoderm                    | S | Unknown | Not Reported |
| Carbamazepine               | S | Oral    | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Jun-2015              | 11223961      | EXPEDITED (15-DAY) | Y                  | HO              | 8030627              |                      | 64 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                 |                                                        |   |      |              |
|---------------------------------|--------------------------------------------------------|---|------|--------------|
| Pulmonary Arterial Hypertension | Levothyrox                                             | S | Oral | Not Reported |
|                                 | Xagrid                                                 | S | Oral | Not Reported |
|                                 | Hydrea                                                 | S | Oral | Not Reported |
|                                 | Exjade                                                 | S | Oral | Not Reported |
|                                 | Aspegic [Acetylsalicylate Lysine]                      | S | Oral | Not Reported |
|                                 | Seroplex (Escitalopram Oxalate) (Escitalopram Oxalate) | S | Oral | Not Reported |
|                                 | Nebilox                                                | S | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Jun-2015              | 11163221      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000077138    |                      | 83 YR      | Female     | FRA            |

| <u>Preferred Term</u>  | <u>Product</u>                                    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------|---------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hyponatraemia; Seizure | Escitalopram                                      |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                        | Escitalopram                                      |              |            | S           | Oral         | 5 Mg               |                 | Forest       |
|                        | Escitalopram                                      |              |            | S           | Oral         | 2.1429 Mg          |                 | Not Reported |
|                        | Exforge                                           |              |            | C           | Unknown      | 1 Df               |                 | Not Reported |
|                        | Reminyl                                           |              |            | C           | Unknown      |                    |                 | Not Reported |
|                        | Cacit D3                                          |              |            | C           | Unknown      |                    |                 | Not Reported |
|                        | Dafalgan                                          |              |            | C           | Unknown      |                    |                 | Not Reported |
|                        | Forlax                                            |              |            | C           | Unknown      |                    |                 | Not Reported |
|                        | Inexium                                           |              |            | C           | Unknown      |                    |                 | Not Reported |
|                        | Spasfon (Phloroglucinol, Trimethylphloroglucinol) |              |            | C           | Unknown      |                    |                 | Not Reported |
|                        | Tardyferon                                        |              |            | C           | Unknown      |                    |                 | Not Reported |
|                        | Ursolvan                                          |              |            | C           | Unknown      |                    |                 | Not Reported |
|                        | Lamaline (Acetaminophen\Caffeine\Opium )          |              |            | C           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 26-Jun-2015              | 11220978      | EXPEDITED (15-DAY) |                    | OT              | ES-009507513-1506ESP012420 |                      | 71 YR      | Male       | ESP            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u> | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Acute Psychosis       | Carbidopa (+) Levodopa  |              |            | S           | Oral         |                    |                 | Merck        |
|                       | Trazodone Hydrochloride |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Escitalopram            |              |            | S           |              |                    |                 | Not Reported |
|                       | Olanzapine              |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------------------|----------------------|------------|------------|----------------|
| 26-Jun-2015              | 11221177      | EXPEDITED (15-DAY) |                    | DS, OT          | ES-JUBILANT<br>GENERIC LIMITED-<br>1040195 |                      | 67 YR      | Female     | ESP            |

| <u>Preferred Term</u> | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blindness; Glaucoma   | Quetiapine Fumarate |              |            | S           |              |                    |                 | Jubilant     |
|                       | Escitalopram        |              |            | S           |              |                    |                 | Not Reported |
|                       | Hydrochlorothiazide |              |            | S           |              |                    |                 | Not Reported |
|                       | Irbesartan          |              |            | S           |              |                    |                 | Not Reported |
|                       | Pantoprazole        |              |            | S           |              |                    |                 | Not Reported |
|                       | Gemfibrozil         |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Jun-2015              | 11222097      | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000077701    |                      | 72 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                                                        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Dizziness; Eye Swelling;<br>Product Use In<br>Unapproved Indication;<br>Renal Disorder; Visual<br>Impairment | Escitalopram   |              |            | S           | Oral         | 10 Mg              |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Jun-2015              | 11224624      | DIRECT           | Y                  |                 |                      |                      | 29 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Headache              | Escitalopram   |              |            | S           | Oral         |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <a href="#">FDA Received Date</a>                                                                                            | <a href="#">Case #</a>    | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|------------------------------------------------------------------------------------------------------------------------------|---------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 26-Jun-2015                                                                                                                  | 11225563                  | DIRECT                    |                             |                          |                               |                               | 33 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                                                               | <a href="#">Product</a>   | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Amnesia; Product Quality Issue                                                                                               | Escitalopram 10mg Unknown |                           |                             | S                        | Oral                          | 1 Per Day                     |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                            | <a href="#">Case #</a>    | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 27-Jun-2015                                                                                                                  | 11223378                  | NON-EXPEDITED             |                             |                          | US-ACCORD-029818              |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                                                               | <a href="#">Product</a>   | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Diarrhoea; Nausea                                                                                                            | Escitalopram Accord       |                           |                             | S                        |                               | For About A Month And A Half  |                          | Accord              |                         |
| <a href="#">FDA Received Date</a>                                                                                            | <a href="#">Case #</a>    | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 27-Jun-2015                                                                                                                  | 11223379                  | NON-EXPEDITED             |                             | OT                       | US-ACCORD-030197              |                               | 48 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                                                               | <a href="#">Product</a>   | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Back Pain;<br>Gastrointestinal Pain;<br>Gastrointestinal Sounds Abnormal;<br>Gastrooesophageal Reflux Disease; Off Label Use | Escitalopram Accord       |                           |                             | S                        | Oral                          |                               |                          | Accord              |                         |
| <a href="#">FDA Received Date</a>                                                                                            | <a href="#">Case #</a>    | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 27-Jun-2015                                                                                                                  | 11223380                  | NON-EXPEDITED             |                             |                          | US-ACCORD-030657              |                               | 55 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>                                                                                               | <a href="#">Product</a>   | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Feeling Abnormal                                                                                                             | Accord Escitalopram       |                           |                             | S                        | Oral                          | Started 3 Or 4 Days Ago       |                          | Accord              |                         |





# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                           | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|------------------------------------------------------------------------------------|---------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 27-Jun-2015                                                                        | 11223396            | EXPEDITED (15-DAY) |                    | DS, HO          | DK-TEVA-572173ISR    |                      | 68 YR           | Female     | DNK            |
| <u>Preferred Term</u>                                                              | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Cerebrovascular Accident;<br>Fall; Hemiparesis;<br>Hypoaesthesia;<br>Hypoaesthesia | Escitalopram "Teva" |                    |                    | S               | Oral                 | 10 Milligram Daily;  |                 | Ivax       |                |

| <u>FDA Received Date</u>   | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------|-------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 29-Jun-2015                | 11054871          | EXPEDITED (15-DAY) | Y                  | HO, OT          | ADR-2015-00735       |                      | 58 YR           | Male         | CHE            |
| <u>Preferred Term</u>      | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Alcohol        | Baclofen          |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
| Abuse; Disinhibition; Drug | Tramadol          |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Abuse; Euphoric Mood;      | Escitalopram      |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Grandiosity; Impulsive     | Quetiapine        |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Behaviour; Irritability;   | Oxazepam          |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Legal Problem; Mania;      | Alprazolam        |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Negativism; Psychomotor    | Zolpidem          |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Hyperactivity; Theft;      | Candesartan       |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Weight Decreased           | Metformin         |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                            | Atorvastatin      |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                            | Alfuzosin         |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                            | Trospium          |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                            | Acetaminophen     |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                            | Ibuprofen         |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                            | Triamcinolone     |                    |                    | S               | Intramuscular        |                      |                 | Not Reported |                |
|                            |                   |                    |                    |                 | Intramuscular        |                      |                 |              |                |
|                            | Cannabis          |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                            | Alcohol (Ethanol) |                    |                    | S               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|------------|----------------|
| 29-Jun-2015              | 11225250       | EXPEDITED (15-DAY) |                    | CA, OT          | US-PFIZER INC-2015214359 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                                       |         |   |                |     |              |
|-----------------------------------------------------------------------|---------|---|----------------|-----|--------------|
| Maternal Exposure During Pregnancy; Multiple Congenital Abnormalities | Zoloft  | S | Transplacental | Unk | Pfizer       |
|                                                                       | Lexapro | S | Transplacental | Unk | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Jun-2015              | 11226417      | EXPEDITED (15-DAY) |                    | HO, OT          | PHHY2015BR074404     |                      | 60 YR      | Female     | BRA            |

| <u>Preferred Term</u>                                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Aggression; Hallucination; Irritability; Pyrexia; Pyrexia; Viral Infection | Exelon Patch   |              |            | S           | Transdermal  | Patch 10 (Cm2), Each 24 Hours |                 | Novartis     |
|                                                                            | Exelon Patch   |              |            | S           | Transdermal  | Patch 10 (Cm2), Each 24 Hours |                 | Novartis     |
|                                                                            | Depakene       |              |            | S           | Unknown      | 2 Tablets, Qd                 |                 | Not Reported |
|                                                                            | Olanzapine     |              |            | S           | Unknown      | 2 Tablets, Qd                 |                 | Not Reported |
|                                                                            | Olanzapine     |              |            | S           | Unknown      | 2 Tablets, Qd                 |                 | Not Reported |
|                                                                            | Olanzapine     |              |            | S           |              |                               |                 | Not Reported |
|                                                                            | Escitalopram   |              |            | S           | Unknown      | 2 Tablets, Qd                 |                 | Not Reported |
|                                                                            | Escitalopram   |              |            | S           | Unknown      | 2 Tablets, Qd                 |                 | Not Reported |
|                                                                            | Mirtazapine    |              |            | S           | Unknown      | 1 Tablet, Qd                  |                 | Not Reported |
|                                                                            | Mirtazapine    |              |            | S           | Unknown      | 1 Tablet, Qd                  |                 | Not Reported |
|                                                                            | Stilnox        |              |            | S           | Unknown      | 1 Tablet, Qd                  |                 | Not Reported |
|                                                                            | Stilnox        |              |            | S           | Unknown      | 1 Tablet, Qd                  |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Jun-2015              | 11230864      | DIRECT           |                    | LT              |                      |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                                                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Crying; Decreased Activity; Impaired Work Ability; Product Substitution Issue; Suicidal Ideation | Lexapro        |              |            | S           | Oral         | 1                  |                 | Forest       |
|                                                                                                  | Lamictal       |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                  | Welbutrin      |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                  | Klonopin       |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                  | Vitamin D Nos  |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

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| <u>FDA Received Date</u>                                                                       | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------|-----------------------|--------------------|--------------------|-----------------|------------------------------------------|----------------------|-----------------|--------------|----------------|
| 29-Jun-2015                                                                                    | 11231000              | EXPEDITED (15-DAY) | Y                  | HO              | 2015RR-99288                             |                      | 51 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                                          | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Abuse;<br>Electrocardiogram Qt<br>Prolonged;<br>Electrocardiogram St<br>Segment Elevation | Lorazepam (Lorazepam) |                    |                    | S               | Oral                                     | 20 Mg, Total         |                 | Not Reported |                |
|                                                                                                | Ciprallex             |                    |                    | S               | Oral                                     | 280 Mg, Total        |                 | Not Reported |                |
|                                                                                                | Benexol               |                    |                    | S               | Oral                                     | 6 Df, Total          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                       | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Jun-2015                                                                                    | 11229281              | EXPEDITED (15-DAY) |                    | HO              | FR-009507513-<br>1506FRA013786           |                      | 73 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                          | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyponatraemia;<br>Inappropriate Antidiuretic<br>Hormone Secretion                              | Daptomycin            |                    |                    | S               | Intravenous (not<br>otherwise specified) | 700 Mg, Qd           |                 | Merck        |                |
|                                                                                                | Omeprazole            |                    |                    | S               | Oral                                     | 20 Mg, Qd            |                 | Merck        |                |
|                                                                                                | Seroplex              |                    |                    | S               | Oral                                     | 10 Mg, Qd            |                 | Not Reported |                |
|                                                                                                | Simvastatin           |                    |                    | C               |                                          |                      |                 | Merck        |                |
|                                                                                                | Desloratadine         |                    |                    | C               |                                          |                      |                 | Merck        |                |
|                                                                                                | Olmetec               |                    |                    | C               |                                          |                      |                 | Not Reported |                |
|                                                                                                | Rifampin              |                    |                    | C               |                                          |                      |                 | Not Reported |                |
|                                                                                                | Cardensiel            |                    |                    | C               |                                          |                      |                 | Not Reported |                |
|                                                                                                | Kardegic              |                    |                    | C               |                                          |                      |                 | Not Reported |                |
|                                                                                                | Exemestane            |                    |                    | C               |                                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                       | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Jun-2015                                                                                    | 11229886              | EXPEDITED (15-DAY) |                    | OT              | DE-FRI-1000077636                        |                      | 48 YR           | Male         | DEU            |
| <u>Preferred Term</u>                                                                          | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Scleral Haemorrhage                                                                            | Escitalopram          |                    |                    | S               | Oral                                     | 5 Milligram          |                 | Forest       |                |
|                                                                                                | Brintellix            |                    |                    | S               | Oral                                     | 5 Milligram          |                 | Not Reported |                |
|                                                                                                | Mirtazapin            |                    |                    | C               | Oral                                     | 7.5 Milligram        |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                            | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------|--------------------|--------------------|--------------------|-----------------|---------------------------------------|----------------------|-----------------|--------------|----------------|
| 01-Jul-2015                                                                                                                         | 11211094           | EXPEDITED (15-DAY) |                    | HO, LT, OT      | CA-ROCHE-1596624                      |                      | 17 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                                                                                               | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Amnesia; Asthenia; Blood Alkaline Phosphatase Increased; Blood Cholesterol Increased; Diarrhoea; Fatigue; Nephritic Syndrome; Shock | Rituxan            |                    |                    | S               | Intravenous (not otherwise specified) |                      |                 | Not Reported |                |
|                                                                                                                                     | Myfortic           |                    |                    | S               | Oral                                  |                      |                 | Not Reported |                |
|                                                                                                                                     | Escitalopram       |                    |                    | S               | Unknown                               |                      |                 | Not Reported |                |
|                                                                                                                                     | Prednisone         |                    |                    | C               |                                       |                      |                 | Not Reported |                |
|                                                                                                                                     | Ranitidine         |                    |                    | C               |                                       |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                            | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Jul-2015                                                                                                                         | 11230407           | EXPEDITED (15-DAY) |                    | HO              | FR-ASTRAZENECA-2015SE63144            |                      | 20 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                                               | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Constipation; Dysuria; Sleep Disorder; Urinary Retention                                                                   | Xeroquel           |                    |                    | S               | Oral                                  |                      |                 | Not Reported |                |
|                                                                                                                                     | Theralene          |                    |                    | S               | Oral                                  |                      |                 | Not Reported |                |
|                                                                                                                                     | Atarax             |                    |                    | S               | Oral                                  |                      |                 | Not Reported |                |
|                                                                                                                                     | Lysanxia           |                    |                    | S               | Oral                                  |                      |                 | Not Reported |                |
|                                                                                                                                     | Seroplex           |                    |                    | S               | Oral                                  |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                            | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Jul-2015                                                                                                                         | 11231051           | EXPEDITED (15-DAY) |                    | OT              | IT-WATSON-2015-12805                  |                      | 66 YR           | Male         | ITA            |
| <u>Preferred Term</u>                                                                                                               | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression                                                                                                                          | Mirtazapine        |                    |                    | S               | Oral                                  | 30 Mg, Daily         |                 | Actavis      |                |
|                                                                                                                                     | Escitalopram       |                    |                    | S               | Oral                                  | 7 Gtt Drop(S), Daily |                 | Not Reported |                |
|                                                                                                                                     | Control /00273201/ |                    |                    | S               | Oral                                  | 1 Df, Daily          |                 | Not Reported |                |

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| <u>FDA Received Date</u>                           | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------|--------------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 01-Jul-2015                                        | 11232174                       | EXPEDITED (15-DAY) |                    | OT              | SE-FRI-1000077802        |                      | 22 YR           | Female       | SWE            |
| <u>Preferred Term</u>                              | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Liver Injury; Product Use In Unapproved Indication | Escitalopram                   |                    |                    | S               | Oral                     | 20 Mg                |                 | Forest       |                |
| <u>FDA Received Date</u>                           | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Jul-2015                                        | 11232619                       | EXPEDITED (15-DAY) |                    | OT              | JP-FRI-1000077775        |                      | 42 YR           | Female       | JPN            |
| <u>Preferred Term</u>                              | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Activation Syndrome                                | Lexapro                        |                    |                    | S               | Oral                     |                      |                 | Forest       |                |
|                                                    | Depromel (Fluvoxamine Maleate) |                    |                    | C               | Oral                     |                      |                 | Not Reported |                |
|                                                    | Depromel (Fluvoxamine Maleate) |                    |                    | C               | Oral                     |                      |                 | Not Reported |                |
|                                                    | Evamyl (Lormetazepam)          |                    |                    | C               | Oral                     |                      |                 | Not Reported |                |
|                                                    | Meilax (Ethyl Loflazepate)     |                    |                    | C               | Oral                     |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                           | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Jul-2015                                        | 11232768                       | EXPEDITED (15-DAY) |                    | OT              | ES-PFIZER INC-2015214785 |                      | 67 YR           | Female       | ESP            |
| <u>Preferred Term</u>                              | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blindness; Glaucoma                                | Gemfibrozil                    |                    |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                                                    | Pantoprazole                   |                    |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                                                    | Irbesartan                     |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                                                    | Escitalopram Oxalate           |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                                                    | Quetiapine Fumarate            |                    |                    | S               | Oral                     | 100 Mg, Unk          |                 | Not Reported |                |
|                                                    | Hydrochlorothiazide            |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |

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| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Jul-2015              | 11233025      | EXPEDITED (15-DAY) |                    | HO              | PHHY2015FR075958     |                      | 73 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                             | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------|----------------|--------------|------------|-------------|------------------------------------------|--------------------|-----------------|--------------|
| Hyponatraemia;<br>Inappropriate Antidiuretic<br>Hormone Secretion | Cubicin        |              |            | S           | Intravenous (not<br>otherwise specified) | 700 Mg, Qd         |                 | Not Reported |
|                                                                   | Omeprazole     |              |            | S           | Oral                                     | 20 Mg, Qd          |                 | Novartis     |
|                                                                   | Seroplex       |              |            | S           | Oral                                     | 10 Mg, Qd          |                 | Not Reported |
|                                                                   | Rifampicine    |              |            | C           | Unknown                                  | 1800 Mg, Qd        |                 | Not Reported |
|                                                                   | Cardensiel     |              |            | C           | Unknown                                  |                    |                 | Not Reported |
|                                                                   | Kardegic       |              |            | C           | Unknown                                  |                    |                 | Not Reported |
|                                                                   | Simvastatine   |              |            | C           | Unknown                                  |                    |                 | Not Reported |
|                                                                   | Desloratadine  |              |            | C           | Unknown                                  |                    |                 | Not Reported |
|                                                                   | Olmotec        |              |            | C           | Unknown                                  |                    |                 | Not Reported |
|                                                                   | Exemestane     |              |            | C           | Unknown                                  |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------|----------------------|------------|------------|----------------|
| 02-Jul-2015              | 11136738      | EXPEDITED (15-DAY) |                    | OT              | US-AUROBINDO-AUR-<br>APL-2015-04483 |                      | 49 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|-------------------------|-----------------|--------------|
| Bipolar I Disorder; Product<br>Substitution Issue;<br>Suicidal Ideation | Alprazolam 1mg |              |            | S           | Unknown      | 1 Mg, Once A Day        |                 | Aurobindo    |
|                                                                         | Escitalopram   |              |            | S           | Unknown      | 25 Mg, Once A Day       |                 | Aurobindo    |
|                                                                         | Lamotrigine    |              |            | S           | Unknown      | 350 Mg, Once A Day      |                 | Aurobindo    |
|                                                                         | Oxcarbazepine  |              |            | S           | Unknown      | 300 Mg, Two Times A Day |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Jul-2015              | 11186029      | EXPEDITED (15-DAY) |                    | HO              | SE-FRI-1000077322    |                      |            | Male       | SWE            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

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|         |              |   |      |       |        |
|---------|--------------|---|------|-------|--------|
| Seizure | Escitalopram | S | Oral | 10 Mg | Forest |
|         | Escitalopram | S | Oral | 20 Mg | Forest |

| <u>FDA Received Date</u>                                          | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|------------------------------------------|----------------------|-----------------|--------------|----------------|
| 02-Jul-2015                                                       | 11234892       | EXPEDITED (15-DAY) |                    | HO              | FR-ASTRAZENECA-2015SE64194               |                      | 73 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                             | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyponatraemia;<br>Inappropriate Antidiuretic<br>Hormone Secretion | Cubicin        |                    |                    | S               | Intravenous (not<br>otherwise specified) |                      |                 | Not Reported |                |
|                                                                   | Omeprazole     |                    |                    | S               | Oral                                     |                      |                 | Not Reported |                |
|                                                                   | Seroplex       |                    |                    | S               | Oral                                     |                      |                 | Not Reported |                |
|                                                                   | Simvastatin    |                    |                    | C               |                                          |                      |                 | Not Reported |                |
|                                                                   | Desloratadine  |                    |                    | C               |                                          |                      |                 | Not Reported |                |
|                                                                   | Olmotec        |                    |                    | C               |                                          |                      |                 | Not Reported |                |
|                                                                   | Rifampin       |                    |                    | C               |                                          |                      |                 | Not Reported |                |
|                                                                   | Cardensiel     |                    |                    | C               |                                          |                      |                 | Not Reported |                |
|                                                                   | Kardegic       |                    |                    | C               |                                          |                      |                 | Not Reported |                |
|                                                                   | Exemestane     |                    |                    | C               |                                          |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                     | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|--------------------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 02-Jul-2015                                                  | 11235671               | EXPEDITED (15-DAY) |                    | OT              | AU-MUNDIPHARMA DS<br>AND<br>PHARMACOVIGILANCE<br>-GBR-2014-0 |                      | 55 YR           | Female       | AUS            |
| <u>Preferred Term</u>                                        | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Incorrect Drug<br>Administration Rate;<br>Serotonin Syndrome | Oxycontin Tablets (Nf) |                    |                    | S               | Oral                                                         | 15mg Bid + 10mg      |                 | Purdue       |                |
|                                                              | Oxycontin Tablets (Nf) |                    |                    | S               | Oral                                                         | 15 Mg, Bid           |                 | Purdue       |                |
|                                                              | Maxalt /01406501/      |                    |                    | S               | Oral                                                         | Unk                  |                 | Not Reported |                |
|                                                              | Lexapro                |                    |                    | S               | Oral                                                         | 10 Mg, Daily         |                 | Not Reported |                |
|                                                              | Lexapro                |                    |                    | S               | Oral                                                         | Unk                  |                 | Not Reported |                |
|                                                              | Verapamil              |                    |                    | C               | Unknown                                                      |                      |                 | Not Reported |                |
|                                                              | Prednisolone           |                    |                    | C               | Unknown                                                      |                      |                 | Not Reported |                |
|                                                              | Panadol Osteo          |                    |                    | C               | Oral                                                         | 3990 Mg, Unk         |                 | Not Reported |                |

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|               |   |         |              |
|---------------|---|---------|--------------|
| Panadol Osteo | C |         | Not Reported |
| Endone        | C | Unknown | Not Reported |
| Imovane       | C | Unknown | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Jul-2015              | 11236009      | EXPEDITED (15-DAY) |                    | OT              | FI-FRI-1000077808    |                      |            | Female     | FIN            |

| <u>Preferred Term</u>   | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Iron Deficiency Anaemia | Escitalopram           |              |            | S           | Oral         | 5 Mg               |                 | Forest       |
|                         | Aerius (Desloratadine) |              |            | C           | Oral         | 5 Mg               |                 | Not Reported |
|                         | Hipeksal               |              |            | C           | Oral         | 2 G                |                 | Not Reported |
|                         | Lyrica                 |              |            | C           | Oral         | 25 Mg              |                 | Not Reported |
|                         | Melatonin              |              |            | C           | Oral         | 3 Mg               |                 | Not Reported |
|                         | Thyroxin               |              |            | C           | Oral         | 0.1 Mg             |                 | Not Reported |
|                         | Tenox (Temazepam)      |              |            | C           | Oral         | 20 Mg              |                 | Not Reported |
|                         | Norspan                |              |            | C           | Transdermal  | 5 Ug/H Microgram   |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Jul-2015              | 11243282      | DIRECT           |                    | DS              |                      |                      | 18 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Diarrhoea; Insomnia;  | Proctofoam Hc           |              |            | S           |              |                    |                 | Not Reported |
| Insomnia              | Ibuprofen 800mg         |              |            | S           |              |                    |                 | Not Reported |
|                       | Escitalopram 5mg Amneal |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 06-Jul-2015              | 11080666      | EXPEDITED (15-DAY) |                    | OT              | JP-<br>ELI_LILLY_AND_COMP<br>ANY-JP201504007225 |                      | 43 YR      | Female     | JPN            |

| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>       |
|--------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------------|
| Glycosylated Haemoglobin | Cymbalta       |              |            | S           | Oral         | 60 Mg, Qd          |                 | Eli Lilly And Co |
| Increased;               | Solanax        |              |            | S           | Oral         | Unk                |                 | Not Reported     |
| Hyperglycaemia;          |                |              |            |             |              |                    |                 |                  |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                              |                          |   |      |                     |              |
|------------------------------|--------------------------|---|------|---------------------|--------------|
| Polydipsia; Polyuria; Thirst | Lexapro                  | S | Oral | Unk                 | Not Reported |
|                              | Hangekobokuto /07984801/ | C | Oral | Unk                 | Not Reported |
|                              | Depas (Etizolam)         | C | Oral | 1 Mg, Prn           | Not Reported |
|                              | Actos                    | C | Oral | 15 Mg, Each Morning | Not Reported |
|                              | Premarin                 | C | Oral | 0.625 Mg, Bid       | Not Reported |
|                              | Duphaston                | C | Oral | 5 Mg, Bid           | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------------------------|----------------------|------------|------------|----------------|
| 06-Jul-2015              | 11239664      | NON-EXPEDITED    |                    | HO              | TR-LUPIN<br>PHARMACEUTICALS<br>INC.-2015-01080 |                      | 64 YR      | Female     | TUR            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Pulmonary Embolism    | Escitalopram   |              |            | S           | Unknown      | 5 Mg               |                 | Not Reported |
|                       | Escitalopram   |              |            | S           | Unknown      | 10 Mg              |                 | Not Reported |
|                       | Escitalopram   |              |            | S           | Unknown      | 15 Mg              |                 | Not Reported |
|                       | Haloperidol    |              |            | S           | Unknown      | 1 Mg               |                 | Not Reported |
|                       | Haloperidol    |              |            | S           | Unknown      | 3.5 Mg             |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------------------------|----------------------|------------|------------|----------------|
| 06-Jul-2015              | 11239730      | NON-EXPEDITED    |                    |                 | TR-LUPIN<br>PHARMACEUTICALS<br>INC.-2015-01112 |                      | 69 YR      | Female     | TUR            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Oedema Peripheral     | Escitalopram   |              |            | S           | Unknown      | 30 Mg              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------------------------|----------------------|------------|------------|----------------|
| 06-Jul-2015              | 11239737      | NON-EXPEDITED    |                    |                 | TR-LUPIN<br>PHARMACEUTICALS<br>INC.-2015-01113 |                      | 71 YR      | Female     | TUR            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Oedema Peripheral     | Escitalopram   |              |            | S           | Unknown      | 10 Mg              |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                               | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u>                                                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|------------------------------------------------|---------------------------------------------------------------------------|-----------------|--------------|----------------|
| 06-Jul-2015                                                                                                            | 11239777       | NON-EXPEDITED    |                    | HO              | US-LUPIN<br>PHARMACEUTICALS<br>INC.-2015-01420 |                                                                           | 60 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>                                                        | <u>Duration</u> | <u>Mfr</u>   |                |
| Serotonin Syndrome                                                                                                     | Methylene Blue |                  |                    | S               | Intravenous (not<br>otherwise specified)       | 1-Mg/Kg Bolus Followed<br>By Continuous Infusion Of<br>0.5 Mg/Kg Per Hour |                 | Not Reported |                |
|                                                                                                                        | Escitalopram   |                  |                    | S               | Oral                                           | 20mg                                                                      |                 | Not Reported |                |
|                                                                                                                        | Trazodone      |                  |                    | S               | Oral                                           | 100mg                                                                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                               | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u>                                                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Jul-2015                                                                                                            | 11239778       | NON-EXPEDITED    |                    |                 | GB-LUPIN<br>PHARMACEUTICALS<br>INC.-2015-01555 |                                                                           | 48 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                                                                  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>                                                        | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Alcoholism;<br>Behaviour Disorder                                                                          | Escitalopram   |                  |                    | S               | Unknown                                        |                                                                           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                               | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u>                                                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Jul-2015                                                                                                            | 11239796       | NON-EXPEDITED    |                    |                 | GB-LUPIN<br>PHARMACEUTICALS<br>INC.-2015-01557 |                                                                           | 42 YR           | Male         | GBR            |
| <u>Preferred Term</u>                                                                                                  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>                                                        | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Agitation;<br>Alcohol Abuse; Anxiety;<br>Decreased Appetite;<br>Impulsive Behaviour;<br>Insomnia; Paranoia | Escitalopram   |                  |                    | S               | Unknown                                        | 10-20 Mg                                                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                               | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u>                                                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Jul-2015                                                                                                            | 11239797       | NON-EXPEDITED    |                    |                 | GB-LUPIN<br>PHARMACEUTICALS<br>INC.-2015-01558 |                                                                           |                 | Unknown      | GBR            |
| <u>Preferred Term</u>                                                                                                  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>                                                        | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|             |              |   |         |              |
|-------------|--------------|---|---------|--------------|
| Alcohol Use | Escitalopram | S | Unknown | Not Reported |
|-------------|--------------|---|---------|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------------------------|----------------------|------------|------------|----------------|
| 06-Jul-2015              | 11239800      | NON-EXPEDITED    |                    |                 | IT-LUPIN<br>PHARMACEUTICALS<br>INC.-2015-01597 |                      | 44 YR      | Female     | ITA            |

| <u>Preferred Term</u> | <u>Product</u>                                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-----------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Bruxism               | Escitalopram                                  |              |            | S           | Unknown      | 20mg               |                 | Not Reported |
|                       | Escitalopram                                  |              |            | S           | Unknown      | 10mg               |                 | Not Reported |
|                       | Escitalopram                                  |              |            | S           | Unknown      | 20mg               |                 | Not Reported |
|                       | Escitalopram                                  |              |            | S           | Unknown      | 15mg               |                 | Not Reported |
|                       | Escitalopram                                  |              |            | S           | Unknown      | Upto 15mg          |                 | Not Reported |
|                       | Escitalopram                                  |              |            | S           | Unknown      | 5mg                |                 | Not Reported |
|                       | Escitalopram                                  |              |            | S           | Unknown      | 4-10 Mg            |                 | Not Reported |
|                       | Indomethacin + Caffeine +<br>Prochlorperazine |              |            | C           | Unknown      |                    |                 | Not Reported |
|                       | Valproate                                     |              |            | C           | Unknown      | 900mg              |                 | Not Reported |
|                       | Valproate                                     |              |            | C           | Unknown      | 600mg              |                 | Not Reported |
|                       | Valproate                                     |              |            | C           | Unknown      | 150mg              |                 | Not Reported |
|                       | Lithium                                       |              |            | C           | Unknown      |                    |                 | Not Reported |
|                       | Lithium                                       |              |            | C           | Unknown      | 300-450mg          |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------------------------|----------------------|------------|------------|----------------|
| 06-Jul-2015              | 11239801      | NON-EXPEDITED    |                    | HO              | US-LUPIN<br>PHARMACEUTICALS<br>INC.-2015-01606 |                      | 27 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Serotonin Syndrome    | Metaxalone     |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Metaxalone     |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Metaxalone     |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Escitalopram   |              |            | S           | Unknown      |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                       |   |         |                     |
|---------------------------------------|---|---------|---------------------|
| Alprazolam                            | C | Unknown | Not Reported        |
| Prazosin                              | C | Unknown | Not Reported        |
| Propranolol                           | C | Unknown | Not Reported        |
| Quetiapine                            | C | Unknown | Not Reported        |
| Clonazepam                            | C | Unknown | Not Reported        |
| Butalbital + Acetaminophen + Caffeine | C | Unknown | Not Reported        |
| Mometasone                            | C | Unknown | 50 Mcg/Act 2 Sprays |
| Prednisone                            | C |         | Not Reported        |
| Triamcinolone                         | C | Topical | Not Reported        |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------------------------|----------------------|------------|------------|----------------|
| 06-Jul-2015              | 11239803      | NON-EXPEDITED    |                    |                 | IT-LUPIN<br>PHARMACEUTICALS<br>INC.-2015-01595 |                      | 54 YR      | Male       | ITA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Bruxism               | Escitalopram   |              |            | S           | Unknown      | 5mg                |                 | Not Reported |
|                       | Escitalopram   |              |            | S           | Unknown      | 10mg               |                 | Not Reported |
|                       | Escitalopram   |              |            | S           | Unknown      | 5mg                |                 | Not Reported |
|                       | Escitalopram   |              |            | S           | Unknown      | 10mg               |                 | Not Reported |
|                       | Valproate      |              |            | C           | Unknown      | 750mg              |                 | Not Reported |
|                       | Valproate      |              |            | C           | Unknown      | 500 Mg             |                 | Not Reported |
|                       | Amisulpride    |              |            | C           | Unknown      | 50 Mg              |                 | Not Reported |
|                       | Lithium        |              |            | C           | Unknown      |                    |                 | Not Reported |
|                       | Lithium        |              |            | C           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------------------------|----------------------|------------|------------|----------------|
| 06-Jul-2015              | 11239815      | NON-EXPEDITED    |                    |                 | IN-LUPIN<br>PHARMACEUTICALS<br>INC.-2015-01607 |                      | 35 YR      | Male       | IND            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Rabbit Syndrome       | Escitalopram   |              |            | S           | Unknown      |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                          |                     |                    |                    |                 |                                                |                          |                 |              |                |
|--------------------------|---------------------|--------------------|--------------------|-----------------|------------------------------------------------|--------------------------|-----------------|--------------|----------------|
| Clonazepam               |                     |                    | C                  |                 | Unknown                                        |                          |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Jul-2015              | 11239818            | NON-EXPEDITED      |                    |                 | BR-LUPIN<br>PHARMACEUTICALS<br>INC.-2015-01763 |                          | 52 YR           | Male         | BRA            |
| <u>Preferred Term</u>    | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Indifference; Yawning    | Venlafaxine Xr      |                    |                    | S               | Unknown                                        | 75 Mg                    |                 | Not Reported |                |
|                          | Escitalopram        |                    |                    | S               | Unknown                                        | 10 Mg                    |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Jul-2015              | 11239881            | NON-EXPEDITED      |                    |                 | US-PFIZER INC-<br>2015218253                   |                          | 65 YR           | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity    | Neurontin           |                    |                    | S               |                                                | Unk                      |                 | Pfizer       |                |
|                          | Effexor             |                    |                    | S               |                                                | Unk                      |                 | Pfizer       |                |
|                          | Phenergan           |                    |                    | S               |                                                | Unk                      |                 | Not Reported |                |
|                          | Elavil              |                    |                    | S               |                                                |                          |                 | Not Reported |                |
|                          | Protamine Sulfate   |                    |                    | S               |                                                | Unk                      |                 | Not Reported |                |
|                          | Lexapro             |                    |                    | S               |                                                | Unk                      |                 | Not Reported |                |
|                          | Advair              |                    |                    | S               |                                                | Unk                      |                 | Not Reported |                |
|                          | Cymbalta            |                    |                    | S               |                                                | Unk                      |                 | Not Reported |                |
|                          | Sotalol             |                    |                    | S               |                                                | Unk                      |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Jul-2015              | 11241784            | EXPEDITED (15-DAY) |                    | HO, OT          | PHHY2015US070353                               |                          | 64 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Hernia;        | Lioresal Intratecal |                    |                    | S               | Intrathecal                                    | 618.6 Ug, Qd             |                 | Not Reported |                |
| Abdominal Wound          | Lioresal Intratecal |                    |                    | S               | Intrathecal                                    | 479.4 Ug, Qd (23 Percent |                 | Not Reported |                |
| Dehiscence; Asthenia;    |                     |                    |                    |                 |                                                | Decrease)                |                 |              |                |
| Hernia Pain; Hypertonia; |                     |                    |                    |                 |                                                |                          |                 |              |                |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                                                                                         |                     |                    |                    |                                                |                               |                      |                 |            |                |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|--------------------|--------------------|------------------------------------------------|-------------------------------|----------------------|-----------------|------------|----------------|
| Implant Site Infection;<br>Medical Device Site<br>Erythema; Medical Device<br>Site Pain; Medical Device<br>Site Swelling; Pain; Pocket<br>Erosion; Pyrexia;<br>Staphylococcal Infection;<br>White Blood Cell Count<br>Increased; Wound<br>Infection; Wound<br>Secretion | Lioresal Intratecal | S                  | Intrathecal        | 199.8 Ug, Qd                                   | Not Reported                  |                      |                 |            |                |
|                                                                                                                                                                                                                                                                         | Lioresal            | S                  | Oral               | 10 Mg, Qid (Four Times<br>Daily)               | Not Reported                  |                      |                 |            |                |
|                                                                                                                                                                                                                                                                         | Voltaren            | S                  | Topical            | 2 G, Qd (As Needed)                            | Novartis                      |                      |                 |            |                |
|                                                                                                                                                                                                                                                                         | Gentamicin          | S                  | Unknown            | 30 G, (Compounded<br>Capsule)                  | Not Reported                  |                      |                 |            |                |
|                                                                                                                                                                                                                                                                         | Gentamicin          | S                  | Unknown            | (30 -15 Mg) (Powder)                           | Not Reported                  |                      |                 |            |                |
|                                                                                                                                                                                                                                                                         | Ferrous Sulfate     | S                  | Oral               | 325 Mg, Bid                                    | Not Reported                  |                      |                 |            |                |
|                                                                                                                                                                                                                                                                         | Wellbutrin Sr       | S                  | Oral               | 150 Mg, Bid                                    | Not Reported                  |                      |                 |            |                |
|                                                                                                                                                                                                                                                                         | Vit D               | S                  | Oral               | 1200 Ot, Qd                                    | Not Reported                  |                      |                 |            |                |
|                                                                                                                                                                                                                                                                         | Restasis            | S                  | Ophthalmic         | 1 Drp, Bid                                     | Not Reported                  |                      |                 |            |                |
|                                                                                                                                                                                                                                                                         | Lomotil             | S                  | Oral               | 1 Df, Qid                                      | Not Reported                  |                      |                 |            |                |
|                                                                                                                                                                                                                                                                         | Lexapro             | S                  | Oral               | 20 Mg, Qd                                      | Not Reported                  |                      |                 |            |                |
|                                                                                                                                                                                                                                                                         | Estrace             | S                  | Oral               | 1.5 Mg, Qd                                     | Not Reported                  |                      |                 |            |                |
|                                                                                                                                                                                                                                                                         | Synthroid           | S                  | Oral               | 100 Ug, Qd                                     | Not Reported                  |                      |                 |            |                |
|                                                                                                                                                                                                                                                                         | Claritin            | S                  | Oral               | 10 Mg, Qd                                      | Not Reported                  |                      |                 |            |                |
|                                                                                                                                                                                                                                                                         | Silica              | S                  | Oral               |                                                | Not Reported                  |                      |                 |            |                |
|                                                                                                                                                                                                                                                                         | Fish Oil            | S                  | Oral               | 1 Df, Qd                                       | Not Reported                  |                      |                 |            |                |
|                                                                                                                                                                                                                                                                         | Ditropan            | S                  | Oral               | 5 Mg, Tid                                      | Not Reported                  |                      |                 |            |                |
|                                                                                                                                                                                                                                                                         | Mylicon             | S                  | Oral               | 250 Mg, Qid (Every 6 (Six)<br>Hours As Needed) | Not Reported                  |                      |                 |            |                |
|                                                                                                                                                                                                                                                                         | Trivitamin          | S                  | Oral               | Unk Unk, Qd                                    | Not Reported                  |                      |                 |            |                |
|                                                                                                                                                                                                                                                                         | Maalox /00416501/   | S                  | Oral               | Unk, Qid                                       | Not Reported                  |                      |                 |            |                |
|                                                                                                                                                                                                                                                                         | Cranberry Berco     | S                  | Oral               | 125 Mg, Qd                                     | Not Reported                  |                      |                 |            |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>                                | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 06-Jul-2015                                                                                                                                                                                                                                                             | 11241958            | EXPEDITED (15-DAY) |                    | DE                                             | ZA-MYLANLABS-<br>2015M1021543 |                      |                 | Unknown    | ZAF            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                   | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                                    | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Neoplasm Malignant                                                                                                                                                                                                                                                      | Escitalopram        |                    |                    | S                                              | Unknown                       | 10 Mg, Qd            |                 |            | Not Reported   |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                         |   |         |                        |              |
|-----------------------------------------|---|---------|------------------------|--------------|
| Symbicord                               | C | Unknown | Unk Unk, Qd (120 Dose) | Not Reported |
| Symbicord                               | C |         |                        | Not Reported |
| Fendermal                               | C | Unknown | 100 Mg, Qd             | Not Reported |
| Xalatan                                 | C | Unknown | 50 Mg, Qd              | Not Reported |
| Purata                                  | C | Unknown | 30 Mg, Qd              | Not Reported |
| Vasomil                                 | C | Unknown | 80 Mg, Qd              | Not Reported |
| Arycor                                  | C | Unknown | 200 Mg, Qd             | Not Reported |
| Zofer                                   | C | Unknown | 4 Mg, Qd               | Not Reported |
| Zofer                                   | C |         |                        | Not Reported |
| Covocort                                | C | Unknown | 10 Mg, Qd              | Not Reported |
| Ecotrin                                 | C | Unknown | 81 Mg, Qd              | Not Reported |
| Euphyllin /00012201/                    | C | Unknown | 250 Mg, Qd             | Not Reported |
| Acetaminophen\Tramadol<br>Hydrochloride | C | Unknown | 325 Mg, Qd             | Not Reported |
| Adco-Zolpidem                           | C | Unknown | 10 Mg, Qd              | Not Reported |
| Be-Tabs Folic Acid                      | C | Unknown | 5 Mg, Qd               | Not Reported |
| Lancap                                  | C | Unknown | 30 Mg, Qd              | Not Reported |
| Evorel                                  | C | Unknown | 503.2 Mg, Qd           | Not Reported |
| Forvent                                 | C | Unknown | 18 Mg, Qd              | Not Reported |
| Clopamon                                | C | Unknown | 10 Mg, Qd              | Not Reported |
| Lanoxin                                 | C | Unknown | 0.25 Mg, Qd            | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 06-Jul-2015              | 11242620       | DIRECT           |                    | DE              |                      |                      | 51 YR           | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain Upper;    | Lexapro        |                  |                    | S               | Oral                 |                      |                 | Not Reported |                |
| Completed Suicide; Gun   | Xanax          |                  |                    | C               |                      |                      |                 | Not Reported |                |
| Shot Wound; Head Injury; |                |                  |                    |                 |                      |                      |                 |              |                |
| Intentional Self-Injury  |                |                  |                    |                 |                      |                      |                 |              |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                     | <u>Case #</u>                                                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                | <u>503B Facility</u>                    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------|--------------------------------------------------------------|--------------------|--------------------|-----------------|-----------------------------------------------------|-----------------------------------------|-----------------|--------------|----------------|
| 06-Jul-2015                                                                  | 11246396                                                     | DIRECT             |                    | DS              |                                                     |                                         | 19 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                        | <u>Product</u>                                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                        | <u>Dosage Text</u>                      | <u>Duration</u> | <u>Mfr</u>   |                |
| Anhedonia; Libido Decreased                                                  | Lexapro                                                      |                    |                    | S               | Oral                                                | 1                                       |                 | Not Reported |                |
|                                                                              | Buspirone                                                    |                    |                    | C               |                                                     |                                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                     | <u>Case #</u>                                                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                | <u>503B Facility</u>                    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Jul-2015                                                                  | 11169210                                                     | EXPEDITED (15-DAY) |                    | HO, OT          | PHHY2015US062853                                    |                                         |                 | Female       | USA            |
| <u>Preferred Term</u>                                                        | <u>Product</u>                                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                        | <u>Dosage Text</u>                      | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Altered State Of Consciousness;                                   | Lioresal Intratecal                                          |                    |                    | S               | Intrathecal                                         | 1173.4 Mcg/Day                          |                 | Not Reported |                |
| Confusional State;                                                           | Lioresal Intratecal                                          |                    |                    | S               | Intrathecal                                         | 1223.3 Ug, Qd                           |                 | Not Reported |                |
| Constipation;                                                                | Lioresal Intratecal                                          |                    |                    | S               | Intrathecal                                         | 1223 Ug, Qd                             |                 | Not Reported |                |
| Hyperhidrosis; Hypertonia;                                                   | Lioresal Intratecal                                          |                    |                    | S               |                                                     | 100 Ug, Unk (Bolous)                    |                 | Not Reported |                |
| Initial Insomnia; Muscle Spasticity;                                         | Lioresal Intratecal                                          |                    |                    | S               | Intrathecal                                         | 720 Ug, Qd                              |                 | Not Reported |                |
| Musculoskeletal Stiffness;                                                   | Trazodone                                                    |                    |                    | S               | Unknown                                             | 2 Df, Prn (1 To 2 Tabs At Bedtime)      |                 | Novartis     |                |
| Pneumonia; Respiratory Tract Congestion; Tooth Disorder; Withdrawal Syndrome | Microgestin                                                  |                    |                    | S               | Unknown                                             | Unk                                     |                 | Not Reported |                |
|                                                                              | Oxytrol                                                      |                    |                    | S               | Unknown                                             | 1 Df, Qw2 (24 Hour Patch, 2 Times Week) |                 | Not Reported |                |
|                                                                              | Lexapro                                                      |                    |                    | S               | Unknown                                             | 20 Mg, Qd (Daily)                       |                 | Not Reported |                |
|                                                                              | Valium                                                       |                    |                    | S               | Unknown                                             | 2 Df, Prn (1 To 2 Tablets)              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                     | <u>Case #</u>                                                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                | <u>503B Facility</u>                    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Jul-2015                                                                  | 11243004                                                     | EXPEDITED (15-DAY) |                    | HO              | FR-MUNDIPHARMA DS AND PHARMACOVIGILANCE -GBR-2015-0 |                                         | 84 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                        | <u>Product</u>                                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                        | <u>Dosage Text</u>                      | <u>Duration</u> | <u>Mfr</u>   |                |
| Ataxia; Extrapyramidal Disorder; Fall; Gait                                  | Oxycontin Lp 5 Mg, Comprime Pellicule A Liberation Prolongee |                    |                    | S               | Oral                                                | 1 Df, Bid                               |                 | Purdue       |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|             |                    |   |      |               |              |
|-------------|--------------------|---|------|---------------|--------------|
| Disturbance | Seroplex           | S | Oral | 0.5 Df, Daily | Not Reported |
|             | Seresta            | S | Oral | 1 Df, Bid     | Not Reported |
|             | Dafalgan           | C |      |               | Not Reported |
|             | Econazole          | C |      |               | Not Reported |
|             | Inexium /01479302/ | C |      |               | Not Reported |
|             | Zymad              | C |      |               | Not Reported |
|             | Ketum              | C |      |               | Not Reported |
|             | Melaxose           | C |      |               | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 07-Jul-2015              | 11245350       | EXPEDITED (15-DAY) | CA                 |                 | US-FRI-1000077700    |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Congenital Anomaly       | Lexapro        |                    |                    | S               | Transplacental       |                      |                 | Forest       |                |
|                          | Zoloft         |                    |                    | S               | Transplacental       |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                    | <u>Case #</u>                                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------|---------------------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 08-Jul-2015                                 | 11026530                                          | EXPEDITED (15-DAY) | HO                 |                 | IT-FRI-1000075858    |                      | 41 YR           | Male         | ITA            |
| <u>Preferred Term</u>                       | <u>Product</u>                                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Self-Injury;<br>Overdose; Sopor | Escitalopram Oral Solution                        |                    |                    | S               | Oral                 | Overdose: 100 Mg     |                 | Forest       |                |
|                                             | Escitalopram Oral Solution                        |                    |                    | S               | Unknown              | 10 Gtt               |                 | Forest       |                |
|                                             | Stilnox 10mg Comprese Riv<br>Con Film-30 Comprese |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                             | Stilnox 10mg Comprese Riv<br>Con Film-30 Comprese |                    |                    | S               | Unknown              |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 08-Jul-2015                                                          | 11239951       | EXPEDITED (15-DAY) | OT                 |                 | IE-FRI-1000076538    |                      | 9 YR            | Male         | IRL            |
| <u>Preferred Term</u>                                                | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain Upper;<br>Accidental Exposure To<br>Product By Child; | Escitalopram   |                    |                    | S               | Oral                 |                      |                 | Forest       |                |
|                                                                      | Buscopan       |                    |                    | C               | Unknown              |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Agitation; Anxiety; Body  
Temperature Increased;  
Vomiting

| <u>FDA Received Date</u>                                 | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------|--------------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|-----------------|--------------|----------------|
| 08-Jul-2015                                              | 11246239           | EXPEDITED (15-DAY) |                    | DE              | US-CIPLA LTD.-<br>2015US05293 |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                    | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                        | Topiramate         |                    |                    | S               | Oral                          | Unk                  |                 | Cipla        |                |
|                                                          | Bupropion          |                    |                    | S               | Oral                          |                      |                 | Not Reported |                |
|                                                          | Escitalopram       |                    |                    | S               | Oral                          | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                 | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Jul-2015                                              | 11246314           | EXPEDITED (15-DAY) |                    | DE, OT          | US-CIPLA LTD.-<br>2015US05299 |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                    | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Completed<br>Suicide; Respiratory Arrest | Zolpidem Tartarate |                    |                    | S               | Oral                          | Unk                  |                 | Cipla        |                |
|                                                          | Escitalopram       |                    |                    | S               | Oral                          | Unk                  |                 | Not Reported |                |
|                                                          | Atenolol           |                    |                    | S               | Oral                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                 | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Jul-2015                                              | 11247113           | NON-EXPEDITED      |                    |                 | US-PFIZER INC.-<br>2015224442 |                      | 65 YR           | Female       | USA            |
| <u>Preferred Term</u>                                    | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective                                         | Zoloft             |                    |                    | S               |                               | Unk                  |                 | Pfizer       |                |
|                                                          | Cymbalta           |                    |                    | S               |                               | Unk                  |                 | Not Reported |                |
|                                                          | Lexapro            |                    |                    | S               |                               | Unk                  |                 | Not Reported |                |
|                                                          | Prozac             |                    |                    | S               |                               | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                 | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Jul-2015                                              | 11247288           | EXPEDITED (15-DAY) |                    | HO              | FR-PFIZER INC.-<br>2015223630 |                      | 44 YR           | Female       | FRA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                   | <u>Product</u>                                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |
|-----------------------------------------------------------------------------------------|------------------------------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|------------------|----------------|
| Overdose; Somnolence;<br>Suicide Attempt; Toxicity<br>To Various Agents                 | Xanax                                          |                    |                    | S               | Oral                                            | 20 Df, Single        |                 | Pfizer           |                |
|                                                                                         | Dioalgo                                        |                    |                    | S               | Oral                                            | 1200 Mg, Single      |                 | Not Reported     |                |
|                                                                                         | Lamaline<br>(Acetaminophen\Caffeine\Opium<br>) |                    |                    | S               | Oral                                            | 25.6 G, Single       |                 | Not Reported     |                |
|                                                                                         | Seroplex                                       |                    |                    | S               | Oral                                            | > 100 Mg, Single     |                 | Not Reported     |                |
| <u>FDA Received Date</u>                                                                | <u>Case #</u>                                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 08-Jul-2015                                                                             | 11247992                                       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000077968                               |                      | 61 YR           | Male             | FRA            |
| <u>Preferred Term</u>                                                                   | <u>Product</u>                                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |
| Disorganised Speech;<br>Echolalia; Logorrhoea;<br>Reduced Facial<br>Expression; Staring | Escitalopram                                   |                    |                    | S               | Oral                                            | 10 Mg                |                 | Forest           |                |
|                                                                                         | Imovane                                        |                    |                    | S               | Oral                                            | 1 Dosage Form        |                 | Not Reported     |                |
|                                                                                         | Artane                                         |                    |                    | S               | Oral                                            | 6 Mg                 |                 | Not Reported     |                |
|                                                                                         | Lamictal                                       |                    |                    | S               | Oral                                            | 50 Mg                |                 | Not Reported     |                |
|                                                                                         | Risperdal                                      |                    |                    | C               | Oral                                            | 1 Mg                 |                 | Not Reported     |                |
| <u>FDA Received Date</u>                                                                | <u>Case #</u>                                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 09-Jul-2015                                                                             | 10785720                                       | EXPEDITED (15-DAY) |                    | HO              | AT-<br>ELI_LILLY_AND_COMP<br>ANY-AT201502000323 |                      | 48 YR           | Male             | AUT            |
| <u>Preferred Term</u>                                                                   | <u>Product</u>                                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |
| Abnormal Behaviour;<br>Delirium; Disorientation;<br>Fatigue; Insomnia                   | Zyprexa                                        |                    |                    | S               | Unknown                                         | 10 Mg, Unknown       |                 | Eli Lilly And Co |                |
|                                                                                         | Zyprexa                                        |                    |                    | S               | Unknown                                         | 15 Mg, Unknown       |                 | Eli Lilly And Co |                |
|                                                                                         | Zyprexa                                        |                    |                    | S               | Unknown                                         | 20 Mg, Unknown       |                 | Eli Lilly And Co |                |
|                                                                                         | Zyprexa                                        |                    |                    | S               | Unknown                                         | 10 Mg, Unknown       |                 | Eli Lilly And Co |                |
|                                                                                         | Substitol                                      |                    |                    | S               | Unknown                                         | 600 Mg, Unknown      |                 | Not Reported     |                |
|                                                                                         | Substitol                                      |                    |                    | S               | Unknown                                         | 480 Mg, Unknown      |                 | Not Reported     |                |
|                                                                                         | Substitol                                      |                    |                    | S               | Unknown                                         | 360 Mg, Qd           |                 | Not Reported     |                |
|                                                                                         | Rivotril                                       |                    |                    | S               | Unknown                                         | 2 Mg, Unknown        |                 | Not Reported     |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                       |   |         |                   |              |
|-----------------------|---|---------|-------------------|--------------|
| Rivotril              | S | Unknown | 1 Mg, Unknown     | Not Reported |
| Depakine /00228501/   | S | Oral    | 1000 Mg, Unknown  | Not Reported |
| Depakine /00228501/   | S | Oral    | 1.5 G, Qd         | Not Reported |
| Cipralelex /01588501/ | S | Oral    | 10-20 Mg, Unknown | Not Reported |
| Cipralelex /01588501/ | S | Oral    | 30 Mg, Qd         | Not Reported |

| <u>FDA Received Date</u>        | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------|----------------|------------------|--------------------|-----------------|--------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 09-Jul-2015                     | 11253077       | NON-EXPEDITED    |                    |                 | IN-LUPIN<br>PHARMACEUTICALS<br>INC.-E2B_00003046 |                      | 32 YR           | Male         | IND            |
| <u>Preferred Term</u>           | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                     | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Insomnia; Product Dose Omission | Stalopam       |                  |                    | S               | Oral                                             |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 09-Jul-2015              | 11253087       | NON-EXPEDITED    |                    |                 | TR-LUPIN<br>PHARMACEUTICALS<br>INC.-2015-01199 |                      | 33 YR           | Male         | TUR            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Sexual Dysfunction       | Escitalopram   |                  |                    | S               | Unknown                                        | 5mg                  |                 | Not Reported |                |
|                          | Escitalopram   |                  |                    | S               | Unknown                                        | 20mg                 |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|--------------------------------|-----------------------------------|-----------------|--------------|----------------|
| 09-Jul-2015                                                                 | 11254898             | EXPEDITED (15-DAY) |                    | HO              | FR-ASTRAZENECA-<br>2015SE65027 |                                   | 81 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |                |
| Accidental Exposure To Product; Fall; Product Prescribing Error; Somnolence | Symbicort Turbuhaler |                    |                    | S               | Respiratory (inhalation)       | 80/4.5 Ug Per Dose, Twice Per Day |                 | Astrazeneca  |                |
|                                                                             | Potassium            |                    |                    | S               | Oral                           |                                   |                 | Not Reported |                |
|                                                                             | Amitriptyline        |                    |                    | S               | Oral                           |                                   |                 | Not Reported |                |
|                                                                             | Amlodipine           |                    |                    | S               | Oral                           |                                   |                 | Not Reported |                |
|                                                                             | Baclofene            |                    |                    | S               | Oral                           |                                   |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |              |   |      |  |  |  |  |  |              |
|--|--------------|---|------|--|--|--|--|--|--------------|
|  | Bisoprolol   | S | Oral |  |  |  |  |  | Not Reported |
|  | Escitalopram | S | Oral |  |  |  |  |  | Not Reported |
|  | Lormetazepam | S | Oral |  |  |  |  |  | Not Reported |
|  | Oxazepam     | S | Oral |  |  |  |  |  | Not Reported |
|  | Nebivolol    | C |      |  |  |  |  |  | Not Reported |

| <u>FDA Received Date</u>                     | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|----------------------------------------------|----------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 09-Jul-2015                                  | 11258952             | DIRECT           | Y                  | OT              |                      |                      |                 | Female     | USA            |
| <u>Preferred Term</u>                        | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective; Product Substitution Issue | Lexapro 20 Mg Camber |                  |                    | S               | Oral                 | 1.5 Tabs, Qd, Po     |                 |            | Not Reported   |

| <u>FDA Received Date</u>                                                                                                   | <u>Case #</u>                    | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                 | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------|----------------------------------|------------------|--------------------|-----------------|----------------------|--------------------------------------|-----------------|------------|----------------|
| 09-Jul-2015                                                                                                                | 11258967                         | DIRECT           |                    | OT              |                      |                                      | 46 YR           | Female     | USA            |
| <u>Preferred Term</u>                                                                                                      | <u>Product</u>                   | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u> |                |
| Anxiety; Dysphagia; Dyspnoea; Insomnia; Muscle Spasms; Product Quality Issue; Product Substitution Issue; Thyroid Disorder | Escitalopram 10 Mg Accord Health |                  |                    | S               | Oral                 | 1 Tablet, Once Daily, Taken By Mouth |                 |            | Accord         |
|                                                                                                                            | Vitamin D Nos                    |                  |                    | C               |                      |                                      |                 |            | Not Reported   |

| <u>FDA Received Date</u>                                                                                                                    | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 09-Jul-2015                                                                                                                                 | 11264051                          | EXPEDITED (15-DAY) | Y                  | HO, OT          | ADR-2015-01228       |                      | 52 YR           | Female     | USA            |
| <u>Preferred Term</u>                                                                                                                       | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Autoinflammatory Disease; Balance Disorder; Coordination Abnormal; Fall; Fatigue; Gait Disturbance; Hypoaesthesia; Inflammation; Intestinal | Baclofen Intrathecal              |                    |                    | S               |                      |                      |                 |            | Not Reported   |
|                                                                                                                                             | Tazarotene (Ta20rac)              |                    |                    | S               |                      |                      |                 |            | Not Reported   |
|                                                                                                                                             | Baclofen (Lioresal)               |                    |                    | S               |                      |                      |                 |            | Not Reported   |
|                                                                                                                                             | Duloxetine (Cymbalta) 60mg        |                    |                    | S               |                      |                      |                 |            | Not Reported   |
|                                                                                                                                             | Ketoconazole (Nizoral) 2%         |                    |                    | S               |                      |                      |                 |            | Not Reported   |
|                                                                                                                                             | Escitalopram Oxalate (Lexapro Po) |                    |                    | S               |                      |                      |                 |            | Not Reported   |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                          |                                      |   |              |
|--------------------------|--------------------------------------|---|--------------|
| Obstruction; Muscular    | Cleocin T                            | S | Not Reported |
| Weakness; Muscular       | Tacrolimus (Protopic) 0.1%           | S | Not Reported |
| Weakness; Neurogenic     | Tysabri (Natalizumab)                | S | Not Reported |
| Bladder; Neurological    | Levetiracetam (Keppra) 1000 Mg       | S | Not Reported |
| Symptom; Nuclear         | Potassium Chloride (Klor-Con)        | S | Not Reported |
| Magnetic Resonance       | Cranberry Vitamin C                  | S | Not Reported |
| Imaging Brain Abnormal;  | Furosemide (Lasix)                   | S | Not Reported |
| Paraesthesia; Pneumonia; | Guaifenesin Er 12 Hr (Mucinex)       | S | Not Reported |
| Urinary Tract Infection  | 600 Mg                               |   |              |
|                          | Tizanidine (Zanaflex)                | S | Not Reported |
|                          | Ascorbic Acide (Vitamin C) 1000 Mg   | S | Not Reported |
|                          | Xanax (Alprazolam)                   | S | Not Reported |
|                          | Acetaminophen (Tylenol) 325 Mg Tab   | S | Not Reported |
|                          | Zolpidem (Ambien) 10 Mg              | S | Not Reported |
|                          | Boniva (Bandronate Sodium)           | S | Not Reported |
|                          | Polyethylene Glycol 3350 (Miralax)   | S | Not Reported |
|                          | Norvasc (Amlodipine)                 | S | Not Reported |
|                          | Levothyroxine (Synthroid)            | S | Not Reported |
|                          | Solifenacin                          | S | Not Reported |
|                          | Cyanocobalamin (Vitamin B-12) 50 Mcg | S | Not Reported |
|                          | Ciclopirox (Loprox) 1%               | S | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Jul-2015              | 11264863      | EXPEDITED (15-DAY) |                    | OT              | BR-TORRENT-00002997  |                      | 57 YR      | Male       | BRA            |

| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abnormal Dreams;         | Espran         |              |            | S           | Oral         |                    |                 | Not Reported |
| Dizziness Postural; Dry  | Rivotril       |              |            | C           |              |                    |                 | Not Reported |
| Mouth; Dysphagia;        | Diovan Amio    |              |            | C           |              |                    |                 | Not Reported |
| Dyspnoea;                |                |              |            |             |              |                    |                 |              |
| Gastrointestinal         |                |              |            |             |              |                    |                 |              |
| Haemorrhage;             |                |              |            |             |              |                    |                 |              |
| Haematochezia;           |                |              |            |             |              |                    |                 |              |
| Hyperhidrosis; Initial   |                |              |            |             |              |                    |                 |              |
| Insomnia; Myalgia; Nasal |                |              |            |             |              |                    |                 |              |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Congestion; Nausea;  
Pollakiuria; Pyrexia;  
Somnolence; Tachycardia;  
Urticaria

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 10-Jul-2015              | 11259121      | EXPEDITED (15-DAY) |                    | HO, OT          | FR-PFIZER INC-2015223572 |                      | 70 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                             | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------|--------------------|--------------|------------|-------------|--------------|------------------------------|-----------------|--------------|
| Depression; Drug Reaction With Eosinophilia And Systemic Symptoms | Lyrica             |              |            | S           | Oral         | 25 Mg, 3x/Day                |                 | Pfizer       |
|                                                                   | Abilify            |              |            | S           | Oral         | 5 Mg, 1x/Day In The Morning  |                 | Not Reported |
|                                                                   | Seroplex           |              |            | S           | Oral         | 30mg, 1x/Day In The Morning  |                 | Not Reported |
|                                                                   | Imovane            |              |            | S           | Oral         | 7.5 Mg, 1x/Day At Bedtime    |                 | Not Reported |
|                                                                   | Seresta            |              |            | S           | Oral         | 10 Mg, 3x/Day                |                 | Not Reported |
|                                                                   | Loxapac /00401801/ |              |            | C           |              | "10-0-10-20 Mg", 3x/Day      |                 | Not Reported |
|                                                                   | Esomeprazole       |              |            | C           |              | 20 Mg, 1x/Day In The Evening |                 | Not Reported |
|                                                                   | Thiopental         |              |            | C           |              | Unk                          |                 | Not Reported |
|                                                                   | Suxamethonium      |              |            | C           |              | Unk                          |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Jul-2015              | 11259915      | EXPEDITED (15-DAY) |                    | HO              | CA-HOSPIRA-2752327   |                      | 31 YR      | Female     | CAN            |

| <u>Preferred Term</u> | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                          | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-------------------|--------------|------------|-------------|---------------------------------------|--------------------|-----------------|--------------|
| Bradycardia           | Docetaxel         |              |            | S           | Intravenous (not otherwise specified) |                    |                 | Not Reported |
|                       | Carboplatin       |              |            | S           | Intravenous (not otherwise specified) | Not Reported       |                 | Not Reported |
|                       | Morphine Sulphate |              |            | S           | Intravenous (not otherwise specified) |                    |                 | Not Reported |
|                       | Ciprofloxacin     |              |            | S           | Intravenous (not otherwise specified) | Not Reported       |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                             |   |                                       |              |
|-----------------------------|---|---------------------------------------|--------------|
| Avastin /00848101/          | S | otherwise specified)                  | Not Reported |
| Piperacillin/Tazobactam     | S | Intravenous (not otherwise specified) | Not Reported |
| Cipralext /01588501/        | S | Unknown                               | Not Reported |
| Herceptin                   | S | Intravenous (not otherwise specified) | Not Reported |
| Herceptin                   | S | Unknown                               | Not Reported |
| Lactulose                   | C | Intravenous (not otherwise specified) | Not Reported |
| Tylenol No.1                | S | Unknown                               | Not Reported |
| Docusate                    | C |                                       | Not Reported |
| Stomatological Preparations | C |                                       | Not Reported |
| Senna /00142201/            | C |                                       | Not Reported |
| Trazodone                   | C |                                       | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|------------|------------|----------------|
| 10-Jul-2015              | 11260862      | EXPEDITED (15-DAY) |                    | HO, OT          | US-GLAXOSMITHKLINE-US2015098324 |                      | 60 YR      | Male       | USA            |

| <u>Preferred Term</u>          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|--------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Neuroleptic Malignant Syndrome | Escitalopram   |              |            | S           |              |                    |                 | Glaxosmithkline |
|                                | Atorvastatin   |              |            | C           |              |                    |                 | Glaxosmithkline |
|                                | Risperidone    |              |            | S           |              |                    |                 | Glaxosmithkline |
|                                | Bupropion      |              |            | S           |              |                    |                 | Glaxosmithkline |
|                                | Valproic Acid  |              |            | S           |              |                    |                 | Not Reported    |
|                                | Fentanyl       |              |            | S           |              |                    |                 | Not Reported    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Jul-2015              | 11261735      | EXPEDITED (15-DAY) |                    | HO              | IT-WATSON-2015-12408 |                      | 51 YR      | Female     | ITA            |

| <u>Preferred Term</u>               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u> |
|-------------------------------------|----------------|--------------|------------|-------------|--------------|---------------------------|-----------------|------------|
| Drug Abuse;<br>Electrocardiogram Qt | Lorazepam      |              |            | S           | Oral         | 20 Mg, Total (20 Tablets) |                 | Watson     |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                      |                                           |        |              |                                                       |                              |
|----------------------------------------------------------------------|-------------------------------------------|--------|--------------|-------------------------------------------------------|------------------------------|
| Prolonged;<br>Electrocardiogram St<br>Segment Elevation;<br>Overdose | Cipralex /01588502/<br>Benexol /00176001/ | S<br>S | Oral<br>Oral | 280 Mg, Total (28 Tablets)<br>6 Df, Total (6 Tablets) | Not Reported<br>Not Reported |
|----------------------------------------------------------------------|-------------------------------------------|--------|--------------|-------------------------------------------------------|------------------------------|

| <u>FDA Received Date</u>                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|-------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 10-Jul-2015                                           | 11263008       | EXPEDITED (15-DAY) |                    | LT              | FR-FRI-1000077985    |                      | 57 YR           | Female     | FRA            |
| <u>Preferred Term</u>                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Cardio-Respiratory Arrest;<br>Diarrhoea; Hypokalaemia | Escitalopram   |                    |                    | S               | Oral                 | 5 Mg                 |                 | Forest     |                |

| <u>FDA Received Date</u>                                                                                               | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
| 13-Jul-2015                                                                                                            | 10973730       | NON-EXPEDITED    |                    | OT              | US-JNJFOC-<br>20150313241 |                      |                 | Male         | USA            |
| <u>Preferred Term</u>                                                                                                  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Weight Gain;<br>Depression;<br>Galactorrhoea;<br>Gynaecomastia;<br>Hyperprolactinaemia;<br>Tardive Dyskinesia | Risperdal      |                  |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                                                                                                                        | Risperdal      |                  |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                                                                                                                        | Risperdal      |                  |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                                                                                                                        | Lexapro        |                  |                    | S               | Unknown                   |                      |                 | Not Reported |                |
|                                                                                                                        | Adderall       |                  |                    | S               | Unknown                   |                      |                 | Not Reported |                |
|                                                                                                                        | Abilify        |                  |                    | S               | Unknown                   |                      |                 | Not Reported |                |
|                                                                                                                        | Geodon         |                  |                    | C               | Unknown                   |                      |                 | Not Reported |                |
|                                                                                                                        | Concerta       |                  |                    | C               | Oral                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|-----------------------|-----------------|--------------|----------------|
| 13-Jul-2015              | 11264748       | EXPEDITED (15-DAY) |                    | HO, LT          | NO-FRI-1000077978    |                       |                 | Female       | NOR            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Acute Kidney Injury      | Escitalopram   |                    |                    | S               | Oral                 |                       |                 | Forest       |                |
|                          | Polaramin      |                    |                    | C               | Oral                 | 4 Mg                  |                 | Not Reported |                |
|                          | Lipitor        |                    |                    | C               | Oral                 | 20 Mg Every Other Day |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|          |   |      |                       |              |
|----------|---|------|-----------------------|--------------|
| Lipitor  | C |      | 40 Mg Every Other Day | Not Reported |
| Selozok  | C | Oral | 50 Mg                 | Not Reported |
| Aprovel  | C | Oral | 150 Mg                | Not Reported |
| Stesolid | C | Oral | 15 Mg                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Jul-2015              | 11264749      | EXPEDITED (15-DAY) | HO                 |                 | FR-FRI-1000077982    |                      | 89 YR      | Female     | FRA            |

| <u>Preferred Term</u>                              | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------|-------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Confusional State; Drug Interaction; Hallucination | Escitalopram      |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                                    | Codoliprane       |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                    | Calcium Vitamin D |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                    | Qvar              |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                    | Ventoline         |              |            | C           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Jul-2015              | 11266397      | EXPEDITED (15-DAY) | OT                 |                 | CN-FRI-1000078039    |                      | 58 YR      | Female     | CHN            |

| <u>Preferred Term</u>                                                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Dementia; Logorrhoea; Mania; Product Use In Unapproved Indication; Sleep Disorder | Escitalopram   |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                                                                   | Escitalopram   |              |            | S           | Unknown      |                    |                 | Forest       |
|                                                                                   | Ebixa          |              |            | C           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Jul-2015              | 11272042      | DIRECT           |                    | DS              |                      |                      | 54 YR      | Female     | USA            |

| <u>Preferred Term</u>         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Panic Attack; Tremor; Vertigo | Lexapro 10mg   |              |            | S           | Oral         |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                               | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|--------------------------------------------------------|--------------------------------|--------------------|--------------------|-----------------|--------------------------------------------------|----------------------|-----------------|----------------------|----------------|
| 13-Jul-2015                                            | 11272045                       | DIRECT             | Y                  |                 |                                                  |                      | 62 YR           | Male                 | USA            |
| <u>Preferred Term</u>                                  | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                     | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Anxiety; Disturbance In Attention; Withdrawal Syndrome | Escitalopram Tabs 10mg Torrent |                    |                    | S               |                                                  |                      |                 | Torrent              |                |
| <u>FDA Received Date</u>                               | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 14-Jul-2015                                            | 10811907                       | EXPEDITED (15-DAY) |                    | HO, OT          | AT-FRI-1000074547                                |                      | 32 YR           | Male                 | AUT            |
| <u>Preferred Term</u>                                  | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                     | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Behaviour Disorder                                     | Escitalopram                   |                    |                    | S               | Oral                                             | 10 Mg In The Morning |                 | Forest               |                |
|                                                        | Trittico                       |                    |                    | C               | Unknown                                          | 200 Mg               |                 | Not Reported         |                |
|                                                        | Mogadon                        |                    |                    | C               | Unknown                                          | 10 Milligram         |                 | Not Reported         |                |
|                                                        | Nozinan                        |                    |                    | C               | Unknown                                          | 15 Mg                |                 | Not Reported         |                |
| <u>FDA Received Date</u>                               | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 14-Jul-2015                                            | 11064246                       | EXPEDITED (15-DAY) |                    | OT              | CH-BRISTOL-MYERS SQUIBB COMPANY- BMS-2015-025489 |                      | 27 YR           | Male                 | CHE            |
| <u>Preferred Term</u>                                  | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                     | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Obesity; Weight Increased                              | Abilify                        |                    |                    | S               | Oral                                             | 10 Mg, Qd            |                 | Bristol Myers Squibb |                |
|                                                        | Abilify                        |                    |                    | S               | Oral                                             | 15 Mg, Qd            |                 | Bristol Myers Squibb |                |
|                                                        | Seroquel                       |                    |                    | S               | Oral                                             | 800 Mg, Qd           |                 | Not Reported         |                |
|                                                        | Cipralext /01588501/           |                    |                    | S               | Oral                                             | 20 Mg, Qd            |                 | Not Reported         |                |
|                                                        | Simvastatin                    |                    |                    | C               | Oral                                             | 20 Mg, Qd            |                 | Not Reported         |                |
|                                                        | Valium                         |                    |                    | C               | Oral                                             | 5 Mg, Qd             |                 | Not Reported         |                |
|                                                        | Temesta /00273201/             |                    |                    | C               | Oral                                             | 2.5 Mg, Bid          |                 | Not Reported         |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                           | <u>Case #</u>                                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------|------------------------------------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 14-Jul-2015                                                                                                        | 11214461                                             | EXPEDITED (15-DAY) |                    | HO              | IT-TEVA-571084ACC        |                      | 51 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                                                              | <u>Product</u>                                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Abuse;<br>Electrocardiogram Qt<br>Prolonged;<br>Electrocardiogram St<br>Segment Elevation;<br>Suicide Attempt | Lorazepam                                            |                    |                    | S               | Oral                     | 20 Mg Total          |                 | Ivax         |                |
|                                                                                                                    | Cipraxel - 10 Mg Compresse                           |                    |                    | S               | Oral                     | 280 Mg Total         |                 | Not Reported |                |
|                                                                                                                    | Rivestite Con Film                                   |                    |                    |                 |                          |                      |                 |              |                |
|                                                                                                                    | Benexol - Compresse                                  |                    |                    | S               | Oral                     | 6 Df Total           |                 | Not Reported |                |
|                                                                                                                    | Gastroresistenti - Bayer S.P.A.                      |                    |                    |                 |                          |                      |                 |              |                |
| <u>FDA Received Date</u>                                                                                           | <u>Case #</u>                                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Jul-2015                                                                                                        | 11269625                                             | EXPEDITED (15-DAY) |                    | HO, OT          | US-ACTAVIS-2015-14366    |                      | 60 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                              | <u>Product</u>                                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Neuroleptic Malignant<br>Syndrome                                                                                  | Escitalopram (Unknown)                               |                    |                    | S               | Unknown                  | Unknown              |                 | Not Reported |                |
|                                                                                                                    | Risperidone (Watson<br>Laboratories)                 |                    |                    | S               | Unknown                  | Unknown              |                 | Watson       |                |
|                                                                                                                    | Bupropion Hydrochloride<br>(Actavis Laboratories FI) |                    |                    | S               | Unknown                  | Unknown              |                 | Actavis      |                |
|                                                                                                                    | Divalproex Sodium Dr (Actavis<br>Laboratories FI )   |                    |                    | S               | Unknown                  | Unknown              |                 | Scherer      |                |
|                                                                                                                    | Fentanyl Patch                                       |                    |                    | S               | Unknown                  | Unknown              |                 | Watson       |                |
|                                                                                                                    | Atorvastatin                                         |                    |                    | C               | Unknown                  |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                           | <u>Case #</u>                                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Jul-2015                                                                                                        | 11270860                                             | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-2015230365 |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                              | <u>Product</u>                                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Crying; Emotional<br>Disorder; Self Esteem<br>Decreased; Suicidal<br>Ideation; Weight Increased                    | Gabapentin                                           |                    |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                                                                                                                    | Celexa                                               |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                                                                                                                    | Lexapro                                              |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                 | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------|-------------------|--------------------|--------------------|-----------------|----------------------|---------------------------------------|-----------------|--------------|----------------|
| 14-Jul-2015                                                                                              | 11270884          | EXPEDITED (15-DAY) |                    | HO, LT          | FR-FRI-1000067098    |                                       | 19 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                    | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Coma; Electrocardiogram Qrs Complex Prolonged; Intentional Overdose; Serotonin Syndrome; Suicide Attempt | Escitalopram      |                    |                    | S               | Oral                 |                                       |                 | Forest       |                |
|                                                                                                          | Escitalopram      |                    |                    | S               |                      | Overdose: 14 Tablets (Estimated Dose) |                 | Forest       |                |
|                                                                                                          | Trimipramine Base |                    |                    | S               | Oral                 | Overdose: Dose Unknown                |                 | Not Reported |                |
|                                                                                                          | Imipramine        |                    |                    | S               | Oral                 | Overdose: Dose Unknown                |                 | Not Reported |                |
|                                                                                                          | Zolpidem          |                    |                    | S               | Oral                 |                                       |                 | Not Reported |                |
|                                                                                                          | Zolpidem          |                    |                    | S               | Oral                 | Overdose: 5 Tablets (Estimated Dose)  |                 | Not Reported |                |
|                                                                                                          | Alprazolam        |                    |                    | S               | Oral                 |                                       |                 | Not Reported |                |
|                                                                                                          | Alprazolam        |                    |                    | S               | Oral                 | Overdose: 25 Tablets (Estimated Dose) |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                         | <u>Case #</u>                                                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 14-Jul-2015                                                                                                                                                                                                                                                                                      | 11275360                                                                    | EXPEDITED (15-DAY) | Y                  | HO              | US-H14001-15-01161   |                      | 60 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                            | <u>Product</u>                                                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Blood Creatine Phosphokinase Increased; Flushing; Hyperhidrosis; Hypernatraemia; Hypertension; Hyperthermia Malignant; Hypocalcaemia; Hyporeflexia; Lipase Increased; Muscle Rigidity; Neuroleptic Malignant Syndrome; Respiratory Failure; Seizure; Serotonin Syndrome; Tachycardia; | Valproate                                                                   |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                  | Fentanyl (Fentanyl) (Fentanyl)                                              |                    |                    | S               |                      | Day 11 - Day 12      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                  | Escitalopram                                                                |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                  | Risperidone                                                                 |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                  | Bupropion (Bupropion) (Unknown) (Bupropion)                                 |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                  | Lorazepam                                                                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                  | Vancomycin                                                                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                  | Piperacillin-Tazobactam (Pip.Tazo) (Piperacillin Sodium, Tazobactam Sodium) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                  | Azithromycin                                                                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                  | Ceftriaxone                                                                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                  |                                                                             |                    |                    |                 |                      |                      |                 |              |                |
|                                                                                                                                                                                                                                                                                                  |                                                                             |                    |                    |                 |                      |                      |                 |              |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Transaminases Increased

| <u>FDA Received Date</u> | <u>Case #</u>    | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|------------------|------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 15-Jul-2015              | 10685125         | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2014351122 |                      |                 | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>   | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity    | Morphine Sulfate |                  |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                          | Ativan           |                  |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                          | Seroquel         |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                          | Lexapro          |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                          | Norco            |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |

| <u>FDA Received Date</u>               | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------|--------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 15-Jul-2015                            | 11228494                             | EXPEDITED (15-DAY) |                    | HO              | IT-FRI-1000077773    |                      | 41 YR           | Female       | ITA            |
| <u>Preferred Term</u>                  | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Coma; Drug Abuse; Intentional Overdose | Escitalopram                         |                    |                    | S               | Oral                 |                      |                 | Forest       |                |
|                                        | Escitalopram                         |                    |                    | S               | Oral                 | Overdose: 14 Df      |                 | Forest       |                |
|                                        | Seroquel                             |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                        | Seroquel                             |                    |                    | S               | Oral                 | Overdose: 60 Df      |                 | Not Reported |                |
|                                        | Gestodiol 30 Mcg/75 Mcg Comprese     |                    |                    | S               |                      | Overdose: 21 Df      |                 | Not Reported |                |
|                                        | Rivestite/Ethinylestradiol+Gestodene |                    |                    |                 |                      |                      |                 |              |                |
|                                        | Depakin Chrono                       |                    |                    | C               | Unknown              |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|--------------------------------------------------|----------------------|-----------------|------------|----------------|
| 15-Jul-2015              | 11271802       | EXPEDITED (15-DAY) |                    | HO              | US-MACLEODS PHARMACEUTICALS US LTD-MAC2015001860 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                     | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

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|                                |                      |   |         |              |
|--------------------------------|----------------------|---|---------|--------------|
| Neuroleptic Malignant Syndrome | Escitalopram Oxalate | S | Unknown | Macleods     |
|                                | Risperidone          | S | Unknown | Not Reported |
|                                | Bupropion            | S | Unknown | Not Reported |
|                                | Valproic Acid        | S | Unknown | Not Reported |
|                                | Fentanyl             | S | Unknown | Not Reported |
|                                | Atorvastatin         | C | Unknown | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 15-Jul-2015              | 11273027      | EXPEDITED (15-DAY) |                    | HO              | US-ABBVIE-15P-163-1425737-00 |                      | 60 YR      | Male       | USA            |

| <u>Preferred Term</u>          | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Neuroleptic Malignant Syndrome | Valproic Acid             |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                | Escitalopram Oxalate      |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                | Risperidone               |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                | Fentanyl                  |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                | Bupropion                 |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                | Atorvastatin              |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                | Vancomycin                |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                | Vancomycin                |              |            | C           |              |                    |                 | Not Reported |
|                                | Piperacillin / Tazobactam |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                | Piperacillin / Tazobactam |              |            | C           |              |                    |                 | Not Reported |
|                                | Azithromycin              |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                | Azithromycin              |              |            | C           |              |                    |                 | Not Reported |
|                                | Lorazepam                 |              |            | C           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------------------|----------------------|------------|------------|----------------|
| 15-Jul-2015              | 11274543      | EXPEDITED (15-DAY) |                    | HO, OT          | US-IMPAX LABORATORIES, INC-2015-IPXL-00755 |                      | 60 YR      | Male       | USA            |

| <u>Preferred Term</u>          | <u>Product</u>             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--------------------------------|----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Neuroleptic Malignant Syndrome | Bupropion Hydrochloride Sr |              |            | S           | Unknown      | Unk                |                 | Impax      |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                         |   |         |     |              |
|-------------------------|---|---------|-----|--------------|
| Divalproex Sodium Er    | S | Unknown | Unk | Impax        |
| Escitalopram            | S | Unknown | Unk | Not Reported |
| Risperidone             | S | Unknown | Unk | Not Reported |
| Vancomycin              | C | Unknown | Unk | Not Reported |
| Vancomycin              | C |         |     | Not Reported |
| Piperacillin/Tazobactam | C | Unknown | Unk | Not Reported |
| Piperacillin/Tazobactam | C |         |     | Not Reported |
| Azithromycin            | C | Unknown | Unk | Not Reported |
| Azithromycin            | C |         |     | Not Reported |
| Ceftriaxone             | C | Unknown | Unk | Not Reported |
| Ceftriaxone             | C |         |     | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Jul-2015              | 11276205      | DIRECT           |                    | LT              |                      |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                                                                                             | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abdominal Discomfort;<br>Condition Aggravated;<br>Diarrhoea; Muscle<br>Spasms; Muscle Spasms;<br>Muscle Twitching;<br>Pollakiuria | Escitalopram 5 Mg   |              |            | S           | Oral         |                    |                 | Camber       |
|                                                                                                                                   | Lisinopril          |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                   | Synthroid           |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                   | Metoprolol Tartrate |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                   | Furosemide          |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                   | Ecotrin             |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                   | Calcium+ Vita D3    |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                   | Potassium Cl        |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Jul-2015              | 11276872      | DIRECT           |                    | DS              |                      |                      | 16 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                          | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Chronic Fatigue<br>Syndrome; Educational<br>Problem; Impaired Work<br>Ability; Orthostatic<br>Intolerance; Postural<br>Orthostatic Tachycardia | Escitalopram        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                | Florinef Seasonique |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                | Ana-Histamine       |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                | L-Glutathione       |              |            | C           |              |                    |                 | Not Reported |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Syndrome

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Jul-2015              | 10570755      | EXPEDITED (15-DAY) |                    | DS              | CN-FRI-1000072126    |                      | 85 YR      | Male       | CHN            |

| <u>Preferred Term</u>                                                                                                                                                                                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Asthenia; Blindness<br>Unilateral; Discomfort;<br>Dizziness; Incorrect Dose<br>Administered; Nausea;<br>Optic Atrophy;<br>Somnolence; Vision<br>Blurred; Visual<br>Impairment; Vitreous<br>Opacities | Escitalopram   |              |            | S           | Oral         | 5 Mg               |                 | Forest       |
|                                                                                                                                                                                                      | Escitalopram   |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                                                                                                                                                                                      | Escitalopram   |              |            | S           | Oral         | 40 Mg              |                 | Not Reported |
|                                                                                                                                                                                                      | Escitalopram   |              |            | S           | Oral         | 10 Mg              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|------------|------------|----------------|
| 16-Jul-2015              | 10731205      | EXPEDITED (15-DAY) |                    | OT              | GR-MYLANLABS-<br>2015M1000874 |                      |            | Unknown    | GRC            |

| <u>Preferred Term</u> | <u>Product</u>                                   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|--------------------------------------------------|--------------|------------|-------------|--------------|---------------------|-----------------|--------------|
| Drug Ineffective      | Escitalopram Generics 10mg<br>Film-Coated Tablet |              |            | S           | Oral         | 1 Tablet, Qd        |                 | Mylan        |
|                       | Escitalopram Generics 10mg<br>Film-Coated Tablet |              |            | S           | Unknown      | 1.5 Df, Unk         |                 | Mylan        |
|                       | Xanax                                            |              |            | C           | Oral         | 1 Tablet Once Daily |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 16-Jul-2015              | 11227511      | EXPEDITED (15-DAY) |                    | OT              | IT-JNJFOC-<br>20150619548 |                      | 46 YR      | Female     | ITA            |

| <u>Preferred Term</u>                                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Abuse; Intentional<br>Overdose; Intentional Self-<br>Injury | Haldol         |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                  | Lendormin      |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                  | Entact         |              |            | S           | Oral         |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|--------------------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 16-Jul-2015                                                                                                                                   | 11275249       | EXPEDITED (15-DAY) |                    | DS, OT          | GB-ACCORD-032196                                             |                      | 42 YR           | Male         | GBR            |
| <u>Preferred Term</u>                                                                                                                         | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Weight Gain;<br>Chest Pain; Fatigue; Male<br>Sexual Dysfunction;<br>Memory Impairment;<br>Oropharyngeal Pain;<br>Somnolence; Yawning | Escitalopram   |                    |                    | S               | Oral                                                         |                      |                 | Accord       |                |
|                                                                                                                                               | Diltiazem      |                    |                    | C               |                                                              |                      |                 | Not Reported |                |
|                                                                                                                                               | Lipitor        |                    |                    | C               |                                                              |                      |                 | Not Reported |                |
|                                                                                                                                               | Nicorandil     |                    |                    | C               |                                                              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Jul-2015                                                                                                                                   | 11275951       | EXPEDITED (15-DAY) |                    | HO, LT          | US-LUPIN<br>PHARMACEUTICALS<br>INC.-2015-02126               |                      | 60 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                         | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Neuroleptic Malignant<br>Syndrome; Serotonin<br>Syndrome                                                                                      | Escitalopram   |                    |                    | S               | Unknown                                                      |                      |                 | Not Reported |                |
|                                                                                                                                               | Risperidone    |                    |                    | S               | Unknown                                                      |                      |                 | Not Reported |                |
|                                                                                                                                               | Bupropion      |                    |                    | S               | Unknown                                                      |                      |                 | Not Reported |                |
|                                                                                                                                               | Valproate      |                    |                    | S               | Unknown                                                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Jul-2015                                                                                                                                   | 11276027       | EXPEDITED (15-DAY) |                    | HO              | US-SUN<br>PHARMACEUTICAL<br>INDUSTRIES LTD-<br>2015RR-100310 |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                                                                                         | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Neuroleptic Malignant<br>Syndrome                                                                                                             | Escitalopram   |                    |                    | S               | Unknown                                                      | Unk                  |                 | Not Reported |                |
|                                                                                                                                               | Risperidone    |                    |                    | S               | Unknown                                                      | Unk                  |                 | Ranbaxy      |                |
|                                                                                                                                               | Bupropion      |                    |                    | S               | Unknown                                                      | Unk                  |                 | Sun          |                |
|                                                                                                                                               | Valproic Acid  |                    |                    | S               | Unknown                                                      | Unk                  |                 | Sun          |                |
|                                                                                                                                               | Fentanyl       |                    |                    | S               | Unknown                                                      | Unk                  |                 | Not Reported |                |
|                                                                                                                                               | Atorvastatin   |                    |                    | C               | Unknown                                                      | Unk                  |                 | Not Reported |                |

# FDA Adverse Event Reporting System

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### Detailed Report

| <u>FDA Received Date</u>                            | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 16-Jul-2015                                         | 11276827               | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000078154    |                      | 45 YR           | Female       | FRA            |
| <u>Preferred Term</u>                               | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Overdose;<br>Toxicity To Various Agents | Escitalopram           |                    |                    | S               | Oral                 |                      |                 | Forest       |                |
|                                                     | Escitalopram           |                    |                    | S               | Oral                 |                      |                 | Forest       |                |
|                                                     | Paracetamol            |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                     | Spiramycine            |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                            | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Jul-2015                                         | 11276830               | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000078150    |                      | 93 YR           | Male         | FRA            |
| <u>Preferred Term</u>                               | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Craniocerebral Injury; Fall                         | Escitalopram           |                    |                    | S               | Oral                 | 20 Mg                |                 | Forest       |                |
|                                                     | Bromazepam             |                    |                    | S               | Oral                 | 4.5 Mg               |                 | Not Reported |                |
|                                                     | Cordarone              |                    |                    | C               | Oral                 | 142.8571 Mg          |                 | Not Reported |                |
|                                                     | Previscan (Fluindione) |                    |                    | C               | Oral                 | 5 Mg                 |                 | Not Reported |                |
|                                                     | Moduretic              |                    |                    | C               | Oral                 | 1 Df                 |                 | Not Reported |                |
|                                                     | Bisoprolol             |                    |                    | C               | Oral                 | 10 Mg                |                 | Not Reported |                |
|                                                     | Zocor                  |                    |                    | C               | Oral                 | 20 Mg                |                 | Not Reported |                |
|                                                     | Permixon               |                    |                    | C               | Oral                 | 320 Mg               |                 | Not Reported |                |
|                                                     | Pariet                 |                    |                    | C               | Oral                 | 20 Mg                |                 | Not Reported |                |
|                                                     | Vitabact               |                    |                    | C               | Ophthalmic           | 4 Gtt                |                 | Not Reported |                |
|                                                     | Motilium               |                    |                    | C               | Oral                 | 3 Df                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                            | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Jul-2015                                         | 11276917               | EXPEDITED (15-DAY) |                    | OT              | SE-FRI-1000078084    |                      |                 | Female       | SWE            |
| <u>Preferred Term</u>                               | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                            |                                  |                    |                    |                 |                               |                      |                 |                        |                |
|------------------------------------------------------------|----------------------------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|-----------------|------------------------|----------------|
| Blindness; Visual Impairment                               |                                  | Escitalopram       |                    | S               | Unknown                       |                      | Forest          |                        |                |
| <u>FDA Received Date</u>                                   | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>             | <u>Country</u> |
| 17-Jul-2015                                                | 11278982                         | EXPEDITED (15-DAY) |                    | HO              | US-FRESENIUS KABI-FK201503386 |                      | 60 YR           | Male                   | USA            |
| <u>Preferred Term</u>                                      | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>             |                |
| Neuroleptic Malignant Syndrome                             | Valproate (Manufacturer Unknown) |                    |                    | S               | Unknown                       |                      |                 | Fresenius Medical Care |                |
|                                                            | Escitalopram                     |                    |                    | S               | Unknown                       |                      |                 | Not Reported           |                |
|                                                            | Risperidone                      |                    |                    | S               | Unknown                       |                      |                 | Not Reported           |                |
|                                                            | Bupropion                        |                    |                    | S               | Unknown                       |                      |                 | Not Reported           |                |
|                                                            | Fentanyl                         |                    |                    | S               | Unknown                       |                      |                 | Not Reported           |                |
|                                                            | Atorvastatin                     |                    |                    | C               | Unknown                       |                      |                 | Not Reported           |                |
| <u>FDA Received Date</u>                                   | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>             | <u>Country</u> |
| 17-Jul-2015                                                | 11279277                         | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2015236314      |                      | 45 YR           | Female                 | USA            |
| <u>Preferred Term</u>                                      | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>             |                |
| Drug Hypersensitivity                                      | Flagyl                           |                    |                    | S               |                               | Unk                  |                 | Pfizer                 |                |
|                                                            | Lexapro                          |                    |                    | S               |                               | Unk                  |                 | Not Reported           |                |
| <u>FDA Received Date</u>                                   | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>             | <u>Country</u> |
| 17-Jul-2015                                                | 11279602                         | EXPEDITED (15-DAY) |                    | OT              | BR-FRI-1000078230             |                      | 52 YR           | Male                   | BRA            |
| <u>Preferred Term</u>                                      | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>             |                |
| Slow Response To Stimuli; Unresponsive To Stimuli; Yawning | Escitalopram                     |                    |                    | S               | Unknown                       | 10 Mg                |                 | Forest                 |                |
| <u>FDA Received Date</u>                                   | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>             | <u>Country</u> |
| 17-Jul-2015                                                | 11279665                         | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000078172             |                      | 70 YR           | Male                   | FRA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Reaction With Eosinophilia And Systemic Symptoms; Overdose | Escitalopram   |              |            | S           | Oral         | 30 Mg              |                 | Forest       |
|                                                                 | Abilify        |              |            | S           | Oral         | 5 Mg               |                 | Not Reported |
|                                                                 | Imovane        |              |            | S           | Oral         | 7.5 Mg             |                 | Not Reported |
|                                                                 | Lyrica         |              |            | S           | Oral         | 75 Mg              |                 | Not Reported |
|                                                                 | Seresta        |              |            | S           | Oral         | 30 Mg              |                 | Not Reported |
|                                                                 | Loxapac        |              |            | C           |              | 40 Mg              |                 | Not Reported |
|                                                                 | Esomeprazole   |              |            | C           |              | 20 Mg              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Jul-2015              | 11280997      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000078148    |                      | 44 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                             | <u>Product</u>                           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------|------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Intentional Overdose; Suicide Attempt; Toxicity To Various Agents | Escitalopram                             |              |            | S           | Oral         | Overdose: >100 Mg  |                 | Forest       |
|                                                                   | Dioalgo                                  |              |            | S           | Oral         | Overdose: 1,200 Mg |                 | Not Reported |
|                                                                   | Lamaline (Acetaminophen\Caffeine\Opium ) |              |            | S           | Oral         | Overdose: 25.6 Mg  |                 | Not Reported |
|                                                                   | Xanax                                    |              |            | S           | Oral         | Overdose: 20 Df.   |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Jul-2015              | 11282996      | EXPEDITED (15-DAY) |                    | DS, OT          | GB-TEVA-576831ACC    |                      | 42 YR      | Male       | GBR            |

| <u>Preferred Term</u>                                                                                                          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abnormal Weight Gain; Chest Pain; Fatigue; Male Sexual Dysfunction; Memory Impairment; Oropharyngeal Pain; Somnolence; Yawning | Escitalopram   |              |            | S           | Oral         |                    |                 | Ivax         |
|                                                                                                                                | Diltiazem      |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                | Lipitor        |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                | Nicorandil     |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

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| <u>FDA Received Date</u>                                                                                                                                                      | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                              | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|---------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 20-Jul-2015                                                                                                                                                                   | 11284999             | EXPEDITED (15-DAY) |                    | HO, OT          | JP-PFIZER INC-2015194358                          |                      | 44 YR           | Male         | JPN            |
| <u>Preferred Term</u>                                                                                                                                                         | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                      | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Creatine Phosphokinase Increased; Blood Lactate Dehydrogenase Increased; Chest Pain; Headache | Lyrica               |                    |                    | S               | Oral                                              | Unk, As Needed       |                 | Pfizer       |                |
|                                                                                                                                                                               | Livalo               |                    |                    | S               | Oral                                              | 2 Mg, 1x/Day         |                 | Not Reported |                |
|                                                                                                                                                                               | Actos                |                    |                    | S               | Oral                                              | 15 Mg, 1x/Day        |                 | Not Reported |                |
|                                                                                                                                                                               | Lexapro              |                    |                    | S               | Oral                                              | 10 Mg, 1x/Day        |                 | Not Reported |                |
|                                                                                                                                                                               | Depas (Etizolam)     |                    |                    | S               | Oral                                              | 0.5 Mg, 3x/Day       |                 | Not Reported |                |
|                                                                                                                                                                               | Depas (Etizolam)     |                    |                    | S               | Oral                                              | 1.0 Mg, 3x/Day       |                 | Not Reported |                |
|                                                                                                                                                                               | Amoxan               |                    |                    | C               |                                                   |                      |                 | Not Reported |                |
|                                                                                                                                                                               | Solanax              |                    |                    | C               |                                                   |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                      | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                              | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Jul-2015                                                                                                                                                                   | 11218733             | EXPEDITED (15-DAY) |                    | HO              | IT-MYLANLABS-2015M1020030                         |                      |                 | Unknown      | ITA            |
| <u>Preferred Term</u>                                                                                                                                                         | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                      | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Drug Abuse; Electrocardiogram Qt Prolonged;                                                                                                                         | Lorazepam            |                    |                    | S               | Oral                                              | 20 Mg, Total         |                 | Mylan        |                |
| Electrocardiogram St Segment Elevation; Intentional Overdose; Suicide Attempt                                                                                                 | Cipralext /01588502/ |                    |                    | S               | Oral                                              | 280 Mg, Total        |                 | Not Reported |                |
|                                                                                                                                                                               | Benexol /00176001/   |                    |                    | S               | Oral                                              | 6 Df, Total          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                      | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                              | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Jul-2015                                                                                                                                                                   | 11221025             | EXPEDITED (15-DAY) |                    | HO              | IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2015RR-99288 |                      |                 | Unknown      | ITA            |
| <u>Preferred Term</u>                                                                                                                                                         | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                      | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Abuse; Electrocardiogram Qt Prolonged;                                                                                                                                   | Lorazepam            |                    |                    | S               | Oral                                              | 20 Mg Total          |                 | Ranbaxy      |                |
|                                                                                                                                                                               | Cipralext            |                    |                    | S               | Oral                                              | 280 Mg Total         |                 | Not Reported |                |

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|                                                         |         |   |      |            |              |
|---------------------------------------------------------|---------|---|------|------------|--------------|
| Electrocardiogram St Segment Elevation; Suicide Attempt | Benexol | S | Oral | 6 Df Total | Not Reported |
|---------------------------------------------------------|---------|---|------|------------|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Jul-2015              | 11226338      | EXPEDITED (15-DAY) |                    | HO              | IT-FRI-1000077776    |                      | 51 YR      | Female     | ITA            |

| <u>Preferred Term</u>                                                                                                     | <u>Product</u>                                       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Drug Abuse; Electrocardiogram Qt Prolonged; Electrocardiogram St Segment Elevation; Intentional Overdose; Suicide Attempt | Escitalopram                                         |              |            | S           | Oral         |                               |                 | Forest       |
|                                                                                                                           | Escitalopram                                         |              |            | S           | Oral         | Overdose: 280 Mg Once         |                 | Forest       |
|                                                                                                                           | Lorazepam 1 Mg                                       |              |            | S           | Oral         |                               |                 | Not Reported |
|                                                                                                                           | Lorazepam 1 Mg                                       |              |            | S           | Oral         | Overdose: 20 Mg Once          |                 | Not Reported |
|                                                                                                                           | Benexol Compresse Gastroresistenti/Vitamin B Complex |              |            | S           | Oral         |                               |                 | Not Reported |
|                                                                                                                           | Benexol Compresse Gastroresistenti/Vitamin B Complex |              |            | S           | Oral         | Overdose: 6 Dosage Forms Once |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 21-Jul-2015              | 11285927      | EXPEDITED (15-DAY) |                    | HO, OT          | US-PAR<br>PHARMACEUTICAL,<br>INC-2015SCPR014149 |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>                              | <u>Product</u>   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                          | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------|------------------|--------------|------------|-------------|---------------------------------------|--------------------|-----------------|--------------|
| Neuroleptic Malignant Syndrome; Serotonin Syndrome | Bupropion Hcl XI |              |            | S           | Unknown                               | Unk Unk, Unknown   |                 | Par          |
|                                                    | Risperidone      |              |            | S           | Unknown                               | Unk Unk, Unknown   |                 | Par          |
|                                                    | Valproate        |              |            | S           | Unknown                               | Unk Unk, Unknown   |                 | Not Reported |
|                                                    | Escitalopram     |              |            | S           | Unknown                               | Unk Unk, Unknown   |                 | Not Reported |
|                                                    | Fentanyl         |              |            | S           | Intravenous (not otherwise specified) | Unk Unk, Unknown   |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Jul-2015              | 11286017      | EXPEDITED (15-DAY) |                    | HO              | US-ACCORD-032379     |                      | 60 YR      | Male       | USA            |

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| <u>Preferred Term</u>                                                                                                                                | <u>Product</u>                       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                                                                              | <u>Duration</u> | <u>Mfr</u>   |                |
|------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|------------------|--------------------|-----------------|------------------------------|-------------------------------------------------------------------------------------------------|-----------------|--------------|----------------|
| Hypernatraemia;<br>Hypocalcaemia;<br>Neuroleptic Malignant<br>Syndrome; Pneumonia;<br>Respiratory Failure;<br>Sepsis; Streptococcus<br>Test Positive | Escitalopram                         |                  |                    | S               |                              | Discontinued Around Day<br>5 Of Hospitalization.                                                |                 | Accord       |                |
|                                                                                                                                                      | Risperidone                          |                  |                    | S               |                              | Discontinued Around Day<br>5 Of Hospitalization.                                                |                 | Not Reported |                |
|                                                                                                                                                      | Bupropion/Bupropion<br>Hydrochloride |                  |                    | S               |                              | Discontinued Around Day<br>5 Of Hospitalization.                                                |                 | Not Reported |                |
|                                                                                                                                                      | Valproic Acid                        |                  |                    | S               |                              | Discontinued Around Day<br>7 Of Hospitalization.                                                |                 | Not Reported |                |
|                                                                                                                                                      | Fentanyl                             |                  |                    | S               |                              | Continuous Infusion<br>Discontinued Around Day<br>5 Of Hospitalization.<br>Restarted On Day 11. |                 | Not Reported |                |
|                                                                                                                                                      | Atorvastatin                         |                  |                    | C               |                              |                                                                                                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                             | <u>Case #</u>                        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                                                                            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Jul-2015                                                                                                                                          | 11287702                             | NON-EXPEDITED    |                    | OT              | US-PFIZER INC-<br>2015242684 |                                                                                                 | 47 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                | <u>Product</u>                       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                                                                              | <u>Duration</u> | <u>Mfr</u>   |                |
| Suicidal Ideation                                                                                                                                    | Zoloft                               |                  |                    | S               |                              | Unk                                                                                             |                 | Pfizer       |                |
|                                                                                                                                                      | Lexapro                              |                  |                    | S               |                              | Unk                                                                                             |                 | Not Reported |                |
|                                                                                                                                                      | Cymbalta                             |                  |                    | S               |                              | Unk                                                                                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                             | <u>Case #</u>                        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                                                                            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Jul-2015                                                                                                                                          | 11289805                             | NON-EXPEDITED    |                    |                 | US-PFIZER INC-<br>2015238792 |                                                                                                 | 71 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                | <u>Product</u>                       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                                                                              | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective; Product<br>Use In Unapproved<br>Indication                                                                                         | Zoloft                               |                  |                    | S               |                              | Unk                                                                                             |                 | Pfizer       |                |
|                                                                                                                                                      | Lexapro                              |                  |                    | S               |                              | Unk                                                                                             |                 | Not Reported |                |
|                                                                                                                                                      | Paxil                                |                  |                    | S               |                              | Unk                                                                                             |                 | Not Reported |                |



# FDA Adverse Event Reporting System

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| <u>FDA Received Date</u>                           | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------|----------------------|--------------------|--------------------|-----------------|---------------------------|------------------------|-----------------|--------------|----------------|
| 21-Jul-2015                                        | 11289854             | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2015238418  |                        |                 | Female       | USA            |
| <u>Preferred Term</u>                              | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Sexual Dysfunction;<br>Weight Increased            | Venlafaxine Hcl      |                    |                    | S               |                           | Unk                    |                 | Pfizer       |                |
|                                                    | Escitalopram Oxalate |                    |                    | S               |                           | Unk                    |                 | Not Reported |                |
| <u>FDA Received Date</u>                           | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Jul-2015                                        | 11289904             | EXPEDITED (15-DAY) |                    | DS, OT          | GB-MYLANLABS-2015M1023090 |                        |                 | Unknown      | GBR            |
| <u>Preferred Term</u>                              | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Weight Gain;<br>Chest Pain; Fatigue; Male | Escitalopram         |                    |                    | S               | Oral                      | 20 Mg, Unk             |                 | Not Reported |                |
| Sexual Dysfunction;<br>Memory Impairment;          | Diltiazem            |                    |                    | C               |                           | Unk                    |                 | Not Reported |                |
| Oropharyngeal Pain;<br>Somnolence; Yawning         | Lipitor              |                    |                    | C               |                           | Unk                    |                 | Not Reported |                |
|                                                    | Nicorandil           |                    |                    | C               |                           | Unk                    |                 | Not Reported |                |
| <u>FDA Received Date</u>                           | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Jul-2015                                        | 11289972             | NON-EXPEDITED      |                    |                 | PHHY2015US076973          |                        | 84 YR           | Unknown      | USA            |
| <u>Preferred Term</u>                              | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Urinary Retention                                  | Lioresal Intrathecal |                    |                    | S               | Intrathecal               | 39.95 Ug, Qd (Per Day) |                 | Not Reported |                |
|                                                    | Benazepril           |                    |                    | S               | Oral                      |                        |                 | Novartis     |                |
|                                                    | Magnesium            |                    |                    | S               | Oral                      |                        |                 | Not Reported |                |
|                                                    | Pravastatin          |                    |                    | S               | Oral                      |                        |                 | Not Reported |                |
|                                                    | Warfarin             |                    |                    | S               | Oral                      |                        |                 | Not Reported |                |
|                                                    | Metformin            |                    |                    | S               | Oral                      |                        |                 | Not Reported |                |
|                                                    | Tylenol              |                    |                    | S               | Oral                      |                        |                 | Not Reported |                |
|                                                    | Vitamin D3           |                    |                    | S               | Oral                      |                        |                 | Not Reported |                |
|                                                    | Lexapro              |                    |                    | S               | Unknown                   |                        |                 | Not Reported |                |

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|  |                  |   |         |              |
|--|------------------|---|---------|--------------|
|  | Insulin Glargine | S | Unknown | Not Reported |
|  | Insulin Lispro   | S | Unknown | Not Reported |
|  | Levothyroxine    | S | Oral    | Not Reported |
|  | Aspirin          | S | Oral    | Not Reported |
|  | Lotrisone        | S | Topical | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|------------|------------|----------------|
| 22-Jul-2015              | 11291362      | EXPEDITED (15-DAY) |                    | DS, OT          | GB-AUROBINDO-AUR-APL-2015-06422 |                      | 42 YR      | Male       | GBR            |

| <u>Preferred Term</u>                                                                                                                         | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------------|--------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abnormal Weight Gain;<br>Chest Pain; Fatigue; Male<br>Sexual Dysfunction;<br>Memory Impairment;<br>Oropharyngeal Pain;<br>Somnolence; Yawning | Escitalopram 20 Mg |              |            | S           | Oral         | 20 Mg              |                 | Aurobindo    |
|                                                                                                                                               | Diltiazem          |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                               | Lipitor            |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                               | Nicorandil         |              |            | C           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|---------------------------------------------|----------------------|------------|------------|----------------|
| 22-Jul-2015              | 11292453      | NON-EXPEDITED    |                    | HO              | DE-EISAI MEDICAL<br>RESEARCH-EC-2015-008613 |                      |            | Female     | DEU            |

| <u>Preferred Term</u>                                               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Depression; Loss Of<br>Personal Independence In<br>Daily Activities | Donepezil      |              |            | S           | Oral         | Unknown            |                 | Not Reported |
|                                                                     | Ciprallex      |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Jul-2015              | 11293066      | EXPEDITED (15-DAY) |                    | OT              | BE-FRI-1000078321    |                      |            | Female     | BEL            |

| <u>Preferred Term</u>              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abdominal Discomfort;              | Escitalopram   |              |            | S           | Unknown      |                    |                 | Forest       |
| Breast Cancer; Drug<br>Interaction | Escitalopram   |              |            | S           | Unknown      |                    |                 | Forest       |
|                                    | Tamoxifen      |              |            | S           | Unknown      |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

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| <u>FDA Received Date</u>                                                               | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|------------------------|----------------------|-----------------|--------------|----------------|
| 23-Jul-2015                                                                            | 9871087                 | NON-EXPEDITED      |                    |                 | US-GILEAD-2013-0073443 |                      | 35 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                  | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Resting Tremor                                                                         | Stribild                |                    |                    | S               |                        | Unk                  |                 | Gilead       |                |
|                                                                                        | Wellbutrin              |                    |                    | S               |                        | 200 Mg, Qd           |                 | Not Reported |                |
|                                                                                        | Abilify                 |                    |                    | S               |                        | 15 Mg, Qd            |                 | Not Reported |                |
|                                                                                        | Lexapro                 |                    |                    | S               |                        | 20 Mg, Qd            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                               | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Jul-2015                                                                            | 9871102                 | NON-EXPEDITED      |                    |                 | US-GILEAD-2013-0075220 |                      | 48 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                  | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Pressure Decreased; Diarrhoea; Drug Interaction                                  | Stribild                |                    |                    | S               |                        | 1 Df, Qd             |                 | Gilead       |                |
|                                                                                        | Pantoprazole            |                    |                    | S               |                        | 40 Mg, Unk           |                 | Not Reported |                |
|                                                                                        | Lexapro                 |                    |                    | S               |                        | 5 Mg, Qd             |                 | Not Reported |                |
|                                                                                        | Xanax                   |                    |                    | S               |                        | 0.5 Mg, Prn          |                 | Not Reported |                |
|                                                                                        | Tylenol /00020001/      |                    |                    | S               |                        |                      |                 | Not Reported |                |
|                                                                                        | Vitamin C /00008001/    |                    |                    | S               |                        |                      |                 | Not Reported |                |
|                                                                                        | Vitamin B               |                    |                    | S               |                        |                      |                 | Not Reported |                |
|                                                                                        | Vitamin D /00107901/    |                    |                    | S               |                        |                      |                 | Not Reported |                |
|                                                                                        | Multivitamin /00097801/ |                    |                    | S               |                        |                      |                 | Not Reported |                |
|                                                                                        | Saw Palmetto /00833501/ |                    |                    | S               |                        |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                               | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Jul-2015                                                                            | 11306548                | EXPEDITED (15-DAY) |                    | DS, OT          | GB-FRI-1000078220      |                      | 42 YR           | Male         | GBR            |
| <u>Preferred Term</u>                                                                  | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Weight Gain; Chest Pain; Fatigue; Male Sexual Dysfunction; Memory Impairment; | Escitalopram            |                    |                    | S               | Oral                   | 20 Mg Daily          |                 | Forest       |                |
|                                                                                        | Diltiazem               |                    |                    | C               | Unknown                |                      |                 | Not Reported |                |
|                                                                                        | Lipitor                 |                    |                    | C               | Unknown                |                      |                 | Not Reported |                |

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|                                            |                                                        |                    |                    |                 |                                |                      |                 |              |                |
|--------------------------------------------|--------------------------------------------------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|-----------------|--------------|----------------|
| Oropharyngeal Pain;<br>Somnolence; Yawning |                                                        | Nicorandil         |                    | C               | Unknown                        |                      | Not Reported    |              |                |
| <u>FDA Received Date</u>                   | <u>Case #</u>                                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Jul-2015                                | 11307195                                               | EXPEDITED (15-DAY) |                    | OT              | FR-009507513-<br>1507FRA010147 |                      | 76 YR           | Male         | FRA            |
| <u>Preferred Term</u>                      | <u>Product</u>                                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Parkinsonism                               | Norset                                                 |                    |                    | S               | Oral                           |                      |                 | Merck        |                |
|                                            | Seroplex                                               |                    |                    | S               | Oral                           |                      |                 | Not Reported |                |
|                                            | Abilify                                                |                    |                    | S               | Oral                           |                      |                 | Not Reported |                |
|                                            | Kardegic                                               |                    |                    | C               |                                |                      |                 | Not Reported |                |
|                                            | Inipomp                                                |                    |                    | C               |                                |                      |                 | Not Reported |                |
|                                            | Aprovel                                                |                    |                    | C               |                                |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                   | <u>Case #</u>                                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Jul-2015                                | 10308211                                               | EXPEDITED (15-DAY) |                    | OT              | DK-FRI-1000069027              |                      | 46 YR           | Female       | DNK            |
| <u>Preferred Term</u>                      | <u>Product</u>                                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Angina Pectoris                            | Escitalopram                                           |                    |                    | S               | Oral                           | 5 Mg                 |                 | Forest       |                |
|                                            | Hjertemagnyl [Acetylsalicylic<br>Acid\Magnesium Oxide] |                    |                    | C               |                                |                      |                 | Not Reported |                |
|                                            | Hjertemagnyl [Acetylsalicylic<br>Acid\Magnesium Oxide] |                    |                    | C               |                                |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                   | <u>Case #</u>                                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Jul-2015                                | 11183245                                               | EXPEDITED (15-DAY) |                    | OT              | PHHY2015US069564               |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                      | <u>Product</u>                                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Pain; Therapeutic<br>Response Decreased    | Lioresal Intratecal                                    |                    |                    | S               | Unknown                        | 160 Ug, Qd           |                 | Not Reported |                |
|                                            | Lisinopril                                             |                    |                    | S               | Unknown                        |                      |                 | Novartis     |                |
|                                            | Albuterol                                              |                    |                    | S               | Unknown                        |                      |                 | Not Reported |                |
|                                            | Vitamin D Nos                                          |                    |                    | S               | Unknown                        |                      |                 | Not Reported |                |
|                                            | Allegra                                                |                    |                    | S               | Unknown                        |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                     |                 |                    |                    |                 |                                                |                      |                 |              |                |
|---------------------------------------------------------------------|-----------------|--------------------|--------------------|-----------------|------------------------------------------------|----------------------|-----------------|--------------|----------------|
| Lexapro                                                             |                 |                    | S                  |                 | Unknown                                        |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                            | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Jul-2015                                                         | 11307704        | NON-EXPEDITED      |                    |                 | IN-LUPIN<br>PHARMACEUTICALS<br>INC.-2015-01865 |                      | 30 YR           | Male         | IND            |
| <u>Preferred Term</u>                                               | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypomania; Product Use<br>In Unapproved Indication                  | Memantine       |                    |                    | S               | Unknown                                        |                      |                 |              | Not Reported   |
|                                                                     | Escitalopram    |                    |                    | S               | Unknown                                        |                      |                 |              | Not Reported   |
| <u>FDA Received Date</u>                                            | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Jul-2015                                                         | 11308207        | EXPEDITED (15-DAY) |                    | HO              | US-LUPIN<br>PHARMACEUTICALS<br>INC.-2015-02208 |                      | 16 YR           | Male         | USA            |
| <u>Preferred Term</u>                                               | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Discomfort;<br>Overdose; Restlessness;<br>Suicide Attempt | Fluoxetine      |                    |                    | S               | Unknown                                        | 10 Mg                |                 |              | Not Reported   |
|                                                                     | Fluoxetine      |                    |                    | S               | Unknown                                        | 20 Mg                |                 |              | Not Reported   |
|                                                                     | Doxycycline     |                    |                    | S               | Unknown                                        |                      |                 |              | Not Reported   |
|                                                                     | Escitalopram    |                    |                    | S               | Unknown                                        |                      |                 |              | Not Reported   |
|                                                                     | Lamotrigine     |                    |                    | C               | Unknown                                        |                      |                 |              | Not Reported   |
|                                                                     | Methylphenidate |                    |                    | C               | Unknown                                        | 27 Mg                |                 |              | Not Reported   |
|                                                                     | Methylphenidate |                    |                    | C               | Unknown                                        | 54 Mg                |                 |              | Not Reported   |
|                                                                     | Methylphenidate |                    |                    | C               | Unknown                                        | 45 Mg                |                 |              | Not Reported   |
|                                                                     | Propranolol     |                    |                    | C               | Unknown                                        | 30 Mg                |                 |              | Not Reported   |
|                                                                     | Clonazepam      |                    |                    | C               | Unknown                                        |                      |                 |              | Not Reported   |
|                                                                     | Risperidone     |                    |                    | C               | Unknown                                        |                      |                 |              | Not Reported   |
| <u>FDA Received Date</u>                                            | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Jul-2015                                                         | 11308307        | EXPEDITED (15-DAY) |                    | DE              | CA-FRESENIUS KABI-<br>FK201503530              |                      | 17 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                               | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                      |                                                                                     |   |         |                           |
|----------------------|-------------------------------------------------------------------------------------|---|---------|---------------------------|
| Sudden Cardiac Death | Diphenhydramine Injection<br>(Manufacturer Unknown)<br>(Diphenhydramine<br>Cipralax | S | Unknown | Fresenius Medical<br>Care |
|                      |                                                                                     | S | Unknown | Not Reported              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------|----------------------|------------|------------|----------------|
| 24-Jul-2015              | 11308654      | EXPEDITED (15-DAY) |                    | HO              | FR-NOVOPROD-<br>457306 |                      | 52 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Pancreatitis Acute    | Novonorm       |              |            | S           | Oral         | 3 Df, Qd           |                 | Novo Nordisk |
|                       | Insulatard     |              |            | S           | Subcutaneous | 42 Iu, Bid         |                 | Novo Nordisk |
|                       | Januvia        |              |            | S           | Oral         | 100 Mg, Qd         |                 | Not Reported |
|                       | Risperdal      |              |            | S           | Oral         | 4 Mg, Qd           |                 | Not Reported |
|                       | Depakote       |              |            | S           | Oral         | 250 Mg, Bid        |                 | Not Reported |
|                       | Inegy          |              |            | S           | Oral         | 1 Df, Qd           |                 | Not Reported |
|                       | Seroplex       |              |            | S           | Oral         | 10 Mg, Qd          |                 | Not Reported |
|                       | Celiprolol     |              |            | S           | Unknown      | 200 Mg             |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|------------|------------|----------------|
| 24-Jul-2015              | 11308793      | EXPEDITED (15-DAY) |                    | OT              | US-CIPLA LTD.-<br>2015US06100 |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>                                                                  | <u>Product</u>                            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------|-------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Adverse Drug Reaction;<br>Decreased Appetite; Drug<br>Ineffective; Weight<br>Decreased | Citalopram                                |              |            | S           | Unknown      |                    |                 | Cipla        |
|                                                                                        | Risperidone                               |              |            | S           | Unknown      |                    |                 | Cipla        |
|                                                                                        | Topiramate                                |              |            | S           | Unknown      | 25 Mg, Qd          |                 | Cipla        |
|                                                                                        | Topiramate                                |              |            | S           | Unknown      | 25 Mg, Bid         |                 | Cipla        |
|                                                                                        | Topiramate                                |              |            | S           | Unknown      | 75 Mg, Bid         |                 | Cipla        |
|                                                                                        | Atomoxetine                               |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                                                                                        | Methylphenidate Extended-<br>Release (Er) |              |            | S           | Unknown      | 36 Mg, Qd          |                 | Not Reported |
|                                                                                        | Methylphenidate Extended-<br>Release (Er) |              |            | S           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                             |   |         |             |              |
|-----------------------------|---|---------|-------------|--------------|
| Lisdexamfetamine Dimesylate | S | Unknown | Unk         | Not Reported |
| Guanfacine                  | S | Unknown | 2 Mg, Qd    | Not Reported |
| Escitalopram                | S | Unknown | Unk         | Not Reported |
| Clomipramine                | S | Unknown | Unk         | Not Reported |
| Mirtazapine                 | S | Unknown | Unk         | Not Reported |
| Aripiprazole                | S | Unknown | Unk         | Not Reported |
| Lithium                     | S | Unknown | Unk         | Not Reported |
| Bupropion                   | S |         | 75 Mg, Bid  | Not Reported |
| Fluvoxamine                 | S | Unknown | 200 Mg, Qd  | Not Reported |
| Divalproex Sodium           | S | Unknown | 1500 Mg, Qd | Not Reported |
| Quetiapine                  | S | Unknown | 200 Mg, Qd  | Not Reported |
| Quetiapine                  | S | Unknown | 400 Mg, Qd  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Jul-2015              | 11312387      | DIRECT           |                    | OT              |                      |                      | 38 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                        | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Anxiety; Condition Aggravated; Dyspnoea; Emotional Disorder; Hypoaesthesia; Mental Disorder; Palpitations; Panic Attack; Product Substitution Issue | Escitalopram 20mg Aur |              |            | S           | Oral         |                    |                 | Aurobindo    |
|                                                                                                                                                              | Lexapro               |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                              | Multi-Vitamin         |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                              | Clairitan             |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 27-Jul-2015              | 11267041      | NON-EXPEDITED    |                    | HO              | US-JNJFOC-20150705870 |                      | 60 YR      | Male       | USA            |

| <u>Preferred Term</u>          | <u>Product</u>   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------|------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Neuroleptic Malignant Syndrome | Risperidone      |              |            | S           |              |                    |                 | Not Reported |
|                                | Fentanyl Citrate |              |            | S           |              |                    |                 | Not Reported |
|                                | Bupropion        |              |            | S           |              |                    |                 | Not Reported |
|                                | Valproic Acid    |              |            | S           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                         |   |              |
|-------------------------|---|--------------|
| Escitalopram            | S | Not Reported |
| Atorvastatin            | C | Not Reported |
| Vancomycin              | C | Not Reported |
| Vancomycin              | C | Not Reported |
| Piperacillin-Tazobactam | C | Not Reported |
| Piperacillin-Tazobactam | C | Not Reported |
| Azithromycin            | C | Not Reported |
| Azithromycin            | C | Not Reported |
| Lorazepam               | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Jul-2015              | 11312191      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000078486    |                      | 46 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>             |
|------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------------------|
| Drug Interaction;<br>Headache; Subdural<br>Haematoma | Escitalopram<br>Arixtra |              |            | S<br>S      |              |                    |                 | Forest<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Jul-2015              | 11319408      | EXPEDITED (15-DAY) | Y                  | HO, OT          | US-ZYDUS-008656      |                      | 16 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                           | <u>Product</u>                                                                                                    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>          | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>                                                       |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------|--------------|------------|----------------------|--------------|----------------------------------|-----------------|------------------------------------------------------------------|
| Amnesia; Anxiety;<br>Attention<br>Deficit/Hyperactivity<br>Disorder; Chest<br>Discomfort; Hallucinations,<br>Mixed; Hypertension;<br>Hypophagia; Insomnia;<br>Intentional Overdose;<br>Panic Reaction; Paranoia;<br>Psychotic Disorder;<br>Restlessness; Suicide<br>Attempt; Tachycardia;<br>Tachyphrenia; Therapy<br>Cessation | Lamotrigine<br><br>Escitalopram (Escitalopram)<br>Fluoxetine (Fluoxetine)<br>Methylphenidate<br>(Methylphenidate) |              |            | S<br><br>S<br>S<br>S |              | 12.50mg 2.00 Times Per-<br>1days |                 | Not Reported<br><br>Not Reported<br>Not Reported<br>Not Reported |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                              | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------|----------------------------|--------------------|--------------------|-----------------|----------------------|--------------------------|-----------------|--------------|----------------|
| 28-Jul-2015                                           | 10867565                   | EXPEDITED (15-DAY) |                    | HO              | IT-FRI-1000074691    |                          | 37 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                 | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Abuse; Intentional Overdose; Sopor; Sopor        | Escitalopram Oral Solution |                    |                    | S               |                      | Overdose: 30 MI          |                 | Forest       |                |
|                                                       | Lexotan                    |                    |                    | S               |                      | Overdose: 30 MI          |                 | Not Reported |                |
|                                                       | Quetipine                  |                    |                    | S               |                      | Overdose: 40 Dosage Form |                 | Not Reported |                |
|                                                       | Mirtazapine                |                    |                    | S               |                      | Overdose: 12 Dosage Form |                 | Not Reported |                |
|                                                       | Xanax                      |                    |                    | S               |                      | Overdose: 46 Dosage Form |                 | Not Reported |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Jul-2015                                           | 11317339                   | EXPEDITED (15-DAY) |                    | OT              | TR-FRI-1000078556    |                          | 75 YR           | Female       | TUR            |
| <u>Preferred Term</u>                                 | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Sinus Bradycardia                                     | Escitalopram               |                    |                    | S               |                      | 5 Mg                     |                 | Forest       |                |
|                                                       | Escitalopram               |                    |                    | S               |                      |                          |                 | Forest       |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Jul-2015                                           | 11317340                   | EXPEDITED (15-DAY) |                    | OT              | TR-FRI-1000078558    |                          | 70 YR           | Female       | TUR            |
| <u>Preferred Term</u>                                 | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Hypotension; Presyncope; Sinus Bradycardia | Escitalopram               |                    |                    | S               |                      | 5 Mg                     |                 | Forest       |                |
|                                                       | Escitalopram               |                    |                    | S               |                      | 10 Mg                    |                 | Forest       |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Jul-2015                                           | 11317342                   | EXPEDITED (15-DAY) |                    | OT              | CN-FRI-1000067890    |                          | 76 YR           | Female       | CHN            |
| <u>Preferred Term</u>                                 | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                              |            |   |                                                                                                      |              |
|------------------------------|------------|---|------------------------------------------------------------------------------------------------------|--------------|
| Overdose; Serotonin Syndrome | Lexapro    | S | 5 Mg                                                                                                 | Forest       |
|                              | Olanzapine | S | Overdose Olanzapine (Amount Unknown) The Dosage Under Physician Prescription Was 1/4 Tablet Per Day, | Not Reported |

| <u>FDA Received Date</u>                     | <u>Case #</u>     | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|----------------------------------------------|-------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 28-Jul-2015                                  | 11320834          | DIRECT           | Y                  | OT              |                      |                      |                 | Female     | USA            |
| <u>Preferred Term</u>                        | <u>Product</u>    | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective; Product Substitution Issue | Escitalopram 20mg |                  |                    | S               | Oral                 |                      |                 | Aurobindo  |                |

| <u>FDA Received Date</u>                                                                           | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|----------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|----------------------|----------------|
| 29-Jul-2015                                                                                        | 11233930             | EXPEDITED (15-DAY) |                    | OT              | CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-040874 |                      | 58 YR           | Female               | CAN            |
| <u>Preferred Term</u>                                                                              | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Agitation; Energy Increased; Euphoric Mood; Hypomania; Impulsive Behaviour; Insomnia; Restlessness | Abilify              |                    |                    | S               | Oral                                            | 2 Mg, Unk            |                 | Bristol Myers Squibb |                |
|                                                                                                    | Ciprallex /01588501/ |                    |                    | S               | Unknown                                         | 20 Mg, Qd            |                 | Not Reported         |                |
|                                                                                                    | Serax /00040901/     |                    |                    | C               | Unknown                                         | 45 Mg, Qd            |                 | Not Reported         |                |

| <u>FDA Received Date</u>                                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|--------------------------|-----------------------|-----------------|--------------|----------------|
| 29-Jul-2015                                             | 11321828             | EXPEDITED (15-DAY) |                    | CA              | CH-PFIZER INC-2015248041 |                       |                 | Female       | CHE            |
| <u>Preferred Term</u>                                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Maternal Exposure During Pregnancy; Oesophageal Atresia | Xanax                |                    |                    | S               | Transplacental           | 0.25 Mg, Occasionally |                 | Pfizer       |                |
|                                                         | Ciprallex /01588501/ |                    |                    | S               | Transplacental           | 15 Mg, Daily          |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Jul-2015              | 11291892      | EXPEDITED (15-DAY) |                    | OT              | FR-TEVA-577520ISR    |                      | 21 YR      | Female     | FRA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                                          | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                            | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|------------------------------------------------------------------------------------------------|-----------------------------------|--------------------|--------------------|-----------------|-----------------------------------------|----------------------|-----------------|--------------|----------------|
| Aphasia; Haematoma; Monoplegia; Nausea; Paraesthesia; Platelet Count Decreased; Swollen Tongue | Escitalopram Teva                 |                    |                    | S               | Unknown                                 |                      |                 | Ivax         |                |
|                                                                                                | Escitalopram Teva                 |                    |                    | S               |                                         |                      |                 | Ivax         |                |
| <u>FDA Received Date</u>                                                                       | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Jul-2015                                                                                    | 11323226                          | NON-EXPEDITED      |                    |                 | US-MYLANLABS-2014M1012605               |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                          | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                            | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Diarrhoea                                                                                      | Levothyroxine Sodium Tablets, Usp |                    |                    | S               |                                         | Unk                  |                 | Mylan        |                |
|                                                                                                | Escitalopram                      |                    |                    | S               |                                         | Unk                  |                 | Forest       |                |
|                                                                                                | Aciphex                           |                    |                    | S               |                                         | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                       | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Jul-2015                                                                                    | 11323760                          | NON-EXPEDITED      |                    |                 | US-MYLANLABS-2014M1008490               |                      |                 | Male         | USA            |
| <u>Preferred Term</u>                                                                          | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                            | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Apathy; Drug Interaction; Libido Decreased; Prescribed Overdose; Somnolence                    | Tramadol                          |                    |                    | S               |                                         |                      |                 | Not Reported |                |
|                                                                                                | Lexapro                           |                    |                    | S               | Oral                                    | 20 Mg, Qd            |                 | Not Reported |                |
|                                                                                                | Lexapro                           |                    |                    | S               | Oral                                    | 20 Mg, Qd            |                 | Not Reported |                |
|                                                                                                | Lexapro                           |                    |                    | S               | Oral                                    | 40 Mg, Qd            |                 | Not Reported |                |
|                                                                                                | Lexapro                           |                    |                    | S               | Oral                                    | 40 Mg, Qd            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                       | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-Jul-2015                                                                                    | 11325600                          | EXPEDITED (15-DAY) |                    | OT              | SG-JUBILANT<br>GENERICs LIMITED-1040872 |                      | 66 YR           | Female       | SGP            |
| <u>Preferred Term</u>                                                                          | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                            | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Withdrawal Syndrome; Mania                                                                | Escitalopram Oxalate              |                    |                    | S               |                                         |                      |                 | Jubilant     |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                           | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|----------------------------------------------------|------------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|-----------------|----------------|
| 31-Jul-2015                                        | 11327892               | EXPEDITED (15-DAY) |                    | OT              | SE-FRI-1000078676            |                      | < 1 DAY         | Male            | SWE            |
| <u>Preferred Term</u>                              | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Foetal Exposure During Pregnancy; Infantile Apnoea | Escitalopram           |                    |                    | S               | Transplacental               | 20 Mg                |                 | Forest          |                |
| <u>FDA Received Date</u>                           | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 31-Jul-2015                                        | 11327893               | EXPEDITED (15-DAY) |                    | DE              | FR-FRI-1000078568            |                      | 95 YR           | Female          | FRA            |
| <u>Preferred Term</u>                              | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Cerebral Haematoma; Drug Interaction               | Escitalopram           |                    |                    | S               | Oral                         |                      |                 | Forest          |                |
|                                                    | Previscan (Fluindione) |                    |                    | S               | Oral                         |                      |                 | Not Reported    |                |
|                                                    | Diffu-K                |                    |                    | C               |                              |                      |                 | Not Reported    |                |
|                                                    | Duphalac               |                    |                    | C               |                              |                      |                 | Not Reported    |                |
|                                                    | Enalapril              |                    |                    | C               |                              |                      |                 | Not Reported    |                |
|                                                    | Speciafoldine          |                    |                    | C               |                              |                      |                 | Not Reported    |                |
|                                                    | Paracetamol            |                    |                    | C               |                              |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                           | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 31-Jul-2015                                        | 11327895               | EXPEDITED (15-DAY) |                    | HO, LT          | CN-FRI-1000074349            |                      | 19 YR           | Female          | CHN            |
| <u>Preferred Term</u>                              | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Intentional Overdose; Suicide Attempt              | Escitalopram           |                    |                    | S               | Oral                         | 20 Mg                |                 | Forest          |                |
| <u>FDA Received Date</u>                           | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 03-Aug-2015                                        | 10538570               | EXPEDITED (15-DAY) |                    | HO, OT          | US-GLAXOSMITHKLINE-A0966434A |                      | 17 YR           | Male            | USA            |
| <u>Preferred Term</u>                              | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Accident At Work; Application Site Burn;           | Androderm              |                    |                    | S               | Transdermal                  | 1 Df, Qd             |                 | Glaxosmithkline |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                            |                                |   |              |                |                 |
|----------------------------|--------------------------------|---|--------------|----------------|-----------------|
| Application Site Pain;     | Advair                         | S | Respiratory  | 1 Puff(S), Bid | Glaxosmithkline |
| Application Site Pruritus; |                                |   | (inhalation) |                |                 |
| Asthma; Ataxia; Back       | Advair                         | S |              | 500/50 Mcg, U  | Glaxosmithkline |
| Injury; Disability; Drug   | Ventolin                       | S | Respiratory  | 2-6 Puffs Prn  | Glaxosmithkline |
| Ineffective; Dyspnoea;     |                                |   | (inhalation) |                |                 |
| Fluid Retention;           | Ventolin                       | S |              | Unk, U         | Glaxosmithkline |
| Hypoaesthesia; Ill-Defined |                                |   |              |                |                 |
| Disorder; Intervertebral   | Biotene Oral Balance Gel (2013 | S |              | Unk, U         | Glaxosmithkline |
| Disc Protrusion; Joint     | Formulation)                   |   |              |                |                 |
| Swelling; Migraine; Oral   | Escitalopram                   | S | Unknown      | Unk, U         | Glaxosmithkline |
| Infection; Overdose; Pain; |                                |   |              |                |                 |
| Pulmonary Congestion;      | Oxycontin                      | C |              |                | Not Reported    |
| Spinal Operation; Spinal   | Oxycodone                      | C |              |                | Not Reported    |
| Operation; Visual          | Valium                         | C |              |                | Glaxosmithkline |
| Impairment; Wheezing       | Gabapentin                     | C |              |                | Glaxosmithkline |
|                            | Duexis                         | C |              |                | Not Reported    |
|                            | Singulair                      | C |              |                | Glaxosmithkline |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 03-Aug-2015              | 11132798      | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2015169445 |                      |            | Female     | USA            |

| <u>Preferred Term</u>                 | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Therapeutic Product Effect Incomplete | Doxepin Hcl          |              |            | S           |              | Unk                |                 | Pfizer       |
|                                       | Effexor              |              |            | S           |              | Unk                |                 | Pfizer       |
|                                       | Geodon               |              |            | S           |              | Unk                |                 | Pfizer       |
|                                       | Lexapro              |              |            | S           |              | Unk                |                 | Not Reported |
|                                       | Thorazine /00011901/ |              |            | S           |              | Unk                |                 | Not Reported |
|                                       | Cymbalta             |              |            | S           |              | Unk                |                 | Not Reported |
|                                       | Zyprexa              |              |            | S           |              | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 03-Aug-2015              | 11238741       | NON-EXPEDITED    |                    | HO              | PHEH2014US021471     |                      | 49 YR           | Female     | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Agitation; Leukocytosis; | Clozaril       |                  |                    | S               | Oral                 | 250 Mg, Qhs          |                 | Novartis   |                |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                |             |   |         |            |              |
|--------------------------------------------------------------------------------|-------------|---|---------|------------|--------------|
| Neutrophil Count Increased; Psychotic Disorder; Schizophrenia; Suicide Attempt | Risperidone | S | Oral    | 2 Ug, Bid  | Not Reported |
|                                                                                | Latuda      | S | Oral    | 80 Ug, Qd  | Not Reported |
|                                                                                | Lexapro     | S | Oral    | 40 Ug, Bid | Not Reported |
|                                                                                | Klonopin    | S | Oral    | 1 Ug, Bid  | Not Reported |
|                                                                                | Haldol      | C | Oral    |            | Not Reported |
|                                                                                | Prolixin    | C | Oral    |            | Not Reported |
|                                                                                | Zyprexa     | C | Oral    |            | Not Reported |
|                                                                                | Metformin   | C | Unknown |            | Not Reported |
|                                                                                | Mobic       | C | Unknown |            | Not Reported |
|                                                                                | Oxycodone   | C | Unknown |            | Not Reported |
|                                                                                | Topamax     | C | Unknown |            | Not Reported |
|                                                                                | Zocor       | C | Unknown |            | Not Reported |
|                                                                                | Vivelle     | C | Unknown |            | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|------------|------------|----------------|
| 03-Aug-2015              | 11330304      | EXPEDITED (15-DAY) |                    | OT              | US-AUROBINDO-AUR-APU-2015-06273 |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>                                                                         | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------------------------------------------------------------------------------|-------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Anxiety; Condition Aggravated; Haematochezia; Product Substitution Issue; Withdrawal Syndrome | Escitalopram Tablets Usp 10mg |              |            | S           | Unknown      |                    |                 | Aurobindo  |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|------------|------------|----------------|
| 03-Aug-2015              | 11330359      | EXPEDITED (15-DAY) |                    | OT              | US-AUROBINDO-AUR-APU-2015-06215 |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>                                                     | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---------------------------------------------------------------------------|-------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Anxiety; Dyspnoea; Hypertension; Palpitations; Product Substitution Issue | Escitalopram Tablets Usp 20mg |              |            | S           | Unknown      | 20 Mg, Unk         |                 | Aurobindo  |

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| <u>FDA Received Date</u>                                                                                                                                                                  | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|-----------------|------------|----------------|
| 03-Aug-2015                                                                                                                                                                               | 11330388                      | EXPEDITED (15-DAY) |                    | OT              | US-AUROBINDO-AUR-APU-2015-06205 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>                                                                                                                                                                     | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Anxiety; Condition Aggravated; Depressed Mood; Fatigue; Headache; Nausea; Product Substitution Issue; Withdrawal Syndrome                                                                 | Escitalopram Tablets Usp 20mg |                    |                    | S               | Unknown                         |                      |                 | Aurobindo  |                |
| <u>FDA Received Date</u>                                                                                                                                                                  | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 03-Aug-2015                                                                                                                                                                               | 11330402                      | EXPEDITED (15-DAY) |                    | DS, OT          | US-AUROBINDO-AUR-APU-2015-06225 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>                                                                                                                                                                     | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Decreased Interest; Depressed Mood; Depressive Symptom; Drug Withdrawal Syndrome; Irritability; Loss Of Personal Independence In Daily Activities; Product Substitution Issue             | Escitalopram Tablets Usp 20mg |                    |                    | S               | Unknown                         |                      |                 | Aurobindo  |                |
| <u>FDA Received Date</u>                                                                                                                                                                  | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 03-Aug-2015                                                                                                                                                                               | 11330404                      | EXPEDITED (15-DAY) |                    | OT              | US-AUROBINDO-AUR-APU-2015-06275 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>                                                                                                                                                                     | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Arthralgia; Bone Pain; Depression; Disturbance In Attention; Feelings Of Worthlessness; Insomnia; Loss Of Personal Independence In Daily Activities; Myalgia; Product Substitution Issue; | Escitalopram Tablets Usp 20mg |                    |                    | S               | Unknown                         | 20 Mg, Unk           |                 | Aurobindo  |                |
|                                                                                                                                                                                           | Escitalopram Tablets Usp 20mg |                    |                    | S               | Unknown                         | 20 Mg, Unk           |                 | Aurobindo  |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Regressive Behaviour

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Aug-2015              | 11331005      | EXPEDITED (15-DAY) |                    | HO              | GXKR2015DE003571     |                      |            | Unknown    | DEU            |

| <u>Preferred Term</u> | <u>Product</u>             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Dystonia              | Metoprolol                 |              |            | S           | Unknown      | 100 Mg, Qd         |                 | Novartis     |
|                       | Hydrochlorothiazide        |              |            | S           | Unknown      | 25 Mg, Qd          |                 | Not Reported |
|                       | Quetiapine                 |              |            | S           | Unknown      | 400 Mg, Qd         |                 | Not Reported |
|                       | Cipralex /Den/             |              |            | S           | Unknown      | 5 Mg, Qd           |                 | Not Reported |
|                       | Remergil                   |              |            | S           | Unknown      | 45 Mg, Qd          |                 | Not Reported |
|                       | Lorazepam                  |              |            | C           | Unknown      | 1 Mg, Qd           |                 | Not Reported |
|                       | Evista                     |              |            | C           | Unknown      | 60 Mg, Unk         |                 | Not Reported |
|                       | Calcium Carbonate          |              |            | C           | Unknown      | 1500 Mg, Qd        |                 | Not Reported |
|                       | L-Thyroxine//Levothyroxine |              |            | C           | Oral         | 75 Ug, Qd          |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Aug-2015              | 11331006      | EXPEDITED (15-DAY) |                    | DE, OT          | PHHY2015US090321     |                      | 40 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                            | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Contusion; Depressed Level Of Consciousness; Overdose; Respiratory Depression; Serotonin Syndrome; Skin Abrasion | Amitriptyline Sandoz |              |            | S           | Oral         | 1 Df, Qd           |                 | Novartis     |
|                                                                                                                  | Nucynta              |              |            | S           | Oral         | 1 Df, Tid          |                 | Not Reported |
|                                                                                                                  | Lexapro              |              |            | S           | Oral         | 1 Df, Qd           |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 03-Aug-2015              | 11333674      | EXPEDITED (15-DAY) |                    | OT              | US-009507513-1507USA011466 |                      | 13 YR      | Female     | USA            |

| <u>Preferred Term</u>                                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Intentional Overdose; Suicidal Ideation; Suicide Attempt | Remeron        |              |            | S           | Oral         | Unk                |                 | Merck        |
|                                                          | Buspar         |              |            | S           | Oral         | Unk                |                 | Not Reported |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| Lexapro                                                                                                                             |                |                    | S                  |                 | Unk                            |                             | Not Reported    |              |                |
|-------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|--------------------------------|-----------------------------|-----------------|--------------|----------------|
| <u>FDA Received Date</u>                                                                                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Aug-2015                                                                                                                         | 11334069       | EXPEDITED (15-DAY) |                    | OT              | IE-FRI-1000078684              |                             | 36 YR           | Female       | IRL            |
| <u>Preferred Term</u>                                                                                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Decreased Appetite;<br>Dysgeusia; Fatigue;<br>Increased Appetite;<br>Overdose; Paraesthesia;<br>Unresponsive To Stimuli;<br>Vertigo | Escitalopram   |                    |                    | S               | Oral                           | 5 Mg                        |                 | Forest       |                |
|                                                                                                                                     | Escitalopram   |                    |                    | S               | Oral                           | Overdose: 5/6 Times Per Day |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Aug-2015                                                                                                                         | 11334676       | NON-EXPEDITED      |                    |                 | US-TEVA-507703USA              |                             | 80 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Discomfort;<br>Dizziness; Laziness                                                                                        | Venlafaxine    |                    |                    | S               | Unknown                        |                             |                 | Teva         |                |
|                                                                                                                                     | Lexapro        |                    |                    | S               | Oral                           | 20 Milligram Daily;         |                 | Not Reported |                |
|                                                                                                                                     | Lexapro        |                    |                    | S               | Oral                           | 20 Milligram Daily;         |                 | Not Reported |                |
|                                                                                                                                     | Synthroid      |                    |                    | C               |                                |                             |                 | Not Reported |                |
|                                                                                                                                     | Protonix       |                    |                    | C               |                                |                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Aug-2015                                                                                                                         | 11335738       | NON-EXPEDITED      |                    |                 | US-TEVA-582296USA              |                             |                 | Male         | USA            |
| <u>Preferred Term</u>                                                                                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective;<br>Somnolence                                                                                                     | Nuvigil        |                    |                    | S               | Oral                           |                             |                 | Cephalon     |                |
|                                                                                                                                     | Lexapro        |                    |                    | S               | Unknown                        |                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Aug-2015                                                                                                                         | 11336266       | EXPEDITED (15-DAY) |                    | HO, OT          | AU-DRREDDYS-USA/AUS/15/0049782 |                             | 44 YR           | Female       | AUS            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                                                  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Affective Disorder; Body Dysmorphic Disorder; Delusional Disorder, Unspecified Type; Depression; Drug Ineffective; Dyskinesia; Obsessive-Compulsive Disorder; Schizoaffective Disorder | Olanzapine     |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                                                                        | Olanzapine     |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                                                                        | Quetiapine     |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                                                                        | Risperidone    |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                                                                        | Citalopram     |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                        | Venlafaxine    |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                                                                        | Escitalopram   |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                                                                        | Clomipramine   |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                                                                        | Clozapine      |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                                                                        | Phenelzine     |              |            | S           | Unknown      | Above 60 Mg A Day  |                 | Not Reported |
|                                                                                                                                                                                        | Aripiprazole   |              |            | S           | Unknown      | Up To 45 Mg        |                 | Not Reported |
|                                                                                                                                                                                        | Amisulpride    |              |            | S           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Aug-2015              | 11337100      | EXPEDITED (15-DAY) |                    | OT              | PHHY2015BR046464     |                      | 44 YR      | Female     | BRA            |

| <u>Preferred Term</u>                                                                                                                                                              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abdominal Discomfort; Central Nervous System Lesion; Discomfort; Drug Ineffective; Headache; Lymphocyte Count Decreased; Urinary Tract Infection; White Blood Cell Count Decreased | Gilenya        |              |            | S           | Oral         | 1 Df, Qd           |                 | Novartis     |
|                                                                                                                                                                                    | Lexapro        |              |            | S           | Oral         | 15 Mg, Qd          |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Aug-2015              | 11398864      | NON-EXPEDITED    |                    | HO              | 1000068061           |                      | 57 YR      | Female     | USA            |

| <u>Preferred Term</u>          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Off Label Use; Seizure; Tremor | Namenda Xr     |              |            | S           | Oral         |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|              |   |      |                           |  |  |              |
|--------------|---|------|---------------------------|--|--|--------------|
| Namenda      | S | Oral |                           |  |  | Not Reported |
|              |   | Oral | 10 Mg (5 Mg 2 In 1 D),    |  |  |              |
|              |   | Oral | Oral                      |  |  |              |
|              |   | Oral | 10 Mg Am, 5 Mg Pm         |  |  |              |
| Escitalopram | S | Oral |                           |  |  | Not Reported |
| Vimpat       | S |      | 100 Mg (50 Mg, 2 In 1 D)  |  |  | Not Reported |
| Vimpat       | S |      | 200 Mg (100 Mg, 2 In 1 D) |  |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>    | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|------------------|------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 05-Aug-2015              | 11340763         | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2015258619 |                      | 56 YR           | Unknown      | USA            |
| <u>Preferred Term</u>    | <u>Product</u>   | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity    | Clindamycin Hcl  |                  |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                          | Zoloft           |                  |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                          | Bactrim          |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                          | Cipro            |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                          | Codeine          |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                          | Lexapro          |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                          | Sulfamethoxazole |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |

| <u>FDA Received Date</u>                                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 05-Aug-2015                                               | 11342246       | EXPEDITED (15-DAY) |                    | CA              | NL-FRI-1000078754    |                      |                 | Female       | NLD            |
| <u>Preferred Term</u>                                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Foetal Exposure During Pregnancy; Single Umbilical Artery | Escitalopram   |                    |                    | S               | Transplacental       |                      |                 | Forest       |                |
|                                                           | Ritalin        |                    |                    | S               | Transplacental       |                      |                 | Not Reported |                |
|                                                           | Ritalin        |                    |                    | S               | Transplacental       |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Aug-2015              | 11342521      | EXPEDITED (15-DAY) |                    | HO              | DE-TEVA-582738GER    |                      | 68 YR      | Female     | DEU            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>            | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>   |                |
|----------------------------------|------------------------------------|--------------------|--------------------|-----------------|----------------------------|--------------------------------------|-----------------|--------------|----------------|
| Drug Interaction; Dystonia       | Quetiapin Retard                   |                    |                    | S               |                            | 400 Dosage Forms Daily;              |                 | Teva         |                |
|                                  | Metoprolol                         |                    |                    | S               |                            | 100 Dosage Forms Daily;              |                 | Teva         |                |
|                                  | Hct                                |                    |                    | S               |                            | 25 Dosage Forms Daily;               |                 | Ivax         |                |
|                                  | Cipralex                           |                    |                    | S               |                            | 5 Dosage Forms Daily;                |                 | Not Reported |                |
|                                  | Remergil                           |                    |                    | S               |                            | 45 Dosage Forms Daily;               |                 | Not Reported |                |
|                                  | Lorazepam                          |                    |                    | C               |                            | 1 Dosage Forms Daily;                |                 | Not Reported |                |
|                                  | Evista                             |                    |                    | C               |                            | 60 Dosage Forms Daily;               |                 | Not Reported |                |
|                                  | Calcium Carbonate                  |                    |                    | C               |                            | 1500 Dosage Forms Daily;             |                 | Not Reported |                |
|                                  | L-Thyroxin                         |                    |                    | C               |                            | .075 Dosage Forms Daily;             |                 | Not Reported |                |
| <u>FDA Received Date</u>         | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Aug-2015                      | 11342570                           | EXPEDITED (15-DAY) |                    | HO              | CH-FRI-1000078694          |                                      | 50 YR           | Female       | CHE            |
| <u>Preferred Term</u>            | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug-Induced Liver Injury        | Escitalopram                       |                    |                    | S               | Oral                       | 20 Mg                                |                 | Forest       |                |
|                                  | Escitalopram                       |                    |                    | S               | Oral                       |                                      |                 | Forest       |                |
|                                  | Trittico (Trazodone Hydrochloride) |                    |                    | S               | Oral                       | 50 Mg                                |                 | Not Reported |                |
|                                  | Coversum N (Perindopril Arginine)  |                    |                    | S               | Oral                       |                                      |                 | Not Reported |                |
| <u>FDA Received Date</u>         | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Aug-2015                      | 11343077                           | EXPEDITED (15-DAY) |                    | HO              | DE-ASTRAZENECA-2015SE74286 |                                      | 68 YR           | Female       | DEU            |
| <u>Preferred Term</u>            | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Dystonia; Fall | Metoprolol                         |                    |                    | S               |                            |                                      |                 | Not Reported |                |
|                                  | Seroquel                           |                    |                    | S               | Oral                       |                                      |                 | Zeneca       |                |
|                                  | Mirtazapine                        |                    |                    | S               | Unknown                    |                                      |                 | Not Reported |                |
|                                  | Hydrochlorothiazide                |                    |                    | S               |                            | 25 Df Daily, Non Astrazeneca Product |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |                          |   |         |              |
|--|--------------------------|---|---------|--------------|
|  | Ciprallex                | S | Unknown | Not Reported |
|  | Lorazepam                | C |         | Not Reported |
|  | Raloxifene Hydrochloride | C |         | Not Reported |
|  | Calcium Carbonate        | C |         | Not Reported |
|  | L-Thyroxin               | C |         | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Aug-2015              | 11344482      | DIRECT           |                    | OT              |                      |                      | 37 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Decreased Activity; Depression; Disease Recurrence; Fatigue; Obsessive-Compulsive Disorder; Product Substitution Issue; Sedation | Escitalopram   |              |            | S           |              | 1 Pill Per Day     |                 | Accord       |
|                                                                                                                                           | Vitamin B      |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Aug-2015              | 11349475      | EXPEDITED (15-DAY) | Y                  | HO, OT          | 2015HINLIT0634       |                      | 60 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                      | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Confusional State; Cough; Dyspnoea;                                                                                                        | Escitalopram (Escitalopram)   |              |            | S           |              |                    |                 | Not Reported |
| Hypernatraemia;                                                                                                                            | Unknown                       |              |            |             |              |                    |                 |              |
| Hyperthermia Malignant;                                                                                                                    | Bupropion (Bupropion) Unknown |              |            | S           |              |                    |                 | Not Reported |
| Hypocalcaemia;                                                                                                                             | Valproate (Valproate)         |              |            | S           |              |                    |                 | Not Reported |
| Leukocytosis; Lipase Increased; Neuroleptic Malignant Syndrome; Respiratory Disorder; Seizure; Serotonin Syndrome; Transaminases Increased | Risperidone (Risperidone)     |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Aug-2015              | 10741522      | EXPEDITED (15-DAY) |                    | DE, OT          | CA-FRI-1000073811    |                      | 40 YR      | Female     | CAN            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                           | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
|-----------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|------------------------------------------|--------------------------|-----------------|--------------|----------------|
| Completed Suicide;<br>Delusion; Homicidal<br>Ideation; Paranoia | Escitalopram   |                    |                    | S               | Oral                                     | 10 Mg                    |                 | Forest       |                |
| <u>FDA Received Date</u>                                        | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Aug-2015                                                     | 10741968       | EXPEDITED (15-DAY) |                    | HO              | CA-FRI-1000073807                        |                          | 31 YR           | Male         | CAN            |
| <u>Preferred Term</u>                                           | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Joint Effusion; Seizure;<br>Suicide Attempt                     | Escitalopram   |                    |                    | S               | Unknown                                  | Daily Dose Not Reported  |                 | Forest       |                |
|                                                                 | Ativan         |                    |                    | S               | Unknown                                  | Daily Dose Not Reported  |                 | Not Reported |                |
|                                                                 | Ativan         |                    |                    | S               | Unknown                                  | Overdose: Dose Unknown   |                 | Not Reported |                |
|                                                                 | Remicade       |                    |                    | S               | Intravenous (not<br>otherwise specified) | 5.5357 Mg                |                 | Not Reported |                |
|                                                                 | Seroquel       |                    |                    | S               | Unknown                                  | Daily Dose Not Reported  |                 | Not Reported |                |
|                                                                 | Seroquel       |                    |                    | S               | Unknown                                  | Overdose: Unknown Dose   |                 | Not Reported |                |
|                                                                 | Imuran         |                    |                    | C               |                                          | Daily Dose Not Reported. |                 | Not Reported |                |
| <u>FDA Received Date</u>                                        | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Aug-2015                                                     | 10742613       | EXPEDITED (15-DAY) |                    | OT              | CA-FRI-1000073814                        |                          | 25 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                           | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated;<br>Depression; Suicidal<br>Ideation       | Escitalopram   |                    |                    | S               | Oral                                     | 10 Mg                    |                 | Forest       |                |
| <u>FDA Received Date</u>                                        | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Aug-2015                                                     | 10742819       | EXPEDITED (15-DAY) |                    | DS              | CA-FRI-1000073821                        |                          | 51 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                           | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Anger; Anxiety; Blood<br>Pressure Increased;                    | Escitalopram   |                    |                    | S               |                                          | Dose Not Reported        |                 | Forest       |                |
|                                                                 | Abilify        |                    |                    | S               |                                          | Dose Not Reported        |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                           |          |   |         |                   |              |
|-------------------------------------------------------------------------------------------|----------|---|---------|-------------------|--------------|
| Depression; Heart Rate Increased; Mental Impairment; Product Use In Unapproved Indication | Seroquel | S | Unknown | Dose Not Reported | Not Reported |
|-------------------------------------------------------------------------------------------|----------|---|---------|-------------------|--------------|

| <u>FDA Received Date</u>                                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|--------------------------|-----------------|--------------|----------------|
| 06-Aug-2015                                               | 10742854       | EXPEDITED (15-DAY) |                    | OT              | CA-FRI-1000073854    |                          | 26 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Dysuria; Hypotension; Urinary Retention | Escitalopram   |                    |                    | S               | Oral                 | 20 Mg Daily              |                 | Forest       |                |
|                                                           | Mirena         |                    |                    | C               |                      | Daily Dose Not Reported. |                 | Not Reported |                |
|                                                           | Modafinil      |                    |                    | C               |                      |                          |                 | Not Reported |                |
|                                                           | Pantoprazole   |                    |                    | C               |                      | 80 Mg                    |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 06-Aug-2015                                                                                         | 10742895       | EXPEDITED (15-DAY) |                    | OT              | CA-FRI-1000073826    |                      | 26 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dry Mouth; Flushing; Headache; Hyperhidrosis; Nausea; Nervousness; Pain; Serotonin Syndrome; Tremor | Escitalopram   |                    |                    | S               | Oral                 | 20 Mg                |                 | Forest       |                |
|                                                                                                     | Effexor        |                    |                    | S               | Oral                 | 150 Mg               |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                                      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|------------------------|-----------------|--------------|----------------|
| 06-Aug-2015                                                                                                                                                   | 10856161       | EXPEDITED (15-DAY) |                    | DE              | CA-FRI-1000073823    |                        | 48 YR           | Male         | CAN            |
| <u>Preferred Term</u>                                                                                                                                         | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Behaviour; Chest Pain; Completed Suicide; Depression; Hallucination, Visual; Hyperhidrosis; Intentional Overdose; Mood Swings; Musculoskeletal Chest | Escitalopram   |                    |                    | S               | Unknown              | Overdose: Dose Unknown |                 | Forest       |                |
|                                                                                                                                                               | Zopiclone      |                    |                    | S               | Unknown              | Overdose: Dose Unknown |                 | Not Reported |                |
|                                                                                                                                                               | Rosuvastatin   |                    |                    | C               | Oral                 | 10 Mg                  |                 | Not Reported |                |
|                                                                                                                                                               | Senna Plus     |                    |                    | C               | Oral                 | 8.6 Mg/50 Mg           |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Pain; Suicidal Ideation

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Aug-2015              | 11030562      | EXPEDITED (15-DAY) |                    | OT              | ES-FRI-1000075850    |                      | 73 YR      | Female     | ESP            |

| <u>Preferred Term</u>                         | <u>Product</u>                                        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------|-------------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Angle Closure Glaucoma;<br>Choroidal Effusion | Escitalopram                                          |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                               | Escitalopram                                          |              |            | S           | Oral         | 20 Mg              |                 | Forest       |
|                                               | Ameride (Amiloride Hydrochloride\Hydrochlorothiazide) |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                               | Montelukast                                           |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                               | Adiro                                                 |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                               | Omeprazole                                            |              |            | C           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Aug-2015              | 11294134      | EXPEDITED (15-DAY) |                    | HO              | US-FRI-1000078323    |                      | 60 YR      | Male       | USA            |

| <u>Preferred Term</u>          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Neuroleptic Malignant Syndrome | Escitalopram   |              |            | S           | Unknown      |                    |                 | Forest       |
|                                | Risperidone    |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                | Bupropion      |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                | Valproic Acid  |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                | Fentanyl       |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                | Atorvastatin   |              |            | C           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|------------|------------|----------------|
| 06-Aug-2015              | 11343235      | EXPEDITED (15-DAY) |                    | HO, OT          | DE-DRREDDYS-GER/GER/15/0049688 |                      | 68 YR      | Female     | DEU            |

| <u>Preferred Term</u>                          | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Condition Aggravated;<br>Delusion; Depression; | Metoprolol          |              |            | S           |              |                    |                 | Not Reported |
|                                                | Hydrochlorothiazide |              |            | S           |              |                    |                 | Not Reported |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                         |                      |   |              |
|---------------------------------------------------------|----------------------|---|--------------|
| Drug Interaction; Dystonia;<br>Impaired Driving Ability | Quetiapine Retard    | S | Not Reported |
|                                                         | Remergil             | S | Not Reported |
|                                                         | Cipralex             | S | Not Reported |
|                                                         | Lorazepam            | C | Not Reported |
|                                                         | Evista               | C | Not Reported |
|                                                         | Calcium Carbonate    | C | Not Reported |
|                                                         | Levothyroxine Sodium | C | Not Reported |

| <u>FDA Received Date</u>                                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|------------------------------------|----------------------|-----------------|--------------|----------------|
| 06-Aug-2015                                                                    | 11344007       | EXPEDITED (15-DAY) |                    | HO, OT          | US-DRREDDYS-<br>USA/USA/15/0049871 |                      | 60 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                       | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Neuroleptic Malignant<br>Syndrome; Pneumonia;<br>Sepsis; Serotonin<br>Syndrome | Risperidone    |                    |                    | S               | Unknown                            |                      |                 | Not Reported |                |
|                                                                                | Bupropion      |                    |                    | S               | Unknown                            |                      |                 | Not Reported |                |
|                                                                                | Escitalopram   |                    |                    | S               | Unknown                            |                      |                 | Not Reported |                |
|                                                                                | Valproate      |                    |                    | S               | Unknown                            |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                                                                              | <u>Case #</u>    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 06-Aug-2015                                                                                                                                                                                           | 11345637         | EXPEDITED (15-DAY) |                    | HO, OT          | JP-KOWA-15JP001007   |                      | 44 YR           | Male         | JPN            |
| <u>Preferred Term</u>                                                                                                                                                                                 | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alanine Aminotransferase<br>Increased; Aspartate<br>Aminotransferase<br>Increased; Blood Creatine<br>Phosphokinase Increased;<br>Blood Lactate<br>Dehydrogenase<br>Increased; Chest Pain;<br>Headache | Livalo           |                    |                    | S               | Oral                 | 2 Mg, Qd             |                 | Kowa Pharm   |                |
|                                                                                                                                                                                                       | Lyrica           |                    |                    | S               | Oral                 | Unk, Prn             |                 | Not Reported |                |
|                                                                                                                                                                                                       | Actos            |                    |                    | S               | Oral                 | 15 Mg, Qd            |                 | Not Reported |                |
|                                                                                                                                                                                                       | Lexapro          |                    |                    | S               | Oral                 | 10 Mg, Qd            |                 | Not Reported |                |
|                                                                                                                                                                                                       | Depas (Etizolam) |                    |                    | S               | Oral                 | 1.0 Mg, Tid          |                 | Not Reported |                |
|                                                                                                                                                                                                       | Depas            |                    |                    | S               | Oral                 | 0.5 Mg, Tid          |                 | Not Reported |                |
|                                                                                                                                                                                                       | Amoxan           |                    |                    | C               | Oral                 | Unk, Unk             |                 | Not Reported |                |
|                                                                                                                                                                                                       | Solanax          |                    |                    | C               | Oral                 | Unk, Unk             |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Aug-2015              | 11345809      | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000078780    |                      |            | Female     | FRA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <a href="#">Preferred Term</a>                                      | <a href="#">Product</a>                      | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>          | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
|---------------------------------------------------------------------|----------------------------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|--------------------------------------|--------------------------|---------------------|-------------------------|
| Optic Neuritis                                                      | Escitalopram                                 |                           |                             | S                        |                               |                                      |                          | Forest              |                         |
| <a href="#">FDA Received Date</a>                                   | <a href="#">Case #</a>                       | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>        | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 06-Aug-2015                                                         | 11348427                                     | EXPEDITED (15-DAY)        |                             | OT                       | PHHY2015TR091650              |                                      | 43 YR                    | Female              | TUR                     |
| <a href="#">Preferred Term</a>                                      | <a href="#">Product</a>                      | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>          | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Restless Legs Syndrome;<br>Therapeutic Response<br>Decreased        | Escitalopram                                 |                           |                             | S                        | Unknown                       |                                      |                          | Not Reported        |                         |
|                                                                     | Citalopram                                   |                           |                             | S                        | Unknown                       |                                      |                          | Novartis            |                         |
|                                                                     | Levothyroxine                                |                           |                             | C                        | Unknown                       | 100 Mg, Qd                           |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                   | <a href="#">Case #</a>                       | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>        | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 06-Aug-2015                                                         | 11350172                                     | DIRECT                    |                             | OT                       |                               |                                      | 56 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>                                      | <a href="#">Product</a>                      | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>          | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Loss Of Consciousness;<br>Loss Of Consciousness                     | Lexapro                                      |                           |                             | S                        |                               |                                      |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                   | <a href="#">Case #</a>                       | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>        | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 06-Aug-2015                                                         | 11350475                                     | DIRECT                    |                             |                          |                               |                                      | 43 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>                                      | <a href="#">Product</a>                      | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>          | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Anorgasmia; Apathy;<br>Apathy; Diarrhoea;<br>Somnolence; Somnolence | Escitalopram Lexapro 10 Mg<br>Torrent Pharma |                           |                             | S                        | Oral                          | 2 Daily Once Daily Taken<br>By Mouth |                          | Torrent             |                         |
|                                                                     | Vitamin D3                                   |                           |                             | C                        |                               |                                      |                          | Not Reported        |                         |
|                                                                     | Fish Oil                                     |                           |                             | C                        |                               |                                      |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                   | <a href="#">Case #</a>                       | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>        | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 06-Aug-2015                                                         | 11358702                                     | EXPEDITED (15-DAY)        | Y                           | HO                       | DE-2015VAL000504              |                                      | 68 YR                    | Female              | DEU                     |
| <a href="#">Preferred Term</a>                                      | <a href="#">Product</a>                      | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>          | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Dystonia                                                            | Metoprolol Tartrate                          |                           |                             | S                        |                               |                                      |                          | Not Reported        |                         |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                           |   |                                        |              |
|-------------------------------------------|---|----------------------------------------|--------------|
| Hydrochlorothiazide                       | S |                                        | Not Reported |
| (Hydrochlorothiazide) 25mg                |   |                                        |              |
| Quetiapine (Quetiapine) 400mg             | S | Extended Release Tablet,<br>400 Mg, Qd | Not Reported |
| Cipralex /01588501/<br>(Escitalopram) 5mg | S |                                        | Not Reported |
| Remergil (Mirtazapine) 45mg               | S |                                        | Not Reported |
| Lorazepam                                 | C |                                        | Not Reported |
| Evista (Raloxifene<br>Hydrochloride)      | C |                                        | Not Reported |
| Calcium Carbonate                         | C |                                        | Not Reported |
| L-Thyroxine /00068001/<br>(Levothyroxine) | C |                                        | Not Reported |

| <u>FDA Received Date</u>                                | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| 07-Aug-2015                                             | 9824319        | NON-EXPEDITED    |                    |                 | US-GILEAD-2011-<br>0037286 |                      | 62 YR           | Female       | USA            |
| <u>Preferred Term</u>                                   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Headache;<br>Nausea; Palpitations;<br>Vomiting | Letairis       |                  |                    | S               | Oral                       |                      |                 | Gilead       |                |
|                                                         | Letairis       |                  |                    | S               |                            |                      |                 | Gilead       |                |
|                                                         | Lexapro        |                  |                    | S               |                            |                      |                 | Not Reported |                |
|                                                         | Adcirca        |                  |                    | C               |                            |                      |                 | Not Reported |                |
|                                                         | Coumadin       |                  |                    | C               |                            |                      |                 | Not Reported |                |
|                                                         | Oxygen         |                  |                    | C               |                            |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                                                                          | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 07-Aug-2015                                                                                                                                                                                       | 10741610       | EXPEDITED (15-DAY) |                    | OT              | CA-FRI-1000073816    |                      | 40 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                                                                                                                                                             | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Diarrhoea; Hallucination;<br>Muscle Spasms; Muscle<br>Tightness; Muscle<br>Twitching; Nausea;<br>Restlessness; Serotonin<br>Syndrome; Skin Burning<br>Sensation; Tachycardia;<br>Tremor; Vomiting | Escitalopram   |                    |                    | S               | Unknown              | 5 Mg                 |                 | Forest       |                |
|                                                                                                                                                                                                   | Effexor Xr     |                    |                    | S               | Oral                 | 1 Dosage Form        |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                     | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------|-----------------------|--------------------|--------------------|-----------------|--------------------------------------------------|-------------------------|-----------------|--------------|----------------|
| 07-Aug-2015                                                                  | 10742765              | EXPEDITED (15-DAY) |                    | HO              | CA-FRI-1000073825                                |                         | < 1 DAY         | Unknown      | CAN            |
| <u>Preferred Term</u>                                                        | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                     | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Trismus | Escitalopram          |                    |                    | S               | Transplacental                                   | 20 Mg                   |                 | Forest       |                |
|                                                                              | Benzotropine Mesylate |                    |                    | S               | Transplacental                                   | 1.5 Mg                  |                 | Not Reported |                |
|                                                                              | Gabapentin            |                    |                    | S               | Transplacental                                   | 1800 Mg                 |                 | Not Reported |                |
|                                                                              | Methadone             |                    |                    | S               | Transplacental                                   | 70 Mg                   |                 | Not Reported |                |
|                                                                              | Nortriptyline         |                    |                    | S               | Transplacental                                   | 20 Mg                   |                 | Not Reported |                |
|                                                                              | Quetiapine            |                    |                    | S               | Transplacental                                   | 600 Mg                  |                 | Not Reported |                |
|                                                                              | Rabeprazole           |                    |                    | S               | Transplacental                                   | Daily Dose Not Reported |                 | Not Reported |                |
|                                                                              | Zopiclone             |                    |                    | S               | Transplacental                                   | Daily Dose Not Reported |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                     | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Aug-2015                                                                  | 11226469              | EXPEDITED (15-DAY) |                    | OT              | DE-GILEAD-2015-0152211                           |                         | 48 YR           | Male         | DEU            |
| <u>Preferred Term</u>                                                        | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                     | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Anaemia; Depression; Drug Dependence; Dyspnoea; Fatigue                      | Ledipasvir/Sofosbuvir |                    |                    | S               | Oral                                             | 1 Df, Qd                |                 | Gilead       |                |
|                                                                              | Ribavirin             |                    |                    | S               | Oral                                             | 1200 Mg, Qd             |                 | Not Reported |                |
|                                                                              | Ribavirin             |                    |                    | S               | Oral                                             | 800 Mg, Qd              |                 | Not Reported |                |
|                                                                              | Ribavirin             |                    |                    | S               | Oral                                             | 600 Mg, Qd              |                 | Not Reported |                |
|                                                                              | Escitalopram          |                    |                    | S               | Oral                                             | 10 Mg, Qd               |                 | Not Reported |                |
|                                                                              | Methadon              |                    |                    | C               |                                                  | Unk                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                     | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Aug-2015                                                                  | 11349157              | EXPEDITED (15-DAY) |                    | HO, OT          | TW-MACLEODS PHARMACEUTICALS US LTD-MAC2015001907 |                         |                 | Unknown      | TWN            |
| <u>Preferred Term</u>                                                        | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                     | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                           |                      |   |         |            |              |
|---------------------------|----------------------|---|---------|------------|--------------|
| Abnormal Behaviour;       | Escitalopram Oxalate | S | Unknown | 10 Mg/Day  | Macleods     |
| Agitation; Delirium;      | Disulfiram           | S | Unknown | 200 Mg, Qd | Not Reported |
| Disturbance In Attention; | Griseofulvin         | S | Unknown | 500 Mg, Qd | Not Reported |
| Drug Interaction;         |                      |   |         |            |              |
| Hallucinations, Mixed;    |                      |   |         |            |              |
| Incoherent                |                      |   |         |            |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Aug-2015              | 11350440      | EXPEDITED (15-DAY) |                    | OT              | CA-FRI-1000078697    |                      |            | Male       | CAN            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Nephrolithiasis       | Escitalopram   |              |            | S           | Oral         | 20 Mg              |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Aug-2015              | 11350546      | EXPEDITED (15-DAY) |                    | HO              | US-FRI-1000078784    |                      |            | Female     | USA            |

| <u>Preferred Term</u>                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Aggression; Drug Ineffective; Psychiatric Symptom | Lexapro        |              |            | S           |              |                    |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|------------|------------|----------------|
| 07-Aug-2015              | 11353311      | EXPEDITED (15-DAY) |                    | HO              | DE-AUROBINDO-AUR-APL-2015-06734 |                      |            | Unknown    | DEU            |

| <u>Preferred Term</u>            | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction; Dystonia; Fall | Hydrochlorothiazide |              |            | S           | Unknown      | 25 Df, Daily       |                 | Aurobindo    |
|                                  | Metoprolol          |              |            | S           | Unknown      | 100 Df, Daily      |                 | Aurobindo    |
|                                  | Quetiapine          |              |            | S           |              | 400 Df, Daily      |                 | Aurobindo    |
|                                  | Cipraxel /01588501/ |              |            | S           |              | 5 Df, Daily        |                 | Not Reported |
|                                  | Remergil            |              |            | S           | Unknown      | 45 Df, Daily       |                 | Not Reported |
|                                  | Lorazepam           |              |            | C           | Unknown      | 1 Df, Daily        |                 | Not Reported |
|                                  | Evista              |              |            | C           | Unknown      | 60 Df, Daily       |                 | Not Reported |
|                                  | Calcium Carbonate   |              |            | C           | Unknown      | 1500 Df, Daily     |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                   |                    |                    |                    |                 |                                                 |                            |                 |                      |                |
|-------------------------------------------------------------------|--------------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------------|-----------------|----------------------|----------------|
| Thyroxin                                                          |                    |                    | C                  | Unknown         | 0.075 Df, Daily                                 |                            |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                          | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 07-Aug-2015                                                       | 11354825           | NON-EXPEDITED      |                    |                 | US-JNJFOC-20150103411                           |                            | 15 YR           | Male                 | USA            |
| <u>Preferred Term</u>                                             | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>           |                |
| Anxiety; Condition                                                | Risperdal          |                    |                    | S               | Unknown                                         |                            |                 | Not Reported         |                |
| Aggravated; Depression;                                           | Lexapro            |                    |                    | S               | Oral                                            |                            |                 | Not Reported         |                |
| Drug Ineffective; Post-Traumatic Stress Disorder                  | Prozac             |                    |                    | S               | Unknown                                         |                            |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                          | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 07-Aug-2015                                                       | 11355280           | EXPEDITED (15-DAY) |                    | HO, OT          | FR-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-050789 |                            | 78 YR           | Female               | FRA            |
| <u>Preferred Term</u>                                             | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>           |                |
| Post Procedural Haemorrhage; Renal Haematoma; Renal Stone Removal | Coumadine          |                    |                    | S               | Oral                                            | 1 Df, Qd                   |                 | Bristol Myers Squibb |                |
|                                                                   | Seroplex           |                    |                    | S               | Oral                                            | 1 Df, Qd                   |                 | Not Reported         |                |
|                                                                   | Inexium /01479302/ |                    |                    | C               | Unknown                                         | 20 Mg, Qd                  |                 | Not Reported         |                |
|                                                                   | Rythmol /00546301/ |                    |                    | C               | Unknown                                         | 1 Df, Bid                  |                 | Not Reported         |                |
|                                                                   | Esidrex            |                    |                    | C               | Unknown                                         | 25 Mg, Qd                  |                 | Not Reported         |                |
|                                                                   | Temesta /00273201/ |                    |                    | C               | Unknown                                         | 1 Mg, Qd                   |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                          | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 10-Aug-2015                                                       | 10756584           | EXPEDITED (15-DAY) |                    | OT              | PHHY2015BR010479                                |                            |                 | Female               | BRA            |
| <u>Preferred Term</u>                                             | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>           |                |
| Blister; Body Height Decreased; Dementia                          | Exelon Patch       |                    |                    | S               | Transdermal                                     | Patch 10 (Cm2)             |                 | Novartis             |                |
| Alzheimer'S Type; Dry Mouth; Dysphagia;                           | Exelon Patch       |                    |                    | S               | Transdermal                                     | Patch 10 (Cm2), In Morning |                 | Novartis             |                |
| Fatigue; Gait Disturbance;                                        | Neotiapim          |                    |                    | S               | Oral                                            | 2 Df, Qd                   |                 | Not Reported         |                |
| Malaise; Memory Impairment; Pain;                                 | Citoneurin         |                    |                    | S               | Unknown                                         | Unk                        |                 | Not Reported         |                |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                           |                          |   |         |             |              |
|-------------------------------------------------------------------------------------------|--------------------------|---|---------|-------------|--------------|
| Somnolence; Speech Disorder; Spinal Deformity; Tremor; Weight Decreased; Weight Increased | Lexapro                  | S | Unknown | 15 Mg, Unk  | Not Reported |
|                                                                                           | Oscal                    | S | Unknown | 400 Iu, Unk | Not Reported |
|                                                                                           | Alois                    | S | Oral    | 2 Df, Qd    | Not Reported |
|                                                                                           | Vitersol D               | S | Oral    | Unk         | Not Reported |
|                                                                                           | Actonel                  | S | Unknown | 150 Ot, Unk | Not Reported |
|                                                                                           | Rivotril                 | S | Oral    | 5 Gtt, Qhs  | Not Reported |
|                                                                                           | Lyrica                   | S | Oral    | 2 Df, Qd    | Not Reported |
|                                                                                           | Lyrica                   | S | Unknown | 75 Mg, Unk  | Not Reported |
|                                                                                           | Dramin B6                | C | Oral    | Unk         | Not Reported |
|                                                                                           | Lescol                   | C | Oral    | Unk         | Not Reported |
|                                                                                           | Lexotan                  | C | Oral    | 1.5 Df, Qhs | Not Reported |
|                                                                                           | Ocuguard Plus            | C | Oral    | 2 Df, Qd    | Not Reported |
|                                                                                           | Harpagophytum Procumbens | C | Oral    | Unk         | Not Reported |
|                                                                                           | Ensure                   | C | Unknown |             | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 10-Aug-2015              | 11302483      | EXPEDITED (15-DAY) |                    | HO              | US-CIPLA LTD.-2015US05893 |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>                                                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Neuroleptic Malignant Syndrome; Pneumonia; Respiratory Failure; Sepsis; Serotonin Syndrome | Risperidone    |              |            | S           | Oral         | 1 Mg, Qhs          |                 | Cipla        |
|                                                                                            | Bupropion      |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                                                                                            | Escitalopram   |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                                                                                            | Valproate      |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                                                                                            | Fentanyl       |              |            | S           |              | Unk                |                 | Not Reported |
|                                                                                            | Lorazepam      |              |            | S           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Aug-2015              | 11319381      | EXPEDITED (15-DAY) |                    | CA              | PHHY2015NL087692     |                      |            | Unknown    | NLD            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                         |         |   |         |           |              |
|-------------------------|---------|---|---------|-----------|--------------|
| Single Umbilical Artery | Ritalin | S | Unknown | 1 Df, Unk | Novartis     |
|                         | Lexapro | S | Unknown | 1 Df, Unk | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                              | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------------------------|----------------------|------------|------------|----------------|
| 10-Aug-2015              | 11359911      | EXPEDITED (15-DAY) |                    | DE              | FR-NOVEN<br>PHARMACEUTICALS,<br>INC.-FR2015000643 |                      |            | Unknown    | FRA            |

| <u>Preferred Term</u>          | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Asphyxia; Completed<br>Suicide | Paroxetine                |              |            | S           | Oral         | 20 Mg, Qd          |                 | Noven        |
|                                | Escitalopram Mylan Pharma |              |            | S           | Oral         | 5 Mg, Qd           |                 | Not Reported |
|                                | Escitalopram Mylan Pharma |              |            | S           | Oral         | 10 Mg, Qd          |                 | Not Reported |
|                                | Seroplex                  |              |            | S           | Oral         | 15 Mg, Qd          |                 | Not Reported |
|                                | Alprazolam                |              |            | C           |              | .25 Mg, Unk        |                 | Not Reported |
|                                | Alprazolam                |              |            | C           |              | 0.25 Mg, Qd        |                 | Not Reported |
|                                | Kardegic                  |              |            | C           | Oral         | 1 Df, Qd           |                 | Not Reported |
|                                | Valaciclovir              |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Aug-2015              | 11363077      | EXPEDITED (15-DAY) |                    | CA, OT          | CH-FRI-1000078893    |                      |            | Female     | CHE            |

| <u>Preferred Term</u>                                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Foetal Exposure During<br>Pregnancy; Oesophageal<br>Atresia | Escitalopram   |              |            | S           | Transplacental |                    |                 | Forest       |
|                                                             | Xanax          |              |            | S           | Transplacental |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Aug-2015              | 11310192      | EXPEDITED (15-DAY) |                    | DE              | FR-FRI-1000078320    |                      | 72 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Haemorrhagic Stroke   | Escitalopram           |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                       | Previscan (Fluindione) |              |            | S           | Oral         | 40 Mg              |                 | Not Reported |
|                       | Doliprane              |              |            | C           | Oral         |                    |                 | Not Reported |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                             | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------|-----------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 11-Aug-2015                                                                          | 11364380        | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2015255380 |                      | 41 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity                                                                | Lipitor         |                    |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                                                                                      | Norvasc         |                    |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                                                                                      | Synthroid       |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                                                                                      | Omeprazole      |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                                                                                      | Escitalopram    |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                                                                                      | Labetalol       |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                                                                                      | Ferrous Sulfate |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                             | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Aug-2015                                                                          | 11364961        | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000078887        |                      | 81 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Behaviour Disorder;<br>Cognitive Disorder;<br>Condition Aggravated; Off<br>Label Use | Escitalopram    |                    |                    | S               | Oral                     | 5 Mg                 |                 | Forest       |                |
| <u>FDA Received Date</u>                                                             | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Aug-2015                                                                          | 11365876        | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000078882        |                      | 31 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hepatocellular Injury                                                                | Escitalopram    |                    |                    | S               | Oral                     | 10 Mg                |                 | Forest       |                |
|                                                                                      | Atarax          |                    |                    | S               | Oral                     | 50 Mg                |                 | Not Reported |                |
|                                                                                      | Tercian         |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                                                                                      | Deroxat         |                    |                    | S               | Oral                     | 10 Mg                |                 | Not Reported |                |

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## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------|--------------------|--------------------|--------------------|-----------------|----------------------|------------------------------------------------------------|-----------------|--------------|----------------|
| 11-Aug-2015                                                             | 11366148           | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000078863    |                                                            | 49 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                   | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Overdose;<br>Suicide Attempt; Toxicity<br>To Various Agents | Escitalopram       |                    |                    | S               | Oral                 |                                                            |                 | Forest       |                |
|                                                                         | Escitalopram       |                    |                    | S               | Oral                 | Overdose: 210 Mg Once.                                     |                 | Forest       |                |
|                                                                         | Klipal             |                    |                    | S               | Oral                 | Overdose: 7.2 G Of<br>Paracetamol And 600 Mg<br>Of Codeine |                 | Not Reported |                |
|                                                                         | Seresta            |                    |                    | S               | Oral                 |                                                            |                 | Not Reported |                |
|                                                                         | Seresta            |                    |                    | S               | Oral                 | Overdose: 300 Mg Once.                                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Aug-2015                                                             | 11368207           | DIRECT             |                    |                 |                      |                                                            | 22 YR           | Female       |                |
| <u>Preferred Term</u>                                                   | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Anger; Bipolar I Disorder;<br>Panic Attack; Suicidal<br>Ideation        | Lexapro            |                    |                    | S               | Oral                 | Taken By Mouth                                             | 2.5 YR          | Not Reported |                |
| <u>FDA Received Date</u>                                                | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Aug-2015                                                             | 11368714           | EXPEDITED (15-DAY) |                    | HO              | CA-ROCHE-1618703     |                                                            |                 | Female       | CAN            |
| <u>Preferred Term</u>                                                   | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated;<br>Dehydration; Dysphagia;<br>Mental Disorder     | Clonazepam         |                    |                    | S               | Unknown              |                                                            |                 | Not Reported |                |
|                                                                         | Ciprallex          |                    |                    | S               | Oral                 |                                                            |                 | Not Reported |                |
|                                                                         | Domperidone        |                    |                    | S               | Unknown              |                                                            |                 | Not Reported |                |
|                                                                         | Ferrous Sulphate   |                    |                    | S               | Unknown              |                                                            |                 | Not Reported |                |
|                                                                         | Gabapentin         |                    |                    | S               | Oral                 |                                                            |                 | Not Reported |                |
|                                                                         | Gabapentin         |                    |                    | S               | Oral                 |                                                            |                 | Not Reported |                |
|                                                                         | Temazepam Capsules |                    |                    | S               | Oral                 |                                                            |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                         |   |      |              |
|-----------------------------------------|---|------|--------------|
| Tylenol With Codeine #3 (United States) | S | Oral | Not Reported |
| Vitalex (Unk Ingredients)               | S | Oral | Not Reported |
| Wellbutrin XL                           | S | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------------------|----------------------|------------|------------|----------------|
| 12-Aug-2015              | 11368736      | EXPEDITED (15-DAY) |                    | OT              | US-JUBILANT<br>GENERIC LIMITED-<br>1041045 |                      | 60 YR      | Male       | USA            |

| <u>Preferred Term</u>                              | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Neuroleptic Malignant Syndrome; Serotonin Syndrome | Bupropion               |              |            | S           |              |                    |                 | Jubilant     |
|                                                    | Escitalopram            |              |            | S           |              |                    |                 | Not Reported |
|                                                    | Valproate Sodium        |              |            | S           |              |                    |                 | Not Reported |
|                                                    | Fentanyl                |              |            | S           |              |                    |                 | Not Reported |
|                                                    | Risperidone             |              |            | S           |              |                    |                 | Not Reported |
|                                                    | Vancomycin Hcl          |              |            | C           |              |                    |                 | Not Reported |
|                                                    | Piperacillin-Tazobactam |              |            | C           |              |                    |                 | Not Reported |
|                                                    | Azithromycin            |              |            | C           |              |                    |                 | Not Reported |
|                                                    | Lorazepam               |              |            | C           |              |                    |                 | Not Reported |
|                                                    | Ceftriaxone             |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 12-Aug-2015              | 11369345      | NON-EXPEDITED    |                    |                 | US-JNJFOC-<br>20150506351 |                      |            | Female     | USA            |

| <u>Preferred Term</u>            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Foetal Exposure During Pregnancy | Stelara        |              |            | S           | Subcutaneous |                    |                 | Not Reported |
|                                  | Adderall       |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                  | Lexapro        |              |            | S           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|------------|------------|----------------|
| 12-Aug-2015              | 11371743      | EXPEDITED (15-DAY) |                    | HO              | DE-MYLANLABS-<br>2015M1026348 |                      |            | Unknown    | DEU            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Dystonia              | Metoprolol     |              |            | S           |              | 100 Df, Unk        |                 | Not Reported |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                   |   |               |              |
|-------------------|---|---------------|--------------|
| Hct               | S | 25 Df, Unk    | Mylan        |
| Cipralex          | S | 5 Df, Unk     | Not Reported |
| Quetiapin Retard  | S | 400 Df, Unk   | Not Reported |
| Remergil          | S | 45 Df, Unk    | Not Reported |
| Lorazepam         | C | 1 Df, Unk     | Not Reported |
| Evista            | C | 60 Df, Unk    | Not Reported |
| Calcium Carbonate | C | 1500 Df, Unk  | Not Reported |
| L-Thyroxin        | C | 0.075 Df, Unk | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Aug-2015              | 11378910      | EXPEDITED (15-DAY) | Y                  | HO              | 2015EDG00030         |                      | 60 YR      | Male       | USA            |

| <u>Preferred Term</u>                              | <u>Product</u>                                    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------|---------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Neuroleptic Malignant Syndrome; Serotonin Syndrome | Bupropion (Bupropion)                             |              |            | S           |              |                    |                 | Not Reported |
|                                                    | Escitalopram (Escitalopram)                       |              |            | S           |              |                    |                 | Not Reported |
|                                                    | Valproate (Valproate)                             |              |            | S           |              |                    |                 | Not Reported |
|                                                    | Fentanyl (Fentanyl) Injection                     |              |            | S           |              |                    |                 | Not Reported |
|                                                    | Risperidone (Risperidone)                         |              |            | S           |              |                    |                 | Not Reported |
|                                                    | Vancomycin (Vancomycin)                           |              |            | C           |              |                    |                 | Not Reported |
|                                                    | Piperacillin-Tazobactam (Piperacillin-Tazobactam) |              |            | C           |              |                    |                 | Not Reported |
|                                                    | Azithromycin (Azithromycin)                       |              |            | C           |              |                    |                 | Not Reported |
|                                                    | Lorazepam (Lorazepam)                             |              |            | C           |              |                    |                 | Not Reported |
|                                                    | Ceftriaxone (Ceftriaxone)                         |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Aug-2015              | 11341581      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000078748    |                      | 78 YR      | Female     | FRA            |

| <u>Preferred Term</u>       | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Post Procedural Haemorrhage | Escitalopram        |              |            | S           | Oral         | 15 Mg              |                 | Forest       |
|                             | Coumadine           |              |            | S           | Oral         | 1 Mg               |                 | Not Reported |
|                             | Inexium             |              |            | C           | Oral         | 20 Mg              |                 | Not Reported |
|                             | Temesta (Lorazepam) |              |            | C           | Oral         |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                 |                | Rythmol            | C                  | Oral            | 300 Mg                    |                          |                 | Not Reported |                |
|---------------------------------|----------------|--------------------|--------------------|-----------------|---------------------------|--------------------------|-----------------|--------------|----------------|
|                                 |                | Esidrex            | C                  | Oral            | 25 Mg                     |                          |                 | Not Reported |                |
| <u>FDA Received Date</u>        | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Aug-2015                     | 11375931       | EXPEDITED (15-DAY) |                    | HO              | FR-PFIZER INC-2015265255  |                          | 68 YR           | Female       | FRA            |
| <u>Preferred Term</u>           | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyponatraemia;<br>Paraesthesia  | Xanax          |                    |                    | S               | Oral                      | 0.25 Mg, Unk             |                 | Pfizer       |                |
|                                 | Xeloda         |                    |                    | S               | Oral                      | Unk                      |                 | Not Reported |                |
|                                 | Seroplex       |                    |                    | S               | Oral                      | 10 Mg, Unk               |                 | Not Reported |                |
|                                 | Oxycontin Lp   |                    |                    | S               | Oral                      | 20 Mg (10mg X 2), 1x/Day |                 | Not Reported |                |
|                                 | Paracetamol    |                    |                    | C               |                           | Unk                      |                 | Not Reported |                |
|                                 | Ixprim         |                    |                    | C               |                           | Unk                      |                 | Not Reported |                |
|                                 | Imodium        |                    |                    | C               |                           | Unk                      |                 | Not Reported |                |
|                                 | Primperan      |                    |                    | C               |                           | Unk                      |                 | Not Reported |                |
| Dexeryl /00557601/              |                |                    | C                  |                 | Unk                       |                          | Not Reported    |              |                |
| <u>FDA Received Date</u>        | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Aug-2015                     | 11375980       | EXPEDITED (15-DAY) |                    | HO              | KR-MYLANLABS-2015M1026954 |                          |                 | Unknown      | KOR            |
| <u>Preferred Term</u>           | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Dystonia; Tardive<br>Dyskinesia | Amitriptyline  |                    |                    | S               |                           | 10 Mg, Qd                |                 | Mylan        |                |
|                                 | Escitalopram   |                    |                    | S               |                           | 5 Mg, Qd                 |                 | Mylan        |                |
|                                 | Trazodone      |                    |                    | S               |                           | 25 Mg, Qd                |                 | Mylan        |                |
|                                 | Benzotropine   |                    |                    | C               |                           | 2mg Qd                   |                 | Not Reported |                |
|                                 | Lorazepam      |                    |                    | C               |                           | 2 Mg, Qd                 |                 | Not Reported |                |
|                                 | Clonazepam     |                    |                    | C               |                           | 1.5 Mg, Qd               |                 | Not Reported |                |
| <u>FDA Received Date</u>        | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Aug-2015                     | 11377207       | NON-EXPEDITED      |                    |                 | US-TAKEDA-2015TUS010567   |                          | 35 YR           | Female       | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                                           | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|-----------------|--------------|----------------|
| Labelled Drug-Drug Interaction Medication Error; Panic Disorder                                                                                                                 | Contrave                  |                    |                    | S               | Oral                            | 8mg/90mg, Qd         |                 | Takeda       |                |
|                                                                                                                                                                                 | Lexapro                   |                    |                    | S               | Oral                            | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                        | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Aug-2015                                                                                                                                                                     | 10390117                  | EXPEDITED (15-DAY) |                    | HO              | FR-PFIZER INC-2014223572        |                      | 76 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                                                                                           | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyperhidrosis; Pyrexia; Tachycardia; Tremor                                                                                                                                     | Zyvoxid                   |                    |                    | S               | Oral                            | 1200 Mg, 1x/Day      |                 | Pfizer       |                |
|                                                                                                                                                                                 | Seroplex                  |                    |                    | S               | Oral                            | 10 Mg, 1x/Day        |                 | Not Reported |                |
|                                                                                                                                                                                 | Flecaine Lp               |                    |                    | C               |                                 |                      |                 | Not Reported |                |
|                                                                                                                                                                                 | Imovane                   |                    |                    | C               |                                 |                      |                 | Not Reported |                |
|                                                                                                                                                                                 | Fraxodi                   |                    |                    | C               |                                 |                      |                 | Not Reported |                |
|                                                                                                                                                                                 | Decontractyl (Mephenesin) |                    |                    | C               |                                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                        | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Aug-2015                                                                                                                                                                     | 11198413                  | EXPEDITED (15-DAY) |                    | OT              | TR-ACCORD-031442                |                      | 18 YR           | Female       | TUR            |
| <u>Preferred Term</u>                                                                                                                                                           | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Pupils Unequal                                                                                                                                                                  | Escitalopram              |                    |                    | S               |                                 |                      |                 | Accord       |                |
| <u>FDA Received Date</u>                                                                                                                                                        | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Aug-2015                                                                                                                                                                     | 11328915                  | EXPEDITED (15-DAY) |                    | HO              | US-AUROBINDO-AUR-APL-2015-06458 |                      | 16 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                           | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Attention Deficit/Hyperactivity Disorder; Chest Discomfort; Depressive Symptom; Feeling Abnormal; Generalised Anxiety Disorder; Hallucination, Auditory; Hypertension; | Escitalopram 10 Mg        |                    |                    | S               | Unknown                         | 10 Mg, Daily         |                 | Aurobindo    |                |
|                                                                                                                                                                                 | Fluoxetine                |                    |                    | S               | Unknown                         | 20 Mg, Daily         |                 | Not Reported |                |
|                                                                                                                                                                                 | Fluoxetine                |                    |                    | S               | Unknown                         | 10 Mg, Daily         |                 | Not Reported |                |
|                                                                                                                                                                                 | Methylphenidate           |                    |                    | S               | Unknown                         | 945 Mg, Unk          |                 | Not Reported |                |
|                                                                                                                                                                                 | Methylphenidate           |                    |                    | S               | Unknown                         | 54 Mg, Daily         |                 | Not Reported |                |
|                                                                                                                                                                                 | Methylphenidate           |                    |                    | S               | Unknown                         | 27 Mg, Daily         |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                |             |   |      |                             |              |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|---|------|-----------------------------|--------------|
| Hypophagia; Insomnia;<br>Mood Altered; Overdose;<br>Panic Reaction; Paranoia;<br>Restlessness; Suicide<br>Attempt; Tachycardia;<br>Tachyphrenia; Toxicity To<br>Various Agents | Lamotrigine | C | Oral | 12.5 Mg, Every Week         | Not Reported |
|                                                                                                                                                                                | Lamotrigine | C | Oral | 12.5 Mg, Two Times A<br>Day | Not Reported |

| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 14-Aug-2015                | 11379669       | EXPEDITED (15-DAY) |                    | HO, OT          | TW-ACCORD-033033     |                      | 38 YR           | Male         | TWN            |
| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Delirium; Drug Interaction | Escitalopram   |                    |                    | S               |                      |                      |                 | Accord       |                |
|                            | Disulfiram     |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                            | Griseofulvin   |                    |                    | S               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 14-Aug-2015                                                                                                                | 11381625       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000078931    |                      | < 1 DAY         | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Withdrawal<br>Syndrome Neonatal;<br>Foetal Exposure During<br>Pregnancy; Neonatal<br>Respiratory Distress<br>Syndrome | Escitalopram   |                    |                    | S               | Transplacental       | 10 Mg                |                 | Forest       |                |
|                                                                                                                            | Skenan         |                    |                    | S               | Transplacental       | 40 Mg                |                 | Not Reported |                |
|                                                                                                                            | Actiskenan     |                    |                    | S               | Transplacental       |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>       | <u>Case #</u>                                                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------------|----------------------------------------------------------------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|-----------------|------------|----------------|
| 14-Aug-2015                    | 11381953                                                             | EXPEDITED (15-DAY) |                    | DE              | FR-MYLANLABS-<br>2015M1026139 |                      |                 | Unknown    | FRA            |
| <u>Preferred Term</u>          | <u>Product</u>                                                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Asphyxia; Completed<br>Suicide | Escitalopram Mylan Génériques<br>5 Mg, Comprimé Pelliculé<br>Sécable |                    |                    | S               | Oral                          | 5 Mg, Qd             |                 | Mylan      |                |
|                                | Escitalopram Mylan Génériques<br>5 Mg, Comprimé Pelliculé<br>Sécable |                    |                    | S               | Oral                          | 10 Mg, Qd            |                 | Mylan      |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                    |   |      |           |              |
|--------------------|---|------|-----------|--------------|
| Alprazolam 0.25 Mg | S | Oral | Unk       | Mylan        |
| Alprazolam 0.25 Mg | S | Oral | Unk       | Mylan        |
| Seroplex           | S | Oral | 15 Mg, Qd | Not Reported |
| Divarius           | S | Oral | 20 Mg, Qd | Not Reported |
| Kardegic           | C | Oral | 1 Df, Qd  | Not Reported |
| Valaciclovir       | C |      | Unk       | Not Reported |

| <u>FDA Received Date</u>          | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------|----------------|------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 14-Aug-2015                       | 11383586       | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2015269930 |                      |                 | Female       | USA            |
| <u>Preferred Term</u>             | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Crying; Drug Ineffective | Sertraline Hcl |                  |                    | S               |                          | 100 Mg, Unk          |                 | Pfizer       |                |
|                                   | Lexapro        |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 17-Aug-2015              | 11387206       | NON-EXPEDITED    |                    |                 | US-TEVA-586742USA    |                      |                 | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Fatigue                  | Provigil       |                  |                    | S               |                      |                      |                 | Cephalon     |                |
|                          | Lexapro        |                  |                    | S               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------|----------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 17-Aug-2015                      | 11387843       | EXPEDITED (15-DAY) |                    | OT              | TR-PFIZER INC-2015262903 |                      | 26 YR           | Male         | TUR            |
| <u>Preferred Term</u>            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Palpitations; Rectal Haemorrhage | Efexor Xr      |                    |                    | S               |                          | 75 Mg, 1x/Day        |                 | Pfizer       |                |
|                                  | Cipralext      |                    |                    | S               |                          | 10 Mg, 1x/Day        |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------|----------------------|------------|------------|----------------|
| 17-Aug-2015              | 11388217      | EXPEDITED (15-DAY) |                    | OT              | FR-APOTEX-2015AP011348 |                      |            | Unknown    | FRA            |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                          | <u>Product</u>                                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |                |
|----------------------------------------------------------------------------------------------------------------|-----------------------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------------------------|-----------------|--------------|----------------|
| Hepatocellular Injury                                                                                          | Paxil Tablets                                       |                    |                    | S               | Oral                 | Unk                                    |                 | Apotex       |                |
|                                                                                                                | Atarax /00058401/                                   |                    |                    | S               | Oral                 | 25 Mg, Bid                             |                 | Not Reported |                |
|                                                                                                                | Seroplex                                            |                    |                    | S               | Oral                 | Unk                                    |                 | Not Reported |                |
|                                                                                                                | Tercian /00759301/                                  |                    |                    | S               | Oral                 | Unk                                    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                       | <u>Case #</u>                                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Aug-2015                                                                                                    | 11389618                                            | EXPEDITED (15-DAY) |                    | CA              | FR-FRI-1000078989    |                                        | < 1 DAY         | Male         | FRA            |
| <u>Preferred Term</u>                                                                                          | <u>Product</u>                                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Murmur;<br>Congenital Foot<br>Malformation; Foetal<br>Exposure During<br>Pregnancy; Talipes;<br>Tremor | Escitalopram                                        |                    |                    | S               | Transplacental       | 20 Mg One Day / 10 Mg<br>The Other Day |                 | Forest       |                |
|                                                                                                                | Escitalopram                                        |                    |                    | S               | Transplacental       |                                        |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                       | <u>Case #</u>                                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Aug-2015                                                                                                    | 11395198                                            | DIRECT             |                    |                 |                      |                                        | 45 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                          | <u>Product</u>                                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated;<br>Hypertension; Weight<br>Increased                                                     | Lexapro                                             |                    |                    | S               |                      | One 20mg Pill A Day -- --              |                 | Not Reported |                |
|                                                                                                                | Lebetalol                                           |                    |                    | C               |                      |                                        |                 | Not Reported |                |
|                                                                                                                | Vitamin C                                           |                    |                    | C               |                      |                                        |                 | Not Reported |                |
|                                                                                                                | Vsl #3                                              |                    |                    | C               |                      |                                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                       | <u>Case #</u>                                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Aug-2015                                                                                                    | 11395441                                            | DIRECT             |                    | OT              |                      |                                        | 26 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                          | <u>Product</u>                                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Dermatitis Contact;<br>Product Formulation<br>Issue; Product                                                   | Escitalopram 20 Mg Intas<br>Pharmaceuticals Limited |                    |                    | S               | Oral                 |                                        |                 | Intas        |                |
|                                                                                                                | Restasis                                            |                    |                    | C               |                      |                                        |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Formulation Issue; Vitamin D2 (Vegan) C Not Reported  
 Product Substitution Issue;  
 Rash

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 18-Aug-2015              | 10527783       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000071633    |                      | 95 YR           | Male         | FRA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Extradural Haematoma     | Escitalopram   |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                          | Kardegic       |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                          | Tahor          |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Burinex        |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                    | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------|-----------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 18-Aug-2015                                                 | 10671821        | EXPEDITED (15-DAY) |                    | HO              | DE-PFIZER INC-2014351850 |                      | 50 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                       | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Agitation;<br>Drug Interaction;<br>Restlessness | Venlafaxine Hcl |                    |                    | S               | Oral                     | 75 Mg, 1x/Day        |                 | Pfizer       |                |
|                                                             | Venlafaxine Hcl |                    |                    | S               | Oral                     | 150 Mg, 1x/Day       |                 | Pfizer       |                |
|                                                             | Venlafaxine Hcl |                    |                    | S               | Oral                     | 75 Mg, 1x/Day        |                 | Pfizer       |                |
|                                                             | Cipralelex      |                    |                    | S               | Oral                     | 10 Mg, 1x/Day        |                 | Not Reported |                |
|                                                             | Cipralelex      |                    |                    | S               | Oral                     | 20 Mg, 1x/Day        |                 | Not Reported |                |
|                                                             | Cipralelex      |                    |                    | S               | Oral                     | 10 Mg, 1x/Day        |                 | Not Reported |                |
|                                                             | Cipralelex      |                    |                    | S               | Oral                     | 10 Mg, 1x/Day        |                 | Not Reported |                |
|                                                             | Cipralelex      |                    |                    | S               | Oral                     | 20 Mg, 1x/Day        |                 | Not Reported |                |
|                                                             | Abilify         |                    |                    | S               | Oral                     | 50 Mg, 1x/Day        |                 | Not Reported |                |
|                                                             | Abilify         |                    |                    | S               | Oral                     | 10 Mg, 1x/Day        |                 | Not Reported |                |
|                                                             | Remergil        |                    |                    | C               | Oral                     | Unk                  |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Aug-2015              | 11389952      | EXPEDITED (15-DAY) |                    | HO, OT          | PHHY2015KR096217     |                      | 56 YR      | Female     | KOR            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Dyskinesia; Dystonia;<br>Excessive Eye Blinking;<br>Tardive Dyskinesia;<br>Torticollis | Amitriptyline  |              |            | S           | Unknown      | 10 Mg, Qd          |                 | Novartis     |
|                                                                                        | Trazodone      |              |            | S           | Unknown      | 25 Mg, Qd          |                 | Not Reported |
|                                                                                        | Flurazepam     |              |            | S           | Unknown      | 15-30 Mg Qd        |                 | Not Reported |
|                                                                                        | Lorazepam      |              |            | S           | Unknown      | 2 Mg, Qd           |                 | Not Reported |
|                                                                                        | Escitalopram   |              |            | S           | Unknown      | 5 Mg, Qd           |                 | Not Reported |
|                                                                                        | Clonazepam     |              |            | S           | Unknown      | 1.5 Mg, Qd         |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 18-Aug-2015              | 11392269      | EXPEDITED (15-DAY) |                    |                 | NO-JNJFOC-20150804485 |                      | 38 YR      | Female     | NOR            |

| <u>Preferred Term</u>                                                                                                                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hyperhidrosis; Incorrect<br>Product Administration<br>Duration; Product<br>Complaint; Wrong<br>Technique In Product<br>Usage Process | Durogesic      |              |            | S           | Transdermal  |                    |                 | Not Reported |
|                                                                                                                                      | Durogesic      |              |            | S           | Transdermal  |                    |                 | Not Reported |
|                                                                                                                                      | Cipralelex     |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                      | Cipralelex     |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                      | Cipralelex     |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                      | Cipralelex     |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                      | Cipralelex     |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                      | Cipralelex     |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                      | Seroquel       |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                      | Seroquel       |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                      | Seroquel       |              |            | S           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Aug-2015              | 11392811      | EXPEDITED (15-DAY) |                    | HO              | IT-FRI-1000079016    |                      | 22 YR      | Female     | ITA            |

| <u>Preferred Term</u>                         | <u>Product</u>             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------------------------------|----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Confusional State; Drug<br>Abuse; Intentional | Escitalopram Oral Solution |              |            | S           | Oral         | Overdose: 15ml     |                 | Forest     |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                   |         |   |         |       |              |
|-----------------------------------|---------|---|---------|-------|--------------|
| Overdose; Intentional Self-Injury | Lexotan | S | Oral    | 10 MI | Not Reported |
|                                   | Alcohol | C | Unknown |       | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Aug-2015              | 11398420      | EXPEDITED (15-DAY) | Y                  | OT              | ABR_02339_2015       |                      | 49 YR      | Female     | USA            |

| <u>Preferred Term</u>                                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Bipolar I Disorder; Product Dispensing Error; Suicidal Ideation | Lamotrigine    |              |            | S           |              | 350 Mg Qhs         |                 | Not Reported |
|                                                                 | Oxcarbazepine  |              |            | S           |              |                    |                 | Not Reported |
|                                                                 | Escitalopram   |              |            | S           |              |                    |                 | Not Reported |
|                                                                 | Alprazolam     |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Aug-2015              | 11399043      | DIRECT           |                    | HO              |                      |                      | 1 DAY      | Female     |                |

| <u>Preferred Term</u>                                                                                | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------|-------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cyanosis Neonatal; Foetal Exposure During Pregnancy; Infantile Apnoea; Neonatal Respiratory Distress | Escitalopram 10mg |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------|----------------------|------------|------------|----------------|
| 19-Aug-2015              | 11215867      | EXPEDITED (15-DAY) |                    | OT              | US-GILEAD-2015-0159460 |                      | 64 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hypotension           | Ambrisentan    |              |            | S           | Unknown      | 10 Mg, Qd          |                 | Gilead       |
|                       | Ambrisentan    |              |            | S           |              |                    |                 | Gilead       |
|                       | Sildenafil     |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Lexapro        |              |            | S           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 19-Aug-2015              | 11247180      | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2015225503 |                      | 54 YR      | Female     | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Hypersensitivity | Zoloft         |              |            | S           |              | Unk                |                 | Pfizer       |
|                       | Lyrica         |              |            | S           | Oral         | 75 Mg, 3x/Day      |                 | Pfizer       |
|                       | Effexor        |              |            | S           |              | Unk                |                 | Pfizer       |
|                       | Advair         |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Wellbutrin     |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Lexapro        |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Paxil          |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Penicillin G   |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Valium         |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Doxycycline    |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Fluticasone    |              |            | S           |              |                    |                 | Not Reported |
|                       | Salmeterol     |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 20-Aug-2015              | 11198510      | EXPEDITED (15-DAY) |                    | HO              | FR-009507513-1506FRA006659 |                      | 36 YR      | Female     | FRA            |

| <u>Preferred Term</u>                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------|----------------|--------------|------------|-------------|--------------|-----------------------------------------------|-----------------|--------------|
| Photosensitivity Reaction;<br>Rash Erythematous | Proglidem      |              |            | S           | Oral         | 175 Mg, Qd                                    |                 | Merck        |
|                                                 | Proglidem      |              |            | S           | Oral         | 550 Mg, Qd                                    |                 | Merck        |
|                                                 | Lexomil        |              |            | S           |              | 3 Mg, If Needed At Bedtime                    |                 | Not Reported |
|                                                 | Theralene      |              |            | S           | Oral         | 10 Drops In The Evening(At Bedtime) If Needed |                 | Not Reported |
|                                                 | Acetaminophen  |              |            | S           | Oral         | Unk, Frequency Reported As "If Pain"          |                 | Not Reported |
|                                                 | Seroplex       |              |            | S           | Oral         | Unk                                           |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Aug-2015              | 11263363      | EXPEDITED (15-DAY) |                    | HO              | US-TEVA-577245USA    |                      | 60 YR      | Male       | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Neuroleptic Malignant Syndrome | Escitalopram   |              |            | S           | Unknown      |                    |                 | Ivax         |
|                                | Risperidone    |              |            | S           | Unknown      |                    |                 | Pliva        |
|                                | Fentanyl       |              |            | S           | Unknown      |                    |                 | Cephalon     |
|                                | Bupropion      |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                | Valproic Acid  |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                | Atorvastatin   |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Aug-2015              | 11317341      | EXPEDITED (15-DAY) |                    | OT              | IT-FRI-1000078436    |                      | 46 YR      | Female     | ITA            |

| <u>Preferred Term</u>                            | <u>Product</u>                                       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------|------------------------------------------------------|--------------|------------|-------------|--------------|----------------------|-----------------|--------------|
| Intentional Overdose;<br>Intentional Self-Injury | Escitalopram Oral Solution                           |              |            | S           | Oral         | Overdose: 15 MI      |                 | Forest       |
|                                                  | Haldol "10 Mg/MI Gocce Orali, Soluzione"/Haloperidol |              |            | S           | Oral         | Overdose:30 MIs      |                 | Not Reported |
|                                                  | Lendormin "0,25 Mg Compresse"/Brotizolam             |              |            | S           | Oral         | Overdose: 10 Tablets |                 | Not Reported |
|                                                  |                                                      |              |            |             |              |                      |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------------------------------------|----------------------|------------|------------|----------------|
| 20-Aug-2015              | 11398102      | EXPEDITED (15-DAY) |                    | HO, OT          | FR-MACLEODS<br>PHARMACEUTICALS<br>US LTD-<br>MAC2015001928 |                      |            | Unknown    | FRA            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Treatment Failure     | Escitalopram Oxalate |              |            | S           | Unknown      | Unk                |                 | Macleods     |
|                       | Escitalopram Oxalate |              |            | S           |              |                    |                 | Macleods     |
|                       | Sertraline           |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                       | Sertraline           |              |            | S           |              |                    |                 | Not Reported |
|                       | Venlafaxime          |              |            | S           | Unknown      | 225 Mg/Day, Qd     |                 | Not Reported |
|                       | Venlafaxime          |              |            | S           |              |                    |                 | Not Reported |
|                       | Risperidone          |              |            | S           | Unknown      | 2 Mg/Day           |                 | Not Reported |
|                       | Risperidone          |              |            | S           |              |                    |                 | Not Reported |
|                       | Paroxetine           |              |            | S           | Unknown      | Unk                |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                     |                         |                    |                    |                 |                                     |                      |                 |              |                |
|---------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|-------------------------------------|----------------------|-----------------|--------------|----------------|
| Paroxetine                                                          |                         |                    | S                  |                 |                                     | Not Reported         |                 |              |                |
| <u>FDA Received Date</u>                                            | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Aug-2015                                                         | 11398607                | EXPEDITED (15-DAY) |                    | HO              | IT-AUROBINDO-AUR-<br>APL-2015-07365 |                      | 56 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                               | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Apathy; Depressed Mood;<br>Drug Interaction; Insomnia               | Escitalopram            |                    |                    | S               | Oral                                |                      |                 | Aurobindo    |                |
|                                                                     | Alprazolam              |                    |                    | S               | Unknown                             |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                            | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Aug-2015                                                         | 11400579                | EXPEDITED (15-DAY) |                    | HO              | CA-BAUSCH-BL-2015-<br>019696        |                      | 54 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                               | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated;<br>Dehydration; Dysphagia;<br>Mental Disorder | Wellbutrin XI           |                    |                    | S               | Oral                                |                      |                 | Not Reported |                |
|                                                                     | Clonazepam              |                    |                    | S               | Oral                                |                      |                 | Not Reported |                |
|                                                                     | Ciprallex               |                    |                    | S               | Oral                                |                      |                 | Not Reported |                |
|                                                                     | Domperidone             |                    |                    | S               | Oral                                |                      |                 | Not Reported |                |
|                                                                     | Ferrous Sulfate         |                    |                    | S               | Oral                                |                      |                 | Not Reported |                |
|                                                                     | Gabapentin              |                    |                    | S               | Oral                                |                      |                 | Not Reported |                |
|                                                                     | Gabapentin              |                    |                    | S               | Oral                                |                      |                 | Not Reported |                |
|                                                                     | Temazepam               |                    |                    | S               | Oral                                |                      |                 | Not Reported |                |
|                                                                     | Tylenol With Codeine    |                    |                    | S               | Oral                                |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                            | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Aug-2015                                                         | 11400998                | EXPEDITED (15-DAY) |                    | HO              | PHHY2015CH096926                    |                      | 77 YR           | Female       | CHE            |
| <u>Preferred Term</u>                                               | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyponatraemia;<br>Inappropriate Antidiuretic<br>Hormone Secretion   | Carboplatin             |                    |                    | S               | Intravenous drip                    |                      |                 | Novartis     |                |
|                                                                     | Mirtazapine             |                    |                    | S               | Oral                                | 15 Mg, Qd            |                 | Not Reported |                |
|                                                                     | Ciprallex//Escitalopram |                    |                    | S               | Oral                                |                      |                 | Not Reported |                |

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|                         |   |                  |           |              |
|-------------------------|---|------------------|-----------|--------------|
| Paclitaxel              | C | Intravenous drip | Unk       | Not Reported |
| Nexium//Esomeprazole    | C | Oral             | 20 Mg, Qd | Not Reported |
| Magnesium<br>Omeprazole | C | Oral             | 40 Mg, Qd | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                              | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------------------------|----------------------|------------|------------|----------------|
| 21-Aug-2015              | 11401609      | EXPEDITED (15-DAY) |                    | HO, OT          | FR-NOVEN<br>PHARMACEUTICALS,<br>INC.-FR2015000721 |                      |            | Unknown    | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Treatment Failure     | Paroxetine     |              |            | S           | Unknown      | Unk, Unknown                     |                 | Noven        |
|                       | Paroxetine     |              |            | S           | Unknown      | 40 Mg, Qd                        |                 | Noven        |
|                       | Escitalopram   |              |            | S           | Unknown      | Unk, Unknown                     |                 | Not Reported |
|                       | Escitalopram   |              |            | S           |              |                                  |                 | Not Reported |
|                       | Sertraline     |              |            | S           | Unknown      | Unk, Unknown                     |                 | Not Reported |
|                       | Sertraline     |              |            | S           |              |                                  |                 | Not Reported |
|                       | Venlafaxine    |              |            | S           | Unknown      | Until The Dosage Of<br>225mg, Qd |                 | Not Reported |
|                       | Venlafaxine    |              |            | S           |              |                                  |                 | Not Reported |
|                       | Risperidone    |              |            | S           | Unknown      | 2 Mg, Qd                         |                 | Not Reported |
|                       | Risperidone    |              |            | S           | Unknown      | 2 Mg, Qd                         |                 | Not Reported |
|                       | Diazepam       |              |            | S           | Unknown      | 20 Mg, Qd                        |                 | Not Reported |
|                       | Diazepam       |              |            | S           |              |                                  |                 | Not Reported |
|                       | Quetiapine     |              |            | S           | Unknown      | 100 Mg, Qd                       |                 | Not Reported |
|                       | Quetiapine     |              |            | S           |              |                                  |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Aug-2015              | 11403586      | NON-EXPEDITED    |                    | HO, OT          | US-TEVA-578833USA    |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                                        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Headache; Somnolence;<br>Somnolence; Suicidal<br>Ideation; Suicidal Ideation | Fluoxetine     |              |            | S           | Unknown      |                    |                 | Barr       |
|                                                                              | Escitalopram   |              |            | S           | Unknown      |                    |                 | Ivax       |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                          | <u>Case #</u>                                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------|--------------------------------------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| 21-Aug-2015                                                       | 11403940                                         | EXPEDITED (15-DAY) |                    | HO              | CH-TEVA-586072ISR            |                      | 78 YR           | Female       | CHE            |
| <u>Preferred Term</u>                                             | <u>Product</u>                                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyponatraemia;<br>Inappropriate Antidiuretic<br>Hormone Secretion | Mirtazapin                                       |                    |                    | S               | Oral                         | 15 Milligram Daily;  |                 | Teva         |                |
|                                                                   | Carboplatin                                      |                    |                    | S               | Intravenous drip             |                      |                 | Not Reported |                |
|                                                                   | Cipralex                                         |                    |                    | S               | Oral                         | Dosage Unknown       |                 | Not Reported |                |
|                                                                   | Paclitaxel                                       |                    |                    | C               | Intravenous drip             |                      |                 | Not Reported |                |
|                                                                   | Nexium                                           |                    |                    | C               | Oral                         | 20 Milligram Daily;  |                 | Not Reported |                |
|                                                                   | Omeprazole                                       |                    |                    | C               | Oral                         | 40 Milligram Daily;  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                          | <u>Case #</u>                                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Aug-2015                                                       | 10654394                                         | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000073103            |                      | 83 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                             | <u>Product</u>                                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Muscle Haemorrhage                                                | Escitalopram                                     |                    |                    | S               | Oral                         | 10 Mg                |                 | Forest       |                |
|                                                                   | Kardegic                                         |                    |                    | S               | Oral                         | 75 Mg                |                 | Not Reported |                |
|                                                                   | Modopar                                          |                    |                    | C               | Unknown                      | 6 Df                 |                 | Not Reported |                |
|                                                                   | Axeler                                           |                    |                    | C               | Unknown                      |                      |                 | Not Reported |                |
|                                                                   | Inexium                                          |                    |                    | C               | Unknown                      |                      |                 | Not Reported |                |
|                                                                   | Atarax                                           |                    |                    | C               | Unknown                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                          | <u>Case #</u>                                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Aug-2015                                                       | 10930265                                         | NON-EXPEDITED      |                    |                 | US-PFIZER INC-<br>2015096140 |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                             | <u>Product</u>                                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity                                             | Doxycycline Calcium                              |                    |                    | S               |                              |                      |                 | Pfizer       |                |
|                                                                   | Septa Ds                                         |                    |                    | S               |                              | Unk                  |                 | Pfizer       |                |
|                                                                   | Penicillin G Benzathine/Penicillin<br>G Procaine |                    |                    | S               |                              | Unk                  |                 | Unknown      |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                    |   |     |              |
|--------------------|---|-----|--------------|
| Haloperidol        | S | Unk | Pfizer       |
| Zolpidem Tartrate  | S | Unk | Pfizer       |
| Metoclopramide Hcl | S | Unk | Pfizer       |
| Depakote           | S | Unk | Not Reported |
| Keflex             | S | Unk | Not Reported |
| Cipro              | S | Unk | Not Reported |
| Wellbutrin         | S | Unk | Not Reported |
| Bactrim            | S | Unk | Not Reported |
| Baclofen           | S | Unk | Not Reported |
| Bupropion          | S | Unk | Not Reported |
| Toradol            | S | Unk | Not Reported |
| Amitriptyline      | S | Unk | Not Reported |
| Cephalexin         | S | Unk | Not Reported |
| Divalproex         | S | Unk | Not Reported |
| Lexapro            | S | Unk | Not Reported |
| Maxalt             | S | Unk | Not Reported |
| Cymbalta           | S | Unk | Not Reported |
| Methadone          | S | Unk | Not Reported |
| Phenazopyridine    | S | Unk | Not Reported |
| Prochlorperazine   | S | Unk | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|------------|------------|----------------|
| 24-Aug-2015              | 11408908      | EXPEDITED (15-DAY) |                    | OT              | IN-CIPLA LTD.-<br>2015IN06733 |                      |            | Unknown    | IND            |

| <u>Preferred Term</u>      | <u>Product</u>                   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|----------------------------|----------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Anxiety; Phobia; Urticaria | Cetirizine Hydrochloride Allergy |              |            | S           | Oral         | 10 Mg, Unk         |                 | Cipla      |
|                            | Cetirizine Hydrochloride Allergy |              |            | S           |              |                    |                 | Cipla      |
|                            | Cetirizine Hydrochloride Allergy |              |            | S           |              |                    |                 | Cipla      |
|                            | Cetirizine Hydrochloride Allergy |              |            | S           |              |                    |                 | Cipla      |
|                            | Cetirizine Hydrochloride Allergy |              |            | S           |              |                    |                 | Cipla      |
|                            | Cetirizine Hydrochloride Allergy |              |            | S           |              |                    |                 | Cipla      |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                |   |         |             |              |
|----------------|---|---------|-------------|--------------|
| Paracetamol    | S | Unknown |             | Not Reported |
| Diclofenac     | S | Oral    | 25 Mg, Unk  | Not Reported |
| Fexofenadine   | S | Oral    | 180 Mg, Unk | Not Reported |
| Levocetirizine | S | Unknown |             | Not Reported |
| Hydroxyzine    | S | Unknown |             | Not Reported |
| Ebastine       | S | Unknown |             | Not Reported |
| Cyproheptadine | S | Unknown |             | Not Reported |
| Omeprazole     | S | Unknown |             | Not Reported |
| Esomeprazole   | S | Unknown |             | Not Reported |
| Cefixime       | S | Unknown |             | Not Reported |
| Ivermectin     | S | Unknown |             | Not Reported |
| Escitalopram   | S | Unknown |             | Not Reported |
| Clonazepam     | S | Unknown |             | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Aug-2015              | 11409245      | EXPEDITED (15-DAY) |                    | HO, OT          | CA-HOSPIRA-2974807   |                      | 23 YR      | Female     | CAN            |

| <u>Preferred Term</u>                                                                                            | <u>Product</u>               | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                          | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------|------------------------------|--------------|------------|-------------|---------------------------------------|--------------------|-----------------|--------------|
| Cholelithiasis; Exposure During Pregnancy; Fall; Hidradenitis; Off Label Use; Product Use Issue; Skin Laceration | Prenatal Vitamins /02014401/ |              |            | C           |                                       |                    |                 | Not Reported |
|                                                                                                                  | Metamucil /00029101/         |              |            | S           | Unknown                               |                    |                 | Not Reported |
|                                                                                                                  | Morphine Sulphate            |              |            | S           | Unknown                               |                    |                 | Not Reported |
|                                                                                                                  | Metformin                    |              |            | S           | Unknown                               |                    |                 | Not Reported |
|                                                                                                                  | Cipralex /01588501/          |              |            | S           | Unknown                               |                    |                 | Not Reported |
|                                                                                                                  | Ativan                       |              |            | S           | Unknown                               |                    |                 | Not Reported |
|                                                                                                                  | Baclofen                     |              |            | S           | Unknown                               |                    |                 | Not Reported |
|                                                                                                                  | Diclectin                    |              |            | S           | Unknown                               |                    |                 | Not Reported |
|                                                                                                                  | Gravol                       |              |            | S           | Unknown                               |                    |                 | Not Reported |
|                                                                                                                  | Rabeprazole                  |              |            | S           | Unknown                               |                    |                 | Not Reported |
|                                                                                                                  | Remicade                     |              |            | S           | Intravenous (not otherwise specified) |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|          |   |                                       |              |
|----------|---|---------------------------------------|--------------|
| Remicade | S | Intravenous (not otherwise specified) | Not Reported |
|----------|---|---------------------------------------|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Aug-2015              | 11410928      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000079073    |                      | 36 YR      | Female     | FRA            |

| <u>Preferred Term</u>                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------|----------------|--------------|------------|-------------|--------------|-------------------------------------|-----------------|--------------|
| Photosensitivity Reaction;<br>Rash Erythematous | Escitalopram   |              |            | S           | Oral         |                                     |                 | Forest       |
|                                                 | Proglicem      |              |            | S           | Oral         | 175 Mcg                             |                 | Not Reported |
|                                                 | Proglicem      |              |            | S           | Oral         | 550 Mcg                             |                 | Not Reported |
|                                                 | Proglicem      |              |            | S           | Oral         | 175 Mg                              |                 | Not Reported |
|                                                 | Lexomil Roche  |              |            | S           | Unknown      | 3 Mg/Day If Needed (At Bedtime)     |                 | Not Reported |
|                                                 | Theralene      |              |            | S           | Oral         | 10 Drops/Day If Needed (At Bedtime) |                 | Not Reported |
|                                                 | Paracetamol    |              |            | S           | Oral         |                                     |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------------|----------------------|------------|------------|----------------|
| 24-Aug-2015              | 11413931      | EXPEDITED (15-DAY) |                    | HO              | CA-GLAXOSMITHKLINE-CA2015GSK120565 |                      | 54 YR      | Female     | CAN            |

| <u>Preferred Term</u>                                                                                                       | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|-----------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Condition Aggravated;<br>Dehydration; Dysphagia;<br>Inappropriate Schedule Of<br>Product Administration;<br>Mental Disorder | Wellbutrin XI        |              |            | S           | Oral         | 150 Mg, Bid        |                 | Glaxosmithkline |
|                                                                                                                             | Clonazepam           |              |            | S           | Oral         | .5 Mg, Tid         |                 | Glaxosmithkline |
|                                                                                                                             | Ciprallex            |              |            | S           | Oral         | 20 Mg, 1d          |                 | Glaxosmithkline |
|                                                                                                                             | Domperidone          |              |            | S           | Oral         | 10 Mg, Bid         |                 | Glaxosmithkline |
|                                                                                                                             | Ferrous Sulfate      |              |            | S           | Oral         | 300 Mg, Tid        |                 | Glaxosmithkline |
|                                                                                                                             | Gabapentin           |              |            | S           | Oral         | 300 Mg, 1d         |                 | Glaxosmithkline |
|                                                                                                                             | Gabapentin           |              |            | S           | Oral         | 600 Mg, Bid        |                 | Glaxosmithkline |
|                                                                                                                             | Temazepam            |              |            | S           | Oral         | 30 Mg, 1d          |                 | Not Reported    |
|                                                                                                                             | Tylenol With Codeine |              |            | S           | Oral         | 1 Df, Tid          |                 | Not Reported    |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| 25-Aug-2015                                                                                                                                             | 11178600                              | EXPEDITED (15-DAY) |                    | HO              | JP-ASTRAZENECA-2015SE55183 |                      | 44 YR           | Male         | JPN            |
| <u>Preferred Term</u>                                                                                                                                   | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Creatine Phosphokinase Increased; Blood Lactate Dehydrogenase Increased | Nexium                                |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                                                                                                                         | Solanax                               |                    |                    | S               | Oral                       | Dose Unknown         |                 | Not Reported |                |
|                                                                                                                                                         | Amoxan                                |                    |                    | S               | Oral                       | Dose Unknown         |                 | Not Reported |                |
|                                                                                                                                                         | Lexapro                               |                    |                    | S               | Unknown                    |                      |                 | Not Reported |                |
|                                                                                                                                                         | Lexapro                               |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                                                                                                                         | Depas (Etizolam)                      |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                                                                                                                         | Depas                                 |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                                                                                                                         | Livalo Od                             |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                                                                                                                         | Actos                                 |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                                                                                                                         | Selbex                                |                    |                    | C               | Oral                       |                      |                 | Not Reported |                |
|                                                                                                                                                         | Statin                                |                    |                    | C               |                            |                      |                 | Not Reported |                |
|                                                                                                                                                         | Anti-Diabetic                         |                    |                    | C               |                            |                      |                 | Not Reported |                |
|                                                                                                                                                         | Anti-Psychotic                        |                    |                    | C               |                            |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Aug-2015                                                                                                                                             | 11414992                              | EXPEDITED (15-DAY) |                    | HO, OT          | FR-ACCORD-033247           |                      | 56 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                                                                   | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cerebellar Infarction; Treatment Failure                                                                                                                | Escitalopram                          |                    |                    | S               |                            |                      |                 | Accord       |                |
|                                                                                                                                                         | Sertraline                            |                    |                    | S               |                            |                      |                 | Accord       |                |
|                                                                                                                                                         | Venlafaxine/Venlafaxine Hydrochloride |                    |                    | S               |                            |                      |                 | Not Reported |                |
|                                                                                                                                                         | Risperidone                           |                    |                    | S               |                            |                      |                 | Not Reported |                |
|                                                                                                                                                         | Paroxetine                            |                    |                    | S               |                            |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Aug-2015                                                                                                                                             | 11420118                              | DIRECT             | Y                  |                 |                            |                      | 64 YR           | Male         | USA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                                     | <u>Product</u>                                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------------------------------------------------------------|-----------------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Anxiety; Depression; Hypervigilance; Irritability; Polydipsia; Product Substitution Issue | Escitalopram 20mg Mylan And Invagen Pharm     |                    |                    | S               | Oral                 | One Pill             |                 | Mylan        |                |
| <u>FDA Received Date</u>                                                                  | <u>Case #</u>                                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Aug-2015                                                                               | 11421206                                      | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000079089    |                      | 88 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                     | <u>Product</u>                                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cholestasis; Withdrawal Syndrome                                                          | Escitalopram                                  |                    |                    | S               | Unknown              | 5 Mg                 |                 | Forest       |                |
|                                                                                           | Paracetamol                                   |                    |                    | S               | Unknown              | 3 Gram               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                  | <u>Case #</u>                                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Aug-2015                                                                               | 11421367                                      | EXPEDITED (15-DAY) |                    | HO              | US-SA-2015SA125492   |                      | 76 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                     | <u>Product</u>                                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Encephalopathy; Hyponatraemia                                                             | Ambien                                        |                    |                    | S               | Oral                 | Frequency: Prn, Qhs  |                 | Not Reported |                |
|                                                                                           | Blinded Therapy                               |                    |                    | S               | Unknown              |                      |                 | Not Reported |                |
|                                                                                           | Lexapro                                       |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                           | Apixaban                                      |                    |                    | C               | Unknown              |                      |                 | Not Reported |                |
|                                                                                           | Acetaminophen                                 |                    |                    | C               | Unknown              |                      |                 | Not Reported |                |
|                                                                                           | Bupropion                                     |                    |                    | C               | Unknown              |                      |                 | Not Reported |                |
|                                                                                           | Chondroitin Sulfate/Glucosamine Hydrochloride |                    |                    | C               | Unknown              |                      |                 | Not Reported |                |
|                                                                                           | Psyllium Husk                                 |                    |                    | C               | Unknown              |                      |                 | Not Reported |                |
|                                                                                           | Loratadine                                    |                    |                    | C               | Unknown              |                      |                 | Not Reported |                |
|                                                                                           | Carvedilol                                    |                    |                    | C               | Unknown              |                      |                 | Not Reported |                |
|                                                                                           | Celebrex                                      |                    |                    | C               | Unknown              |                      |                 | Not Reported |                |
|                                                                                           | Trazodone                                     |                    |                    | C               | Unknown              |                      |                 | Not Reported |                |
|                                                                                           | Lactobacillus Acidophilus                     |                    |                    | C               | Unknown              |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|            |   |         |              |
|------------|---|---------|--------------|
| Vitamin C  | C | Unknown | Not Reported |
| Vitamin D3 | C | Unknown | Not Reported |
| Furosemide | C | Unknown | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 27-Aug-2015              | 6526659       | EXPEDITED (15-DAY) |                    | HO, LT, OT      | AU-PFIZER INC-2007105903 |                      | 42 YR      | Female     | AUS            |

| <u>Preferred Term</u>                                                                                                                | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------|--------------------|--------------|------------|-------------|--------------|----------------------------------------|-----------------|--------------|
| Aggression; Agitation; Depression; Homicidal Ideation; Intentional Overdose; Poor Quality Sleep; Suicidal Behaviour; Suicide Attempt | Champix            |              |            | S           | Oral         | 1 Df, Daily                            |                 | Pfizer       |
|                                                                                                                                      | Methylprednisolone |              |            | S           |              | 40 Mg, Daily                           |                 | Pfizer       |
|                                                                                                                                      | Escitalopram       |              |            | S           | Oral         | 30 Mg, Daily                           |                 | Not Reported |
|                                                                                                                                      | Valproate Sodium   |              |            | S           | Oral         | 200 Mg Three Daily And 500 Mg At Night |                 | Not Reported |
|                                                                                                                                      | Valproate Sodium   |              |            | S           | Oral         | 1.5 G, Daily                           |                 | Not Reported |
|                                                                                                                                      | Efexor             |              |            | C           |              | 150 Mg, Daily                          |                 | Not Reported |
|                                                                                                                                      | Seroquel           |              |            | C           |              | 800 Mg, Daily                          |                 | Not Reported |
|                                                                                                                                      | Valium             |              |            | C           |              | 5 Mg, Daily                            |                 | Not Reported |
|                                                                                                                                      | Valium             |              |            | C           |              | 10 Mg, Daily                           |                 | Not Reported |
|                                                                                                                                      | Kalma (Tryptophan) |              |            | C           |              | As Required                            |                 | Not Reported |
|                                                                                                                                      | Alprazolam         |              |            | C           | Oral         | 1 Mg, Daily                            |                 | Not Reported |
|                                                                                                                                      | Avanza             |              |            | C           | Oral         | 30 Mg, 1x/Day                          |                 | Not Reported |
|                                                                                                                                      | Lexapro            |              |            | C           | Oral         | 10 Mg, One And A Half, Daily           |                 | Not Reported |
|                                                                                                                                      | Atrovent           |              |            | C           |              | Unk                                    |                 | Not Reported |
|                                                                                                                                      | Mobic              |              |            | C           |              | Unk                                    |                 | Not Reported |
|                                                                                                                                      | Nystatin           |              |            | C           |              | Unk                                    |                 | Not Reported |
|                                                                                                                                      | Rabeprazole Sodium |              |            | C           | Oral         | 20 Mg, Daily                           |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 27-Aug-2015              | 11422412      | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2015283091 |                      | 48 YR      | Male       | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                    | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|------------------------------------------------------------------------------------------|------------------------------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|-----------------|--------------|----------------|
| Anxiety; Disease Progression; Fatigue; Hyperhidrosis; Insomnia; Somnolence; Tremor       | Effexor Xr                         |                    |                    | S               | Oral                            | 75 Mg, 1x/Day        |                 | Pfizer       |                |
|                                                                                          | Lexapro                            |                    |                    | S               | Oral                            | 20 Mg, 1x/Day        |                 | Not Reported |                |
|                                                                                          | Lexapro                            |                    |                    | S               | Oral                            | 10 Mg, 1x/Day        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                 | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Aug-2015                                                                              | 11424553                           | EXPEDITED (15-DAY) |                    | HO              | US-FRI-1000079129               |                      | 76 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                    | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Encephalopathy; Hyponatraemia                                                            | Lexapro                            |                    |                    | S               | Oral                            | 20mg                 |                 | Forest       |                |
|                                                                                          | Tafamidis Meglumine (Double-Blind) |                    |                    | S               |                                 |                      |                 | Not Reported |                |
|                                                                                          | Ambien                             |                    |                    | S               | Oral                            |                      |                 | Not Reported |                |
|                                                                                          | Apixaban                           |                    |                    | C               |                                 |                      |                 | Not Reported |                |
|                                                                                          | Acetaminophen                      |                    |                    | C               |                                 |                      |                 | Not Reported |                |
|                                                                                          | Bupropion                          |                    |                    | C               |                                 |                      |                 | Not Reported |                |
|                                                                                          | Glucosamine Chondroitin            |                    |                    | C               |                                 |                      |                 | Not Reported |                |
|                                                                                          | Psyllium Husk                      |                    |                    | C               |                                 |                      |                 | Not Reported |                |
|                                                                                          | Loratadine                         |                    |                    | C               |                                 |                      |                 | Not Reported |                |
|                                                                                          | Carvedilol                         |                    |                    | C               |                                 |                      |                 | Not Reported |                |
|                                                                                          | Celebrex                           |                    |                    | C               |                                 |                      |                 | Not Reported |                |
|                                                                                          | Trazodone                          |                    |                    | C               |                                 |                      |                 | Not Reported |                |
|                                                                                          | Lactobacillus Acidophilus          |                    |                    | C               |                                 |                      |                 | Not Reported |                |
|                                                                                          | Vitamin C                          |                    |                    | C               |                                 |                      |                 | Not Reported |                |
|                                                                                          | Vitamin D3                         |                    |                    | C               |                                 |                      |                 | Not Reported |                |
|                                                                                          | Furosemide                         |                    |                    | C               |                                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                 | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Aug-2015                                                                              | 11318556                           | EXPEDITED (15-DAY) |                    | HO, OT          | US-AUROBINDO-AUR-APL-2015-06291 |                      | 60 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                    | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Body Temperature Increased; Confusional State; Cough; Crepitations; Dyspnoea; | Escitalopram                       |                    |                    | S               | Unknown                         |                      |                 | Aurobindo    |                |
|                                                                                          | Risperidone                        |                    |                    | S               | Unknown                         |                      |                 | Aurobindo    |                |
|                                                                                          | Bupropion                          |                    |                    | S               | Unknown                         |                      |                 | Not Reported |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Flushing; Hyperhidrosis; Valproate S Unknown Not Reported  
Hypertnatraemia;  
Hypocalcaemia;  
Leukocytosis; Lipase  
Increased; Muscle  
Rigidity; Neuroleptic  
Malignant Syndrome;  
Respiratory Failure;  
Transaminases Increased

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Aug-2015              | 11432665      | EXPEDITED (15-DAY) |                    | OT              | DE-FRI-1000078228    |                      | 59 YR      | Male       | DEU            |

| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|----------------|--------------|------------|-------------|--------------|------------------------|-----------------|--------------|
| Anaesthetic Complication; | Escitalopram   |              |            | S           | Unknown      | 5 Mg                   |                 | Forest       |
| Arrhythmia; Differential  | Escitalopram   |              |            | S           | Unknown      | 10 Mg                  |                 | Forest       |
| White Blood Cell Count    | Escitalopram   |              |            | S           | Unknown      | 20 Mg                  |                 | Not Reported |
| Abnormal; Enuresis;       | Escitalopram   |              |            | S           | Unknown      | Overdose: 30 Mg/Day    |                 | Not Reported |
| Influenza Like Illness;   | Escitalopram   |              |            | S           | Unknown      | Overdose: 40 Mg/Day    |                 | Not Reported |
| Nightmare; Oxygen         | Escitalopram   |              |            | S           | Unknown      | Overdose: 30 Mg/Day    |                 | Not Reported |
| Saturation Decreased;     | Escitalopram   |              |            | S           | Unknown      | Overdose: 40 Mg/Day    |                 | Not Reported |
| Prescribed Overdose;      | Escitalopram   |              |            | S           | Unknown      | 20 Mg                  |                 | Not Reported |
| Pyrexia; Serotonin        | Escitalopram   |              |            | S           | Unknown      | Succinylcholine 100 /  |                 | Not Reported |
| Syndrome                  | Anaesthetics   |              |            | S           | Unknown      | Methohexital Sodium 90 |                 | Not Reported |
|                           | Anaesthetics   |              |            | S           | Unknown      | Succinylcholine 100 /  |                 | Not Reported |
|                           | Anaesthetics   |              |            | S           | Unknown      | Methohexital Sodium 90 |                 | Not Reported |
|                           | Anaesthetics   |              |            | S           | Unknown      | Succinylcholine 90 /   |                 | Not Reported |
|                           | Anaesthetics   |              |            | S           | Unknown      | Methohexital Sodium 90 |                 | Not Reported |
|                           | Anaesthetics   |              |            | S           | Unknown      | Succinylcholine 90 /   |                 | Not Reported |
|                           | Anaesthetics   |              |            | S           | Unknown      | Methohexital Sodium 90 |                 | Not Reported |

**FDA Adverse Event Reporting System  
Freedom of Information Act (FOIA)  
Detailed Report**

|              |   |         |                                                |              |
|--------------|---|---------|------------------------------------------------|--------------|
| Anaesthetics | S | Unknown | Succinylcholine 90 /<br>Methohexital Sodium 90 | Not Reported |
| Anaesthetics | S | Unknown | Succinylcholine 90 /<br>Methohexital Sodium 90 | Not Reported |
| Anaesthetics | S | Unknown | Succinylcholine 90 /<br>Methohexital Sodium 90 | Not Reported |
| Anaesthetics | S | Unknown | Succinylcholine 90 /<br>Methohexital Sodium 90 | Not Reported |
| Anaesthetics | S | Unknown | Succinylcholine 90 /<br>Methohexital Sodium 90 | Not Reported |
| Anaesthetics | S | Unknown | Succinylcholine 90 /<br>Methohexital Sodium 90 | Not Reported |
| Anaesthetics | S | Unknown | Succinylcholine 90 /<br>Methohexital Sodium 90 | Not Reported |
| Anaesthetics | S | Unknown | Succinylcholine 90 /<br>Methohexital Sodium 90 | Not Reported |
| Anaesthetics | S | Unknown | Succinylcholine 90 /<br>Methohexital Sodium 90 | Not Reported |
| Anaesthetics | S | Unknown | Succinylcholine 90 /<br>Methohexital Sodium 90 | Not Reported |
| Anaesthetics | S | Unknown | Succinylcholine 90 /<br>Methohexital Sodium 90 | Not Reported |
| Anaesthetics | S | Unknown | Succinylcholine 90 /<br>Methohexital Sodium 90 | Not Reported |
| Anaesthetics | S | Unknown | Succinylcholine 90 /<br>Methohexital Sodium 90 | Not Reported |
| Anaesthetics | S | Unknown | Succinylcholine 90 /<br>Methohexital Sodium 90 | Not Reported |
| Anaesthetics | S | Unknown | Succinylcholine 90 /<br>Methohexital Sodium 90 | Not Reported |
| Anaesthetics | S | Unknown | Succinylcholine 90 /<br>Methohexital Sodium 90 | Not Reported |
| Anaesthetics | S | Unknown | Succinylcholine 90 /<br>Methohexital Sodium 90 | Not Reported |
| Anaesthetics | S | Unknown | Succinylcholine 90 /<br>Methohexital Sodium 90 | Not Reported |

**FDA Adverse Event Reporting System  
Freedom of Information Act (FOIA)  
Detailed Report**

|                                  |   |         |          |              |
|----------------------------------|---|---------|----------|--------------|
| Mirtazapine                      | S | Unknown | 15 Mg    | Not Reported |
| Mirtazapine                      | S | Unknown | 30 Mg    | Not Reported |
| Mirtazapine                      | S | Unknown | 45 Mg    | Not Reported |
| Mirtazapine                      | S | Unknown | 30 Mg    | Not Reported |
| Mirtazapine                      | S | Unknown | 15 Mg    | Not Reported |
| Mirtazapine                      | S | Unknown | 30 Mg    | Not Reported |
| Mirtazapine                      | S | Unknown | 15 Mg    | Not Reported |
| Mirtazapine                      | S | Unknown | 30 Mg    | Not Reported |
| Mirtazapine                      | S | Unknown | 45 Mg    | Not Reported |
| Mirtazapine                      | S | Unknown | 60 Mg    | Not Reported |
| Beloc Zok (Metoprolol Succinate) | C | Unknown | 23.75 Mg | Not Reported |
| Beloc Zok (Metoprolol Succinate) | C | Unknown | 47.5 Mg  | Not Reported |
| Beloc Zok (Metoprolol Succinate) | C | Unknown | 23.75 Mg | Not Reported |
| Thyroxin                         | C | Unknown | 150 Mcg  | Not Reported |
| Ass                              | C | Unknown | 100 Mg   | Not Reported |
| Seroquel                         | C | Unknown | 100 Mg   | Not Reported |
| Seroquel                         | C | Unknown | 200 Mg   | Not Reported |
| Seroquel                         | C | Unknown | 250 Mg   | Not Reported |
| Seroquel                         | C | Unknown | 300 Mg   | Not Reported |
| Seroquel                         | C | Unknown | 400 Mg   | Not Reported |
| Seroquel                         | C | Unknown | 600 Mg   | Not Reported |
| Seroquel                         | C | Unknown | 800 Mg   | Not Reported |
| Seroquel                         | C | Unknown | 400 Mg   | Not Reported |
| Seroquel                         | C | Unknown | 600 Mg   | Not Reported |
| Seroquel                         | C | Unknown | 800 Mg   | Not Reported |
| Seroquel                         | C | Unknown | 400 Mg   | Not Reported |
| Seroquel                         | C | Unknown | 600 Mg   | Not Reported |
| Rivotril                         | C | Unknown | 1 Mg     | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                          |   |                                       |         |              |
|----------------------------------------------------------|---|---------------------------------------|---------|--------------|
| Rivotril                                                 | C | Unknown                               | 0.5 Mg  | Not Reported |
| Rivotril                                                 | C | Unknown                               | 0.25 Mg | Not Reported |
| Rivotril                                                 | C | Unknown                               | 0.75 Mg | Not Reported |
| Rivotril                                                 | C | Unknown                               | 0.5 Mg  | Not Reported |
| Tavor (Lorazepam)                                        | C | Unknown                               | 1 Mg    | Not Reported |
| Clexane                                                  | C | Unknown                               | 0.3 Mg  | Not Reported |
| Clexane                                                  | C | Unknown                               | 0.6 Mg  | Not Reported |
| Kalinor Brause (Potassium Bicarbonate\Potassium Citrate) | C | Oral                                  | 1 Df    | Not Reported |
| Kalinor Brause (Potassium Bicarbonate\Potassium Citrate) | C | Oral                                  | 2 Df    | Not Reported |
| Kalinor Brause (Potassium Bicarbonate\Potassium Citrate) | C | Oral                                  | 1 Df    | Not Reported |
| Cotrim                                                   | C | Unknown                               | 960 Mg  | Not Reported |
| Cotrim                                                   | C | Unknown                               | 1920 Mg | Not Reported |
| Cotrim                                                   | C | Unknown                               | 960 Mg  | Not Reported |
| Cotrim                                                   | C | Unknown                               | 1920 Mg | Not Reported |
| Sterofundin                                              | C | Unknown                               | 500 MI  | Not Reported |
| Sterofundin                                              | C | Unknown                               | 500 MI  | Not Reported |
| Sterofundin                                              | C | Unknown                               | 500 MI  | Not Reported |
| Acc Long                                                 | C | Unknown                               | 600 Mg  | Not Reported |
| Acc Long                                                 | C | Unknown                               | 800 Mg  | Not Reported |
| Paracetamol                                              | C | Unknown                               | 500 Mg  | Not Reported |
| Paracetamol                                              | C | Unknown                               | 500 Mg  | Not Reported |
| Cefuroxim                                                | C | Intravenous (not otherwise specified) | 1 Df    | Not Reported |
| Cefuroxim                                                | C | Intravenous (not otherwise specified) | 0.5 Df  | Not Reported |
| Cefuroxim                                                | C | Unknown                               | 500 Mg  | Not Reported |
| Ibuprofen                                                | C | Unknown                               | 800 Mg  | Not Reported |
| Ranitidin                                                | C | Unknown                               | 300 Mg  | Not Reported |
| Ranitidin                                                | C | Unknown                               | 300 Mg  | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |           |   |         |        |              |
|--|-----------|---|---------|--------|--------------|
|  | Ranitidin | C | Unknown | 300 Mg | Not Reported |
|  | Ranitidin | C | Unknown | 300 Mg | Not Reported |
|  | Ranitidin | C | Unknown | 300 Mg | Not Reported |
|  | Ranitidin | C | Unknown | 300 Mg | Not Reported |
|  | Ranitidin | C | Unknown | 300 Mg | Not Reported |
|  | Ranitidin | C | Unknown | 300 Mg | Not Reported |
|  | Aricept   | C | Unknown | 5 Mg   | Not Reported |
|  | Ciprobay  | C | Unknown | 500 Mg | Not Reported |
|  | Atropin   | C | Unknown |        | Not Reported |

| <u>FDA Received Date</u>                                                               | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 31-Aug-2015                                                                            | 11441050       | DIRECT           |                    |                 |                      |                      | 46 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Fatigue;<br>Feeling Abnormal;<br>Headache; Myalgia;<br>Withdrawal Syndrome | Lexapro 10 Mg  |                  |                    | S               |                      | Taken By Mouth       |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                                 | <u>Case #</u>                    | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                             | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|----------------------------------------|----------------|
| 31-Aug-2015                                                                                                                                              | 11444748                         | DIRECT           |                    | DS              |                      |                      | 47 YR           | Female                                 | USA            |
| <u>Preferred Term</u>                                                                                                                                    | <u>Product</u>                   | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                             |                |
| Abnormal Dreams;<br>Bruxism; Coordination<br>Abnormal; Dizziness;<br>Dizziness; Feeling Jittery;<br>Headache; Malaise;<br>Nausea; Somnolence;<br>Vertigo | Escitalopram<br>Tylenol<br>Advil |                  |                    | S<br>C<br>C     | Oral                 |                      |                 | Accord<br>Not Reported<br>Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 01-Sep-2015              | 11316592      | EXPEDITED (15-DAY) |                    | HO, LT, OT      | FR-<br>ELI_LILLY_AND_COMP |                      | 35 YR      | Female     | FRA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

ANY-FR201507006507

| <u>Preferred Term</u>                                                                                                                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>       |
|-------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------------|
| Bone Marrow Failure;<br>Cardiogenic Shock; Cell<br>Death; Coagulopathy;<br>Hepatitis; Intentional<br>Overdose; Renal Failure;<br>Rhabdomyolysis | Cymbalta       |              |            | S           | Oral         | 180 Mg, Single     |                 | Eli Lilly And Co |
|                                                                                                                                                 | Paracetamol    |              |            | S           | Oral         | 64 G, Single       |                 | Not Reported     |
|                                                                                                                                                 | Seroplex       |              |            | S           | Oral         | 560 Mg, Single     |                 | Not Reported     |
|                                                                                                                                                 | Nocertone      |              |            | S           | Oral         | 1.8 G, Single      |                 | Not Reported     |
|                                                                                                                                                 | Xanax          |              |            | S           | Oral         | 7.5 Mg, Single     |                 | Not Reported     |
|                                                                                                                                                 | Selokeen       |              |            | S           | Oral         | 3 G, Single        |                 | Not Reported     |
|                                                                                                                                                 | Depamine       |              |            | S           | Oral         | 4.8 G, Single      |                 | Not Reported     |
|                                                                                                                                                 | Ketum          |              |            | S           | Oral         | 3 G, Single        |                 | Not Reported     |
|                                                                                                                                                 | Myolastan      |              |            | S           | Oral         | 20 Df, Single      |                 | Not Reported     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Sep-2015              | 11389268      | EXPEDITED (15-DAY) |                    | HO, OT          | TW-FRI-1000079044    |                      | 38 YR      | Male       | TWN            |

| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Delirium; Drug Interaction | Escitalopram   |              |            | S           | Unknown      | 10 Mg              |                 | Forest       |
|                            | Disulfiram     |              |            | S           | Unknown      | 200 Mg             |                 | Not Reported |
|                            | Griseofulvin   |              |            | S           | Unknown      | 500 Mg             |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Sep-2015              | 11442990      | EXPEDITED (15-DAY) |                    | OT              | IT-FRI-1000079188    |                      | 16 YR      | Female     | ITA            |

| <u>Preferred Term</u>             | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------|-------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Face Oedema; Product<br>Use Issue | Escitalopram                  |              |            | S           | Oral         |                    |                 | Forest       |
|                                   | Aircort 200                   |              |            | C           | Respiratory  |                    |                 | Not Reported |
|                                   | Microgrammi/Erogazione        |              |            |             | (inhalation) |                    |                 |              |
|                                   | Sospensione Pressurizzata Per |              |            |             |              |                    |                 |              |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Inal  
Montegen Compresse  
Masticabili 5 Mg/ Montelukast

C Oral

Not Reported

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Sep-2015              | 11443352      | EXPEDITED (15-DAY) | HO                 |                 | FR-FRI-1000079238    |                      | 86 YR      | Female     | FRA            |

| <u>Preferred Term</u>    | <u>Product</u>  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|-----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Seizure; Speech Disorder | Escitalopram    |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                          | Exelon          |              |            | S           | Transdermal  | 4.6 Mg             |                 | Not Reported |
|                          | Prazepam        |              |            | S           | Oral         |                    |                 | Not Reported |
|                          | Tamoxifene Base |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 02-Sep-2015              | 11273935      | EXPEDITED (15-DAY) | HO                 |                 | FR-PFIZER INC-2015232652 |                      | 89 YR      | Female     | FRA            |

| <u>Preferred Term</u>         | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Fall; Orthostatic Hypotension | Epinitril            |              |            | S           | Transdermal  | 5 Mg, 1x/Day       |                 | Not Reported |
|                               | Bisoce               |              |            | S           |              | 5 Mg, 1x/Day       |                 | Not Reported |
|                               | Lasilix /00032601/   |              |            | S           | Oral         | 40 Mg, 1x/Day      |                 | Not Reported |
|                               | Seroplex             |              |            | S           |              | 5 Mg, 1x/Day       |                 | Not Reported |
|                               | Inexium /01479303/   |              |            | C           |              | Unk                |                 | Not Reported |
|                               | Previscan /00789001/ |              |            | C           |              | 20 Mg, Unk         |                 | Not Reported |
|                               | Digoxine Nativelle   |              |            | C           |              | 0.25 Mg, Unk       |                 | Not Reported |
|                               | Valsartan            |              |            | C           |              | Unk                |                 | Not Reported |
|                               | Temesta /00273201/   |              |            | C           |              | Unk                |                 | Not Reported |
|                               | Atorvastatin         |              |            | C           |              | Unk                |                 | Not Reported |
|                               | Levothyrox           |              |            | C           |              | 100 Mg, Unk        |                 | Not Reported |
|                               | Hemigoxine Nativelle |              |            | C           |              | 0.125 Mg, Unk      |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Sep-2015              | 11445156      | EXPEDITED (15-DAY) |                    | HO, OT          | PHHY2012US121340     |                      | 54 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                              | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                           | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|----------------------------------------------|-----------------|--------------|
| Arthralgia; Arthritis;<br>Decreased Activity; Pain;<br>Therapy Non-Responder;<br>Unevaluable Event | Baclofen Intrathecal |              |            | S           | Intrathecal  | 780 Mg, Qd                                   |                 | Not Reported |
|                                                                                                    | Transderm-Scop       |              |            | S           | Transdermal  | 1.5 Mg, Prn (Pt72)                           |                 | Novartis     |
|                                                                                                    | Robaxin              |              |            | S           | Unknown      | 2 Df, Qd                                     |                 | Not Reported |
|                                                                                                    | Robaxin              |              |            | S           |              |                                              |                 | Not Reported |
|                                                                                                    | Robaxin              |              |            | S           |              |                                              |                 | Not Reported |
|                                                                                                    | Symbicort            |              |            | S           | Unknown      | 160 To 4.5 Mcg Per Auction                   |                 | Not Reported |
|                                                                                                    | Imitrex//Sumatriptan |              |            | S           | Unknown      | 20 Mg, Per Auction                           |                 | Not Reported |
|                                                                                                    | Neurotin//Gabapentin |              |            | S           | Unknown      | 400 Mg, Tid                                  |                 | Not Reported |
|                                                                                                    | Flexeril             |              |            | S           | Unknown      | 10 Mg, Prn                                   |                 | Not Reported |
|                                                                                                    | Vesicare             |              |            | S           | Unknown      | 5 Mg, Unk                                    |                 | Not Reported |
|                                                                                                    | Lortab               |              |            | S           | Unknown      | 1 Df, (One Tab 3 To 4 Times Daily As Needed) |                 | Not Reported |
|                                                                                                    | Flector              |              |            | S           | Unknown      | 1.3 % For Left Knee Every 12 Hours           |                 | Not Reported |
|                                                                                                    | Nasonex              |              |            | S           | Unknown      | 50 Ug, Per Auction                           |                 | Not Reported |
|                                                                                                    | Albuterol            |              |            | S           | Unknown      | 90 Ug, Per Auction                           |                 | Not Reported |
|                                                                                                    | Medrol               |              |            | S           | Unknown      | 4 Mg, Use As Directed (Pak)                  |                 | Not Reported |
|                                                                                                    | Lexapro              |              |            | S           | Unknown      | Unk, 10 Mg Tabs 1.5 Tabs Daily               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------|----------------------|------------|------------|----------------|
| 02-Sep-2015              | 11448432      | EXPEDITED (15-DAY) |                    | HO, OT          | US-APOTEX-2015AP011517 |                      | 60 YR      | Male       | USA            |

| <u>Preferred Term</u>                     | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Neuroleptic Malignant Syndrome; Pneumonia | Escitalopram Oxalate |              |            | S           | Unknown      |                    |                 | Apotex     |



## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                 |   |                                       |     |              |
|---------------------------------|---|---------------------------------------|-----|--------------|
| Risperidone                     | S | Unknown                               |     | Apotex       |
| Bupropion Hydrochloride         | S | Unknown                               |     | Apotex       |
| Valproic Acid Oral Solution USP | S | Unknown                               |     | Apotex       |
| Fentanyl /00174602/             | S | Intravenous (not otherwise specified) | Unk | Not Reported |
| Fentanyl /00174602/             | S | Unknown                               | Unk | Not Reported |
| Atorvastatin                    | C | Unknown                               |     | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Sep-2015              | 11451710      | DIRECT           |                    | HO              |                      |                      | 56 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                      | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Arrhythmia; Blood Glucose Decreased; Blood Potassium Decreased; Chest Discomfort; Chest Pain; Hypertension | Escitalopram              |              |            | S           | Oral         |                    | 9 MTH           | Torrent      |
|                                                                                                            | Alprazolam                |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                            | Chlorzoxazone             |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                            | Levothyroxine             |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                            | Metoprolol                |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                            | Melatonin                 |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                            | Ibuprofen                 |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                            | Docusate Sodium           |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                            | Nasocort                  |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                            | Chloropheniramine Maleate |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Sep-2015              | 11473572      | NON-EXPEDITED    |                    | RI, OT          | 1000078190           |                      |            | Female     | USA            |

| <u>Preferred Term</u>                       | <u>Product</u>                   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------|----------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Crying; Suicidal Ideation; Weight Increased | Celexa (Citalopram Hydrobromide) |              |            | S           |              |                    |                 | Not Reported |
|                                             | Lexapro (Escitalopram Oxalate)   |              |            | S           |              |                    |                 | Not Reported |
|                                             | Gabapentin                       |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 03-Sep-2015              | 10751855      | EXPEDITED (15-DAY) |                    | HO              | IT-PFIZER INC-2015018669 |                      | 53 YR      | Female     | ITA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                                                                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |                |
|-----------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|--------------------------|------------------------------------|-----------------|--------------|----------------|
| Bradyphrenia; Drug Abuse; Drug Abuse; Dyslalia; Intentional Overdose; Poisoning Deliberate; Somnolence; Suicide Attempt; Toxicity To Various Agents | Xanax          |                    |                    | S               | Oral                     | 0.75 Mg/MI A Bottle (20 MI, Total) |                 | Pfizer       |                |
|                                                                                                                                                     | Lexotan        |                    |                    | S               | Oral                     | 37.5 Mg, Total                     |                 | Not Reported |                |
|                                                                                                                                                     | Cipralexx      |                    |                    | S               | Oral                     | Unk                                |                 | Not Reported |                |
|                                                                                                                                                     | Cipralexx      |                    |                    | S               | Oral                     | 280 Mg, Total                      |                 | Not Reported |                |
|                                                                                                                                                     | Nurofen        |                    |                    | S               | Oral                     | 12 Tablets, Total                  |                 | Not Reported |                |
|                                                                                                                                                     | Enantyum       |                    |                    | S               | Oral                     | 25 Mg Tablets, 10 Tablets, Total   |                 | Not Reported |                |
|                                                                                                                                                     | Sereupin       |                    |                    | S               | Oral                     | 280 Mg, Total                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Sep-2015                                                                                                                                         | 11276918       | EXPEDITED (15-DAY) |                    |                 | AT-FRI-1000078063        |                                    | 53 YR           | Female       | AUT            |
| <u>Preferred Term</u>                                                                                                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Vitreous Opacities                                                                                                                                  | Escitalopram   |                    |                    | S               | Oral                     | 5 Milligram                        |                 | Forest       |                |
|                                                                                                                                                     | Escitalopram   |                    |                    | S               | Oral                     | 2.5 Milligram                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Sep-2015                                                                                                                                         | 11309078       | EXPEDITED (15-DAY) |                    | HO              | FR-PFIZER INC-2015242297 |                                    | 35 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiogenic Shock; Hepatitis; Neutropenia; Rhabdomyolysis; Toxicity To Various Agents                                                               | Xanax          |                    |                    | S               | Oral                     | 7.5 Mg, Single                     |                 | Pfizer       |                |
|                                                                                                                                                     | Paracetamol    |                    |                    | S               | Oral                     | 64 G, Single                       |                 | Not Reported |                |
|                                                                                                                                                     | Seroplexx      |                    |                    | S               | Oral                     | 560 Mg, Single                     |                 | Not Reported |                |
|                                                                                                                                                     | Nocertone      |                    |                    | S               | Oral                     | 1.8 G, Single                      |                 | Not Reported |                |
|                                                                                                                                                     | Selokeen       |                    |                    | S               | Oral                     | 300 Mg, Single                     |                 | Not Reported |                |
|                                                                                                                                                     | Depamide       |                    |                    | S               | Oral                     | 4.8 G, Single                      |                 | Not Reported |                |
|                                                                                                                                                     | Ketum          |                    |                    | S               | Oral                     | 3 G, Single                        |                 | Not Reported |                |
|                                                                                                                                                     | Cymbalta       |                    |                    | S               | Oral                     | 180 Mg, Single                     |                 | Not Reported |                |

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|                                                                                                                                |                 |                    |                    |                 |                                                 |                      |                 |                  |                |
|--------------------------------------------------------------------------------------------------------------------------------|-----------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|------------------|----------------|
| Myolastan                                                                                                                      |                 |                    | S                  | Oral            | 20 Df, Single                                   |                      |                 | Not Reported     |                |
| <u>FDA Received Date</u>                                                                                                       | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 03-Sep-2015                                                                                                                    | 11455176        | EXPEDITED (15-DAY) | HO                 |                 | ES-FRI-1000079179                               |                      | 68 YR           | Female           | ESP            |
| <u>Preferred Term</u>                                                                                                          | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |
| Post Procedural<br>Haemorrhage; Procedural<br>Haemorrhage                                                                      | Escitalopram    |                    |                    | S               | Oral                                            |                      |                 | Forest           |                |
|                                                                                                                                | Green Tea       |                    |                    | S               | Unknown                                         |                      |                 | Not Reported     |                |
|                                                                                                                                | Phenylephrine   |                    |                    | C               | Unknown                                         |                      |                 | Not Reported     |                |
|                                                                                                                                | Atropine        |                    |                    | C               | Unknown                                         |                      |                 | Not Reported     |                |
|                                                                                                                                | Simvastatin     |                    |                    | C               | Unknown                                         |                      |                 | Not Reported     |                |
|                                                                                                                                | Ephedrine       |                    |                    | C               | Unknown                                         |                      |                 | Not Reported     |                |
|                                                                                                                                | Augmentine      |                    |                    | C               | Unknown                                         |                      |                 | Not Reported     |                |
|                                                                                                                                | Emconcor Cor    |                    |                    | C               | Unknown                                         |                      |                 | Not Reported     |                |
|                                                                                                                                | Enema Casen     |                    |                    | C               | Unknown                                         |                      |                 | Not Reported     |                |
|                                                                                                                                | Esmeron         |                    |                    | C               | Unknown                                         |                      |                 | Not Reported     |                |
|                                                                                                                                | Fentanest       |                    |                    | C               | Unknown                                         |                      |                 | Not Reported     |                |
|                                                                                                                                | Propofol Lipuro |                    |                    | C               | Unknown                                         |                      |                 | Not Reported     |                |
|                                                                                                                                | Solu-Moderin    |                    |                    | C               | Unknown                                         |                      |                 | Not Reported     |                |
| <u>FDA Received Date</u>                                                                                                       | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 03-Sep-2015                                                                                                                    | 11526694        | NON-EXPEDITED      |                    | OT              | US-<br>ELI_LILLY_AND_COMP<br>ANY-US201403005514 |                      |                 | Male             | USA            |
| <u>Preferred Term</u>                                                                                                          | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |
| Amnesia; Disturbance In<br>Attention; Drug Ineffective;<br>Dysphonia; Off Label Use;<br>Suicidal Ideation; Tinnitus;<br>Tremor | Cymbalta        |                    |                    | S               | Unknown                                         | 60 Mg, Unknown       |                 | Eli Lilly And Co |                |
|                                                                                                                                | Cymbalta        |                    |                    | S               | Unknown                                         | 90 Mg, Qd            |                 | Eli Lilly And Co |                |
|                                                                                                                                | Lexapro         |                    |                    | S               | Unknown                                         | Unk, Unknown         |                 | Not Reported     |                |
|                                                                                                                                | Clonazepam      |                    |                    | C               | Unknown                                         | Unk, Unknown         |                 | Not Reported     |                |

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| <u>FDA Received Date</u>                                                                                                                                                                                  | <u>Case #</u>                                        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u>       | <u>Mfr Control #</u>                            | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------|------------------|--------------------|-----------------------|-------------------------------------------------|----------------------------------|-----------------|------------------|----------------|
| 03-Sep-2015                                                                                                                                                                                               | 11526975                                             | NON-EXPEDITED    |                    |                       | US-<br>ELI_LILLY_AND_COMP<br>ANY-US201312007589 |                                  |                 | Female           | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                     | <u>Product</u>                                       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>           | <u>Route</u>                                    | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>       |                |
| Antisocial Behaviour; Cold<br>Sweat; Decreased<br>Appetite; Diarrhoea; Drug<br>Withdrawal Syndrome;<br>Fatigue; Feeling<br>Abnormal; Nausea;<br>Paraesthesia; Tinnitus;<br>Urinary Retention;<br>Vomiting | Cymbalta                                             |                  |                    | S                     | Unknown                                         | 30 Mg, Qd                        |                 | Eli Lilly And Co |                |
|                                                                                                                                                                                                           | Cymbalta                                             |                  |                    | S                     |                                                 | 60 Mg, Qd                        |                 | Eli Lilly And Co |                |
|                                                                                                                                                                                                           | Cymbalta                                             |                  |                    | S                     |                                                 |                                  |                 | Eli Lilly And Co |                |
|                                                                                                                                                                                                           | Lexapro                                              |                  |                    | S                     |                                                 |                                  |                 | Not Reported     |                |
|                                                                                                                                                                                                           | Welchol                                              |                  |                    | C                     |                                                 |                                  |                 | Not Reported     |                |
| <u>FDA Received Date</u>                                                                                                                                                                                  | <u>Case #</u>                                        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u>       | <u>Mfr Control #</u>                            | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 04-Sep-2015                                                                                                                                                                                               | 9227349                                              | NON-EXPEDITED    | Y                  | RI, OT                | 1000026745                                      |                                  | 49 YR           | Male             | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                     | <u>Product</u>                                       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>           | <u>Route</u>                                    | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>       |                |
| Diabetes Mellitus;<br>Dysphagia                                                                                                                                                                           | Lexapro                                              |                  |                    | S                     | Oral                                            | 5 Mg (5mg, 1 In 1 D), Oral       |                 | Not Reported     |                |
|                                                                                                                                                                                                           | Lexapro                                              |                  |                    | S                     | Oral                                            | 2.5mg (2.5mg, 1 In 1 D),<br>Oral |                 | Not Reported     |                |
| <u>FDA Received Date</u>                                                                                                                                                                                  | <u>Case #</u>                                        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u>       | <u>Mfr Control #</u>                            | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 04-Sep-2015                                                                                                                                                                                               | 10540471                                             | NON-EXPEDITED    | Y                  | DS, HO, LT, RI,<br>OT | 1000069740                                      |                                  | 41 YR           | Female           | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                     | <u>Product</u>                                       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>           | <u>Route</u>                                    | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>       |                |
| Suicidal Ideation; Swelling                                                                                                                                                                               | Lexapro                                              |                  |                    | S                     |                                                 |                                  |                 | Not Reported     |                |
|                                                                                                                                                                                                           | Benlysta                                             |                  |                    | S                     |                                                 | 850mg (850mg, 1 In 1m)           |                 | Not Reported     |                |
|                                                                                                                                                                                                           | Prenatal Vitamins (Mineral Nos,<br>Vitamins Nos))    |                  |                    | S                     |                                                 |                                  |                 | Not Reported     |                |
|                                                                                                                                                                                                           | Hydroxychloroquine                                   |                  |                    | C                     |                                                 |                                  |                 | Not Reported     |                |
|                                                                                                                                                                                                           | Triamcinolone Acetonide<br>(Triamcinolone Acetonide) |                  |                    | C                     |                                                 |                                  |                 | Not Reported     |                |
|                                                                                                                                                                                                           | Trazodone                                            |                  |                    | C                     |                                                 |                                  |                 | Not Reported     |                |

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|                |   |              |
|----------------|---|--------------|
| Gabapentin     | C | Not Reported |
| Furosemide     | C | Not Reported |
| Cyanocobalamin | C | Not Reported |
| Fentanyl       | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Sep-2015              | 11460803      | NON-EXPEDITED    |                    |                 | PHEH2015US008142     |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                                             | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Depressed Mood; Fatigue;<br>Headache; Hot Flush;<br>Hypermetropia;<br>Photophobia | Gilenya              |              |            | S           | Oral         | 0.5 Mg, Qd         |                 | Novartis     |
|                                                                                   | Lexapro              |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                   | Wellbutrin           |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                                   | Lamictal             |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                                   | Aciphex              |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                                   | Vitamin D Nos        |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                                   | Probiotic /07343501/ |              |            | C           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Sep-2015              | 11473226      | DIRECT           |                    |                 |                      |                      | 43 YR      | Female     | USA            |

| <u>Preferred Term</u>                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Nausea; Product<br>Substitution Issue | Lexapro        |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Sep-2015              | 11483860      | NON-EXPEDITED    | Y                  | RI, OT          | 1000069618           |                      | 29 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>                                                     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|--------------------------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Thrombocytopenia      | Lexapro                                                            |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Gilenya (Fingolimod<br>Hydrochloride) (0.5 Milligram,<br>Capsules) |              |            | S           | Oral<br>Oral |                    |                 | Not Reported |
|                       | Vitamin D (Vitamin D) (Vitamin                                     |              |            | C           |              |                    |                 | Not Reported |

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D)  
Ampyra (Fampridine)  
(Fampridine)

C

Not Reported

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Sep-2015              | 11483877      | NON-EXPEDITED    |                    | RI, OT          | 1000070687           |                      | 36 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                 | <u>Product</u>                                                    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------|--------------|------------|-------------|----------------------|--------------------|-----------------|--------------|
| Anxiety; Autophobia;<br>Erectile Dysfunction;<br>Feeling Abnormal; Libido<br>Decreased; Paraesthesia;<br>Paranoia; Suicidal<br>Ideation; Thinking<br>Abnormal; Tremor;<br>Violence-Related<br>Symptom | Lexapro                                                           |              |            | S           | Oral<br>Oral<br>Oral |                    |                 | Not Reported |
|                                                                                                                                                                                                       | Valium (Diazepam) (Diazepam)                                      |              |            | C           |                      |                    |                 | Not Reported |
|                                                                                                                                                                                                       | Zubsolv (Buprenorphine,<br>Naloxone) (Buprenorphine,<br>Naloxone) |              |            | C           |                      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Sep-2015              | 11483917      | NON-EXPEDITED    |                    | RI, OT          | 1000071668           |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                       | <u>Product</u>                        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------|---------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anger; Drug Ineffective;<br>Irritability; Suicidal Ideation | Lexapro                               |              |            | S           |              |                    |                 | Not Reported |
|                                                             | Pristiq (Desvenlafaxine<br>Succinate) |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Sep-2015              | 11483953      | NON-EXPEDITED    | Y                  | RI, OT          | 1000072460           |                      | 38 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|-------------------------|-----------------|--------------|
| Exposure Via Father;<br>Miscarriage Of Partner;<br>Pregnancy Of Partner | Lexapro        |              |            | S           |              | 10 Mg (10 Mg, 1 In 1 D) |                 | Not Reported |
|                                                                         | Enalapril      |              |            | C           |              |                         |                 | Not Reported |

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| <u>FDA Received Date</u>                          | <u>Case #</u>                            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---------------------------------------------------|------------------------------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 04-Sep-2015                                       | 11483976                                 | NON-EXPEDITED    |                    | DE              | 1000073948           |                      | 26 YR           | Female     | USA            |
| <u>Preferred Term</u>                             | <u>Product</u>                           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Completed Suicide                                 | Lexapro (Escitalopram Oxalate) (Tablets) |                  |                    | S               |                      |                      |                 |            | Not Reported   |
| <u>FDA Received Date</u>                          | <u>Case #</u>                            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 04-Sep-2015                                       | 11483998                                 | NON-EXPEDITED    |                    | RI, OT          | 1000074180           |                      |                 | Female     | USA            |
| <u>Preferred Term</u>                             | <u>Product</u>                           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Suicidal Ideation                                 | Lexapro                                  |                  |                    | S               |                      |                      |                 |            | Not Reported   |
| <u>FDA Received Date</u>                          | <u>Case #</u>                            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 04-Sep-2015                                       | 11484018                                 | NON-EXPEDITED    |                    | HO              | 1000075398           |                      |                 | Male       | USA            |
| <u>Preferred Term</u>                             | <u>Product</u>                           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Parkinsonism; Suicidal Ideation; Suicide Attempt  | Lexapro                                  |                  |                    | S               |                      |                      |                 |            | Not Reported   |
| <u>FDA Received Date</u>                          | <u>Case #</u>                            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 04-Sep-2015                                       | 11484036                                 | NON-EXPEDITED    |                    | RI, OT          | 1000076473           |                      |                 | Male       | USA            |
| <u>Preferred Term</u>                             | <u>Product</u>                           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective; Irritability; Suicidal Ideation | Lexapro                                  |                  |                    | S               |                      |                      |                 |            | Not Reported   |
| <u>FDA Received Date</u>                          | <u>Case #</u>                            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 04-Sep-2015                                       | 11484513                                 | NON-EXPEDITED    | Y                  | RI, OT          | 1000078670           |                      |                 | Female     | USA            |
| <u>Preferred Term</u>                             | <u>Product</u>                           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Suicidal Ideation                                 | Lexapro                                  |                  |                    | S               | Oral                 |                      |                 |            | Not Reported   |

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| <u>FDA Received Date</u> | <u>Case #</u>                  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|--------------------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 04-Sep-2015              | 11484536                       | NON-EXPEDITED    | Y                  | RI, OT          | 1000078727           |                      |                 | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>                 | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Suicidal Ideation        | Lexapro (Escitalopram Oxalate) |                  |                    | S               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                               | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|------------------------------|-----------------|--------------|----------------|
| 04-Sep-2015                                                                            | 11484561       | NON-EXPEDITED    |                    | RI, OT          | 1000078816           |                              | 40 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Decreased Appetite; Depression; Drug Ineffective; Insomnia; Suicidal Ideation | Lexapro        |                  |                    | S               | Oral                 | 10 Mg 1 In 1 D 10 Yeaars Ago |                 | Not Reported |                |
|                                                                                        | Losartan       |                  |                    | C               |                      |                              |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|--------------------------------------|-----------------|--------------|----------------|
| 07-Sep-2015              | 11465529       | EXPEDITED (15-DAY) |                    | HO              | FR-UCBSA-2015027976  |                                      | 74 YR           | Female       | FRA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Pneumonia Aspiration     | Keppra         |                    |                    | S               | Oral                 | 500 Mg, Once Daily (Qd)              |                 | Ucb          |                |
|                          | Seroquel       |                    |                    | S               | Oral                 | 150 Mg, Once Daily (Qd)              |                 | Not Reported |                |
|                          | Loxapac        |                    |                    | S               | Oral                 | Unk                                  |                 | Not Reported |                |
|                          | Seroplex       |                    |                    | S               | Oral                 | 10 Mg, 3x/Day (Tid)                  |                 | Not Reported |                |
|                          | Noctamide      |                    |                    | S               | Oral                 | 2 Mg, Once Daily (Qd) In The Evening |                 | Not Reported |                |
|                          | Imovane        |                    |                    | S               | Oral                 | 7.5 Mg, Once Daily (Qd)              |                 | Not Reported |                |
|                          | Laroxyl        |                    |                    | S               | Oral                 | 50 Mg, Once Daily (Qd)               |                 | Not Reported |                |
|                          | Effexor        |                    |                    | S               | Oral                 | 75 Mg, 2x/Day (Bid)                  |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 07-Sep-2015              | 11466276      | EXPEDITED (15-DAY) |                    | HO, LT          | FR-ASTRAZENECA-2015SE86252 |                      | 74 YR      | Female     | FRA            |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Aggression; Pneumonia<br>Aspiration; Respiratory<br>Arrest | Xeroquel       |              |            | S           | Oral         |                    |                 | Astrazeneca  |
|                                                            | Xeroquel       |              |            | S           | Oral         |                    |                 | Astrazeneca  |
|                                                            | Effexor        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                            | Laroxyl        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                            | Seroplex       |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                            | Loxapac        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                            | Loxapac        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                            | Noctamide      |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                            | Keppra         |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                            | Imovane        |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------|----------------------|------------|------------|----------------|
| 08-Sep-2015              | 11235398      | EXPEDITED (15-DAY) |                    | DE, HO, OT      | FR-GILEAD-2015-0160844 |                      | 74 YR      | Female     | FRA            |

| <u>Preferred Term</u>                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Death; Drug Interaction;<br>Vertigo; Vomiting | Harvoni        |              |            | S           | Unknown      | Unk Df, Unk        |                 | Gilead       |
|                                               | Seroplex       |              |            | S           | Oral         | 5 Mg, Qd           |                 | Not Reported |
|                                               | Cordarone      |              |            | S           | Oral         | 200 Mg, Qd         |                 | Not Reported |
|                                               | Bisoprolol     |              |            | C           | Oral         | 1.25 Mg, Qd        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 08-Sep-2015              | 11434028      | EXPEDITED (15-DAY) |                    | OT              | CH-JNJFOC-20150818250 |                      |            | Female     | CHE            |

| <u>Preferred Term</u>        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Exposure During<br>Pregnancy | Zyrtec         |              | Y          | S           | Oral         |                    |                 | Not Reported |
|                              | Zyrtec         |              |            | S           | Oral         |                    |                 | Not Reported |
|                              | Cipralelex     |              |            | S           | Oral         |                    |                 | Not Reported |
|                              | Cipralelex     |              |            | S           | Oral         |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                        |   |         |           |              |
|------------------------|---|---------|-----------|--------------|
| Atarax                 | S | Oral    | As Needed | Not Reported |
| Nutritional Supplement | C | Unknown |           | Not Reported |
| Sedatif Pc             | C | Unknown |           | Not Reported |

| <u>FDA Received Date</u>                                                                                               | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------|--------------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|-----------------|--------------|----------------|
| 08-Sep-2015                                                                                                            | 11467150           | EXPEDITED (15-DAY) |                    | HO, LT          | FR-AUROBINDO-AUR-APL-2015-07783 |                      | 78 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                  | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agranulocytosis;<br>Bedridden; Dehydration;<br>General Physical Health<br>Deterioration; Neutrophil<br>Count Decreased | Escitalopram       |                    |                    | S               | Unknown                         |                      |                 | Aurobindo    |                |
|                                                                                                                        | Pantoprazole Arrow |                    |                    | S               | Oral                            |                      |                 | Aurobindo    |                |
|                                                                                                                        | Tercian /00759301/ |                    |                    | S               | Oral                            |                      |                 | Not Reported |                |
|                                                                                                                        | Memantine          |                    |                    | C               | Unknown                         | Unk                  |                 | Not Reported |                |
|                                                                                                                        | Exelon             |                    |                    | C               | Unknown                         |                      |                 | Not Reported |                |
|                                                                                                                        | Nebivolol          |                    |                    | C               | Unknown                         |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                    | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|------------------------|----------------------|-----------------|--------------|----------------|
| 08-Sep-2015                                                                                                                                 | 11472951       | EXPEDITED (15-DAY) |                    | OT              | US-JAZZ-2013-US-003619 |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                       | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Arthritis; Asthma;<br>Depression; Enuresis;<br>Fatigue; Feeling Jittery;<br>Peripheral Vascular<br>Disorder; Personality<br>Change; Vertigo | Xyrem          |                    |                    | S               | Oral                   | 2.25 G, Bid          |                 | Jazz         |                |
|                                                                                                                                             | Xyrem          |                    |                    | S               | Oral                   | Dose Adjustments     |                 | Jazz         |                |
|                                                                                                                                             | Xyrem          |                    |                    | S               | Oral                   | 4.5 G, Bid           |                 | Jazz         |                |
|                                                                                                                                             | Topamax        |                    |                    | S               |                        | Unknown Dose         |                 | Not Reported |                |
|                                                                                                                                             | Zanaflex       |                    |                    | S               |                        | Unknown Dose         |                 | Not Reported |                |
|                                                                                                                                             | Xanax          |                    |                    | S               |                        | Unknown Dose         |                 | Not Reported |                |
|                                                                                                                                             | Roxicodone     |                    |                    | S               |                        | Unknown Dose         |                 | Not Reported |                |
|                                                                                                                                             | Wellbutrin     |                    |                    | S               |                        | Unknown Dose         |                 | Not Reported |                |
|                                                                                                                                             | Spiriva        |                    |                    | S               |                        | Unknown Dose         |                 | Not Reported |                |
|                                                                                                                                             | Lexapro        |                    |                    | S               |                        | Unknown Dose         |                 | Not Reported |                |
|                                                                                                                                             | Albuterol      |                    |                    | S               |                        | Unknown Dose         |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                                                  |                |                    |                    |                 |                                                 |                      |                 |                      |                |  |
|----------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|----------------------|----------------|--|
| Elavil                                                                           |                |                    | S                  |                 |                                                 | Unknown Dose         |                 |                      | Not Reported   |  |
| <u>FDA Received Date</u>                                                         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |  |
| 08-Sep-2015                                                                      | 11473165       | EXPEDITED (15-DAY) |                    | OT              | US-JAZZ-2014-US-012146                          |                      |                 | Female               | USA            |  |
| <u>Preferred Term</u>                                                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |  |
| Cataplexy                                                                        | Xyrem          |                    |                    | S               | Oral                                            | 2.25 G, Bid          |                 | Jazz                 |                |  |
|                                                                                  | Xyrem          |                    |                    | S               | Oral                                            | Dose Adjustments     |                 | Jazz                 |                |  |
|                                                                                  | Xyrem          |                    |                    | S               | Oral                                            | 4.5 G, Bid           |                 | Jazz                 |                |  |
|                                                                                  | Lexapro        |                    |                    | S               |                                                 | Unk                  |                 | Not Reported         |                |  |
| <u>FDA Received Date</u>                                                         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |  |
| 08-Sep-2015                                                                      | 11474169       | NON-EXPEDITED      |                    |                 | US-JAZZ-2013-US-004362                          |                      | 22 YR           | Female               | USA            |  |
| <u>Preferred Term</u>                                                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |  |
| Asthenia; Muscular Weakness                                                      | Xyrem          |                    |                    | S               | Oral                                            | 2.25 G, Bid          |                 | Jazz                 |                |  |
|                                                                                  | Xyrem          |                    |                    | S               | Oral                                            | Dose Adjustments     |                 | Jazz                 |                |  |
|                                                                                  | Xyrem          |                    |                    | S               | Oral                                            | 2.25 G, Bid          |                 | Jazz                 |                |  |
|                                                                                  | Xyrem          |                    |                    | S               | Oral                                            | Unknown Dose         |                 | Jazz                 |                |  |
|                                                                                  | Xyrem          |                    |                    | S               | Oral                                            | 4.5 G, Total Dose    |                 | Jazz                 |                |  |
|                                                                                  | Xyrem          |                    |                    | S               |                                                 | 6 G, Total Dose      |                 | Jazz                 |                |  |
|                                                                                  | Lexapro        |                    |                    | S               |                                                 | Unk                  |                 | Not Reported         |                |  |
| <u>FDA Received Date</u>                                                         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |  |
| 09-Sep-2015                                                                      | 11457008       | NON-EXPEDITED      |                    |                 | US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-058624 |                      |                 | Female               | USA            |  |
| <u>Preferred Term</u>                                                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |  |
| Blood Cholesterol Increased; Myalgia; Pain In Extremity; Weight Increased; Wrong | Abilify        |                    |                    | S               | Unknown                                         | 2 Mg, Unk            |                 | Bristol Myers Squibb |                |  |
|                                                                                  | Abilify        |                    |                    | S               | Unknown                                         | 0.5 Df, Qd           |                 | Bristol Myers Squibb |                |  |
|                                                                                  | Abilify        |                    |                    | S               |                                                 |                      |                 | Bristol Myers Squibb |                |  |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                       |         |   |         |     |              |
|---------------------------------------|---------|---|---------|-----|--------------|
| Technique In Product<br>Usage Process | Lexapro | S | Unknown | Unk | Not Reported |
|                                       | Lexapro | S |         |     | Not Reported |
|                                       | Lexapro | S |         |     | Not Reported |
|                                       | Ativan  | S | Unknown | Unk | Not Reported |
|                                       | Ativan  | S |         |     | Not Reported |
|                                       | Ativan  | S |         |     | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>     | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|-------------------|------------------|--------------------|-----------------|------------------------|----------------------|-----------------|--------------|----------------|
| 09-Sep-2015              | 11476090          | NON-EXPEDITED    |                    |                 | US-JAZZ-2015-US-007057 |                      |                 | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u>    | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Migraine                 | Xyrem             |                  |                    | S               | Oral                   | 2.25 G, Bid          |                 | Jazz         |                |
|                          | Xyrem             |                  |                    | S               | Oral                   | Dose Adjustments     |                 | Jazz         |                |
|                          | Xyrem             |                  |                    | S               | Oral                   | 5.5 G, Bid           |                 | Jazz         |                |
|                          | Lexapro           |                  |                    | S               |                        | Unk                  |                 | Not Reported |                |
|                          | Sonata            |                  |                    | C               |                        | Unk                  |                 | Not Reported |                |
|                          | Adderall          |                  |                    | C               |                        | Unk                  |                 | Not Reported |                |
|                          | Amitriptyline Hcl |                  |                    | C               |                        | Unk                  |                 | Not Reported |                |
|                          | Melatonin         |                  |                    | C               |                        | Unk                  |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|------------------------|----------------------|-----------------|--------------|----------------|
| 09-Sep-2015              | 11476804       | NON-EXPEDITED    |                    |                 | US-JAZZ-2014-US-010886 |                      | 38 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective         | Xyrem          |                  |                    | S               | Oral                   | 2.25 G, Bid          |                 | Jazz         |                |
|                          | Xyrem          |                  |                    | S               | Oral                   | 3 G, Bid             |                 | Jazz         |                |
|                          | Lexapro        |                  |                    | S               |                        | Unk                  |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|------------------------|----------------------|-----------------|------------|----------------|
| 09-Sep-2015              | 11478260       | NON-EXPEDITED    |                    |                 | US-JAZZ-2014-US-011599 |                      | 62 YR           | Female     | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                       |                                |   |      |             |              |
|-----------------------|--------------------------------|---|------|-------------|--------------|
| Bradyphrenia; Feeling | Xyrem                          | S | Oral | 2.25 G, Bid | Jazz         |
| Abnormal; Hot Flush;  | Xyrem                          | S |      |             | Jazz         |
| Memory Impairment;    | Ambien                         | S |      | Unk         | Not Reported |
| Performance Status    | Lexapro                        | S |      | Unk         | Not Reported |
| Decreased             | All Other Therapeutic Products | S |      | Unk         | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Sep-2015              | 11479126      | EXPEDITED (15-DAY) |                    | HO              | FR-SA-2015SA133621   |                      | 81 YR      | Female     | FRA            |

| <u>Preferred Term</u>      | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hypokalaemia;              | Coaprovel           |              |            | S           | Oral         |                    |                 | Not Reported |
| Inappropriate Antidiuretic | Seroplex            |              |            | S           | Oral         |                    |                 | Not Reported |
| Hormone Secretion          | Temesta (Lorazepam) |              |            | C           | Oral         |                    |                 | Not Reported |
|                            | Dafalgan Codeine    |              |            | C           |              |                    |                 | Not Reported |
|                            | Mono-Tildiem        |              |            | C           |              |                    |                 | Not Reported |
|                            | Fractal             |              |            | C           |              | Strength: 40mg     |                 | Not Reported |
|                            | Ganfort             |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------|----------------------|------------|------------|----------------|
| 09-Sep-2015              | 11479358      | NON-EXPEDITED    |                    |                 | US-JAZZ-2015-US-010477 |                      | 54 YR      | Female     | USA            |

| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Agitation; Anxiety;    | Xyrem          |              |            | S           | Oral         | 2.25 G, Bid        |                 | Jazz         |
| Bruxism; Hypertension; | Xyrem          |              |            | S           | Oral         | Dose Adjustments   |                 | Jazz         |
| Swelling               | Xyrem          |              |            | S           | Oral         | 4.5 G, Bid         |                 | Jazz         |
|                        | Norvasc        |              |            | S           |              | Unk                |                 | Not Reported |
|                        | Effexor        |              |            | S           |              | Unk                |                 | Not Reported |
|                        | Effexor        |              |            | S           |              |                    |                 | Not Reported |
|                        | Lexapro        |              |            | S           |              | Unk                |                 | Not Reported |
|                        | Lexapro        |              |            | S           |              |                    |                 | Not Reported |
|                        | Nuvigil        |              |            | C           |              | Unk                |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                     |   |     |              |
|---------------------|---|-----|--------------|
| Ammonium Lactate    | C | Unk | Not Reported |
| Ciclopirox          | C | Unk | Not Reported |
| Fluorometholone     | C | Unk | Not Reported |
| Furosemide          | C | Unk | Not Reported |
| Halobetasol Prop    | C | Unk | Not Reported |
| Hydrocortisone      | C | Unk | Not Reported |
| Kenalog             | C | Unk | Not Reported |
| Levothyroxine       | C | Unk | Not Reported |
| Medroxyprogesterone | C | Unk | Not Reported |
| Mometasone Furoate  | C | Unk | Not Reported |
| Montelukast Sodium  | C | Unk | Not Reported |
| Omeprazole          | C | Unk | Not Reported |
| Premarin            | C | Unk | Not Reported |
| Triamcinolone       | C | Unk | Not Reported |
| Valtrex             | C | Unk | Not Reported |
| Ventolin Hfa        | C | Unk | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------|----------------------|------------|------------|----------------|
| 09-Sep-2015              | 11479410      | NON-EXPEDITED    |                    |                 | US-JAZZ-2014-US-012354 |                      | 45 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Depressed Mood; Fatigue; Feeling Abnormal; Malaise; Pain; Product Use In Unapproved Indication | Xyrem          |              |            | S           | Oral         | 2.25 G, Bid        |                 | Jazz         |
|                                                                                                | Xyrem          |              |            | S           | Oral         | 3 G, Bid           |                 | Jazz         |
|                                                                                                | Xyrem          |              |            | S           | Oral         | 3.75 G, Bid        |                 | Jazz         |
|                                                                                                | Xyrem          |              |            | S           | Oral         | 2.75 G, Bid        |                 | Jazz         |
|                                                                                                | Xyrem          |              |            | S           | Oral         | 3.75 G,First Dose  |                 | Jazz         |
|                                                                                                | Xyrem          |              |            | S           | Oral         | 4.5 G, Second Dose |                 | Jazz         |
|                                                                                                | Lexapro        |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                | Amitriptyline  |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                | Neurontin      |              |            | S           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| Pristiq                                                                                        |                     |                    | C                  |                 |                      | Unk                  |                 |              | Not Reported   |  |
|------------------------------------------------------------------------------------------------|---------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|--|
| <u>FDA Received Date</u>                                                                       | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |  |
| 09-Sep-2015                                                                                    | 11482159            | EXPEDITED (15-DAY) |                    | HO              | PHHY2015FR107756     |                      | 88 YR           | Female       | FRA            |  |
| <u>Preferred Term</u>                                                                          | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |  |
| Bradycardia; Loss Of Consciousness; Malaise                                                    | Exelon              |                    |                    | S               | Unknown              | 9.5 Mg, Qd           |                 | Novartis     |                |  |
|                                                                                                | Zyprexa             |                    |                    | S               | Unknown              | Unk                  |                 | Not Reported |                |  |
|                                                                                                | Seroplex            |                    |                    | S               | Unknown              | 10 Mg, Qd            |                 | Not Reported |                |  |
|                                                                                                | Coumadine           |                    |                    | C               | Unknown              | Unk                  |                 | Not Reported |                |  |
|                                                                                                | Tahor               |                    |                    | C               | Unknown              | Unk                  |                 | Not Reported |                |  |
|                                                                                                | Diffu K             |                    |                    | C               | Unknown              |                      |                 | Not Reported |                |  |
|                                                                                                | Tareg               |                    |                    | C               | Unknown              |                      |                 | Not Reported |                |  |
|                                                                                                | Lantus              |                    |                    | C               | Unknown              | Unk                  |                 | Not Reported |                |  |
|                                                                                                | Transipeg//Macrogol |                    |                    | C               | Unknown              | Unk                  |                 | Not Reported |                |  |
|                                                                                                | Tardyferon          |                    |                    | C               | Unknown              | Unk                  |                 | Not Reported |                |  |
|                                                                                                | Paracetamol         |                    |                    | C               | Unknown              |                      |                 | Not Reported |                |  |
| <u>FDA Received Date</u>                                                                       | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |  |
| 09-Sep-2015                                                                                    | 11484940            | DIRECT             |                    |                 |                      |                      | 72 YR           | Female       | USA            |  |
| <u>Preferred Term</u>                                                                          | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |  |
| Constipation; Drug Ineffective; Haematochezia; Product Shape Issue; Product Substitution Issue | Escitalopram        |                    |                    | S               | Oral                 | 1 Pill               |                 | Aurobindo    |                |  |
|                                                                                                | Vitamin D Nos       |                    |                    | C               |                      |                      |                 | Not Reported |                |  |
| <u>FDA Received Date</u>                                                                       | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |  |
| 09-Sep-2015                                                                                    | 11485178            | DIRECT             |                    |                 |                      |                      | 59 YR           | Female       | USA            |  |
| <u>Preferred Term</u>                                                                          | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |  |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Abdominal Pain; Escitalopram 5 Mg S Oral Taken By Mouth Not Reported  
 Depression; Insomnia;  
 Panic Attack

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------|----------------------|------------|------------|----------------|
| 09-Sep-2015              | 11486209      | NON-EXPEDITED    |                    |                 | US-JAZZ-2014-US-016810 |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Drug Ineffective;<br>Product Use Issue | Xyrem          |              |            | S           | Oral         | 2.25 G, Bid        |                 | Jazz         |
|                                                 | Xyrem          |              |            | S           | Oral         | Dose Adjustments   |                 | Jazz         |
|                                                 | Xyrem          |              |            | S           | Oral         | 4.5 G, Bid         |                 | Jazz         |
|                                                 | Lexapro        |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                                                 | Junel          |              |            | C           | Oral         | Unk                |                 | Not Reported |
|                                                 | Allegra        |              |            | C           |              | Unk                |                 | Not Reported |
|                                                 | Adderall       |              |            | C           |              | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Sep-2015              | 11490313      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000079392    |                      | 60 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------|-------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cutaneous Vasculitis;<br>Henoch-Schonlein<br>Purpura | Escitalopram      |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                                      | Loxapac           |              |            | S           | Oral         | 400 Mg             |                 | Not Reported |
|                                                      | Sulfarlem S 25 Mg |              |            | S           | Oral         | 6 Df               |                 | Not Reported |
|                                                      | Kardegic          |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                      | Ramipril          |              |            | C           |              |                    |                 | Not Reported |
|                                                      | Metformine        |              |            | C           |              |                    |                 | Not Reported |
|                                                      | Noctamide         |              |            | C           |              |                    |                 | Not Reported |
|                                                      | Atarax            |              |            | C           |              |                    |                 | Not Reported |
|                                                      | Crestor           |              |            | C           |              |                    |                 | Not Reported |
| Levemir                                              |                   |              | C          |             |              |                    | Not Reported    |              |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                          | <u>Case #</u>           | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------|-------------------------|------------------|--------------------|-----------------|--------------------------|---------------------------------------------|-----------------|--------------|----------------|
| 10-Sep-2015                                       | 8438787                 | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2012049389 |                                             | 85 YR           | Female       | USA            |
| <u>Preferred Term</u>                             | <u>Product</u>          | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity                             | Ibuprofen               |                  |                    | S               |                          | Unk                                         |                 | Pfizer       |                |
|                                                   | Zoloft                  |                  |                    | S               |                          | Unk                                         |                 | Pfizer       |                |
|                                                   | Oxycodone Hydrochloride |                  |                    | S               |                          | Unk                                         |                 | Pfizer       |                |
|                                                   | Morphine Sulfate        |                  |                    | S               |                          |                                             |                 | Pfizer       |                |
|                                                   | Prednisone              |                  |                    | S               |                          | Unk                                         |                 | Not Reported |                |
|                                                   | Cipro "Bayer"           |                  |                    | S               |                          | Unk                                         |                 | Not Reported |                |
|                                                   | Hydrocodone             |                  |                    | S               |                          | Unk                                         |                 | Not Reported |                |
|                                                   | Lexapro                 |                  |                    | S               |                          | Unk                                         |                 | Not Reported |                |
|                                                   | Bactrim                 |                  |                    | S               |                          | Unk                                         |                 | Not Reported |                |
|                                                   | Zetia                   |                  |                    | S               |                          | Unk                                         |                 | Not Reported |                |
|                                                   | Percocet                |                  |                    | S               |                          | Unk                                         |                 | Not Reported |                |
|                                                   | Tylox                   |                  |                    | S               |                          | Unk                                         |                 | Not Reported |                |
|                                                   | Reglan                  |                  |                    | S               |                          | Unk                                         |                 | Not Reported |                |
|                                                   | Demerol                 |                  |                    | S               |                          | Unk                                         |                 | Not Reported |                |
|                                                   | Darvocet-N              |                  |                    | S               |                          | Unk                                         |                 | Not Reported |                |
|                                                   | Codeine                 |                  |                    | S               |                          |                                             |                 | Not Reported |                |
|                                                   | Naproxen                |                  |                    | S               |                          |                                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                          | <u>Case #</u>           | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Sep-2015                                       | 11383598                | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2015270158 |                                             |                 | Female       | USA            |
| <u>Preferred Term</u>                             | <u>Product</u>          | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Drug Ineffective;<br>Dry Mouth; Insomnia | Zoloft                  |                  |                    | S               |                          | Unk                                         |                 | Pfizer       |                |
|                                                   | Sertraline Hcl          |                  |                    | S               |                          | (25 For 5days,50,75,100<br>For Three Weeks) |                 | Not Reported |                |
|                                                   | Lexapro                 |                  |                    | S               |                          | Unk                                         |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------------------------------------|----------------------|------------|------------|----------------|
| 10-Sep-2015              | 11419481      | EXPEDITED (15-DAY) |                    | OT              | KR-SUN<br>PHARMACEUTICAL<br>INDUSTRIES LTD-<br>2015RR-102083 |                      |            | Unknown    | KOR            |

| <u>Preferred Term</u>                                                          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Dry Mouth;<br>Dystonia; Nausea; Tardive<br>Dyskinesia; Vision Blurred | Etravil        |              |            | S           | Unknown      | 10 Mg, Daily       |                 | Not Reported |
|                                                                                | Trittico       |              |            | S           | Unknown      | 25 Mg, Daily       |                 | Not Reported |
|                                                                                | Benztropine    |              |            | S           | Unknown      | 1-2 Mg/Day         |                 | Not Reported |
|                                                                                | Benztropine    |              |            | S           | Unknown      | 2 Mg, Daily        |                 | Not Reported |
|                                                                                | Lexapro        |              |            | S           | Unknown      | 5 Mg, Daily        |                 | Not Reported |
|                                                                                | Trittico       |              |            | S           | Unknown      | 25 Mg, Daily       |                 | Not Reported |
|                                                                                | Benztropine    |              |            | S           | Unknown      | 2 Mg, Daily        |                 | Not Reported |
|                                                                                | Benztropine    |              |            | S           | Unknown      | 2 Mg, Daily        |                 | Not Reported |
|                                                                                | Trihexin       |              |            | S           | Unknown      | 2 Mg, Daily        |                 | Not Reported |
|                                                                                | Perkin         |              |            | S           | Unknown      | 50/200 Mg/Day      |                 | Not Reported |
|                                                                                | Ativan         |              |            | S           | Unknown      | 2 Mg, Daily        |                 | Not Reported |
|                                                                                | Baclofen       |              |            | C           | Unknown      | 20 Mg, Daily       |                 | Not Reported |
|                                                                                | Flurazepam     |              |            | C           | Unknown      | 15-30 Mg/Day       |                 | Not Reported |
|                                                                                | Procyclidine   |              |            | C           | Unknown      | 5 Mg, Daily        |                 | Not Reported |
|                                                                                | Clonazepam     |              |            | C           | Unknown      | 1.5 Mg, Daily      |                 | Not Reported |
|                                                                                | Clonazepam     |              |            | C           | Unknown      | 1.5 Mg, Daily      |                 | Not Reported |
|                                                                                | Aripiprazole   |              |            | C           | Unknown      | 0.5 Mg, Daily      |                 | Not Reported |
|                                                                                | Aripiprazole   |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|--------------------------------------------|----------------------|-----------------|-----------------|----------------|
| 10-Sep-2015              | 11492002       | EXPEDITED (15-DAY) |                    | HO              | SE-<br>GLAXOSMITHKLINE-<br>SE2015GSK130135 |                      |                 | Male            | SWE            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Dyspnoea; Foetal         | Voxra          |                    |                    | S               | Transplacental                             |                      |                 | Glaxosmithkline |                |

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|                                                                     |                |                    |                    |                 |             |                                |                      |                 |              |                |
|---------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|-------------|--------------------------------|----------------------|-----------------|--------------|----------------|
| Exposure During Pregnancy                                           | Ciprallex      |                    |                    | S               |             | Transplacental                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> |             | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Sep-2015                                                         | 11492441       | EXPEDITED (15-DAY) |                    | OT              |             | CN-FRI-1000079534              |                      | 17 YR           | Female       | CHN            |
| <u>Preferred Term</u>                                               | <u>Product</u> |                    | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u> | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Product Use Issue;<br>Tongue Paralysis;<br>Torticollis              | Lexapro        |                    |                    |                 | S           | Oral                           | 10 Mg                |                 |              | Forest         |
|                                                                     | Paliperidone   |                    |                    |                 | S           | Oral                           | 6 Mg                 |                 |              | Not Reported   |
|                                                                     | Paliperidone   |                    |                    |                 | S           | Oral                           | 3 Mg                 |                 |              | Not Reported   |
| <u>FDA Received Date</u>                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> |             | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Sep-2015                                                         | 11334070       | EXPEDITED (15-DAY) |                    | HO              |             | FR-FRI-1000078664              |                      | 35 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                               | <u>Product</u> |                    | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u> | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hepatitis; Intentional<br>Overdose; Neutropenia;<br>Suicide Attempt | Escitalopram   |                    |                    |                 | S           | Oral                           | Overdose 560 Mg.     |                 |              | Forest         |
|                                                                     | Paracetamol    |                    |                    |                 | S           | Oral                           | Overdose 64 G.       |                 |              | Not Reported   |
|                                                                     | Nocertone      |                    |                    |                 | S           | Oral                           | Overdose 1.8 G.      |                 |              | Not Reported   |
|                                                                     | Xanax          |                    |                    |                 | S           | Oral                           | Overdose 7.5 Mg.     |                 |              | Not Reported   |
|                                                                     | Selokeen       |                    |                    |                 | S           | Oral                           | Overdose 3 G.        |                 |              | Not Reported   |
|                                                                     | Depamide       |                    |                    |                 | S           | Oral                           | Overdose 4.8 G.      |                 |              | Not Reported   |
|                                                                     | Ketum          |                    |                    |                 | S           | Oral                           | Overdose 3 G.        |                 |              | Not Reported   |
|                                                                     | Cymbalta       |                    |                    |                 | S           | Oral                           | Overdose 180 Mg.     |                 |              | Not Reported   |
|                                                                     | Myolastan      |                    |                    |                 | S           | Oral                           | Overdose 20 Df.      |                 |              | Not Reported   |
| <u>FDA Received Date</u>                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> |             | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Sep-2015                                                         | 11495073       | EXPEDITED (15-DAY) |                    | OT              |             | FR-009507513-<br>1509FRA004878 |                      | 52 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                               | <u>Product</u> |                    | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u> | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypoglycaemia                                                       | Januvia        |                    |                    |                 | S           | Oral                           | 1 Tablet Per Day     |                 |              | Merck          |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                              |   |      |                                   |              |
|------------------------------|---|------|-----------------------------------|--------------|
| Metformin                    | S | Oral | 2 To 3 Tablets Per Day            | Not Reported |
| Glimepiride                  | S | Oral | 1 Mg, Qd (1 Tablet Per Day)       | Not Reported |
| Risperidone                  | S | Oral | 4 Mg, Qd (1 Tablet Per Day)       | Not Reported |
| Seroplex                     | S | Oral | 1 Tablet Per Day                  | Not Reported |
| Depamide                     | C | Oral | 2 Tablets (600 Mg) Per Day        | Not Reported |
| Doliprane                    | C | Oral | 2 Tablets (2 G) Per Day If Needed | Not Reported |
| Kardegic                     | C | Oral | 1 Sachet (75 Mg) Per Day          | Not Reported |
| Lipanthyl                    | C | Oral | 1 Tablet (160 Mg) Per Day         | Not Reported |
| Lormetazepam                 | C | Oral | 1 Tablet (2 Mg) Per Day If Needed | Not Reported |
| Loxapac (Loxapine Succinate) | C | Oral | 2 To 3 Tablets Per Day            | Not Reported |
| Saw Palmetto                 | C | Oral | 1 Capsule (160 Mg) Per Day        | Not Reported |
| Tenordate                    | C | Oral | 1 Capsule Per Day                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Sep-2015              | 11496239      | EXPEDITED (15-DAY) |                    |                 | JP-FRI-1000079460    |                      | 23 YR      | Female     | JPN            |

| <u>Preferred Term</u>                                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Convulsions Local; Liver Function Test Abnormal; Nausea; Vomiting | Escitalopram   |              |            | S           | Oral         | 10 Mg              |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 11-Sep-2015              | 11496283      | EXPEDITED (15-DAY) |                    | LT              | CH-PFIZER INC-2015302804 |                      | 30 YR      | Male       | CHE            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Suicide Attempt       | Neurontin      |              |            | S           | Oral         | 400 Mg, 4x/Day     |                 | Pfizer     |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                 |   |      |               |              |
|-----------------|---|------|---------------|--------------|
| Temesta Expidet | S | Oral | 2.5 Mg, Unk   | Pfizer       |
| Abilify         | S | Oral | 10 Mg, 1x/Day | Not Reported |
| Ciprallex       | S | Oral | 30 Mg, 1x/Day | Not Reported |
| Truxal          | C | Oral | 50 Mg, 2x/Day | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Sep-2015              | 11497522      | NON-EXPEDITED    |                    |                 | PHEH2015US014885     |                      | 41 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                        | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Affect Lability; Aggression; Anger; Anxiety; Asthenia; Depression; Diplopia; Dysphemia; Fall; Feeling Abnormal; Frustration Tolerance Decreased; General Physical Health Deterioration; Headache; Hypoaesthesia; Insomnia; Limb Discomfort; Malaise; Memory Impairment; Muscle Spasms; Pain; Pain In Extremity; Relapsing-Remitting Multiple Sclerosis; Vision Blurred; Vitamin D Deficiency | Gilenya                       |              |            | S           | Oral         | 0.5 Mg, Qd         |                 | Novartis     |
|                                                                                                                                                                                                                                                                                                                                                                                              | Solumedrol                    |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                              | Acthar                        |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                              | Lexapro                       |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                              | Valium                        |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                              | Flomax "Boehringer Ingelheim" |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                              | Neurontin                     |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                              | Magnesium                     |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                              | B12-Vitamin                   |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                              | Co Q-10                       |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                              | Fish Oil                      |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                              | Vitamin D Nos                 |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                              | Oxycodon                      |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                              | Zanaflex                      |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                              | Gabantin                      |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                              | Prednisone                    |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                              | Ultram /01573601/             |              |            | C           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------|----------------------|------------|------------|----------------|
| 14-Sep-2015              | 10776843      | EXPEDITED (15-DAY) |                    | HO              | IT-APOTEX-2015AP006335 |                      | 53 YR      | Female     | ITA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                  | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Psychomotor Retardation;<br>Toxicity To Various Agents | Paxil Tablets        |              |            | S           | Oral         | 280 Mg, Daily      |                 | Apotex       |
|                                                        | Lexotan              |              |            | S           | Oral         | 15 MI, Single      |                 | Not Reported |
|                                                        | Xanax                |              |            | S           | Oral         | 20 MI, Single      |                 | Not Reported |
|                                                        | Cipralext /01588501/ |              |            | S           | Unknown      | 280 Mg, Single     |                 | Not Reported |
|                                                        | Nurofen              |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                        | Enantyum             |              |            | S           |              | 250 Mg, Single     |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 14-Sep-2015              | 11500553      | NON-EXPEDITED    |                    |                 | US-PFIZER INC-<br>2015295347 |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Hypersensitivity | Cleocin        |              |            | S           |              | Unk                |                 | Pfizer       |
|                       | Cipra Pro      |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Levaquin       |              |            | S           |              | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------------------|----------------------|------------|------------|----------------|
| 15-Sep-2015              | 11420380      | EXPEDITED (15-DAY) |                    |                 | US-<br>GLAXOSMITHKLINE-<br>CA2015GSK121189 |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>                  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|----------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Drug Ineffective; Product<br>Complaint | Paxil          |              |            | S           |              |                    |                 | Glaxosmithkline |
|                                        | Lexapro        |              |            | S           |              |                    |                 | Not Reported    |
|                                        | Celexa         |              |            | S           |              |                    |                 | Not Reported    |
|                                        | Wellbutrin     |              |            | S           |              |                    |                 | Glaxosmithkline |
|                                        | Prozac         |              |            | S           |              |                    |                 | Not Reported    |
|                                        | Remeron        |              |            | S           |              |                    |                 | Not Reported    |
|                                        | Pristiq        |              |            | C           |              |                    |                 | Not Reported    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Sep-2015              | 11448470      | EXPEDITED (15-DAY) |                    | HO              | CN-FRI-1000079244    |                      | 25 YR      | Male       | CHN            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                          |           |   |         |       |              |
|--------------------------|-----------|---|---------|-------|--------------|
| Cardiac Discomfort;      | Lexapro   | S | Oral    | 5 Mg  | Forest       |
| Dizziness; Glassy Eyes;  | Lexapro   | S | Oral    | 10 Mg | Forest       |
| Head Discomfort;         | Lexapro   | S | Oral    | 5 Mg  | Not Reported |
| Intentional Self-Injury; | Lorazepam | C | Unknown |       | Not Reported |
| Memory Impairment        |           |   |         |       |              |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 15-Sep-2015              | 11500594       | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2015306330 |                      | 55 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective         | Pristiq        |                  |                    | S               |                          | 50 Mg, Unk           |                 | Pfizer       |                |
|                          | Lexapro        |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                          | Prozac         |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |

| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------|----------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 15-Sep-2015               | 11507513       | EXPEDITED (15-DAY) |                    | OT              | FR-PFIZER INC-2015305913 |                      | 81 YR           | Female       | FRA            |
| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;         | Cordarone      |                    |                    | S               | Oral                     | 1 Df, Daily          |                 | Pfizer       |                |
| Ventricular Extrasystoles | Seroplex       |                    |                    | S               | Oral                     | 1 Df, Daily          |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 15-Sep-2015              | 11509231       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000079454    |                      | 74 YR           | Female       | FRA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Pneumonia Aspiration;    | Escitalopram   |                    |                    | S               | Oral                 | 30 Mg                |                 | Forest       |                |
| Prescribed Overdose      | Xeroquel       |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                          | Loxapac        |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                          | Laroxyl        |                    |                    | S               | Oral                 | 50 Mg                |                 | Not Reported |                |
|                          | Noctamide      |                    |                    | S               | Oral                 | 2 Mg                 |                 | Not Reported |                |
|                          | Keppra         |                    |                    | S               | Oral                 | 500 Mg               |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                | Imovane                    |                    | S                  | Oral            | 7.5 Mg                                |                      |                 | Not Reported |                |
|------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|--------------------|--------------------|-----------------|---------------------------------------|----------------------|-----------------|--------------|----------------|
|                                                                                                                                                | Effexor                    |                    | S                  | Oral            | 150 Mg                                |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                       | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Sep-2015                                                                                                                                    | 11510036                   | NON-EXPEDITED      |                    |                 | US-JNJFOC-20150811632                 |                      | 51 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                          | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Adverse Event; Anxiety; Crying; General Physical Health Deterioration; Mania; Product Dose Omission; Tearfulness                               | Invega                     |                    |                    | S               | Oral                                  |                      |                 | Not Reported |                |
|                                                                                                                                                | Lexapro                    |                    |                    | S               | Unknown                               |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                       | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Sep-2015                                                                                                                                    | 11510828                   | EXPEDITED (15-DAY) |                    | HO, LT, OT      | CA-JNJFOC-20150905060                 |                      | 54 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                                                                                                          | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Body Temperature Increased; Diarrhoea; Flushing; Hallucination, Auditory; Hallucination, Visual; Insomnia; Rash; Serotonin Syndrome | Concerta                   |                    |                    | S               | Oral                                  |                      |                 | Not Reported |                |
|                                                                                                                                                | Atasol (Acetaminophen)     |                    |                    | S               | Oral                                  |                      |                 | Not Reported |                |
|                                                                                                                                                | Cipralext                  |                    |                    | S               | Oral                                  |                      |                 | Not Reported |                |
|                                                                                                                                                | Meperidine                 |                    |                    | S               | Oral                                  |                      |                 | Not Reported |                |
|                                                                                                                                                | Morphine Sulfate           |                    |                    | S               | Intravenous (not otherwise specified) |                      |                 | Not Reported |                |
|                                                                                                                                                | Diprosone                  |                    |                    | C               | Unknown                               |                      |                 | Not Reported |                |
|                                                                                                                                                | Docusate Sodium            |                    |                    | C               | Unknown                               |                      |                 | Not Reported |                |
|                                                                                                                                                | Glucagon                   |                    |                    | C               | Unknown                               |                      |                 | Not Reported |                |
|                                                                                                                                                | Lantus                     |                    |                    | C               | Subcutaneous                          |                      |                 | Not Reported |                |
|                                                                                                                                                | Metformin                  |                    |                    | C               | Unknown                               |                      |                 | Not Reported |                |
|                                                                                                                                                | PhisoHex (Hexachlorophene) |                    |                    | C               | Unknown                               |                      |                 | Not Reported |                |
|                                                                                                                                                | Proctodan-Hc               |                    |                    | C               | Rectal                                |                      |                 | Not Reported |                |
|                                                                                                                                                | Hydrocortisone             |                    |                    | C               | Unknown                               |                      |                 | Not Reported |                |



## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|             |   |         |              |
|-------------|---|---------|--------------|
| Ramipril    | C | Unknown | Not Reported |
| Simvastatin | C | Unknown | Not Reported |
| Tecta       | C | Unknown | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|------------------------|----------------------|-----------------|--------------|----------------|
| 16-Sep-2015              | 11443210       | EXPEDITED (15-DAY) |                    | HO, OT          | FR-APOTEX-2015AP012437 |                      | 56 YR           | Male         | FRA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Treatment Failure        | Paxil Tablets  |                    |                    | S               | Unknown                |                      |                 | Apotex       |                |
|                          | Paxil Tablets  |                    |                    | S               | Unknown                | 40 Mg, Qd            |                 | Apotex       |                |
|                          | Escitalopram   |                    |                    | S               | Unknown                |                      |                 | Not Reported |                |
|                          | Escitalopram   |                    |                    | S               |                        |                      |                 | Not Reported |                |
|                          | Risperidone    |                    |                    | S               | Unknown                | 2 Mg, Qd             |                 | Not Reported |                |
|                          | Risperidone    |                    |                    | S               |                        |                      |                 | Not Reported |                |
|                          | Venlafaxine    |                    |                    | S               | Unknown                | 225 Mg, Qd           |                 | Not Reported |                |
|                          | Venlafaxine    |                    |                    | S               |                        |                      |                 | Not Reported |                |
|                          | Sertraline     |                    |                    | S               | Unknown                | Unk                  |                 | Not Reported |                |
|                          | Sertraline     |                    |                    | S               |                        |                      |                 | Not Reported |                |
|                          | Diazepam       |                    |                    | S               | Unknown                | 20 Mg, Qd            |                 | Not Reported |                |
|                          | Diazepam       |                    |                    | S               |                        |                      |                 | Not Reported |                |
|                          | Quetiapine     |                    |                    | S               | Unknown                | 100 Mg, Qd           |                 | Not Reported |                |
|                          | Quetiapine     |                    |                    | S               |                        |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>          | <u>Case #</u>    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|-----------------------------------|------------------|--------------------|--------------------|-----------------|------------------------|----------------------|-----------------|------------|----------------|
| 16-Sep-2015                       | 11514457         | EXPEDITED (15-DAY) |                    | HO, OT          | CA-APOTEX-2015AP012609 |                      | 37 YR           | Male       | CAN            |
| <u>Preferred Term</u>             | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Eye Disorder;<br>Hypersensitivity | Apo-Escitalopram |                    |                    | S               | Unknown                | 10 Mg, Qd            |                 | Apotex     |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Sep-2015              | 11515395      | EXPEDITED (15-DAY) |                    | DS              | CA-FRI-1000079544    |                      | 29 YR      | Female     | CAN            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                             | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                  | <u>Duration</u> | <u>Mfr</u>   |                |
|-----------------------------------------------------------------------------------|-------------------|--------------------|--------------------|-----------------|----------------------|---------------------------------------------------------------------|-----------------|--------------|----------------|
| Fatigue; Lethargy;<br>Sedation                                                    | Escitalopram      |                    |                    | S               | Oral                 | 5 Mg                                                                |                 | Forest       |                |
|                                                                                   | Magnesium Citrate |                    |                    | C               | Unknown              | Daily Dose Not Reported                                             |                 | Not Reported |                |
|                                                                                   | Riboflavin        |                    |                    | C               | Unknown              | Daily Dose Not Reported                                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                          | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Sep-2015                                                                       | 11515476          | EXPEDITED (15-DAY) |                    | HO              | CH-FRI-1000079448    |                                                                     |                 | Male         | CHE            |
| <u>Preferred Term</u>                                                             | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Chills; Muscle Twitching;<br>Prescribed Overdose                                  | Escitalopram      |                    |                    | S               | Unknown              | Overdose: 30 Mg                                                     |                 | Forest       |                |
| <u>FDA Received Date</u>                                                          | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Sep-2015                                                                       | 11516972          | DIRECT             |                    |                 |                      |                                                                     | 37 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                             | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Amnesia; Aphasia;<br>Cerebral Disorder;<br>Memory Impairment;<br>Weight Increased | Lexapro 10 Mg     |                    |                    | S               | Oral                 |                                                                     |                 | Not Reported |                |
|                                                                                   | Beyaz             |                    |                    | C               |                      |                                                                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                          | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Sep-2015                                                                       | 11288199          | EXPEDITED (15-DAY) |                    | HO              | CH-TEVA-579477ISR    |                                                                     | 37 YR           | Female       | CHE            |
| <u>Preferred Term</u>                                                             | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Cerebral Haemorrhage;<br>Hemiparesis; Speech<br>Disorder                          | Irfen             |                    |                    | S               | Oral                 | As Required, For Several<br>Weeks, Sometimes Taken<br>Up To 4 X/Day |                 | Ivax         |                |
|                                                                                   | Cipralext         |                    |                    | S               | Oral                 | 20 Milligram Daily;                                                 |                 | Not Reported |                |
|                                                                                   | Risperdal         |                    |                    | C               | Oral                 | 2 Milligram Daily; Taken<br>For Months                              |                 | Not Reported |                |
|                                                                                   | Xanax             |                    |                    | C               | Oral                 | Long Term, 6 Mg In The                                              |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Morning, 6 Mg At Midday,  
6 Mg In The Evening

| <u>FDA Received Date</u>    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------|----------------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 17-Sep-2015                 | 11518623             | EXPEDITED (15-DAY) |                    | HO              | FR-<br>ELI_LILLY_AND_COMP<br>ANY-FR201509001096 |                      | 88 YR           | Female       | FRA            |
| <u>Preferred Term</u>       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anaemia; Areflexia;         | Zyprexa              |                    |                    | S               | Unknown                                         | Unk, Unknown         |                 | Unknown      |                |
| Bradycardia;                | Exelon               |                    |                    | S               | Unknown                                         | 9.5 Mg, Qd           |                 | Not Reported |                |
| Disorientation; Dyskinesia; | Seroplex             |                    |                    | S               | Unknown                                         | 10 Mg, Qd            |                 | Not Reported |                |
| Electrocardiogram Qrs       | Coumadine            |                    |                    | C               | Unknown                                         | Unk, Unknown         |                 | Not Reported |                |
| Complex Shortened; Loss     | Tahor                |                    |                    | C               | Unknown                                         | Unk, Unknown         |                 | Not Reported |                |
| Of Consciousness;           | Diffu K              |                    |                    | C               | Unknown                                         | Unk, Unknown         |                 | Not Reported |                |
| Malaise; Tremor; Urinary    | Tareg                |                    |                    | C               | Unknown                                         | Unk, Unknown         |                 | Not Reported |                |
| Incontinence; Ventricular   | Lantus               |                    |                    | C               | Unknown                                         | Unk, Unknown         |                 | Not Reported |                |
| Extrasystoles               | Transipeg /00754501/ |                    |                    | C               | Unknown                                         | Unk, Unknown         |                 | Not Reported |                |
|                             | Tardyferon           |                    |                    | C               | Unknown                                         | Unk, Unknown         |                 | Not Reported |                |
|                             | Paracetamol          |                    |                    | C               | Unknown                                         | Unk, Unknown         |                 | Not Reported |                |
| <u>FDA Received Date</u>    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Sep-2015                 | 11518794             | EXPEDITED (15-DAY) |                    | HO              | US-MYLANLABS-<br>2015M1031038                   |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Coagulopathy; Laryngeal     | Warfarin             |                    |                    | S               | Oral                                            |                      |                 | Not Reported |                |
| Haemorrhage; Overdose;      | Escitalopram         |                    |                    | S               | Oral                                            |                      |                 | Not Reported |                |
| Self-Medication             |                      |                    |                    |                 |                                                 |                      |                 |              |                |
| <u>FDA Received Date</u>    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Sep-2015                 | 11518820             | EXPEDITED (15-DAY) |                    | HO, LT          | FR-FRI-1000079642                               |                      | 53 YR           | Male         | FRA            |
| <u>Preferred Term</u>       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                    |              |   |         |              |
|--------------------|--------------|---|---------|--------------|
| Anaphylactic Shock | Escitalopram | S | Unknown | Forest       |
|                    | Esmeron      | S | Unknown | Not Reported |
|                    | Diprivan     | S | Unknown | Not Reported |
|                    | Sufentanil   | S | Unknown | Not Reported |
|                    | Hypnovel     | S | Unknown | Not Reported |
|                    | Atenolol     | S | Unknown | Not Reported |
|                    | Inexium      | C | Unknown | Not Reported |

| <u>FDA Received Date</u>        | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---------------------------------|--------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 17-Sep-2015                     | 11519209           | EXPEDITED (15-DAY) |                    | OT              | IT-FRI-1000079476    |                      | 23 YR           | Female     | ITA            |
| <u>Preferred Term</u>           | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Interaction;<br>Presyncope | Escitalopram       |                    |                    | S               | Oral                 | 10 Gtt               |                 | Forest     |                |
|                                 | Olanzapina Zentiva |                    |                    | S               | Oral                 | 5 Mg                 |                 | Sanofi     |                |

| <u>FDA Received Date</u>                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 17-Sep-2015                                    | 11519210       | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000079563    |                      | 81 YR           | Female       | FRA            |
| <u>Preferred Term</u>                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;<br>Ventricular Extrasystoles | Escitalopram   |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                                | Cordarone      |                    |                    | S               | Oral                 | 200 Mg               |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                    | <u>Case #</u>     | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------|-------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 17-Sep-2015                                                                                                                 | 11519924          | DIRECT           |                    | CA, DE          |                      |                      | 35 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                       | <u>Product</u>    | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Foetal Death; Foetal<br>Growth Restriction;<br>Maternal Drugs Affecting<br>Foetus; Maternal<br>Exposure During<br>Pregnancy | Escitalopram      |                  |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                             | Prenatal Vitamins |                  |                    | S               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                      | <u>Case #</u>                            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------|------------------------------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 17-Sep-2015                                                   | 11520768                                 | DIRECT           |                    | OT              |                      |                      | 72 YR           | Male         | USA            |
| <u>Preferred Term</u>                                         | <u>Product</u>                           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated;<br>Depression; Product<br>Quality Issue | Escitalopram 20mg Torrent                |                  |                    | S               | Oral                 | 1 Qd Oral            |                 | Torrent      |                |
|                                                               | Bactrim Ds (Generic) 800mg<br>Rx#6564016 |                  |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                     | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------|------------------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|-----------------|--------------|----------------|
| 18-Sep-2015                                  | 10743587               | EXPEDITED (15-DAY) |                    | LT, OT          | JP-TAKEDA-<br>2015TJP000989AA |                      | 68 YR           | Female       | JPN            |
| <u>Preferred Term</u>                        | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;<br>Ventricular Tachycardia | Takepron Od Tablets 15 |                    |                    | S               | Oral                          | 15 Mg, Qd            |                 | Takeda       |                |
|                                              | Lexapro                |                    |                    | S               | Oral                          | 10 Mg, Qd            |                 | Not Reported |                |
|                                              | Toledomin              |                    |                    | C               | Oral                          | 15 Mg, Qd            |                 | Not Reported |                |
|                                              | Maglax                 |                    |                    | C               | Oral                          | 330 Mg, Tid          |                 | Not Reported |                |
|                                              | Singulair              |                    |                    | C               | Oral                          | 10 Mg, Qd            |                 | Not Reported |                |
|                                              | Predonine /00016201/   |                    |                    | C               | Oral                          | 20 Mg, Qd            |                 | Not Reported |                |
|                                              | Mucodyne               |                    |                    | C               | Oral                          | 250 Mg, Tid          |                 | Not Reported |                |
|                                              | Foipan                 |                    |                    | C               | Oral                          | 200 Mg, Tid          |                 | Not Reported |                |
|                                              | Baktar                 |                    |                    | C               | Oral                          | 1 Df, Qd             |                 | Not Reported |                |
|                                              | Jzoloft                |                    |                    | C               | Oral                          | 25 Mg, Qd            |                 | Not Reported |                |
|                                              | Paxil /00830802/       |                    |                    | C               |                               | 10 Mg, Qd            |                 | Not Reported |                |
|                                              | Paxil /00830802/       |                    |                    | C               | Oral                          | 20 Mg, Qd            |                 | Not Reported |                |
|                                              | Paxil /00830802/       |                    |                    | C               | Oral                          | 30 Mg, Qd            |                 | Not Reported |                |
|                                              | Paxil /00830802/       |                    |                    | C               | Oral                          | 40 Mg, Qd            |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 18-Sep-2015              | 10746990      | EXPEDITED (15-DAY) |                    | DE              | US-PAR<br>PHARMACEUTICAL,<br>INC-2015SCPR009917 |                      | 69 YR      | Male       | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                           | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|-----------------------------------------------------------------|--------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| Completed Suicide; Death                                        | Clonazepam         |                    |                    | S               | Oral                     | Unk, Unknown         |                 | Par          |                |
|                                                                 | Lamotrigine        |                    |                    | S               | Oral                     | Unk, Unknown         |                 | Par          |                |
|                                                                 | Cardiac Glycosides |                    |                    | S               | Oral                     | Unk, Unknown         |                 | Not Reported |                |
|                                                                 | Trazodone          |                    |                    | S               | Oral                     | Unk, Unknown         |                 | Not Reported |                |
|                                                                 | Oxybutynin         |                    |                    | S               | Oral                     | Unk, Unknown         |                 | Not Reported |                |
|                                                                 | Quetiapine         |                    |                    | S               | Oral                     | Unk, Unknown         |                 | Not Reported |                |
|                                                                 | Escitalopram       |                    |                    | S               | Oral                     | Unk, Unknown         |                 | Not Reported |                |
|                                                                 | Finasteride        |                    |                    | S               | Oral                     | Unk, Unknown         |                 | Not Reported |                |
|                                                                 | Salicylates Nos    |                    |                    | S               | Oral                     | Unk, Unknown         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                        | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Sep-2015                                                     | 11247268           | EXPEDITED (15-DAY) |                    | DE, HO          | FR-PFIZER INC-2015225889 |                      | 74 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                           | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Death; Dizziness; Drug Interaction; Sinus Bradycardia; Vomiting | Cordarone          |                    |                    | S               | Oral                     | 1 Df, Daily          |                 | Pfizer       |                |
|                                                                 | Seroplex           |                    |                    | S               | Oral                     | 5 Mg, Daily          |                 | Not Reported |                |
|                                                                 | Harvoni            |                    |                    | S               | Unknown                  | Unk                  |                 | Not Reported |                |
|                                                                 | Bisoprolol         |                    |                    | S               |                          | 1.25 Mg, 1x/Day      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                        | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Sep-2015                                                     | 11519421           | EXPEDITED (15-DAY) |                    | HO              | FR-ROCHE-1635621         |                      | 65 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                           | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyponatraemia; Somnolence                                       | Valium             |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                                                                 | Seroplex           |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                                                                 | Speciafoldine      |                    |                    | C               |                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                        | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Sep-2015                                                     | 11521426           | NON-EXPEDITED      |                    |                 | US-ROCHE-729199          |                      | 50 YR           | Female       | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anaemia; Asthenia;         | Pegasys        |              |            | S           | Subcutaneous |                    |                 | Not Reported |
| Depression; Feeling        | Copegus        |              |            | S           | Oral         |                    |                 | Not Reported |
| Abnormal; Headache;        | Copegus        |              |            | S           | Oral         |                    |                 | Not Reported |
| Nausea; Pain; Platelet     | Lexapro        |              |            | S           | Unknown      |                    |                 | Not Reported |
| Count Decreased;           | Lexapro        |              |            | S           | Unknown      |                    |                 | Not Reported |
| Pyrexia; Toxicity To       | Phenergan      |              |            | C           | Unknown      |                    |                 | Not Reported |
| Various Agents; Viral Load | Hctz           |              |            | C           | Unknown      |                    |                 | Not Reported |
| Increased; Weight          |                |              |            |             |              |                    |                 |              |
| Decreased                  |                |              |            |             |              |                    |                 |              |

  

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Sep-2015              | 11522469      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000079580    |                      | 80 YR      | Female     | FRA            |

  

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Epilepsy              | Escitalopram   |              |            | S           | Oral         |                    |                 | Forest     |

  

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Sep-2015              | 11523168      | NON-EXPEDITED    |                    |                 | US-MEDA-2014110053   |                      | 49 YR      | Female     | USA            |

  

| <u>Preferred Term</u>       | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------|--------------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Dry Mouth;                  | Demadex                  |              |            | S           |              |                               |                 | Meda         |
| Hypercholesterolaemia;      | Lyrica                   |              |            | S           |              |                               |                 | Not Reported |
| Oropharyngeal Pain; Type    | Tizanidine               |              |            | S           |              |                               |                 | Not Reported |
| 2 Diabetes Mellitus; Visual | Tizanidine               |              |            | S           |              |                               |                 | Not Reported |
| Impairment                  | Oxycodone Apap 10/325 Mg |              |            | S           |              | 10/325 Mg                     |                 | Not Reported |
|                             | Seroquel                 |              |            | S           |              | 50 Mg In The Morning And Noon |                 | Not Reported |
|                             | Seroquel                 |              |            | S           |              | 200 Mg At Night               |                 | Not Reported |
|                             | Seroquel                 |              |            | S           |              | 50 Mg In The Morning And Noon |                 | Not Reported |
|                             | Seroquel                 |              |            | S           |              | 200 Mg At Night               |                 | Not Reported |
|                             | Metformin                |              |            | S           |              |                               |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |                |   |                         |              |
|--|----------------|---|-------------------------|--------------|
|  | Effexor        | S | 75 Mg + 150 Mg Together | Not Reported |
|  | Lexapro        | S |                         | Not Reported |
|  | Valium         | S |                         | Not Reported |
|  | Aspirin        | S |                         | Not Reported |
|  | Simvastatin    | S |                         | Not Reported |
|  | Topamax        | S |                         | Not Reported |
|  | Ibuprofen      | S | 800 Mg In The Morning   | Not Reported |
|  | Ibuprofen      | S |                         | Not Reported |
|  | Fentanyl Patch | S |                         | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Sep-2015              | 11523486      | NON-EXPEDITED    |                    |                 | US-ROCHE-713835      |                      | 43 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------------|-----------------|--------------|
| Arthralgia; Diarrhoea;<br>Dizziness; Nausea;<br>Procedural Complication;<br>Rash | Pegasys        |              |            | S           | Subcutaneous | Form: Pre-Filled Syringe |                 | Not Reported |
|                                                                                  | Ribavirin      |              |            | S           | Oral         | Taken In Divided Doses   |                 | Not Reported |
|                                                                                  | Ribavirin      |              |            | S           | Oral         | Dosage Decreased         |                 | Not Reported |
|                                                                                  | Ribavirin      |              |            | S           | Oral         |                          |                 | Not Reported |
|                                                                                  | Lexapro        |              |            | S           | Unknown      |                          |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|------------|------------|----------------|
| 18-Sep-2015              | 11525687      | EXPEDITED (15-DAY) |                    | DE, OT          | CH-CIPLA LTD.-<br>2015CH07453 |                      |            | Unknown    | CHE            |

| <u>Preferred Term</u>                                          | <u>Product</u>  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------|-----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Abuse;<br>Electrocardiogram Qt<br>Prolonged; Sudden Death | Zidovudine      |              |            | S           | Unknown      | 600 Mg, Unk        |                 | Cipla        |
|                                                                | Lamivudine      |              |            | S           | Unknown      | 300 Mg, Unk        |                 | Cipla        |
|                                                                | Methadone       |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                | Escitalopram    |              |            | S           | Unknown      | 30 Mg, Unk         |                 | Not Reported |
|                                                                | Atazanavir      |              |            | S           | Unknown      | 400 Mg, Unk        |                 | Not Reported |
|                                                                | Levomepromazine |              |            | S           | Unknown      | 50 Mg, Unk         |                 | Not Reported |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|---------------------------------|-------------------------|-----------------|--------------|----------------|
| 19-Sep-2015                                                               | 10915678       | EXPEDITED (15-DAY) |                    | HO              | IT-AUROBINDO-AUR-APL-2015-02198 |                         | 55 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Bradycardia; Drug Abuse; Oxygen Saturation Decreased                      | Escitalopram   |                    |                    | S               | Oral                            | 400 Mg Total, Unk       |                 | Aurobindo    |                |
|                                                                           | Cardioaspirin  |                    |                    | C               | Unknown                         | Unk                     |                 | Not Reported |                |
|                                                                           | En             |                    |                    | C               | Unknown                         | Unk                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Sep-2015                                                               | 11526230       | EXPEDITED (15-DAY) |                    | OT              | CH-CIPLA LTD.-2015CH07445       |                         |                 | Unknown      | CHE            |
| <u>Preferred Term</u>                                                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Electrocardiogram Qt Prolonged; Torsade De Pointes                        | Zidovudine     |                    |                    | S               | Unknown                         | 600 Mg, Unk             |                 | Cipla        |                |
|                                                                           | Ritonavir      |                    |                    | S               | Unknown                         | 200 Mg, Unk             |                 | Cipla        |                |
|                                                                           | Lamivudine     |                    |                    | S               | Unknown                         | 300 Mg, Unk             |                 | Cipla        |                |
|                                                                           | Atazanavir     |                    |                    | S               | Unknown                         | 400 Mg, Unk             |                 | Not Reported |                |
|                                                                           | Methadone      |                    |                    | S               | Unknown                         | 80 Mg, Unk              |                 | Not Reported |                |
|                                                                           | Escitalopram   |                    |                    | S               | Unknown                         | 30 Mg, Unk              |                 | Not Reported |                |
|                                                                           | Fluoxetine     |                    |                    | S               | Unknown                         | 20 Mg, Unk              |                 | Not Reported |                |
|                                                                           | Zuclopenthixol |                    |                    | S               | Unknown                         | 20 Mg, Unk              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Sep-2015                                                               | 11082134       | EXPEDITED (15-DAY) |                    | HO              | PHHY2015FR049879                |                         | 76 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Haemarthrosis; International Normalised Ratio Increased | Sintrom        |                    |                    | S               | Oral                            | (According To Inr)      |                 | Not Reported |                |
|                                                                           | Ibuprofen      |                    |                    | S               | Oral                            | Unk                     |                 | Novartis     |                |
|                                                                           | Escitalopram   |                    |                    | S               | Oral                            | 10 Mg, Qd               |                 | Not Reported |                |
|                                                                           | Acenocoumarol  |                    |                    | C               | Unknown                         | Unk Unk, Prn (According |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                 |   |         |                         |              |
|---------------------------------|---|---------|-------------------------|--------------|
| Acenocoumarol                   | C | Unknown | To Inr)                 | Not Reported |
| Acenocoumarol                   | C | Unknown | 3 Mg, Qd (In Evening)   | Not Reported |
| Acenocoumarol                   | C | Unknown | 0.5 Df For 3 Days, Unk  | Not Reported |
| Potassium Chloride              | C | Unknown | 0.75 Df On 4th Day, Unk | Not Reported |
| Furosemide                      | C | Unknown | 2 Df, Bid               | Not Reported |
| Amlodipine                      | C | Unknown | 40 Mg, Qd               | Not Reported |
| Perindopril Tert-Butylamine     | C | Unknown | 10 Mg, Qd               | Not Reported |
| Lamaline                        | C | Unknown | 4 Mg, Qd                | Not Reported |
| (Acetaminophen\Caffeine\Opium ) | C | Unknown | 4 Daily                 | Not Reported |
| Paracetamol                     | C | Unknown | 500 Mg, Bid             | Not Reported |
| Zolpidem                        | C | Unknown | 10 Mg, Qd               | Not Reported |
| Cholecalciferol                 | C | Unknown | 1 Df, Unk               | Not Reported |
| Magne B6                        | C | Unknown | Unk Unk, Qd             | Not Reported |
| Alprazolam                      | C | Unknown | 1.5 Mg, Qd              | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 21-Sep-2015              | 11311713      | EXPEDITED (15-DAY) |                    | HO              | FR-JNJFOC-20150709120 |                      | 49 YR      | Female     | FRA            |

| <u>Preferred Term</u>      | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Disorder; Melaena;   | Risperdal           |              |            | S           | Oral         |                    |                 | Not Reported |
| Multiple Organ             | Propranolol         |              |            | S           | Oral         | 1-0-0              |                 | Not Reported |
| Dysfunction Syndrome;      | Temesta (Lorazepam) |              |            | S           | Oral         | 1-1-1              |                 | Not Reported |
| Toxicity To Various Agents | Atarax              |              |            | S           | Oral         |                    |                 | Not Reported |
|                            | Seroplex            |              |            | S           | Oral         | 0-0-1              |                 | Not Reported |
|                            | Mogadon             |              |            | C           | Unknown      | 1-0-0              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------------|----------------------|------------|------------|----------------|
| 21-Sep-2015              | 11530621      | EXPEDITED (15-DAY) |                    |                 | US-GLAXOSMITHKLINE-US2015GSK129374 |                      |            | Unknown    | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|-----------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Drug Ineffective      | Wellbutrin XI Tablet |              |            | S           |              |                    |                 | Glaxosmithkline |
|                       | Lexapro              |              |            | S           |              |                    |                 | Not Reported    |
|                       | Celexa               |              |            | S           |              |                    |                 | Not Reported    |
|                       | Wellbutrin           |              |            | S           |              |                    |                 | Glaxosmithkline |
|                       | Cymbalta             |              |            | S           |              |                    |                 | Not Reported    |
|                       | Paxil                |              |            | S           |              |                    |                 | Not Reported    |
|                       | Prozac               |              |            | S           |              |                    |                 | Not Reported    |
|                       | Remeron              |              |            | S           |              |                    |                 | Not Reported    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------------------------------|----------------------|------------|------------|----------------|
| 21-Sep-2015              | 11532944      | EXPEDITED (15-DAY) |                    | OT              | CH-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>BMS-2013-000029 |                      | < 1 DAY    | Female     | CHE            |

| <u>Preferred Term</u>                                                              | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>           |
|------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|----------------|--------------------|-----------------|----------------------|
| Foetal Exposure During Pregnancy; Foetal Growth Restriction; Low Birth Weight Baby | Abilify              |              |            | S           | Transplacental | 10 Mg, Qd          |                 | Bristol Myers Squibb |
|                                                                                    | Ciprallex /01588501/ |              |            | S           | Transplacental | 5 Mg, Qd           |                 | Not Reported         |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Sep-2015              | 11533101      | EXPEDITED (15-DAY) |                    | HO              | IT-BAYER-2015-422486 |                      | 66 YR      | Male       | ITA            |

| <u>Preferred Term</u>               | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Amylase Increased; Lipase Increased | Cardioaspirin           |              |            | S           | Oral         | 100 Mg, Unk        |                 | Bayer        |
|                                     | Metformin Hydrochloride |              |            | S           | Oral         | 3 Mg, Unk          |                 | Not Reported |
|                                     | Entact                  |              |            | S           | Oral         | 10 Mg, Unk         |                 | Not Reported |
|                                     | Pramipexole             |              |            | C           | Oral         |                    |                 | Not Reported |
|                                     | Deursil                 |              |            | C           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Sep-2015              | 11533117      | NON-EXPEDITED    |                    |                 | PHEH2015US017619     |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                   |              |   |         |                                                               |              |
|-----------------------------------|--------------|---|---------|---------------------------------------------------------------|--------------|
| Erythema; Pruritus; Skin Reaction | Exelon Patch | S | Unknown | Unk                                                           | Novartis     |
|                                   | Exelon Patch | S | Unknown | 9.5 Mg/24hours (Patch 10 Cm2, 18 Mg Daily Rivastigmine Base)  | Novartis     |
|                                   | Exelon Patch | S | Unknown | 4.6 Mg(Patch 5 Cm2, 09 Mg Daily Rivastigmine Base) For 2 Days | Novartis     |
|                                   | Lexapro      | S | Unknown | Unk                                                           | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Sep-2015              | 11535410      | DIRECT           |                    | OT              |                      |                      | 4 YR       | Female     | USA            |

| <u>Preferred Term</u>                                                               | <u>Product</u>               | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------|------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Hypersensitivity; General Physical Health Deterioration; Reaction To Excipient | Lexipro 20 Mg Aurobindo/Teva |              |            | S           | Oral         |                    | 6 YR            | Aurobindo    |
|                                                                                     | Buspirone 5 Mg Teva          |              |            | S           | Oral         |                    |                 | Teva         |
|                                                                                     | Atenolol                     |              |            | C           |              |                    |                 | Not Reported |
|                                                                                     | Klonopin                     |              |            | C           |              |                    |                 | Not Reported |
|                                                                                     | Multiple Vitamin             |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Sep-2015              | 11536909      | DIRECT           |                    | OT              |                      |                      | 45 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|------------------|--------------|------------|-------------|--------------|----------------------------|-----------------|--------------|
| Weight Increased      | Escitalopram     |              |            | S           |              | Taken By Mouth             |                 | Not Reported |
|                       | Pramipexole      |              |            | S           |              | At Bedtime, Taken By Mouth |                 | Walmart      |
|                       | Tramadol         |              |            | C           |              |                            |                 | Not Reported |
|                       | Loestrin         |              |            | C           |              |                            |                 | Not Reported |
|                       | Iron             |              |            | C           |              |                            |                 | Not Reported |
|                       | Multivitamin     |              |            | C           |              |                            |                 | Not Reported |
|                       | Vit. B Complex   |              |            | C           |              |                            |                 | Not Reported |
|                       | Motrin           |              |            | C           |              |                            |                 | Not Reported |
|                       | Tylenol          |              |            | C           |              |                            |                 | Not Reported |
|                       | Generic Prilosec |              |            | C           |              |                            |                 | Not Reported |

# FDA Adverse Event Reporting System

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| <u>FDA Received Date</u>                                                                 | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>                                                              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|---------------------------------------|-----------------------------------------------------------------------------------|-----------------|--------------|----------------|
| 22-Sep-2015                                                                              | 11325297                | EXPEDITED (15-DAY) |                    | HO              | CH-FRI-1000078635                     |                                                                                   | 37 YR           | Female       | CHE            |
| <u>Preferred Term</u>                                                                    | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>                                                                | <u>Duration</u> | <u>Mfr</u>   |                |
| Cerebral Haemorrhage;<br>Hemiparesis                                                     | Escitalopram            |                    |                    | S               | Oral                                  | 20 Mg                                                                             |                 | Forest       |                |
|                                                                                          | Irfen                   |                    |                    | S               | Oral                                  | As Needed: Treatment In Reserve Since Several Weeks, Taken Sometimes Up To 4x/Day |                 | Not Reported |                |
|                                                                                          | Risperdal               |                    |                    | C               | Oral                                  | 2 Mg                                                                              |                 | Not Reported |                |
|                                                                                          | Xanax                   |                    |                    | C               | Oral                                  | 3x/Day: 6 Mg In The Morning, 6 Mg Midday, 9 Mg In The Evening.                    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                 | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>                                                              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Sep-2015                                                                              | 11533775                | EXPEDITED (15-DAY) |                    | CA, DE, OT      | PHHY2015GB110755                      |                                                                                   | 2 DAY           | Female       | GBR            |
| <u>Preferred Term</u>                                                                    | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>                                                                | <u>Duration</u> | <u>Mfr</u>   |                |
| Congenital Pulmonary Valve Atresia                                                       | Citalopram              |                    |                    | S               | Transplacental                        | 20 Mg, 1x/Day                                                                     |                 | Novartis     |                |
|                                                                                          | Escitalopram            |                    |                    | S               | Transplacental                        | 20 Mg, 1x/Day                                                                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                 | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>                                                              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Sep-2015                                                                              | 11534297                | EXPEDITED (15-DAY) |                    | HO, LT, OT      | FR-ALVOGEN-2015AL003689               |                                                                                   | 53 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                    | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>                                                                | <u>Duration</u> | <u>Mfr</u>   |                |
| Anaphylactic Shock; Hilar Lymphadenopathy; Lung Disorder;<br>Lymphadenopathy Mediastinal | Atenolol                |                    |                    | S               | Intravenous (not otherwise specified) |                                                                                   |                 | Not Reported |                |
|                                                                                          | Esmeron                 |                    |                    | S               |                                       |                                                                                   |                 | Not Reported |                |
|                                                                                          | Diprivan                |                    |                    | S               |                                       |                                                                                   |                 | Not Reported |                |
|                                                                                          | Sufentanil              |                    |                    | S               |                                       |                                                                                   |                 | Not Reported |                |
|                                                                                          | Midazolam Hydrochloride |                    |                    | S               |                                       |                                                                                   |                 | Not Reported |                |
|                                                                                          | Seroplex                |                    |                    | S               |                                       |                                                                                   |                 | Not Reported |                |
|                                                                                          | Esomeprazole Magnesium  |                    |                    | C               |                                       |                                                                                   |                 | Not Reported |                |

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| <u>FDA Received Date</u>           | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|-----------------------------------|-----------------|--------------|----------------|
| 22-Sep-2015                        | 11535401             | EXPEDITED (15-DAY) |                    | CA, DE, OT      | GB-TEVA-593542ACC    |                                   |                 | Female       | GBR            |
| <u>Preferred Term</u>              | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |                |
| Congenital Pulmonary Valve Atresia | Citalopram           |                    |                    | S               | Transplacental       | 20 Milligram Daily; 20 Mg, 1x/Day |                 | Pliva        |                |
|                                    | Escitalopram Oxalate |                    |                    | S               | Transplacental       | 20 Milligram Daily; 20 Mg, 1x/Day |                 | Not Reported |                |
| <u>FDA Received Date</u>           | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Sep-2015                        | 11537141             | EXPEDITED (15-DAY) |                    | OT              | PHHY2015AT112208     |                                   |                 | Male         | AUT            |
| <u>Preferred Term</u>              | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |                |
| Serotonin Syndrome                 | Gabapentin           |                    |                    | S               | Unknown              | 300 Mg, Unk                       |                 | Novartis     |                |
|                                    | Gabapentin           |                    |                    | S               |                      |                                   |                 | Novartis     |                |
|                                    | Tramadol             |                    |                    | S               | Unknown              | 450 Mg, Unk                       |                 | Not Reported |                |
|                                    | Tramadol             |                    |                    | S               | Unknown              | 20-60 Ggt/Day                     |                 | Not Reported |                |
|                                    | Hydromorphone        |                    |                    | S               | Unknown              | 18 Mg, Bid                        |                 | Not Reported |                |
|                                    | Hydromorphone        |                    |                    | S               |                      |                                   |                 | Not Reported |                |
|                                    | Naproxen             |                    |                    | S               | Unknown              | 500 Mg, Bid                       |                 | Not Reported |                |
|                                    | Cipralelex           |                    |                    | S               | Unknown              | 15 Mg, Qd                         |                 | Not Reported |                |
|                                    | Cipralelex           |                    |                    | S               |                      |                                   |                 | Not Reported |                |
|                                    | Midazolam            |                    |                    | C               | Unknown              | 2 Df, Unk                         |                 | Not Reported |                |
|                                    | Midazolam            |                    |                    | C               |                      |                                   |                 | Not Reported |                |
|                                    | Mirtazapine          |                    |                    | C               | Unknown              | 15 Mg, Unk                        |                 | Not Reported |                |
|                                    | Spironolacton        |                    |                    | C               | Unknown              |                                   |                 | Not Reported |                |
|                                    | Doxazosin            |                    |                    | C               | Unknown              |                                   |                 | Not Reported |                |
|                                    | Bisoprolol           |                    |                    | C               | Unknown              |                                   |                 | Not Reported |                |
|                                    | Levothyroxin         |                    |                    | C               | Unknown              |                                   |                 | Not Reported |                |
|                                    | Furosemide           |                    |                    | C               | Unknown              |                                   |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                      | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
|-------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|------------------|----------------|
| 22-Sep-2015                                                                   | 11537655               | NON-EXPEDITED      |                    |                 | US-<br>ELI_LILLY_AND_COMP<br>ANY-US201509006738 |                      | 17 YR           | Female           | USA            |
| <u>Preferred Term</u>                                                         | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |
| Drug Ineffective;<br>Screaming                                                | Prozac                 |                    |                    | S               | Unknown                                         | Unk                  |                 | Eli Lilly And Co |                |
|                                                                               | Xanax                  |                    |                    | S               | Unknown                                         | Unk                  |                 | Not Reported     |                |
|                                                                               | Lexapro                |                    |                    | S               | Unknown                                         | Unk                  |                 | Not Reported     |                |
| <u>FDA Received Date</u>                                                      | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 23-Sep-2015                                                                   | 8049653                | EXPEDITED (15-DAY) |                    | CA, DE, OT      | GB-ARROW GEN-2011-<br>10568                     |                      |                 | Female           | GBR            |
| <u>Preferred Term</u>                                                         | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |
| Congenital Pulmonary<br>Valve Atresia; Foetal<br>Exposure During<br>Pregnancy | Citalopram             |                    |                    | S               | Transplacental                                  | 20 Mg, Daily         |                 | Watson           |                |
|                                                                               | Escitalopram (Unknown) |                    |                    | S               | Transplacental                                  | 20 Mg, Daily         |                 | Not Reported     |                |
| <u>FDA Received Date</u>                                                      | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 23-Sep-2015                                                                   | 11266398               | EXPEDITED (15-DAY) |                    | DE              | FR-FRI-1000078060                               |                      | 74 YR           | Female           | FRA            |
| <u>Preferred Term</u>                                                         | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |
| Death; Dizziness; Drug<br>Interaction; Vomiting                               | Escitalopram           |                    |                    | S               | Oral                                            | 1 Df                 |                 | Forest           |                |
|                                                                               | Harvoni                |                    |                    | S               |                                                 |                      |                 | Not Reported     |                |
|                                                                               | Cordarone              |                    |                    | S               | Oral                                            | 1 Df                 |                 | Not Reported     |                |
|                                                                               | Bisoprolol             |                    |                    | C               | Oral                                            |                      |                 | Not Reported     |                |
| <u>FDA Received Date</u>                                                      | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 23-Sep-2015                                                                   | 11325311               | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000078484                               |                      | 49 YR           | Female           | FRA            |
| <u>Preferred Term</u>                                                         | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                           |                     |   |         |                         |              |
|---------------------------------------------------------------------------|---------------------|---|---------|-------------------------|--------------|
| Multiple Organ Dysfunction Syndrome; Overdose; Toxicity To Various Agents | Escitalopram        | S | Oral    | 15 Mg                   | Forest       |
|                                                                           | Escitalopram        | S | Oral    | Overdose: Dose Unknown. | Forest       |
|                                                                           | Propranolol         | S | Oral    | 40 Mg                   | Not Reported |
|                                                                           | Propranolol         | S | Oral    | Overdose: Dose Unknown. | Not Reported |
|                                                                           | Temesta (Lorazepam) | S | Oral    | 7.5 Mg                  | Not Reported |
|                                                                           | Temesta (Lorazepam) | S | Oral    | Overdose: Dose Unknown. | Not Reported |
|                                                                           | Atarax              | S | Oral    |                         | Not Reported |
|                                                                           | Atarax              | S | Oral    | Overdose: Dose Unknown. | Not Reported |
|                                                                           | Risperdal           | S | Oral    |                         | Not Reported |
|                                                                           | Risperdal           | S | Oral    | Overdose: Dose Unknown. | Not Reported |
|                                                                           | Mogadon             | C | Unknown | 1 Dosage Form           | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Sep-2015              | 11449057      | EXPEDITED (15-DAY) |                    |                 | DE-FRI-1000079315    |                      | 60 YR      | Female     | DEU            |

| <u>Preferred Term</u>                                                                                                                                        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Asthenia; Blood Thyroid Stimulating Hormone Increased; Diarrhoea; Dizziness; Drug Interaction; Dysstasia; Fatigue; Gait Disturbance; Nausea; Tremor | Escitalopram   |              |            | S           | Unknown      | 5 Milligram        |                 | Forest       |
|                                                                                                                                                              | Escitalopram   |              |            | S           | Unknown      | 5 Milligram        |                 | Forest       |
|                                                                                                                                                              | Euthyrox       |              |            | S           | Unknown      | 50 Microgram       |                 | Not Reported |
|                                                                                                                                                              | Euthyrox       |              |            | S           | Unknown      | 25 Microgram       |                 | Not Reported |
|                                                                                                                                                              | Metoprolol     |              |            | C           | Oral         | 50 Milligram       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 23-Sep-2015              | 11538773      | EXPEDITED (15-DAY) |                    | CA, DE, OT      | GB-CIPLA LTD.-2015GB07526 |                      |            | Unknown    | GBR            |

| <u>Preferred Term</u>              | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------|----------------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Congenital Pulmonary Valve Atresia | Citalopram           |              |            | S           | Transplacental | 20 Mg, Qd          |                 | Cipla        |
|                                    | Escitalopram Oxalate |              |            | S           | Transplacental | 20 Mg, Qd          |                 | Not Reported |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| 23-Sep-2015                                                                                                               | 11539169                 | EXPEDITED (15-DAY) |                    | OT              | US-ACCORD-033930           |                      | 21 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                     | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Acne Cystic; Aggression;<br>Crying; Depression; Fear;<br>Hypokinesia; Panic Attack;<br>Restlessness; Suicidal<br>Ideation | Escitalopram Accord      |                    |                    | S               | Oral                       |                      |                 | Accord       |                |
| <u>FDA Received Date</u>                                                                                                  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Sep-2015                                                                                                               | 11540033                 | EXPEDITED (15-DAY) |                    | LT              | FR-FRI-1000079640          |                      | 71 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                                     | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Haemorrhagic Stroke;<br>Overdose                                                                                          | Escitalopram             |                    |                    | S               | Unknown                    | 20 Mg                |                 | Forest       |                |
|                                                                                                                           | Kardegic                 |                    |                    | S               | Oral                       | 75 Mg                |                 | Not Reported |                |
|                                                                                                                           | Tahor                    |                    |                    | C               | Unknown                    |                      |                 | Not Reported |                |
|                                                                                                                           | Azantac                  |                    |                    | C               | Unknown                    |                      |                 | Not Reported |                |
|                                                                                                                           | Bi-Tildiem               |                    |                    | C               | Unknown                    | 180 Mg               |                 | Not Reported |                |
|                                                                                                                           | Zestril                  |                    |                    | C               | Unknown                    |                      |                 | Not Reported |                |
|                                                                                                                           | Lioresal                 |                    |                    | C               | Unknown                    |                      |                 | Not Reported |                |
|                                                                                                                           | Keppra                   |                    |                    | C               | Unknown                    | 1000 Mg              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Sep-2015                                                                                                               | 11541221                 | NON-EXPEDITED      |                    |                 | US-APOTEX-<br>2015AP005186 |                      | 48 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                     | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Adverse Event; Drug<br>Ineffective; Treatment<br>Failure; Vomiting                                                        | Paroxetine Hydrochloride |                    |                    | S               | Unknown                    | 10 Mg, Daily         |                 | Apotex       |                |
|                                                                                                                           | Sertraline Hydrochloride |                    |                    | S               | Unknown                    | 10 Mg, Daily         |                 | Apotex       |                |
|                                                                                                                           | Mirtazapine              |                    |                    | S               | Unknown                    | 22.5 Mg, Daily       |                 | Apotex       |                |
|                                                                                                                           | Citalopram               |                    |                    | S               | Unknown                    |                      |                 | Apotex       |                |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                       |   |         |               |              |
|-----------------------|---|---------|---------------|--------------|
| Venlafaxine           | S | Unknown | At Low Dose   | Not Reported |
| Escitalopram Oxalate  | S | Unknown | 2.5 Mg, Daily | Apotex       |
| Doxepin               | S | Unknown |               | Not Reported |
| Fluoxetine /00724402/ | C | Unknown | 10 Mg, Daily  | Not Reported |
| Diazepam              | C | Unknown | 0.5 Mg, Daily | Not Reported |

| <u>FDA Received Date</u>                                                  | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 23-Sep-2015                                                               | 11544411       | DIRECT           |                    |                 |                      |                      | 72 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                     | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anger; Anxiety;<br>Depression; Mood Swings;<br>Product Substitution Issue | Escitalopram   |                  |                    | S               | Oral                 | 1 Pill               |                 | Torrent      |                |
|                                                                           | Clopidogrel    |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                           | Microzide      |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                           | Atorvastatin   |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                           | Vitamin D Nos  |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                           | Vitamin C      |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                           | Beta Prostate  |                  |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| 24-Sep-2015              | 11213840       | EXPEDITED (15-DAY) |                    | HO              | FR-ASTRAZENECA-2015SE60505 |                      | 74 YR           | Female       | FRA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyponatraemia            | Inexium        |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                          | Seroplex       |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                          | Kardegic       |                    |                    | C               | Oral                       |                      |                 | Not Reported |                |
|                          | Seresta        |                    |                    | C               | Oral                       |                      |                 | Not Reported |                |
|                          | Sinemet        |                    |                    | C               | Oral                       |                      |                 | Not Reported |                |
|                          | Tahor          |                    |                    | C               | Oral                       |                      |                 | Not Reported |                |
|                          | Zopiclone      |                    |                    | C               | Oral                       |                      |                 | Not Reported |                |
|                          | Tardyferon     |                    |                    | C               | Oral                       |                      |                 | Not Reported |                |
|                          | Uvedose        |                    |                    | C               | Oral                       |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                                                |                 |                    |                    |                 |                              |                                     |                 |            |                |
|--------------------------------------------------------------------------------|-----------------|--------------------|--------------------|-----------------|------------------------------|-------------------------------------|-----------------|------------|----------------|
| Doliprane                                                                      |                 |                    | C                  | Oral            |                              | Not Reported                        |                 |            |                |
| <u>FDA Received Date</u>                                                       | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 24-Sep-2015                                                                    | 11397335        | EXPEDITED (15-DAY) |                    | OT              | DE-ABBVIE-15P-062-1445305-00 |                                     | 77 YR           | Male       | DEU            |
| <u>Preferred Term</u>                                                          | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u> |                |
| Hernia; Hyperkinesia                                                           | Duodopa         |                    |                    | S               | Other                        | Md 5.0 MI, Crd 2.3 MI/Hr, Ed 1.0 MI |                 |            | Not Reported   |
|                                                                                | Escitalopram    |                    |                    | S               | Unknown                      |                                     |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                                       | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 24-Sep-2015                                                                    | 11544256        | EXPEDITED (15-DAY) |                    | HO              | IT-ACCORD-033792             |                                     | 55 YR           | Female     | ITA            |
| <u>Preferred Term</u>                                                          | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u> |                |
| Bradycardia; Drug Abuse; Oxygen Saturation Decreased                           | Escitalopram    |                    |                    | S               | Oral                         |                                     |                 |            | Accord         |
|                                                                                | Cardioaspirin   |                    |                    | C               |                              |                                     |                 |            | Not Reported   |
|                                                                                | En              |                    |                    | C               |                              |                                     |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                                       | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 24-Sep-2015                                                                    | 11544586        | EXPEDITED (15-DAY) |                    | HO              | CH-FRI-1000079584            |                                     | 83 YR           | Female     | CHE            |
| <u>Preferred Term</u>                                                          | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u> |                |
| Blood Loss Anaemia; Gastric Ulcer; Melaena; Upper Gastrointestinal Haemorrhage | Escitalopram    |                    |                    | S               | Oral                         | 15 Mg                               |                 |            | Forest         |
|                                                                                | Voltaren Retard |                    |                    | S               | Oral                         | 100 Mg                              |                 |            | Not Reported   |
|                                                                                | Aspirin Cardio  |                    |                    | S               | Oral                         | 100 Mg                              |                 |            | Not Reported   |
|                                                                                | Pantozol        |                    |                    | C               | Unknown                      | 20 Mg                               |                 |            | Not Reported   |
|                                                                                | Aricept         |                    |                    | C               | Unknown                      |                                     |                 |            | Not Reported   |
|                                                                                | Haldol          |                    |                    | C               | Unknown                      |                                     |                 |            | Not Reported   |
|                                                                                | Lyrica          |                    |                    | C               | Unknown                      |                                     |                 |            | Not Reported   |
|                                                                                | Remeron         |                    |                    | C               | Unknown                      |                                     |                 |            | Not Reported   |
|                                                                                | Seroquel        |                    |                    | C               | Unknown                      |                                     |                 |            | Not Reported   |

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|               |   |         |              |
|---------------|---|---------|--------------|
| Dafalgan      | C | Unknown | Not Reported |
| Oxycontin     | C | Unknown | Not Reported |
| Pradif Retard | C | Unknown | Not Reported |
| Torem         | C | Unknown | Not Reported |
| Vi De3        | C | Unknown | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Sep-2015              | 11544771      | EXPEDITED (15-DAY) |                    | OT              | US-FRI-1000079618    |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Colon Cancer          | Lexapro        |              |            | S           |              |                    |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-------------------------|----------------------|------------|------------|----------------|
| 24-Sep-2015              | 11545198      | NON-EXPEDITED    |                    |                 | US-TAKEDA-2015TUS012847 |                      | 56 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                          | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Chills; Diarrhoea; Headache; Labelled Drug-Drug Interaction Medication Error; Nausea; Vomiting | Contrave                 |              |            | S           | Oral         | 8mg/90mg, Qd       |                 | Takeda       |
|                                                                                                | Escitalopram             |              |            | S           | Oral         | 20 Mg, Unk         |                 | Not Reported |
|                                                                                                | Pantoprazole             |              |            | C           | Oral         | 40 Mg, Unk         |                 | Not Reported |
|                                                                                                | Singulair                |              |            | C           | Oral         | 10 Mg, Unk         |                 | Not Reported |
|                                                                                                | Simvastatin              |              |            | C           | Oral         | 20 Mg, Unk         |                 | Not Reported |
|                                                                                                | Fluticasone W/Salmeterol |              |            | C           | Other        | Unk                |                 | Not Reported |
|                                                                                                | Lisinopril/Hctz          |              |            | C           | Oral         | Unk                |                 | Not Reported |
|                                                                                                | Metformin                |              |            | C           | Oral         | 1000 Mg, Unk       |                 | Not Reported |
|                                                                                                | Liraglutide              |              |            | C           | Subcutaneous | 1.2 Mg, Unk        |                 | Not Reported |
|                                                                                                | Amaryl                   |              |            | C           | Oral         | 2 Mg, Unk          |                 | Not Reported |
|                                                                                                | Albuterol /00139501/     |              |            | C           | Other        | Unk                |                 | Not Reported |
|                                                                                                | Mvi /07504101/           |              |            | C           | Oral         | Unk                |                 | Not Reported |
|                                                                                                | B12 /00056201/           |              |            | C           | Oral         | Unk                |                 | Not Reported |
|                                                                                                | Vitamin D3               |              |            | C           | Oral         | Unk                |                 | Not Reported |

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| <u>FDA Received Date</u>                                             | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
| 24-Sep-2015                                                          | 11547203             | EXPEDITED (15-DAY) |                    | CA, DE, OT      | GB-MYLANLABS-2015M1031304 |                      |                 | Unknown      | GBR            |
| <u>Preferred Term</u>                                                | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Congenital Pulmonary Valve Atresia; Foetal Exposure During Pregnancy | Citalopram           |                    |                    | S               | Transplacental            | 20 Mg, 1x/Day        |                 | Not Reported |                |
|                                                                      | Escitalopram Oxalate |                    |                    | S               | Transplacental            | 20 Mg, 1x/Day        |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                     | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|----------------------|------------------------------------------------|-----------------|--------------|----------------|
| 24-Sep-2015                                                                                  | 11548647                      | EXPEDITED (15-DAY) |                    | DE, HO          | CH-FRI-1000079686    |                                                | 87 YR           | Male         | CHE            |
| <u>Preferred Term</u>                                                                        | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                             | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated; Delirium; International Normalised Ratio Increased; Subdural Haematoma | Escitalopram                  |                    |                    | S               | Oral                 | Half A Tablet Taken In The Mornings            |                 | Forest       |                |
|                                                                                              | Marcoumar                     |                    |                    | S               | Oral                 |                                                |                 | Not Reported |                |
|                                                                                              | Mirtazapin                    |                    |                    | C               | Oral                 | 1 Dosage Form                                  |                 | Not Reported |                |
|                                                                                              | Pantoprazol                   |                    |                    | C               | Unknown              |                                                |                 | Not Reported |                |
|                                                                                              | Amlodipin                     |                    |                    | C               | Unknown              |                                                |                 | Not Reported |                |
|                                                                                              | Bilol                         |                    |                    | C               | Unknown              |                                                |                 | Not Reported |                |
|                                                                                              | Eltroxin                      |                    |                    | C               | Unknown              |                                                |                 | Not Reported |                |
|                                                                                              | Atorvastatin                  |                    |                    | C               | Unknown              |                                                |                 | Not Reported |                |
|                                                                                              | Novalgine (Metamizole Sodium) |                    |                    | C               | Unknown              |                                                |                 | Not Reported |                |
|                                                                                              | Dipiperon                     |                    |                    | C               | Unknown              |                                                |                 | Not Reported |                |
|                                                                                              | Torem                         |                    |                    | C               | Unknown              |                                                |                 | Not Reported |                |
|                                                                                              | Tramadol                      |                    |                    | C               | Unknown              |                                                |                 | Not Reported |                |
|                                                                                              | Haldol                        |                    |                    | C               | Unknown              |                                                |                 | Not Reported |                |
|                                                                                              | Vi De3                        |                    |                    | C               | Unknown              |                                                |                 | Not Reported |                |
|                                                                                              | Fentanyl                      |                    |                    | C               | Unknown              | 25mg Patch, A New Patch Applied Every 72 Hours |                 | Not Reported |                |
|                                                                                              | Candesartan                   |                    |                    | C               | Unknown              |                                                |                 | Not Reported |                |

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| Solmucaim                                                                                           |                                        |                    | C                  |                 | Unknown                    |                      |                 | Not Reported |                |
|-----------------------------------------------------------------------------------------------------|----------------------------------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| <u>FDA Received Date</u>                                                                            | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Sep-2015                                                                                         | 9924619                                | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2014053762   |                      | 38 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                               | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypersensitivity                                                                                    | Chantix                                |                    |                    | S               |                            | Unk                  |                 | Pfizer       |                |
|                                                                                                     | Pristiq                                |                    |                    | S               |                            | Unk                  |                 | Pfizer       |                |
|                                                                                                     | Wellbutrin                             |                    |                    | S               |                            | Unk                  |                 | Not Reported |                |
|                                                                                                     | Keflex                                 |                    |                    | S               |                            | Unk                  |                 | Not Reported |                |
|                                                                                                     | Lexapro                                |                    |                    | S               |                            | Unk                  |                 | Not Reported |                |
|                                                                                                     | Penicillin Vk                          |                    |                    | S               |                            | Unk                  |                 | Not Reported |                |
|                                                                                                     | Bactrim                                |                    |                    | S               |                            | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                            | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Sep-2015                                                                                         | 11553207                               | EXPEDITED (15-DAY) |                    | HO              | FR-ASTRAZENECA-2015SE91859 |                      | 51 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                               | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Ascites; Blood Pressure Decreased; Face Injury; Fall; Hepatic Cirrhosis; Hyponatraemia; Limb Injury | Inexium                                |                    |                    | S               | Oral                       |                      |                 | Astrazeneca  |                |
|                                                                                                     | Inexium                                |                    |                    | S               | Oral                       |                      |                 | Astrazeneca  |                |
|                                                                                                     | Seroplex                               |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                            | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Sep-2015                                                                                         | 11567639                               | EXPEDITED (15-DAY) | Y                  | OT              | 2015HINLIT0690             |                      | 70 YR           | Female       | TUR            |
| <u>Preferred Term</u>                                                                               | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiomyopathy; Dizziness; Hypotension; Presyncope; Sinus Bradycardia                               | Escitalopram (Escitalopram)<br>Unknown |                    |                    | S               |                            |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                              | <u>Case #</u>                                                                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------|---------------------------------------------------------------------------------|--------------------|--------------------|-----------------|---------------------------------------|----------------------|-----------------|--------------|----------------|
| 28-Sep-2015                                                                           | 10933796                                                                        | EXPEDITED (15-DAY) |                    | OT              | IT-MYLANLABS-2015M1007993             |                      |                 | Unknown      | ITA            |
| <u>Preferred Term</u>                                                                 | <u>Product</u>                                                                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Electrocardiogram Qt Prolonged; Labelled Drug-Drug Interaction Medication Error       | Escitalopram Mylan Pharma                                                       |                    |                    | S               |                                       | 20 Mg Daily          |                 | Mylan        |                |
|                                                                                       | Anafranil                                                                       |                    |                    | S               | Oral                                  | 112.5 Mg Daily       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                              | <u>Case #</u>                                                                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Sep-2015                                                                           | 11521908                                                                        | EXPEDITED (15-DAY) |                    | HO, LT, OT      | FR-PFIZER INC-2015311876              |                      | 53 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                 | <u>Product</u>                                                                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anaphylactic Shock; Hilar Lymphadenopathy; Lung Disorder; Lymphadenopathy Mediastinal | Atenolol                                                                        |                    |                    | S               |                                       | Unk                  |                 | Pfizer       |                |
|                                                                                       | Diprivan                                                                        |                    |                    | S               | Intravenous (not otherwise specified) | Unk                  |                 | Not Reported |                |
|                                                                                       | Esmeron                                                                         |                    |                    | S               |                                       | Unk                  |                 | Not Reported |                |
|                                                                                       | Sufentanil                                                                      |                    |                    | S               |                                       | Unk                  |                 | Not Reported |                |
|                                                                                       | Hypnovel                                                                        |                    |                    | S               |                                       | Unk                  |                 | Not Reported |                |
|                                                                                       | Seroplex                                                                        |                    |                    | S               | Unknown                               | Unk                  |                 | Not Reported |                |
|                                                                                       | Inexium                                                                         |                    |                    | C               |                                       | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                              | <u>Case #</u>                                                                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Sep-2015                                                                           | 11558620                                                                        | EXPEDITED (15-DAY) |                    | HO              | IT-AUROBINDO-AUR-APL-2015-05280       |                      | 66 YR           | Male         | ITA            |
| <u>Preferred Term</u>                                                                 | <u>Product</u>                                                                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Drug Withdrawal Syndrome; Hallucination, Visual                           | Escitalopram                                                                    |                    |                    | S               | Oral                                  | 7 Gtt, Daily         |                 | Aurobindo    |                |
|                                                                                       | Escitalopram                                                                    |                    |                    | S               | Oral                                  | 7 Gtt Daily          |                 | Aurobindo    |                |
|                                                                                       | Mirtazapine Aurobindo Pharma Italia 30mg Film-Coated Tablets Control /00273201/ |                    |                    | S               | Oral                                  | 30 Mg, Daily         |                 | Aurobindo    |                |
|                                                                                       |                                                                                 |                    |                    | S               | Oral                                  | 1 Df Daily           |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

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| <u>FDA Received Date</u>                                                                                                   | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| 28-Sep-2015                                                                                                                | 11559736                | EXPEDITED (15-DAY) |                    | OT              | PHHY2015US113970           |                      | 90 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                      | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Orthostatic Hypotension                                                                                                    | Clopidogrel             |                    |                    | S               | Unknown                    | 75 Mg, Qod           |                 | Not Reported |                |
|                                                                                                                            | Escitalopram            |                    |                    | S               | Unknown                    | 10 Mg, Qd            |                 | Not Reported |                |
|                                                                                                                            | Memantine Hydrochloride |                    |                    | S               | Unknown                    | 10 Mg, Qd            |                 | Not Reported |                |
|                                                                                                                            | Acetylsalicylic Acid    |                    | Y                  | S               | Unknown                    | 81 Mg, Qd            |                 | Novartis     |                |
|                                                                                                                            | Seroquel                |                    |                    | S               | Unknown                    | 75 Mg, Qod           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                   | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Sep-2015                                                                                                                | 11561275                | EXPEDITED (15-DAY) |                    | DS              | LT-JNJFOC-20150913521      |                      | 21 YR           | Male         | LTU            |
| <u>Preferred Term</u>                                                                                                      | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dystonia; Gynaecomastia; Neuropathy Peripheral; Product Use In Unapproved Indication; Sexual Dysfunction; Weight Increased | Risperidone             |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                                                                                            | Parkopan                |                    |                    | S               | Unknown                    |                      |                 | Not Reported |                |
|                                                                                                                            | Ciprallex               |                    |                    | S               | Unknown                    |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                   | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Sep-2015                                                                                                                | 11555478                | EXPEDITED (15-DAY) |                    | HO, LT          | CH-ASTRAZENECA-2015SE91810 |                      | 32 YR           | Female       | CHE            |
| <u>Preferred Term</u>                                                                                                      | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Acute Hepatic Failure; Colitis; Disseminated Intravascular Coagulation; Hepatic Necrosis; Jaundice; Klebsiella Sepsis      | Quetiapine              |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                                                                                            | Quetiapine              |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                                                                                            | Zyprexa                 |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                                                                                            | Ciprallex               |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                                                                                            | Euthyrox                |                    |                    | C               | Oral                       |                      |                 | Not Reported |                |



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| <u>FDA Received Date</u>                                                                                                                                                                                                   | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|------------------------------------|-----------------|------------------|----------------|
| 29-Sep-2015                                                                                                                                                                                                                | 11568109                  | EXPEDITED (15-DAY) |                    | HO, LT, OT      | CH-<br>ELI_LILLY_AND_COMP<br>ANY-CH201509008422 |                                    |                 | Female           | CHE            |
| <u>Preferred Term</u>                                                                                                                                                                                                      | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>       |                |
| Acute Hepatic Failure;<br>Ascites; Benign Hepatic<br>Neoplasm; Colitis;<br>Disseminated<br>Intravascular Coagulation;<br>Gastrointestinal Oedema;<br>Hepatic Necrosis;<br>Jaundice; Klebsiella<br>Sepsis; Pleural Effusion | Zyprexa                   |                    |                    | S               | Oral                                            | 2.5 Mg, Qd                         |                 | Eli Lilly And Co |                |
|                                                                                                                                                                                                                            | Quetiapin                 |                    |                    | S               | Oral                                            | 50 Mg, Qd                          |                 | Not Reported     |                |
|                                                                                                                                                                                                                            | Cipralext /01588501/      |                    |                    | S               | Oral                                            | 10 Mg, Qd                          |                 | Not Reported     |                |
|                                                                                                                                                                                                                            | Euthyrox                  |                    |                    | C               | Oral                                            | 50 Ug, Tid                         |                 | Not Reported     |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                   | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 29-Sep-2015                                                                                                                                                                                                                | 11568944                  | EXPEDITED (15-DAY) |                    | HO, OT          | CA-APOTEX-<br>2015AP013094                      |                                    | 31 YR           | Female           | CAN            |
| <u>Preferred Term</u>                                                                                                                                                                                                      | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>       |                |
| Bradycardia; Neutropenia;<br>Pleural Effusion                                                                                                                                                                              | Piperacillin & Tazobactam |                    |                    | S               | Unknown                                         | Unk                                |                 | Hospira          |                |
|                                                                                                                                                                                                                            | Apo-Ciproflox             |                    |                    | S               | Oral                                            | 1000 Mg, Unk                       |                 | Apotex           |                |
|                                                                                                                                                                                                                            | Apo-Ciproflox             |                    |                    | S               | Intravenous (not<br>otherwise specified)        | One Every Three Weeks              |                 | Apotex           |                |
|                                                                                                                                                                                                                            | Avastin /00848101/        |                    |                    | S               | Intravenous (not<br>otherwise specified)        | 15 Mg/Kg, One Every<br>Three Weeks |                 | Not Reported     |                |
|                                                                                                                                                                                                                            | Carboplatin               |                    |                    | S               | Intravenous (not<br>otherwise specified)        | One Every Three Weeks              |                 | Not Reported     |                |
|                                                                                                                                                                                                                            | Cipralext /01588501/      |                    |                    | S               | Unknown                                         | 10 Mg, Qd                          |                 | Not Reported     |                |
|                                                                                                                                                                                                                            | Docetaxel                 |                    |                    | S               | Intravenous (not<br>otherwise specified)        | 75 Mg/M2, Unk                      |                 | Not Reported     |                |
|                                                                                                                                                                                                                            | Docetaxel                 |                    |                    | S               | Intravenous (not<br>otherwise specified)        | 75 Mg/Kg, One Every<br>Three Weeks |                 | Not Reported     |                |
|                                                                                                                                                                                                                            | Morphine                  |                    |                    | S               | Unknown                                         | 2.5 Mg, Q.4h.                      |                 | Not Reported     |                |
|                                                                                                                                                                                                                            | Trastuzumab               |                    |                    | S               | Intravenous (not                                | 8 Mg/Kg, One Every Three           |                 | Not Reported     |                |

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|                    |                      |         |     |
|--------------------|----------------------|---------|-----|
|                    | otherwise specified) | Weeks   |     |
| Tylenol /00020001/ | S                    | Unknown | Unk |
| Tylenol No.1       | S                    | Unknown | Unk |
| Codeine            | C                    | Unknown | Unk |
| Docusate           | C                    | Unknown | Unk |
| Gravol             | C                    | Unknown | Unk |
| Lactulose          | C                    | Oral    | Unk |
| Senna /00142201/   | C                    | Unknown | Unk |
| Trazodone          | C                    | Unknown | Unk |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 29-Sep-2015              | 11569144      | EXPEDITED (15-DAY) |                    | DE, OT          | FR-PFIZER INC-2015316594 |                      | 62 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                                                | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|-------------------------|-----------------|--------------|
| Drug Interaction;<br>Electrocardiogram Qt<br>Prolonged; Product<br>Prescribing Error | Triflucan              |              |            | S           | Buccal       | 200 Mg, 3x/Day          |                 | Pfizer       |
|                                                                                      | Atarax /00058401/      |              |            | S           | Oral         | 25 Mg, 2x/Day As Needed |                 | Not Reported |
|                                                                                      | Seroplex               |              |            | S           | Oral         | 10 Mg, 1x/Day           |                 | Not Reported |
|                                                                                      | Primperan              |              |            | S           | Oral         | 10 Mg, 3x/Day As Needed |                 | Not Reported |
|                                                                                      | Eupantol               |              |            | C           | Oral         | 40 Mg, 2x/Day           |                 | Not Reported |
|                                                                                      | Creon                  |              |            | C           | Oral         | 75000 Iu, 3x/Day        |                 | Not Reported |
|                                                                                      | Allopurinol            |              |            | C           | Oral         | 100 Mg, Alternate Day   |                 | Not Reported |
|                                                                                      | Carbosylane /00814601/ |              |            | C           | Oral         | 1 Df, 3x/Day            |                 | Not Reported |
|                                                                                      | Amlodipine             |              |            | C           | Oral         | 5 Mg, 1x/Day            |                 | Not Reported |
|                                                                                      | Spasfon /00765801/     |              |            | C           | Oral         | 2 Df, 3x/Day            |                 | Not Reported |
|                                                                                      | Oxycontin Lp           |              |            | C           | Oral         | 10 Mg, 2x/Day           |                 | Not Reported |
|                                                                                      | Oxynorm                |              |            | C           | Oral         | 5 Mg, 6x/Day As Needed  |                 | Not Reported |
|                                                                                      | Smecta /07327601/      |              |            | C           | Oral         | 1 Df, 3x/Day As Needed  |                 | Not Reported |
|                                                                                      | Imodium Enfants        |              |            | C           | Oral         | 2 Mg, 3x/Day As Needed  |                 | Not Reported |
|                                                                                      | Doliprane              |              |            | C           | Oral         | 1 G, 3x/Day             |                 | Not Reported |

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Augmentin /00756801/

C

Intravenous (not otherwise specified)

1 G, Single

Not Reported

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Sep-2015              | 11570189      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000079788    |                      | 99 YR      | Female     | FRA            |

| <u>Preferred Term</u>         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction;<br>Hyphaema | Escitalopram   |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                               | Kardegic       |              |            | S           | Oral         | 75 Mg              |                 | Not Reported |
|                               | Zolpidem       |              |            | C           | Unknown      |                    |                 | Not Reported |
|                               | Tahor          |              |            | C           | Unknown      |                    |                 | Not Reported |
|                               | Macrogol       |              |            | C           | Unknown      |                    |                 | Not Reported |
|                               | Heptamyl       |              |            | C           | Unknown      |                    |                 | Not Reported |
|                               | Educyl         |              |            | C           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Sep-2015              | 8771784       | EXPEDITED (15-DAY) |                    | OT              | DE-ROCHE-611106      |                      |            | Unknown    | DEU            |

| <u>Preferred Term</u>                                                                                                            | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                           | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|----------------------------------------------|-----------------|--------------|
| Brain Neoplasm; Drug Abuse; Glioblastoma; Intentional Self-Injury; Jaundice; Major Depression; Mania; Renal Failure; Retinopathy | Peg-Interferon Alfa 2a |              |            | S           | Subcutaneous |                                              |                 | Not Reported |
|                                                                                                                                  | Ribavirin              |              |            | S           | Oral         | Tdd: 800 Mg To 1200 Mg                       |                 | Not Reported |
|                                                                                                                                  | Blinded Escitalopram   |              |            | S           | Unknown      | Started 2 Weeks Prior To Hepatitis C Therapy |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Sep-2015              | 10828641      | EXPEDITED (15-DAY) |                    | HO              | US-ROCHE-1539040     |                      | 58 YR      | Female     | USA            |

| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cerebrovascular Accident | Clonazepam     |              |            | S           | Oral         |                    |                 | Not Reported |
|                          | Escitalopram   |              |            | S           | Oral         |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                        | Tramadol                                             | S                  | Oral               | As Needed       |                                                              |                                  |                 | Not Reported |                |
|----------------------------------------------------------------------------------------|------------------------------------------------------|--------------------|--------------------|-----------------|--------------------------------------------------------------|----------------------------------|-----------------|--------------|----------------|
|                                                                                        | Risperidone                                          | S                  | Oral               |                 |                                                              |                                  |                 | Not Reported |                |
|                                                                                        | Simvastatin                                          | S                  | Oral               |                 |                                                              |                                  |                 | Not Reported |                |
|                                                                                        | Blinded Bococizumab                                  | S                  | Subcutaneous       |                 |                                                              |                                  |                 | Not Reported |                |
|                                                                                        | Ambien                                               | C                  |                    |                 |                                                              |                                  |                 | Not Reported |                |
|                                                                                        | Proair Hfa                                           | C                  |                    |                 |                                                              |                                  |                 | Not Reported |                |
|                                                                                        | Vitamin D2                                           | C                  |                    |                 |                                                              |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                               | <u>Case #</u>                                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                         | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Sep-2015                                                                            | 11575184                                             | EXPEDITED (15-DAY) |                    | OT              | CA-SUN<br>PHARMACEUTICAL<br>INDUSTRIES LTD-<br>2015US-103831 |                                  |                 | Female       | CAN            |
| <u>Preferred Term</u>                                                                  | <u>Product</u>                                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                 | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Exposure Via Breast Milk;<br>Seizure; Therapeutic<br>Agent Urine Positive;<br>Vomiting | Escitalopram                                         |                    |                    | S               | Transmammary                                                 | Unk, Daily For Several<br>Months |                 |              | Not Reported   |
|                                                                                        | Bupropion                                            |                    |                    | S               | Transmammary                                                 | Unk                              |                 |              | Sun            |
| <u>FDA Received Date</u>                                                               | <u>Case #</u>                                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                         | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Sep-2015                                                                            | 11575707                                             | NON-EXPEDITED      |                    |                 | US-TORRENT-<br>00000947                                      |                                  | 75 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                  | <u>Product</u>                                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                 | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective; Product<br>Substitution Issue                                        | Escitalopram Oxalate-<br>Escitalopram Oxalate Tablet |                    |                    | S               |                                                              | Twice A Day                      |                 |              | Torrent        |
| <u>FDA Received Date</u>                                                               | <u>Case #</u>                                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                         | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Sep-2015                                                                            | 11575710                                             | NON-EXPEDITED      |                    |                 | US-TORRENT-<br>00000956                                      |                                  |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                  | <u>Product</u>                                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                 | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Alopecia; Product<br>Substitution Issue                                                | Escitalopram Oxalate-<br>Escitalopram Oxalate Tablet |                    |                    | S               |                                                              |                                  |                 |              | Torrent        |
|                                                                                        | Allegra                                              |                    |                    | C               |                                                              |                                  |                 |              | Unknown        |
|                                                                                        | Zegerid                                              |                    |                    | C               |                                                              |                                  |                 |              | Bayer          |
|                                                                                        | Vitamin D Nos                                        |                    |                    | C               |                                                              |                                  |                 |              | Unknown        |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                             |                                                      |                    |                    |                 |                      |                      |                 |              |                |
|-------------------------------------------------------------------------------------------------------------|------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Melatonin                                                                                                   |                                                      |                    | C                  |                 |                      | Unknown              |                 |              |                |
| <u>FDA Received Date</u>                                                                                    | <u>Case #</u>                                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Sep-2015                                                                                                 | 11575727                                             | NON-EXPEDITED      |                    |                 | US-TORRENT-00000962  |                      |                 | Male         | USA            |
| <u>Preferred Term</u>                                                                                       | <u>Product</u>                                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Disturbance In Attention;<br>Product Substitution Issue;<br>Withdrawal Syndrome                             | Escitalopram Oxalate-<br>Escitalopram Oxalate Tablet |                    |                    | S               |                      |                      |                 | Torrent      |                |
| <u>FDA Received Date</u>                                                                                    | <u>Case #</u>                                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Sep-2015                                                                                                 | 11576978                                             | EXPEDITED (15-DAY) |                    | DS, OT          | NO-FRI-1000079838    |                      | 25 YR           | Female       | NOR            |
| <u>Preferred Term</u>                                                                                       | <u>Product</u>                                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Drug<br>Withdrawal Syndrome;                                                                     | Escitalopram                                         |                    |                    | S               | Unknown              | 10 Mg                |                 | Forest       |                |
| Headache; Hypoacusis;<br>Nausea; Panic Attack;<br>Paraesthesia; Tinnitus;<br>Visual Impairment;<br>Vomiting | Escitalopram                                         |                    |                    | S               | Unknown              | 5 Mg                 |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                    | <u>Case #</u>                                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Sep-2015                                                                                                 | 11578211                                             | EXPEDITED (15-DAY) |                    | OT              | IT-FRI-1000079779    |                      | 31 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                                                       | <u>Product</u>                                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Balance Disorder;<br>Paraesthesia; Vertigo;<br>Withdrawal Syndrome                                          | Escitalopram                                         |                    |                    | S               | Oral                 |                      |                 | Forest       |                |
|                                                                                                             | Escitalopram                                         |                    |                    | S               | Oral                 |                      |                 | Forest       |                |
|                                                                                                             | Lorazepam                                            |                    |                    | C               | Unknown              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                    | <u>Case #</u>                                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Sep-2015                                                                                                 | 11583253                                             | DIRECT             |                    | OT              |                      |                      | 48 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                       | <u>Product</u>                                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                            |                          |   |      |        |      |
|------------------------------------------------------------|--------------------------|---|------|--------|------|
| Drug Ineffective; Memory Impairment; Product Quality Issue | Escitalopram 10 Mg Teva  | S | Oral | 1 Pill | Teva |
|                                                            | Water Pill               | C |      |        |      |
|                                                            | High Blood Pressure Pill | C |      |        |      |
|                                                            | Diabetes Pill            | C |      |        |      |
|                                                            | Iron                     | C |      |        |      |
|                                                            | Vitamin D Nos            | C |      |        |      |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Oct-2015              | 11581793      | NON-EXPEDITED    |                    |                 | US-ROCHE-679322      |                      | 42 YR      | Female     | USA            |

| <u>Preferred Term</u>                                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cough; Decreased Appetite; Dyspepsia; Dyspnoea; Haemoptysis | Pegasys        |              |            | S           | Unknown      | Form: Pfs          |                 | Not Reported |
|                                                             | Ribavirin      |              |            | S           | Unknown      | Divided Doses      |                 | Not Reported |
|                                                             | Lexapro        |              |            | S           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------------------------|----------------------|------------|------------|----------------|
| 01-Oct-2015              | 11582578      | NON-EXPEDITED    |                    |                 | TR-LUPIN<br>PHARMACEUTICALS<br>INC.-2015-02429 |                      | 43 YR      | Female     | TUR            |

| <u>Preferred Term</u>           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Bruxism; Restless Legs Syndrome | Fluoxetine     |              |            | S           | Unknown      | 20 Mg              |                 | Not Reported |
|                                 | Citalopram     |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                 | Escitalopram   |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                 | Gabapentin     |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                 | Gabapentin     |              |            | C           | Unknown      | 150 Mg             |                 | Not Reported |
|                                 | Gabapentin     |              |            | C           | Unknown      | 300 Mg             |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------------------------|----------------------|------------|------------|----------------|
| 01-Oct-2015              | 11582632      | NON-EXPEDITED    |                    | HO              | TR-LUPIN<br>PHARMACEUTICALS<br>INC.-2015-02489 |                      | 65 YR      | Male       | TUR            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Bradycardia;          | Escitalopram   |              |            | S           | Unknown      | 10mg               |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Electrocardiogram Qt  
Prolonged

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 01-Oct-2015              | 11582867       | NON-EXPEDITED    |                    |                 | TR-LUPIN<br>PHARMACEUTICALS<br>INC.-2015-02500 |                      | 75 YR           | Female       | TUR            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bradycardia              | Escitalopram   |                  |                    | S               | Unknown                                        | 5mg                  |                 | Not Reported |                |
|                          | Escitalopram   |                  |                    | S               |                                                |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>        | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------|----------------|------------------|--------------------|-----------------|------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 01-Oct-2015                     | 11582869       | NON-EXPEDITED    |                    | HO              | KR-LUPIN<br>PHARMACEUTICALS<br>INC.-2015-02524 |                      | 56 YR           | Female       | KOR            |
| <u>Preferred Term</u>           | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dystonia; Tardive<br>Dyskinesia | Escitalopram   |                  |                    | S               | Unknown                                        | 5 Mg/ Day            |                 | Not Reported |                |
|                                 | Amitriptyline  |                  |                    | S               | Unknown                                        | 10 Mg /Day           |                 | Not Reported |                |
|                                 | Amitriptyline  |                  |                    | S               | Unknown                                        | 10 Mg /Day           |                 | Not Reported |                |
|                                 | Trazodone      |                  |                    | S               | Unknown                                        | 25 Mg /Day           |                 | Not Reported |                |
|                                 | Trazodone      |                  |                    | S               | Unknown                                        | 25 Mg /Day           |                 | Not Reported |                |
|                                 | Clonazepam     |                  |                    | S               | Unknown                                        | 1.5 Mg /Day          |                 | Not Reported |                |

| <u>FDA Received Date</u>       | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------|----------------|------------------|--------------------|-----------------|--------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 01-Oct-2015                    | 11582873       | NON-EXPEDITED    |                    |                 | IN-LUPIN<br>PHARMACEUTICALS<br>INC.-E2B_00003916 |                      | 45 YR           | Female       | IND            |
| <u>Preferred Term</u>          | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                     | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Insomnia; Muscular<br>Weakness | Stalopam 10    |                  |                    | S               | Oral                                             |                      |                 | Not Reported |                |
|                                | Lelock Dsr     |                  |                    | C               | Oral                                             |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>        | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-----------------------------|----------------------|------------|------------|----------------|
| 01-Oct-2015              | 11582874      | NON-EXPEDITED    |                    |                 | US-LUPIN<br>PHARMACEUTICALS |                      | 22 YR      | Female     | USA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

INC.-E2B\_00004042

| <a href="#">Preferred Term</a>                                          | <a href="#">Product</a>                                         | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                          | <a href="#">Dosage Text</a>                                            | <a href="#">Duration</a> | <a href="#">Mfr</a>          |                         |
|-------------------------------------------------------------------------|-----------------------------------------------------------------|---------------------------|-----------------------------|--------------------------|------------------------------------------------|------------------------------------------------------------------------|--------------------------|------------------------------|-------------------------|
| Product Substitution Issue;<br>Pruritus Generalised;<br>Rash; Urticaria | Escitalopram Tablets Usp 20mg<br>Gildess                        |                           |                             | S<br>C                   |                                                |                                                                        |                          | Lupin<br>Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                       | <a href="#">Case #</a>                                          | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>                  | <a href="#">503B Facility</a>                                          | <a href="#">Age</a>      | <a href="#">Sex</a>          | <a href="#">Country</a> |
| 01-Oct-2015                                                             | 11582929                                                        | NON-EXPEDITED             |                             |                          | US-TORRENT-00000958                            |                                                                        |                          | Female                       | USA                     |
| <a href="#">Preferred Term</a>                                          | <a href="#">Product</a>                                         | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                          | <a href="#">Dosage Text</a>                                            | <a href="#">Duration</a> | <a href="#">Mfr</a>          |                         |
| Dizziness; Heart Rate Increased;<br>Hyperventilation                    | Escitalopram Oxalate-<br>Escitalopram Oxalate Tablet<br>Jolessa |                           |                             | S<br>C                   |                                                | Once A Day<br><br>Levonorgestrel 0.15mg<br>And Ethinylestradiol 0.03mg |                          | Torrent<br><br>Unknown       |                         |
| <a href="#">FDA Received Date</a>                                       | <a href="#">Case #</a>                                          | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>                  | <a href="#">503B Facility</a>                                          | <a href="#">Age</a>      | <a href="#">Sex</a>          | <a href="#">Country</a> |
| 01-Oct-2015                                                             | 11583194                                                        | NON-EXPEDITED             |                             |                          | TR-LUPIN<br>PHARMACEUTICALS<br>INC.-2015-02506 |                                                                        | 70 YR                    | Female                       | TUR                     |
| <a href="#">Preferred Term</a>                                          | <a href="#">Product</a>                                         | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                          | <a href="#">Dosage Text</a>                                            | <a href="#">Duration</a> | <a href="#">Mfr</a>          |                         |
| Bradycardia; Dizziness;<br>Hypotension                                  | Escitalopram<br>Escitalopram                                    |                           |                             | S<br>S                   | Unknown<br>Unknown                             | 5mg<br>10mg                                                            |                          | Not Reported<br>Not Reported |                         |
| <a href="#">FDA Received Date</a>                                       | <a href="#">Case #</a>                                          | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>                  | <a href="#">503B Facility</a>                                          | <a href="#">Age</a>      | <a href="#">Sex</a>          | <a href="#">Country</a> |
| 01-Oct-2015                                                             | 11583219                                                        | NON-EXPEDITED             |                             |                          | TR-LUPIN<br>PHARMACEUTICALS<br>INC.-2015-02336 |                                                                        | 18 YR                    | Female                       | TUR                     |
| <a href="#">Preferred Term</a>                                          | <a href="#">Product</a>                                         | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                          | <a href="#">Dosage Text</a>                                            | <a href="#">Duration</a> | <a href="#">Mfr</a>          |                         |
| Pupils Unequal                                                          | Escitalopram<br>Escitalopram                                    |                           |                             | S<br>S                   | Unknown<br>Unknown                             |                                                                        |                          | Not Reported<br>Not Reported |                         |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                      |                |                    |                    |                 |                                                |                                |                 |              |                |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|------------------------------------------------|--------------------------------|-----------------|--------------|----------------|
| Escitalopram                                                                                                                                                                         |                |                    | S                  |                 | Unknown                                        |                                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Oct-2015                                                                                                                                                                          | 11583246       | NON-EXPEDITED      |                    |                 | SG-LUPIN<br>PHARMACEUTICALS<br>INC.-2015-02388 |                                | 66 YR           | Female       | SGP            |
| <u>Preferred Term</u>                                                                                                                                                                | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Mania                                                                                                                                                                                | Escitalopram   |                    |                    | S               | Unknown                                        | 10 Mg                          |                 | Not Reported |                |
|                                                                                                                                                                                      | Escitalopram   |                    |                    | S               | Unknown                                        | 10 Mg                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Oct-2015                                                                                                                                                                          | 11584099       | NON-EXPEDITED      |                    |                 | US-ROCHE-665152                                |                                | 52 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Alopecia; Back Pain;<br>Choking; Depression; Dry<br>Mouth; Dyspepsia;<br>Fatigue; Hair Texture<br>Abnormal; Increased<br>Appetite; Injection Site<br>Erythema; Pruritus;<br>Vomiting | Pegasys        |                    |                    | S               | Subcutaneous                                   | Form:Pre Filled Syringe        |                 | Not Reported |                |
|                                                                                                                                                                                      | Copegus        |                    |                    | S               | Oral                                           | 2 In Morning And 3 At<br>Night |                 | Not Reported |                |
|                                                                                                                                                                                      | Lexapro        |                    |                    | S               | Unknown                                        |                                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Oct-2015                                                                                                                                                                          | 11585500       | EXPEDITED (15-DAY) |                    | OT              | FR-PFIZER INC-<br>2015323159                   |                                | 67 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Heart Valve Incompetence                                                                                                                                                             | Zoloft         |                    |                    | S               | Oral                                           | 1 Df, 1x/Day                   |                 | Pfizer       |                |
|                                                                                                                                                                                      | Effexor        |                    |                    | S               | Oral                                           | 1 Df, 1x/Day                   |                 | Pfizer       |                |
|                                                                                                                                                                                      | Seroplex       |                    |                    | S               | Oral                                           | 1 Df, 1x/Day                   |                 | Not Reported |                |
|                                                                                                                                                                                      | Deroxat        |                    |                    | S               | Oral                                           | 1 Df, 1x/Day                   |                 | Not Reported |                |
|                                                                                                                                                                                      | Cymbalta       |                    |                    | S               | Oral                                           | 30 Mg, 1x/Day                  |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                      | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                                                                                            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------|---------------------|--------------------|--------------------|-----------------|------------------------------|-----------------------------------------------------------------------------------------------------------------|-----------------|--------------|----------------|
| 01-Oct-2015                                                                                   | 11585713            | EXPEDITED (15-DAY) |                    | DS              | LT-FRI-1000079830            |                                                                                                                 | 21 YR           | Male         | LTU            |
| <u>Preferred Term</u>                                                                         | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                                                                                              | <u>Duration</u> | <u>Mfr</u>   |                |
| Dystonia; Gynaecomastia;<br>Neuropathy Peripheral;<br>Sexual Dysfunction;<br>Weight Increased | Escitalopram        |                    |                    | S               | Oral                         | 10 Mg                                                                                                           |                 | Forest       |                |
|                                                                                               | Risperidone         |                    |                    | S               | Unknown                      | 3 Mg                                                                                                            |                 | Not Reported |                |
|                                                                                               | Parkopan            |                    |                    | S               | Oral                         | 2 Mg                                                                                                            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                      | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                                                                                            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Oct-2015                                                                                   | 11223381            | NON-EXPEDITED      |                    |                 | US-ACCORD-030696             |                                                                                                                 | 64 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                         | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                                                                                              | <u>Duration</u> | <u>Mfr</u>   |                |
| Appetite Disorder; Drug<br>Ineffective                                                        | Escitalopram        |                    |                    | S               |                              | Strength: 5 Mg, 10<br>Mg,15mg,20 Mg, Initially<br>Received 5 Mg Daily For 2<br>Weeks, Then 10mg For 2<br>Weeks. |                 | Accord       |                |
|                                                                                               | Klonopin            |                    |                    | C               |                              |                                                                                                                 |                 | Not Reported |                |
|                                                                                               | Xanax               |                    |                    | C               |                              | 0.25 Mg Prn                                                                                                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                      | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                                                                                            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Oct-2015                                                                                   | 11471806            | NON-EXPEDITED      |                    | OT              | US-AMGEN-<br>USASP2015090677 |                                                                                                                 | 52 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                         | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                                                                                              | <u>Duration</u> | <u>Mfr</u>   |                |
| Bladder Disorder; Colitis;<br>Irritable Bowel Syndrome;<br>Rash                               | Enbrel              |                    |                    | S               | Unknown                      | 50 Mg, Qwk                                                                                                      |                 | Amgen        |                |
|                                                                                               | Zoloft              |                    |                    | S               | Unknown                      | Unk                                                                                                             |                 | Not Reported |                |
|                                                                                               | Lexapro             |                    |                    | S               | Unknown                      | Unk                                                                                                             |                 | Not Reported |                |
|                                                                                               | Ditropan            |                    |                    | S               | Unknown                      | Unk                                                                                                             |                 | Not Reported |                |
|                                                                                               | Synthroid           |                    |                    | S               | Unknown                      | Unk                                                                                                             |                 | Not Reported |                |
|                                                                                               | Naprosyn /00256201/ |                    |                    | C               |                              | Unk                                                                                                             |                 | Not Reported |                |
|                                                                                               | Pepcid /00305201/   |                    |                    | C               |                              | Unk                                                                                                             |                 | Not Reported |                |

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|                     |   |            |              |
|---------------------|---|------------|--------------|
| Protonix /00661201/ | C | Unk        | Not Reported |
| Tramadol            | C | 50 Mg, Unk | Not Reported |
| Norco               | C | Unk 5/325  | Not Reported |
| Baclofen            | C | Unk        | Not Reported |
| Lyrica              | C | Unk        | Not Reported |
| Baby Aspirin        | C | Unk        | Not Reported |

| <u>FDA Received Date</u>                | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                                       | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|-----------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|------------------------------------------------------------------------------------------------------------|-----------------|------------|----------------|
| 02-Oct-2015                             | 11588371       | NON-EXPEDITED    |                    |                 | US-ACCORD-031468     |                                                                                                            |                 | Female     | USA            |
| <u>Preferred Term</u>                   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                                         | <u>Duration</u> | <u>Mfr</u> |                |
| Decreased Appetite;<br>Weight Decreased | Escitalopram   |                  |                    | S               |                      | Started 5 Mg Once Daily,<br>Increase To 2 Tab Daily<br>After 2 Weeks, And Then<br>3 Tab Daily(15mg) 2 Week |                 | Accord     |                |

| <u>FDA Received Date</u> | <u>Case #</u>       | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 02-Oct-2015              | 11588372            | NON-EXPEDITED    |                    |                 | US-ACCORD-031951     |                      | 15 YR           | Male       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>      | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Irritability             | Escitalopram Accord |                  |                    | S               | Oral                 |                      |                 | Accord     |                |

| <u>FDA Received Date</u> | <u>Case #</u>       | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|---------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 02-Oct-2015              | 11588373            | NON-EXPEDITED    |                    |                 | US-ACCORD-032322     |                      | 63 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>      | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Diarrhoea                | Escitalopram Accord |                  |                    | S               | Oral                 |                      |                 | Accord       |                |
|                          | Premarin            |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Spironolactone      |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Alprazolam          |                  |                    | C               |                      |                      |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                                                                                                                                                                                             | <u>Case #</u>                                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                             | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------|--------------------|--------------------|------------------|----------------------|----------------------|-----------------|--------------------------------------------------------|----------------|
| 02-Oct-2015                                                                                                                                                                                                                                          | 11588377                                             | NON-EXPEDITED      |                    |                  | US-ACCORD-032560     |                      | 48 YR           | Female                                                 | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                | <u>Product</u>                                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                             |                |
| Anger; Arthralgia; Crying; Fatigue; Feeling Abnormal; Irritability; Myalgia; Pain; Product Substitution Issue; Therapy Non-Responder                                                                                                                 | Escitalopram Accord<br>Amlodipine<br>Camrese         |                    |                    | S<br>C<br>C      |                      |                      |                 | Accord<br>Not Reported<br>Not Reported                 |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                             | <u>Case #</u>                                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                             | <u>Country</u> |
| 02-Oct-2015                                                                                                                                                                                                                                          | 11588378                                             | NON-EXPEDITED      |                    |                  | US-ACCORD-032859     |                      | 37 YR           | Female                                                 | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                | <u>Product</u>                                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                             |                |
| Agitation; Condition Aggravated; Depression; Drug Ineffective; Fatigue; Fear; Product Substitution Issue                                                                                                                                             | Escitalopram Accord                                  |                    |                    | S                |                      | Pill                 |                 | Accord                                                 |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                             | <u>Case #</u>                                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                             | <u>Country</u> |
| 02-Oct-2015                                                                                                                                                                                                                                          | 11588382                                             | EXPEDITED (15-DAY) |                    | OT               | US-ACCORD-033413     |                      | 87 YR           | Female                                                 | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                | <u>Product</u>                                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                             |                |
| Burning Sensation; Confusional State; Decreased Appetite; Dizziness; Dry Mouth; Dyspnoea; Feeling Cold; Frustration Tolerance Decreased; Headache; Joint Stiffness; Lip Swelling; Malaise; Mouth Swelling; Nausea; Suicidal Ideation; Swelling Face; | Escitalopram<br>Ergocalciferol<br>Tenormin<br>Ativan |                    |                    | S<br>C<br>C<br>C | Oral<br>Oral         | Strength: 25 Mg      |                 | Accord<br>Not Reported<br>Not Reported<br>Not Reported |                |

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Swollen Tongue; Vomiting

| <u>FDA Received Date</u>              | <u>Case #</u>       | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------|---------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 02-Oct-2015                           | 11588383            | NON-EXPEDITED    |                    |                 | US-ACCORD-033757     |                      | 64 YR           | Female       | USA            |
| <u>Preferred Term</u>                 | <u>Product</u>      | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Product Substitution Issue; Urticaria | Escitalopram Accord |                  |                    | S               | Oral                 |                      |                 | Accord       |                |
|                                       | Levothyroxine       |                  |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                             | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|-------------------------|----------------------|-----------------|--------------|----------------|
| 02-Oct-2015                                                          | 11590065       | NON-EXPEDITED    |                    |                 | US-TAKEDA-2015TUS013382 |                      | 33 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alopecia; Labelled Drug-Drug Interaction<br>Medication Error; Tremor | Contrave       |                  |                    | S               | Oral                    | 8mg/90mg, Qd         |                 | Takeda       |                |
|                                                                      | Contrave       |                  |                    | S               | Oral                    | 8mg/90mg, Bid        |                 | Takeda       |                |
|                                                                      | Contrave       |                  |                    | S               | Oral                    | 8mg/90mg, Tid        |                 | Takeda       |                |
|                                                                      | Contrave       |                  |                    | S               | Oral                    | 8mg/90mg, Qid        |                 | Takeda       |                |
|                                                                      | Escitalopram   |                  |                    | S               | Oral                    | Unk                  |                 | Not Reported |                |
|                                                                      | Synthroid      |                  |                    | C               | Oral                    | Unk                  |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>      | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|--------------------|------------------|--------------------|-----------------|----------------------|------------------------------------|-----------------|--------------|----------------|
| 02-Oct-2015              | 11592908           | DIRECT           |                    |                 |                      |                                    | 39 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>     | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Alopecia                 | Escitalopram 10mg  |                  |                    | S               | Oral                 | 1/2 Pill Once Daily Taken By Mouth |                 | Not Reported |                |
|                          | 5 Htp [Oxtripatan] |                  |                    | C               |                      |                                    |                 | Not Reported |                |
|                          | Multivitamin       |                  |                    | C               |                      |                                    |                 | Not Reported |                |
|                          | Calcium            |                  |                    | C               |                      |                                    |                 | Not Reported |                |
|                          | B6 Supplement      |                  |                    | C               |                      |                                    |                 | Not Reported |                |
|                          | Vitamin C          |                  |                    | C               |                      |                                    |                 | Not Reported |                |

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## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                              | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|------------------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 02-Oct-2015                                           | 11610703                      | NON-EXPEDITED      |                    | HO              | AUR-APU-2015-06145                                         |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Extrapyramidal Disorder                               | Escitalopram Tablets Usp 20mg |                    |                    | S               |                                                            |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Oct-2015                                           | 11591152                      | NON-EXPEDITED      |                    |                 | US-INVAGEN<br>PHARMACEUTICALS,<br>INC.-1042536             |                      | 61 YR           | Female       | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Decreased Appetite;<br>Diarrhoea; Fatigue;<br>Malaise | Escitalopram                  |                    |                    | S               | Oral                                                       |                      |                 | Invagen      |                |
|                                                       | Ramipril                      |                    |                    | C               |                                                            |                      |                 | Not Reported |                |
|                                                       | Synthroid                     |                    |                    | C               |                                                            |                      |                 | Not Reported |                |
|                                                       | Vitamins A And D              |                    |                    | C               |                                                            |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Oct-2015                                           | 11592219                      | EXPEDITED (15-DAY) |                    | HO, OT          | AU-MACLEODS<br>PHARMACEUTICALS<br>US LTD-<br>MAC2015002028 |                      |                 | Unknown      | AUS            |
| <u>Preferred Term</u>                                 | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State; Drug<br>Interaction;               | Escitalopram Oxalate          |                    |                    | S               | Unknown                                                    | 30 Mg, Daily         |                 | Macleods     |                |
| Hyponatraemia;                                        | Escitalopram Oxalate          |                    |                    | S               | Unknown                                                    | Unk                  |                 | Macleods     |                |
| Inappropriate Antidiuretic<br>Hormone Secretion       | Bupropion                     |                    |                    | S               | Oral                                                       | 75 Mg, Unk           |                 | Not Reported |                |
|                                                       | Dothiepin                     |                    |                    | S               | Unknown                                                    | Unk                  |                 | Not Reported |                |
|                                                       | Dothiepin                     |                    |                    | S               | Unknown                                                    | 225 Mg, Unk          |                 | Not Reported |                |
|                                                       | Dothiepin                     |                    |                    | S               | Unknown                                                    | 175 Mg, Unk          |                 | Not Reported |                |
|                                                       | Quetiapine                    |                    |                    | S               | Unknown                                                    | 400 Mg,At Night      |                 | Not Reported |                |
|                                                       | Lamotrogine                   |                    |                    | C               | Unknown                                                    | 75 Mg, Bid           |                 | Not Reported |                |
|                                                       | Atorvastatin                  |                    |                    | C               | Unknown                                                    |                      |                 | Not Reported |                |
|                                                       | Oestradiol                    |                    |                    | C               | Unknown                                                    |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |                |   |         |             |              |
|--|----------------|---|---------|-------------|--------------|
|  | Ramipril       | C | Unknown |             | Not Reported |
|  | Glipizide      | C | Unknown |             | Not Reported |
|  | Metformin      | C | Unknown | Unk         | Not Reported |
|  | Lantus Insulin | C | Unknown |             | Not Reported |
|  | Aspirin        | C | Unknown |             | Not Reported |
|  | Norfloxacin    | C |         | 400 Mg, Bid | Not Reported |

| <u>FDA Received Date</u>                                                            | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 05-Oct-2015                                                                         | 11594559       | NON-EXPEDITED    |                    |                 | US-INVAGEN<br>PHARMACEUTICALS,<br>INC.-1042578 |                      | 69 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                               | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Chest Pain; Decreased<br>Appetite; Diarrhoea;<br>Hyperhidrosis; Weight<br>Decreased | Escitalopram   |                  |                    | S               | Oral                                           |                      |                 | Invagen      |                |
|                                                                                     | Celebrex       |                  |                    | S               | Oral                                           |                      |                 | Not Reported |                |
|                                                                                     | Nexium         |                  |                    | C               |                                                |                      |                 | Not Reported |                |
|                                                                                     | Kombiglyze Xr  |                  |                    | C               |                                                |                      |                 | Not Reported |                |
|                                                                                     | Jardiance      |                  |                    | C               |                                                |                      |                 | Not Reported |                |
|                                                                                     | Votrient       |                  |                    | S               |                                                |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|-----------------------------------|-----------------|--------------|----------------|
| 05-Oct-2015                                            | 11594584       | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000079976    |                                   | 62 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;<br>Electrocardiogram Qt<br>Prolonged | Escitalopram   |                    |                    | S               | Oral                 | 10 Mg                             |                 | Forest       |                |
|                                                        | Atarax         |                    |                    | S               | Oral                 | 50 Mg                             |                 | Not Reported |                |
|                                                        | Triflucan      |                    |                    | S               | Buccal               |                                   |                 | Not Reported |                |
|                                                        | Primperan      |                    |                    | S               | Oral                 | 30 Mg                             |                 | Not Reported |                |
|                                                        | Eupantol       |                    |                    | C               | Oral                 | 80 Mg                             |                 | Not Reported |                |
|                                                        | Creon          |                    |                    | C               | Oral                 | 225000 Iu (International<br>Unit) |                 | Not Reported |                |
|                                                        | Allopurinol    |                    |                    | C               | Oral                 |                                   |                 | Not Reported |                |
|                                                        | Carbosylane    |                    |                    | C               | Oral                 | 3 Dosage Forms                    |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                      |   |                                          |                |              |
|------------------------------------------------------|---|------------------------------------------|----------------|--------------|
| Amlodipine                                           | C | Oral                                     | 5 Mg           | Not Reported |
| Spasfon (Phloroglucinol,<br>Trimethylphloroglucinol) | C | Oral                                     | 6 Dosage Forms | Not Reported |
| Oxycontin                                            | C | Oral                                     | 20 Mg          | Not Reported |
| Oxynorm                                              | C | Oral                                     | 30 Mg          | Not Reported |
| Smecta                                               | C | Oral                                     | 3 Dosage Forms | Not Reported |
| Imodium                                              | C | Oral                                     | 1.2 Mg         | Not Reported |
| Doliprane                                            | C | Oral                                     | 3000 Mg        | Not Reported |
| Augmentin                                            | C | Intravenous (not<br>otherwise specified) | Only Once      | Not Reported |

| <u>FDA Received Date</u>                                     | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------------------------------------------|----------------|------------------|--------------------|-----------------|------------------------------------------------|----------------------|-----------------|------------|----------------|
| 05-Oct-2015                                                  | 11594600       | NON-EXPEDITED    |                    |                 | US-INVAGEN<br>PHARMACEUTICALS,<br>INC.-1042580 |                      | 8 YR            | Female     | USA            |
| <u>Preferred Term</u>                                        | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Abnormal Behaviour;<br>Aggression; Aggression;<br>Aggression | Escitalopram   |                  |                    | S               | Oral                                           |                      |                 | Invagen    |                |

| <u>FDA Received Date</u>                | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|-----------------------------------------|----------------|------------------|--------------------|-----------------|------------------------------------------------|----------------------|-----------------|------------|----------------|
| 05-Oct-2015                             | 11594623       | NON-EXPEDITED    |                    |                 | US-INVAGEN<br>PHARMACEUTICALS,<br>INC.-1042583 |                      | 60 YR           | Female     | USA            |
| <u>Preferred Term</u>                   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Flushing; Product<br>Substitution Issue | Escitalopram   |                  |                    | S               | Oral                                           |                      |                 | Invagen    |                |

| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------------|------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| 05-Oct-2015              | 11594630             | NON-EXPEDITED    |                    |                 | US-APOTEX-<br>2015AP010618 |                      | 16 YR           | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Activation Syndrome      | Escitalopram Oxalate |                  |                    | S               | Unknown                    | 10 Mg/Day            |                 | Apotex       |                |
|                          | Cefalexin            |                  |                    | C               | Oral                       |                      |                 | Not Reported |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |             |   |         |              |  |              |
|--|-------------|---|---------|--------------|--|--------------|
|  | Propranolol | C | Unknown | 30 Mg, Qd    |  | Not Reported |
|  | Clonazepam  | C | Unknown | 0.25 Mg, Bid |  | Not Reported |
|  | Clonazepam  | C |         |              |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------------------------|----------------------|------------|------------|----------------|
| 05-Oct-2015              | 11594648      | NON-EXPEDITED    |                    |                 | US-INVAGEN<br>PHARMACEUTICALS,<br>INC.-1042585 |                      |            | Female     | USA            |

| <u>Preferred Term</u>                        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|----------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Drug Ineffective; Product Substitution Issue | Escitalopram   |              |            | S           | Oral         |                    |                 | Invagen    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------------------------|----------------------|------------|------------|----------------|
| 05-Oct-2015              | 11594670      | NON-EXPEDITED    |                    |                 | US-INVAGEN<br>PHARMACEUTICALS,<br>INC.-1042587 |                      | 70 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Nausea                | Escitalopram   |              |            | S           | Oral         |                    |                 | Invagen      |
|                       | Synthroid      |              |            | C           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Oct-2015              | 11597059      | DIRECT           |                    | DS              |                      |                      | 59 YR      | Unknown    | USA            |

| <u>Preferred Term</u>                                                                                                | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Amnesia; Anxiety; Disturbance In Attention; Eye Pain; Impaired Work Ability; Impatience; Insomnia; Learning Disorder | Escitalopram 10 Mg Lupin |              |            | S           | Oral         |                    |                 | Lupin        |
|                                                                                                                      | Xanax                    |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                      | Conazepam                |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Oct-2015              | 11603151      | DIRECT           |                    | OT              |                      |                      | 17 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                             |                 |   |      |        |       |              |
|-------------------------------------------------------------|-----------------|---|------|--------|-------|--------------|
| Hallucination; Homicidal Ideation; Mania; Thinking Abnormal | Lexapro         | S | Oral | 1 Pill | 1 MTH | Not Reported |
|                                                             | St. John'S Wart | C |      |        |       | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|------------|----------------|
| 06-Oct-2015              | 11569860       | EXPEDITED (15-DAY) |                    | OT              | IT-PFIZER INC-2015323123 |                      | 69 YR           | Female     | ITA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Spinocerebellar Ataxia   | Ciprallex      |                    |                    | S               |                          | Unk                  |                 |            | Not Reported   |

| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---------------------------|----------------|--------------------|--------------------|-----------------|----------------------|-------------------------------|-----------------|------------|----------------|
| 06-Oct-2015               | 11599108       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000079983    |                               | 83 YR           | Female     | FRA            |
| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u> |                |
| Anaemia; Haematoma Muscle | Escitalopram   |                    |                    | S               | Oral                 |                               |                 |            | Forest         |
|                           | Calciparine    |                    |                    | S               | Subcutaneous         | 30000 Iu (International Unit) |                 |            | Not Reported   |
|                           | Perindopril    |                    |                    | C               | Unknown              |                               |                 |            | Not Reported   |
|                           | Trivastal      |                    |                    | C               | Unknown              |                               |                 |            | Not Reported   |
|                           | Seresta        |                    |                    | C               | Oral                 |                               |                 |            | Not Reported   |
|                           | Lorazepam      |                    |                    | C               | Unknown              |                               |                 |            | Not Reported   |
|                           | Pantoprazole   |                    |                    | C               | Unknown              |                               |                 |            | Not Reported   |

| <u>FDA Received Date</u> | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|------------------------|--------------------|--------------------|-----------------|------------------------|-----------------------|-----------------|------------|----------------|
| 07-Oct-2015              | 11134544               | EXPEDITED (15-DAY) |                    | HO, OT          | US-MERCK-1505USA009221 |                       | 58 YR           | Female     | USA            |
| <u>Preferred Term</u>    | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u> |                |
| Cerebrovascular Accident | Zocor                  |                    |                    | S               | Oral                   | 40 Mg, Qd             |                 |            | Merck          |
|                          | Escitalopram           |                    |                    | S               | Oral                   | 20 Mg, Daily          |                 |            | Not Reported   |
|                          | Tramadol Hydrochloride |                    |                    | S               | Oral                   | 50 Mg, Bid, As Needed |                 |            | Not Reported   |
|                          | Clonazepam             |                    |                    | S               | Oral                   | 0.5 Mg, Daily         |                 |            | Not Reported   |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |                            |   |      |               |              |
|--|----------------------------|---|------|---------------|--------------|
|  | Risperidone                | S | Oral | 0.5 Mg, Daily | Not Reported |
|  | Ambien                     | C |      |               | Not Reported |
|  | Proair (Albuterol Sulfate) | C |      |               | Not Reported |
|  | Ergocalciferol             | C |      |               | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Oct-2015              | 11459104      | EXPEDITED (15-DAY) |                    | OT              | DE-FRI-1000079321    |                      | 19 YR      | Female     | DEU            |

| <u>Preferred Term</u>                                                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Aggression; Decreased Appetite; Intentional Self-Injury; Irritability | Escitalopram   |              |            | S           | Oral         | 10 Milligram       |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Oct-2015              | 11576976      | EXPEDITED (15-DAY) |                    | OT              | JP-FRI-1000079607    |                      | 64 YR      | Female     | JPN            |

| <u>Preferred Term</u>                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Activation Syndrome; Feeling Abnormal; Nausea | Lexapro        |              |            | S           | Oral         | 5 Mg               |                 | Forest       |
|                                               | Meilax         |              |            | C           | Oral         | 1 Mg               |                 | Not Reported |
|                                               | Reflex         |              |            | C           | Oral         | 7.5 Mg             |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 07-Oct-2015              | 11597264      | EXPEDITED (15-DAY) |                    | HO              | CH-ASTRAZENECA-2015SE94069 |                      | 69 YR      | Female     | CHE            |

| <u>Preferred Term</u>                                                                                      | <u>Product</u>                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------|--------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction; Hypertonia; Psychomotor Retardation; Pyrexia; Renal Impairment; Tremor; Weight Increased | Quetiapine                     |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                            | Escitalopram                   |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                            | Escitalopram                   |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                            | Tramadol                       |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                            | Temgesic                       |              |            | S           | Sublingual   |                    |                 | Not Reported |
|                                                                                                            | Sifrol                         |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                            | Flector (Diclofenac Epolamine) |              |            | C           | Topical      |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|             |   |                  |              |
|-------------|---|------------------|--------------|
| Lasix       | C | Intravenous drip | Not Reported |
| Amlodipin   | C | Oral             | Not Reported |
| Beloc-Zok   | C | Oral             | Not Reported |
| Aprovel     | C | Oral             | Not Reported |
| Lantus      | C | Subcutaneous     | Not Reported |
| Novorapid   | C | Subcutaneous     | Not Reported |
| Vitamin B 6 | C | Oral             | Not Reported |
| Vi-De 3     | C | Oral             | Not Reported |
| Laxoberon   | C | Oral             | Not Reported |
| Movicol     | C | Oral             | Not Reported |

| <u>FDA Received Date</u>                                                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 07-Oct-2015                                                               | 11604758       | EXPEDITED (15-DAY) |                    | HO              | CH-FRI-1000080045    |                      | 32 YR           | Female       | CHE            |
| <u>Preferred Term</u>                                                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Acute Hepatic Failure;<br>Hepatic Necrosis;<br>Jaundice; Liver Transplant | Escitalopram   |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                                                           | Zyprexa        |                    |                    | S               | Oral                 | 2.5 Mg               |                 | Not Reported |                |
|                                                                           | Quetiapin      |                    |                    | S               | Oral                 | 25 Mg                |                 | Not Reported |                |
|                                                                           | Quetiapin      |                    |                    | S               | Oral                 | 50 Mg                |                 | Not Reported |                |
|                                                                           | Euthyrox       |                    |                    | C               | Oral                 | 0.15 Mg              |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                        | <u>Case #</u>                      | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---------------------------------------------------------------------------------|------------------------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 07-Oct-2015                                                                     | 11605685                           | NON-EXPEDITED    |                    |                 | US-TORRENT-00000996  |                      |                 | Female     | USA            |
| <u>Preferred Term</u>                                                           | <u>Product</u>                     | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Abdominal Discomfort;<br>Agitation; Irritability;<br>Product Substitution Issue | Escitalopram Oxalate Tablets 10 Mg |                  |                    | S               |                      |                      |                 | Torrent    |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Oct-2015              | 10660021      | EXPEDITED (15-DAY) |                    | OT              | CH-GLAXOSMITHKLINE-  |                      |            | Unknown    | CHE            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

CH2014034392

| <u>Preferred Term</u>                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|---------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|-----------------|
| Abortion Induced;<br>Exposure During<br>Pregnancy | Cipralext      |              |            | S           | Transplacental | 5 Mg, Qd           |                 | Glaxosmithkline |
|                                                   | Lamictal       |              |            | S           | Transplacental |                    |                 | Glaxosmithkline |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 08-Oct-2015              | 11184732      | EXPEDITED (15-DAY) |                    | HO              | US-JNJFOC-<br>20150608944 |                      | 58 YR      | Female     | USA            |

| <u>Preferred Term</u>    | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cerebrovascular Accident | Tramadol Hydrochloride |              |            | S           | Oral         |                    |                 | Not Reported |
|                          | Risperidone            |              |            | S           | Oral         |                    |                 | Not Reported |
|                          | Placebo                |              |            | S           | Subcutaneous |                    |                 | Not Reported |
|                          | Simvastatin            |              |            | S           | Oral         |                    |                 | Not Reported |
|                          | Escitalopram           |              |            | S           | Oral         |                    |                 | Not Reported |
|                          | Clonazepam             |              |            | S           | Oral         |                    |                 | Not Reported |
|                          | Ambien                 |              |            | C           | Unknown      |                    |                 | Not Reported |
|                          | Vitamin D Nos          |              |            | C           | Unknown      |                    |                 | Not Reported |
|                          | Proair Hfa             |              |            | C           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------------------------|----------------------|------------|------------|----------------|
| 08-Oct-2015              | 11610124      | NON-EXPEDITED    |                    |                 | AU-LUPIN<br>PHARMACEUTICALS<br>INC.-2015-02347 |                      | 11 YR      | Female     | AUS            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Bruxism               | Escitalopram   |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Escitalopram   |              |            | S           | Unknown      | Dose Reduced       |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|----------------------------------|----------------|--------------------|--------------------|-----------------|------------------------------------------------|----------------------|-----------------|------------|----------------|
| 08-Oct-2015                      | 11610168       | NON-EXPEDITED      |                    |                 | IN-LUPIN<br>PHARMACEUTICALS<br>INC.-2015-02288 |                      | 45 YR           | Female     | IND            |
| <u>Preferred Term</u>            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Myoclonus                        | Escitalopram   |                    |                    | S               | Unknown                                        | 10 Mg                |                 |            | Not Reported   |
| <u>FDA Received Date</u>         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 08-Oct-2015                      | 11611845       | EXPEDITED (15-DAY) |                    | OT              | FR-APOTEX-<br>2015AP013361                     |                      | 67 YR           | Female     | FRA            |
| <u>Preferred Term</u>            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Heart Valve Incompetence         | Paxil Tablets  |                    |                    | S               | Oral                                           | 1 Df, Qd             |                 |            | Apotex         |
|                                  | Seroplex       |                    |                    | S               | Oral                                           | 1 Df, Qd             |                 |            | Not Reported   |
|                                  | Zoloft         |                    |                    | S               | Oral                                           | 1 Df, Qd             |                 |            | Not Reported   |
|                                  | Effexor        |                    |                    | S               | Oral                                           | 1 Df, Qd             |                 |            | Not Reported   |
|                                  | Cymbalta       |                    |                    | S               | Oral                                           | 30 Mg, Qd            |                 |            | Not Reported   |
|                                  | Norepinephrine |                    |                    | C               | Unknown                                        | Unk                  |                 |            | Not Reported   |
| <u>FDA Received Date</u>         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 08-Oct-2015                      | 11613704       | EXPEDITED (15-DAY) |                    | OT              | DE-FRI-1000080080                              |                      | 81 YR           | Female     | DEU            |
| <u>Preferred Term</u>            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Renal Impairment                 | Escitalopram   |                    |                    | S               | Unknown                                        | 10 Milligram         |                 |            | Forest         |
| <u>FDA Received Date</u>         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 08-Oct-2015                      | 11613926       | EXPEDITED (15-DAY) |                    | HO              | US-ASTRAZENECA-<br>2015SE96280                 |                      | 87 YR           | Female     | FRA            |
| <u>Preferred Term</u>            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Fall; Orthostatic<br>Hypotension | Kenzen         |                    |                    | S               | Oral                                           | 8 Mg, Qd             |                 |            | Astrazeneca    |
|                                  | Bisoprolol     |                    |                    | S               | Oral                                           | 5 Mg, Qd             |                 |            | Not Reported   |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                             |   |                                                                      |              |
|-----------------------------|---|----------------------------------------------------------------------|--------------|
| Seroplex                    | S | Unknown                                                              | Not Reported |
| Umuline Profil              | C |                                                                      | Not Reported |
| Umuline Profil              | C |                                                                      | Not Reported |
| Clopidogrel                 | C | Oral                                                                 | Not Reported |
| Levothyrox                  | C | Oral                                                                 | Not Reported |
|                             |   | 1 Tablet Of 75 Mcg In Morning Alternating With One Tablet Of 100 Mcg |              |
| Inexium                     | C | Oral                                                                 | Not Reported |
| Tanakan                     | C | Oral                                                                 | Not Reported |
| Vasten [Pravastatin Sodium] | C | Oral                                                                 | Not Reported |
|                             |   | 20 Mg, Qd                                                            |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Oct-2015              | 11614234      | EXPEDITED (15-DAY) | HO                 |                 | FR-FRI-1000080138    |                      | 80 YR      | Male       | FRA            |

| <u>Preferred Term</u>                | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------|-----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction; Subdural Haematoma | Escitalopram          |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                      | Clopidogrel Base      |              |            | S           | Oral         | 75 Mg              |                 | Not Reported |
|                                      | Indapamide            |              |            | C           | Oral         | 1.5 Mg             |                 | Not Reported |
|                                      | Candesartan Cilexetil |              |            | C           | Oral         | 8 Mg               |                 | Not Reported |
|                                      | Diffu K               |              |            | C           | Oral         |                    |                 | Not Reported |
|                                      | Simvastatine          |              |            | C           | Oral         | 200 Mg             |                 | Not Reported |
|                                      | Allopurinol           |              |            | C           | Oral         | 300 Mg             |                 | Not Reported |
|                                      | Alprazolam            |              |            | C           | Oral         | 0.25 Mg            |                 | Not Reported |
|                                      | Oxazepam              |              |            | C           | Oral         | 10 Mg              |                 | Not Reported |
|                                      | Silodosine            |              |            | C           | Oral         | 8 Mg               |                 | Not Reported |
|                                      | Pantoprazole          |              |            | C           | Unknown      | 40 Mg              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Oct-2015              | 11614236      | EXPEDITED (15-DAY) | HO                 |                 | DE-FRI-1000080041    |                      | 22 YR      | Female     | DEU            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                            |                        |                    |                    |                 |                              |                                                                                |                 |              |                |
|----------------------------------------------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|------------------------------|--------------------------------------------------------------------------------|-----------------|--------------|----------------|
| Dermatitis Allergic; Rash                                                                                                  |                        | Escitalopram       |                    | S               | Oral                         | 5 Milligram                                                                    |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                   | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                                                           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Oct-2015                                                                                                                | 11614237               | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000080066            |                                                                                | 67 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                      | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                                                             | <u>Duration</u> | <u>Mfr</u>   |                |
| Heart Valve Incompetence                                                                                                   | Escitalopram           |                    |                    | S               | Oral                         | 1 Df                                                                           |                 | Forest       |                |
|                                                                                                                            | Zoloft                 |                    |                    | S               | Oral                         | 1 Df                                                                           |                 | Not Reported |                |
|                                                                                                                            | Effexor                |                    |                    | S               | Oral                         | 1 Df                                                                           |                 | Not Reported |                |
|                                                                                                                            | Deroxat                |                    |                    | S               | Oral                         | 1 Df                                                                           |                 | Not Reported |                |
|                                                                                                                            | Cymbalta               |                    |                    | S               | Oral                         | 1 Df                                                                           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                   | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                                                           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Oct-2015                                                                                                                | 11614246               | EXPEDITED (15-DAY) |                    | OT              | DE-FRI-1000080062            |                                                                                | 36 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                                                                                      | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                                                             | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated;<br>Foetal Death;<br>Oligohydramnios;<br>Pregnancy; Retroplacental<br>Haematoma; Uterine<br>Leiomyoma | Escitalopram           |                    |                    | S               | Oral                         | 20 Milligram (Temporarily<br>Discontinued For 4 Days<br>In Gestational Week 4) |                 | Forest       |                |
|                                                                                                                            | Folsaeure              |                    |                    | C               | Oral                         |                                                                                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                   | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                                                           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Oct-2015                                                                                                                | 11615443               | DIRECT             |                    | OT              |                              |                                                                                | 13 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                      | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                                                             | <u>Duration</u> | <u>Mfr</u>   |                |
| Eye Swelling; Pyrexia;<br>Swelling Face; Urticaria                                                                         | Generic Lexapro 2.5 Mg |                    |                    | S               | Oral                         |                                                                                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                   | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                                                           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Oct-2015                                                                                                                | 11498243               | NON-EXPEDITED      |                    | OT              | US-PFIZER INC-<br>2015301664 |                                                                                | 52 YR           | Female       | USA            |



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| <u>Preferred Term</u>                                                                    | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Bladder Disorder; Colitis;<br>Condition Aggravated;<br>Irritable Bowel Syndrome;<br>Rash | Enbrel              |              |            | S           | Unknown      | 50 Mg, Qwk         |                 | Unknown      |
|                                                                                          | Zoloft              |              |            | S           | Unknown      | Unk                |                 | Pfizer       |
|                                                                                          | Lexapro             |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                                                                                          | Ditropan            |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                                                                                          | Synthroid           |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                                                                                          | Naprosyn /00256201/ |              |            | C           |              | Unk                |                 | Not Reported |
|                                                                                          | Pepcid /00305201/   |              |            | C           |              | Unk                |                 | Not Reported |
|                                                                                          | Protonix /00661201/ |              |            | C           |              | Unk                |                 | Not Reported |
|                                                                                          | Tramadol            |              |            | C           |              | 50 Mg, Unk         |                 | Not Reported |
|                                                                                          | Norco               |              |            | C           |              | Unk 5/325          |                 | Not Reported |
|                                                                                          | Baclofen            |              |            | C           |              | Unk                |                 | Not Reported |
|                                                                                          | Lyrica              |              |            | C           |              | Unk                |                 | Not Reported |
|                                                                                          | Baby Aspirin        |              |            | C           |              | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------------------------------------|----------------------|------------|------------|----------------|
| 09-Oct-2015              | 11614703      | NON-EXPEDITED    |                    |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>BMS-2015-069032 |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>           |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------|
| Drug Ineffective      | Abilify        |              |            | S           | Unknown      |                    |                 | Bristol Myers Squibb |
|                       | Xyrem          |              |            | S           | Unknown      |                    |                 | Not Reported         |
|                       | Lexapro        |              |            | S           | Unknown      |                    |                 | Not Reported         |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Oct-2015              | 11616570      | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000080067    |                      |            | Male       | USA            |

| <u>Preferred Term</u>                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|------------|
| Congenital Anomaly;<br>Ventricular Septal Defect | Lexapro        |              |            | S           | Transplacental |                    |                 | Forest     |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                       | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>        | <u>503B Facility</u>                                                                                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------|-------------------|--------------------|--------------------|-----------------|-----------------------------|-------------------------------------------------------------------------------------------------------------|-----------------|--------------|----------------|
| 09-Oct-2015                                    | 11617096          | EXPEDITED (15-DAY) |                    | HO              | US-JNJFOC-20151001967       |                                                                                                             | 44 YR           | Female       | USA            |
| <u>Preferred Term</u>                          | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                | <u>Dosage Text</u>                                                                                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Pulmonary Embolism;<br>Treatment Noncompliance | Xarelto           |                    |                    | S               | Oral                        |                                                                                                             |                 | Not Reported |                |
|                                                | Xarelto           |                    |                    | S               | Oral                        |                                                                                                             |                 | Not Reported |                |
|                                                | Gabapentin        |                    |                    | S               | Oral                        |                                                                                                             |                 | Not Reported |                |
|                                                | Lasix             |                    |                    | S               | Oral                        |                                                                                                             |                 | Not Reported |                |
|                                                | Lexapro           |                    |                    | S               | Oral                        |                                                                                                             |                 | Not Reported |                |
|                                                | Paxil             |                    |                    | S               | Oral                        |                                                                                                             |                 | Not Reported |                |
|                                                | Tricor            |                    |                    | S               | Oral                        |                                                                                                             |                 | Not Reported |                |
|                                                | Estradiol         |                    |                    | S               | Oral                        |                                                                                                             |                 | Not Reported |                |
|                                                | Dicyclomine       |                    |                    | C               | Oral                        |                                                                                                             |                 | Not Reported |                |
|                                                | Advair Diskus     |                    |                    | C               | Respiratory<br>(inhalation) | 250-50 Mcg/Dose<br>Inhalation, 1 Puff Twice A<br>Day Approximately 12<br>Hours Apart Morning And<br>Evening |                 | Not Reported |                |
|                                                | Albuterol Sulfate |                    |                    | C               | Respiratory<br>(inhalation) | 90 Mcg, Every 4 Hours As<br>Needed For 30 Days                                                              |                 | Not Reported |                |
|                                                | Aldactone         |                    |                    | C               | Oral                        |                                                                                                             |                 | Not Reported |                |
|                                                | Apidra            |                    |                    | C               | Subcutaneous                | 100 Unit/MI                                                                                                 |                 | Not Reported |                |
|                                                | Benzonatate       |                    |                    | C               | Oral                        |                                                                                                             |                 | Not Reported |                |
|                                                | Clonidine Hcl     |                    |                    | C               | Oral                        |                                                                                                             |                 | Not Reported |                |
|                                                | Elocon            |                    |                    | C               | Topical                     | A Thin Layer To Be<br>Applied Topically To<br>Affected Area                                                 |                 | Not Reported |                |
|                                                | Ferrous Sulfate   |                    |                    | C               | Oral                        | After Meals                                                                                                 |                 | Not Reported |                |
|                                                | Humalog Mix       |                    |                    | C               | Subcutaneous                | 40 Units In The Morning<br>And 20 Units In The<br>Evening                                                   |                 | Not Reported |                |

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|                 |   |                          |                                                                    |              |
|-----------------|---|--------------------------|--------------------------------------------------------------------|--------------|
| Hydroxyzine Hcl | C | Oral                     | As Needed                                                          | Not Reported |
| Hyzaar          | C | Oral                     | 100-25 Mg                                                          | Not Reported |
| Ibuprofen       | C | Oral                     |                                                                    | Not Reported |
| Imitrex         | C | Oral                     |                                                                    | Not Reported |
| Klor-Con        | C | Oral                     |                                                                    | Not Reported |
| Lipitor         | C | Oral                     | At Bedtime                                                         | Not Reported |
| Nexium          | C | Oral                     | For 90 Days                                                        | Not Reported |
| Prilosec        | C | Oral                     |                                                                    | Not Reported |
| Proair Hfa      | C | Respiratory (inhalation) | 2 Puffs Every 4 Hours As Needed                                    | Not Reported |
| Promethazine Dm | C | Oral                     | 6.25-15 Mg/5ml, One Teaspoonful 4 Times A Day As Needed For 5 Days | Not Reported |
| Reglan          | C | Oral                     | 30 Minutes Before Meals And At Bedtime For 30 Days                 | Not Reported |
| Remeron         | C | Oral                     | At Bedtime                                                         | Not Reported |
| Soma            | C | Oral                     | As Needed                                                          | Not Reported |
| Sumatriptan     | C | Oral                     |                                                                    | Not Reported |
| Synthroid       | C | Oral                     |                                                                    | Not Reported |
| Zolpidem        | C | Oral                     | At Bed Time As Needed For 90 Days                                  | Not Reported |
| Ultram          | C | Oral                     | As Needed For 30 Days                                              | Not Reported |
| Folic Acid      | C | Unknown                  |                                                                    | Not Reported |
| Toprol XL       | C | Oral                     |                                                                    | Not Reported |
| Xyzal           | C | Oral                     | Every Evening                                                      | Not Reported |
| Insulin         | C | Unknown                  | 250 (Units Unspecified)                                            | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Oct-2015              | 11617147      | EXPEDITED (15-DAY) | HO                 |                 | CH-TEVA-551226ISR    |                      | 79 YR      | Male       | CHE            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                            | <u>Product</u>             | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                  | <u>Dosage Text</u>                                                                                           | <u>Duration</u> | <u>Mfr</u>           |                |
|--------------------------------------------------------------------------------------------------|----------------------------|------------------|--------------------|-----------------|---------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------|-----------------|----------------------|----------------|
| Cholestasis; Fall;<br>Transaminases Increased                                                    | Irfen-400 Lactab           |                  |                    | S               | Oral                                                          |                                                                                                              |                 | Ivax                 |                |
|                                                                                                  | Dafalgan 1 G Filmdabletten |                  |                    | S               | Oral                                                          | 3 Gram Daily; Taken<br>Inconstantly Since The<br>Beginning Of Feb-2015,<br>On Average: On 2 Out Of<br>3 Days |                 | Not Reported         |                |
|                                                                                                  | Cipralext Meltz            |                  |                    | S               | Oral                                                          | 20 Milligram Daily;                                                                                          |                 | Not Reported         |                |
|                                                                                                  | Anxiolit                   |                  |                    | C               | Oral                                                          | 7.5 Milligram Daily;                                                                                         |                 | Not Reported         |                |
|                                                                                                  | Clexane 100 Mg/MI          |                  |                    | C               | Subcutaneous                                                  | 40 Milligram Daily;                                                                                          |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                                         | <u>Case #</u>              | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                          | <u>503B Facility</u>                                                                                         | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 09-Oct-2015                                                                                      | 11617577                   | NON-EXPEDITED    |                    | OT              | US-B.I.<br>PHARMACEUTICALS,I<br>NC./RIDGEFIELD-2015-<br>BI-55 |                                                                                                              | 90 YR           | Female               | USA            |
| <u>Preferred Term</u>                                                                            | <u>Product</u>             | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                  | <u>Dosage Text</u>                                                                                           | <u>Duration</u> | <u>Mfr</u>           |                |
| Drug Interaction;<br>Intraventricular<br>Haemorrhage; Medication<br>Error; Subdural<br>Haematoma | Pradaxa                    |                  |                    | S               | Oral                                                          | 300 Mg                                                                                                       |                 | Boehringer Ingelheim |                |
|                                                                                                  | Dronedarone                |                  |                    | S               | Unknown                                                       |                                                                                                              |                 | Not Reported         |                |
|                                                                                                  | Escitalopram               |                  |                    | S               | Unknown                                                       |                                                                                                              |                 | Not Reported         |                |
|                                                                                                  | Simvastatin                |                  |                    | C               | Unknown                                                       |                                                                                                              |                 | Not Reported         |                |
|                                                                                                  | Metoprolol                 |                  |                    | C               | Unknown                                                       |                                                                                                              |                 | Not Reported         |                |
|                                                                                                  | Mirtazapine                |                  |                    | C               | Unknown                                                       |                                                                                                              |                 | Not Reported         |                |
|                                                                                                  | Digoxin                    |                  |                    | C               | Unknown                                                       |                                                                                                              |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                                         | <u>Case #</u>              | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                          | <u>503B Facility</u>                                                                                         | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 09-Oct-2015                                                                                      | 11622474                   | DIRECT           |                    |                 |                                                               |                                                                                                              | 61 YR           | Female               | USA            |
| <u>Preferred Term</u>                                                                            | <u>Product</u>             | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                  | <u>Dosage Text</u>                                                                                           | <u>Duration</u> | <u>Mfr</u>           |                |
| Anxiety; Confusional<br>State; Coordination<br>Abnormal; Drug<br>Ineffective; Myalgia;           | Escitalopram               |                  |                    | S               | Oral                                                          |                                                                                                              |                 | Aurobindo            |                |
|                                                                                                  | Lexapro                    |                  |                    | C               |                                                               |                                                                                                              |                 | Not Reported         |                |
|                                                                                                  | Snorepin Nose Insert       |                  |                    | C               |                                                               |                                                                                                              |                 | Not Reported         |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                        |                 |   |              |
|------------------------|-----------------|---|--------------|
| Product Quality Issue; | Cpap            | C | Not Reported |
| Tremor; Withdrawal     | Ca              | C | Not Reported |
| Syndrome               | Mg              | C | Not Reported |
|                        | K               | C | Not Reported |
|                        | Zn              | C | Not Reported |
|                        | Vitamins C      | C | Not Reported |
|                        | Vitamin B       | C | Not Reported |
|                        | Vitamin D Nos   | C | Not Reported |
|                        | Naproxen Sodium | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 12-Oct-2015              | 11501917      | EXPEDITED (15-DAY) |                    | CA, OT          | US-PFIZER INC-2015303448 |                      |            | Female     | USA            |

| <u>Preferred Term</u>                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------|----------------|--------------|------------|-------------|----------------|---------------------------------------|-----------------|--------------|
| Aorta Hypoplasia;                                 | Zoloft         |              |            | S           | Transplacental | Unk                                   |                 | Pfizer       |
| Bicuspid Aortic Valve;                            | Zoloft         |              |            | S           | Transplacental | 50 Mg, Daily (100 Mg Half Tablet)     |                 | Pfizer       |
| Coarctation Of The Aorta;                         |                |              |            |             |                |                                       |                 |              |
| Heart Disease Congenital;                         | Zoloft         |              |            | S           |                |                                       |                 | Pfizer       |
| Maternal Exposure During Pregnancy; Shone Complex | Lexapro        |              |            | S           | Transplacental | Unk                                   |                 | Not Reported |
|                                                   | Lexapro        |              |            | S           |                |                                       |                 | Not Reported |
|                                                   | Lexapro        |              |            | S           |                |                                       |                 | Not Reported |
|                                                   | Cefzil         |              |            | C           | Transplacental | 500 Mg, 2x/Day                        |                 | Not Reported |
|                                                   | Phenergan      |              |            | C           | Transplacental | 25 Mg, As Needed (Every 4 To 6 Times) |                 | Not Reported |
|                                                   | Zantac         |              |            | C           | Transplacental | 150 Mg, 2x/Day (As Needed)            |                 | Not Reported |
|                                                   | Maxifed Dm     |              |            | C           | Transplacental | Unk, 2x/Day (As Needed)               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------------------|----------------------|------------|------------|----------------|
| 12-Oct-2015              | 11619045      | EXPEDITED (15-DAY) |                    | OT              | FR-ELI_LILLY_AND_COMP<br>ANY-FR201509009335 |                      | 67 YR      | Female     | FRA            |

| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>       |
|--------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------------|
| Heart Valve Incompetence | Cymbalta       |              |            | S           | Oral         | 30 Mg, Qd          |                 | Eli Lilly And Co |
|                          | Seroplex       |              |            | S           | Oral         | 1 Df, Qd           |                 | Not Reported     |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|         |   |      |           |              |
|---------|---|------|-----------|--------------|
| Zoloft  | S | Oral | 1 Df, Unk | Not Reported |
| Effexor | S | Oral | 1 Df, Qd  | Not Reported |
| Deroxat | S | Oral | 1 Df, Unk | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 12-Oct-2015              | 11620608      | EXPEDITED (15-DAY) |                    | HO              | TR-MYLANLABS-2015M1034258 |                      |            | Unknown    | TUR            |

| <u>Preferred Term</u>                   | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Depressive Symptom;<br>Drug Interaction | Escitalopram        |              |            | S           | Unknown      | 10 Mg/Day          |                 | Mylan        |
|                                         | Dabigatran Etxilate |              |            | S           | Unknown      | 110 Mg/Day         |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Oct-2015              | 11621391      | EXPEDITED (15-DAY) |                    | OT              | CA-HOSPIRA-3031961   |                      | 62 YR      | Female     | CAN            |

| <u>Preferred Term</u>                                | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Alopecia; Arthritis; Breath<br>Sounds Abnormal;      | Ibuprofen           |              |            | S           | Unknown      |                    |                 | Not Reported |
| Bronchitis; Chondropathy;                            | Bupropion Hcl Er    |              |            | C           | Oral         |                    |                 | Not Reported |
| Cough; Depression; Fall;                             | Morphine Sulphate   |              |            | S           | Unknown      |                    |                 | Not Reported |
| Fatigue; Feeling Of Body<br>Temperature Change;      | Cipralex /01588501/ |              |            | S           | Unknown      |                    |                 | Not Reported |
| Hyperhidrosis;                                       | Gabapentin          |              |            | S           | Unknown      |                    |                 | Not Reported |
| Inappropriate Schedule Of<br>Product Administration; | Gabapentin          |              |            | S           | Unknown      |                    |                 | Not Reported |
| Incorrect Product                                    | Trazodone           |              |            | S           | Unknown      |                    |                 | Not Reported |
| Administration Duration;                             | Voltaren            |              |            | S           | Topical      |                    |                 | Not Reported |
| Intervertebral Disc                                  | Voltaren            |              |            | S           | Topical      |                    |                 | Not Reported |
| Disorder; Lymphoedema;                               | Voltaren            |              |            | S           | Topical      |                    |                 | Not Reported |
| Lymphoma; Mobility                                   | Voltaren            |              |            | S           | Topical      |                    |                 | Not Reported |
| Decreased; Motor                                     | Voltaren            |              |            | S           | Topical      |                    |                 | Not Reported |
| Dysfunction; Nausea;                                 | Zopiclone           |              |            | S           | Unknown      |                    |                 | Not Reported |
| Pain; Panic Attack;                                  | Clorazepate         |              |            | S           | Oral         |                    |                 | Not Reported |
| Peripheral Swelling;                                 | Co Etidrocal        |              |            | S           | Unknown      |                    |                 | Not Reported |
| Photopsia; Pneumonia;                                | Esomeprazole        |              |            | S           | Unknown      |                    |                 | Not Reported |
| Respiratory Arrest;                                  |                     |              |            |             |              |                    |                 |              |
| Therapeutic Response                                 |                     |              |            |             |              |                    |                 |              |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Decreased; Therapeutic  
Response Unexpected;  
Tremor

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 13-Oct-2015              | 11306183      | NON-EXPEDITED    |                    |                 | US-PFIZER INC-<br>2015139513 |                      | 68 YR      | Male       | USA            |

| <u>Preferred Term</u>               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------|----------------|--------------|------------|-------------|--------------|------------------------------------|-----------------|--------------|
| Drug Interaction; Vision<br>Blurred | Norpace Cr     |              |            | S           | Oral         | 100 Mg, 2x/Day                     |                 | Pfizer       |
|                                     | Norpace Cr     |              |            | S           |              |                                    |                 | Pfizer       |
|                                     | Norpace Cr     |              |            | S           |              |                                    |                 | Pfizer       |
|                                     | Zoloft         |              |            | S           |              | 100 Mg, 1x/Day                     |                 | Pfizer       |
|                                     | Zoloft         |              |            | S           |              | 150 Mg, 1x/Day                     |                 | Pfizer       |
|                                     | Zoloft         |              |            | S           |              | 200 Mg, 1x/Day                     |                 | Pfizer       |
|                                     | Zoloft         |              |            | S           |              | 100 Mg, 1x/Day                     |                 | Pfizer       |
|                                     | Lexapro        |              |            | S           |              | Unk                                |                 | Not Reported |
|                                     | Tenormin       |              |            | C           |              | 50 Mg, 1x/Day                      |                 | Not Reported |
|                                     | Sular Er       |              |            | C           |              | 8.5 Mg, 1x/Day (In The<br>Evening) |                 | Not Reported |
|                                     | Xanax          |              |            | C           |              | As Needed (At 12pm And<br>8pm )    |                 | Not Reported |
|                                     | Acidophilus    |              |            | C           |              | Unk                                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 13-Oct-2015              | 11625630      | NON-EXPEDITED    |                    | HO              | US-JNJFOC-<br>20150914983 |                      |            | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                                                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|------------------------------------------|-----------------|--------------|
| Adverse Drug Reaction;<br>Affect Lability; Depression;<br>Disturbance In Social<br>Behaviour; Dysphonia;<br>Feeling Abnormal;<br>Neoplasm; Off Label Use;<br>Product Use In | Risperdal      |              |            | S           | Oral         |                                          |                 | Not Reported |
|                                                                                                                                                                             | Risperdal      |              |            | S           | Oral         |                                          |                 | Not Reported |
|                                                                                                                                                                             | Risperdal      |              |            | S           | Oral         |                                          |                 | Not Reported |
|                                                                                                                                                                             | Risperdal      |              |            | S           | Oral         | 2 Mg In The Morning And<br>3 Mg At Night |                 | Not Reported |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                              |           |   |      |                                           |  |              |
|----------------------------------------------|-----------|---|------|-------------------------------------------|--|--------------|
| Unapproved Indication;<br>Psychotic Disorder | Risperdal | S | Oral | 2 Mg In The Morning And<br>3 Mg At Night. |  | Not Reported |
|                                              | Risperdal | S | Oral |                                           |  | Not Reported |
|                                              | Lexapro   | S | Oral |                                           |  | Not Reported |
|                                              | Lexapro   | S | Oral |                                           |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Oct-2015              | 11629356      | DIRECT           |                    | OT              |                      |                      | 50 YR      | Female     | USA            |

| <u>Preferred Term</u>                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Ineffective; Product<br>Substitution Issue | Escitalopram   |              |            | S           | Oral         |                    |                 | Cvs Caremark |
|                                                 | Lexapro        |              |            | C           |              |                    |                 | Not Reported |
|                                                 | Aspirin        |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 14-Oct-2015              | 7574741       | EXPEDITED (15-DAY) |                    | DE, OT          | FR-JNJFOC-<br>20100809281 |                      | 27 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                               | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                             | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------|-------------------------------|--------------|------------|-------------|------------------------------------------|--------------------|-----------------|--------------|
| Completed Suicide;<br>Depression; Insomnia;<br>Intentional Overdose | Remicade                      |              |            | S           | Intravenous (not<br>otherwise specified) |                    |                 | Not Reported |
|                                                                     | Remicade                      |              |            | S           | Intravenous (not<br>otherwise specified) |                    |                 | Not Reported |
|                                                                     | Tercian                       |              |            | S           | Oral                                     |                    |                 | Not Reported |
|                                                                     | Seroplex                      |              |            | S           |                                          | 1 Df Qd            |                 | Not Reported |
|                                                                     | Stilnox                       |              |            | S           |                                          |                    |                 | Not Reported |
|                                                                     | Voltarene (Diclofenac Sodium) |              |            | C           |                                          |                    |                 | Not Reported |
|                                                                     | Ventoline Inhaler             |              |            | C           |                                          |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------|----------------------|------------|------------|----------------|
| 14-Oct-2015              | 11628161      | EXPEDITED (15-DAY) |                    | DE              | GB-MHRA-ADR<br>20652148 |                      | 25 YR      | Female     | GBR            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                            |                                                      |   |      |                                        |              |
|--------------------------------------------|------------------------------------------------------|---|------|----------------------------------------|--------------|
| Completed Suicide;<br>Intentional Overdose | Fluoxetine (Unknown)                                 | S | Oral | Overdose: Small Amount                 | Watson       |
|                                            | Ibuprofen (Unknown)                                  | S | Oral | Overdose: Small Amount                 | Watson       |
|                                            | Nortriptyline Hydrochloride<br>(Watson Laboratories) | S | Oral | Unk                                    | Watson       |
|                                            | Oxazepam (Unknown)                                   | S | Oral | Overdose: Small Amount                 | Watson       |
|                                            | Temazepam (Unknown)                                  | S | Oral | Overdose: Small Amount                 | Watson       |
|                                            | Cipralex                                             | S | Oral | Unk                                    | Not Reported |
|                                            | Cipralex                                             | S | Oral | Unk                                    | Not Reported |
|                                            | Cipralex                                             | S | Oral | Overdose: 22 X 10mg<br>Tablets (220mg) | Not Reported |
|                                            | Alcohol                                              | S | Oral | 5x Driving Limit                       | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Oct-2015              | 11630152      | EXPEDITED (15-DAY) | HO                 |                 | CH-FRI-1000080158    |                      | 69 YR      | Female     | CHE            |

| <u>Preferred Term</u>                       | <u>Product</u>                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>     | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------|--------------------------------|--------------|------------|-------------|------------------|--------------------|-----------------|--------------|
| Psychomotor Retardation;<br>Pyrexia; Tremor | Escitalopram                   |              |            | S           | Oral             | 5 Mg               |                 | Forest       |
|                                             | Escitalopram                   |              |            | S           | Oral             | 15 Mg              |                 | Forest       |
|                                             | Quetiapin                      |              |            | S           | Oral             | 6 Mg               |                 | Not Reported |
|                                             | Tramadol                       |              |            | S           | Oral             | 300 Mg             |                 | Not Reported |
|                                             | Temgesic                       |              |            | S           | Sublingual       | 0.9 Mg             |                 | Not Reported |
|                                             | Sifrol                         |              |            | C           | Oral             | 0.125 Mg           |                 | Not Reported |
|                                             | Flector (Diclofenac Epolamine) |              |            | C           | Topical          | 2 Df               |                 | Not Reported |
|                                             | Lasix                          |              |            | C           | Intravenous drip | 20 Mg              |                 | Not Reported |
|                                             | Amlodipin                      |              |            | C           | Oral             | 10 Mg              |                 | Not Reported |
|                                             | Beloc [Metoprolol]             |              |            | C           | Oral             | 100 Mg             |                 | Not Reported |
|                                             | Aprovel                        |              |            | C           | Oral             | 75 Mg              |                 | Not Reported |
|                                             | Lantus                         |              |            | C           | Subcutaneous     | 28 lu              |                 | Not Reported |
|                                             | Novorapid                      |              |            | C           | Subcutaneous     |                    |                 | Not Reported |
|                                             | Vitamin B6                     |              |            | C           | Oral             | 20 Mg              |                 | Not Reported |

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|                                                                                                                                                                   | Vi-De 3              |                    | C                  | Oral            | 800 lu                                  |                                |                 | Not Reported    |                |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|-----------------------------------------|--------------------------------|-----------------|-----------------|----------------|
|                                                                                                                                                                   | Laxoberon            |                    | C                  | Oral            | 10 Mg                                   |                                |                 | Not Reported    |                |
|                                                                                                                                                                   | Movicol              |                    | C                  | Oral            | 1 Df                                    |                                |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                                                          | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                    | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 14-Oct-2015                                                                                                                                                       | 11630733             | EXPEDITED (15-DAY) |                    | OT              | DK-<br>GLAXOSMITHKLINE-<br>DK2015144569 |                                | 59 YR           | Male            | DNK            |
| <u>Preferred Term</u>                                                                                                                                             | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                            | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>      |                |
| Disturbance In Attention;<br>Fatigue; Haemoptysis;<br>Mouth Haemorrhage;<br>Muscle Spasms;<br>Nightmare; Prescribed<br>Overdose; Restlessness;<br>Seizure; Tremor | Lamictal             |                    |                    | S               |                                         |                                |                 | Glaxosmithkline |                |
|                                                                                                                                                                   | Ciprallex            |                    |                    | S               |                                         |                                |                 | Glaxosmithkline |                |
|                                                                                                                                                                   | Escitalopram Sandoz  |                    |                    | S               |                                         |                                |                 | Sandoz          |                |
| <u>FDA Received Date</u>                                                                                                                                          | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                    | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 14-Oct-2015                                                                                                                                                       | 11631391             | EXPEDITED (15-DAY) |                    | HO              | ES-AMGEN-<br>ESPSP2015106111            |                                | 63 YR           | Female          | ESP            |
| <u>Preferred Term</u>                                                                                                                                             | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                            | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>      |                |
| Paresis Cranial Nerve                                                                                                                                             | Prolia               |                    |                    | S               | Unknown                                 |                                |                 | Amgen           |                |
|                                                                                                                                                                   | Escitalopram         |                    |                    | S               | Oral                                    | 10 Mg, Qd                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                                                          | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                    | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 14-Oct-2015                                                                                                                                                       | 11632418             | DIRECT             |                    | LT              |                                         |                                | 65 YR           | Female          | ZAF            |
| <u>Preferred Term</u>                                                                                                                                             | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                            | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>      |                |
| Depression; Drug<br>Ineffective; Product<br>Substitution Issue; Quality<br>Of Life Decreased;<br>Suicidal Ideation                                                | Escitalopram Mylan   |                    |                    | S               | Oral                                    | 1 Once Daily Taken By<br>Mouth | 6 MTH           | Mylan           |                |
|                                                                                                                                                                   | Ritalin              |                    |                    | C               |                                         |                                |                 | Not Reported    |                |
|                                                                                                                                                                   | Eltroxin             |                    |                    | C               |                                         |                                |                 | Not Reported    |                |
|                                                                                                                                                                   | Lansoprazole         |                    |                    | C               |                                         |                                |                 | Not Reported    |                |
|                                                                                                                                                                   | Estrofem [Estradiol] |                    |                    | C               |                                         |                                |                 | Not Reported    |                |

# FDA Adverse Event Reporting System

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|                                                                                            | Alprazolam      |                    |                    | C               |                                                              |                      |                 |              | Not Reported   |
|--------------------------------------------------------------------------------------------|-----------------|--------------------|--------------------|-----------------|--------------------------------------------------------------|----------------------|-----------------|--------------|----------------|
|                                                                                            | Stilnox         |                    |                    | C               |                                                              |                      |                 |              | Not Reported   |
| <u>FDA Received Date</u>                                                                   | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Oct-2015                                                                                | 11633081        | DIRECT             |                    | OT              |                                                              |                      | 23 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                      | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Disease Recurrence;<br>Presyncope; Product Dose<br>Omission; Product<br>Substitution Issue | Lexapro 10 Mg   |                    |                    | S               | Oral                                                         | 1 Pill               |                 | Not Reported |                |
|                                                                                            | Lexapro         |                    |                    | C               |                                                              |                      |                 | Not Reported |                |
|                                                                                            | Aspirin         |                    |                    | C               |                                                              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                   | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Oct-2015                                                                                | 7575250         | EXPEDITED (15-DAY) |                    | DE              | CHPA2010GB13592                                              |                      | 25 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                                      | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Intentional Overdose                                                 | Ibuprofen       |                    |                    | S               | Oral                                                         | Unk, Unk             |                 | Not Reported |                |
|                                                                                            | Temazepam       |                    |                    | S               | Oral                                                         | Unk, Unk             |                 | Novartis     |                |
|                                                                                            | Fluoxetine      |                    |                    | S               | Oral                                                         | Unk, Unk             |                 | Not Reported |                |
|                                                                                            | Nortriptyline   |                    |                    | S               | Oral                                                         | Unk, Unk             |                 | Not Reported |                |
|                                                                                            | Oxazepam        |                    |                    | S               | Oral                                                         | Unk, Unk             |                 | Not Reported |                |
|                                                                                            | Cipralext /Den/ |                    |                    | S               | Oral                                                         | 10 Mg, Qd            |                 | Not Reported |                |
|                                                                                            | Cipralext /Den/ |                    |                    | S               | Oral                                                         | 10 Mg, Qd            |                 | Not Reported |                |
|                                                                                            | Cipralext /Den/ |                    |                    | S               | Oral                                                         | 220 Mg, Once/Single  |                 | Not Reported |                |
|                                                                                            | Alcohol         |                    |                    | S               | Oral                                                         | Unk, Unk             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                   | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Oct-2015                                                                                | 11631721        | NON-EXPEDITED      |                    |                 | IT-GLENMARK<br>PHARMACEUTICALS<br>INC, USA.-<br>2015GMK01496 |                      | 76 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                                      | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective For                                                                       | Gabapentin      |                    |                    | S               | Unknown                                                      | Unk                  |                 | Glenmark     |                |

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|                                                                       |                                           |   |         |            |              |
|-----------------------------------------------------------------------|-------------------------------------------|---|---------|------------|--------------|
| Unapproved Indication; Off Label Use; Therapeutic Response Unexpected | Quetiapine                                | S |         | 25 Mg, Unk | Not Reported |
|                                                                       | Escitalopram Oxalate 10mg Accord Hlthcare | S |         | 10 Mg, Unk | Not Reported |
|                                                                       | Benzodiazepine Derivatives                | C | Unknown | Unk        | Not Reported |
|                                                                       | Amitriptyline                             | C | Unknown | Unk        | Not Reported |
|                                                                       | Mirtazapine                               | C | Unknown | Unk        | Not Reported |
|                                                                       | Promazine                                 | C | Unknown | Unk        | Not Reported |
|                                                                       | Trazodone                                 | C |         | 50 Mg, Unk | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                       | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|------------------------------------------------------------|----------------------------------|-----------------|--------------|----------------|
| 15-Oct-2015              | 11631912       | EXPEDITED (15-DAY) |                    | OT              | DE-MACLEODS<br>PHARMACEUTICALS<br>US LTD-<br>MAC2015002054 |                                  |                 | Unknown      | DEU            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                               | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Faecaloma; Rash          | Escitalopram   |                    |                    | S               | Oral                                                       | 10 Mg, Qd                        |                 | Macleods     |                |
|                          | Amitriptylin   |                    |                    | C               | Oral                                                       | 50 Mg, Qd Application For Months |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|--------------------------------------------------------------------|-----------------|--------------|----------------|
| 15-Oct-2015              | 11632311               | EXPEDITED (15-DAY) |                    | DS              | GB-WATSON-2015-22020 |                                                                    |                 | Female       | GBR            |
| <u>Preferred Term</u>    | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Muscle Twitching         | Citalopram (Unknown)   |                    |                    | S               | Oral                 | 10mg Once A Day Increasing To 20mg Once A Day Then 30mg Once A Day |                 | Watson       |                |
|                          | Citalopram (Unknown)   |                    |                    | S               | Oral                 | 20 Mg, Daily                                                       |                 | Watson       |                |
|                          | Citalopram (Unknown)   |                    |                    | S               | Oral                 | 30 Mg, Daily                                                       |                 | Watson       |                |
|                          | Escitalopram (Unknown) |                    |                    | S               | Oral                 | Unknown                                                            |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Oct-2015              | 11632720      | EXPEDITED (15-DAY) |                    | HO              | FR-JNJFOC-           |                      | 95 YR      | Female     | FRA            |

# FDA Adverse Event Reporting System

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20151005617

| <u>Preferred Term</u>                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                         | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------------------------------|-----------------|--------------|
| Abnormal Behaviour;<br>Hallucination; Mania | Risperdal      |              |            | S           | Oral         |                                            |                 | Not Reported |
|                                             | Seroplex       |              |            | S           | Oral         |                                            |                 | Not Reported |
|                                             | Seroplex       |              |            | S           | Oral         |                                            |                 | Not Reported |
|                                             | Xanax          |              |            | S           | Unknown      |                                            |                 | Not Reported |
|                                             | Xanax          |              |            | S           | Unknown      | Dose: 0.25 Mg, ½ Tablet 3<br>Times Per Day |                 | Not Reported |
|                                             | Imovane        |              |            | S           | Oral         |                                            |                 | Not Reported |
|                                             | Imovane        |              |            | S           | Oral         | Dose: ½ Tablet Of 7.5 Mg<br>Per Day        |                 | Not Reported |
|                                             | Monuril        |              |            | C           | Unknown      |                                            |                 | Not Reported |
|                                             | Cardensiel     |              |            | C           | Unknown      |                                            |                 | Not Reported |
|                                             | Hyperium       |              |            | C           | Unknown      |                                            |                 | Not Reported |
|                                             | Lercan         |              |            | C           | Unknown      |                                            |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 15-Oct-2015              | 11633327      | EXPEDITED (15-DAY) |                    | HO, OT          | US-PFIZER INC-<br>2015342231 |                      | 51 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Creatine<br>Phosphokinase Increased;<br>Extrapyramidal Disorder;<br>Rhabdomyolysis | Lipitor        |              |            | S           |              | 10 Mg, Daily       |                 | Pfizer       |
|                                                                                          | Lexapro        |              |            | S           |              | 15 Mg, Daily       |                 | Not Reported |
|                                                                                          | Mirtazapine    |              |            | S           |              | 15 Mg, Daily       |                 | Not Reported |
|                                                                                          | Seroquel       |              |            | S           |              | Unk                |                 | Not Reported |
|                                                                                          | Depakote       |              |            | S           |              | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Oct-2015              | 11633748      | NON-EXPEDITED    |                    |                 | US-INDIVIOR-RB-      |                      | 25 YR      | Male       | USA            |

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73546-2014

| <u>Preferred Term</u>                | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>        |
|--------------------------------------|-------------------|--------------|------------|-------------|--------------|--------------------|-----------------|-------------------|
| Product Prescribing Error;<br>Tremor | Suboxone 8mg Film |              |            | S           | Unknown      | 8 Mg, Tid          |                 | Reckitt Benckiser |
|                                      | Lexapro           |              |            | S           | Unknown      | Unk                |                 | Not Reported      |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Oct-2015              | 11635446      | EXPEDITED (15-DAY) |                    | HO              | US-ZYDUS-009227      |                      | 78 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u>                         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Torticollis           | Escitalopram                           |              |            | S           |              |                    |                 | Not Reported |
|                       | Clonazepam                             |              |            | C           |              |                    |                 | Not Reported |
|                       | Ibuprofen                              |              |            | C           |              |                    |                 | Not Reported |
|                       | Amlodipine                             |              |            | C           |              |                    |                 | Not Reported |
|                       | Celecoxib                              |              |            | C           |              |                    |                 | Not Reported |
|                       | Tamsulosin/Tamsulosin<br>Hydrochloride |              |            | C           |              |                    |                 | Not Reported |
|                       | Omeprazole                             |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 16-Oct-2015              | 11635592      | NON-EXPEDITED    |                    |                 | US-PFIZER INC-<br>2015312465 |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Hypersensitivity | Ativan         |              |            | S           |              | Unk                |                 | Pfizer       |
|                       | Effexor Xr     |              |            | S           |              | Unk                |                 | Pfizer       |
|                       | Wellbutrin     |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Ceclor         |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Cipro          |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Lexapro        |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Prevacid       |              |            | S           |              | Unk                |                 | Not Reported |

# FDA Adverse Event Reporting System

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|                   |   |     |              |
|-------------------|---|-----|--------------|
| Lisinopril        | S | Unk | Not Reported |
| Compazine         | S | Unk | Not Reported |
| Zantac            | S | Unk | Not Reported |
| Divalproex Sodium | S | Unk | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|------------|------------|----------------|
| 16-Oct-2015              | 11635728      | EXPEDITED (15-DAY) |                    | OT              | AU-HETERO LABS<br>LTD-1043025 |                      | 70 YR      | Female     | AUS            |

| <u>Preferred Term</u>                              | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Confusional State; Drug Interaction; Hyponatraemia | Escitalopram            |              |            | S           | Unknown      |                    |                 | Hetero       |
|                                                    | Bupropion Hydrochloride |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                    | Dothiepin               |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                    | Quetiapine Fumarate     |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                    | Lamotrigine             |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                    | Estradiol               |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                    | Ramipril                |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                    | Glipizide               |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                    | Metformin               |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                    | Lantus                  |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                    | Atorvastatin Calcium    |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                    | Aspirin                 |              |            | C           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Oct-2015              | 11636203      | EXPEDITED (15-DAY) |                    | DS              | GB-TEVA-600246ACC    |                      |            | Female     | GBR            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                                     | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|----------------------------------------------------------------------------------------|-----------------|------------|
| Muscle Twitching      | Citalopram     |              |            | S           | Oral         | 10 Milligram Daily; 10mg Once A Day Increasing To 20mg Once A Day Then 30mg Once A Day |                 | Pliva      |

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|  |              |   |      |                     |       |
|--|--------------|---|------|---------------------|-------|
|  | Citalopram   | S | Oral | 30 Milligram Daily; | Pliva |
|  | Citalopram   | S | Oral | 20 Milligram Daily; | Pliva |
|  | Escitalopram | S | Oral | Unknown             | Ivax  |

| <u>FDA Received Date</u>                   | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------|---------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------------|-----------------|--------------|----------------|
| 16-Oct-2015                                | 11636660                  | EXPEDITED (15-DAY) |                    | DE              | GB-BANPHARM-20154308 |                                     | 25 YR           | Female       | GBR            |
| <u>Preferred Term</u>                      | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Intentional Overdose | Ibuprofen Unknown Product |                    |                    | S               | Oral                 | Overdose: Small Amount              |                 | Not Reported |                |
|                                            | Alcohol                   |                    |                    | S               | Oral                 | 5x Driving Limit                    |                 | Not Reported |                |
|                                            | Cipralelex                |                    |                    | S               | Oral                 |                                     |                 | Not Reported |                |
|                                            | Cipralelex                |                    |                    | S               | Oral                 |                                     |                 | Not Reported |                |
|                                            | Cipralelex                |                    |                    | S               | Oral                 | Overdose: 22 X 10mg Tablets (220mg) |                 | Not Reported |                |
|                                            | Fluoxetine                |                    |                    | S               | Oral                 | Overdose: Small Amount              |                 | Not Reported |                |
|                                            | Oxazepam                  |                    |                    | S               | Oral                 | Overdose: Small Amount              |                 | Not Reported |                |
|                                            | Temazepam                 |                    |                    | S               | Oral                 | Overdose: Small Amount              |                 | Not Reported |                |
|                                            | Nortriptyline             |                    |                    | S               | Oral                 |                                     |                 | Not Reported |                |

| <u>FDA Received Date</u>             | <u>Case #</u>                                        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------------------|------------------------------------------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 16-Oct-2015                          | 11637253                                             | NON-EXPEDITED    |                    |                 | US-TORRENT-00000984  |                      |                 | Male       | USA            |
| <u>Preferred Term</u>                | <u>Product</u>                                       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Headache; Product Substitution Issue | Escitalopram Oxalate-<br>Escitalopram Oxalate Tablet |                  |                    | S               |                      |                      |                 | Torrent    |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 16-Oct-2015              | 11637315       | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000080206    |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Multiple Cardiac Defects | Lexapro        |                    |                    | S               | Transplacental       |                      |                 | Forest     |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                          |                |                    |                    |                 |                            |                              |                 |              |                |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------------|------------------------------|-----------------|--------------|----------------|
| Zoloft                   |                |                    | S                  |                 | Transplacental             |                              |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Oct-2015              | 11637720       | EXPEDITED (15-DAY) |                    | OT              | GB-FRI-1000080285          |                              | 37 YR           | Female       | GBR            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Feeling         | Escitalopram   |                    |                    | S               | Oral                       |                              |                 | Forest       |                |
| Abnormal; Insomnia;      | Propranolol    |                    |                    | S               | Unknown                    |                              |                 | Not Reported |                |
| Paranoia; Product Use In | Selincro       |                    |                    | C               | Oral                       | One Tablet Daily As Required |                 | Not Reported |                |
| Unapproved Indication;   |                |                    |                    |                 |                            |                              |                 |              |                |
| Tachyphrenia; Withdrawal |                |                    |                    |                 |                            |                              |                 |              |                |
| Syndrome                 |                |                    |                    |                 |                            |                              |                 |              |                |
| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Oct-2015              | 11638526       | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2015348475   |                              |                 | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective         | Zoloft         |                    |                    | S               |                            | Unk                          |                 | Pfizer       |                |
|                          | Effexor        |                    |                    | S               |                            | Unk                          |                 | Pfizer       |                |
|                          | Lexapro        |                    |                    | S               |                            | Unk                          |                 | Not Reported |                |
|                          | Cymbalta       |                    |                    | S               |                            | Unk                          |                 | Not Reported |                |
|                          | Prozac         |                    |                    | S               |                            | Unk                          |                 | Not Reported |                |
|                          | Paxil          |                    |                    | S               |                            | Unk                          |                 | Not Reported |                |
|                          | Remeron        |                    |                    | C               |                            |                              |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Oct-2015              | 11638774       | EXPEDITED (15-DAY) |                    | OT              | CH-ASTRAZENECA-2015SE97586 |                              | 59 YR           | Female       | CHE            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Angle Closure Glaucoma;  | Seroquel Xr    |                    |                    | S               | Oral                       |                              |                 | Astrazeneca  |                |
| Drug Interaction;        | Seroquel Xr    |                    |                    | S               | Oral                       |                              |                 | Astrazeneca  |                |
| Photopsia                | Cipralext      |                    |                    | S               | Oral                       |                              |                 | Not Reported |                |

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|  |                     |   |      |              |
|--|---------------------|---|------|--------------|
|  | Cipralex            | S | Oral | Not Reported |
|  | Zolpidem            | C | Oral | Not Reported |
|  | Temesta (Lorazepam) | C | Oral | Not Reported |

| <u>FDA Received Date</u>                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------|----------------|--------------------|--------------------|-----------------|--------------------------------|--------------------------------|-----------------|--------------|----------------|
| 19-Oct-2015                                | 7553830        | EXPEDITED (15-DAY) |                    | DE              | GB-PFIZER INC-GB-WYE-G06578910 |                                | 25 YR           | Female       | GBR            |
| <u>Preferred Term</u>                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Intentional Overdose | Ibuprofen      |                    |                    | S               | Oral                           | Unk                            |                 | Pfizer       |                |
|                                            | Ethanol        |                    |                    | S               | Oral                           | 5 Times Over The Driving Limit |                 | Not Reported |                |
|                                            | Cipralex       |                    |                    | S               | Oral                           | 10.0 Mg, 22x/Tot               |                 | Not Reported |                |
|                                            | Cipralex       |                    |                    | S               |                                |                                |                 | Not Reported |                |
|                                            | Fluoxetine     |                    |                    | S               | Oral                           | Unk                            |                 | Not Reported |                |
|                                            | Nortriptyline  |                    |                    | S               | Oral                           | Unk                            |                 | Not Reported |                |
|                                            | Oxazepam       |                    |                    | S               | Oral                           | Unk                            |                 | Not Reported |                |
|                                            | Temazepam      |                    |                    | S               | Oral                           | Unk                            |                 | Not Reported |                |

| <u>FDA Received Date</u>                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------|----------------|--------------------|--------------------|-----------------|-------------------------|---------------------------|-----------------|--------------|----------------|
| 19-Oct-2015                                | 7573969        | EXPEDITED (15-DAY) |                    | DE              | GB-RANBAXY-2010RR-35516 |                           |                 | Unknown      | GBR            |
| <u>Preferred Term</u>                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Intentional Overdose | Nortriptyline  |                    |                    | S               | Oral                    | Unk                       |                 | Taro         |                |
|                                            | Ibuprofen      |                    | Y                  | S               | Oral                    | Unk                       |                 | Ranbaxy      |                |
|                                            | Cipralex       |                    |                    | S               | Oral                    | Unk                       |                 | Not Reported |                |
|                                            | Cipralex       |                    |                    | S               | Oral                    | Unk                       |                 | Not Reported |                |
|                                            | Cipralex       |                    |                    | S               | Oral                    | 22 X 10mg Tablets (220mg) |                 | Not Reported |                |
|                                            | Fluoxetine     |                    |                    | S               | Oral                    | Overdose: Small Amount    |                 | Sun          |                |
|                                            | Alcohol        |                    |                    | S               | Oral                    | 5x Driving Limit          |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                            | Oxazepam       | S                  | Oral               | Overdose: Small Amount | Mutual                    |                                |                 |              |                |
|--------------------------------------------|----------------|--------------------|--------------------|------------------------|---------------------------|--------------------------------|-----------------|--------------|----------------|
|                                            | Temazepam      | S                  | Oral               | Unk                    | Mutual                    |                                |                 |              |                |
| <u>FDA Received Date</u>                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>        | <u>Mfr Control #</u>      | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Oct-2015                                | 7575286        | EXPEDITED (15-DAY) |                    | DE                     | GB-MYLANLABS-2010S1015525 |                                |                 | Unknown      | GBR            |
| <u>Preferred Term</u>                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>            | <u>Route</u>              | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Intentional Overdose | Fluoxetine     |                    |                    | S                      | Oral                      | Overdose: Small Amount         |                 | Not Reported |                |
|                                            | Temazepam      |                    |                    | S                      | Oral                      | Overdose: Small Amount         |                 | Not Reported |                |
|                                            | Alcohol        |                    |                    | S                      | Oral                      | 5x Driving Limit               |                 | Not Reported |                |
|                                            | Cipralelex     |                    |                    | S                      | Oral                      | 220 Mg,Once                    |                 | Not Reported |                |
|                                            | Cipralelex     |                    |                    | S                      | Oral                      | 10 Mg,Qd                       |                 | Not Reported |                |
|                                            | Cipralelex     |                    |                    | S                      | Oral                      | Overdose: 22 X 10mg<br>Tablets |                 | Not Reported |                |
|                                            | Ibuprofen      |                    |                    | S                      | Oral                      | Overdose: Small Amount         |                 | Not Reported |                |
|                                            | Nortriptyline  |                    |                    | S                      | Oral                      | 5x Driving Limit               |                 | Not Reported |                |
|                                            | Oxazepam       |                    |                    | S                      | Oral                      | Overdose: Small Amount         |                 | Not Reported |                |
| <u>FDA Received Date</u>                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>        | <u>Mfr Control #</u>      | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Oct-2015                                | 9420228        | NON-EXPEDITED      |                    |                        | US-PFIZER INC-2013216441  |                                | 61 YR           | Female       | USA            |
| <u>Preferred Term</u>                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>            | <u>Route</u>              | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity                      | Relpax         |                    |                    | S                      |                           | Unk                            |                 | Pfizer       |                |
|                                            | Neurontin      |                    |                    | S                      |                           | Unk                            |                 | Pfizer       |                |
|                                            | Cipro          |                    |                    | S                      |                           | Unk                            |                 | Not Reported |                |
|                                            | Codeine        |                    |                    | S                      |                           | Unk                            |                 | Not Reported |                |
|                                            | Levaquin       |                    |                    | S                      |                           | Unk                            |                 | Not Reported |                |
|                                            | Paxil          |                    |                    | S                      |                           | Unk                            |                 | Not Reported |                |
|                                            | Topamax        |                    |                    | S                      |                           | Unk                            |                 | Not Reported |                |
|                                            | Diovan         |                    |                    | S                      |                           | Unk                            |                 | Not Reported |                |

# FDA Adverse Event Reporting System

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### Detailed Report

|         |   |     |              |
|---------|---|-----|--------------|
| Lexapro | S | Unk | Not Reported |
| Bonna   | S | Unk | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------|----------------------|------------|------------|----------------|
| 19-Oct-2015              | 11613655      | EXPEDITED (15-DAY) |                    | HO, OT          | US-APOTEX-2015AP013089 |                      | 78 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Torticollis           | Escitalopram Oxalate |              |            | S           | Unknown      | 5 Mg, Daily        |                 | Apotex       |
|                       | Escitalopram Oxalate |              |            | S           | Unknown      | 10 Mg, Unk         |                 | Apotex       |
|                       | Escitalopram Oxalate |              |            | S           | Unknown      | 15 Mg, Unk         |                 | Apotex       |
|                       | Clonazepam Ic        |              |            | C           | Unknown      | 0.25 Mg, Q.H.S.    |                 | Not Reported |
|                       | Clonazepam Ic        |              |            | C           | Unknown      | 0.25- 0.5 Mg, Prn  |                 | Not Reported |
|                       | Ibuprofen            |              |            | C           | Unknown      | Unk                |                 | Not Reported |
|                       | Amlodipine           |              |            | C           | Unknown      | Unk                |                 | Not Reported |
|                       | Celecoxib            |              |            | C           | Unknown      | Unk                |                 | Not Reported |
|                       | Clonazepam           |              |            | C           | Unknown      | Unk                |                 | Not Reported |
|                       | Tamsulosin           |              |            | C           | Unknown      | Unk                |                 | Not Reported |
|                       | Omeprazole           |              |            | C           | Unknown      | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|------------|------------|----------------|
| 19-Oct-2015              | 11639144      | EXPEDITED (15-DAY) |                    | DS              | GB-AUROBINDO-AUR-APL-2015-09075 |                      |            | Female     | GBR            |

| <u>Preferred Term</u> | <u>Product</u>                      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                                | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|-------------------------------------|--------------|------------|-------------|--------------|-----------------------------------------------------------------------------------|-----------------|------------|
| Muscle Twitching      | Citalopram Film-Coated Tablets 10mg |              |            | S           | Oral         | 10 Mg, Daily (10mg Once A Day Increasing To 20mg Once A Day Then 30mg Once A Day) |                 | Aurobindo  |
|                       | Citalopram Film-Coated Tablets 10mg |              |            | S           | Oral         | 20 Mg, Once A Day                                                                 |                 | Aurobindo  |
|                       | Citalopram Film-Coated Tablets 10mg |              |            | S           | Oral         | 30 Mg, Once A Day                                                                 |                 | Aurobindo  |
|                       | Escitalopram                        |              |            | S           | Oral         | Unknown                                                                           |                 | Aurobindo  |

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| <u>FDA Received Date</u>                                                             | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                         | <u>503B Facility</u>                                    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|----------------------------------------------|---------------------------------------------------------|-----------------|--------------|----------------|
| 19-Oct-2015                                                                          | 11639181                 | EXPEDITED (15-DAY) |                    | OT              | US-JUBILANT<br>GENERICIS LIMITED-<br>1043080 |                                                         | 78 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                 | <u>Dosage Text</u>                                      | <u>Duration</u> | <u>Mfr</u>   |                |
| Torticollis                                                                          | Escitalopram Oxalate     |                    |                    | S               |                                              |                                                         |                 | Jubilant     |                |
|                                                                                      | Clonazepam               |                    |                    | C               |                                              |                                                         |                 | Not Reported |                |
|                                                                                      | Ibuprofen                |                    |                    | C               |                                              |                                                         |                 | Not Reported |                |
|                                                                                      | Amlodipine               |                    |                    | C               |                                              |                                                         |                 | Not Reported |                |
|                                                                                      | Celecoxib                |                    |                    | C               |                                              |                                                         |                 | Not Reported |                |
|                                                                                      | Tamsulosin Hydrochloride |                    |                    | C               |                                              |                                                         |                 | Not Reported |                |
|                                                                                      | Omeprazole               |                    |                    | C               |                                              |                                                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                             | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                         | <u>503B Facility</u>                                    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Oct-2015                                                                          | 11640086                 | EXPEDITED (15-DAY) |                    | HO, OT          | CH-ACTAVIS-2015-<br>21836                    |                                                         | 38 YR           | Female       | CHE            |
| <u>Preferred Term</u>                                                                | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                 | <u>Dosage Text</u>                                      | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;<br>Serotonin Syndrome                                              | Mirtazapine (Unknown)    |                    |                    | S               | Unknown                                      | 15 Mg, Qhs                                              |                 | Actavis      |                |
|                                                                                      | Mirtazapine (Unknown)    |                    |                    | S               |                                              |                                                         |                 | Actavis      |                |
|                                                                                      | Escitalopram (Unknown)   |                    |                    | S               | Unknown                                      | 20 Mg, Daily                                            |                 | Not Reported |                |
|                                                                                      | Escitalopram (Unknown)   |                    |                    | S               | Unknown                                      | Unk (Doses Increasing<br>Progressively Up To<br>20mg/D) |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                             | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                         | <u>503B Facility</u>                                    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Oct-2015                                                                          | 11643551                 | DIRECT             |                    |                 |                                              |                                                         | 21 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                 | <u>Dosage Text</u>                                      | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Crying; Feeling<br>Abnormal; Nausea;<br>Palpitations; Somnolence;<br>Tremor | Escitalopram 5mg Walmart |                    |                    | S               | Oral                                         | 1 Pill Once Daily                                       |                 | Walmart      |                |
|                                                                                      | Essential Oils           |                    |                    | C               |                                              |                                                         |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                       | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------|-----------------------|--------------------|--------------------|-----------------|------------------------------------------|----------------------|-----------------|--------------|----------------|
| 19-Oct-2015                                                                    | 11643632              | DIRECT             |                    |                 |                                          |                      | 35 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                                          | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Impaired Work Ability;<br>Product Quality Issue;<br>Product Substitution Issue | Escitalopram          |                    |                    | S               | Oral                                     |                      |                 | Ranbaxy      |                |
|                                                                                | Omega-3 Fish Oil      |                    |                    | C               |                                          |                      |                 | Not Reported |                |
|                                                                                | Omega-6 Primrose Oil  |                    |                    | C               |                                          |                      |                 | Not Reported |                |
|                                                                                | Zinc                  |                    |                    | C               |                                          |                      |                 | Not Reported |                |
|                                                                                | Siemens Light Therapy |                    |                    | C               |                                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                       | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Oct-2015                                                                    | 11643673              | DIRECT             | Y                  |                 |                                          |                      | 31 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                          | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Depression; Drug<br>Ineffective; Product<br>Substitution Issue        | Escitalopram 20 Mg    |                    |                    | S               | Oral                                     |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                       | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Oct-2015                                                                    | 10637299              | EXPEDITED (15-DAY) |                    | OT              | CA-JNJFOC-<br>20140503666                |                      | 26 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                                          | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Caesarean Section;<br>Exposure During<br>Pregnancy                             | Remicade              |                    |                    | S               | Intravenous (not<br>otherwise specified) |                      |                 | Not Reported |                |
|                                                                                | Cipralext             |                    |                    | S               | Unknown                                  |                      |                 | Not Reported |                |
|                                                                                | Azathioprine          |                    |                    | S               | Unknown                                  |                      |                 | Not Reported |                |
|                                                                                | Domperidone           |                    |                    | S               | Unknown                                  |                      |                 | Not Reported |                |
|                                                                                | Wellbutrin            |                    |                    | S               | Unknown                                  |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                       | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Oct-2015                                                                    | 11639165              | EXPEDITED (15-DAY) |                    | OT              | DE-AUROBINDO-AUR-<br>APL-2015-09345      |                      | 42 YR           | Female       | DEU            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                          | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|--------------------|--------------------|-----------------|---------------------------------------|----------------------|-----------------|--------------|----------------|
| Faecaloma; Rash                                                                                                                                | Escitalopram 10 Mg             |                    |                    | S               | Oral                                  | 10 Mg, Daily         |                 | Aurobindo    |                |
|                                                                                                                                                | Amitriptylin                   |                    |                    | C               | Oral                                  | 50 Mg, Daily         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                       | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Oct-2015                                                                                                                                    | 11642548                       | EXPEDITED (15-DAY) |                    | HO, LT, OT      | CA-HOSPIRA-3038091                    |                      | 54 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                                                                                                          | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Body Temperature Increased; Diarrhoea; Flushing; Hallucination, Auditory; Hallucination, Visual; Insomnia; Rash; Serotonin Syndrome | Morphine Sulphate              |                    |                    | S               | Intravenous (not otherwise specified) |                      |                 | Not Reported |                |
|                                                                                                                                                | Metformin                      |                    |                    | C               |                                       |                      |                 | Not Reported |                |
|                                                                                                                                                | Tecta                          |                    |                    | C               |                                       |                      |                 | Not Reported |                |
|                                                                                                                                                | Atasol 30                      |                    |                    | S               | Oral                                  |                      |                 | Not Reported |                |
|                                                                                                                                                | Lantus                         |                    |                    | C               | Oral                                  |                      |                 | Not Reported |                |
|                                                                                                                                                | Phisohex /00107601/            |                    |                    | C               |                                       |                      |                 | Not Reported |                |
|                                                                                                                                                | Cipralext /01588501/           |                    |                    | S               |                                       |                      |                 | Not Reported |                |
|                                                                                                                                                | Proctodan-Hc                   |                    |                    | C               | Oral                                  |                      |                 | Not Reported |                |
|                                                                                                                                                | Ramipril                       |                    |                    | C               |                                       |                      |                 | Not Reported |                |
|                                                                                                                                                | Simvastatin                    |                    |                    | C               |                                       |                      |                 | Not Reported |                |
|                                                                                                                                                | Diprosone /00008502/           |                    |                    | C               | Oral                                  |                      |                 | Not Reported |                |
|                                                                                                                                                | Docusate Sodium                |                    |                    | C               |                                       |                      |                 | Not Reported |                |
|                                                                                                                                                | Concerta                       |                    |                    | S               |                                       |                      |                 | Not Reported |                |
|                                                                                                                                                | Meperidine                     |                    |                    | S               | Oral                                  |                      |                 | Not Reported |                |
|                                                                                                                                                | Glucagon                       |                    |                    | C               |                                       |                      |                 | Not Reported |                |
|                                                                                                                                                | Proctol                        |                    |                    | C               |                                       |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                       | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Oct-2015                                                                                                                                    | 11643821                       | EXPEDITED (15-DAY) |                    | LT              | NL-JNJFOC-20151013775                 |                      | 46 YR           | Male         | NLD            |
| <u>Preferred Term</u>                                                                                                                          | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Drug Interaction; Suicide Attempt                                                                                                  | Zaldiar                        |                    |                    | S               | Oral                                  |                      |                 | Not Reported |                |
|                                                                                                                                                | Escitalopram                   |                    |                    | S               | Oral                                  |                      |                 | Not Reported |                |
|                                                                                                                                                | All Other Therapeutic Products |                    |                    | C               | Unknown                               |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                        | Symbicort           |                    | C                  | Respiratory (inhalation) |                                              |                      |                 | Not Reported |                |
|----------------------------------------|---------------------|--------------------|--------------------|--------------------------|----------------------------------------------|----------------------|-----------------|--------------|----------------|
|                                        | Paracetamol         |                    | C                  | Oral                     |                                              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>               | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>          | <u>Mfr Control #</u>                         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Oct-2015                            | 11644151            | EXPEDITED (15-DAY) |                    | OT                       | CH-FRI-1000080222                            |                      | 38 YR           | Female       | CHE            |
| <u>Preferred Term</u>                  | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>              | <u>Route</u>                                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Serotonin Syndrome   | Escitalopram        |                    |                    | S                        | Unknown                                      | 20 Mg                |                 | Forest       |                |
|                                        | Escitalopram        |                    |                    | S                        |                                              |                      |                 | Forest       |                |
|                                        | Mirtazapine         |                    |                    | S                        | Unknown                                      | 15 Mg At Bedtime     |                 | Not Reported |                |
|                                        | Mirtazapine         |                    |                    | S                        |                                              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>               | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>          | <u>Mfr Control #</u>                         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Oct-2015                            | 11644218            | EXPEDITED (15-DAY) |                    | OT                       | CH-FRI-1000080349                            |                      | 59 YR           | Female       | CHE            |
| <u>Preferred Term</u>                  | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>              | <u>Route</u>                                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Angle Closure Glaucoma; Photopsia      | Escitalopram        |                    |                    | S                        | Oral                                         | 10 Mg                |                 | Forest       |                |
|                                        | Seroquel Xr         |                    |                    | S                        | Oral                                         | 300 Mg               |                 | Not Reported |                |
|                                        | Zolpidem            |                    |                    | C                        | Oral                                         | 10 Mg                |                 | Not Reported |                |
|                                        | Temesta (Lorazepam) |                    |                    | C                        | Oral                                         |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>               | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>          | <u>Mfr Control #</u>                         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Oct-2015                            | 11644554            | EXPEDITED (15-DAY) |                    | OT                       | CA-ROXANE LABORATORIES, INC.-2015-RO-01708RO |                      | 71 YR           | Male         | CAN            |
| <u>Preferred Term</u>                  | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>              | <u>Route</u>                                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Erectile Dysfunction; Libido Decreased | Ramipril            |                    |                    | S                        | Unknown                                      | 5 Mg                 |                 | Roxane       |                |
|                                        | Escitalopram        |                    |                    | S                        | Unknown                                      | 20 Mg                |                 | Not Reported |                |
|                                        | Pregabalin          |                    |                    | S                        | Unknown                                      | 150 Mg               |                 | Not Reported |                |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 21-Oct-2015              | 11647683      | EXPEDITED (15-DAY) |                    | OT              | FR-009507513-1510FRA008413 |                      | 57 YR      | Male       | FRA            |

| <u>Preferred Term</u> | <u>Product</u>                   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                          | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------------------|--------------|------------|-------------|---------------------------------------|--------------------|-----------------|--------------|
| Pancytopenia          | Cancidas                         |              |            | S           | Intravenous (not otherwise specified) | 1 Df, Qd           |                 | Merck        |
|                       | Ancotil                          |              |            | S           | Intravenous (not otherwise specified) | Unk                |                 | Not Reported |
|                       | Imipenem                         |              |            | S           | Intravenous (not otherwise specified) | Unk                |                 | Not Reported |
|                       | Inexium (Esomeprazole Magnesium) |              |            | S           | Oral                                  | 1 Df, Qd           |                 | Not Reported |
|                       | Seroplex                         |              |            | S           | Oral                                  | 1 Df, Qd           |                 | Not Reported |
|                       | Fluconazole                      |              |            | S           | Intravenous (not otherwise specified) | 800 Mg, Qd         |                 | Not Reported |
|                       | Zyvoxid                          |              |            | C           |                                       |                    |                 | Not Reported |
|                       | Seroplex                         |              |            | C           |                                       |                    |                 | Not Reported |
|                       | Rifadin                          |              |            | C           |                                       |                    |                 | Not Reported |
|                       | Amikacin                         |              |            | C           |                                       |                    |                 | Not Reported |
|                       | Vancomycin                       |              |            | C           |                                       |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------------------|----------------------|------------|------------|----------------|
| 21-Oct-2015              | 11647686      | EXPEDITED (15-DAY) |                    | HO              | TR-LUPIN PHARMACEUTICALS INC.-2015-03242 |                      | 68 YR      | Male       | TUR            |

| <u>Preferred Term</u>                                  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction; Therapeutic Product Effect Decreased | Dabigatran     |              |            | S           | Unknown      | 110mg              |                 | Not Reported |
|                                                        | Dabigatran     |              |            | S           | Unknown      | 110mg              |                 | Not Reported |
|                                                        | Escitalopram   |              |            | S           | Unknown      | 10mg               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 21-Oct-2015              | 11651068      | NON-EXPEDITED    |                    | OT              | US-BAUSCH-SYM-2013-13500 |                      | 39 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

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|                           |            |   |         |                  |              |
|---------------------------|------------|---|---------|------------------|--------------|
| Arthritis; Asthma;        | Wellbutrin | S | Unknown |                  | Not Reported |
| Depression; Enuresis;     | Xyrem      | S | Oral    |                  | Not Reported |
| Fatigue; Feeling Jittery; | Xyrem      | S | Oral    | Dose Adjustments | Not Reported |
| Peripheral Vascular       | Xyrem      | S | Oral    |                  | Not Reported |
| Disorder; Personality     | Topamax    | S | Unknown |                  | Not Reported |
| Change; Vertigo           | Zanaflex   | S | Unknown |                  | Not Reported |
|                           | Xanax      | S | Unknown |                  | Not Reported |
|                           | Roxicodone | S | Unknown |                  | Not Reported |
|                           | Spiriva    | S | Unknown |                  | Not Reported |
|                           | Lexapro    | S | Unknown |                  | Not Reported |
|                           | Albuterol  | S | Unknown |                  | Not Reported |
|                           | Elavil     | S | Unknown |                  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|------------|----------------|
| 21-Oct-2015              | 11651131       | NON-EXPEDITED    |                    |                 | US-BAUSCH-BL-2015-009250 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Balance Disorder         | Wellbutrin XI  |                  |                    | S               | Oral                     |                      |                 |            | Not Reported   |
|                          | Lexapro        |                  |                    | S               | Oral                     |                      |                 |            | Not Reported   |

| <u>FDA Received Date</u>    | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|-----------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 22-Oct-2015                 | 11327894       | EXPEDITED (15-DAY) |                    | HO              | IT-FRI-1000078566    |                      | 21 YR           | Female     | ITA            |
| <u>Preferred Term</u>       | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Agitation; Dissociation;    | Escitalopram   |                    |                    | S               | Oral                 | Overdose: 120 Mg     |                 |            | Forest         |
| Euphoric Mood; Intentional  |                |                    |                    |                 |                      |                      |                 |            |                |
| Overdose; Intentional Self- |                |                    |                    |                 |                      |                      |                 |            |                |
| Injury                      |                |                    |                    |                 |                      |                      |                 |            |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Oct-2015              | 11653382      | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000080373    |                      | 57 YR      | Male       | FRA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u> | <u>Product</u>                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                          | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|--------------------------------|--------------|------------|-------------|---------------------------------------|--------------------|-----------------|--------------|
| Pancytopenia          | Escitalopram                   |              |            | S           | Oral                                  | 5 Mg               |                 | Forest       |
|                       | Ancotil                        |              |            | S           | Intravenous (not otherwise specified) | 1900 Mg            |                 | Not Reported |
|                       | Imipenem Cilastatine Panpharma |              |            | S           | Intravenous (not otherwise specified) |                    |                 | Not Reported |
|                       | Inexium                        |              |            | S           | Oral                                  | 20 Mg              |                 | Not Reported |
|                       | Cancidas                       |              |            | S           | Intravenous (not otherwise specified) | 1 Dosage Form      |                 | Not Reported |
|                       | Fluconazole Kabi               |              |            | S           | Intravenous (not otherwise specified) | 800 Mg             |                 | Not Reported |
|                       | Zyvoxid                        |              |            | C           | Unknown                               |                    |                 | Not Reported |
|                       | Rifadine                       |              |            | C           | Unknown                               |                    |                 | Not Reported |
|                       | Amikacine                      |              |            | C           | Unknown                               |                    |                 | Not Reported |
|                       | Vancomycine                    |              |            | C           | Unknown                               |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Oct-2015              | 11653430      | EXPEDITED (15-DAY) |                    | OT              | GB-FRI-1000080359    |                      | 49 YR      | Male       | GBR            |

| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Glucose Increased | Escitalopram   |              |            | S           | Oral         |                    |                 | Forest       |
|                         | Amlodipine     |              |            | C           | Unknown      | 1 Df               |                 | Not Reported |
|                         | Bisoprolol     |              |            | C           | Unknown      | 1 Df               |                 | Not Reported |
|                         | Candesartan    |              |            | C           | Unknown      | 1 Df               |                 | Not Reported |
|                         | Doxazosin      |              |            | C           | Unknown      | 1 Df               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Oct-2015              | 11653937      | EXPEDITED (15-DAY) |                    | OT              | DE-TEVA-601076GER    |                      | 42 YR      | Female     | DEU            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                 |              |   |      |                                                 |              |
|-----------------|--------------|---|------|-------------------------------------------------|--------------|
| Faecaloma; Rash | Escitalopram | S | Oral | 10 Milligram Daily;                             | Ivax         |
|                 | Amitriptylin | C | Oral | 50 Milligram Daily; Has<br>Been Used For Months | Not Reported |

| <u>FDA Received Date</u>                          | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------|----------------------|--------------------|--------------------|-----------------|-------------------------------------|------------------------|-----------------|--------------|----------------|
| 23-Oct-2015                                       | 11418852             | EXPEDITED (15-DAY) |                    | HO              | US-AUROBINDO-AUR-<br>APU-2015-07313 |                        | 58 YR           | Female       | USA            |
| <u>Preferred Term</u>                             | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                        | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Cerebrovascular<br>Accident; Dysarthria | Escitalopram 20 Mg   |                    |                    | S               | Oral                                | 20 Mg, Daily           |                 | Aurobindo    |                |
|                                                   | Risperidone 0.5mg    |                    |                    | S               | Oral                                | 0.5 Mg, Daily          |                 | Aurobindo    |                |
|                                                   | Simvastatin 40mg     |                    |                    | S               | Oral                                | 40 Mg, Daily           |                 | Aurobindo    |                |
|                                                   | Tramadol 50mg        |                    |                    | S               | Oral                                | 50 Mg, Two Times A Day |                 | Aurobindo    |                |
|                                                   | Clonazepam           |                    |                    | S               | Oral                                | 0.5 Mg, Daily          |                 | Not Reported |                |
|                                                   | Ambien               |                    |                    | C               | Unknown                             |                        |                 | Not Reported |                |
|                                                   | Vitamin D /00107901/ |                    |                    | C               | Unknown                             |                        |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|---------------------------------|-----------------|--------------|----------------|
| 23-Oct-2015                                                                                                                             | 11630185       | EXPEDITED (15-DAY) |                    | OT              | DK-FRI-1000080081    |                                 |                 | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                                   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Disturbance In Attention;<br>Dizziness; Fatigue;<br>Haemoptysis; Nightmare;<br>Prescribed Overdose;<br>Restlessness; Seizure;<br>Tremor | Escitalopram   |                    |                    | S               | Unknown              |                                 |                 | Forest       |                |
|                                                                                                                                         | Escitalopram   |                    |                    | S               | Unknown              | Prescribed Overdose Of<br>30 Mg |                 | Forest       |                |
|                                                                                                                                         | Lamictal       |                    |                    | S               | Unknown              |                                 |                 | Not Reported |                |

| <u>FDA Received Date</u>                | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|-----------------------------------------|----------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|-----------------|------------|----------------|
| 23-Oct-2015                             | 11654783       | EXPEDITED (15-DAY) |                    | HO              | TR-HETERO LABS<br>LTD-1043318 |                      | 68 YR           | Male       | TUR            |
| <u>Preferred Term</u>                   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Depressive Symptom;<br>Drug Interaction | Escitalopram   |                    |                    | S               |                               |                      |                 | Hetero     |                |

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|                                      |                     |                    |                    |                 |                               |                      |                 |              |                |
|--------------------------------------|---------------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|-----------------|--------------|----------------|
| Dabigatran                           |                     |                    | S                  |                 | Unknown                       |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>             | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Oct-2015                          | 11654844            | EXPEDITED (15-DAY) |                    | OT              | TR-HETERO LABS<br>LTD-1043320 |                      | 21 YR           | Female       | TUR            |
| <u>Preferred Term</u>                | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Metrorrhagia                         | Escitalopram        |                    |                    | S               | Unknown                       |                      |                 | Hetero       |                |
| <u>FDA Received Date</u>             | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Oct-2015                          | 11655088            | EXPEDITED (15-DAY) |                    | HO              | FR-PFIZER INC-<br>2015351006  |                      | 90 YR           | Male         | FRA            |
| <u>Preferred Term</u>                | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Pancytopenia                         | Amlor               |                    |                    | S               | Oral                          | 5 Mg, 1x/Day         |                 | Pfizer       |                |
|                                      | Forlax              |                    |                    | S               | Oral                          | 10 G, 1x/Day         |                 | Not Reported |                |
|                                      | Furosemide          |                    |                    | S               | Oral                          | 20 Mg, 1x/Day        |                 | Not Reported |                |
|                                      | Gaviscon /00237601/ |                    |                    | S               | Oral                          | 10 ML, 1x/Day        |                 | Not Reported |                |
|                                      | Kardegic            |                    |                    | S               | Oral                          | 75 Mg, 1x/Day        |                 | Not Reported |                |
|                                      | Seroplex            |                    |                    | S               | Oral                          | 5 Mg, 1x/Day         |                 | Not Reported |                |
| <u>FDA Received Date</u>             | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Oct-2015                          | 11655277            | EXPEDITED (15-DAY) |                    | DE              | CH-JNJFOC-<br>20151015487     |                      | 90 YR           | Female       | CHE            |
| <u>Preferred Term</u>                | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Circulatory Collapse | Risperdal           |                    |                    | S               | Oral                          |                      |                 | Not Reported |                |
|                                      | Escitalopram        |                    |                    | S               | Oral                          |                      |                 | Not Reported |                |
|                                      | Diovan              |                    |                    | C               | Oral                          |                      |                 | Not Reported |                |
|                                      | Ginkgo Biloba       |                    |                    | C               | Oral                          |                      |                 | Not Reported |                |
|                                      | Temesta (Lorazepam) |                    |                    | C               | Oral                          |                      |                 | Not Reported |                |

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| <u>FDA Received Date</u>                               | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>                             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|-----------------------|--------------------------------------------------|-----------------|--------------|----------------|
| 23-Oct-2015                                            | 11655279                      | EXPEDITED (15-DAY) |                    | DE              | CH-JNJFOC-20151015568 |                                                  | 89 YR           | Female       | CHE            |
| <u>Preferred Term</u>                                  | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>                               | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Failure; General Physical Health Deterioration | Risperdal                     |                    |                    | S               | Oral                  |                                                  |                 | Not Reported |                |
|                                                        | Risperdal                     |                    |                    | S               | Oral                  |                                                  |                 | Not Reported |                |
|                                                        | Risperdal                     |                    |                    | S               | Oral                  |                                                  |                 | Not Reported |                |
|                                                        | Cipralex                      |                    |                    | S               | Unknown               |                                                  |                 | Not Reported |                |
|                                                        | Seroquel                      |                    |                    | S               | Unknown               |                                                  |                 | Not Reported |                |
|                                                        | Coversum                      |                    |                    | C               | Unknown               | 10 Mg/Day From 21-May-2015 To 28-May-2015.       |                 | Not Reported |                |
|                                                        | Aspirin Cardio                |                    |                    | C               | Unknown               |                                                  |                 | Not Reported |                |
|                                                        | Euthyrox                      |                    |                    | C               | Unknown               |                                                  |                 | Not Reported |                |
|                                                        | Temesta (Lorazepam)           |                    |                    | C               | Unknown               | 13/05/15, 15/05/15, 16/05/15, 21/05/15, 27/05/15 |                 | Not Reported |                |
|                                                        | Morphine                      |                    |                    | C               | Unknown               |                                                  |                 | Not Reported |                |
|                                                        | Atorvastatin                  |                    |                    | C               | Unknown               |                                                  |                 | Not Reported |                |
|                                                        | Novalgine (Metamizole Sodium) |                    |                    | C               | Unknown               |                                                  |                 | Not Reported |                |
|                                                        | Adalat                        |                    |                    | C               | Unknown               |                                                  |                 | Not Reported |                |
|                                                        | Ringer Lactate                |                    |                    | C               | Transdermal           |                                                  |                 | Not Reported |                |
|                                                        | Rivastigmine                  |                    |                    | C               | Unknown               | Once Daily.                                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                               | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>                             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Oct-2015                                            | 11656096                      | EXPEDITED (15-DAY) |                    | DS              | GB-FRI-1000080347     |                                                  |                 | Female       | GBR            |
| <u>Preferred Term</u>                                  | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>                               | <u>Duration</u> | <u>Mfr</u>   |                |
| Muscle Twitching                                       | Citalopram                    |                    |                    | S               | Oral                  | 10 Mg                                            |                 | Forest       |                |
|                                                        | Citalopram                    |                    |                    | S               | Oral                  | 20 Mg                                            |                 | Forest       |                |
|                                                        | Citalopram                    |                    |                    | S               | Oral                  | 30 Mg                                            |                 | Not Reported |                |

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|                                                                                                                                                                                                          |                |                    |                    |                 |                                                 |                                              |                 |                  |                |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------------------------------|-----------------|------------------|----------------|
| Escitalopram                                                                                                                                                                                             |                |                    | S                  |                 | Oral                                            |                                              |                 | Forest           |                |
| <u>FDA Received Date</u>                                                                                                                                                                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                         | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 23-Oct-2015                                                                                                                                                                                              | 11656620       | NON-EXPEDITED      |                    |                 | US-<br>ELI_LILLY_AND_COMP<br>ANY-US201510002626 |                                              |                 | Female           | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                           | <u>Duration</u> | <u>Mfr</u>       |                |
| Drug Intolerance;<br>Somnolence                                                                                                                                                                          | Cymbalta       |                    |                    | S               | Unknown                                         |                                              |                 | Eli Lilly And Co |                |
|                                                                                                                                                                                                          | Prozac         |                    |                    | S               | Unknown                                         |                                              |                 | Not Reported     |                |
|                                                                                                                                                                                                          | Xyrem          |                    |                    | S               | Unknown                                         |                                              |                 | Not Reported     |                |
|                                                                                                                                                                                                          | Lexapro        |                    |                    | S               | Unknown                                         |                                              |                 | Not Reported     |                |
| <u>FDA Received Date</u>                                                                                                                                                                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                         | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 23-Oct-2015                                                                                                                                                                                              | 11657059       | EXPEDITED (15-DAY) |                    | OT              | DE-MYLANLABS-<br>2015M1035173                   |                                              |                 | Unknown          | DEU            |
| <u>Preferred Term</u>                                                                                                                                                                                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                           | <u>Duration</u> | <u>Mfr</u>       |                |
| Faecaloma; Rash                                                                                                                                                                                          | Escitalopram   |                    |                    | S               | Oral                                            | 10 Mg, Qd (10 Mg<br>Milligram(S) Every Days) |                 | Not Reported     |                |
|                                                                                                                                                                                                          | Amitriptylin   |                    |                    | C               | Oral                                            | 50 Mg, Qd (50 Mg<br>Milligram(S) Every Days) |                 | Not Reported     |                |
| <u>FDA Received Date</u>                                                                                                                                                                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                         | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 23-Oct-2015                                                                                                                                                                                              | 11657547       | EXPEDITED (15-DAY) |                    | OT              | DK-FRI-1000080385                               |                                              | 59 YR           | Male             | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                           | <u>Duration</u> | <u>Mfr</u>       |                |
| Disturbance In Attention;<br>Dizziness; Fatigue;<br>Haemoptysis; Mouth<br>Haemorrhage; Muscle<br>Spasms; Nightmare;<br>Prescribed Overdose;<br>Restlessness;<br>Restlessness; Seizure;<br>Tremor; Tremor | Escitalopram   |                    |                    | S               | Unknown                                         |                                              |                 | Forest           |                |
|                                                                                                                                                                                                          | Escitalopram   |                    |                    | S               | Unknown                                         | Overdose: 30 Mg                              |                 | Not Reported     |                |
|                                                                                                                                                                                                          | Lamictal       |                    |                    | S               | Unknown                                         |                                              |                 | Not Reported     |                |

# FDA Adverse Event Reporting System

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| <u>FDA Received Date</u>                                                 | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|---------------------------------------|----------------------|-----------------|--------------|----------------|
| 26-Oct-2015                                                              | 11656629                      | EXPEDITED (15-DAY) |                    | DE, OT          | CH-ASTRAZENECA-2015SF02068            |                      | 89 YR           | Female       | CHE            |
| <u>Preferred Term</u>                                                    | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Failure; Drug Interaction; General Physical Health Deterioration | Seroquel                      |                    |                    | S               | Oral                                  |                      |                 | Not Reported |                |
|                                                                          | Risperdal                     |                    |                    | S               | Oral                                  |                      |                 | Not Reported |                |
|                                                                          | Risperdal                     |                    |                    | S               | Oral                                  |                      |                 | Not Reported |                |
|                                                                          | Risperdal                     |                    |                    | S               | Oral                                  |                      |                 | Not Reported |                |
|                                                                          | Cipralex                      |                    |                    | S               | Oral                                  |                      |                 | Not Reported |                |
|                                                                          | Coversum                      |                    |                    | C               | Oral                                  |                      |                 | Not Reported |                |
|                                                                          | Coversum                      |                    |                    | C               | Oral                                  |                      |                 | Not Reported |                |
|                                                                          | Coversum                      |                    |                    | C               | Oral                                  |                      |                 | Not Reported |                |
|                                                                          | Aspirin Cardio                |                    |                    | C               | Oral                                  |                      |                 | Not Reported |                |
|                                                                          | Euthyrox                      |                    |                    | C               | Oral                                  |                      |                 | Not Reported |                |
|                                                                          | Temesta (Lorazepam)           |                    |                    | C               | Oral                                  |                      |                 | Not Reported |                |
|                                                                          | Temesta (Lorazepam)           |                    |                    | C               | Oral                                  |                      |                 | Not Reported |                |
|                                                                          | Temesta (Lorazepam)           |                    |                    | C               | Oral                                  |                      |                 | Not Reported |                |
|                                                                          | Temesta (Lorazepam)           |                    |                    | C               | Oral                                  |                      |                 | Not Reported |                |
|                                                                          | Temesta (Lorazepam)           |                    |                    | C               | Oral                                  |                      |                 | Not Reported |                |
|                                                                          | Morphine                      |                    |                    | C               | Oral                                  |                      |                 | Not Reported |                |
|                                                                          | Atorvastatin                  |                    |                    | C               | Oral                                  |                      |                 | Not Reported |                |
|                                                                          | Novalgine (Metamizole Sodium) |                    |                    | C               | Oral                                  |                      |                 | Not Reported |                |
|                                                                          | Adalat                        |                    |                    | C               | Oral                                  |                      |                 | Not Reported |                |
|                                                                          | Ringer Lactat                 |                    |                    | C               | Intravenous (not otherwise specified) |                      |                 | Not Reported |                |
|                                                                          | Exelon Patch                  |                    |                    | C               | Transdermal                           |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                 | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Oct-2015                                                              | 11658954                      | NON-EXPEDITED      |                    |                 | US-JUBILANT GENERICS LIMITED-         |                      | 70 YR           | Male         | USA            |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

1043365

| <u>Preferred Term</u>                                                                                 | <u>Product</u>                                                         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>           | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                                                               |
|-------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------|--------------|------------|-----------------------|--------------|--------------------|-----------------|--------------------------------------------------------------------------|
| Abdominal Pain Upper;<br>Blood Pressure Increased;<br>Diarrhoea; Heart Rate<br>Decreased; Rhinorrhoea | Escitalopram Oxalate<br>Allopurinol<br>Lovastatin<br>Xanax<br>Atenolol |              |            | S<br>C<br>C<br>C<br>C |              |                    |                 | Jubilant<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Oct-2015              | 11661283      | EXPEDITED (15-DAY) |                    | OT              | IT-FRI-1000080362    |                      |            | Female     | ITA            |

| <u>Preferred Term</u>  | <u>Product</u>                      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                  | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                             |
|------------------------|-------------------------------------|--------------|------------|-------------|-------------------------------|--------------------|-----------------|----------------------------------------|
| Spinocerebellar Ataxia | Escitalopram<br>Fosicombi<br>Plavix |              |            | S<br>C<br>C | Unknown<br>Unknown<br>Unknown |                    |                 | Forest<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|------------|------------|----------------|
| 26-Oct-2015              | 11662082      | EXPEDITED (15-DAY) |                    | OT              | TR-MYLANLABS-<br>2015M1035911 |                      |            | Unknown    | TUR            |

| <u>Preferred Term</u> | <u>Product</u>                          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                  | <u>Dosage Text</u>                              | <u>Duration</u> | <u>Mfr</u>              |
|-----------------------|-----------------------------------------|--------------|------------|-------------|-------------------------------|-------------------------------------------------|-----------------|-------------------------|
| Seizure               | Escitalopram<br>Valproate<br>Topiramate |              |            | S<br>S<br>S | Unknown<br>Unknown<br>Unknown | He Received Three Doses<br>Of 2.5mg<br>30 Mg/Kg |                 | Mylan<br>Mylan<br>Mylan |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Oct-2015              | 11665226      | DIRECT           |                    | OT              |                      |                      | 33 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                       |                           |   |      |        |              |
|-----------------------|---------------------------|---|------|--------|--------------|
| Migraine; Product     | Escitalopram Oxalate 10mg | S | Oral | 1 Pill | Accord       |
| Formulation Issue;    | Accord Hlthcare           |   |      |        |              |
| Product Quality Issue | Gnc Multivitamin          | C |      |        | Not Reported |
|                       | Cla                       | C |      |        | Not Reported |
|                       | Magnesium                 | C |      |        | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Oct-2015              | 11665436      | DIRECT           |                    |                 |                      |                      | 58 YR      | Female     | USA            |

| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u>   |
|------------------------|----------------|--------------|------------|-------------|--------------|---------------------|-----------------|--------------|
| Depression; Drug       | Lexapro        |              |            | S           |              | 2 Pills Twice Daily |                 | Teva         |
| Ineffective; Product   | Lipitor        |              |            | C           |              |                     |                 | Not Reported |
| Quality Issue; Product |                |              |            |             |              |                     |                 |              |
| Substitution Issue     |                |              |            |             |              |                     |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Oct-2015              | 11665499      | DIRECT           |                    |                 |                      |                      | 37 YR      | Female     | USA            |

| <u>Preferred Term</u>     | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|--------------------|--------------|------------|-------------|--------------|------------------------|-----------------|--------------|
| Drug Ineffective; Product | Escitalopram 20 Mg |              |            | S           | Oral         | Alternating Name Brand | 1 YR            | Not Reported |
| Substitution Issue        | Armour Thyroid     |              |            | C           |              |                        |                 | Not Reported |
|                           | Lexapro            |              |            | C           |              |                        |                 | Not Reported |
|                           | Multivitamin       |              |            | C           |              |                        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Oct-2015              | 11658861      | EXPEDITED (15-DAY) |                    | DE, OT          | PHHY2015US095132     |                      |            | Female     | USA            |

| <u>Preferred Term</u>     | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Impaired Healing;         | Baclofen Intrathecal |              |            | S           | Intrathecal  |                    |                 | Not Reported |
| Pneumonia; Respiratory    | Baclofen             |              |            | S           | Oral         | Unk                |                 | Not Reported |
| Disorder; Wound Infection | Tizanidine           |              |            | S           | Unknown      |                    |                 | Novartis     |
|                           | Valium               |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                           | Lexapro              |              |            | S           | Unknown      | Unk                |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                              |                |                    |                    |                 |                                       |                                 |                 |              |                |
|----------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|---------------------------------------|---------------------------------|-----------------|--------------|----------------|
| Lyrica                                                                                       |                |                    | S                  |                 | Unknown                               |                                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Oct-2015                                                                                  | 11669853       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000080487                     |                                 | 67 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Toxic Skin Eruption                                                                          | Escitalopram   |                    |                    | S               | Oral                                  |                                 |                 | Forest       |                |
|                                                                                              | Speciafoldine  |                    |                    | S               | Oral                                  | 0.4 Mg                          |                 | Not Reported |                |
|                                                                                              | Iomeron        |                    |                    | S               | Intravenous (not otherwise specified) |                                 |                 | Not Reported |                |
|                                                                                              | Atenolol       |                    |                    | C               |                                       | 1 Dosage Form                   |                 | Not Reported |                |
|                                                                                              | Alimta         |                    |                    | C               | Unknown                               |                                 |                 | Not Reported |                |
|                                                                                              | Carboplatine   |                    |                    | C               | Unknown                               |                                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Oct-2015                                                                                  | 11669855       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000080447                     |                                 | 62 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Coma Scale Abnormal;<br>Hypotension; Intentional<br>Overdose; Somnolence;<br>Suicide Attempt | Escitalopram   |                    |                    | S               | Oral                                  | 10 Mg                           |                 | Forest       |                |
|                                                                                              | Escitalopram   |                    |                    | S               | Oral                                  |                                 |                 | Forest       |                |
|                                                                                              | Zolpidem       |                    |                    | S               | Oral                                  | 1 Dosage Form                   |                 | Not Reported |                |
|                                                                                              | Zolpidem       |                    |                    | S               | Oral                                  | Intentional Overdose Of 280 Mg. |                 | Not Reported |                |
|                                                                                              | Lercanidipine  |                    |                    | C               | Oral                                  | 10 Mg                           |                 | Not Reported |                |
|                                                                                              | Alprazolam     |                    |                    | C               | Oral                                  | 1.5 Dosage Form                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Oct-2015                                                                                  | 8057314        | EXPEDITED (15-DAY) |                    | CA, DE, OT      | GB-ARROW GEN-2011-10896               |                                 |                 | Female       | GBR            |
| <u>Preferred Term</u>                                                                        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                    |                                   |   |                |              |              |
|------------------------------------|-----------------------------------|---|----------------|--------------|--------------|
| Congenital Pulmonary Valve Atresia | Citalopram Hydrobromide (Unknown) | S | Transplacental | 20 Mg, Daily | Watson       |
|                                    | Escitalopram                      | S | Transplacental | 20 Mg, Daily | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 28-Oct-2015              | 11657043      | EXPEDITED (15-DAY) |                    | HO              | US-ABBVIE-15P-163-1483119-00 |                      | 51 YR      | Male       | USA            |

| <u>Preferred Term</u>             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Rhabdomyolysis; Unevaluable Event | Depakote       |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                   | Lipitor        |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                   | Lexapro        |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                   | Mirtazapine    |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                   | Seroquel       |              |            | S           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------------------------|----------------------|------------|------------|----------------|
| 28-Oct-2015              | 11672645      | EXPEDITED (15-DAY) |                    | HO, OT          | JP-MACLEODS PHARMACEUTICALS US LTD-MAC2015002087 |                      |            | Unknown    | JPN            |

| <u>Preferred Term</u>                                                                                                                                                                                           | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Bradykinesia; Confusional State; Dehydration; Hyperreflexia; Insomnia; Loss Of Consciousness; Myoclonus; Oxygen Saturation Decreased; Pyrexia; Seizure; Serotonin Syndrome; Somnolence; Urinary Tract Infection | Escitalopram Oxalate |              |            | S           | Unknown      | 10 Mg Per Day      |                 | Macleods     |
|                                                                                                                                                                                                                 | Escitalopram Oxalate |              |            | S           | Unknown      | 10 Mg Per Day      |                 | Macleods     |
|                                                                                                                                                                                                                 | Mirtazapine          |              |            | C           | Unknown      | 30 Mg Per Day      |                 | Not Reported |
|                                                                                                                                                                                                                 | Nitrazepam           |              |            | C           | Unknown      | 5 Mg Per Day       |                 | Not Reported |
|                                                                                                                                                                                                                 | Risperidone          |              |            | C           | Unknown      | 1 Mg Per Day       |                 | Not Reported |
|                                                                                                                                                                                                                 | Risperidone          |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                 | Levofloxacin         |              |            | C           | Unknown      | 500 Mg, Unk        |                 | Macleods     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 28-Oct-2015              | 11673926      | EXPEDITED (15-DAY) |                    | HO, OT          | US-ACTAVIS-2015-22651 |                      | 51 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                            |                      |   |         |             |                   |
|--------------------------------------------|----------------------|---|---------|-------------|-------------------|
| Extrapyramidal Disorder;<br>Rhabdomyolysis | Mirtazapine (Aellic) | S | Unknown | 15 Mg Daily | Actavis Elizabeth |
|                                            | Lipitor              | S | Unknown | 10 Mg Daily | Not Reported      |
|                                            | Lexapro /01588501/   | S | Unknown | 15 Mg Daily | Not Reported      |
|                                            | Seroquel             | S | Unknown | Unknown     | Not Reported      |
|                                            | Depakote             | S | Unknown | Unknown     | Not Reported      |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 28-Oct-2015              | 11674625      | EXPEDITED (15-DAY) |                    | OT              | TR-APOTEX-<br>2015AP013691 |                      | 4 YR       | Male       | TUR            |

| <u>Preferred Term</u>               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------|----------------|--------------|------------|-------------|--------------|----------------------------------------|-----------------|--------------|
| Paresis; Rebound Effect;<br>Seizure | Topiramate     |              |            | S           | Unknown      | Unk                                    |                 | Apotex       |
|                                     | Escitalopram   |              |            | S           | Unknown      | 2.5 Mg, 2 Hours Before<br>Each Session |                 | Not Reported |
|                                     | Valproate      |              |            | S           | Unknown      | 30 Mg/Kg, Unk                          |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Oct-2015              | 11676804      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000080508    |                      | 90 YR      | Male       | FRA            |

| <u>Preferred Term</u> | <u>Product</u>   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Pancytopenia          | Escitalopram     |              |            | S           | Oral         | 5 Mg               |                 | Forest       |
|                       | Amlor            |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Forlax           |              |            | S           | Oral         | 10 Gram            |                 | Not Reported |
|                       | Furosemide Arrow |              |            | S           | Oral         | 20 Mg              |                 | Not Reported |
|                       | Gaviscon         |              |            | S           | Oral         | 10 MI              |                 | Not Reported |
|                       | Kardegic         |              |            | S           | Oral         | 75 Mg              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>              | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------------------|----------------------|------------|------------|----------------|
| 28-Oct-2015              | 11676852      | EXPEDITED (15-DAY) |                    | OT              | TR-FRESENIUS KABI-<br>FK201505273 |                      | 4 YR       | Male       | TUR            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                   |                                   |   |         |                        |
|---------------------------------------------------|-----------------------------------|---|---------|------------------------|
| Paresis; Seizure; Therapy Change; Viral Infection | Valproate (Manufacturer Unknown)  | S | Unknown | Fresenius Medical Care |
|                                                   | Valproate (Manufacturer Unknown)  | S | Unknown | Fresenius Medical Care |
|                                                   | Topiramate (Manufacturer Unknown) | S | Unknown | Not Reported           |
|                                                   | Escitalopram                      | S | Unknown | Not Reported           |
|                                                   |                                   |   |         |                        |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Oct-2015              | 11677086      | EXPEDITED (15-DAY) |                    | DE, HO          | PE-TEVA-602402ISR    |                      | 79 YR      | Female     | PER            |

| <u>Preferred Term</u>                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u> |
|------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|---------------------|-----------------|------------|
| Constipation; Intestinal Obstruction; Pulmonary Infarction | Prolide        |              |            | S           | Oral         | 10 Milligram Daily; |                 | Ivax       |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Oct-2015              | 11682000      | DIRECT           |                    | HO, RI          |                      |                      | 55 YR      | Male       |                |

| <u>Preferred Term</u>                                                                                                                                                                | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Agitation; Amnesia; Anxiety; Decreased Activity; Histrionic Personality Disorder; Loss Of Employment; Personality Change; Psychiatric Symptom; Restlessness; Social Anxiety Disorder | Lexapro 20mg - Generic |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                      | Remeron                |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                      | Olanzapine             |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                      | Britellix              |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                      | Valium                 |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                      | Benzos (Xanax)         |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                      | Magnesium              |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                      | Fish Oil               |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                      | Vit C                  |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 29-Oct-2015              | 11682362      | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2015364446 |                      | 17 YR      | Female     | USA            |

| <u>Preferred Term</u>                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Abnormal Behaviour; Drug Ineffective; Screaming | Xanax          |              |            | S           |              | Unk                |                 | Pfizer     |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                | Prozac               |                    | S                  |                 | Unk                        |                         |                 | Not Reported |                |
|----------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------------|-------------------------|-----------------|--------------|----------------|
|                                                                | Lexapro              |                    | S                  |                 | Unk                        |                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Oct-2015                                                    | 11682705             | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000080479          |                         | 22 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Mixed Liver Injury;<br>Transaminases Increased                 | Escitalopram         |                    |                    | S               | Oral                       |                         |                 | Forest       |                |
|                                                                | Xanax                |                    |                    | C               | Unknown                    |                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Oct-2015                                                    | 11684230             | EXPEDITED (15-DAY) |                    | OT              | US-APOTEX-<br>2015AP013977 |                         |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug-Induced Liver Injury                                      | Escitalopram Oxalate |                    |                    | S               | Unknown                    |                         |                 | Apotex       |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Oct-2015                                                    | 11685360             | DIRECT             |                    |                 |                            |                         | 46 YR           | Male         | USA            |
| <u>Preferred Term</u>                                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Drug<br>Intolerance; Product<br>Substitution Issue | Escitalopram 10mg    |                    |                    | S               | Oral                       |                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Oct-2015                                                    | 11624674             | EXPEDITED (15-DAY) |                    | HO              | AT-TEVA-600394ISR          |                         | 34 YR           | Female       | AUT            |
| <u>Preferred Term</u>                                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Creatine                                                 | Pantoprazol 40mg     |                    |                    | S               |                            | 1-0-0                   |                 | Teva         |                |
| Phosphokinase Increased;                                       | Cipralext 10 Mg      |                    |                    | S               |                            | 1-0-0                   |                 | Not Reported |                |
| Epilepsy; General Physical<br>Health Deterioration;            | Deanxit              |                    |                    | S               |                            | 1-0-0, Neuroleptica And |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Generalised Tonic-Clonic  
Seizure; Hepatic Function  
Abnormal; Seizure;  
Thrombocytopenia

Antidepressive  
Combination: Flupentixol  
0.5mg And Melitracen  
10mg

|                 |   |         |              |
|-----------------|---|---------|--------------|
| Acemin 5mg      | S | 1/2-0-0 | Not Reported |
| Legalon 70 Mg   | S | 1-0-0   | Not Reported |
| Ursofalk 250 Mg | S | 1-0-0   | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 30-Oct-2015              | 11686722      | NON-EXPEDITED    |                    |                 | US-PFIZER INC-<br>2015364759 |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Hypersensitivity | Metoclopramide Hcl    |              |            | S           |              | Unk                |                 | Unknown      |
|                       | Venlafaxine Hcl       |              |            | S           |              | Unk                |                 | Pfizer       |
|                       | Zoloft                |              |            | S           |              | Unk                |                 | Pfizer       |
|                       | Lexapro               |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Flonase               |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Mometasone Furoate    |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Clavulanate Potassium |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Advair                |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Augmentin             |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Aspirin               |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Omnicef               |              |            | S           |              | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 30-Oct-2015              | 11687369      | EXPEDITED (15-DAY) |                    | HO              | AU-APOTEX-<br>2015AP013818 |                      | 55 YR      | Female     | AUS            |

| <u>Preferred Term</u>                                    | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------|--------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Dizziness; Dyspnoea;<br>Feeling Jittery; Panic<br>Attack | Escitalopram       |              |            | S           | Unknown      | 10 Mg, Unk         |                 | Apotex       |
|                                                          | Panadol /00020001/ |              |            | C           | Unknown      |                    |                 | Not Reported |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Vitamin D /00107901/

C

Unknown

Not Reported

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 30-Oct-2015              | 11687977      | EXPEDITED (15-DAY) |                    | HO              | US-ABBVIE-15P-163-1487615-00 |                      | 44 YR      | Female     | USA            |

| <u>Preferred Term</u>                          | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>             | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------|-------------------|--------------|------------|-------------|--------------------------|--------------------|-----------------|--------------|
| Pulmonary Embolism;<br>Treatment Noncompliance | Tricor            |              |            | S           | Oral                     |                    |                 | Not Reported |
|                                                | Xarelto           |              |            | S           | Oral                     |                    |                 | Not Reported |
|                                                | Xarelto           |              |            | S           | Oral                     |                    |                 | Not Reported |
|                                                | Gabapentin        |              |            | S           | Oral                     |                    |                 | Not Reported |
|                                                | Lasix             |              |            | S           | Oral                     |                    |                 | Not Reported |
|                                                | Lexapro           |              |            | S           | Oral                     |                    |                 | Not Reported |
|                                                | Paxil             |              |            | S           | Oral                     |                    |                 | Not Reported |
|                                                | Estradiol         |              |            | S           | Oral                     |                    |                 | Not Reported |
|                                                | Dicyclomine       |              |            | C           | Oral                     |                    |                 | Not Reported |
|                                                | Advair            |              |            | C           | Respiratory (inhalation) |                    |                 | Not Reported |
|                                                | Albuterol Sulfate |              |            | C           | Respiratory (inhalation) |                    |                 | Not Reported |
|                                                | Aldactone         |              |            | C           | Oral                     |                    |                 | Not Reported |
|                                                | Apidra            |              |            | C           | Subcutaneous             | 100 Unit/MI        |                 | Not Reported |
|                                                | Benzonatate       |              |            | C           | Oral                     |                    |                 | Not Reported |
|                                                | Clonidine Hcl     |              |            | C           | Oral                     |                    |                 | Not Reported |
|                                                | Elocon            |              |            | C           | Topical                  |                    |                 | Not Reported |
|                                                | Ferrous Sulfate   |              |            | C           | Oral                     |                    |                 | Not Reported |
|                                                | Humalog Mix       |              |            | C           | Subcutaneous             | In The Morning     |                 | Not Reported |
|                                                | Humalog Mix       |              |            | C           | Subcutaneous             | In The Evening     |                 | Not Reported |
|                                                | Hydroxyzine Hcl   |              |            | C           | Oral                     |                    |                 | Not Reported |
| Hyzaar                                         |                   |              | C          | Oral        |                          |                    | Not Reported    |              |
| Ibuprofen                                      |                   |              | C          | Oral        |                          |                    | Not Reported    |              |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                 |   |                             |            |              |
|-----------------|---|-----------------------------|------------|--------------|
| Imitrex         | C | Oral                        | Once Daily | Not Reported |
| Klor-Con        | C | Oral                        |            | Not Reported |
| Lipitor         | C | Oral                        |            | Not Reported |
| Nexium          | C | Oral                        |            | Not Reported |
| Prilosec        | C | Oral                        |            | Not Reported |
| Proair Hfa      | C | Respiratory<br>(inhalation) |            | Not Reported |
| Promethazine Dm | C | Oral                        |            | Not Reported |
| Reglan          | C | Oral                        |            | Not Reported |
| Remeron         | C | Oral                        |            | Not Reported |
| Soma            | C | Oral                        |            | Not Reported |
| Sumatriptan     | C | Oral                        |            | Not Reported |
| Synthroid       | C | Oral                        |            | Not Reported |
| Zolpidem        | C | Oral                        |            | Not Reported |
| Ultram          | C | Oral                        |            | Not Reported |
| Folic Acid      | C | Unknown                     |            | Not Reported |
| Toprol XL       | C | Oral                        |            | Not Reported |
| Xyzal           | C | Oral                        |            | Not Reported |
| Insulin         | C | Unknown                     |            | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-Oct-2015              | 11688303      | EXPEDITED (15-DAY) |                    | HO, OT          | JP-ACCORD-034911     |                      | 78 YR      | Female     | JPN            |

  

| <u>Preferred Term</u>                                                                                    | <u>Product</u>                        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------|---------------------------------------|--------------|------------|-------------|--------------|------------------------|-----------------|--------------|
| Bradykinesia;<br>Dehydration; Insomnia;<br>Serotonin Syndrome;<br>Somnolence; Urinary Tract<br>Infection | Escitalopram                          |              |            | S           |              | For More Than 6 Months |                 | Accord       |
|                                                                                                          | Nitrazepam                            |              |            | S           |              |                        |                 | Not Reported |
|                                                                                                          | Risperidone                           |              |            | S           |              |                        |                 | Not Reported |
|                                                                                                          | Mirtazapine                           |              |            | C           |              |                        |                 | Not Reported |
|                                                                                                          | Levofloxacin/Levofloxacin<br>Mesylate |              |            | C           |              |                        |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Nov-2015              | 11692151      | EXPEDITED (15-DAY) |                    | OT              | US-ACCORD-034966     |                      | 55 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------|--------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Ejaculation Failure;<br>Gastroesophageal Reflux<br>Disease; Insomnia; Off<br>Label Use; Peptic Ulcer | Escitalopram       |              |            | S           | Oral         | Strength: 10 Mg    |                 | Accord       |
|                                                                                                      | Fenofibrate        |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                      | Crestor            |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                      | Levothyroxine      |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                      | Metoprolol Succ Er |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                      | Aspirin            |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                      | Lisinopril         |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                      | Effient            |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                      | Fluticasone        |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                      | Ambient            |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                      | Nitro Stat         |              |            | C           |              | Only When Needed   |                 | Not Reported |
|                                                                                                      | Lansoprazole       |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 03-Nov-2015              | 11692486      | NON-EXPEDITED    |                    |                 | US-PFIZER INC-<br>2015354371 |                      | 66 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Hypersensitivity | Lipitor        |              |            | S           |              | Unk                |                 | Pfizer       |
|                       | Lopid          |              |            | S           |              | Unk                |                 | Pfizer       |
|                       | Zoloft         |              |            | S           |              | Unk                |                 | Pfizer       |
|                       | Erythromycin   |              |            | S           |              | Unk                |                 | Pfizer       |
|                       | Iodine         |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Keflex         |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Lexapro        |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Prozac         |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Vytorin        |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Zanaflex       |              |            | S           |              | Unk                |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                                                                                       | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
| 03-Nov-2015                                                                                                                                                                                                                                                                    | 11693794                            | EXPEDITED (15-DAY) |                    | HO, OT          | JP-MYLANLABS-2015M1037409 |                      |                 | Unknown      | JPN            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                          | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bradykinesia; Serotonin Syndrome                                                                                                                                                                                                                                               | Escitalopram                        |                    |                    | S               | Unknown                   | 10 Mg, Qd            |                 | Mylan        |                |
|                                                                                                                                                                                                                                                                                | Escitalopram                        |                    |                    | S               | Unknown                   | 10 Mg, Qd            |                 | Mylan        |                |
|                                                                                                                                                                                                                                                                                | Mirtazapine                         |                    |                    | S               | Unknown                   | 30 Mg, Qd            |                 | Mylan        |                |
|                                                                                                                                                                                                                                                                                | Risperidone                         |                    |                    | S               | Unknown                   | 1 Mg, Qd             |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                | Nitrazepam                          |                    |                    | S               | Unknown                   | 5 Mg, Qd             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                       | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Nov-2015                                                                                                                                                                                                                                                                    | 11695763                            | DIRECT             |                    |                 |                           |                      | 47 YR           | Unknown      | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                          | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Nausea; Tinnitus; Vertigo                                                                                                                                                                                                                                                      | Escitalopram                        |                    |                    | S               | Oral                      |                      |                 | Accord       |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                       | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Nov-2015                                                                                                                                                                                                                                                                    | 11696043                            | EXPEDITED (15-DAY) |                    | DS, HO          | US-WATSON-2015-17592      |                      | 44 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                          | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Accident At Work; Asthma; Ataxia; Back Injury; Disability; Drug Ineffective; Dyspnoea; Fluid Retention; Hypoaesthesia; Ill-Defined Disorder; Intervertebral Disc Protrusion; Joint Swelling; Migraine; Oral Infection; Pain; Pulmonary Congestion; Visual Impairment; Wheezing | Androderm (Actavis Laboratories Ut) |                    |                    | S               | Transdermal               | 1 Df, Daily          |                 | Actavis      |                |
|                                                                                                                                                                                                                                                                                | Advair                              |                    |                    | S               | Respiratory (inhalation)  | 1 Puff Twice Daily   |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                | Ventolin /00139501/                 |                    |                    | S               | Respiratory (inhalation)  | 2-6 Puffs As Needed  |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                | Biotene Oral Balance                |                    |                    | S               | Unknown                   | Unk                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                | Escitalopram                        |                    |                    | S               | Unknown                   | Unk                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                | Oxycontin                           |                    |                    | C               |                           |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                | Oxycodone                           |                    |                    | C               |                           |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                | Valium                              |                    |                    | C               |                           |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                      |                                    | Gabapentin         |                    | C               |                          |                      |                 |              | Not Reported   |
|--------------------------------------|------------------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
|                                      |                                    | Duexis             |                    | C               |                          |                      |                 |              | Not Reported   |
|                                      |                                    | Singulair          |                    | C               |                          |                      |                 |              | Not Reported   |
| <u>FDA Received Date</u>             | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Nov-2015                          | 11697413                           | EXPEDITED (15-DAY) |                    | DE              | CH-FRI-1000080660        |                      | 90 YR           | Female       | CHE            |
| <u>Preferred Term</u>                | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Circulatory Collapse | Escitalopram                       |                    |                    | S               | Oral                     | 5 Mg                 |                 | Forest       |                |
|                                      | Risperdal 2 Mg Film-Coated Tablets |                    |                    | S               | Oral                     | 2 Mg                 |                 | Not Reported |                |
|                                      | Diovan                             |                    |                    | C               | Oral                     | 80 Mg                |                 | Not Reported |                |
|                                      | Symfona (Ginkgo Biloba)            |                    |                    | C               | Oral                     |                      |                 | Not Reported |                |
|                                      | Temesta (Lorazepam)                |                    |                    | C               | Oral                     | 1 Mg                 |                 | Not Reported |                |
| <u>FDA Received Date</u>             | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Nov-2015                          | 11698409                           | EXPEDITED (15-DAY) |                    | OT              | US-FRI-1000080677        |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Central Nervous System Stimulation   | Lexapro                            |                    |                    | S               |                          |                      |                 | Forest       |                |
| <u>FDA Received Date</u>             | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Nov-2015                          | 11673916                           | EXPEDITED (15-DAY) |                    | HO, OT          | JP-WATSON-2015-23017     |                      | 78 YR           | Female       | JPN            |
| <u>Preferred Term</u>                | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bradykinesia                         | Escitalopram (Unknown)             |                    |                    | S               | Unknown                  | 10 Mg, Daily         |                 | Not Reported |                |
|                                      | Nitrazepam (Unknown)               |                    |                    | S               | Unknown                  | 5 Mg, Daily          |                 | Not Reported |                |
|                                      | Risperidone (Unknown)              |                    |                    | S               | Unknown                  | 1 Mg, Daily          |                 | Watson       |                |
| <u>FDA Received Date</u>             | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Nov-2015                          | 11700353                           | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2015370867 |                      | 50 YR           | Female       | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                                                                   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                      | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|---------------------------------------------------------|-----------------|--------------|----------------|
| Drug Ineffective;<br>Headache                                                                                                                                                                           | Sertraline Hcl |                    |                    | S               |                      | Unk                                                     |                 | Pfizer       |                |
|                                                                                                                                                                                                         | Escitalopram   |                    |                    | S               | Oral                 | 10 Mg, 1x/Day                                           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Nov-2015                                                                                                                                                                                             | 11702254       | NON-EXPEDITED      |                    | OT              | BR-TORRENT-00003180  |                                                         | 68 YR           | Female       | BRA            |
| <u>Preferred Term</u>                                                                                                                                                                                   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                      | <u>Duration</u> | <u>Mfr</u>   |                |
| Amnesia; Blood Disorder;<br>Contusion; Drug Ineffective For<br>Unapproved Indication;<br>Fall; Intracardiac Thrombus;<br>Off Label Use; Osteopenia;<br>Petechiae; Spinal Pain;<br>Stress Cardiomyopathy | Neblock        |                    |                    | S               | Oral                 | Once Every 12 Hours/<br>Oral                            |                 | Torrent      |                |
|                                                                                                                                                                                                         | Espran         |                    |                    | S               | Oral                 | Once Daily/ Oral                                        |                 | Torrent      |                |
|                                                                                                                                                                                                         | Rivotril       |                    |                    | C               | Oral                 | Dose Number Is Unknown/<br>Once Daily/ Oral             |                 | Roche        |                |
|                                                                                                                                                                                                         | Aradois        |                    |                    | C               | Oral                 | Dose Number Is Unknown/<br>Once Every 12 Hours/<br>Oral |                 | Not Reported |                |
|                                                                                                                                                                                                         | Puran T4       |                    |                    | C               | Oral                 | Once Daily/ Oral                                        |                 | Aventis      |                |
|                                                                                                                                                                                                         | Marevan        |                    |                    | C               | Oral                 | Marevan 5 Mg Half Of A<br>Tablet Daily/ Oral            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Nov-2015                                                                                                                                                                                             | 11443351       | EXPEDITED (15-DAY) |                    | HO              | IT-FRI-1000079228    |                                                         | 90 YR           | Male         | ITA            |
| <u>Preferred Term</u>                                                                                                                                                                                   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                      | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Melaena                                                                                                                                                                               | Escitalopram   |                    |                    | S               | Oral                 | 1 Df                                                    |                 | Forest       |                |
|                                                                                                                                                                                                         | Pradaxa        |                    |                    | S               | Oral                 | 2 Df                                                    |                 | Not Reported |                |
|                                                                                                                                                                                                         | Selokeen       |                    |                    | C               | Oral                 |                                                         |                 | Not Reported |                |
|                                                                                                                                                                                                         | Lucen          |                    |                    | C               | Oral                 |                                                         |                 | Not Reported |                |
|                                                                                                                                                                                                         | Lasix          |                    |                    | C               | Oral                 |                                                         |                 | Not Reported |                |
|                                                                                                                                                                                                         | Enapren        |                    |                    | C               | Oral                 |                                                         |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                          | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------|--------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 06-Nov-2015                                                                                       | 11704487           | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2015374347 |                      | 72 YR           | Unknown      | USA            |
| <u>Preferred Term</u>                                                                             | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity                                                                             | Effexor            |                    |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                                                                                                   | Hydrocodone        |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                                                                                                   | Lexapro            |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                                                                                                   | Paxil /00830802/   |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                          | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Nov-2015                                                                                       | 10874084           | EXPEDITED (15-DAY) |                    | HO              | JP-FRI-1000074472        |                      | < 1 DAY         | Male         | JPN            |
| <u>Preferred Term</u>                                                                             | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Foetal Exposure During Pregnancy; Hypotonia; Neonatal Oversedation; Respiratory Disorder Neonatal | Lexapro            |                    |                    | S               | Transplacental           | 10 Mg                |                 | Forest       |                |
|                                                                                                   | Lexapro            |                    |                    | S               | Transplacental           | 10 Mg                |                 | Forest       |                |
|                                                                                                   | Meilax             |                    |                    | S               | Transplacental           | 1 Mg                 |                 | Not Reported |                |
|                                                                                                   | Meilax             |                    |                    | S               | Transplacental           | 1 Mg                 |                 | Not Reported |                |
|                                                                                                   | Sodium Rabeprazole |                    |                    | C               | Transplacental           | 10 Mg                |                 | Not Reported |                |
|                                                                                                   | Sodium Rabeprazole |                    |                    | C               | Transplacental           | 10 Mg                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                          | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Nov-2015                                                                                       | 11667976           | EXPEDITED (15-DAY) |                    | HO              | JP-FRI-1000080477        |                      | 78 YR           | Female       | JPN            |
| <u>Preferred Term</u>                                                                             | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bradykinesia; Serotonin Syndrome                                                                  | Escitalopram       |                    |                    | S               | Unknown                  | 10 Mg                |                 | Forest       |                |
|                                                                                                   | Mirtazapine        |                    |                    | C               | Unknown                  | 30 Mg                |                 | Not Reported |                |
|                                                                                                   | Nitrazepam         |                    |                    | C               | Unknown                  | 5 Mg                 |                 | Not Reported |                |
|                                                                                                   | Risperidone        |                    |                    | C               | Unknown                  | 1 Mg                 |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                                                                                                              | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u>                                                                                             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------|--------------------|-----------------|-------------------------------------|------------------------------------------------------------------------------------------------------------------|-----------------|--------------|----------------|
| 09-Nov-2015                                                                                                                                                                                                                                                                                                                                                                                                                           | 11713392                               | EXPEDITED (15-DAY) |                    | OT              | MY-ACCORD-035142                    |                                                                                                                  | 17 YR           | Female       | MYS            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                                                 | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                        | <u>Dosage Text</u>                                                                                               | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Behaviour;<br>Amenorrhoea; Condition<br>Aggravated; Delusion;<br>Delusion Of Reference;<br>Extrapyramidal Disorder;<br>Fear; Loss Of Personal<br>Independence In Daily<br>Activities; Musculoskeletal<br>Stiffness; Obsessive-<br>Compulsive Disorder;<br>Psychotic Disorder;<br>Salivary Hypersecretion;<br>Schizophrenia;<br>Tachycardia; Thinking<br>Abnormal; Tongue<br>Disorder; Treatment<br>Failure; Weight Increased | Quetiapine                             |                    |                    | S               |                                     | Initially Started At The<br>Dose 50 Mg, Then<br>Increased To 100 Mg, And<br>Subsequently Increased<br>To 200 Mg. |                 | Accord       |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                       | Risperidone                            |                    |                    | S               |                                     |                                                                                                                  |                 | Accord       |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                       | Olanzapine                             |                    |                    | S               |                                     |                                                                                                                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                       | Haloperidol                            |                    |                    | S               |                                     |                                                                                                                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                       | Lexapro                                |                    |                    | S               |                                     | Dose: 10 Mg Nocte Dose<br>Was Increased To 30 Mg<br>Daily Over The Period Of<br>Two Months                       |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                       | Aripiprazole                           |                    |                    | S               |                                     | Started At 5mg/Day, Then<br>Gradually Increased In<br>Two Weeks Up To 30 Mg<br>Daily.                            |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                       | Clozapine                              |                    |                    | S               |                                     | Started At 12.5mg Daily<br>And Gradually Increased<br>Up To 300 Mg Daily Over<br>The Period Of 2 Months          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                       | Paliperidone/Paliperidone<br>Palmitate |                    |                    | S               |                                     | Gradually Increased To 12<br>Mg Daily Over The Period<br>Of 4 Months                                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                                                                                                              | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u>                                                                                             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Nov-2015                                                                                                                                                                                                                                                                                                                                                                                                                           | 11713910                               | EXPEDITED (15-DAY) |                    | OT              | GB-AUROBINDO-AUR-<br>APL-2015-09923 |                                                                                                                  | 26 YR           | Male         | GBR            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                                                 | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                        | <u>Dosage Text</u>                                                                                               | <u>Duration</u> | <u>Mfr</u>   |                |
| Dyskinesia; Quality Of Life<br>Decreased                                                                                                                                                                                                                                                                                                                                                                                              | Escitalopram                           |                    |                    | S               | Oral                                | 15 Mg, Daily                                                                                                     |                 | Aurobindo    |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                       | Escitalopram                           |                    |                    | S               | Oral                                | 10 Mg, Daily                                                                                                     |                 | Aurobindo    |                |



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| <u>FDA Received Date</u>                                                             | <u>Case #</u>    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------|------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 09-Nov-2015                                                                          | 11715911         | EXPEDITED (15-DAY) |                    | CA              | FR-FRI-1000080786    |                      | < 1 DAY         | Female       | FRA            |
| <u>Preferred Term</u>                                                                | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Coarctation Of The Aorta                                                             | Escitalopram     |                    |                    | S               | Transplacental       |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                             | <u>Case #</u>    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Nov-2015                                                                          | 11718264         | DIRECT             |                    |                 |                      |                      | 35 YR           | Female       |                |
| <u>Preferred Term</u>                                                                | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blepharospasm; Drug Withdrawal Syndrome; Fatigue                                     | Lexapro          |                    |                    | S               | Oral                 |                      | 10 YR           | Teva         |                |
|                                                                                      | Omega-3 Fish Oil |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                      | Prenatal Vitamin |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                             | <u>Case #</u>    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Nov-2015                                                                          | 11717498         | EXPEDITED (15-DAY) |                    | HO              | GB-DEXPHARM-20152092 |                      |                 | Female       | GBR            |
| <u>Preferred Term</u>                                                                | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Sepsis Neonatal | Azathioprine     |                    |                    | S               | Transplacental       |                      |                 | Not Reported |                |
|                                                                                      | Co-Dydramol      |                    |                    | S               | Transplacental       | Strength: 10/500     |                 | Not Reported |                |
|                                                                                      | Escitalopram     |                    |                    | S               | Transplacental       |                      |                 | Not Reported |                |
|                                                                                      | Omeprazole       |                    |                    | S               | Transplacental       |                      |                 | Not Reported |                |
|                                                                                      | Oramorph         |                    |                    | S               | Transplacental       |                      |                 | Not Reported |                |
|                                                                                      | Oramorph         |                    |                    | S               | Unknown              |                      |                 | Not Reported |                |
|                                                                                      | Tapentadol       |                    |                    | S               | Transplacental       | 100 Mg               |                 | Not Reported |                |
|                                                                                      | Daktarin         |                    |                    | C               | Unknown              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                             | <u>Case #</u>    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Nov-2015                                                                          | 11720338         | EXPEDITED (15-DAY) |                    | OT              | GB-TEVA-606510ACC    |                      | 26 YR           | Male         | GBR            |

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| <u>Preferred Term</u>                                                                                                          | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|--------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Dyskinesia; Emotional Distress; Impaired Work Ability                                                                          | Escitalopram                      |                    |                    | S               | Oral                 | 15 Mg Daily          |                 | Ivax         |                |
|                                                                                                                                | Escitalopram                      |                    |                    | S               | Oral                 | 10 Mg Daily          |                 | Ivax         |                |
| <u>FDA Received Date</u>                                                                                                       | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Nov-2015                                                                                                                    | 11720359                          | EXPEDITED (15-DAY) |                    | HO              | AU-FRI-1000080693    |                      |                 | Male         | AUS            |
| <u>Preferred Term</u>                                                                                                          | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Seizure                                                                                                                        | Escitalopram                      |                    |                    | S               | Unknown              |                      |                 | Forest       |                |
|                                                                                                                                | "Ice" / Methamphetamine           |                    |                    | C               | Unknown              |                      |                 | Not Reported |                |
|                                                                                                                                | Cocaine                           |                    |                    | C               | Unknown              |                      |                 | Not Reported |                |
|                                                                                                                                | Marijuana                         |                    |                    | C               | Unknown              |                      |                 | Not Reported |                |
|                                                                                                                                | Valium / Diazepam                 |                    |                    | C               | Unknown              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                       | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Nov-2015                                                                                                                    | 11722416                          | DIRECT             | Y                  | HO, LT          |                      |                      | 11 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                          | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hallucination, Auditory; Intentional Self-Injury; Memory Impairment; Mood Altered; Skin Laceration; Staring; Suicidal Ideation | Escitalopram 10 Mg                |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                       | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Nov-2015                                                                                                                    | 11723191                          | DIRECT             |                    | DS, HO, LT, OT  |                      |                      | 63 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                          | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cerebrovascular Accident; Headache; Product Substitution Issue; Product                                                        | Escitalopram                      |                    |                    | S               | Oral                 |                      |                 | Accord       |                |
|                                                                                                                                | Clonozepam (Generic For Klonopin) |                    |                    | C               |                      |                      |                 | Not Reported |                |

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Substitution Issue;  
Therapy Cessation

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 11-Nov-2015              | 11722440      | EXPEDITED (15-DAY) |                    | DS, OT          | US-ACTAVIS-2015-24090 |                      |            | Male       | USA            |

| <u>Preferred Term</u>                                             | <u>Product</u>                   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                   |
|-------------------------------------------------------------------|----------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------------------------|
| Feeling Jittery;<br>Neuromyopathy; Sedation;<br>Suicidal Ideation | Escitalopram (Unknown)           |              |            | S           | Unknown      | 20 Mg, Unknown     |                 | Not Reported                 |
|                                                                   | Escitalopram (Unknown)           |              |            | S           | Unknown      | 10 Mg, Unknown     |                 | Not Reported                 |
|                                                                   | Escitalopram (Unknown)           |              |            | S           | Unknown      | Titrated To 20 Mg  |                 | Not Reported                 |
|                                                                   | Fluoxetine (Watson Laboratories) |              |            | S           | Unknown      | Unk                |                 | Watson                       |
|                                                                   | Olanzapine (Unknown)             |              |            | S           | Unknown      | Unk                |                 | Not Reported                 |
|                                                                   | Sertraline                       |              |            | C           | Unknown      | 25 Mg, Unknown     |                 | Not Reported                 |
|                                                                   | Sertraline<br>Mirtazapine        |              |            | C<br>C      | Unknown      | Unk                |                 | Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Nov-2015              | 11723055      | EXPEDITED (15-DAY) |                    | HO, OT          | JP-TEVA-603552ISR    |                      | 78 YR      | Female     | JPN            |

| <u>Preferred Term</u>                                                                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                         | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------------------------------|-----------------|--------------|
| Aggression; Bradykinesia;<br>Delusion; Hallucination;<br>Pyrexia; Serotonin Syndrome; Somnolence | Nitrazepam     |              |            | S           |              | 5 Milligram Daily; For More Than 6 Months  |                 | Not Reported |
|                                                                                                  | Risperidone    |              |            | S           |              | 1 Milligram Daily; For More Than 6 Months  |                 | Pliva        |
|                                                                                                  | Escitalopram   |              |            | S           |              | 10 Milligram Daily; For More Than 6 Months |                 | Not Reported |
|                                                                                                  | Mirtazapine    |              |            | C           |              | 30 Milligram Daily;                        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Nov-2015              | 11723082      | NON-EXPEDITED    |                    |                 | US-TORRENT-00001013  |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                            |                                         |                             |                    |                 |                                       |                      |                 |              |                |
|--------------------------------------------|-----------------------------------------|-----------------------------|--------------------|-----------------|---------------------------------------|----------------------|-----------------|--------------|----------------|
| Drug Ineffective                           |                                         | Escitalopram Oxalate Tablet |                    | S               |                                       | Torrent              |                 |              |                |
| <u>FDA Received Date</u>                   | <u>Case #</u>                           | <u>Case Type</u>            | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Nov-2015                                | 11734616                                | EXPEDITED (15-DAY)          |                    | HO              | CA-PURDUE PHARMA-CAN-2015-0006235     |                      | 31 YR           | Female       | CAN            |
| <u>Preferred Term</u>                      | <u>Product</u>                          | <u>Comp.</u>                | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bradycardia; Neutropenia; Pleural Effusion | Morphine Sulfate                        |                             |                    | S               | Unknown                               | 2.5 Mg, Q4h          |                 | Purdue       |                |
|                                            | Avastin /01555201/                      |                             |                    | S               | Intravenous (not otherwise specified) | 15 Mg/Kg, See Text   |                 | Not Reported |                |
|                                            | Carboplatin                             |                             |                    | S               | Intravenous (not otherwise specified) | Unk Unk, See Text    |                 | Not Reported |                |
|                                            | Cipraxex                                |                             |                    | S               | Unknown                               | 10 Mg, Daily         |                 | Not Reported |                |
|                                            | Ciprofloxacin                           |                             |                    | S               | Intravenous (not otherwise specified) | Unk, See Text        |                 | Not Reported |                |
|                                            | Ciprofloxacin                           |                             |                    | S               | Oral                                  | 1000 Mg, Unk         |                 | Not Reported |                |
|                                            | Docetaxel                               |                             |                    | S               | Intravenous (not otherwise specified) | 75 Mg/M2, See Text   |                 | Not Reported |                |
|                                            | Docetaxel                               |                             |                    | S               | Intravenous (not otherwise specified) | 75 Mg/M2, Unk        |                 | Not Reported |                |
|                                            | Piperacillin Sodium W/Tazobactam Sodium |                             |                    | S               | Unknown                               | Unk                  |                 | Not Reported |                |
|                                            | Trastuzumab                             |                             |                    | S               | Intravenous (not otherwise specified) | 8 Mg/Kg, See Text    |                 | Not Reported |                |
|                                            | Tylenol /00020001/                      |                             |                    | S               | Unknown                               | Unk                  |                 | Not Reported |                |
|                                            | Tylenol No.1                            |                             |                    | S               | Unknown                               | Unk                  |                 | Not Reported |                |
|                                            | Codeine                                 |                             |                    | C               | Unknown                               | Unk                  |                 | Purdue       |                |
|                                            | Docusate                                |                             |                    | C               | Unknown                               | Unk                  |                 | Not Reported |                |
|                                            | Gravol                                  |                             |                    | C               | Unknown                               | Unk                  |                 | Not Reported |                |
|                                            | Lactulose                               |                             |                    | C               | Unknown                               | Unk                  |                 | Not Reported |                |
|                                            | Senna /00142201/                        |                             |                    | C               | Unknown                               | Unk                  |                 | Not Reported |                |
|                                            | Trazodone                               |                             |                    | C               | Unknown                               | Unk                  |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>              | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------------------|----------------------|------------|------------|----------------|
| 13-Nov-2015              | 11734944      | EXPEDITED (15-DAY) |                    | OT              | CA-PURDUE PHARMA-CAN-2015-0006248 |                      | 62 YR      | Female     | CAN            |

| <u>Preferred Term</u>                                            | <u>Product</u>   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------|------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Alopecia; Arthritis; Breath Sounds Abnormal;                     | Morphine Sulfate |              |            | S           | Unknown      | Unk, Tid           |                 | Purdue       |
| Bronchitis; Chondropathy;                                        | Ciprallex        |              |            | S           | Unknown      | 20 Mg, Unk         |                 | Not Reported |
| Cough; Depression; Fall;                                         | Clorazepate      |              |            | S           | Oral         | 15 Mg, Tid         |                 | Not Reported |
| Fatigue; Feeling Of Body Temperature Change;                     | Co Etidrocal     |              |            | S           | Unknown      | 500 Mg, Daily      |                 | Not Reported |
| Hyperhidrosis;                                                   | Esomeprazole     |              |            | S           | Unknown      | 40 Mg, Daily       |                 | Not Reported |
| Inappropriate Schedule Of Product Administration;                | Gabapentin       |              |            | S           | Unknown      | Unk, Bid           |                 | Not Reported |
| Incorrect Product Administration Duration;                       | Gabapentin       |              |            | S           | Unknown      | Unk, Tid           |                 | Not Reported |
| Intervertebral Disc Disorder; Lymphoedema;                       | Ibuprofen        |              |            | S           | Unknown      | 100 Mg, Daily      |                 | Not Reported |
| Lymphoma; Mobility Decreased; Motor Dysfunction; Nausea;         | Trazodone        |              |            | S           | Unknown      | 50 Mg, Unk         |                 | Not Reported |
| Pain; Panic Attack;                                              | Voltaren Emulgel |              |            | S           | Topical      | Unk                |                 | Not Reported |
| Peripheral Swelling;                                             | Voltaren Emulgel |              |            | S           |              |                    |                 | Not Reported |
| Photopsia; Pneumonia;                                            | Voltaren Emulgel |              |            | S           |              |                    |                 | Not Reported |
| Respiratory Arrest;                                              | Voltaren Emulgel |              |            | S           |              |                    |                 | Not Reported |
| Therapeutic Response Decreased; Therapeutic Response Unexpected; | Zopiclone        |              |            | S           | Unknown      | 15 Mg, Unk         |                 | Not Reported |
| Tremor                                                           | Bupropion Hcl Er |              |            | C           | Oral         | 300 Mg, Unk        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Nov-2015              | 11737010      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000080903    |                      | 87 YR      | Female     | FRA            |

| <u>Preferred Term</u>    | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|--------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Atrial Tachycardia;      | Escitalopram       |              |            | S           | Oral         |                    |                 | Forest       |
| Confusional State;       | Digoxine Nativelle |              |            | S           | Oral         |                    |                 | Not Reported |
| Hallucination, Auditory; | Tiapridal          |              |            | S           | Oral         |                    |                 | Not Reported |
| Hallucination, Visual    |                    |              |            |             |              |                    |                 |              |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                            |   |              |
|--------------------------------------------|---|--------------|
| Coumadine                                  | C | Not Reported |
| Lasilix                                    | C | Not Reported |
| Doliprane                                  | C | Not Reported |
| Speciafoldine                              | C | Not Reported |
| Tardyferon B9 [Ferrous Sulfate;Folic Acid] | C | Not Reported |
| Levothyrox                                 | C | Not Reported |
| Triatec (Ramipril)                         | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Nov-2015              | 11737978      | EXPEDITED (15-DAY) | HO                 |                 | US-SA-2015SA177570   |                      | 44 YR      | Female     | USA            |

| <u>Preferred Term</u>                              | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>             | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------|-------------------------|--------------|------------|-------------|--------------------------|--------------------|-----------------|--------------|
| Cough; Pulmonary Embolism; Treatment Noncompliance | Lasix                   |              |            | S           | Oral                     |                    |                 | Not Reported |
|                                                    | Xarelto                 |              |            | S           | Oral                     |                    |                 | Not Reported |
|                                                    | Gabapentin              |              |            | S           | Oral                     |                    |                 | Not Reported |
|                                                    | Lexapro                 |              |            | S           | Oral                     |                    |                 | Not Reported |
|                                                    | Paxil                   |              |            | S           | Oral                     |                    |                 | Not Reported |
|                                                    | Tricor                  |              |            | S           | Oral                     |                    |                 | Not Reported |
|                                                    | Estradiol               |              |            | S           | Oral                     |                    |                 | Not Reported |
|                                                    | Dicyclomine             |              |            | C           | Oral                     |                    |                 | Not Reported |
|                                                    | Advair Diskus           |              |            | C           | Respiratory (inhalation) |                    |                 | Not Reported |
|                                                    | Albuterol Sulfate       |              |            | C           | Respiratory (inhalation) |                    |                 | Not Reported |
|                                                    | Aldactone               |              |            | C           | Oral                     |                    |                 | Not Reported |
|                                                    | Apidra                  |              |            | C           | Subcutaneous             | 100 Unit/MI        |                 | Not Reported |
|                                                    | Benzonatate             |              |            | C           | Oral                     |                    |                 | Not Reported |
|                                                    | Clonidine Hydrochloride |              |            | C           | Oral                     |                    |                 | Not Reported |
|                                                    | Elocon                  |              |            | C           | Topical                  |                    |                 | Not Reported |
|                                                    | Ferrous Sulfate         |              |            | C           | Oral                     |                    |                 | Not Reported |
|                                                    | Humalog Mix             |              |            | C           | Subcutaneous             |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                           |   |                             |              |
|---------------------------|---|-----------------------------|--------------|
| Hydroxyzine Hydrochloride | C | Oral                        | Not Reported |
| Hyzaar                    | C | Oral                        | Not Reported |
| Ibuprofen                 | C | Oral                        | Not Reported |
| Imitrex                   | C | Oral                        | Not Reported |
| Klor-Con                  | C | Oral                        | Not Reported |
| Lipitor                   | C | Oral                        | Not Reported |
| Nexium                    | C | Oral                        | Not Reported |
| Prilosec                  | C | Oral                        | Not Reported |
| Proair Hfa                | C | Respiratory<br>(inhalation) | Not Reported |
| Promethazine Dm           | C | Oral                        | Not Reported |
| Reglan                    | C | Oral                        | Not Reported |
| Remeron                   | C | Oral                        | Not Reported |
| Soma                      | C | Oral                        | Not Reported |
| Sumatriptan               | C | Oral                        | Not Reported |
| Synthroid                 | C | Oral                        | Not Reported |
| Zolpidem                  | C | Oral                        | Not Reported |
| Ultram                    | C | Oral                        | Not Reported |
| Folic Acid                | C |                             | Not Reported |
| Toprol XL                 | C | Oral                        | Not Reported |
| Xyzal                     | C | Oral                        | Not Reported |
| Insulin                   | C |                             | Not Reported |
| Amitiza                   | C |                             | Not Reported |
| Seretide                  | C |                             | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Nov-2015              | 11741830      | DIRECT           |                    | OT              |                      |                      | 64 YR      | Female     | USA            |

| <u>Preferred Term</u>  | <u>Product</u>             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------|----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Amnesia; Aura;         | Lexapro 10 Mg. Forest Labs |              |            | S           | Oral         | 1 Pill             |                 | Forest       |
| Hallucination, Visual; | Synthroid                  |              |            | C           |              |                    |                 | Not Reported |
| Heart Rate Irregular;  |                            |              |            |             |              |                    |                 |              |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                          |               |   |              |
|--------------------------|---------------|---|--------------|
| Hypersensitivity; Mania; | Vitamin D Nos | C | Not Reported |
| Panic Attack; Product    | Calcium       | C | Not Reported |
| Complaint; Restlessness  | Fish Oil      | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 16-Nov-2015              | 11382937      | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2015260924 |                      | 48 YR      | Female     | USA            |

| <u>Preferred Term</u>                          | <u>Product</u>                    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------|-----------------------------------|--------------|------------|-------------|--------------|---------------------|-----------------|--------------|
| Contraindicated Product Administered; Headache | Tikosyn                           |              |            | S           | Oral         | 250 Mg, 2x/Day      |                 | Pfizer       |
|                                                | Tikosyn                           |              |            | S           |              |                     |                 | Pfizer       |
|                                                | Lexapro                           |              |            | S           | Oral         | 10 Mg, 1x/Day       |                 | Not Reported |
|                                                | Pradaxa                           |              |            | C           | Oral         | 150 Mg, 2x/Day      |                 | Not Reported |
|                                                | Metoprolol                        |              |            | C           | Oral         | 100 Mg, 2x/Day      |                 | Not Reported |
|                                                | Diltiazem                         |              |            | C           | Oral         | 360 Mg, 1x/Day      |                 | Not Reported |
|                                                | Coenzyme Q10                      |              |            | C           | Oral         | 100 Mg, Liquid, Unk |                 | Not Reported |
|                                                | Vitamin D Nos                     |              |            | C           | Oral         | 1000 Iu, 1x/Day     |                 | Not Reported |
|                                                | Calcium Magnesium Zinc /01320801/ |              |            | C           | Oral         | 500 Mg, 2x/Day      |                 | Not Reported |
|                                                | Aspirin Low                       |              |            | C           | Oral         | 81 Mg, 1x/Day       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 16-Nov-2015              | 11741272      | EXPEDITED (15-DAY) |                    | OT              | US-ORION CORPORATION ORION PHARMA-SERO2015-0026 |                      |            | Male       | USA            |

| <u>Preferred Term</u>                                                                                          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Feeling Jittery; Motor Dysfunction; Psychiatric Decompensation; Sedation; Suicidal Ideation; Treatment Failure | Fluoxetine     |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                                | Escitalopram   |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                                | Escitalopram   |              |            | S           | Unknown      |                    |                 | Not Reported |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 16-Nov-2015                | 11746401       | DIRECT           |                    | DS, HO          |                      |                      | 56 YR           | Male         | USA            |
| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dysuria; Urinary Retention | Lexapro        |                  |                    | S               |                      | One In The Morning   |                 | Not Reported |                |
|                            | Inderal        |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                            | Potassium      |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                            | Flomax         |                  |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                          | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|-------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 17-Nov-2015                                                       | 11687444       | EXPEDITED (15-DAY) |                    | HO, LT          | FR-FRI-1000080481    |                      |                 | Male       | FRA            |
| <u>Preferred Term</u>                                             | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Exposure During Pregnancy; Neonatal Respiratory Distress Syndrome | Escitalopram   |                    |                    | S               | Transplacental       | 10 Mg                |                 | Forest     |                |

| <u>FDA Received Date</u>                                                                                             | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>     | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|---------------------------------------|-------------------------------|-----------------|----------------|----------------|
| 17-Nov-2015                                                                                                          | 11745712               | EXPEDITED (15-DAY) |                    | HO              | FR-ACTAVIS-2015-24417                 |                               | 87 YR           | Male           | FRA            |
| <u>Preferred Term</u>                                                                                                | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>     |                |
| Acute Kidney Injury; Confusional State; Encephalopathy; Incoherent; Platelet Count Decreased; Uraemic Encephalopathy | Zolpidem (Unknown)     |                    |                    | S               | Oral                                  | 1 Df, Daily In Evening        |                 | Watson         |                |
|                                                                                                                      | Pantoprazole (Unknown) |                    |                    | S               | Oral                                  | 1 Df, Daily In Morning        |                 | Actavis Totowa |                |
|                                                                                                                      | Pravastatine Arrow     |                    |                    | S               | Oral                                  | 1 Df, Daily In Evening        |                 | Not Reported   |                |
|                                                                                                                      | Escitalopram           |                    |                    | S               | Oral                                  | 1 Df, Daily In Evening        |                 | Not Reported   |                |
|                                                                                                                      | Bromazepam             |                    |                    | S               | Oral                                  | 0.25 Df, Daily In Evening     |                 | Not Reported   |                |
|                                                                                                                      | Cefepime Mylan         |                    |                    | S               | Intravenous (not otherwise specified) | 2 G, Bid Every 12 Hours       |                 | Not Reported   |                |
|                                                                                                                      | Lasilix /00032601/     |                    |                    | S               | Oral                                  | 0.5 Df, Daily At Noon         |                 | Not Reported   |                |
|                                                                                                                      | Ferograd               |                    |                    | S               | Oral                                  | 1 Df, Bid Morning And Evening |                 | Not Reported   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                      |   |              |                               |              |
|----------------------|---|--------------|-------------------------------|--------------|
| Calciparine          | S | Subcutaneous | 1 Df, Bid Morning And Evening | Not Reported |
| Kardegic             | S | Oral         | 1 Df, Daily                   | Not Reported |
| Ezetrol              | S | Oral         | 1 Df, Daily In Evening        | Not Reported |
| Ikorel               | C | Unknown      | Unk Unk, Unknown              | Not Reported |
| Aldactone /00006201/ | C | Unknown      | Unk Unk, Unknown              | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------------------|----------------------|------------|------------|----------------|
| 17-Nov-2015              | 11745799      | EXPEDITED (15-DAY) |                    | OT              | JP-JUBILANT<br>GENERICs LIMITED-<br>1044269 |                      | 78 YR      | Female     | JPN            |

| <u>Preferred Term</u>                                                                                                                                                        | <u>Product</u>                                    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                               |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------------------------------------|
| Dehydration; Haematuria;<br>Oxygen Saturation<br>Decreased; Protein Urine<br>Present; Serotonin<br>Syndrome; Urine<br>Leukocyte Esterase<br>Positive; Withdrawal<br>Syndrome | Escitalopram Oxalate<br>Risperidone<br>Nitrazepam |              |            | S<br>C<br>C |              |                    |                 | Jubilant<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|------------|------------|----------------|
| 17-Nov-2015              | 11746468      | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-<br>2015M1039650 |                      |            | Unknown    | USA            |

| <u>Preferred Term</u> | <u>Product</u>             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>       | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                   |
|-----------------------|----------------------------|--------------|------------|-------------|--------------------|--------------------|-----------------|------------------------------|
| Motor Neurone Disease | Fluoxetine<br>Escitalopram |              |            | S<br>S      | Unknown<br>Unknown | 10mg               |                 | Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|------------|------------|----------------|
| 17-Nov-2015              | 11746470      | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-<br>2015M1039654 |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Headache; Motor Neurone<br>Disease | Escitalopram   |              |            | S           | Unknown      |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|            |   |         |       |              |
|------------|---|---------|-------|--------------|
| Sertraline | S | Unknown |       | Not Reported |
| Bupropion  | C | Unknown | 300mg | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Nov-2015              | 11748609      | EXPEDITED (15-DAY) | HO                 |                 | FR-FRI-1000080952    |                      | 76 YR      | Female     | FRA            |

| <u>Preferred Term</u>                           | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                       | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------|------------------------|--------------|------------|-------------|--------------|----------------------------------------------------------|-----------------|--------------|
| Anaemia; Drug Interaction;<br>Wound Haemorrhage | Escitalopram           |              |            | S           | Oral         | 10 Mg                                                    |                 | Forest       |
|                                                 | Escitalopram           |              |            | S           | Oral         | Daily Dose Increased On<br>10/Aug/2015 (Unknown<br>Dose) |                 | Forest       |
|                                                 | Escitalopram           |              |            | S           | Oral         |                                                          |                 | Not Reported |
|                                                 | Previscan (Fluindione) |              |            | S           | Oral         | 20 Mg                                                    |                 | Not Reported |
|                                                 | Levothyrox             |              |            | C           | Unknown      | 112.5 Mcg                                                |                 | Not Reported |
|                                                 | Crestor                |              |            | C           | Unknown      | 10 Mg                                                    |                 | Not Reported |
|                                                 | Atenolol               |              |            | C           | Unknown      | 50 Mg                                                    |                 | Not Reported |
|                                                 | Triatec (Ramipril)     |              |            | C           | Unknown      | 1.25 Mg                                                  |                 | Not Reported |
|                                                 | Zolpidem               |              |            | C           | Unknown      | 5 Mg                                                     |                 | Not Reported |
|                                                 | Lamictal               |              |            | C           | Unknown      | 100 Mg                                                   |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|------------|------------|----------------|
| 18-Nov-2015              | 11740981      | EXPEDITED (15-DAY) | HO, OT             |                 | FR-009507513-<br>1511FRA005269 |                      | 87 YR      | Male       | FRA            |

| <u>Preferred Term</u>                               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                             | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------|----------------|--------------|------------|-------------|------------------------------------------|--------------------|-----------------|--------------|
| Confusional State;<br>Encephalopathy;<br>Incoherent | Ezetrol        |              |            | S           | Oral                                     | 10 Mg, Qpm         |                 | Merck        |
|                                                     | Cefepime       |              |            | S           | Intravenous (not<br>otherwise specified) | 2 G, Q12h          |                 | Not Reported |
|                                                     | Escitalopram   |              |            | S           |                                          | 1 Tablet, Qpm      |                 | Not Reported |
|                                                     | Bromazepam     |              |            | S           |                                          | 0.25 Tablet, Qpm   |                 | Not Reported |
|                                                     | Zolpidem       |              |            | S           |                                          | 1 Tablet, Qpm      |                 | Not Reported |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                    |   |              |                                           |              |
|----------------------------------------------------|---|--------------|-------------------------------------------|--------------|
| Lasilix                                            | S | Oral         | 20 Mg, At Midday (Daily)                  | Not Reported |
| Lasilix                                            | S | Oral         | Unk                                       | Not Reported |
| Ferrograd C (Ascorbic Acid (+)<br>Ferrous Sulfate) | S |              | 1 Tablet Qam And 1<br>Tablet Qpm          | Not Reported |
| Ferrograd C (Ascorbic Acid (+)<br>Ferrous Sulfate) | S |              | Unk                                       | Not Reported |
| Calciparine                                        | S | Subcutaneous | 1 Injection In The Morning<br>And Evening | Not Reported |
| Kardegic                                           | S |              | 1 Bag At Midday                           | Not Reported |
| Pantoprazole                                       | S |              | 1 Tablet, Qam                             | Not Reported |
| Pravastatin                                        | S |              | 40 Mg, Qpm                                | Not Reported |
| Ikorel                                             | C |              | 0.5 Tablet Qam                            | Not Reported |
| Ikorel                                             | C |              | 0.75 Tablet , Qpm                         | Not Reported |
| Aldactone (Spironolactone)                         | C |              | 1 Tablet, At Midday (Daily)               | Not Reported |
| Pyridoxine (+) Thiamine                            | C |              |                                           | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------|----------------------|------------|------------|----------------|
| 18-Nov-2015              | 11748883      | EXPEDITED (15-DAY) | HO                 |                 | FR-AUROBINDO-AUR-<br>APL-2015-10171 |                      | 86 YR      | Female     | FRA            |

| <u>Preferred Term</u>     | <u>Product</u>                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|--------------------------------|--------------|------------|-------------|-----------------------------|--------------------|-----------------|--------------|
| Blood Pressure Increased; | Escitalopram Arrow Film-Coated |              |            | S           | Oral                        | 5 Mg, Daily        |                 | Aurobindo    |
| Cognitive Disorder;       | Tablet 5mg                     |              |            |             |                             |                    |                 |              |
| Confusional State;        | Perindopril Actavis            |              |            | S           | Oral                        | 8 Mg, Daily        |                 | Not Reported |
| Disorientation;           | Esidrex                        |              |            | S           | Oral                        | 12.5 Mg, Daily     |                 | Not Reported |
| Hypercreatininaemia;      | Esomeprazole                   |              |            | S           | Oral                        | 40 Mg, Daily       |                 | Not Reported |
| Hypoalbuminaemia;         | Aerius /01009701/              |              |            | C           | Oral                        | 5 Mg, Daily        |                 | Not Reported |
| Hypochloraemia;           | Movicol /01625101/             |              |            | C           | Oral                        | 1 Df, Daily        |                 | Not Reported |
| Hypokalaemia;             | Seresta                        |              |            | C           | Oral                        | 10 Mg, Daily       |                 | Not Reported |
| Hyponatraemia;            | Dexeryl /00557601/             |              |            | C           | Subcutaneous                | Unk                |                 | Not Reported |
| Hypoproteinaemia;         | Monazol                        |              |            | C           | Subcutaneous                | Unk                |                 | Not Reported |
| Leukoencephalopathy;      | Avamys                         |              |            | C           | Respiratory<br>(inhalation) | Unk                |                 | Not Reported |
| Renal Failure;            |                                |              |            |             |                             |                    |                 |              |
| Tachycardia               |                                |              |            |             |                             |                    |                 |              |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                      |   |         |                      |              |
|----------------------|---|---------|----------------------|--------------|
| Uvedose              | C | Oral    | 0.0333 Once Monthly  | Not Reported |
| Lercan               | C | Oral    | 20 Mg, Daily         | Not Reported |
| Aerius /01009701/    | C | Oral    | 5 Mg, Daily          | Not Reported |
| Proctolog /01026901/ | C | Unknown | 3 Applications Daily | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Nov-2015              | 11749762      | EXPEDITED (15-DAY) |                    | OT              | CH-FRI-1000080850    |                      | 64 YR      | Male       | CHE            |

| <u>Preferred Term</u>        | <u>Product</u>                                     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------|----------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Chronotropic<br>Incompetence | Escitalopram                                       |              |            | S           | Oral         | 20 Mg              |                 | Forest       |
|                              | Aspirin (Acetylsalicylic Acid)                     |              |            | C           | Oral         | 100 Mg             |                 | Not Reported |
|                              | Lisitril Comp.<br>(Hydrochlorithiazide/Lisinopril) |              |            | C           | Oral         |                    |                 | Not Reported |
|                              | Crestor (Rosuvastatin Calcium)                     |              |            | C           | Oral         | 10 Mg              |                 | Not Reported |
|                              | Brilique (Ticagrelor)                              |              |            | C           | Oral         | 180 Mg             |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 18-Nov-2015              | 11751171      | EXPEDITED (15-DAY) |                    | OT              | US-APOTEX-<br>2015AP014530 |                      | 30 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Ineffective; Fatigue;<br>Headache; Movement<br>Disorder; Pain In Jaw;<br>Rapid Eye Movements<br>Sleep Abnormal;<br>Restlessness | Escitalopram Oxalate     |              |            | S           | Unknown      |                    |                 | Apotex       |
|                                                                                                                                      | Sertraline Hydrochloride |              |            | S           | Unknown      |                    |                 | Apotex       |
|                                                                                                                                      | Bupropion                |              |            | C           | Unknown      | 300 Mg, Unk        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------------------|----------------------|------------|------------|----------------|
| 18-Nov-2015              | 11751994      | EXPEDITED (15-DAY) |                    | OT              | US-<br>GLAXOSMITHKLINE-<br>US2015GSK160733 |                      |            | Female     | USA            |

| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|---------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Bipolar Disorder; Chronic | Lamictal       |              |            | S           | Unknown      | Unk                |                 | Glaxosmithkline |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                             |                |   |         |     |                 |
|-----------------------------------------------------------------------------|----------------|---|---------|-----|-----------------|
| Obstructive Pulmonary Disease; Depression; Glucose Tolerance Impaired; Rash | Spironolactone | S | Unknown | Unk | Glaxosmithkline |
|                                                                             | Lexapro        | S | Unknown | Unk | Not Reported    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------|----------------------|------------|------------|----------------|
| 18-Nov-2015              | 11752280      | EXPEDITED (15-DAY) |                    | OT              | US-APOTEX-2015AP014529 |                      | 20 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                | <u>Product</u>               | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------|------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Ineffective; Feeling Jittery; Movement Disorder; Neurological Decompensation; Suicidal Ideation | Fluoxetine Oral Solution Usp |              |            | S           | Unknown      | Unk                |                 | Apotex       |
|                                                                                                      | Escitalopram Oxalate         |              |            | S           | Unknown      | 10 Mg, Unk         |                 | Apotex       |
|                                                                                                      | Escitalopram Oxalate         |              |            | S           | Unknown      | 20 Mg, Unk         |                 | Apotex       |
|                                                                                                      | Sertraline Hydrochloride     |              |            | S           | Unknown      | 25 Mg, Unk         |                 | Apotex       |
|                                                                                                      | Sertraline Hydrochloride     |              |            | S           |              |                    |                 | Apotex       |
|                                                                                                      | Zyprexa                      |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                      | Mirtazapine                  |              |            | C           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Nov-2015              | 11753628      | EXPEDITED (15-DAY) |                    | HO              | PHHY2015ES148840     |                      | 81 YR      | Female     | ESP            |

| <u>Preferred Term</u>                                                      | <u>Product</u>  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------|-----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Depressed Level Of Consciousness; Drug Interaction; Hyponatraemia; Syncope | Co-Diovan Forte |              |            | S           | Oral         | Unk                |                 | Novartis     |
|                                                                            | Escitalopram    |              |            | S           | Oral         | 10 Mg, Unk         |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|------------|------------|----------------|
| 19-Nov-2015              | 11754230      | EXPEDITED (15-DAY) |                    | HO              | FR-AUROBINDO-AUR-APL-2015-10291 |                      | 87 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                                                        | <u>Product</u>                         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------|----------------------------------------|--------------|------------|-------------|--------------|--------------------------------|-----------------|--------------|
| Acute Kidney Injury; Agitation; Blood Creatinine Increased; Blood Urea Increased; C-Reactive | Bromazepam Tablet                      |              |            | S           | Oral         | 0.25 Df, Once A Day in Evening |                 | Not Reported |
|                                                                                              | Escitalopram Arrow Film-Coated Tablets |              |            | S           | Oral         | 1 Df, Once A Day In            |                 | Aurobindo    |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                  |                                                |   |                                          |                                                |              |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|---|------------------------------------------|------------------------------------------------|--------------|
| Protein Increased; Clonus;<br>Condition Aggravated;<br>Confusional State;<br>Dysphagia;<br>Encephalopathy;<br>Incoherent; Platelet Count<br>Decreased; Uraemic<br>Encephalopathy | Pantoprazole Arrow Gastro-<br>Resistant Tablet | S | Oral                                     | Evening<br>1 Df, Once A Day, In<br>Morning     | Aurobindo    |
|                                                                                                                                                                                  | Pravastatin Arrow Tablets 40mg                 | S | Oral                                     | 1 Df, Once A Day In<br>Evening                 | Not Reported |
|                                                                                                                                                                                  | Zolpidem Film-Coated Tablet                    | S | Oral                                     | 1 Df, Once A Day In<br>Evening                 | Aurobindo    |
|                                                                                                                                                                                  | Cefipime                                       | S | Intravenous (not<br>otherwise specified) | 2 G, Every 12 Hours                            | Not Reported |
|                                                                                                                                                                                  | Lasilix /00032601/                             | S | Oral                                     | 0.5 Df, Once A Day                             | Not Reported |
|                                                                                                                                                                                  | Ferograd                                       | S | Oral                                     | 1 Df, In The Morning And<br>Evening            | Not Reported |
|                                                                                                                                                                                  | Calciparine                                    | S | Subcutaneous                             | 1 Df, In The Morning And<br>Evening            | Not Reported |
|                                                                                                                                                                                  | Kardegic                                       | S |                                          | 1 Sachet At Noon                               | Not Reported |
|                                                                                                                                                                                  | Ezetrol                                        | S | Oral                                     | 1 Df, In Evening                               | Not Reported |
|                                                                                                                                                                                  | Ikorel                                         | C |                                          | 0.5 Tablet Morning, And<br>0.75 Tablet Evening | Not Reported |
|                                                                                                                                                                                  | Aldactone /00006201/                           | C |                                          | 1 Tablet At Noon                               | Not Reported |
|                                                                                                                                                                                  | Vitamin B                                      | C |                                          | 1 Tablet Morning                               | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Nov-2015              | 11755199      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000081012    |                      | 87 YR      | Male       | FRA            |

| <u>Preferred Term</u>                               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                             | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------|----------------|--------------|------------|-------------|------------------------------------------|--------------------|-----------------|--------------|
| Confusional State;<br>Encephalopathy;<br>Incoherent | Escitalopram   |              |            | S           | Oral                                     | 10 Mg              |                 | Forest       |
|                                                     | Cefepime Mylan |              |            | S           | Intravenous (not<br>otherwise specified) | 4 G                |                 | Not Reported |
|                                                     | Bromazepam     |              |            | S           | Oral                                     | 0.25 Mg            |                 | Not Reported |
|                                                     | Zolpidem       |              |            | S           | Oral                                     | 10 Mg              |                 | Not Reported |
|                                                     | Lasilix        |              |            | S           | Oral                                     | 20 Mg              |                 | Not Reported |
|                                                     | Ferograd       |              |            | S           | Oral                                     | 1000 Mg            |                 | Not Reported |
|                                                     |                |              |            |             |                                          |                    |                 |              |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                   |   |              |        |              |
|-------------------|---|--------------|--------|--------------|
| Calciparine       | S | Subcutaneous | 0.4 MI | Not Reported |
| Kardegic          | S | Oral         | 75 Mg  | Not Reported |
| Pantoprazole      | S | Oral         | 20 Mg  | Not Reported |
| Ezetrol           | S | Oral         | 10 Mg  | Not Reported |
| Pravastatin Arrow | S | Oral         | 40 Mg  | Not Reported |
| Ikorel            | C | Oral         | 20 Mg  | Not Reported |
| Aldactone         | C | Oral         | 25 Mg  | Not Reported |
| Vitamin B1 And B6 | C | Oral         | 1 Df   | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Nov-2015              | 11756837      | EXPEDITED (15-DAY) |                    | OT              | US-ACCORD-035293     |                      | 65 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u> |
|----------------------------------------------------------------------|---------------------|--------------|------------|-------------|--------------|-----------------------------------|-----------------|------------|
| Cerebral Disorder;<br>Diarrhoea; Hypoaesthesia;<br>Malaise; Vomiting | Escitalopram Accord |              |            | S           | Oral         | Strength: 5 Mg 2 Tablets<br>Daily |                 | Accord     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Nov-2015              | 11757002      | EXPEDITED (15-DAY) |                    | OT              | US-ZYDUS-009521      |                      | 10 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                              | <u>Product</u>                                         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                   |
|------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------------------------|
| Anxiety; Depression;<br>Neuromyopathy; Sedation;<br>Sleep Disorder; Suicidal<br>Ideation; Therapeutic<br>Product Effect Incomplete | Escitalopram<br>Fluoxetine/Fluoxetine<br>Hydrochloride |              |            | S<br>S      |              |                    |                 | Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Nov-2015              | 11757307      | EXPEDITED (15-DAY) |                    | DE, OT          | PHHY2015US151881     |                      | 48 YR      | Female     | USA            |

| <u>Preferred Term</u>          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Death; Drug Level<br>Increased | Metoprolol     |              |            | S           | Unknown      |                    |                 | Not Reported |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                         |   |         |              |
|-------------------------|---|---------|--------------|
| Diclofenac              | S | Unknown | Novartis     |
| Ibuprofeno              | S | Unknown | Not Reported |
| Oxycodone Hydrochloride | S | Unknown | Not Reported |
| Cyclobenzaprine         | S | Unknown | Not Reported |
| Nitroglycerin Sandoz    | S | Unknown | Unk          |
| Clonidine               | S | Unknown | Not Reported |
| Lisinopril              | S | Unknown | Not Reported |
| Escitalopram            | S | Unknown | Not Reported |
| Azithromycin            | S | Unknown | Not Reported |
| Methylprednisolone      | S | Unknown | Not Reported |
| Doxycycline             | S | Unknown | Not Reported |
| Cefalexin               | S | Unknown | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Nov-2015              | 11757362      | EXPEDITED (15-DAY) | DE                 |                 | PHHY2015US151883     |                      | 34 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Diclofenac                  |              |            | S           | Oral         |                    |                 | Novartis     |
|                       | Ondansetron                 |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Zolpidem                    |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Liothyronine                |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Escitalopram                |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Amitriptyline               |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Sertraline                  |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Gabapentin                  |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Tramadol                    |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Acetaminophen W/Hydrocodone |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Linaclotide                 |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Lubiprostone                |              |            | S           | Oral         |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Nov-2015              | 11760980      | EXPEDITED (15-DAY) |                    | HO              | FR-SA-2015SA180120   |                      | 87 YR      | Male       | FRA            |

| <u>Preferred Term</u>                               | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                             | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------|----------------------|--------------|------------|-------------|------------------------------------------|------------------------------------|-----------------|--------------|
| Confusional State;<br>Encephalopathy;<br>Incoherent | Bromazepam           |              |            | S           | Unknown                                  |                                    |                 | Not Reported |
|                                                     | Zolpidem             |              |            | S           | Oral                                     |                                    |                 | Not Reported |
|                                                     | Lasilix              |              |            | S           | Oral                                     |                                    |                 | Not Reported |
|                                                     | Lasilix              |              |            | S           | Oral                                     |                                    |                 | Not Reported |
|                                                     | Calciparine          |              |            | S           | Subcutaneous                             |                                    |                 | Not Reported |
|                                                     | Kardegic             |              |            | S           | Unknown                                  |                                    |                 | Not Reported |
|                                                     | Pantoprazole         |              |            | S           | Unknown                                  |                                    |                 | Not Reported |
|                                                     | Escitalopram         |              |            | S           | Unknown                                  |                                    |                 | Not Reported |
|                                                     | Cefepime             |              |            | S           | Intravenous (not<br>otherwise specified) |                                    |                 | Not Reported |
|                                                     | Fero Grad Vitamine C |              |            | S           | Unknown                                  |                                    |                 | Not Reported |
|                                                     | Ezetrol              |              |            | S           | Unknown                                  |                                    |                 | Not Reported |
|                                                     | Pravastatine         |              |            | S           | Unknown                                  |                                    |                 | Not Reported |
|                                                     | Ikorel               |              |            | C           | Unknown                                  | 0,5 Df Morning, 0,75 Df<br>Evening |                 | Not Reported |
|                                                     | Aldactone            |              |            | C           | Unknown                                  |                                    |                 | Not Reported |
|                                                     | Vitamin B1 And B6    |              |            | C           | Unknown                                  |                                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------------------|----------------------|------------|------------|----------------|
| 20-Nov-2015              | 11761478      | EXPEDITED (15-DAY) |                    | OT              | US-<br>GLAXOSMITHKLINE-<br>US2015GSK165203 |                      | 17 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                     | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|-----------------------------------------------------------------------------------------------------------|-------------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Agitation; Alanine<br>Aminotransferase<br>Increased; Aphasia;<br>Aphasia; Appetite<br>Disorder; Aspartate | Clonazepam        |              |            | S           |              |                    |                 | Glaxosmithkline |
|                                                                                                           | Lamotrigine       |              |            | S           |              |                    |                 | Glaxosmithkline |
|                                                                                                           | Lithium Carbonate |              |            | S           |              |                    |                 | Glaxosmithkline |
|                                                                                                           | Escitalopram      |              |            | S           |              |                    |                 | Glaxosmithkline |
|                                                                                                           | Bupropion         |              |            | S           |              |                    |                 | Glaxosmithkline |

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|                           |                          |   |  |             |  |                 |
|---------------------------|--------------------------|---|--|-------------|--|-----------------|
| Aminotransferase          | Diphenhydramine Hcl      | S |  |             |  | Glaxosmithkline |
| Increased; Blood Insulin  | Quetiapine               | S |  |             |  | Glaxosmithkline |
| Increased; Body Mass      | Minocycline\Minocycline  | S |  |             |  | Glaxosmithkline |
| Index Increased;          | Hydrochloride            |   |  |             |  |                 |
| Distractibility; Exercise | Metformin                | S |  |             |  | Glaxosmithkline |
| Lack Of; Fibrosis; Food   | Sertraline               | S |  | 50 Mg, Qd   |  | Not Reported    |
| Craving; Hepatic          | Cetirizine               | S |  | Unk         |  | Not Reported    |
| Steatosis; Hyperphagia;   | Naproxen                 | S |  | Unk         |  | Not Reported    |
| Liver Function Test       |                          |   |  |             |  |                 |
| Increased; Mania; Mental  | Cyclobenzaprine          | S |  |             |  | Not Reported    |
| Impairment; Non-Alcoholic | Lorazepam                | S |  | 0.5 Mg, Unk |  | Not Reported    |
| Steatohepatitis; Obesity; | Oxcarbazepine            | S |  |             |  | Not Reported    |
| Restlessness; Sleep       | Aripiprazole             | S |  |             |  | Not Reported    |
| Disorder; Splenomegaly;   | Docusate Sodium          | S |  |             |  | Not Reported    |
| Steatohepatitis; Stress;  | Acetylcysteine           | S |  |             |  | Not Reported    |
| Weight Increased          | Methylphenidate          | S |  |             |  | Not Reported    |
|                           | Clonidine                | S |  |             |  | Not Reported    |
|                           | Pregabalin               | S |  |             |  | Not Reported    |
|                           | Levothyroxine            | S |  |             |  | Not Reported    |
|                           | Vitamin B Complex        | S |  | Unk         |  | Not Reported    |
|                           | Cholecalciferol          | S |  | Unk         |  | Not Reported    |
|                           | Melatonin                | S |  |             |  | Not Reported    |
|                           | Tizanidine               | S |  | Unk         |  | Not Reported    |
|                           | Ondansetron              | S |  |             |  | Not Reported    |
|                           | Amphetamine              | S |  |             |  | Not Reported    |
|                           | Dextroamphetamine        | S |  |             |  | Not Reported    |
|                           | Norgestimate And Ethinyl | S |  |             |  | Not Reported    |
|                           | Estradiol                |   |  |             |  |                 |
|                           | Lurasidone               | S |  |             |  | Not Reported    |
|                           | Polyethylene Glycol      | S |  |             |  | Not Reported    |

| <u>FDA Received Date</u>                                                      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                  | <u>Country</u> |
|-------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|------------------------------------------------|----------------------|-----------------|-----------------------------|----------------|
| 20-Nov-2015                                                                   | 11762768       | EXPEDITED (15-DAY) |                    | OT              | FR-SYMLMED<br>PHARMACEUTICALS-<br>2014SYM00055 |                      | 80 YR           | Male                        | FRA            |
| <u>Preferred Term</u>                                                         | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                  |                |
| Bradycardia; Confusional<br>State; Incorrect Dose<br>Administered; Medication | Aceon          |                    |                    | S               | Oral                                           | 10 Mg, Qd            |                 | Symplmed<br>Pharmaceuticals |                |

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|       |               |   |      |             |                          |
|-------|---------------|---|------|-------------|--------------------------|
| Error | Aceon         | S | Oral | 10 Mg, Bid  | Symplmed Pharmaceuticals |
|       | Diamicron Nos | S | Oral | 1 Df, Qd    | Not Reported             |
|       | Diamicron Nos | S | Oral | 1 Df, Bid   | Not Reported             |
|       | Mono-Tildiem  | S | Oral | 300 Mg, Qd  | Not Reported             |
|       | Mono-Tildiem  | S | Oral | 300 Mg, Bid | Not Reported             |
|       | Seroplex      | S | Oral | 10 Mg, Qd   | Not Reported             |
|       | Seroplex      | S | Oral | 10 Mg, Bid  | Not Reported             |

| <u>FDA Received Date</u>     | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------|----------------|------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 23-Nov-2015                  | 11768075       | NON-EXPEDITED    |                    |                 | US-JNJFOC-20151019552 |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>        | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Product Administration Error | Zyrtec         |                  | Y                  | S               | Unknown               |                      |                 | Not Reported |                |
|                              | Zyrtec         |                  |                    | S               | Unknown               |                      |                 | Not Reported |                |
|                              | Zantac         |                  | Y                  | S               | Unknown               |                      |                 | Not Reported |                |
|                              | Advil          |                  |                    | S               | Unknown               |                      |                 | Not Reported |                |
|                              | Lexapro        |                  |                    | S               | Unknown               |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 23-Nov-2015              | 11768786       | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2015389789 |                      |                 | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Somnolence               | Lyrica         |                  |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                          | Lexapro        |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|------------|----------------|
| 23-Nov-2015              | 11770774       | EXPEDITED (15-DAY) |                    | DE, OT          | US-VALIDUS PHARMACEUTICALS LLC-US-2015VAL000770 |                      | 48 YR           | Female     | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

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|                             |                               |   |     |              |
|-----------------------------|-------------------------------|---|-----|--------------|
| Death; Drug Level Increased | Metoprolol Tartrate           | S | Unk | Validus      |
|                             | Diclofenac                    | S | Unk | Not Reported |
|                             | Ibuprofeno (Ngx)              | S | Unk | Not Reported |
|                             | Oxycodone Hydrochloride (Ngx) | S | Unk | Not Reported |
|                             | Cyclobenzaprine (Ngx)         | S | Unk | Not Reported |
|                             | Nitroglycerin Sandoz (Ngx)    | S | Unk | Not Reported |
|                             | Clonidine (Ngx)               | S | Unk | Not Reported |
|                             | Lisinopril (Ngx)              | S | Unk | Not Reported |
|                             | Escitalopram (Ngx)            | S | Unk | Not Reported |
|                             | Azithromycin (Ngx)            | S | Unk | Not Reported |
|                             | Methylprednisolone (Ngx)      | S | Unk | Not Reported |
|                             | Doxycycline (Ngx)             | S | Unk | Not Reported |
|                             | Cefalexin (Ngx)               | S | Unk | Not Reported |

| <u>FDA Received Date</u>                                                  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|---------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|--------------------------------------------------------|----------------------|-----------------|----------------------|----------------|
| 24-Nov-2015                                                               | 11699112             | EXPEDITED (15-DAY) |                    | HO, LT, OT      | CH-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>BMS-2015-076260 |                      | 66 YR           | Female               | CHE            |
| <u>Preferred Term</u>                                                     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Arthralgia; Bone Pain;<br>Delirium; Disorientation;<br>Psychotic Disorder | Nivolumab            |                    |                    | S               | Intravenous (not<br>otherwise specified)               | Unk Mg, Unk          |                 | Bristol Myers Squibb |                |
|                                                                           | Morphine Sulfate     |                    |                    | S               | Unknown                                                |                      |                 | Bristol Myers Squibb |                |
|                                                                           | Ciprallex /01588501/ |                    |                    | S               | Unknown                                                | 20 Mg/MI, Unk        |                 | Not Reported         |                |
|                                                                           | Palladon             |                    |                    | S               | Unknown                                                | 4 Mg, Unk            |                 | Not Reported         |                |
|                                                                           | Zyprexa              |                    |                    | S               | Unknown                                                | 5 Mg, Unk            |                 | Not Reported         |                |
|                                                                           | Novalglin /00169801/ |                    |                    | S               | Unknown                                                | 500 Mg, Unk          |                 | Not Reported         |                |
|                                                                           | Stilnox              |                    |                    | S               | Unknown                                                | 12.5 Mg, Unk         |                 | Not Reported         |                |
|                                                                           | Palexia              |                    |                    | S               | Unknown                                                | 100 Mg, Unk          |                 | Not Reported         |                |
|                                                                           | Motilium /00498201/  |                    |                    | C               | Unknown                                                | 10 Mg, Tid           |                 | Not Reported         |                |
|                                                                           | Ponstan              |                    |                    | C               | Unknown                                                | 500 Mg, Tid          |                 | Not Reported         |                |

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|                      |   |         |            |              |
|----------------------|---|---------|------------|--------------|
| Dafalgan             | C | Unknown | 1 G, Unk   | Not Reported |
| Neupogen             | C | Unknown |            | Not Reported |
| Paspertin /00041902/ | C | Unknown | 10 Mg, Unk | Not Reported |
| Folvite /00024201/   | C | Unknown | 1 Mg, Qd   | Not Reported |
| Pantozol /01263204/  | C | Unknown | 40 Mg, Unk | Not Reported |
| Emend /01627301/     | C | Unknown |            | Not Reported |
| Prednison            | C | Unknown | 20 Mg, Unk | Not Reported |
| Transipeg /00754501/ | C | Unknown |            | Not Reported |
| Imodium              | C | Unknown | 2 Mg, Unk  | Not Reported |
| Zofran /00955301/    | C | Unknown | 4 Mg, Unk  | Not Reported |
| Alopxy               | C | Unknown | 60 MI, Unk | Not Reported |
| Pantoprazol          | C | Unknown | 20 Mg, Unk | Not Reported |

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|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Nov-2015              | 11772212      | EXPEDITED (15-DAY) |                    | HO              | TR-FRI-1000081105    |                      | 68 YR      | Male       | TUR            |

| <u>Preferred Term</u>                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Depressive Symptom;<br>Drug Interaction | Escitalopram   |              |            | S           | Unknown      | 10 Mg              |                 | Forest       |
|                                         | Dabigatran     |              |            | S           | Unknown      | 110 Mg             |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 24-Nov-2015              | 11772953      | NON-EXPEDITED    |                    |                 | US-PFIZER INC-<br>2015394302 |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Hypersensitivity | Celebrex       |              |            | S           |              | Unk                |                 | Pfizer       |
|                       | Nexium         |              |            | S           |              | Unk                |                 | Unknown      |
|                       | Erythromycin   |              |            | S           |              | Unk                |                 | Pfizer       |
|                       | Escitalopram   |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Hctz           |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Toprol XL      |              |            | S           |              | Unk                |                 | Not Reported |

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|          |   |     |              |
|----------|---|-----|--------------|
| Ventolin | S | Unk | Not Reported |
| Crestor  | S | Unk | Not Reported |

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|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Nov-2015              | 11774506      | EXPEDITED (15-DAY) |                    | HO, OT          | DE-FRI-1000081180    |                      | 36 YR      | Female     | DEU            |

| <u>Preferred Term</u>                                                                                                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Circulatory Collapse;<br>Diarrhoea; Electrolyte<br>Imbalance; Fall; Muscle<br>Spasms; Product Use In<br>Unapproved Indication | Escitalopram   |              |            | S           | Unknown      | 10 Mg              |                 | Forest       |
|                                                                                                                               | Escitalopram   |              |            | S           | Unknown      | 15 Mg              |                 | Forest       |
|                                                                                                                               | Atarax         |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                                                                               | Cetirizin      |              |            | C           | Unknown      |                    |                 | Not Reported |

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|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Nov-2015              | 11777504      | EXPEDITED (15-DAY) |                    | HO              | KR-FRI-1000081118    |                      | 76 YR      | Male       | KOR            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Subdural Haemorrhage  | Escitalopram   |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                       | Xanax          |              |            | C           | Oral         | 0.25 Mg            |                 | Not Reported |
|                       | Xanax          |              |            | C           | Oral         |                    |                 | Not Reported |
|                       | Mirapex        |              |            | C           | Oral         | 0.125 Mg           |                 | Not Reported |
|                       | Harnal-D       |              |            | C           | Oral         | 0.2 Mg             |                 | Not Reported |
|                       | Motilium-M     |              |            | C           | Oral         | 30 Mg              |                 | Not Reported |
|                       | Sinemet 25/100 |              |            | C           | Oral         | 25/100 Mg          |                 | Not Reported |
|                       | Synthroid      |              |            | C           | Oral         | 0.1 Mg             |                 | Not Reported |
|                       | Solondo        |              |            | C           | Oral         | 10 Mg              |                 | Not Reported |
|                       | Minirin        |              |            | C           | Oral         | 120 Mcg            |                 | Not Reported |
|                       | Vytorin 10/10  |              |            | C           | Oral         |                    |                 | Not Reported |
|                       | Superpirin     |              |            | C           | Oral         |                    |                 | Not Reported |
|                       | Vastinan       |              |            | C           | Oral         | 35 Mg              |                 | Not Reported |
|                       | Nexium         |              |            | C           | Oral         | 20 Mg              |                 | Not Reported |

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|                                      |                |                    |                    |                 |                                                              |                      |                 |            |                |  |
|--------------------------------------|----------------|--------------------|--------------------|-----------------|--------------------------------------------------------------|----------------------|-----------------|------------|----------------|--|
| Azilect                              |                |                    | C                  |                 | Oral                                                         |                      | 1 Mg            |            | Not Reported   |  |
| <u>FDA Received Date</u>             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |  |
| 25-Nov-2015                          | 11777576       | EXPEDITED (15-DAY) |                    | OT              | US-LUPIN<br>PHARMACEUTICALS<br>INC.-2015-03800               |                      |                 | Male       | USA            |  |
| <u>Preferred Term</u>                | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |  |
| Feeling Jittery;                     | Fluoxetine     |                    |                    | S               | Unknown                                                      |                      |                 |            | Not Reported   |  |
| Neuromyopathy;                       | Escitalopram   |                    |                    | S               | Unknown                                                      |                      |                 |            | Not Reported   |  |
| Psychiatric                          | Escitalopram   |                    |                    | S               | Unknown                                                      |                      |                 |            | Not Reported   |  |
| Decompensation;                      | Olanzapine     |                    |                    | S               | Unknown                                                      |                      |                 |            | Not Reported   |  |
| Sedation; Suicidal Ideation          | Olanzapine     |                    |                    | S               | Unknown                                                      |                      |                 |            | Not Reported   |  |
|                                      | Sertraline     |                    |                    | C               | Unknown                                                      |                      |                 |            | Not Reported   |  |
|                                      | Sertraline     |                    |                    | C               | Unknown                                                      |                      |                 |            | Not Reported   |  |
|                                      | Mirtazapine    |                    |                    | C               | Unknown                                                      |                      |                 |            | Not Reported   |  |
| <u>FDA Received Date</u>             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |  |
| 25-Nov-2015                          | 11777625       | EXPEDITED (15-DAY) |                    | OT              | US-WEST-WARD<br>PHARMACEUTICALS<br>CORP.-US-H14001-15-<br>01 |                      |                 | Male       | USA            |  |
| <u>Preferred Term</u>                | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |  |
| Neuromyopathy;                       | Escitalopram   |                    |                    | S               | Unknown                                                      |                      |                 |            | Hikma          |  |
| Psychiatric                          | Escitalopram   |                    |                    | S               | Unknown                                                      |                      |                 |            | Hikma          |  |
| Decompensation; Suicidal<br>Ideation |                |                    |                    |                 |                                                              |                      |                 |            |                |  |
| <u>FDA Received Date</u>             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |  |
| 25-Nov-2015                          | 11778169       | NON-EXPEDITED      |                    |                 | US-ASTRAZENECA-<br>2015SF17951                               |                      |                 | Male       | USA            |  |
| <u>Preferred Term</u>                | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |  |
| Diabetes Mellitus                    | Lexapro        |                    |                    | S               | Unknown                                                      |                      |                 |            | Not Reported   |  |
|                                      | Seroquel       |                    |                    | S               | Oral                                                         |                      |                 |            | Zeneca         |  |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                            | Suboxone             |                  | S                  | Unknown         |                                                 |                      |                 | Not Reported         |                |
|--------------------------------------------|----------------------|------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|----------------------|----------------|
|                                            | Lunesta              |                  | S                  | Unknown         |                                                 |                      |                 | Not Reported         |                |
| <u>FDA Received Date</u>                   | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 25-Nov-2015                                | 11779395             | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2015399794                        |                      |                 | Female               | USA            |
| <u>Preferred Term</u>                      | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Drug Ineffective For Unapproved Indication | Pristiq              |                  |                    | S               |                                                 | Unk                  |                 | Pfizer               |                |
|                                            | Lexapro              |                  |                    | S               |                                                 | Unk                  |                 | Not Reported         |                |
| <u>FDA Received Date</u>                   | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 25-Nov-2015                                | 11784968             | DIRECT           |                    | DS, HO          |                                                 |                      | 70 YR           | Female               | USA            |
| <u>Preferred Term</u>                      | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Nightmare; Paranoia; Psychotic Disorder    | Lexapro 20 Mg Camber |                  |                    | S               | Oral                                            | 1 Pill               |                 | Not Reported         |                |
|                                            | Acarbose             |                  |                    | C               |                                                 |                      |                 | Not Reported         |                |
|                                            | Norvasc              |                  |                    | C               |                                                 |                      |                 | Not Reported         |                |
|                                            | Calcium 600mg + D3   |                  |                    | C               |                                                 |                      |                 | Not Reported         |                |
|                                            | Vitamin D3           |                  |                    | C               |                                                 |                      |                 | Not Reported         |                |
|                                            | Lexapro              |                  |                    | C               |                                                 |                      |                 | Not Reported         |                |
|                                            | Vagifem              |                  |                    | C               |                                                 |                      |                 | Not Reported         |                |
|                                            | Prenatal Vitamins    |                  |                    | C               |                                                 |                      |                 | Not Reported         |                |
|                                            | Ambien               |                  |                    | C               |                                                 |                      |                 | Not Reported         |                |
|                                            | Systane              |                  |                    | C               |                                                 |                      |                 | Not Reported         |                |
| Vitamin E                                  |                      |                  | C                  |                 |                                                 |                      | Not Reported    |                      |                |
| <u>FDA Received Date</u>                   | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 26-Nov-2015                                | 11780540             | NON-EXPEDITED    |                    |                 | US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-082450 |                      |                 | Unknown              | USA            |
| <u>Preferred Term</u>                      | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Weight Increased                           | Abilify              |                  |                    | S               | Unknown                                         | Unk                  |                 | Bristol Myers Squibb |                |
|                                            | Lexapro              |                  |                    | S               | Unknown                                         |                      |                 | Not Reported         |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 26-Nov-2015              | 11780979      | NON-EXPEDITED    |                    |                 | US-JNJFOC-20151113302 |                      | 14 YR      | Male       | USA            |

| <u>Preferred Term</u>                          | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------|-----------------------|--------------|------------|-------------|--------------|--------------------------------------|-----------------|--------------|
| Drug Interaction;<br>Psychomotor Hyperactivity | Zyrtec 10mg Ir Tablet |              | Y          | S           | Oral         |                                      |                 | Not Reported |
|                                                | Zyrtec 10mg Ir Tablet |              |            | S           | Oral         | 1 Tablet, 1x Per Day                 |                 | Not Reported |
|                                                | Focalin               |              |            | S           | Unknown      | 1 Tab Once Every Morning For 2+Years |                 | Not Reported |
|                                                | Lexapro               |              |            | S           | Unknown      | 1 Tab Once Qd Am For 2 Years         |                 | Not Reported |
|                                                | Singulair             |              |            | S           | Unknown      | 1 Tab/1x Qd Hs 3-4 Years             |                 | Not Reported |
|                                                | Ritalin               |              |            | S           | Unknown      | 1 Tab/1x Qd Afternoon (1 Years)      |                 | Not Reported |
|                                                | Melatonin             |              |            | S           | Unknown      | 2 Tabs/1x Qd Hs 1 Year               |                 | Not Reported |
|                                                | Nasonex               |              |            | S           | Unknown      | 1 Sq/1x Qd Bilat As Needed           |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 26-Nov-2015              | 11780981      | EXPEDITED (15-DAY) |                    | OT              | US-HETERO LABS LTD-1044689 |                      | 15 YR      | Male       | USA            |

| <u>Preferred Term</u>            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|----------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Neuromyopathy; Suicidal Ideation | Escitalopram   |              |            | S           | Unknown      |                    |                 | Hetero     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Nov-2015              | 11762447      | NON-EXPEDITED    |                    | OT              | PHEH2015US024125     |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                                   | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Apnoea; Asthenopia; Cd4 Lymphocytes Decreased; Cd8 Lymphocytes | Gilenya             |              |            | S           | Oral         | 0.5 Mg, Qod        |                 | Novartis     |
|                                                                         | Nuedexta /07198301/ |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                         | Nuedexta /07198301/ |              |            | S           |              |                    |                 | Not Reported |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                      |   |         |                                    |              |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|---|---------|------------------------------------|--------------|
| Decreased; Cervical Radiculopathy; Cognitive Disorder; Constipation; Contusion; Coordination Abnormal; Depression; Disturbance In Attention; Dizziness; Dry Eye; Fatigue; Headache; Herpes Zoster; Macular Oedema; Malaise; Middle Insomnia; Migraine; Multiple Sclerosis; Relapse; Muscle Spasms; Neck Pain; Neuralgia; Pain; Prescribed Underdose; Restlessness; Snoring; Stress; Vision Blurred; Vitamin B12 Deficiency; Vitamin D Deficiency; White Blood Cell Count Decreased | Lexapro              | S | Oral    | 20 Mg, (0.5 Tablet) For 7 Days     | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Lexapro              | S | Oral    | 20 Mg, Qd                          | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Alprazolam           | C | Oral    | 0.5 Mg, Tid                        | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Calcium + Vit D      | C | Unknown | 500 Mg, Unk                        | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Crestor              | C | Oral    | 10 Mg, (At Bed Time)               | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Escitalopram Oxalate | C | Unknown | 20 Mg, Unk                         | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Bupropion Hcl        | C | Oral    | 100 Mg, (In Morning)               | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Levetiracetam        | C | Oral    | 500 Mg, (1 In The Am And 2 In Qhs) | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Nexum                | C | Oral    | 40 Mg, Qd                          | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Tizanidine Hcl       | C | Oral    | 4 Mg, Qd (At Bed)                  | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Tysabri              | C | Unknown |                                    | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Copaxone             | C | Unknown |                                    | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Tamsulosin Hcl       | C | Unknown | 0.4 Mg, (1 Daily As Needed)        | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Carbamazepine        | C | Unknown | 200 Mg, (1 Tablet At Bed Time)     | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 30-Nov-2015              | 11787247      | EXPEDITED (15-DAY) |                    | HO, OT          | TW-ACTAVIS-2015-16624 |                      | 38 YR      | Male       | TWN            |

| <u>Preferred Term</u>                                                   | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>           |
|-------------------------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------|
| Alcoholism; Delirium; Drug Interaction; Refusal Of Treatment By Patient | Disulfiram (Unknown)   |              |            | S           | Unknown      | 200 Mg, Daily      |                 | Watson               |
|                                                                         | Griseofulvin (Unknown) |              |            | S           | Unknown      | 500 Mg, Daily      |                 | Actavis Mid Atlantic |
|                                                                         | Escitalopram (Unknown) |              |            | S           | Unknown      | 10 Mg/D            |                 | Not Reported         |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Nov-2015              | 11787849      | NON-EXPEDITED    |                    |                 | GXBR2015US000936     |                      | 26 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                               |              |   |         |                     |              |
|-------------------------------|--------------|---|---------|---------------------|--------------|
| Abdominal Distension;<br>Rash | Nadolol      | S | Oral    | 10 Mg Am / 30 Mg Hs | Novartis     |
|                               | Escitalopram | S | Unknown | 5 Mg, Unk           | Not Reported |
|                               | Mirtazapine  | C | Oral    | 15 Mg, Unk          | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Dec-2015              | 11519211      | EXPEDITED (15-DAY) |                    | HO              | IT-FRI-1000079608    |                      | 66 YR      | Male       | ITA            |

  

| <u>Preferred Term</u>                  | <u>Product</u>                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------|--------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Amylase Increased;<br>Lipase Increased | Escitalopram                   |              |            | S           | Oral         |                    |                 | Forest       |
|                                        | Metfonorm 1000mg Compresse     |              |            | S           | Oral         | 3 Gram             |                 | Not Reported |
|                                        | Rivestite Con Film/Metformin   |              |            |             |              |                    |                 |              |
|                                        | Cardio Aspirin                 |              |            | S           | Oral         |                    |                 | Not Reported |
|                                        | Pramipexolo Eg 0,18mg          |              |            | C           | Oral         |                    |                 | Not Reported |
|                                        | Compresse/Pramipexole          |              |            |             |              |                    |                 |              |
|                                        | Deursil 450mg Capsule Rigide A |              |            | C           | Oral         |                    |                 | Not Reported |
|                                        | Rilascio                       |              |            |             |              |                    |                 |              |
|                                        | Prolungato/Ursodeoxycholic Aci |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Dec-2015              | 11784017      | EXPEDITED (15-DAY) |                    | OT              | PHHY2015SI152993     |                      | 87 YR      | Female     | SVN            |

  

| <u>Preferred Term</u>                                                                                                                                                         | <u>Product</u>                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|--------------|------------|-------------|--------------|--------------------------|-----------------|--------------|
| Constipation; Dizziness;<br>Fall; Hypotonia; Insomnia;<br>Musculoskeletal Pain;<br>Pain In Extremity; Spinal<br>Pain; Tachycardia; Urinary<br>Incontinence; Vision<br>Blurred | Quetiapine                     |              |            | S           | Unknown      | 100 Mg, Qd (In Evening)  |                 | Not Reported |
|                                                                                                                                                                               | Escitalopram                   |              |            | S           | Unknown      | 10 Mg, Qd (In Morning)   |                 | Not Reported |
|                                                                                                                                                                               | Acetylsalicylic Acid           |              |            | S           | Unknown      | 100 Mg, Qd (At Noon)     |                 | Not Reported |
|                                                                                                                                                                               | Furosemide                     |              |            | S           | Unknown      | 40 Mg, Qd (3 Days)       |                 | Not Reported |
|                                                                                                                                                                               | Bisoprolol                     |              |            | S           | Unknown      | 1.25 Mg, Qd (In Morning) |                 | Not Reported |
|                                                                                                                                                                               | Omeprazole                     |              |            | S           | Unknown      | 20 Mg, Qd (In Morning)   |                 | Not Reported |
|                                                                                                                                                                               | Rivastigmine Sandoz            |              |            | S           | Unknown      | 13.3 Mg, Qd (24 Hour)    |                 | Not Reported |
|                                                                                                                                                                               | Metformin Hydrochloride Sandoz |              |            | S           | Unknown      | 1000 Mg, Bid             |                 | Not Reported |
|                                                                                                                                                                               | Gliclazide                     |              |            | S           | Unknown      | 60 Mg, Qd                |                 | Not Reported |
|                                                                                                                                                                               | Atorvastatin                   |              |            | S           | Unknown      | 40 Mg, Qd                |                 | Not Reported |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                      |   |         |                       |              |
|----------------------|---|---------|-----------------------|--------------|
| Atorvastatin         | S | Unknown | 20 Mg, Unk            | Not Reported |
| Tramadol+Paracetamol | S | Unknown | Unk                   | Not Reported |
| Butylscopolamine     | S | Unknown | 10 Mg, Tid            | Not Reported |
| Nitrazepam           | S | Unknown | 5 Mg, Qd (In Evening) | Not Reported |
| Bisacodyl            | S | Unknown | When Needed           | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|--------------------------------------------------------|----------------------|-----------------|----------------------|----------------|
| 01-Dec-2015              | 11788440       | NON-EXPEDITED    |                    |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>BMS-2015-082369 |                      |                 | Unknown              | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Adverse Event            | Abilify        |                  |                    | S               | Unknown                                                |                      |                 | Bristol Myers Squibb |                |
|                          | Clonopin       |                  |                    | S               | Unknown                                                |                      |                 | Not Reported         |                |
|                          | Lexapro        |                  |                    | S               | Unknown                                                |                      |                 | Not Reported         |                |

| <u>FDA Received Date</u> | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 01-Dec-2015              | 11788863               | EXPEDITED (15-DAY) |                    | OT              | FR-WATSON-2015-<br>17253 |                      |                 | Unknown      | FRA            |
| <u>Preferred Term</u>    | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Treatment Failure        | Escitalopram (Unknown) |                    |                    | S               | Unknown                  | Unk                  |                 | Not Reported |                |
|                          | Escitalopram (Unknown) |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                          | Sertraline (Unknown)   |                    |                    | S               | Unknown                  | Unk                  |                 | Watson       |                |
|                          | Sertraline (Unknown)   |                    |                    | S               |                          |                      |                 | Watson       |                |
|                          | Venlafaxine (Unknown)  |                    |                    | S               | Unknown                  | 225 Mg, Daily        |                 | Not Reported |                |
|                          | Risperidone (Unknown)  |                    |                    | S               | Unknown                  | 2 Mg/Day             |                 | Watson       |                |
|                          | Risperidone (Unknown)  |                    |                    | S               |                          | 2 Mg/Day             |                 | Watson       |                |
|                          | Paroxetine (Unknown)   |                    |                    | S               | Unknown                  | 40 Mg, Daily         |                 | Not Reported |                |
|                          | Paroxetine (Unknown)   |                    |                    | S               |                          |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 01-Dec-2015              | 11789353      | EXPEDITED (15-DAY) |                    | HO, LT, OT      | FR-<br>ELI_LILLY_AND_COMP<br>ANY-FR201511008927 |                      | < 1 DAY    | Unknown    | FRA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                                                                                                               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>       |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|------------------|
| Agitation; Foetal Distress Syndrome; Foetal Heart Rate Decreased; Hypotonia Neonatal; Infantile Apnoea; Large For Dates Baby; Meconium In Amniotic Fluid; Neonatal Respiratory Distress Syndrome; Neurological Symptom; Tremor; Withdrawal Syndrome | Prozac         |              |            | S           | Transplacental | Unk, Unknown       |                 | Eli Lilly And Co |
|                                                                                                                                                                                                                                                     | Anafranil      |              |            | S           | Transplacental | 75 Mg, Bid         |                 | Not Reported     |
|                                                                                                                                                                                                                                                     | Seroplex       |              |            | S           | Transplacental | 10 Mg, Qd          |                 | Not Reported     |
|                                                                                                                                                                                                                                                     | Seresta        |              |            | S           | Transplacental | 10 Mg, Qid         |                 | Not Reported     |
|                                                                                                                                                                                                                                                     | Seresta        |              |            | S           | Transplacental | 10 Mg, Qid         |                 | Not Reported     |
|                                                                                                                                                                                                                                                     | Valium         |              |            | S           | Transplacental | Unk, Unknown       |                 | Not Reported     |
|                                                                                                                                                                                                                                                     | Tegeline       |              |            | C           | Transplacental | 2 Courses, Unknown |                 | Not Reported     |
|                                                                                                                                                                                                                                                     | Prednisolone   |              |            | C           | Transplacental | 1mg/Kg/24hour      |                 | Not Reported     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 01-Dec-2015              | 11789725      | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2015M1041487 |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>                                        | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Coeliac Disease; Condition Aggravated; Reaction To Excipient | Clonazepam Tablets, Usp |              |            | S           |              | Unk                |                 | Mylan        |
|                                                              | Escitalopram            |              |            | S           |              | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 01-Dec-2015              | 11792232      | NON-EXPEDITED    |                    |                 | US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-081236 |                      |            | Male       | USA            |

| <u>Preferred Term</u>                                                                                                     | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>           |
|---------------------------------------------------------------------------------------------------------------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------|
| Amnesia; Disturbance In Attention; Dizziness; Fatigue; Gait Disturbance; Hyperhidrosis; Hypotension; Pruritus Generalised | Abilify             |              |            | S           | Oral         | 10 Mg, Qd          |                 | Bristol Myers Squibb |
|                                                                                                                           | Escitalopram        |              |            | S           | Oral         | 10 Mg, Qd          |                 | Not Reported         |
|                                                                                                                           | Trihexyphenidyl     |              |            | S           | Oral         | 2 Mg, Qd           |                 | Not Reported         |
|                                                                                                                           | Risperidone         |              |            | S           | Unknown      | Unk                |                 | Not Reported         |
|                                                                                                                           | Quetiapine Fumarate |              |            | S           | Unknown      | Unk                |                 | Not Reported         |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 01-Dec-2015              | 11792254      | EXPEDITED (15-DAY) |                    | OT              | IL-MUNDIPHARMA DS AND |                      | 83 YR      | Male       | ISR            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

PHARMACOVIGILANCE  
-GBR-2015-0

| <u>Preferred Term</u>                                                                     | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Ineffective; Drug Interaction; Euphoric Mood; Hypervigilance; Insomnia; Restlessness | Targin 10/5 Mg Cr Tablet |              |            | S           | Unknown      | 10 Mg, Bid         |                 | Purdue       |
|                                                                                           | Targin 10/5 Mg Cr Tablet |              |            | S           | Unknown      | 10 Mg, Bid         |                 | Purdue       |
|                                                                                           | Ciprallex                |              |            | S           | Unknown      | 15 Mg, Unk         |                 | Not Reported |
|                                                                                           | Ciprallex                |              |            | S           | Unknown      | 10 Mg, Unk         |                 | Not Reported |
|                                                                                           | Lyrica                   |              |            | C           |              | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Dec-2015              | 11793195      | DIRECT           | Y                  |                 |                      |                      | 67 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                  | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|------------------------------------------------------------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Anxiety; Depression; Product Quality Issue; Product Substitution Issue | Escitalopram 20mg Accord |              |            | S           | Oral         | 1 Tab Qd Oral      |                 | Accord     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Dec-2015              | 11793744      | DIRECT           |                    | OT              |                      |                      | 83 YR      | Female     | USA            |

| <u>Preferred Term</u>                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Exposure During Pregnancy; Pregnancy | Lexapro        |              |            | S           | Oral         | Po Qam             |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------------|----------------------|------------|------------|----------------|
| 02-Dec-2015              | 11553113      | EXPEDITED (15-DAY) |                    |                 | US-GLAXOSMITHKLINE-US2015GSK136512 |                      |            | Male       | USA            |

| <u>Preferred Term</u>                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|-----------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Adverse Drug Reaction; Drug Hypersensitivity; | Paxil          |              |            | S           |              | Unk, U             |                 | Glaxosmithkline |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                     |          |   |            |                 |
|-------------------------------------|----------|---|------------|-----------------|
| Drug Ineffective; Product Complaint | Seroquel | S | Unk Unk, U | Glaxosmithkline |
|                                     | Effexor  | S | Unk, U     | Glaxosmithkline |
|                                     | Cymbalta | S | Unk, U     | Glaxosmithkline |
|                                     | Lexapro  | S | Unk, U     | Not Reported    |
|                                     | Prozac   | S | Unk, U     | Not Reported    |
|                                     | Zoloft   | S | Unk, U     | Not Reported    |
|                                     | Remeron  | C |            | Not Reported    |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|----------------------------------------|----------------------|-----------------|-----------------|----------------|
| 02-Dec-2015              | 11794534       | NON-EXPEDITED    |                    |                 | US-WARNER<br>CHILCOTT, LLC-<br>1044942 |                      | 16 YR           | Female          | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Paraesthesia             | Lo Loestrin Fe |                  |                    | S               | Oral                                   |                      |                 | Warner Chilcott |                |
|                          | Lexapro        |                  |                    | S               |                                        |                      |                 | Not Reported    |                |

| <u>FDA Received Date</u>                                                             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 02-Dec-2015                                                                          | 11795133       | EXPEDITED (15-DAY) |                    | OT              | DE-FRI-1000081344    |                      | 1 DAY           | Male         | DEU            |
| <u>Preferred Term</u>                                                                | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Withdrawal Syndrome Neonatal; Exposure During Pregnancy; Hypoglycaemia Neonatal | Escitalopram   |                    |                    | S               | Transplacental       | 20 Mg                |                 | Forest       |                |
|                                                                                      | Euthyrox       |                    |                    | C               | Unknown              | 100 Microgram        |                 | Not Reported |                |
|                                                                                      | Folic Acid     |                    |                    | C               | Unknown              |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                 | <u>Case #</u>    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------|------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| 02-Dec-2015                                                                              | 11795299         | EXPEDITED (15-DAY) |                    | CA, DS          | FR-PFIZER INC-<br>2015413184 |                      |                 | Female       | FRA            |
| <u>Preferred Term</u>                                                                    | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Congenital Anomaly; Foetal Malnutrition; Low Birth Weight Baby; Maternal Drugs Affecting | Xanax            |                    |                    | S               | Transplacental               | Unk                  |                 | Pfizer       |                |
|                                                                                          | Baclofen Zentiva |                    |                    | S               | Transplacental               | 21 Df, Daily         |                 | Not Reported |                |
|                                                                                          | Baclofen Zentiva |                    |                    | S               |                              | 12 Df, Daily         |                 | Not Reported |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                             |                            |                  |                    |                 |                                               |                      |                 |              |                |
|-----------------------------------------------------------------------------------------------------------------------------|----------------------------|------------------|--------------------|-----------------|-----------------------------------------------|----------------------|-----------------|--------------|----------------|
| Foetus; Maternal Exposure During Pregnancy                                                                                  |                            | Seresta          | S                  | Transplacental  | Unk                                           | Not Reported         |                 |              |                |
|                                                                                                                             |                            | Seroplex         | S                  | Transplacental  | 1 Df, 1x/Day                                  | Not Reported         |                 |              |                |
| <u>FDA Received Date</u>                                                                                                    | <u>Case #</u>              | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Dec-2015                                                                                                                 | 11796973                   | DIRECT           |                    | DS, OT          |                                               |                      | 33 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                       | <u>Product</u>             | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Paraesthesia; Paraesthesia                                                                                                  | Lexapro                    |                  |                    | S               | Oral                                          | 1 Pill               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                    | <u>Case #</u>              | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Dec-2015                                                                                                                 | 11796384                   | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2015407924                      |                      | 60 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                       | <u>Product</u>             | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity                                                                                                       | Benzylpenicillin Potassium |                  |                    | S               |                                               | Unk                  |                 | Pfizer       |                |
|                                                                                                                             | Sulfa /00076401/           |                  |                    | S               |                                               | Unk                  |                 | Not Reported |                |
|                                                                                                                             | Methotrexate               |                  |                    | S               |                                               | Unk                  |                 | Not Reported |                |
|                                                                                                                             | Cymbalta                   |                  |                    | S               |                                               | Unk                  |                 | Not Reported |                |
|                                                                                                                             | Lexapro                    |                  |                    | S               |                                               | Unk                  |                 | Not Reported |                |
|                                                                                                                             | Plaquenil /00072602/       |                  |                    | S               |                                               | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                    | <u>Case #</u>              | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Dec-2015                                                                                                                 | 11798517                   | NON-EXPEDITED    |                    |                 | US-REGENERON PHARMACEUTICALS, INC.-2015-11719 |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                                                                       | <u>Product</u>             | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Diplopia; Erythema Of Eyelid; Foreign Body Sensation In Eyes; Hordeolum; Metamorphopsia; Swelling Of Eyelid; Vision Blurred | Eylea                      |                  |                    | S               | Intraocular                                   | Every 4 Weeks, Od    |                 | Regeneron    |                |
|                                                                                                                             | Eylea                      |                  |                    | S               | Intraocular                                   | Every 4 Weeks, Od    |                 | Regeneron    |                |
|                                                                                                                             | Eylea                      |                  |                    | S               | Intraocular                                   | Every 4-5 Weeks, Od  |                 | Regeneron    |                |
|                                                                                                                             | Eylea                      |                  |                    | S               |                                               | Every 4-5 Weeks, Od  |                 | Regeneron    |                |
|                                                                                                                             | Lexapro                    |                  |                    | S               |                                               | Unk                  |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                     |   |                  |              |
|---------------------|---|------------------|--------------|
| Synthroid           | C | Unk              | Not Reported |
| Potassium           | C | Unk              | Not Reported |
| Furosemide          | C | Unk              | Not Reported |
| Metoprolol          | C | Unk              | Not Reported |
| Lisinopril          | C | Unk              | Not Reported |
| Aspirin /00002701/  | C | Unk              | Not Reported |
| Vitamins /00067501/ | C | Unk              | Not Reported |
| Reclast             | C | Unk, Once A Year | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Dec-2015              | 11801593      | DIRECT           |                    | OT              |                      |                      | 64 YR      | Female     |                |

| <u>Preferred Term</u>                                                     | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---------------------------------------------------------------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Headache; Nausea;<br>Product Quality Issue;<br>Product Substitution Issue | Escitalopram 20mg Camber |              |            | S           | Oral         |                    | 1 WEEK          | Camber     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Dec-2015              | 11771941      | EXPEDITED (15-DAY) |                    | HO              | FR-WATSON-2015-25450 |                      |            | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|--------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drop Attacks          | Zolpidem (Unknown) |              |            | S           | Oral         | 1 Df, Daily        |                 | Watson       |
|                       | Gabapentine        |              |            | S           | Oral         | 100 Mg, Tid        |                 | Not Reported |
|                       | Esidrex            |              |            | S           | Oral         | 12.5 Mg, Daily     |                 | Not Reported |
|                       | Irbesartan Arrow   |              |            | S           | Oral         | 300 Mg, Daily      |                 | Not Reported |
|                       | Plavix             |              |            | S           | Oral         | 75 Mg, Daily       |                 | Not Reported |
|                       | Valium             |              |            | S           | Oral         | 5 Mg, Bid          |                 | Not Reported |
|                       | Seroplex           |              |            | S           | Oral         | 15 Mg, Daily       |                 | Not Reported |
|                       | Seroplex           |              |            | S           | Oral         | 10 Mg, Daily       |                 | Not Reported |
|                       | Levothyrox         |              |            | S           | Oral         | 150 Mg, Daily      |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|-------------------------|----------------------|-----------------|--------------|----------------|
| 04-Dec-2015                                                          | 11802687       | EXPEDITED (15-DAY) |                    | OT              | DE-FRI-1000081349       |                      | 1 DAY           | Male         | DEU            |
| <u>Preferred Term</u>                                                | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Foetal Exposure During Pregnancy; Microcephaly; Small For Dates Baby | Escitalopram   |                    |                    | S               | Transplacental          | 10 Mg                |                 | Forest       |                |
|                                                                      | Haes-Steril    |                    |                    | C               | Transplacental          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Dec-2015                                                          | 11803440       | EXPEDITED (15-DAY) |                    | OT              | DE-FRI-1000081347       |                      | < 1 DAY         | Female       | DEU            |
| <u>Preferred Term</u>                                                | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Foetal Exposure During Pregnancy; Small For Dates Baby               | Escitalopram   |                    |                    | S               | Transplacental          | 20 Mg                |                 | Forest       |                |
|                                                                      | Escitalopram   |                    |                    | S               | Transplacental          | 15 Mg                |                 | Forest       |                |
|                                                                      | Escitalopram   |                    |                    | S               | Transplacental          | 10 Mg                |                 | Not Reported |                |
|                                                                      | Thyronajod     |                    |                    | C               | Transplacental          | 100 Mcg/150 Mcg      |                 | Not Reported |                |
|                                                                      | Utrogest       |                    |                    | C               | Transplacental          | 600 Mg               |                 | Not Reported |                |
|                                                                      | Vitaverlan     |                    |                    | C               | Transplacental          | .4 Mg                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Dec-2015                                                          | 11786567       | EXPEDITED (15-DAY) |                    | OT              | DE-TAKEDA-2015TUS017087 |                      | 23 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                                | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hepatic Enzyme Increased; Liver Injury                               | Brintellix     |                    |                    | S               | Oral                    | 10 Mg, Qd            |                 | Takeda       |                |
|                                                                      | Escitalopram   |                    |                    | S               | Unknown                 | 20 Mg, Qd            |                 | Not Reported |                |
|                                                                      | Seroquel       |                    |                    | S               | Unknown                 | 75 Mg, Qd            |                 | Not Reported |                |
|                                                                      | Quilonum       |                    |                    | C               | Oral                    | 62.5 Mg, Qd          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Dec-2015                                                          | 11795100       | EXPEDITED (15-DAY) |                    | OT              | KR-JNJFOC-20151122831   |                      | 66 YR           | Male         | KOR            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------|----------------|--------------|------------|-------------|--------------|-------------------------|-----------------|--------------|
| Asthenia; Delirium;<br>Pneumonia; Tremor | Velcade        |              |            | S           | Subcutaneous | Cycle 6                 |                 | Not Reported |
|                                          | Velcade        |              |            | S           | Subcutaneous | Cycle 7                 |                 | Not Reported |
|                                          | Velcade        |              |            | S           | Subcutaneous | Cycle 5                 |                 | Not Reported |
|                                          | Velcade        |              |            | S           | Subcutaneous | Cycle 4                 |                 | Not Reported |
|                                          | Velcade        |              |            | S           | Subcutaneous | Cycle 3 Day 1 To Day 50 |                 | Not Reported |
|                                          | Velcade        |              |            | S           | Subcutaneous | Cycle 2 Day 1 To Day 50 |                 | Not Reported |
|                                          | Velcade        |              |            | S           | Subcutaneous | Cycle 1 Day 1 To Day 43 |                 | Not Reported |
|                                          | Risperidone    |              |            | S           | Unknown      |                         |                 | Not Reported |
|                                          | Risperidone    |              |            | S           | Unknown      |                         |                 | Not Reported |
|                                          | Melphalan      |              |            | S           | Unknown      |                         |                 | Not Reported |
|                                          | Pregabalin     |              |            | S           | Unknown      |                         |                 | Not Reported |
|                                          | Pregabalin     |              |            | S           | Unknown      |                         |                 | Not Reported |
|                                          | Tramadol       |              |            | S           | Unknown      |                         |                 | Not Reported |
|                                          | Prednisone     |              |            | S           | Unknown      |                         |                 | Not Reported |
|                                          | Etravil        |              |            | S           | Unknown      |                         |                 | Not Reported |
|                                          | Lamotrigine    |              |            | S           | Unknown      |                         |                 | Not Reported |
|                                          | Gabapentin     |              |            | S           | Unknown      |                         |                 | Not Reported |
|                                          | Gabapentin     |              |            | S           | Unknown      |                         |                 | Not Reported |
|                                          | Aripiprazole   |              |            | S           | Unknown      |                         |                 | Not Reported |
|                                          | Escitalopram   |              |            | S           | Unknown      |                         |                 | Not Reported |
|                                          | Escitalopram   |              |            | S           | Unknown      |                         |                 | Not Reported |
|                                          | Morphine       |              |            | S           | Unknown      |                         |                 | Not Reported |
|                                          | Loperamide     |              |            | C           | Unknown      |                         |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 07-Dec-2015              | 11806205      | NON-EXPEDITED    |                    |                 | US-ASTRAZENECA-2015SF18971 |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                       |              |   |         |     |              |
|-----------------------|--------------|---|---------|-----|--------------|
| Drug Hypersensitivity | Nexium       | S | Oral    | Unk | Not Reported |
|                       | Toprol XL    | S | Oral    | Unk | Not Reported |
|                       | Crestor      | S | Oral    | Unk | Not Reported |
|                       | Hctz         | S | Unknown | Unk | Not Reported |
|                       | Celebrex     | S | Unknown | Unk | Not Reported |
|                       | Escitalopram | S | Unknown | Unk | Not Reported |
|                       | Ventolin     | S | Unknown | Unk | Not Reported |
|                       | Erythromycin | S | Unknown | Unk | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Dec-2015              | 11808339      | NON-EXPEDITED    |                    |                 | US-ROCHE-1494235     |                      | 49 YR      | Female     | USA            |

| <u>Preferred Term</u>                        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                           | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------|----------------|--------------|------------|-------------|--------------|----------------------------------------------|-----------------|--------------|
| Oropharyngeal Pain;<br>Visual Acuity Reduced | Valium         |              |            | S           | Unknown      |                                              |                 | Not Reported |
|                                              | Metformin      |              |            | S           | Unknown      |                                              |                 | Not Reported |
|                                              | Lyrica         |              |            | S           | Unknown      |                                              |                 | Not Reported |
|                                              | Tizanidine     |              |            | S           | Nasal        |                                              |                 | Not Reported |
|                                              | Oxycodone      |              |            | S           | Unknown      | 10/325 Mg One Of Them                        |                 | Not Reported |
|                                              | Seroquel       |              |            | S           | Unknown      |                                              |                 | Not Reported |
|                                              | Seroquel       |              |            | S           | Unknown      | Night                                        |                 | Not Reported |
|                                              | Effexor        |              |            | S           | Unknown      | 75mg Capsule And A<br>150mg Capsule Together |                 | Not Reported |
|                                              | Lexapro        |              |            | S           | Unknown      |                                              |                 | Not Reported |
|                                              | Aspirin        |              |            | S           | Unknown      | 2 Tablet At Night                            |                 | Not Reported |
|                                              | Simvastatin    |              |            | S           | Unknown      |                                              |                 | Not Reported |
|                                              | Topamax        |              |            | S           | Unknown      |                                              |                 | Not Reported |
|                                              | Ibuprofen      |              |            | S           | Unknown      |                                              |                 | Not Reported |
|                                              | Fentanyl Patch |              |            | S           | Unknown      |                                              |                 | Not Reported |
|                                              | Demadex        |              |            | S           | Unknown      |                                              |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Dec-2015              | 11808405      | NON-EXPEDITED    |                    |                 | US-ROCHE-1645581     |                      |            | Female     | USA            |

| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|----------------|--------------|------------|-------------|--------------|------------------------------|-----------------|--------------|
| Cough; Fatigue; Insomnia | Valium         |              |            | S           | Unknown      | 2 MI At Night                |                 | Not Reported |
|                          | Valium         |              |            | S           | Unknown      | 2 And Half MI In The Morning |                 | Not Reported |
|                          | Lexapro        |              |            | S           | Unknown      | 2 MI At Night                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Dec-2015              | 11810143      | DIRECT           | Y                  | HO              |                      |                      | 83 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                     | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Atrial Fibrillation; Bipolar Disorder; Dementia; Mania; Suicidal Ideation | Escitalopram 20 Mg  |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                           | Metformin           |              |            | C           |              |                    |                 | Not Reported |
|                                                                           | Januvia             |              |            | C           |              |                    |                 | Not Reported |
|                                                                           | Metoprolol Tartrate |              |            | C           |              |                    |                 | Not Reported |
|                                                                           | Glimepiride         |              |            | C           |              |                    |                 | Not Reported |
|                                                                           | Lexapro             |              |            | C           |              |                    |                 | Not Reported |
|                                                                           | Xarelto             |              |            | C           |              |                    |                 | Not Reported |
|                                                                           | Diltiazem           |              |            | C           |              |                    |                 | Not Reported |
|                                                                           | Tamsulosin          |              |            | C           |              |                    |                 | Not Reported |
|                                                                           | Simvastatin         |              |            | C           |              |                    |                 | Not Reported |
|                                                                           | Oxybutynin          |              |            | C           |              |                    |                 | Not Reported |
|                                                                           | Temazepam           |              |            | C           |              |                    |                 | Not Reported |
|                                                                           | Irbesartan          |              |            | C           |              |                    |                 | Not Reported |
|                                                                           | Doxepin             |              |            | C           |              |                    |                 | Not Reported |
|                                                                           | Trazodone           |              |            | C           |              |                    |                 | Not Reported |
|                                                                           | Glyburide           |              |            | C           |              |                    |                 | Not Reported |
|                                                                           | Enalapril           |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Dec-2015              | 11810173      | DIRECT           |                    | HO              |                      |                      | 19 YR      | Female     |                |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|          |         |   |      |        |       |              |
|----------|---------|---|------|--------|-------|--------------|
| Vomiting | Zoloft  | S | Oral | 1 Pill | 1 DAY | Not Reported |
|          | Lexapro | S | Oral | 1 Pill | 2 DAY | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Dec-2015              | 11810177      | DIRECT           |                    |                 |                      |                      | 33 YR      | Female     | CAN            |

| <u>Preferred Term</u>                                                                                                                   | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Intolerance;<br>Dysphagia;<br>Gastroesophageal Reflux<br>Disease; Maternal<br>Exposure During<br>Pregnancy; Pregnancy;<br>Vomiting | Cirpalex             |              |            | S           | Oral         | 1 Pill             | 6 YR            | Lundbeck     |
|                                                                                                                                         | Cipralelex Diclectin |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                         | Folic Acid           |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Dec-2015              | 11810681      | DIRECT           |                    |                 |                      |                      | 48 YR      | Male       | USA            |

| <u>Preferred Term</u>                                | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Adverse Drug Reaction;<br>Product Substitution Issue | Escitalopram 20 Mg Mylan |              |            | S           | Oral         |                    |                 | Mylan        |
|                                                      | Lorazepam                |              |            | C           |              |                    |                 | Not Reported |
|                                                      | Sam-E                    |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------|----------------------|------------|------------|----------------|
| 08-Dec-2015              | 11627978      | EXPEDITED (15-DAY) |                    | OT              | IT-AUROBINDO-AUR-<br>APL-2015-08982 |                      | 57 YR      | Male       | ITA            |

| <u>Preferred Term</u>                   | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------|-----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Bradyphrenia; Drug<br>Abuse; Presyncope | Mirtazapine           |              |            | S           | Oral         | 60 Mg Total        |                 | Aurobindo    |
|                                         | Mirtazapine           |              |            | S           | Oral         | 30 Mg, Daily       |                 | Aurobindo    |
|                                         | Olanzapine            |              |            | S           | Oral         | 20 Mg Total        |                 | Aurobindo    |
|                                         | Olanzapine            |              |            | S           | Oral         | 10 Mg, Daily       |                 | Aurobindo    |
|                                         | Cipralelex /01588501/ |              |            | S           | Oral         | 2 Df Total         |                 | Not Reported |
|                                         | Cipralelex /01588501/ |              |            | S           | Oral         | 20 Mg, Daily       |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                   |   |         |            |              |
|-------------------|---|---------|------------|--------------|
| Lyrica            | C | Unknown | 75 Mg, Unk | Not Reported |
| Folina /00024201/ | C | Unknown |            | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 08-Dec-2015              | 11652680      | EXPEDITED (15-DAY) |                    | CA, LT, OT      | JP-ASTRAZENECA-2015SF01971 |                      |            | Female     | JPN            |

| <u>Preferred Term</u>                                                                                                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|----------------------|-----------------|--------------|
| Drug Withdrawal Syndrome Neonatal; Dyspnoea; Infantile Apnoea; Neonatal Asphyxia; Transient Tachypnoea Of The Newborn | Seroquel       |              |            | S           | Transplacental | 25-50 Mg, Once Daily |                 | Not Reported |
|                                                                                                                       | Lexapro        |              |            | S           | Transplacental |                      |                 | Not Reported |
|                                                                                                                       | Utemerin       |              |            | S           | Transplacental |                      |                 | Not Reported |
|                                                                                                                       | Selbex         |              |            | S           | Transplacental |                      |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Dec-2015              | 11771088      | EXPEDITED (15-DAY) |                    | HO, OT          | FR-ROCHE-1662324     |                      |            | Female     | FRA            |

| <u>Preferred Term</u>                                       | <u>Product</u>   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------|------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Condition Aggravated; Drop Attacks; Fall; Muscular Weakness | Valium           |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                             | Esidrex          |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                             | Irbesartan Arrow |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                             | Gabapentin       |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                             | Plavix           |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                             | Zolpidem         |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                             | Seroplex         |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                             | Levothyrox       |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 08-Dec-2015              | 11809692      | EXPEDITED (15-DAY) |                    | HO              | FR-009507513-1512FRA001916 |                      | 72 YR      | Male       | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|           |                        |   |      |     |              |
|-----------|------------------------|---|------|-----|--------------|
| Psoriasis | Inegy                  | S | Oral | Unk | Merck        |
|           | Chibro-Proscar         | S | Oral | Unk | Merck        |
|           | Seroplex               | S | Oral | Unk | Not Reported |
|           | Amiodarone             | S | Oral | Unk | Not Reported |
|           | Previscan (Fluindione) | S | Oral | Unk | Not Reported |
|           | Bisoprolol Fumarate    | S | Oral | Unk | Not Reported |
|           | Tareg                  | S | Oral | Unk | Not Reported |
|           | Lasilix                | S | Oral | Unk | Not Reported |
|           | Novo-Norm              | S | Oral | Unk | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 08-Dec-2015              | 11810850      | EXPEDITED (15-DAY) |                    | DE              | US-PFIZER INC-2015424373 |                      | 34 YR      | Male       | USA            |

| <u>Preferred Term</u>                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiac Arrest; Death; Respiratory Arrest | Alprazolam     |              |            | S           | Oral         | Unk                |                 | Pfizer       |
|                                           | Gabapentin     |              |            | S           | Oral         | Unk                |                 | Pfizer       |
|                                           | Oxycodone      |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                                           | Oxymorphone    |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                                           | Escitalopram   |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                                           | Trazodone      |              |            | S           | Oral         | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------|----------------------|------------|------------|----------------|
| 09-Dec-2015              | 11801311      | EXPEDITED (15-DAY) |                    | OT              | KR-TAKEDA-2015MPI008137 |                      |            | Unknown    | KOR            |

| <u>Preferred Term</u>                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Asthenia; Delirium; Pneumonia; Tremor | Velcade        |              |            | S           | Subcutaneous | 1.3 Mg/M2, Unk     |                 | Takeda     |
|                                       | Velcade        |              |            | S           | Subcutaneous | 1.3 Mg/M2, Unk     |                 | Takeda     |
|                                       | Velcade        |              |            | S           | Subcutaneous | 1.3 Mg/M2, Unk     |                 | Takeda     |
|                                       | Velcade        |              |            | S           | Subcutaneous | 1.3 Mg/M2, Unk     |                 | Takeda     |
|                                       | Velcade        |              |            | S           | Subcutaneous | 1.3 Mg/M2, Unk     |                 | Takeda     |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|              |   |              |                |              |
|--------------|---|--------------|----------------|--------------|
| Velcade      | S | Subcutaneous | 1.3 Mg/M2, Unk | Takeda       |
| Velcade      | S | Subcutaneous | 1.3 Mg/M2, Unk | Takeda       |
| Risperidone  | S | Unknown      | 0.25 Mg, Unk   | Not Reported |
| Risperidone  | S | Unknown      | 0.5 Mg, Unk    | Not Reported |
| Tramadol     | S | Unknown      | 150 Mg, Unk    | Not Reported |
| Prednisone   | S | Unknown      | 7.5 Mg/M2, Unk | Not Reported |
| Gabapentin   | S | Unknown      | 100 Mg, Tid    | Not Reported |
| Gabapentin   | S | Unknown      | 300 Mg, Bid    | Not Reported |
| Melphalan    | S | Unknown      | 60 Mg/M2, Unk  | Not Reported |
| Pregabalin   | S | Unknown      | 75 Mg, Qd      | Not Reported |
| Pregabalin   | S | Unknown      | 150 Mg, Qd     | Not Reported |
| Etravil      | S | Unknown      | 10 Mg, Qd      | Not Reported |
| Lamotrigine  | S | Unknown      | Unk            | Not Reported |
| Aripiprazole | S | Unknown      | 2.5 Mg, Unk    | Not Reported |
| Escitalopram | S | Unknown      | 2.5 Mg, Unk    | Not Reported |
| Escitalopram | S | Unknown      | 5 Mg, Unk      | Not Reported |
| Morphine     | S | Unknown      | 5 Mg, Unk      | Not Reported |
| Loperamide   | C | Unknown      | Unk            | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Dec-2015              | 11814084      | EXPEDITED (15-DAY) | HO                 |                 | FR-SA-2015SA205511   |                      |            | Male       | FRA            |

| <u>Preferred Term</u> | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Psoriasis             | Amiodarone             |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Bisoprolol Fumarate    |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Lasilix                |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Seroplex               |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Previscan (Fluindione) |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Tareg                  |              |            | S           | Oral         |                    |                 | Not Reported |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                             | Inegy          |                    | S                  | Oral            |                          |                               |                 | Not Reported |                |
|---------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|--------------------------|-------------------------------|-----------------|--------------|----------------|
|                                                                                             | Novonorm       |                    | S                  | Oral            |                          |                               |                 | Not Reported |                |
|                                                                                             | Chibro-Proscar |                    | S                  | Oral            |                          |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                    | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Dec-2015                                                                                 | 11814324       | EXPEDITED (15-DAY) |                    | OT              | FR-JNJFOC-20151202286    |                               | 48 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                       | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Intentional Self-Injury; Sleep Disorder; Treatment Noncompliance; Weight Decreased | Risperdal      |                    |                    | S               | Unknown                  | Half A Tablet 4 Times Per Day |                 | Not Reported |                |
|                                                                                             | Seroplex       |                    |                    | S               | Unknown                  |                               |                 | Not Reported |                |
|                                                                                             | Stilnox        |                    |                    | S               | Unknown                  |                               |                 | Not Reported |                |
|                                                                                             | Anafranil      |                    |                    | S               | Unknown                  |                               |                 | Not Reported |                |
|                                                                                             | Lyrica         |                    |                    | S               | Unknown                  |                               |                 | Not Reported |                |
|                                                                                             | Lysanxia       |                    |                    | S               | Unknown                  |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                    | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Dec-2015                                                                                 | 11815422       | EXPEDITED (15-DAY) |                    | DE              | US-PFIZER INC-2015428978 |                               | 25 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                       | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Completed Suicide; Respiratory Arrest                                       | Propanolol Hcl |                    |                    | S               |                          |                               |                 | Unknown      |                |
|                                                                                             | Escitalopram   |                    |                    | S               |                          |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                    | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Dec-2015                                                                                 | 11815594       | EXPEDITED (15-DAY) |                    | HO              | DE-FRI-1000081547        |                               | 53 YR           | Male         | DEU            |
| <u>Preferred Term</u>                                                                       | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Erectile Dysfunction                                                                        | Escitalopram   |                    |                    | S               | Oral                     | 5 Mg                          |                 | Forest       |                |
|                                                                                             | Escitalopram   |                    |                    | S               | Oral                     | 10 Mg                         |                 | Forest       |                |
|                                                                                             | Escitalopram   |                    |                    | S               | Oral                     | 5 Mg                          |                 | Not Reported |                |
|                                                                                             | Bupropion      |                    |                    | C               | Oral                     | 150 Mg                        |                 | Not Reported |                |

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|  |            |   |      |        |              |
|--|------------|---|------|--------|--------------|
|  | Bupropion  | C | Oral | 300 Mg | Not Reported |
|  | Bisoprolol | C | Oral | 5 Mg   | Not Reported |
|  | Ramipril   | C | Oral | 5 Mg   | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 09-Dec-2015              | 11815912       | EXPEDITED (15-DAY) |                    | DE              | US-PFIZER INC-2015429533 |                      | 46 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Death                    | Sertraline Hcl |                    |                    | S               | Oral                     |                      |                 | Pfizer       |                |
|                          | Acetaminophen  |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                          | Quetiapine     |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                          | Escitalopram   |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                          | Buspirone      |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                        | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------|----------------|--------------------|--------------------|-----------------|---------------------------|----------------------------|-----------------|--------------|----------------|
| 09-Dec-2015                                     | 11815915       | EXPEDITED (15-DAY) |                    | HO, OT          | US-SUNOVION-2015SUN001182 |                            |                 | Female       | USA            |
| <u>Preferred Term</u>                           | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>   |                |
| Insomnia; Suicidal Behaviour; Suicidal Ideation | Latuda         |                    |                    | S               | Oral                      | Unk                        |                 | Sunovion     |                |
|                                                 | Latuda         |                    |                    | S               | Oral                      | Unk                        |                 | Sunovion     |                |
|                                                 | Lexapro        |                    |                    | S               |                           | 30 Mg, Unk                 |                 | Not Reported |                |
|                                                 | Lexapro        |                    |                    | S               |                           | 20 Mg, Unk                 |                 | Not Reported |                |
|                                                 | Lexapro        |                    |                    | S               |                           | 10 Mg, Unk                 |                 | Not Reported |                |
|                                                 | Lexapro        |                    |                    | S               |                           | 5 Mg, Unk                  |                 | Not Reported |                |
|                                                 | Xanax          |                    |                    | C               |                           | 0.25 Mg, About Once Weekly |                 | Not Reported |                |
|                                                 | Effexor        |                    |                    | C               |                           | Unk                        |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 09-Dec-2015              | 11815949      | EXPEDITED (15-DAY) |                    | DE              | US-PFIZER INC-2015425860 |                      | 16 YR      | Male       | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                        | <u>Product</u>                                          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------|---------------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiac Arrest; Death;<br>Respiratory Arrest | Morphine Sulfate                                        |              |            | S           | Oral         |                    |                 | Pfizer       |
|                                              | Hydrocodone/Acetaminophen<br>/00607101/<br>Escitalopram |              |            | S           | Oral         |                    |                 | Not Reported |
|                                              | Escitalopram                                            |              |            | S           | Oral         |                    |                 | Not Reported |
|                                              | Cyclobenzaprine                                         |              |            | S           | Oral         |                    |                 | Not Reported |
|                                              | Aripiprazole                                            |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Dec-2015              | 11818846      | DIRECT           | Y                  | HO              |                      |                      | 91 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Loss Anaemia;<br>Oesophagitis Ulcerative;<br>Upper Gastrointestinal<br>Haemorrhage; Vitamin K<br>Deficiency | Xarelto        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                   | Escitalopram   |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                   | Xanax          |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                   | Norvasc        |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                   | Vit. B12       |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                   | Folvite        |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                   | Norco          |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                   | Mvi            |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                   | Zegerid        |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                   | Zofran         |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                   | Exelon         |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                   | Restoril       |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Dec-2015              | 11839405      | NON-EXPEDITED    | Y                  | HO              | AUR-APL-2015-06984   |                      |            | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u>                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|--------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Atrial Fibrillation   | Toraseamide 20mg (Toraseamide) |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Unknown, 20mg                  |              |            |             |              |                    |                 |              |
|                       | Ascorbic Acid (Ascorbic Acid)  |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Lexapro (Escitalopram Oxalate) |              |            | S           |              |                    |                 | Not Reported |
|                       | Magnesium Oxide (Magnesium)    |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                        |   |      |  |  |  |  |  |  |              |
|----------------------------------------|---|------|--|--|--|--|--|--|--------------|
| Oxide)                                 |   |      |  |  |  |  |  |  |              |
| Vasotec /00574902/ (Enalapril Maleate) | C | Oral |  |  |  |  |  |  | Not Reported |
| Vitamin D3 (Colecalciferol)            | S | Oral |  |  |  |  |  |  | Not Reported |
| Glucosamine                            | C |      |  |  |  |  |  |  | Not Reported |
| Fish Oil                               | C |      |  |  |  |  |  |  | Not Reported |
| Aspirin (Acetylsalicylic Acid)         | C |      |  |  |  |  |  |  | Not Reported |
| Mvi (Vitamins Nos)                     | C |      |  |  |  |  |  |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 10-Dec-2015              | 10738702      | EXPEDITED (15-DAY) |                    | DS, OT          | NO-PFIZER INC-2015028989 |                      | 19 YR      | Female     | NOR            |

| <u>Preferred Term</u>                                                                          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Facial Spasm; Limb Injury; Loss Of Personal Independence In Daily Activities; Muscle Twitching | Zeldox         |              |            | S           |              | 80-40 Mg Per Day   |                 | Pfizer       |
|                                                                                                | Ciprallex      |              |            | S           |              | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Dec-2015              | 11802665      | EXPEDITED (15-DAY) |                    | HO, LT          | NO-FRI-1000081334    |                      | < 1 DAY    | Female     | NOR            |

| <u>Preferred Term</u>                                                                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|------------|
| Bradycardia; Foetal Exposure During Pregnancy; Hypotonia Neonatal; Respiratory Failure; Seizure | Escitalopram   |              |            | S           | Transplacental | 10 Mg              |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Dec-2015              | 11806069      | EXPEDITED (15-DAY) |                    | HO              | PHHY2015FR158941     |                      | 72 YR      | Male       | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Psoriasis             | Tareg          |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                       | Amiodarone     |              |            | S           | Oral         | Unk                |                 | Novartis     |

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|  |                        |   |      |     |              |
|--|------------------------|---|------|-----|--------------|
|  | Bisoprolol             | S | Oral | Unk | Not Reported |
|  | Seroplex               | S | Oral | Unk | Not Reported |
|  | Previscan (Fluindione) | S | Oral | Unk | Not Reported |
|  | Inegy                  | S | Oral | Unk | Not Reported |
|  | Lasilix                | S | Oral | Unk | Not Reported |
|  | Novonorm               | S | Oral | Unk | Not Reported |
|  | Chibro-Proscar         | S | Oral | Unk | Not Reported |

| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------|----------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| 10-Dec-2015                | 11821263       | EXPEDITED (15-DAY) |                    | DE, HO          | US-ASTRAZENECA-2015SF23051 |                      | 46 YR           | Female       | USA            |
| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Toxicity To Various Agents | Quetiapine     |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                            | Sertraline     |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                            | Acetaminophen  |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                            | Escitalopram   |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                            | Buspirone      |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 10-Dec-2015              | 11823045             | EXPEDITED (15-DAY) |                    | HO              | FR-NOVOPROD-472830   |                      | 73 YR           | Male         | FRA            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Psoriasis                | Novonorm             |                    |                    | S               | Oral                 | Unk                  |                 | Novo Nordisk |                |
|                          | Seroplex             |                    |                    | S               | Unknown              | Unk                  |                 | Not Reported |                |
|                          | Amiodarone           |                    |                    | S               | Oral                 | Unk                  |                 | Not Reported |                |
|                          | Previscan /00261401/ |                    |                    | S               | Oral                 | Unk                  |                 | Not Reported |                |
|                          | Bisoprolol           |                    |                    | S               | Oral                 | Unk                  |                 | Not Reported |                |
|                          | Tareg                |                    |                    | S               | Oral                 | Unk                  |                 | Not Reported |                |
|                          | Inegy                |                    |                    | S               | Oral                 | Unk                  |                 | Not Reported |                |
|                          | Lasilix /00032601/   |                    |                    | S               | Oral                 | Unk                  |                 | Not Reported |                |

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|                                                                         |                     |                    |                    |                 |                          |                      |                 |              |                |
|-------------------------------------------------------------------------|---------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| Chibro-Proscar                                                          |                     |                    | S                  | Oral            | Unk                      | Not Reported         |                 |              |                |
| <u>FDA Received Date</u>                                                | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Dec-2015                                                             | 11823232            | EXPEDITED (15-DAY) |                    | HO              | AU-FRI-1000081461        |                      | 14 YR           | Male         | AUS            |
| <u>Preferred Term</u>                                                   | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hallucination; Product Use Issue; Psychotic Disorder; Suicidal Ideation | Escitalopram        |                    |                    | S               | Unknown                  | 20 Mg                |                 | Forest       |                |
|                                                                         | Escitalopram        |                    |                    | S               |                          |                      |                 | Forest       |                |
|                                                                         | Escitalopram        |                    |                    | S               |                          |                      |                 | Forest       |                |
|                                                                         | Escitalopram        |                    |                    | S               |                          |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Dec-2015                                                             | 11824333            | EXPEDITED (15-DAY) |                    | DE              | US-PFIZER INC-2015427277 |                      | 64 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                   | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                                       | Amlodipine Besilate |                    |                    | S               | Oral                     | Unk                  |                 | Pfizer       |                |
|                                                                         | Escitalopram        |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Dec-2015                                                             | 11825346            | DIRECT             | Y                  | HO              |                          |                      | 71 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                   | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Torsade De Pointes                                      | Methadone           |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                                                                         | Escitalopram        |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Dec-2015                                                             | 11790775            | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000081179        |                      |                 | Female       | FRA            |
| <u>Preferred Term</u>                                                   | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated; Drop Attacks; Fall                                | Escitalopram        |                    |                    | S               | Oral                     | 10 Mg                |                 | Forest       |                |
|                                                                         | Escitalopram        |                    |                    | S               | Oral                     | 15 Mg                |                 | Forest       |                |



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|                  |   |         |               |              |
|------------------|---|---------|---------------|--------------|
| Esidrex          | S | Oral    | 12.5 Mg       | Not Reported |
| Irbesartan Arrow | S | Oral    | 300 Mg        | Not Reported |
| Gabapentine      | S | Oral    | 300 Mg        | Not Reported |
| Plavix           | S | Oral    | 75 Mg         | Not Reported |
| Valium Roche     | S | Oral    | 10 Mg         | Not Reported |
| Zolpidem         | S | Oral    | 10 Mg         | Not Reported |
| Levothyrox       | S | Oral    | 150 Microgram | Not Reported |
| Oxazepam         | C | Unknown |               | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Dec-2015              | 11826549      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000081464    |                      | 71 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                                                                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Haemorrhage Intracranial;<br>Prescribed Overdose;<br>Subarachnoid<br>Haematoma; Subdural<br>Haematoma | Escitalopram   |              |            | S           | Oral         | 30 Mg              |                 | Forest       |
|                                                                                                       | Xarelto        |              |            | S           | Oral         | 20 Mg              |                 | Not Reported |
|                                                                                                       | Xarelto        |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                       | Xarelto        |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                       | Lasilix        |              |            | C           | Oral         | 40 Mg              |                 | Not Reported |
|                                                                                                       | Cordarone      |              |            | C           | Oral         | 142.8571 Mg        |                 | Not Reported |
|                                                                                                       | Atacand        |              |            | C           | Oral         | 16 Mg              |                 | Not Reported |
|                                                                                                       | Lercan         |              |            | C           | Oral         | 20 Mg              |                 | Not Reported |
|                                                                                                       | Urbanyl        |              |            | C           | Oral         | 30 Mg              |                 | Not Reported |
|                                                                                                       | Revia          |              |            | C           | Oral         | 50 Mg              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Dec-2015              | 11826550      | EXPEDITED (15-DAY) |                    | CA              | FR-FRI-1000081462    |                      | < 1 DAY    | Female     | FRA            |

| <u>Preferred Term</u>                                                  | <u>Product</u>   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------|------------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Foetal Exposure During<br>Pregnancy; Foetal<br>Malnutrition; Low Birth | Escitalopram     |              |            | S           | Transplacental | 1 Dosage Form      |                 | Forest       |
|                                                                        | Baclofen Zentiva |              |            | S           | Transplacental | 21 Dosage Forms    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|             |                  |   |                |                 |              |
|-------------|------------------|---|----------------|-----------------|--------------|
| Weight Baby | Baclofen Zentiva | S | Transplacental | 12 Dosage Forms | Not Reported |
|             | Seresta          | S | Transplacental |                 | Not Reported |
|             | Xanax            | S | Transplacental |                 | Not Reported |

| <u>FDA Received Date</u>                         | <u>Case #</u>    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------|------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 11-Dec-2015                                      | 11827315         | EXPEDITED (15-DAY) |                    | DE, HO          | US-JNJFOC-20151204139 |                      | 33 YR           | Male         | USA            |
| <u>Preferred Term</u>                            | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Toxicity To Various Agents | Topiramate       |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                  | Escitalopram     |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                  | Dextromethorphan |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                  | Cyclobenzaprine  |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                  | Chlorpheniramine |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                  | Meloxicam        |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                  | Trazodone        |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                  | Olanzapine       |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                  | Sumatriptan      |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                  | Benzonatate      |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                  | Buspirone        |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>           | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------|------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 11-Dec-2015                        | 11828046               | EXPEDITED (15-DAY) |                    | HO              | FR-PFIZER INC-2015439100 |                      | 73 YR           | Male         | FRA            |
| <u>Preferred Term</u>              | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated;<br>Psoriasis | Amiodarone Hcl         |                    |                    | S               | Oral                     | Unk                  |                 | Pfizer       |                |
|                                    | Bisoprolol Fumarate    |                    |                    | S               | Oral                     | Unk                  |                 | Not Reported |                |
|                                    | Seroplex               |                    |                    | S               | Oral                     | Unk                  |                 | Not Reported |                |
|                                    | Tareg                  |                    |                    | S               | Oral                     | Unk                  |                 | Not Reported |                |
|                                    | Lasilix                |                    |                    | S               | Oral                     | Unk                  |                 | Not Reported |                |
|                                    | Previscan (Fluindione) |                    |                    | S               | Oral                     | Unk                  |                 | Not Reported |                |

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|                                       | Inegy                      |                    | S                  | Oral            |                      | Unk                     |                 |              | Not Reported   |
|---------------------------------------|----------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------|-----------------|--------------|----------------|
|                                       | Novonorm                   |                    | S                  | Oral            |                      | Unk                     |                 |              | Not Reported   |
|                                       | Chibro-Proscar             |                    | S                  | Oral            |                      | Unk                     |                 |              | Not Reported   |
| <u>FDA Received Date</u>              | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Dec-2015                           | 11645622                   | EXPEDITED (15-DAY) |                    |                 | JP-FRI-1000080327    |                         | 56 YR           | Female       | JPN            |
| <u>Preferred Term</u>                 | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Hyperkalaemia;<br>Nausea     | Lexapro                    |                    |                    | S               | Oral                 | 5 Mg                    |                 | Forest       |                |
|                                       | Lexapro                    |                    |                    | S               | Oral                 | 2.5 Mg                  |                 | Forest       |                |
|                                       | Sepazon                    |                    |                    | C               | Oral                 | 1 Mg                    |                 | Not Reported |                |
| <u>FDA Received Date</u>              | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Dec-2015                           | 11653375                   | EXPEDITED (15-DAY) |                    | OT              | DE-FRI-1000080357    |                         | 42 YR           | Female       | DEU            |
| <u>Preferred Term</u>                 | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Faecaloma; Rash                       | Escitalopram               |                    |                    | S               | Oral                 | 10 Mg                   |                 | Forest       |                |
|                                       | Amitriptyline-Form Unknown |                    |                    | C               | Oral                 | 50 Mg                   |                 | Not Reported |                |
| <u>FDA Received Date</u>              | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Dec-2015                           | 11770485                   | EXPEDITED (15-DAY) |                    | HO              | FR-SA-2015SA186473   |                         | 70 YR           | Female       | FRA            |
| <u>Preferred Term</u>                 | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated;<br>Drop Attacks | Gabapentin                 |                    |                    | S               | Oral                 |                         |                 | Not Reported |                |
|                                       | Plavix                     |                    |                    | S               | Oral                 |                         |                 | Not Reported |                |
|                                       | Zolpidem                   |                    |                    | S               | Oral                 |                         |                 | Not Reported |                |
|                                       | Seroplex                   |                    |                    | S               | Oral                 |                         |                 | Not Reported |                |
|                                       | Levothyrox                 |                    |                    | S               | Oral                 |                         |                 | Not Reported |                |
|                                       | Valium                     |                    |                    | S               | Oral                 |                         |                 | Not Reported |                |
|                                       | Irbesartan                 |                    |                    | S               | Oral                 | Long Standing Treatment |                 | Not Reported |                |

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| Esidrex                                                      |                      |                    | S                  |                 | Unknown                                                  |                      |                 | Not Reported |                |
|--------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------------------------------------------|----------------------|-----------------|--------------|----------------|
| <u>FDA Received Date</u>                                     | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Dec-2015                                                  | 11787727             | NON-EXPEDITED      |                    |                 | US-GILEAD-2015-0184903                                   |                      | 63 YR           | Female       | USA            |
| <u>Preferred Term</u>                                        | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Headache; Lethargy; Nausea; Somnolence            | Harvoni              |                    |                    | S               | Unknown                                                  | Unk                  |                 | Gilead       |                |
|                                                              | Harvoni              |                    |                    | S               | Unknown                                                  | Unk                  |                 | Gilead       |                |
|                                                              | Adderall             |                    |                    | S               | Oral                                                     | 30 Mg, Unk           |                 | Not Reported |                |
|                                                              | Bupropion            |                    |                    | S               | Oral                                                     | 150 Mg, Unk          |                 | Not Reported |                |
|                                                              | Clonazepam           |                    |                    | S               | Oral                                                     | 1 Mg, Unk            |                 | Not Reported |                |
|                                                              | Escitalopram         |                    |                    | S               | Oral                                                     | 20 Mg, Unk           |                 | Not Reported |                |
|                                                              | Lamotrigine          |                    |                    | S               | Oral                                                     | 200 Mg, Unk          |                 | Not Reported |                |
|                                                              | Dandelion Root       |                    |                    | C               |                                                          | Unk                  |                 | Not Reported |                |
|                                                              | Excedrin /00110301/  |                    |                    | C               |                                                          | Unk                  |                 | Not Reported |                |
|                                                              | Fiber                |                    |                    | C               |                                                          | Unk                  |                 | Not Reported |                |
|                                                              | Gas-X                |                    |                    | C               |                                                          | Unk                  |                 | Not Reported |                |
|                                                              | Protein Powder       |                    |                    | C               |                                                          | Unk                  |                 | Not Reported |                |
|                                                              | Vitamin D /00107901/ |                    |                    | C               |                                                          | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Dec-2015                                                  | 11831410             | EXPEDITED (15-DAY) |                    | DE              | US-PAR<br>PHARMACEUTICAL<br>COMPANIES-<br>2015SCPR014583 |                      | 34 YR           | Male         | USA            |
| <u>Preferred Term</u>                                        | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardio-Respiratory Arrest; Death; Toxicity To Various Agents | Oxymorphone Hcl      |                    |                    | S               | Oral                                                     | Unk, Unknown         |                 | Par          |                |
|                                                              | Alprazolam           |                    |                    | S               | Oral                                                     | Unk, Unknown         |                 | Par          |                |
|                                                              | Oxycodone            |                    |                    | S               | Oral                                                     | Unk, Unknown         |                 | Not Reported |                |
|                                                              | Gabapentin           |                    |                    | S               | Oral                                                     | Unk, Unknown         |                 | Not Reported |                |
|                                                              | Escitalopram         |                    |                    | S               | Oral                                                     | Unk, Unknown         |                 | Not Reported |                |

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|                                                                                                                                                                                                 |                     |                    |                    |                 |                                                          |                      |                 |                  |                |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|--------------------|--------------------|-----------------|----------------------------------------------------------|----------------------|-----------------|------------------|----------------|
| Trazodone                                                                                                                                                                                       |                     |                    | S                  | Oral            | Unk, Unknown                                             |                      |                 | Not Reported     |                |
| <u>FDA Received Date</u>                                                                                                                                                                        | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 14-Dec-2015                                                                                                                                                                                     | 11831704            | EXPEDITED (15-DAY) |                    | DE              | US-PAR<br>PHARMACEUTICAL<br>COMPANIES-<br>2015SCPR014601 |                      | 52 YR           | Male             | USA            |
| <u>Preferred Term</u>                                                                                                                                                                           | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |
| Completed Suicide; Death                                                                                                                                                                        | Lamotrigine         |                    |                    | S               | Oral                                                     | Unk Unk, Unknown     |                 | Par              |                |
|                                                                                                                                                                                                 | Escitalopram        |                    |                    | S               | Oral                                                     | Unk, Unknown         |                 | Not Reported     |                |
|                                                                                                                                                                                                 | Atenolol            |                    |                    | S               | Oral                                                     | Unk, Unknown         |                 | Not Reported     |                |
| <u>FDA Received Date</u>                                                                                                                                                                        | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 14-Dec-2015                                                                                                                                                                                     | 11831718            | EXPEDITED (15-DAY) |                    | OT              | CH-<br>ELI_LILLY_AND_COMP<br>ANY-CH201512003636          |                      | 33 YR           | Female           | CHE            |
| <u>Preferred Term</u>                                                                                                                                                                           | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |
| Exposure During<br>Pregnancy; Gestational<br>Diabetes; Placental<br>Insufficiency                                                                                                               | Zyprexa             |                    |                    | S               | Oral                                                     | 10 Mg, Qd            |                 | Eli Lilly And Co |                |
|                                                                                                                                                                                                 | Zyprexa             |                    |                    | S               | Unknown                                                  | 2.5 Mg, Qd           |                 | Eli Lilly And Co |                |
|                                                                                                                                                                                                 | Cipralex /01588501/ |                    |                    | S               | Oral                                                     | 10 Mg, Qd            |                 | Not Reported     |                |
|                                                                                                                                                                                                 | Tegretol            |                    |                    | S               | Oral                                                     | Unk, Bid             |                 | Not Reported     |                |
| <u>FDA Received Date</u>                                                                                                                                                                        | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 14-Dec-2015                                                                                                                                                                                     | 11831721            | EXPEDITED (15-DAY) |                    | OT              | CH-<br>ELI_LILLY_AND_COMP<br>ANY-CH201512001460          |                      | < 1 DAY         | Female           | CHE            |
| <u>Preferred Term</u>                                                                                                                                                                           | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |
| Alloimmunisation; Breech<br>Presentation; False<br>Positive Investigation<br>Result; Foetal Exposure<br>During Pregnancy; Foetal<br>Growth Restriction;<br>Hypoglycaemia Neonatal;<br>Petechiae | Zyprexa             |                    |                    | S               | Transplacental                                           | 10 Mg, Qd            |                 | Eli Lilly And Co |                |
|                                                                                                                                                                                                 | Zyprexa             |                    |                    | S               | Transplacental                                           | 10 Mg, Qd            |                 | Eli Lilly And Co |                |
|                                                                                                                                                                                                 | Zyprexa             |                    |                    | S               | Unknown                                                  | 2.5 Mg, Qd           |                 | Eli Lilly And Co |                |
|                                                                                                                                                                                                 | Zyprexa             |                    |                    | S               | Unknown                                                  | 2.5 Mg, Qd           |                 | Eli Lilly And Co |                |
|                                                                                                                                                                                                 | Cipralex /01588501/ |                    |                    | S               | Transplacental                                           | 10 Mg, Qd            |                 | Not Reported     |                |

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|                                                                                                               | Ciprallex /01588501/ |                    | S                  | Transplacental  | 10 Mg, Qd                                                |                       |                 | Not Reported |                |
|---------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------------------------------------------|-----------------------|-----------------|--------------|----------------|
|                                                                                                               | Tegretol             |                    | S                  | Transplacental  |                                                          |                       |                 | Not Reported |                |
|                                                                                                               | Tegretol             |                    | S                  | Transplacental  |                                                          |                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                      | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                     | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Dec-2015                                                                                                   | 11832299             | EXPEDITED (15-DAY) |                    | CA, HO, OT      | BR-FRI-1000081530                                        |                       | 1 DAY           | Male         | BRA            |
| <u>Preferred Term</u>                                                                                         | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                             | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Cholestasis; Foetal Exposure During Pregnancy                                                                 | Lexapro              |                    |                    | S               | Transplacental                                           | 10 Mg                 |                 | Forest       |                |
|                                                                                                               | Omega-3 Fatty Acid   |                    |                    | C               | Transplacental                                           |                       |                 | Not Reported |                |
|                                                                                                               | Folic Acid           |                    |                    | C               | Transplacental                                           |                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                      | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                     | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Dec-2015                                                                                                   | 11838852             | EXPEDITED (15-DAY) |                    | DE              | US-PAR<br>PHARMACEUTICAL<br>COMPANIES-<br>2015SCPR014637 |                       | 25 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                         | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                             | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Cardio-Respiratory Arrest; Completed Suicide; Death; Poisoning Deliberate; Respiratory Arrest | Propranolol Hcl      |                    |                    | S               | Oral                                                     | Unk Unk, Unknown      |                 | Par          |                |
|                                                                                                               | Escitalopram         |                    |                    | S               | Oral                                                     | Unk, Unknown          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                      | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                     | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Dec-2015                                                                                                   | 11783032             | EXPEDITED (15-DAY) |                    | HO              | PHHY2015FR152634                                         |                       |                 | Female       | FRA            |
| <u>Preferred Term</u>                                                                                         | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                             | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated; Drop Attacks                                                                            | Esidrex              |                    |                    | S               | Oral                                                     | 12.5 Mg, Qd           |                 | Not Reported |                |
|                                                                                                               | Zolpidem             |                    |                    | S               | Oral                                                     | 10 Mg, Qd, In Evening |                 | Novartis     |                |
|                                                                                                               | Irbesartan           |                    |                    | S               | Oral                                                     | 300 Mg, Qd            |                 | Not Reported |                |
|                                                                                                               | Gabapentin           |                    |                    | S               | Oral                                                     | 100 Mg, Tid           |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|            |   |         |            |              |
|------------|---|---------|------------|--------------|
| Plavix     | S | Oral    | 75 Mg, Qd  | Not Reported |
| Valium     | S | Unknown | 5 Mg, Bid  | Not Reported |
| Seroplex   | S | Oral    | 15 Mg, Qd  | Not Reported |
| Seroplex   | S | Oral    | 10 Mg, Qd  | Not Reported |
| Levothyrox | S | Oral    | 150 Ug, Qd | Not Reported |
| Oxazepam   | C | Unknown | Unk        | Not Reported |

| <u>FDA Received Date</u>                                                                                                               | <u>Case #</u>                 | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|------------------|--------------------|-----------------|--------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 16-Dec-2015                                                                                                                            | 11839326                      | NON-EXPEDITED    |                    |                 | US-LUPIN<br>PHARMACEUTICALS<br>INC.-E2B_00004298 |                      | 59 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                  | <u>Product</u>                | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                     | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Disturbance In Attention;<br>Dry Eye; Dyspnoea;<br>Feeling Hot; Memory<br>Impairment; Palpitations;<br>Panic Attack; Sleep<br>Disorder | Escitalopram Tablets Usp 10mg |                  |                    | S               | Unknown                                          |                      |                 | Lupin        |                |
|                                                                                                                                        | Escitalopram Tablets Usp 10mg |                  |                    | S               | Unknown                                          |                      |                 | Lupin        |                |
|                                                                                                                                        | Lisinopril                    |                  |                    | C               | Oral                                             |                      |                 | Not Reported |                |
|                                                                                                                                        | Xanax                         |                  |                    | C               | Oral                                             | 0.5mg                |                 | Not Reported |                |
|                                                                                                                                        | Clonazepam                    |                  |                    | C               | Oral                                             |                      |                 | Not Reported |                |
|                                                                                                                                        | Vagifem                       |                  |                    | C               | Vaginal                                          |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                          | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------|-----------------------|--------------------|--------------------|-----------------|----------------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 16-Dec-2015                                       | 11839358              | EXPEDITED (15-DAY) |                    | DE              | US-PAR<br>PHARMACEUTICAL<br>COMPANIES-<br>2015SCPR014618 |                      | 33 YR           | Male         | USA            |
| <u>Preferred Term</u>                             | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Death;<br>Poisoning Deliberate | Olanzapine            |                    |                    | S               | Oral                                                     | Unk Unk, Unknown     |                 | Par          |                |
|                                                   | Sumatriptan Succinate |                    |                    | S               | Oral                                                     | Unk, Unknown         |                 | Par          |                |
|                                                   | Escitalopram          |                    |                    | S               | Oral                                                     | Unk, Unknown         |                 | Not Reported |                |
|                                                   | Dextromethorphan      |                    |                    | S               | Oral                                                     | Unk, Unknown         |                 | Not Reported |                |
|                                                   | Cyclobenzaprine       |                    |                    | S               | Oral                                                     | Unk, Unknown         |                 | Not Reported |                |
|                                                   | Topiramate            |                    |                    | S               | Oral                                                     | Unk, Unknown         |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                             |   |      |                  |              |
|-----------------------------|---|------|------------------|--------------|
| Chlorpheniramine /00072501/ | S | Oral | Unk, Unknown     | Not Reported |
| Meloxicam                   | S | Oral | Unk, Unknown     | Not Reported |
| Trazodone                   | S | Oral | Unk, Unknown     | Not Reported |
| Benzonatate                 | S | Oral | Unk Unk, Unknown | Not Reported |
| Buspirone                   | S | Oral | Unk, Unknown     | Not Reported |

| <u>FDA Received Date</u>                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------|----------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 16-Dec-2015                                           | 11839653       | EXPEDITED (15-DAY) |                    | DE, HO          | US-JNJFOC-20151205946 |                      | 46 YR           | Female       | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Exposure Via Ingestion;<br>Toxicity To Various Agents | Acetaminophen  |                    | Y                  | S               | Oral                  |                      |                 | Not Reported |                |
|                                                       | Acetaminophen  |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                       | Quetiapine     |                    |                    | S               |                       |                      |                 | Not Reported |                |
|                                                       | Escitalopram   |                    |                    | S               |                       |                      |                 | Not Reported |                |
|                                                       | Sertraline     |                    |                    | S               |                       |                      |                 | Not Reported |                |
|                                                       | Buspirone      |                    |                    | S               |                       |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                   | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------|-----------------------|--------------------|--------------------|-----------------|--------------------------|-------------------------|-----------------|--------------|----------------|
| 17-Dec-2015                                                | 11471954              | EXPEDITED (15-DAY) |                    | HO              | FR-PFIZER INC-2015291119 |                         | 66 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                      | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Metabolic<br>Encephalopathy; Toxicity<br>To Various Agents | Lyrica                |                    |                    | S               | Oral                     | 50 Mg, Daily            |                 | Pfizer       |                |
|                                                            | Lyrica                |                    |                    | S               | Oral                     | 600 Mg, Daily           |                 | Pfizer       |                |
|                                                            | Seroplex              |                    |                    | S               | Oral                     | 10 Mg, 1x/Day           |                 | Not Reported |                |
|                                                            | Dafalgan Codeine      |                    |                    | S               | Oral                     | Maximum 6 Tablets Daily |                 | Not Reported |                |
|                                                            | Seresta               |                    |                    | S               | Oral                     | 25 Mg, 1x/Day           |                 | Not Reported |                |
|                                                            | Victoza               |                    |                    | C               | Subcutaneous             | 1.8 MI, 1x/Day          |                 | Not Reported |                |
|                                                            | Lantus                |                    |                    | C               | Subcutaneous             | 36 lu, 1x/Day           |                 | Not Reported |                |
|                                                            | Avlocardyl /00030001/ |                    |                    | C               | Oral                     | 40 Mg, 1x/Day           |                 | Not Reported |                |
|                                                            | Aprovel               |                    |                    | C               | Oral                     | 300 Mg, 1x/Day          |                 | Not Reported |                |
|                                                            | Fluvastatin           |                    |                    | C               | Oral                     | 40 Mg, 1x/Day           |                 | Not Reported |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|            |   |      |                |              |
|------------|---|------|----------------|--------------|
| Glucophage | C | Oral | 500 Mg, 3x/Day | Not Reported |
|------------|---|------|----------------|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Dec-2015              | 11503970      | EXPEDITED (15-DAY) | HO                 |                 | FR-FRI-1000079450    |                      | 66 YR      | Female     | FRA            |

| <u>Preferred Term</u>    | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|-------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Metabolic Encephalopathy | Escitalopram      |              |            | S           | Oral         | 10 Mg/Kg           |                 | Forest       |
|                          | Lyrica            |              |            | S           | Oral         | 50 Mg              |                 | Not Reported |
|                          | Lyrica            |              |            | S           | Oral         | 600 Mg             |                 | Not Reported |
|                          | Dafalgan Codeine  |              |            | S           | Oral         |                    |                 | Not Reported |
|                          | Seresta           |              |            | S           | Oral         | 25 Mg              |                 | Not Reported |
|                          | Victoza           |              |            | C           | Subcutaneous | 1.8 MI             |                 | Not Reported |
|                          | Lantus            |              |            | C           | Subcutaneous | 36 lu              |                 | Not Reported |
|                          | Avlocardyl        |              |            | C           | Oral         | 1 Dosage Form      |                 | Not Reported |
|                          | Approvel          |              |            | C           | Oral         | 300 Mg             |                 | Not Reported |
|                          | Fluvastatine Base |              |            | C           | Oral         | 40 Mg              |                 | Not Reported |
|                          | Glucophage        |              |            | C           | Oral         | 1500 Mg            |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Dec-2015              | 11696675      | EXPEDITED (15-DAY) | HO                 |                 | JP-FRI-1000080573    |                      | 74 YR      | Male       | JPN            |

| <u>Preferred Term</u>                                   | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------|-------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Electrocardiogram Qt Prolonged; Ventricular Tachycardia | Lexapro           |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                                         | Trazenta          |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                         | Enalapril Maleate |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                         | Prednisolone      |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                         | Mobic             |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                         | Lyrica            |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                         | Basen             |              |            | C           | Oral         |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>              | <u>Case #</u>                                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------|-------------------------------------------------|--------------------|--------------------|-----------------|---------------------------------|-----------------------|-----------------|--------------|----------------|
| 17-Dec-2015                           | 11794347                                        | EXPEDITED (15-DAY) |                    | HO              | FR-AUROBINDO-AUR-APL-2015-10871 |                       |                 | Female       | FRA            |
| <u>Preferred Term</u>                 | <u>Product</u>                                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated;<br>Drop Attacks | Zolpidem                                        |                    |                    | S               | Oral                            | Unk, Once A Day       |                 | Aurobindo    |                |
|                                       | Irbesartan Arrow Lab 300 Mg Film-Coated Tablets |                    |                    | S               | Oral                            | 300 Mg, Once A Day    |                 | Aurobindo    |                |
|                                       | Gabapentin                                      |                    |                    | S               | Oral                            | 100 Mg, 3 Times A Day |                 | Aurobindo    |                |
|                                       | Plavix                                          |                    |                    | S               | Oral                            | 75 Mg, Once A Day     |                 | Not Reported |                |
|                                       | Esidrex                                         |                    |                    | S               | Oral                            | 12.5 Mg, Once A Day   |                 | Not Reported |                |
|                                       | Valium /00017001/                               |                    |                    | S               | Oral                            | 5 Mg, Two Times A Day |                 | Not Reported |                |
|                                       | Seroplex                                        |                    |                    | S               | Oral                            | 10 Mg, Once A Day     |                 | Not Reported |                |
|                                       | Seroplex                                        |                    |                    | S               | Oral                            | 15 Mg, Daily          |                 | Not Reported |                |
|                                       | Levothyrox                                      |                    |                    | S               | Oral                            | 150 Mg, Once A Day    |                 | Not Reported |                |
| <u>FDA Received Date</u>              | <u>Case #</u>                                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Dec-2015                           | 11814757                                        | EXPEDITED (15-DAY) |                    | DE              | US-PFIZER INC-2015424768        |                       | 33 YR           | Male         | USA            |
| <u>Preferred Term</u>                 | <u>Product</u>                                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                     | Dextromethorphan Hbr                            |                    | Y                  | S               | Oral                            | Unk                   |                 | Unknown      |                |
|                                       | Sumatriptan Succinate                           |                    |                    | S               | Oral                            | Unk                   |                 | Pfizer       |                |
|                                       | Benzonatate                                     |                    |                    | S               | Oral                            | Unk                   |                 | Pfizer       |                |
|                                       | Escitalopram                                    |                    |                    | S               | Oral                            | Unk                   |                 | Not Reported |                |
|                                       | Cyclobenzaprine                                 |                    |                    | S               | Oral                            | Unk                   |                 | Not Reported |                |
|                                       | Topiramate                                      |                    |                    | S               | Oral                            | Unk                   |                 | Not Reported |                |
|                                       | Chlorphenamine                                  |                    |                    | S               | Oral                            | Unk                   |                 | Not Reported |                |
|                                       | Meloxicam                                       |                    |                    | S               | Oral                            | Unk                   |                 | Not Reported |                |
|                                       | Trazodone                                       |                    |                    | S               | Oral                            | Unk                   |                 | Not Reported |                |
|                                       | Olanzapine                                      |                    |                    | S               | Oral                            | Unk                   |                 | Not Reported |                |

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|                                          | Buspirone            |                    | S                  | Oral            |                      | Unk                                                      |                 |              | Not Reported   |
|------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------------------------------------------|-----------------|--------------|----------------|
|                                          | Citalopram           |                    | S                  | Oral            |                      | Unk                                                      |                 |              | Not Reported   |
| <u>FDA Received Date</u>                 | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Dec-2015                              | 11822273             | EXPEDITED (15-DAY) |                    | LT              |                      | IT-TEVA-614657ACC                                        | 66 YR           | Female       | ITA            |
| <u>Preferred Term</u>                    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                       | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Ventricular Fibrillation | Escitalopram Oxalate |                    |                    | S               | Oral                 | 5 Gtt Daily; 5 Gtt Daily, Oral Drops, Solution           |                 | Ivax         |                |
| <u>FDA Received Date</u>                 | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Dec-2015                              | 11843755             | EXPEDITED (15-DAY) |                    | DE              |                      | US-PAR<br>PHARMACEUTICAL<br>COMPANIES-<br>2015SCPR014859 | 25 YR           | Male         | USA            |
| <u>Preferred Term</u>                    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                       | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Death                 | Bupropion Hcl XI     |                    |                    | S               |                      | Unk, Unknown, Ingst + Aspir                              |                 | Par          |                |
|                                          | Lamotrigine          |                    |                    | S               |                      | Unk, Unknown, Ingst + Aspir                              |                 | Par          |                |
|                                          | Clonazepam           |                    |                    | S               |                      | Unk, Unknown Ingst + Aspir                               |                 | Par          |                |
|                                          | Escitalopram         |                    |                    | S               |                      | Unk, Unknown, Ingst + Aspir                              |                 | Not Reported |                |
| <u>FDA Received Date</u>                 | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Dec-2015                              | 11843843             | EXPEDITED (15-DAY) |                    | DE              |                      | US-PAR<br>PHARMACEUTICAL<br>COMPANIES-<br>2015SCPR014877 | 14 YR           | Male         | USA            |
| <u>Preferred Term</u>                    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                       | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Death                 | Bupropion Hcl XI     |                    |                    | S               | Oral                 | Unk Unk, Unknown                                         |                 | Par          |                |
|                                          | Metoprolol           |                    |                    | S               | Oral                 | Unk, Unknown                                             |                 | Not Reported |                |

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|                                     |                         |                           |                             |                          |                               |                       |                               |                          |                     |                         |
|-------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-----------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Escitalopram                        |                         |                           | S                           |                          | Oral                          |                       | Unk, Unknown                  |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> |                       | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 17-Dec-2015                         | 11845567                | NON-EXPEDITED             |                             |                          | US-FRI-1000077918             |                       |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>      | <a href="#">Product</a> |                           | <a href="#">Comp.</a>       | <a href="#">OTC</a>      | <a href="#">Role</a>          | <a href="#">Route</a> | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Ageusia; Hyposmia; Sinusitis        | Lexapro Oral Solution   |                           |                             |                          | S                             |                       |                               |                          | Forest              |                         |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> |                       | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 17-Dec-2015                         | 11845568                | NON-EXPEDITED             |                             |                          | US-FRI-1000080266             |                       |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>      | <a href="#">Product</a> |                           | <a href="#">Comp.</a>       | <a href="#">OTC</a>      | <a href="#">Role</a>          | <a href="#">Route</a> | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Cough; Fatigue; Insomnia            | Lexapro Oral Solution   |                           |                             |                          | S                             | Oral                  | 2.5ml                         |                          | Forest              |                         |
|                                     | Lexapro Oral Solution   |                           |                             |                          | S                             | Oral                  | 2ml                           |                          | Forest              |                         |
|                                     | Valium                  |                           |                             |                          | S                             |                       |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> |                       | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 17-Dec-2015                         | 11845569                | NON-EXPEDITED             |                             |                          | US-FRI-1000079831             |                       |                               |                          | Male                | USA                     |
| <a href="#">Preferred Term</a>      | <a href="#">Product</a> |                           | <a href="#">Comp.</a>       | <a href="#">OTC</a>      | <a href="#">Role</a>          | <a href="#">Route</a> | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Abdominal Distension; Muscle Spasms | Lexapro Oral Solution   |                           |                             |                          | S                             | Oral                  |                               |                          | Forest              |                         |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> |                       | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 17-Dec-2015                         | 11845570                | NON-EXPEDITED             |                             |                          | US-FRI-1000078381             |                       |                               |                          | Male                | USA                     |
| <a href="#">Preferred Term</a>      | <a href="#">Product</a> |                           | <a href="#">Comp.</a>       | <a href="#">OTC</a>      | <a href="#">Role</a>          | <a href="#">Route</a> | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Cataract; Dry Eye; Myopia           | Lexapro Oral Solution   |                           |                             |                          | S                             | Oral                  |                               |                          | Forest              |                         |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> |                       | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 17-Dec-2015                         | 11846466                | EXPEDITED (15-DAY)        |                             | HO                       | FR-FRI-1000081528             |                       |                               | 72 YR                    | Male                | FRA                     |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                               | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Psoriasis                                                                                                                           | Escitalopram             |                    |                    | S               | Oral                 |                      |                 | Forest       |                |
|                                                                                                                                     | Amiodarone               |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                                     | Previscan (Fluindione)   |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                                     | Bisoprolol               |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                                     | Tareg                    |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                                     | Inegy                    |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                                     | Lasilix                  |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                                     | Novonorm                 |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                                     | Chibro Proscar           |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                            | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Dec-2015                                                                                                                         | 11847672                 | EXPEDITED (15-DAY) |                    | OT              | CH-FRI-1000081605    |                      |                 | Female       | CHE            |
| <u>Preferred Term</u>                                                                                                               | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| False Positive Investigation Result; Foetal Exposure During Pregnancy; Foetal Growth Restriction; Hypoglycaemia Neonatal; Petechiae | Escitalopram             |                    |                    | S               | Transplacental       | 10 Mg                |                 | Forest       |                |
|                                                                                                                                     | Tegretol (Carbamazepine) |                    |                    | S               | Transplacental       | Unknown              |                 | Not Reported |                |
|                                                                                                                                     | Zyprexa (Olanzapine)     |                    |                    | S               | Transplacental       | 10 Mg                |                 | Not Reported |                |
|                                                                                                                                     | Zyprexa (Olanzapine)     |                    |                    | S               | Transplacental       | 2.5 Mg               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                            | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Dec-2015                                                                                                                         | 11847682                 | NON-EXPEDITED      |                    |                 | US-SHIRE-US201516489 |                      | 63 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                               | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Headache; Lethargy; Nausea; Prescribed Overdose; Product Use In Unapproved Indication; Somnolence                        | Adderall Xr              |                    |                    | S               | Oral                 | 30 Mg, Unknown       |                 | Shire        |                |
|                                                                                                                                     | Harvoni                  |                    |                    | S               | Unknown              | Unk, Unknown         |                 | Not Reported |                |
|                                                                                                                                     | Bupropion                |                    |                    | S               | Oral                 | 150 Mg, Unknown      |                 | Not Reported |                |
|                                                                                                                                     | Clonazepam               |                    |                    | S               | Oral                 | 1 Mg, Unknown        |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                      |   |         |                 |              |
|----------------------|---|---------|-----------------|--------------|
| Escitalopram         | S | Oral    | 20 Mg, Unknown  | Not Reported |
| Lamotrigine          | S | Oral    | 200 Mg, Unknown | Not Reported |
| Excedrin /00110301/  | C | Unknown | Unk, Unknown    | Not Reported |
| Fiber                | C | Unknown | Unk, Unknown    | Not Reported |
| Gas-X                | C | Unknown | Unk, Unknown    | Not Reported |
| Vitamin D /00107901/ | C | Unknown | Unk, Unknown    | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 17-Dec-2015              | 11847838      | EXPEDITED (15-DAY) |                    | HO, OT          | AT-ASTRAZENECA-2015SE56435 |                      | 56 YR      | Male       | AUT            |

| <u>Preferred Term</u>                           | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Pressure Increased;<br>Delirium; Pruritus | Seroquel            |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                 | Mirtazapine         |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                 | Mirtazapine         |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                 | Mirtazapine         |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                 | Mirtazapine         |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                 | Mirtazapine         |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                 | Mirtazapine         |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                 | Mirtazapine         |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                 | Mirtazapine         |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                 | Dibondrin           |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                 | Cipralex            |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                 | Atarax              |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                 | Temesta (Lorazepam) |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                 | Temesta (Lorazepam) |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                 | Temesta (Lorazepam) |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                 | Temesta (Lorazepam) |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                 | Temesta (Lorazepam) |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                 | Naproxen            |              |            | C           |              |                    |                 | Not Reported |
|                                                 | Pantoloc            |              |            | C           |              |                    |                 | Not Reported |
|                                                 | Seractil            |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                          | Omega 3        |                    | C                  |                 | 1x1, Daily                                     |                                   | Not Reported    |              |                |
|------------------------------------------|----------------|--------------------|--------------------|-----------------|------------------------------------------------|-----------------------------------|-----------------|--------------|----------------|
|                                          | Aqua Tears     |                    | C                  |                 | Once Daily                                     |                                   | Not Reported    |              |                |
| <u>FDA Received Date</u>                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Dec-2015                              | 11611736       | EXPEDITED (15-DAY) |                    | HO, LT          | AT-ASTRAZENECA-2015SE96346                     |                                   | 44 YR           | Female       | AUT            |
| <u>Preferred Term</u>                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |                |
| Overdose; Suicide Attempt                | Seroquel       |                    |                    | S               | Oral                                           | 10 G Seroquel (50 Tablets 200 Mg) |                 | Not Reported |                |
|                                          | Cipralex       |                    |                    | S               | Unknown                                        |                                   |                 | Not Reported |                |
|                                          | Trittico       |                    |                    | S               | Oral                                           | About 20 Tablets Of 150 Mg        |                 | Not Reported |                |
| <u>FDA Received Date</u>                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Dec-2015                              | 11824324       | EXPEDITED (15-DAY) |                    | HO, LT          | IT-MYLANLABS-2015M1043429                      |                                   |                 | Unknown      | ITA            |
| <u>Preferred Term</u>                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Ventricular Fibrillation | Escitalopram   |                    |                    | S               | Oral                                           | 5 Gtt, Qd                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Dec-2015                              | 11830883       | EXPEDITED (15-DAY) |                    | LT              | IT-ACCORD-036304                               |                                   | 66 YR           | Female       | ITA            |
| <u>Preferred Term</u>                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Ventricular Fibrillation | Escitalopram   |                    |                    | S               | Oral                                           |                                   |                 | Accord       |                |
| <u>FDA Received Date</u>                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Dec-2015                              | 11848513       | EXPEDITED (15-DAY) |                    | DE              | US-PAR PHARMACEUTICAL COMPANIES-2015SCPR014758 |                                   | 42 YR           | Female       | USA            |
| <u>Preferred Term</u>                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                   |                      |   |      |                  |              |
|---------------------------------------------------|----------------------|---|------|------------------|--------------|
| Completed Suicide; Death;<br>Poisoning Deliberate | Zolpidem Tartrate Er | S | Oral | Unk Unk, Unknown | Par          |
|                                                   | Diazepam             | S | Oral | Unk Unk, Unknown | Par          |
|                                                   | Metoprolol           | S | Oral | Unk Unk, Unknown | Not Reported |
|                                                   | Oxycodone            | S | Oral | Unk Unk, Unknown | Not Reported |
|                                                   | Escitalopram         | S | Oral | Unk Unk, Unknown | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------------------------------------|----------------------|------------|------------|----------------|
| 18-Dec-2015              | 11848658      | EXPEDITED (15-DAY) |                    | DE              | US-PAR<br>PHARMACEUTICAL<br>COMPANIES-<br>2015SCPR014893 |                      | 53 YR      | Female     | USA            |

| <u>Preferred Term</u>                             | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide; Death;<br>Poisoning Deliberate | Clonazepam           |              |            | S           | Oral         | Unk, Unknown       |                 | Par          |
|                                                   | Duloxetine           |              |            | S           | Oral         | Unk, Unknown       |                 | Not Reported |
|                                                   | Baclofen             |              |            | S           | Oral         | Unk, Unknown       |                 | Not Reported |
|                                                   | Escitalopram         |              |            | S           | Oral         | Unk, Unknown       |                 | Not Reported |
|                                                   | Thyroid Preparations |              |            | S           | Oral         | Unk, Unknown       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------------------------------------|----------------------|------------|------------|----------------|
| 18-Dec-2015              | 11848710      | EXPEDITED (15-DAY) |                    | DE              | US-PAR<br>PHARMACEUTICAL<br>COMPANIES-<br>2015SCPR014897 |                      | 37 YR      | Female     | USA            |

| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide; Death | Clonazepam     |              |            | S           | Oral         | Unk, Unknown       |                 | Par          |
|                          | Beta Blocker   |              |            | S           | Oral         | Unk, Unknown       |                 | Not Reported |
|                          | Lisinopril     |              |            | S           | Oral         | Unk, Unknown       |                 | Not Reported |
|                          | Escitaopram    |              |            | S           | Oral         | Unk, Unknown       |                 | Not Reported |
|                          | Trazodone      |              |            | S           | Oral         | Unk, Unknown       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Dec-2015              | 11851887      | EXPEDITED (15-DAY) |                    | CA, DE          | FR-FRI-1000081670    |                      | 1 DAY      | Female     | FRA            |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                            | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|--------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| Exposure During Pregnancy;<br>Holoprosencephaly  | Escitalopram            |                    |                    | S               | Transplacental             |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Dec-2015                                      | 11853044                | EXPEDITED (15-DAY) |                    | DE              | US-DEP_13242_2015          |                      | 32 YR           | Male         | USA            |
| <u>Preferred Term</u>                            | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Toxicity To Various Agents | Citalopram              |                    |                    | S               |                            | Df                   |                 | Not Reported |                |
|                                                  | Metaxalone              |                    |                    | S               |                            | Df                   |                 | Not Reported |                |
|                                                  | Phenytoin               |                    |                    | S               |                            | Df                   |                 | Not Reported |                |
|                                                  | Indomethacin            |                    |                    | S               |                            | Df                   |                 | Not Reported |                |
|                                                  | Allopurinol             |                    |                    | S               |                            | Df                   |                 | Not Reported |                |
|                                                  | Lamictal                |                    |                    | S               |                            | Df                   |                 | Unknown      |                |
|                                                  | Lexapro                 |                    |                    | S               |                            | Df                   |                 | Unknown      |                |
|                                                  | Altace                  |                    |                    | S               |                            | Df                   |                 | Unknown      |                |
|                                                  | Prilosec                |                    |                    | S               |                            | Df                   |                 | Unknown      |                |
|                                                  | Gabapentin              |                    |                    | S               |                            | Df                   |                 | Not Reported |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Dec-2015                                      | 11855468                | DIRECT             |                    |                 |                            |                      | 62 YR           | Female       | USA            |
| <u>Preferred Term</u>                            | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective; Product<br>Quality Issue       | Escitalopram 10mg Mylan |                    |                    | S               | Oral                       | 8 Tabs               |                 | Mylan        |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Dec-2015                                      | 11854274                | EXPEDITED (15-DAY) |                    | HO              | FR-009507513-1512FRA009294 |                      | 55 YR           | Female       | FRA            |
| <u>Preferred Term</u>                            | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                 |          |   |      |     |              |
|-----------------|----------|---|------|-----|--------------|
| Dermatomyositis | Januvia  | S | Oral | Unk | Merck        |
|                 | Lasilix  | S | Oral | Unk | Not Reported |
|                 | Seroplex | S | Oral | Unk | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 21-Dec-2015              | 11786488      | EXPEDITED (15-DAY) |                    | HO              | IT-PFIZER INC-2015405930 |                      | 84 YR      | Female     | ITA            |

| <u>Preferred Term</u>                       | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------|--------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Disorientation; Drug Abuse; Overdose; Sopor | Alprazolam         |              |            | S           |              | Unk, One Bottle    |                 | Pfizer       |
|                                             | Cardioaspirin      |              |            | S           |              | Unk                |                 | Not Reported |
|                                             | Triatec (Ramipril) |              |            | S           |              | Unk                |                 | Not Reported |
|                                             | Entact             |              |            | S           |              | Unk, One Box       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Dec-2015              | 11827851      | EXPEDITED (15-DAY) |                    | HO, LT          | IT-FRI-1000081424    |                      | 66 YR      | Female     | ITA            |

| <u>Preferred Term</u>                    | <u>Product</u>                                                         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------|------------------------------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiac Arrest; Ventricular Fibrillation | Escitalopram Oral Solution                                             |              |            | S           | Oral         | 5 Gtt              |                 | Forest       |
|                                          | Alpivigor (Food Supplement)/Mg, Guarana, Caffeine, Royal Jelly, Fe, Ar |              |            | C           | Oral         | 1 Vial Per Day     |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------------------------|----------------------|------------|------------|----------------|
| 21-Dec-2015              | 11854409      | EXPEDITED (15-DAY) |                    | DE              | US-PAR PHARMACEUTICAL COMPANIES-2015SCPR014781 |                      | 22 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardio-Respiratory Arrest; Completed Suicide; Death; Poisoning; Poisoning Deliberate | Diazepam       |              |            | S           | Oral         | Unk Unk, Unknown   |                 | Par          |
|                                                                                      | Escitalopram   |              |            | S           | Oral         | Unk, Unknown       |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                           | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                     | <u>503B Facility</u>                         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|----------------------------------------------------------|----------------------------------------------|-----------------|--------------|----------------|
| 21-Dec-2015                                                                        | 11854481                    | EXPEDITED (15-DAY) |                    | HO, OT          | CH-009507513-1512CHE009253                               |                                              | 47 YR           | Female       | CHE            |
| <u>Preferred Term</u>                                                              | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                             | <u>Dosage Text</u>                           | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Coma; Intentional Overdose                                              | Remeron                     |                    |                    | S               | Oral                                                     | 75 Mg, Once                                  |                 | Merck        |                |
|                                                                                    | Quetiapine Fumarate         |                    |                    | S               | Oral                                                     | 125 Mg, Once                                 |                 | Not Reported |                |
|                                                                                    | Escitalopram                |                    |                    | S               | Oral                                                     | 100 Mg, Once                                 |                 | Not Reported |                |
|                                                                                    | Alcohol                     |                    |                    | S               | Oral                                                     | One Glass Of Wine, Once                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                           | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                     | <u>503B Facility</u>                         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Dec-2015                                                                        | 11854953                    | EXPEDITED (15-DAY) |                    | DE              | US-PAR<br>PHARMACEUTICAL<br>COMPANIES-<br>2015SCPR014917 |                                              | 16 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                              | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                             | <u>Dosage Text</u>                           | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardio-Respiratory Arrest; Death; Poisoning Deliberate; Toxicity To Various Agents | Morphine Sulfate            |                    |                    | S               | Oral                                                     | Unk Unk, Unknown                             |                 | Par          |                |
|                                                                                    | Acetaminophen W/Hydrocodone |                    |                    | S               | Oral                                                     | Unk, Unknown                                 |                 | Not Reported |                |
|                                                                                    | Escitalopram                |                    |                    | S               | Oral                                                     | Unk, Unknown                                 |                 | Not Reported |                |
|                                                                                    | Cyclobenzaprine             |                    |                    | S               | Oral                                                     | Unk, Unknown                                 |                 | Not Reported |                |
|                                                                                    | Aripiprazole                |                    |                    | S               | Oral                                                     | Unk, Unknown                                 |                 | Not Reported |                |
|                                                                                    | Drug, Unknown               |                    |                    | S               | Oral                                                     | Unk, Unknown                                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                           | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                     | <u>503B Facility</u>                         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Dec-2015                                                                        | 11856714                    | EXPEDITED (15-DAY) |                    | HO              | SE-FRI-1000081801                                        |                                              | 59 YR           | Female       | SWE            |
| <u>Preferred Term</u>                                                              | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                             | <u>Dosage Text</u>                           | <u>Duration</u> | <u>Mfr</u>   |                |
| Heart Rate Decreased; Intentional Overdose; Nausea; Poisoning                      | Escitalopram                |                    |                    | S               | Unknown                                                  | Overdose: Took 20 Tables A 20 Mg Of CipraleX |                 | Forest       |                |
|                                                                                    | Atenolol                    |                    |                    | S               | Unknown                                                  | Took 14 Tables A 50 Mg Of Atenolol           |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                                 | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------------------------------------|-----------------|--------------|----------------|
| 21-Dec-2015                                                                              | 11856715                      | EXPEDITED (15-DAY) |                    | HO, LT          | FR-FRI-1000081821    |                                                    | 23 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                    | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Overdose;<br>Somnolence; Toxicity To<br>Various Agents                       | Escitalopram                  |                    |                    | S               | Oral                 | Intentional Overdose Of<br>220 Mg Of Escitalopram. |                 | Forest       |                |
|                                                                                          | Escitalopram                  |                    |                    | S               |                      |                                                    |                 | Forest       |                |
|                                                                                          | Lexomil Roche                 |                    |                    | S               | Oral                 | Intentional Overdose Of 30<br>Df Of Bromazepam.    |                 | Not Reported |                |
|                                                                                          | Lexomil Roche                 |                    |                    | S               |                      |                                                    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                 | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Dec-2015                                                                              | 11856813                      | DIRECT             |                    | CA, DE          |                      |                                                    | 34 YR           | Female       |                |
| <u>Preferred Term</u>                                                                    | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Maternal Drugs Affecting<br>Foetus; Maternal<br>Exposure During<br>Pregnancy; Stillbirth | Lexapro                       |                    |                    | S               | Oral                 |                                                    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                 | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Dec-2015                                                                              | 11856949                      | EXPEDITED (15-DAY) |                    | HO, LT          | CH-TEVA-617760ISR    |                                                    | 39 YR           | Female       | CHE            |
| <u>Preferred Term</u>                                                                    | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Hyperhidrosis;<br>Serotonin Syndrome;<br>Tachycardia                          | Fentanyl-Mepha Matrixpflaster |                    |                    | S               | Topical              |                                                    |                 | Cephalon     |                |
|                                                                                          | 50mcg/Hr                      |                    |                    |                 |                      |                                                    |                 |              |                |
|                                                                                          | Ciprallex                     |                    |                    | S               | Oral                 |                                                    |                 | Not Reported |                |
|                                                                                          | Targin                        |                    |                    | C               | Oral                 |                                                    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                 | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Dec-2015                                                                              | 10783009                      | EXPEDITED (15-DAY) |                    | OT              | NO-FRI-1000074346    |                                                    | 19 YR           | Female       | NOR            |
| <u>Preferred Term</u>                                                                    | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                 | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System

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|                                                                     |              |   |         |                  |              |
|---------------------------------------------------------------------|--------------|---|---------|------------------|--------------|
| Facial Spasm; Limb Injury;                                          | Escitalopram | S | Unknown | Unk              | Forest       |
| Loss Of Personal Independence In Daily Activities; Muscle Twitching | Zeldox       | S | Unknown | 80-40 Mg Per Day | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Dec-2015              | 11185436      | EXPEDITED (15-DAY) |                    | HO              | AT-FRI-1000077314    |                      | 87 YR      | Female     | AUT            |

| <u>Preferred Term</u>                   | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------|------------------------|--------------|------------|-------------|--------------|---------------------|-----------------|--------------|
| Decubitus Ulcer;<br>Parkinson'S Disease | Escitalopram           |              |            | S           | Unknown      | 10 Mg               |                 | Forest       |
|                                         | Risperdal              |              |            | S           | Unknown      | 0.5 Mg              |                 | Not Reported |
|                                         | Memantine-Form-Unknown |              |            | C           | Oral         | 20 Mg               |                 | Not Reported |
|                                         | Zoldem                 |              |            | C           | Oral         | 10 Mg               |                 | Not Reported |
|                                         | Akineton Retard        |              |            | C           | Oral         | 2 Mg                |                 | Not Reported |
|                                         | Mirtabene              |              |            | C           | Unknown      | 30 Mg               |                 | Not Reported |
|                                         | Dominal Forte          |              |            | C           | Oral         | 40 Mg               |                 | Not Reported |
|                                         | Exelon                 |              |            | C           | Transdermal  | 9.5 Mg Per 24 Hours |                 | Not Reported |
|                                         | Thrombo Ass            |              |            | C           | Oral         | 50 Mg               |                 | Not Reported |
|                                         | Durotiv                |              |            | C           | Unknown      | 20 Mg               |                 | Not Reported |
|                                         | Cal-D-Vita             |              |            | C           | Unknown      | 1 Tablet            |                 | Not Reported |
|                                         | Cerebokan              |              |            | C           | Oral         | 240 Mg              |                 | Not Reported |
|                                         | Esomep                 |              |            | C           | Unknown      | Unit Dose: 20       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Dec-2015              | 11858169      | NON-EXPEDITED    |                    |                 | US-TEVA-608643USA    |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Rash                  | Trazodone      |              |            | S           | Unknown      |                    |                 | Barr         |
|                       | Escitalopram   |              |            | S           | Unknown      |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                           | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|------------------------------------|----------------------|-----------------|--------------|----------------|
| 22-Dec-2015                                                                                                                        | 11858477                | EXPEDITED (15-DAY) |                    | HO              | PHEH2015US026307                   |                      | 36 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                              | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                       | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Back Pain;<br>Lymphadenopathy; Mania;<br>Multiple Sclerosis; Pain In<br>Extremity; Weight<br>Decreased                    | Gilenya                 |                    |                    | S               | Oral                               | 0.5 Mg, Qd           |                 | Novartis     |                |
|                                                                                                                                    | Lexapro                 |                    |                    | S               | Unknown                            |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                           | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Dec-2015                                                                                                                        | 11858923                | EXPEDITED (15-DAY) |                    | DE              | US-ALVOGEN-2015-<br>ALVOGEN-020454 |                      | 52 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                              | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                       | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Exposure Via Ingestion                                                                                       | Oxycodone               |                    |                    | S               | Unknown                            |                      |                 | Not Reported |                |
|                                                                                                                                    | Trazodone Hydrochloride |                    |                    | S               | Unknown                            |                      |                 | Not Reported |                |
|                                                                                                                                    | Atenolol                |                    |                    | S               | Oral                               |                      |                 | Not Reported |                |
|                                                                                                                                    | Escitalopram            |                    |                    | S               | Oral                               |                      |                 | Not Reported |                |
|                                                                                                                                    | Lamotrigine             |                    |                    | S               | Oral                               |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                           | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Dec-2015                                                                                                                        | 11860894                | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000081796                  |                      | 80 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                              | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                       | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Balance Disorder; Coma;<br>Product Use In<br>Unapproved Indication;<br>Speech Disorder;<br>Syncope; Vertigo; Walking<br>Disability | Escitalopram            |                    |                    | S               | Oral                               | 5 Mg                 |                 | Forest       |                |
|                                                                                                                                    | Lyrica                  |                    |                    | C               | Unknown                            | 25 Mg                |                 | Not Reported |                |
|                                                                                                                                    | Tramadol                |                    |                    | C               | Unknown                            |                      |                 | Not Reported |                |
|                                                                                                                                    | Versatis                |                    |                    | C               | Transdermal                        |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                           | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Dec-2015                                                                                                                        | 11860897                | EXPEDITED (15-DAY) |                    | DE              | FR-FRI-1000081830                  |                      | 87 YR           | Female       | FRA            |

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| <u>Preferred Term</u> | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Coma; Hypoglycaemia   | Escitalopram           |              |            | S           | Oral         | 5 Mg               |                 | Forest       |
|                       | Tramadol Base          |              |            | S           | Oral         | 100 Mg             |                 | Not Reported |
|                       | Glimepiride            |              |            | S           | Oral         | 1 Mg               |                 | Not Reported |
|                       | Previscan (Fluindione) |              |            | C           |              |                    |                 | Not Reported |
|                       | Movicol                |              |            | C           |              |                    |                 | Not Reported |
|                       | Sotalax                |              |            | C           |              |                    |                 | Not Reported |
|                       | Propylex               |              |            | C           |              |                    |                 | Not Reported |
|                       | Discotrine             |              |            | C           |              |                    |                 | Not Reported |
|                       | Clopidogrel            |              |            | C           |              |                    |                 | Not Reported |
|                       | Coversyl               |              |            | C           |              |                    |                 | Not Reported |
|                       | Crestor                |              |            | C           |              |                    |                 | Not Reported |
|                       | Fumafer                |              |            | C           |              |                    |                 | Not Reported |
|                       | Furosemide             |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 22-Dec-2015              | 11861503      | EXPEDITED (15-DAY) |                    | DE, HO, OT      | CH-JNJFOC-20151217801 |                      | 59 YR      | Female     | CHE            |

| <u>Preferred Term</u>                               | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------|-------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Decreased Appetite; Nausea; Transaminases Increased | Xarelto           |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                     | Xarelto           |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                     | Remeron           |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                     | Cipralex          |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                     | Pantoprazole      |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                     | Lorazepam         |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                     | Metamizole Sodium |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                     | Lisinopril        |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                     | Metoclopramide    |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                     | Torasemid         |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                     | Nebivolol         |              |            | C           | Oral         |                    |                 | Not Reported |

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| <u>FDA Received Date</u>                             | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|--------------------------------|-----------------------------------|-----------------|--------------|----------------|
| 23-Dec-2015                                          | 11862593                | EXPEDITED (15-DAY) |                    | DE              | US-ALVOGEN-2015-ALVOGEN-020372 |                                   | 37 YR           | Female       | USA            |
| <u>Preferred Term</u>                                | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                    | Lisinopril              |                    |                    | S               | Oral                           |                                   |                 | Not Reported |                |
|                                                      | Atenolol                |                    |                    | S               | Oral                           |                                   |                 | Not Reported |                |
|                                                      | Trazodone Hydrochloride |                    |                    | S               |                                |                                   |                 | Not Reported |                |
|                                                      | Escitalopram            |                    |                    | S               | Oral                           |                                   |                 | Not Reported |                |
|                                                      | Clonazepam              |                    |                    | S               | Oral                           |                                   |                 | Not Reported |                |
| <u>FDA Received Date</u>                             | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Dec-2015                                          | 11863841                | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000081826              |                                   | 88 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyperkalaemia; Hyponatraemia; Renal Failure          | Escitalopram            |                    |                    | S               | Oral                           |                                   |                 | Forest       |                |
|                                                      | Lasilix                 |                    |                    | S               | Oral                           |                                   |                 | Not Reported |                |
|                                                      | Inspira                 |                    |                    | S               | Oral                           |                                   |                 | Not Reported |                |
|                                                      | Tavanic                 |                    |                    | S               | Oral                           |                                   |                 | Not Reported |                |
|                                                      | Triatec (Ramipril)      |                    |                    | S               | Oral                           |                                   |                 | Not Reported |                |
|                                                      | Previscan (Fluindione)  |                    |                    | C               | Unknown                        |                                   |                 | Not Reported |                |
|                                                      | Mediatensyl             |                    |                    | C               | Unknown                        |                                   |                 | Not Reported |                |
| <u>FDA Received Date</u>                             | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Dec-2015                                          | 11865271                | EXPEDITED (15-DAY) |                    | HO, OT          | FR-PFIZER INC-2015454470       |                                   | 39 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |                |
| Malaise; Suicide Attempt; Toxicity To Various Agents | Xanax                   |                    |                    | S               | Oral                           | 0.5 Mg, 4 Dosage Forms (Df) A Day |                 | Pfizer       |                |
|                                                      | Xanax                   |                    |                    | S               | Oral                           | Unk, Single                       |                 | Pfizer       |                |
|                                                      | Xanax                   |                    |                    | S               | Oral                           | Unk                               |                 | Pfizer       |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |          |   |      |                            |              |
|--|----------|---|------|----------------------------|--------------|
|  | Tercian  | S | Oral | 25 Mg 1 Df Daily (Evening) | Not Reported |
|  | Tercian  | S | Oral | Unk; Single Dose           | Not Reported |
|  | Tercian  | S | Oral | Unk                        | Not Reported |
|  | Seroplex | S | Oral | 20 Mg 1 Df Daily (Morning) | Not Reported |
|  | Seroplex | S | Oral | Unk Single Dose            | Not Reported |
|  | Seroplex | S | Oral | Unk                        | Not Reported |
|  | Imovane  | S | Oral | 1 Df Daily (At Bedtime)    | Not Reported |
|  | Imovane  | S | Oral | Unk, Single                | Not Reported |
|  | Imovane  | S | Oral | Unk                        | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|---------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
| 23-Dec-2015              | 11865581            | EXPEDITED (15-DAY) |                    | OT              | ES-MYLANLABS-2015M1046622 |                      |                 | Unknown      | ESP            |
| <u>Preferred Term</u>    | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blindness; Glaucoma      | Quetiapine          |                    |                    | S               | Oral                      | 100mg                |                 | Not Reported |                |
|                          | Escitalopram        |                    |                    | S               | Unknown                   |                      |                 | Not Reported |                |
|                          | Pantoprazole        |                    |                    | S               | Unknown                   |                      |                 | Not Reported |                |
|                          | Irbesartan          |                    |                    | S               | Unknown                   |                      |                 | Not Reported |                |
|                          | Gemfibrozil         |                    |                    | S               | Unknown                   |                      |                 | Not Reported |                |
|                          | Hydrochlorothiazide |                    |                    | S               | Unknown                   |                      |                 | Not Reported |                |
|                          | Ropinirole          |                    |                    | C               | Unknown                   |                      |                 | Mylan        |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 23-Dec-2015              | 11865846       | EXPEDITED (15-DAY) |                    | OT              | JP-SA-2015SA216953   |                      | 18 YR           | Female       | JPN            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Deafness                 | Myslee         |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                          | Lexapro        |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                          | Nauzelin       |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                          | Gasmotin       |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|---------------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|-----------------|--------------|----------------|
| 24-Dec-2015              | 11866452            | EXPEDITED (15-DAY) |                    | DE              | US-ALVOGEN-2015-ALVOGEN-020462 |                      | 42 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide        | Oxycodone           |                    |                    | S               | Oral                           |                      |                 | Not Reported |                |
|                          | Metoprolol          |                    |                    | S               | Oral                           |                      |                 | Not Reported |                |
|                          | Zolpidem            |                    |                    | S               | Oral                           |                      |                 | Not Reported |                |
|                          | Escitalopram        |                    |                    | S               | Oral                           |                      |                 | Not Reported |                |
|                          | Diazepam            |                    |                    | S               | Oral                           |                      |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Dec-2015              | 11866738            | EXPEDITED (15-DAY) |                    | OT              | ES-APOTEX-2015AP015455         |                      | 71 YR           | Male         | ESP            |
| <u>Preferred Term</u>    | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Acute Psychosis          | Olanzapine          |                    |                    | S               | Oral                           | Unk                  |                 | Apotex       |                |
|                          | Escitalopram Apotex |                    |                    | S               | Unknown                        | Unk                  |                 | Apotex       |                |
|                          | Trazodone           |                    |                    | S               | Unknown                        | Unk                  |                 | Not Reported |                |
|                          | Levodopa/Carbidopa  |                    |                    | S               | Unknown                        | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Dec-2015              | 11866823            | EXPEDITED (15-DAY) |                    | OT              | ES-APOTEX-2015AP015457         |                      | 67 YR           | Female       | ESP            |
| <u>Preferred Term</u>    | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blindness; Glaucoma      | Quetiapine          |                    |                    | S               | Oral                           | 100 Mg, Unk          |                 | Apotex       |                |
|                          | Pantoprazole        |                    |                    | S               | Unknown                        |                      |                 | Apotex       |                |
|                          | Escitalopram        |                    |                    | S               | Unknown                        |                      |                 | Not Reported |                |
|                          | Hydrochlorothiazide |                    |                    | S               | Unknown                        |                      |                 | Not Reported |                |
|                          | Gemfibrozil         |                    |                    | S               | Unknown                        |                      |                 | Not Reported |                |
|                          | Irbesartan          |                    |                    | S               | Unknown                        |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                   |                      |                    |                    |                 |                          |                      |                 |              |                |
|---------------------------------------------------|----------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| Ropinirole                                        |                      |                    | C                  |                 | Unknown                  |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                          | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Dec-2015                                       | 11867191             | EXPEDITED (15-DAY) |                    | DE, HO          | FR-JNJFOC-20151215498    |                      | 85 YR           | Male         | FRA            |
| <u>Preferred Term</u>                             | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Serotonin Syndrome                                | Risperdal            |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                                                   | Seroplex             |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                                                   | Seroplex             |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                                                   | Seroplex             |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                                                   | Tramadol             |                    |                    | S               | Unknown                  |                      |                 | Not Reported |                |
|                                                   | Paracetamol          |                    |                    | C               |                          |                      |                 | Not Reported |                |
|                                                   | Macrogol 3350        |                    |                    | C               | Unknown                  |                      |                 | Not Reported |                |
|                                                   | Bisoprolol           |                    |                    | C               | Unknown                  |                      |                 | Not Reported |                |
|                                                   | Perindopril          |                    |                    | C               | Unknown                  |                      |                 | Not Reported |                |
|                                                   | Kardegic             |                    |                    | C               | Unknown                  |                      |                 | Not Reported |                |
|                                                   | Tahor                |                    |                    | C               | Unknown                  |                      |                 | Not Reported |                |
|                                                   | Inexium              |                    |                    | C               | Unknown                  |                      |                 | Not Reported |                |
|                                                   | Seresta              |                    |                    | C               | Unknown                  | A Half Tablet A Day. |                 | Not Reported |                |
| <u>FDA Received Date</u>                          | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Dec-2015                                       | 11868373             | EXPEDITED (15-DAY) |                    | HO              | FR-PFIZER INC-2015451565 |                      |                 | Female       | FRA            |
| <u>Preferred Term</u>                             | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyperkalaemia;<br>Hyponatraemia; Renal<br>Failure | Inspra               |                    |                    | S               | Oral                     | Unk                  |                 | Pfizer       |                |
|                                                   | Triatec (Ramipril)   |                    |                    | S               | Oral                     | Unk                  |                 | Pfizer       |                |
|                                                   | Lasilix /00032601/   |                    |                    | S               | Oral                     | Unk                  |                 | Not Reported |                |
|                                                   | Tavanic              |                    |                    | S               | Oral                     | Unk                  |                 | Not Reported |                |
|                                                   | Seroplex             |                    |                    | S               | Oral                     | Unk                  |                 | Not Reported |                |
|                                                   | Previscan /00789001/ |                    |                    | C               |                          |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                    |                         |                    |                    |                 |                                    |                      |                 |              |                |
|------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|------------------------------------|----------------------|-----------------|--------------|----------------|
| Mediatusyl /00631801/                                                              |                         |                    | C                  |                 |                                    | Not Reported         |                 |              |                |
| <u>FDA Received Date</u>                                                           | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Dec-2015                                                                        | 11871009                | DIRECT             | Y                  | OT              |                                    |                      | 50 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                              | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                       | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Nausea; Palpitations                                                               | Lexapro                 |                    |                    | S               |                                    | Anxiety              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                           | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Dec-2015                                                                        | 11871104                | DIRECT             | Y                  | HO              |                                    |                      | 37 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                              | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                       | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Agitation;<br>Psychotic Disorder;<br>Serotonin Syndrome                | Escitalopram            |                    |                    | S               | Oral                               |                      |                 | Not Reported |                |
|                                                                                    | Clonazepam              |                    |                    | C               |                                    |                      |                 | Not Reported |                |
|                                                                                    | Quetiapine              |                    |                    | C               |                                    |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                           | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Dec-2015                                                                        | 11869170                | EXPEDITED (15-DAY) |                    | HO              | US-ACCORD-036441                   |                      | 51 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                              | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                       | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dehydration; Diarrhoea;<br>Malaise; Pancreatitis;<br>Vomiting; Weight<br>Decreased | Escitalopram            |                    |                    | S               | Oral                               |                      |                 | Accord       |                |
|                                                                                    | Synthroid               |                    |                    | C               |                                    |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                           | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Dec-2015                                                                        | 11869843                | EXPEDITED (15-DAY) |                    | DE              | US-ALVOGEN-2015-<br>ALVOGEN-020509 |                      | 34 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                              | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                       | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Death; Exposure Via<br>Ingestion                                                   | Oxycodone               |                    |                    | S               | Unknown                            |                      |                 | Not Reported |                |
|                                                                                    | Trazodone Hydrochloride |                    |                    | S               | Unknown                            |                      |                 | Not Reported |                |
|                                                                                    | Oxycodone               |                    |                    | S               | Oral                               |                      |                 | Not Reported |                |

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|                         |   |      |              |
|-------------------------|---|------|--------------|
| Alprazolam              | S | Oral | Not Reported |
| Trazodone Hydrochloride | S | Oral | Not Reported |
| Gabapentin              | S | Oral | Not Reported |
| Escitalopram            | S | Oral | Not Reported |
| Oxymorphone             | S | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Dec-2015              | 11871712      | EXPEDITED (15-DAY) |                    | DE              | US-NSR_02299_2015    |                      | 32 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide; Loss Of Consciousness; Overdose; Toxicity To Various Agents | Allopurinol    |              |            | S           |              | Df                 |                 | Not Reported |
|                                                                                | Prilosec       |              |            | S           |              | Df                 |                 | Unknown      |
|                                                                                | Lexapro        |              |            | S           |              | Df                 |                 | Unknown      |
|                                                                                | Altace         |              |            | S           |              | Df                 |                 | Unknown      |
|                                                                                | Gabapentin     |              |            | S           |              | Df                 |                 | Not Reported |
|                                                                                | Indomethacin   |              |            | S           |              | Df                 |                 | Not Reported |
|                                                                                | Skelaxin       |              |            | S           |              | Df                 |                 | Unknown      |
|                                                                                | Citalopram     |              |            | S           |              | Df                 |                 | Not Reported |
|                                                                                | Phenytoin      |              |            | S           |              | Df                 |                 | Not Reported |
|                                                                                | Lamictal       |              |            | S           |              | Df                 |                 | Unknown      |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 28-Dec-2015              | 11872486      | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-2015467333 |                      | 19 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>                       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|--------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Suicide Attempt       | Desvenlafaxine Succinate Monohydrate |              |            | S           |              | Unk, 1x/Day        |                 | Pfizer       |
|                       | Cymbalta                             |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Viibryd                              |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Lexapro                              |              |            | S           |              | Unk                |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------|----------------|--------------------|--------------------|-----------------|------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 29-Dec-2015                              | 11734630       | EXPEDITED (15-DAY) |                    | DE, OT          | CA-FRI-1000080852                              |                      | 65 YR           | Male         | CAN            |
| <u>Preferred Term</u>                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                        | Citalopram     |                    |                    | S               | Oral                                           | 10 Mg                |                 | Forest       |                |
|                                          | Escitalopram   |                    |                    | S               | Oral                                           |                      |                 | Forest       |                |
|                                          | Clonazepam     |                    |                    | C               | Oral                                           |                      |                 | Not Reported |                |
|                                          | Flomax         |                    |                    | C               |                                                |                      |                 | Not Reported |                |
|                                          | Crestor        |                    |                    | C               |                                                |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Dec-2015                              | 11775029       | EXPEDITED (15-DAY) |                    | DE              | GB-TEVA-609795ACC                              |                      | 51 YR           | Male         | GBR            |
| <u>Preferred Term</u>                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                        | Escitalopram   |                    |                    | S               | Oral                                           |                      |                 | Ivax         |                |
|                                          | Mirtazapine    |                    |                    | C               |                                                |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Dec-2015                              | 11874204       | NON-EXPEDITED      |                    |                 | CA-LUPIN<br>PHARMACEUTICALS<br>INC.-2015-02878 |                      | 71 YR           | Male         | CAN            |
| <u>Preferred Term</u>                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Erectile Dysfunction;<br>Libido Disorder | Escitalopram   |                    |                    | S               | Unknown                                        | 20mg                 |                 | Not Reported |                |
|                                          | Pregabalin     |                    |                    | S               | Unknown                                        | 150mg                |                 | Not Reported |                |
|                                          | Pregabalin     |                    |                    | S               | Unknown                                        | 50mg                 |                 | Not Reported |                |
|                                          | Ramipril       |                    |                    | C               | Unknown                                        | 5mg                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Dec-2015                              | 11874212       | NON-EXPEDITED      |                    |                 | IN-LUPIN<br>PHARMACEUTICALS<br>INC.-2015-03265 |                      | 71 YR           | Female       | IND            |
| <u>Preferred Term</u>                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                   |              |   |         |         |              |
|-------------------|--------------|---|---------|---------|--------------|
| Oedema Peripheral | Escitalopram | S | Unknown | 10 Mg   | Not Reported |
|                   | Clonazepam   | C | Unknown | 0.75 Mg | Not Reported |
|                   | Clonazepam   | C | Unknown | 0.5 Mg  | Not Reported |
|                   | Warfarin     | C | Unknown |         | Not Reported |
|                   | Warfarin     | C |         |         | Not Reported |
|                   | Bisoprolol   | C | Unknown |         | Not Reported |
|                   | Bisoprolol   | C |         |         | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------------------------|----------------------|------------|------------|----------------|
| 29-Dec-2015              | 11874219      | NON-EXPEDITED    |                    | OT              | TR-LUPIN<br>PHARMACEUTICALS<br>INC.-2015-03305 |                      | 4 YR       | Male       | TUR            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Seizure               | Escitalopram   |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Valproate      |              |            | C           | Unknown      |                    |                 | Not Reported |
|                       | Valproate      |              |            | C           | Unknown      |                    |                 | Not Reported |
|                       | Acth           |              |            | C           | Unknown      |                    |                 | Not Reported |
|                       | Topiramate     |              |            | C           | Unknown      |                    |                 | Not Reported |
|                       | Topiramate     |              |            | C           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------------------------|----------------------|------------|------------|----------------|
| 29-Dec-2015              | 11874239      | NON-EXPEDITED    |                    |                 | US-LUPIN<br>PHARMACEUTICALS<br>INC.-2015-03817 |                      |            | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Headache; Pain In Jaw | Escitalopram   |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Escitalopram   |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Sertraline     |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Pramipexole    |              |            | C           | Unknown      |                    |                 | Not Reported |
|                       | Bupropion      |              |            | C           | Unknown      |                    |                 | Not Reported |
|                       | Bupropion      |              |            | C           | Unknown      |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|---------------------|--------------------|--------------------|-----------------|------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 29-Dec-2015              | 11874240            | NON-EXPEDITED      |                    |                 | IT-LUPIN<br>PHARMACEUTICALS<br>INC.-2015-03869 |                      | 81 YR           | Male         | ITA            |
| <u>Preferred Term</u>    | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Telangiectasia           | Escitalopram        |                    |                    | S               | Unknown                                        |                      |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Dec-2015              | 11875885            | EXPEDITED (15-DAY) |                    | HO              | FR-SA-2015SA217259                             |                      | 55 YR           | Female       | FRA            |
| <u>Preferred Term</u>    | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dermatomyositis          | Lasilix             |                    |                    | S               | Oral                                           |                      |                 | Not Reported |                |
|                          | Januvia             |                    |                    | S               | Oral                                           |                      |                 | Not Reported |                |
|                          | Seroplex            |                    |                    | S               | Oral                                           |                      |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Dec-2015              | 11876211            | EXPEDITED (15-DAY) |                    | OT              | ES-TEVA-621387ISR                              |                      | 67 YR           | Female       | ESP            |
| <u>Preferred Term</u>    | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blindness; Glaucoma      | Quetiapine          |                    |                    | S               | Oral                                           | 100mg                |                 | Teva         |                |
|                          | Escitalopram        |                    |                    | S               | Unknown                                        |                      |                 | Ivax         |                |
|                          | Pantoprazole        |                    |                    | S               | Unknown                                        |                      |                 | Teva         |                |
|                          | Irbesartan          |                    |                    | S               | Unknown                                        |                      |                 | Teva         |                |
|                          | Gemfibrozil         |                    |                    | S               | Unknown                                        |                      |                 | Not Reported |                |
|                          | Hydrochlorothiazide |                    |                    | S               | Unknown                                        |                      |                 | Not Reported |                |
|                          | Ropinirole          |                    |                    | C               | Unknown                                        |                      |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Dec-2015              | 11876536            | EXPEDITED (15-DAY) |                    | OT              | FR-JNJFOC-<br>20151219889                      |                      | 56 YR           | Female       | FRA            |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                  | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
|--------------------------------------------------------|--------------------------------------|--------------------|--------------------|-----------------|------------------------------------------|----------------------|-----------------|----------------------|----------------|
| Deep Vein Thrombosis                                   | Risperdal                            |                    |                    | S               | Unknown                                  |                      |                 | Not Reported         |                |
|                                                        | Escitalopram                         |                    |                    | S               | Unknown                                  |                      |                 | Not Reported         |                |
|                                                        | Colprone                             |                    |                    | C               | Unknown                                  |                      |                 | Not Reported         |                |
| <u>FDA Received Date</u>                               | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 29-Dec-2015                                            | 11876936                             | EXPEDITED (15-DAY) |                    | DE              | US-MALLINCKRODT-T201505784               |                      | 16 YR           | Male                 | USA            |
| <u>Preferred Term</u>                                  | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Intentional Product Use Issue                          | Morphine                             |                    |                    | S               | Oral                                     | Unk                  |                 | Mallinckrodt         |                |
|                                                        | Acetaminophen\Hydrocodone Bitartrate |                    |                    | S               | Oral                                     | Unk                  |                 | Mallinckrodt         |                |
|                                                        | Escitalopram                         |                    |                    | S               | Oral                                     | Unk                  |                 | Not Reported         |                |
|                                                        | Cyclobenzaprine                      |                    |                    | S               | Oral                                     | Unk                  |                 | Not Reported         |                |
|                                                        | Aripiprazole                         |                    |                    | S               | Oral                                     | Unk                  |                 | Not Reported         |                |
| <u>FDA Received Date</u>                               | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 30-Dec-2015                                            | 6884855                              | NON-EXPEDITED      |                    |                 | US-BRISTOL-MYERS SQUIBB COMPANY-14390819 |                      |                 | Male                 | USA            |
| <u>Preferred Term</u>                                  | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Foetal Exposure During Pregnancy; Large For Dates Baby | Abilify                              |                    |                    | S               | Transplacental                           | 10 Mg, Qd            |                 | Bristol Myers Squibb |                |
|                                                        | Lexapro                              |                    |                    | S               | Transplacental                           | 20 Mg, Qd            |                 | Not Reported         |                |
|                                                        | Tylenol                              |                    |                    | C               | Transplacental                           | Unk Unk, Prn         |                 | Not Reported         |                |
|                                                        | Proventil Inhaler                    |                    |                    | C               | Transplacental                           | Unk Unk, Prn         |                 | Not Reported         |                |
|                                                        | Prenatal Vitamin                     |                    |                    | C               | Transplacental                           | Unk                  |                 | Not Reported         |                |
| <u>FDA Received Date</u>                               | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 30-Dec-2015                                            | 10868697                             | EXPEDITED (15-DAY) |                    | DE, HO          | FR-PFIZER INC-2015067198                 |                      | 76 YR           | Female               | FRA            |
| <u>Preferred Term</u>                                  | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                   |            |   |              |                              |              |
|-------------------|------------|---|--------------|------------------------------|--------------|
| Fall; Head Injury | Aldactone  | S | Oral         |                              | Pfizer       |
|                   | Avlocardyl | S |              | 10 Mg, 3x/Day                | Pfizer       |
|                   | Lantus     | S | Subcutaneous | 10 Iu, 1x/Day In The Evening | Not Reported |
|                   | Humalog    | S | Subcutaneous | 6 Iu, 2x/Day                 | Not Reported |
|                   | Seroplex   | S | Oral         | 10 Mg, 1x/Day                | Not Reported |
|                   | Heptaminol | C | Oral         | 1 Df, 3x/Day                 | Not Reported |
|                   | Gaviscon   | C | Oral         | 1 Df, Daily                  | Not Reported |
|                   | Duphalac   | C | Oral         | 1 Df, 3x/Day                 | Not Reported |
|                   | Dafalgan   | C | Oral         | 500 Mg, 3x/Day               | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Dec-2015              | 10873630      | EXPEDITED (15-DAY) |                    | DE, HO          | FR-SA-2015SA022450   |                      | 76 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Fall                  | Lantus         |              |            | S           | Subcutaneous |                    |                 | Not Reported |
|                       | Lantus         |              |            | S           | Subcutaneous |                    |                 | Not Reported |
|                       | Avlocardyl     |              |            | S           | Unknown      | Strength: 40 Mg    |                 | Not Reported |
|                       | Humalog        |              |            | S           | Subcutaneous |                    |                 | Not Reported |
|                       | Seroplex       |              |            | S           | Oral         | Strength: 10 Mg    |                 | Not Reported |
|                       | Aldactone      |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Heptaminol     |              |            | C           | Oral         |                    |                 | Not Reported |
|                       | Gaviscon       |              |            | C           | Oral         |                    |                 | Not Reported |
|                       | Duphalac       |              |            | C           | Oral         |                    |                 | Not Reported |
|                       | Dafalgan       |              |            | C           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 30-Dec-2015              | 11633113      | EXPEDITED (15-DAY) |                    | HO              | FR-PFIZER INC-2015338533 |                      | 95 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                             |            |   |      |                  |              |
|---------------------------------------------|------------|---|------|------------------|--------------|
| Abnormal Behaviour;<br>Hallucination; Mania | Xanax      | S |      | 0.25 Mg, 1x/Day  | Pfizer       |
|                                             | Xanax      | S |      | 0.125 Mg, 1x/Day | Pfizer       |
|                                             | Seroplex   | S | Oral | 10 Mg, Daily     | Not Reported |
|                                             | Seroplex   | S | Oral | 20 Mg, Daily     | Not Reported |
|                                             | Imovane    | S | Oral | 7.5 Mg, Daily    | Not Reported |
|                                             | Imovane    | S | Oral | 3.75 Mg, Daily   | Not Reported |
|                                             | Risperdal  | S | Oral | 0.25 Ml, 2x/Day  | Not Reported |
|                                             | Monuril    | C |      | Unk              | Not Reported |
|                                             | Cardensiel | C |      | Unk              | Not Reported |
|                                             | Hyperium   | C |      | Unk              | Not Reported |
|                                             | Lercan     | C |      | Unk              | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 30-Dec-2015              | 11727794       | EXPEDITED (15-DAY) |                    |                 | BR-PFIZER INC-2015384003 |                      | 13 YR           | Female       | BRA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Product Use Issue        | Lexapro        |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                          | Tegretol       |                    |                    | C               |                          | 1 Tablet, 2x/Day     |                 | Not Reported |                |

| <u>FDA Received Date</u>                                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|-------------------------------------|-----------------|--------------|----------------|
| 30-Dec-2015                                               | 11777755       | EXPEDITED (15-DAY) |                    | OT              | CH-TEVA-610945ISR    |                                     | 46 YR           | Female       | CHE            |
| <u>Preferred Term</u>                                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Creatinine Decreased; C-Reactive Protein Increased; | Escitalopram   |                    |                    | S               | Unknown              | 20 Milligram Daily;                 |                 | Ivax         |                |
| Conduction Disorder; Drug Interaction;                    | Olanzapine     |                    |                    | S               | Unknown              | 12.5 Milligram Daily;               |                 | Teva         |                |
| Hyponatraemia                                             | Pantoprazole   |                    |                    | S               | Unknown              | 40 Milligram Daily;                 |                 | Teva         |                |
|                                                           | Valproic Acid  |                    |                    | C               | Unknown              | 1000 Milligram Daily;               |                 | Not Reported |                |
|                                                           | Levothyroxine  |                    |                    | C               | Unknown              | .125 Milligram Daily;               |                 | Not Reported |                |
|                                                           | Vitamin D3     |                    |                    | C               | Unknown              | 1000 Iu (International Unit) Daily; |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Dec-2015              | 11860893      | EXPEDITED (15-DAY) |                    | OT              | JP-FRI-1000081817    |                      | 70 YR      | Female     | JPN            |

| <u>Preferred Term</u>                                     | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Condition Aggravated; Depressive Symptom; Tremor | Lexapro                 |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                                           | Dopacal                 |              |            | S           | Oral         | 200 Mg             |                 | Not Reported |
|                                                           | Flunitrazepam           |              |            | C           | Oral         | Unknown            |                 | Not Reported |
|                                                           | Rebamipide              |              |            | C           | Oral         | Unknown            |                 | Not Reported |
|                                                           | Amlodipine              |              |            | C           | Oral         | Unknown            |                 | Not Reported |
|                                                           | Etizolam                |              |            | C           | Oral         | Unknown            |                 | Not Reported |
|                                                           | Verapamil Hydrochloride |              |            | C           | Oral         | Unknown            |                 | Not Reported |
|                                                           | Magmitt                 |              |            | C           | Oral         | Unknown            |                 | Not Reported |
|                                                           | Famotidine              |              |            | C           | Oral         | Unknown            |                 | Not Reported |
|                                                           | Tasmolin                |              |            | C           | Oral         | Unknown            |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------------------------|----------------------|------------|------------|----------------|
| 30-Dec-2015              | 11877708      | NON-EXPEDITED    |                    | OT              | US-LUPIN<br>PHARMACEUTICALS<br>INC.-2015-02966 |                      | 78 YR      | Male       | USA            |

| <u>Preferred Term</u>                  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Insomnia; Nausea; Torticollis | Citalopram     |              |            | S           | Unknown      | 10mg               |                 | Not Reported |
|                                        | Escitalopram   |              |            | S           | Unknown      | 5mg                |                 | Not Reported |
|                                        | Escitalopram   |              |            | S           | Unknown      | 10mg               |                 | Not Reported |
|                                        | Escitalopram   |              |            | S           | Unknown      | 15mg               |                 | Not Reported |
|                                        | Clonazepam     |              |            | C           | Unknown      | 0.25mg             |                 | Not Reported |
|                                        | Clonazepam     |              |            | C           | Unknown      | 0.25-0.5mg         |                 | Not Reported |
|                                        | Ibuprofen      |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                        | Amlodipine     |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                        | Celecoxib      |              |            | C           | Unknown      |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|            |   |         |              |
|------------|---|---------|--------------|
| Tamsulosin | C | Unknown | Not Reported |
| Omeprazole | C | Unknown | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------------------------|----------------------|------------|------------|----------------|
| 30-Dec-2015              | 11877709      | NON-EXPEDITED    |                    |                 | TR-LUPIN<br>PHARMACEUTICALS<br>INC.-2015-03284 |                      | 21 YR      | Female     | TUR            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Vaginal Haemorrhage   | Escitalopram   |              |            | S           | Unknown      | 5mg                |                 | Not Reported |
|                       | Escitalopram   |              |            | S           | Unknown      | 10mg               |                 | Not Reported |
|                       | Escitalopram   |              |            | S           | Unknown      | 5mg                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------------------------|----------------------|------------|------------|----------------|
| 30-Dec-2015              | 11877738      | NON-EXPEDITED    |                    |                 | KP-LUPIN<br>PHARMACEUTICALS<br>INC.-2015-03288 |                      | 24 YR      | Male       | PRK            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Ineffective      | Escitalopram   |              |            | S           | Unknown      | 40 Mg              |                 | Not Reported |
|                       | Valproic Acid  |              |            | S           | Unknown      | 250 Mg             |                 | Not Reported |
|                       | Alprazolam     |              |            | S           | Unknown      | 0.25 Mg            |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------------------------|----------------------|------------|------------|----------------|
| 30-Dec-2015              | 11877741      | NON-EXPEDITED    |                    |                 | KP-LUPIN<br>PHARMACEUTICALS<br>INC.-2015-03289 |                      | 29 YR      | Male       | PRK            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Ineffective      | Escitalopram   |              |            | S           | Unknown      | 30 Mg              |                 | Not Reported |
|                       | Fluoxetine     |              |            | S           | Unknown      | 80 Mg              |                 | Not Reported |
|                       | Buspirone      |              |            | S           | Unknown      | 40 Mg              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>        | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-----------------------------|----------------------|------------|------------|----------------|
| 30-Dec-2015              | 11877742      | NON-EXPEDITED    |                    | HO              | JP-LUPIN<br>PHARMACEUTICALS |                      | 78 YR      | Female     | JPN            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

INC.-2015-03307

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Serotonin Syndrome    | Escitalopram   |              |            | S           | Unknown      | 10mg               |                 | Not Reported |
|                       | Escitalopram   |              |            | S           | Unknown      | 10mg               |                 | Not Reported |
|                       | Mirtazapine    |              |            | C           | Unknown      | 30mg               |                 | Not Reported |
|                       | Nitrazepam     |              |            | C           | Unknown      | 5mg                |                 | Not Reported |
|                       | Risperidone    |              |            | C           | Unknown      | 1mg                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Dec-2015              | 11878972      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000081888    |                      | 55 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Dermatomyositis       | Escitalopram   |              |            | S           | Oral         |                    |                 | Forest       |
|                       | Januvia        |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Lasilix        |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Dec-2015              | 11879906      | EXPEDITED (15-DAY) |                    | CA              | FR-FRI-1000081827    |                      | < 1 DAY    | Female     | FRA            |

| <u>Preferred Term</u>                                                        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Exposure During Pregnancy; Spine Malformation; Talipes; Urinary Incontinence | Escitalopram   |              |            | S           | Transplacental | 20 Mg              |                 | Forest       |
|                                                                              | Escitalopram   |              |            | S           | Transplacental | 10 Mg              |                 | Forest       |
|                                                                              | Seresta        |              |            | S           | Transplacental |                    |                 | Not Reported |
|                                                                              | Omeprazole     |              |            | S           | Transplacental |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Dec-2015              | 11880240      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000081909    |                      | 57 YR      | Male       | FRA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                            | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cerebral Haemorrhage;<br>Drug Interaction; Subdural<br>Haematoma | Escitalopram           |              |            | S           | Oral         | 20 Mg              |                 | Forest       |
|                                                                  | Previscan (Fluindione) |              |            | S           | Oral         | 12.8571 Mg         |                 | Not Reported |
|                                                                  | Esomeprazole           |              |            | C           | Oral         | 20 Mg              |                 | Not Reported |
|                                                                  | Bisoprolol             |              |            | C           | Oral         | 5 Mg               |                 | Not Reported |
|                                                                  | Furosemide             |              |            | C           | Oral         | 40 Mg              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Dec-2015              | 11880695      | EXPEDITED (15-DAY) |                    | DE              | FR-FRI-1000081926    |                      | 85 YR      | Male       | FRA            |

| <u>Preferred Term</u>                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------|----------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Drug Interaction;<br>Serotonin Syndrome | Escitalopram   |              |            | S           | Oral         |                               |                 | Forest       |
|                                         | Escitalopram   |              |            | S           | Oral         |                               |                 | Forest       |
|                                         | Risperdal      |              |            | S           |              |                               |                 | Not Reported |
|                                         | Tramadol Base  |              |            | S           | Oral         |                               |                 | Not Reported |
|                                         | Bisoprolol     |              |            | C           |              | 1.25 Mg                       |                 | Not Reported |
|                                         | Perindopril    |              |            | C           |              | 4 Mg                          |                 | Not Reported |
|                                         | Kardegic       |              |            | C           |              | 75 Mg                         |                 | Not Reported |
|                                         | Tahor          |              |            | C           |              | 10 Mg                         |                 | Not Reported |
|                                         | Paracetamol    |              |            | C           |              | 3 Gram                        |                 | Not Reported |
|                                         | Macrogol       |              |            | C           |              | 1 Dosage Form If<br>Necessary |                 | Not Reported |
|                                         | Inexium        |              |            | C           |              | 20 Mg                         |                 | Not Reported |
|                                         | Seresta        |              |            | C           |              | 7.5 Mg                        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Dec-2015              | 11880718      | EXPEDITED (15-DAY) |                    | HO, OT          | CH-FRI-1000081890    |                      | 59 YR      | Female     | CHE            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Decreased Appetite;   | Escitalopram   |              |            | S           | Oral         | 20 Mg              |                 | Forest     |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                 |                                          |   |         |        |              |
|---------------------------------|------------------------------------------|---|---------|--------|--------------|
| Nausea; Transaminases Increased | Xarelto                                  | S | Oral    | 20 Mg  | Not Reported |
|                                 | Pantoprazol                              | S | Oral    | 40 Mg  | Not Reported |
|                                 | Remeron                                  | S | Oral    | 15 Mg  | Not Reported |
|                                 | Torasemid                                | C | Oral    | 2.5 Mg | Not Reported |
|                                 | Lisinopril                               | C | Oral    | 5 Mg   | Not Reported |
|                                 | Nebivolol                                | C | Oral    | 2.5 Mg | Not Reported |
|                                 | Novalgine (Metamizole Sodium)            | C | Oral    |        | Not Reported |
|                                 | Temesta (Lorazepam)                      | C | Oral    |        | Not Reported |
|                                 | Paspertin [Metoclopramide Hydrochloride] | C | Unknown |        | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Dec-2015              | 11880747      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000081921    |                      |            | Female     | FRA            |

| <u>Preferred Term</u>                                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Aortic Valve Incompetence; Mitral Valve Incompetence | Escitalopram   |              |            | S           |              |                    |                 | Forest       |
|                                                      | Mediator       |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                      | Isomeride      |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Dec-2015              | 11880765      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000081925    |                      | 39 YR      | Female     | FRA            |

| <u>Preferred Term</u>               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------|----------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Malaise; Toxicity To Various Agents | Escitalopram   |              |            | S           | Oral         | 20 Mg                            |                 | Forest       |
|                                     | Escitalopram   |              |            | S           | Oral         | Overdose On An Unknown Dose Once |                 | Forest       |
|                                     | Tercian        |              |            | S           | Oral         | 25 Mg                            |                 | Not Reported |
|                                     | Tercian        |              |            | S           | Oral         | Overdose On An Unknown Dose Once |                 | Not Reported |
|                                     | Imovane        |              |            | S           | Oral         | 1 Dosage Form                    |                 | Not Reported |
|                                     | Imovane        |              |            | S           | Oral         | Overdose On An Unknown Dose Once |                 | Not Reported |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|       |   |      |                                  |              |
|-------|---|------|----------------------------------|--------------|
| Xanax | S | Oral | 8 Mg                             | Not Reported |
| Xanax | S | Oral | Overdose Of An Unknown Dose Once | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Dec-2015              | 11881979      | DIRECT           |                    |                 |                      |                      | 44 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                        | <u>Product</u>                             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                                   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------------------------------|
| Condition Aggravated;<br>Dizziness; Drug<br>Ineffective; Paraesthesia;<br>Post-Traumatic Stress<br>Disorder; Product Quality<br>Issue; Product Substitution<br>Issue; Withdrawal<br>Syndrome | Lexapro 20<br>Lamotrigine<br>Multi Vitamin |              |            | S<br>C<br>C | Oral         | 1 Pill             |                 | Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-Dec-2015              | 11881425      | EXPEDITED (15-DAY) |                    | OT              | TW-ACCORD-036667     |                      | 37 YR      | Male       | TWN            |

| <u>Preferred Term</u>                         | <u>Product</u>                                                                                                               | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>               | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                                                           |
|-----------------------------------------------|------------------------------------------------------------------------------------------------------------------------------|--------------|------------|---------------------------|--------------|--------------------|-----------------|----------------------------------------------------------------------|
| Drug Resistance;<br>Gastrointestinal Disorder | Escitalopram<br>Sertraline<br>Bupropion/Bupropion<br>Hydrochloride<br>Duloxetine<br>Venlafaxine/Venlafaxine<br>Hydrochloride |              |            | S<br>S<br>S<br><br>S<br>S |              |                    |                 | Accord<br>Accord<br>Not Reported<br><br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------------------------|----------------------|------------|------------|----------------|
| 31-Dec-2015              | 11881891      | EXPEDITED (15-DAY) |                    | OT              | ES-LUPIN<br>PHARMACEUTICALS<br>INC.-2015-04469 |                      | 67 YR      | Female     | ESP            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blindness; Glaucoma   | Quetiapine     |              |            | S           | Oral         | 100 Mg             |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                     |   |         |              |
|---------------------|---|---------|--------------|
| Escitalopram        | S | Unknown | Not Reported |
| Irbesartan          | S | Unknown | Not Reported |
| Gemfibrozil         | S | Unknown | Not Reported |
| Pantoprazole        | S | Unknown | Not Reported |
| Hydrochlorothiazide | S | Unknown | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-Dec-2015              | 11884520      | DIRECT           | Y                  | HO              |                      |                      | 52 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                               | <u>Product</u>               | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------|------------------------------|--------------|------------|-------------|--------------|------------------------|-----------------|--------------|
| Blood Pressure Increased;<br>Hyperreflexia; Mental<br>Status Changes;<br>Serotonin Syndrome;<br>Tachycardia; Tremor | Escitalopram 20 Mg           |              |            | S           | Oral         | Years, 40 Mg, Qd, Oral | 3 WEEK          | Not Reported |
|                                                                                                                     | Nuvigil 150 Mg Teva/Cephalon |              |            | S           | Oral         |                        |                 | Not Reported |
|                                                                                                                     | Acetaminophen                |              |            | C           |              |                        |                 | Not Reported |
|                                                                                                                     | Albuterol Inhaler            |              |            | C           |              |                        |                 | Not Reported |
|                                                                                                                     | Nuvigil                      |              |            | C           |              |                        |                 | Not Reported |
|                                                                                                                     | Pepto-Bismol                 |              |            | C           |              |                        |                 | Not Reported |
|                                                                                                                     | Celecoxib                    |              |            | C           |              |                        |                 | Not Reported |
|                                                                                                                     | Cetirizine                   |              |            | C           |              |                        |                 | Not Reported |
|                                                                                                                     | Escitalopram                 |              |            | C           |              |                        |                 | Not Reported |
|                                                                                                                     | Fish Oil                     |              |            | C           |              |                        |                 | Not Reported |
|                                                                                                                     | Fluticasone Propionate       |              |            | C           |              |                        |                 | Not Reported |
|                                                                                                                     | Fluocinonide Ointment        |              |            | C           |              |                        |                 | Not Reported |
|                                                                                                                     | Gabapentin                   |              |            | C           |              |                        |                 | Not Reported |
|                                                                                                                     | Ginger Root                  |              |            | C           |              |                        |                 | Not Reported |
|                                                                                                                     | Ibuprofen                    |              |            | C           |              |                        |                 | Not Reported |
|                                                                                                                     | Lamotrigine                  |              |            | C           |              |                        |                 | Not Reported |
|                                                                                                                     | Lotemax                      |              |            | C           |              |                        |                 | Not Reported |
|                                                                                                                     | Omeprazole                   |              |            | C           |              |                        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-Dec-2015              | 11885478      | DIRECT           | Y                  |                 |                      |                      | 45 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Bruxism               | Escitalopram   |              |            | S           | Oral         |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                          | <u>Case #</u>                                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------|--------------------|--------------------|-----------------|---------------------------------|-----------------------|-----------------|--------------|----------------|
| 01-Jan-2016                                                                                                                                                                       | 11590932                                                  | EXPEDITED (15-DAY) |                    | OT              | FR-AUROBINDO-AUR-APL-2015-08060 |                       |                 | Male         | FRA            |
| <u>Preferred Term</u>                                                                                                                                                             | <u>Product</u>                                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Chest Discomfort;<br>Contraindicated Product<br>Administered; Drug<br>Interaction                                                                                                 | Allopurinol Arrow Tablets                                 |                    |                    | S               | Oral                            | 200 Mg, Unk           |                 | Not Reported |                |
|                                                                                                                                                                                   | Escitalopram Arrow Film-Coated Tablets                    |                    |                    | S               | Oral                            | 10 Mg, Unk            |                 | Aurobindo    |                |
|                                                                                                                                                                                   | Escitalopram Arrow Film-Coated Tablets                    |                    |                    | S               | Oral                            | 5 Unk, Unk            |                 | Aurobindo    |                |
|                                                                                                                                                                                   | Hydroxyzine Arrow Film-Coated Tablet                      |                    |                    | S               | Oral                            | 25 Mg, Unk            |                 | Not Reported |                |
|                                                                                                                                                                                   | Ketoprofen Arrow Lp 100 Mg Scored Tablet Extended Release |                    |                    | S               | Oral                            | Unk                   |                 | Not Reported |                |
|                                                                                                                                                                                   | Tercian /00759301/                                        |                    |                    | S               | Unknown                         |                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                          | <u>Case #</u>                                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Jan-2016                                                                                                                                                                       | 11883916                                                  | EXPEDITED (15-DAY) |                    | HO              | US-HETERO LABS LTD-1046070      |                       | 72 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                             | <u>Product</u>                                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Overdose; Suicide Attempt; Treatment Failure                                                                                                                                      | Escitalopram                                              |                    |                    | S               |                                 |                       |                 | Hetero       |                |
|                                                                                                                                                                                   | Olanzapine                                                |                    |                    | C               | Unknown                         |                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                          | <u>Case #</u>                                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Jan-2016                                                                                                                                                                       | 11790680                                                  | EXPEDITED (15-DAY) |                    | HO              | US-PFIZER INC-2015397613        |                       | 64 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                             | <u>Product</u>                                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Chills; Crying; Depression; Diplopia; Disturbance In Attention; Fatigue; Feeling Abnormal; Feeling Hot; Hyperhidrosis; Impaired Driving Ability; Nasopharyngitis; Rash; | Lyrica                                                    |                    |                    | S               |                                 | 75 Mg, 3x/Day         |                 | Pfizer       |                |
|                                                                                                                                                                                   | Lyrica                                                    |                    |                    | S               |                                 | 50 Mg, 1x/Day         |                 | Pfizer       |                |
|                                                                                                                                                                                   | Lexapro                                                   |                    |                    | S               |                                 | 20 Mg, Unk            |                 | Not Reported |                |
|                                                                                                                                                                                   | Amitriptyline Hcl                                         |                    |                    | S               |                                 | 10 Mg, (1 Or 2 A Day) |                 | Not Reported |                |
|                                                                                                                                                                                   | Gabapentin                                                |                    |                    | C               |                                 | 300 Mg, 1x/Day        |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Tremor; Vision Blurred;  
Visual Impairment

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Jan-2016              | 11888663      | DIRECT           |                    | OT              |                      |                      | 29 YR      | Female     | USA            |

| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Adverse Drug Reaction; | Lexapro 10mg   |              |            | S           | Oral         | 1 Pill Once Daily  |                 | Not Reported |
| Agitation; Anxiety;    | Multi-Vitamin  |              |            | C           |              |                    |                 | Not Reported |
| Asthenia; Crying;      |                |              |            |             |              |                    |                 |              |
| Depression; Diarrhoea; |                |              |            |             |              |                    |                 |              |
| Feeling Abnormal;      |                |              |            |             |              |                    |                 |              |
| Insomnia; Nausea;      |                |              |            |             |              |                    |                 |              |
| Suicidal Ideation      |                |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 05-Jan-2016              | 7216270       | NON-EXPEDITED    |                    |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>14684997 |                      | 36 YR      | Female     | USA            |

| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>           |
|--------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------|
| Maternal Exposure During | Abilify        |              |            | S           | Oral         | 5 Mg, Unk          |                 | Bristol Myers Squibb |
| Pregnancy; Normal        | Desyrel        |              |            | S           | Oral         | 1 Df, Qd           |                 | Not Reported         |
| Newborn                  | Lexapro        |              |            | S           | Oral         | 10 Mg, Qd          |                 | Not Reported         |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 05-Jan-2016              | 8296669       | NON-EXPEDITED    |                    |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>15703317 |                      | 27 YR      | Female     | USA            |

| <u>Preferred Term</u>       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>           |
|-----------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------|
| Breast Feeding; Live Birth; | Abilify        |              |            | S           | Oral         | 2.5 Mg, Qd         |                 | Bristol Myers Squibb |
| Maternal Exposure During    | Abilify        |              |            | S           |              |                    |                 | Bristol Myers Squibb |
| Pregnancy; Stress;          | Abilify        |              |            | S           |              |                    |                 | Bristol Myers Squibb |
| Suppressed Lactation        | Lexapro        |              |            | S           | Unknown      | 20 Mg, Qd          |                 | Not Reported         |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Jan-2016              | 9467456       | EXPEDITED (15-DAY) |                    | HO, OT          | PHHY2013IL076818     |                      | 53 YR      | Female     | ISR            |

| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abdominal Distension;      | Tasigna        |              |            | S           | Oral         | 150 Mg, Bid        |                 | Novartis     |
| Alopecia; Amnesia; Blood   | Cipraxel       |              |            | S           | Unknown      |                    |                 | Not Reported |
| Bilirubin Increased; Blood | Bondormin      |              |            | C           | Unknown      |                    |                 | Not Reported |
| Cholesterol Increased;     | Multi Vit      |              |            | C           | Unknown      |                    |                 | Not Reported |
| Blood Glucose Increased;   |                |              |            |             |              |                    |                 |              |
| Chills; Constipation;      |                |              |            |             |              |                    |                 |              |
| Diarrhoea; Fatigue;        |                |              |            |             |              |                    |                 |              |
| Feeling Abnormal;          |                |              |            |             |              |                    |                 |              |
| Gastroenteritis;           |                |              |            |             |              |                    |                 |              |
| Hypersomnia;               |                |              |            |             |              |                    |                 |              |
| Hypothermia; Immune        |                |              |            |             |              |                    |                 |              |
| System Disorder;           |                |              |            |             |              |                    |                 |              |
| Insomnia; Low Density      |                |              |            |             |              |                    |                 |              |
| Lipoprotein Increased;     |                |              |            |             |              |                    |                 |              |
| Myalgia; Nausea; Pain;     |                |              |            |             |              |                    |                 |              |
| Somnolence; Vomiting;      |                |              |            |             |              |                    |                 |              |
| Weight Increased           |                |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 05-Jan-2016              | 11837311      | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2015443708 |                      | 20 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Panic Attack          | Pristiq        |              |            | S           | Oral         | 50 Mg,             |                 | Pfizer       |
|                       | Lexapro        |              |            | S           |              | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------------------|----------------------|------------|------------|----------------|
| 05-Jan-2016              | 11890732      | EXPEDITED (15-DAY) |                    | OT              | US-LUPIN PHARMACEUTICALS INC.-2015-04523 |                      | 25 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Dizziness; Drug       | Escitalopram   |              |            | S           | Unknown      | 10 Mg              |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                |              |   |         |          |  |              |
|--------------------------------|--------------|---|---------|----------|--|--------------|
| Interaction;<br>Rhabdomyolysis | Escitalopram | S |         |          |  | Not Reported |
|                                | Mirtazapine  | S | Unknown | At Night |  | Not Reported |
|                                | Mirtazapine  | S |         |          |  | Not Reported |
|                                | Risperidone  | S | Unknown | At Night |  | Not Reported |
|                                | Risperidone  | S | Unknown | At Night |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------------------------------------|----------------------|------------|------------|----------------|
| 06-Jan-2016              | 11688686      | EXPEDITED (15-DAY) |                    | HO, OT          | GB-MACLEODS<br>PHARMACEUTICALS<br>US LTD-<br>MAC2015002126 |                      |            | Unknown    | GBR            |

| <u>Preferred Term</u>                                                                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u>                      | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|-----------------------------------------|-----------------|--------------|
| Drug Withdrawal<br>Syndrome Neonatal;<br>Foetal Exposure During<br>Pregnancy; Sepsis<br>Neonatal | Escitalopram   |              |            | S           | Transplacental | Unk                                     |                 | Macleods     |
|                                                                                                  | Azathioprine   |              |            | S           | Transplacental |                                         |                 | Not Reported |
|                                                                                                  | Co-Dydramol    |              |            | S           | Transplacental | 10/500, Qid                             |                 | Not Reported |
|                                                                                                  | Omeprazole     |              |            | S           | Transplacental | Unk                                     |                 | Not Reported |
|                                                                                                  | Oramorph       |              |            | S           | Transplacental | 15 Mg, 3-6 Times Per Day<br>As Required |                 | Not Reported |
|                                                                                                  | Oramorph       |              |            | S           | Transplacental | Unk                                     |                 | Not Reported |
|                                                                                                  | Tapentadol     |              |            | S           | Transplacental | 100 Mg                                  |                 | Not Reported |
|                                                                                                  | Daktarin       |              |            | C           | Unknown        | Unk                                     |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 06-Jan-2016              | 11826419      | EXPEDITED (15-DAY) |                    | HO              | FR-JNJFOC-<br>20151202331 |                      | 51 YR      | Female     | FRA            |

| <u>Preferred Term</u>                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Dyskinesia; Muscle<br>Spasms; Myalgia | Durogesic      |              |            | S           | Transdermal  |                    |                 | Not Reported |
|                                       | Xarelto        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                       | Votrient       |              |            | S           | Oral         |                    |                 | Not Reported |
|                                       | Actiskenan     |              |            | S           | Oral         |                    |                 | Not Reported |
|                                       | Lyrica         |              |            | S           | Oral         |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|          |   |      |              |
|----------|---|------|--------------|
| Laroxyl  | S | Oral | Not Reported |
| Seroplex | S | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Jan-2016              | 11880497      | EXPEDITED (15-DAY) |                    | HO              | US-FRI-1000081875    |                      | 84 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Sodium Decreased;<br>Confusional State; Fall;<br>Feeling Abnormal;<br>Seizure; Transient<br>Ischaemic Attack | Escitalopram   |              |            | S           | Oral         | 10mg               |                 | Forest       |
|                                                                                                                    | Lasix          |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                    | Plavix         |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                    | Welchol        |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                    | Zetia          |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------------------------------------|----------------------|------------|------------|----------------|
| 06-Jan-2016              | 11890904      | EXPEDITED (15-DAY) |                    | OT              | US-PAR<br>PHARMACEUTICAL<br>COMPANIES-<br>2016SCPR015056 |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction;<br>Rhabdomyolysis | Risperidone    |              |            | S           | Unknown      | 0.5 Mg, Qhs        |                 | Par          |
|                                     | Risperidone    |              |            | S           | Unknown      | 1 Mg, Qhs          |                 | Par          |
|                                     | Escitalopram   |              |            | S           | Unknown      | 10 Mg, Daily       |                 | Not Reported |
|                                     | Escitalopram   |              |            | S           |              |                    |                 | Not Reported |
|                                     | Mirtazapine    |              |            | C           | Unknown      | 15 Mg, Qhs         |                 | Not Reported |
|                                     | Mirtazapine    |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Jan-2016              | 11892142      | EXPEDITED (15-DAY) |                    | DS, OT          | GB-FRI-1000081932    |                      |            | Male       | GBR            |

| <u>Preferred Term</u>                                                                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anger; Blindness;<br>Disorientation; Feeling<br>Abnormal; Homicidal<br>Ideation; Libido | Escitalopram   |              |            | S           | Oral         | 10 Mg Daily        |                 | Forest       |
|                                                                                         | Diazepam       |              |            | C           | Unknown      | 5 Mg As Necessary  |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Decreased; Mood Swings;  
Paraesthesia;  
Photosensitivity Reaction

| <u>FDA Received Date</u>              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------|----------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
| 06-Jan-2016                           | 11893215       | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2015M1046936 |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Suicide Attempt;<br>Treatment Failure | Escitalopram   |                    |                    | S               | Unknown                   |                      |                 | Not Reported |                |
|                                       | Olanzapine     |                    |                    | S               | Unknown                   |                      |                 | Not Reported |                |
|                                       | Lithium        |                    |                    | S               | Unknown                   |                      |                 | Not Reported |                |
|                                       | Liothyronine   |                    |                    | S               | Unknown                   |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                           | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 06-Jan-2016                                        | 11893279       | EXPEDITED (15-DAY) |                    | HO              | JP-FRI-1000081939    |                      | 52 YR           | Female       | JPN            |
| <u>Preferred Term</u>                              | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated;<br>Drug-Induced Liver Injury | Lexapro        |                    |                    | S               | Oral                 |                      |                 | Forest       |                |
|                                                    | Paxil Cr       |                    |                    | S               | Oral                 | 25 Mg                |                 | Not Reported |                |
|                                                    | Paxil Cr       |                    |                    | S               | Oral                 | 37.5 Mg              |                 | Not Reported |                |
|                                                    | Brotizolam     |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                 | <u>Case #</u>             | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------|---------------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 06-Jan-2016                              | 11894248                  | DIRECT           |                    | OT              |                      |                      | 33 YR           | Female       | USA            |
| <u>Preferred Term</u>                    | <u>Product</u>            | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Homicidal Ideation;<br>Suicidal Ideation | Escitalopram 20mg Generic |                  |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                          | Prozac 10 Mg              |                  |                    | S               | Oral                 |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------------|----------------------|------------|------------|----------------|
| 07-Jan-2016              | 6001673       | EXPEDITED (15-DAY) |                    | HO, OT          | US-BRISTOL-MYERS SQUIBB COMPANY- |                      | < 1 DAY    | Unknown    | USA            |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

13297247

| <u>Preferred Term</u>                                                                                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>           |
|----------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|----------------------|
| Exposure Via Breast Milk;<br>Foetal Exposure During<br>Pregnancy; Sedation;<br>Selective Eating Disorder | Abilify        |              |            | S           | Transplacental | Unk                |                 | Bristol Myers Squibb |
|                                                                                                          | Topamax        |              |            | S           | Transplacental | Unk                |                 | Not Reported         |
|                                                                                                          | Lexapro        |              |            | S           | Transplacental | Unk                |                 | Not Reported         |
|                                                                                                          | Remeron        |              |            | S           | Transplacental | Unk                |                 | Not Reported         |
|                                                                                                          | Zyprexa        |              |            | S           | Transplacental | Unk                |                 | Not Reported         |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Jan-2016              | 11723525      | EXPEDITED (15-DAY) |                    | HO              | GB-FRI-1000080783    |                      |            | Female     | GBR            |

| <u>Preferred Term</u>                                                                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|------------------------------------------|-----------------|--------------|
| Drug Withdrawal<br>Syndrome Neonatal;<br>Foetal Exposure During<br>Pregnancy; Sepsis<br>Neonatal | Escitalopram   |              |            | S           | Transplacental |                                          |                 | Forest       |
|                                                                                                  | Azathioprine   |              |            | S           | Transplacental |                                          |                 | Not Reported |
|                                                                                                  | Co-Dydramol    |              |            | S           | Transplacental | (10/500) Four Times Daily<br>As Required |                 | Not Reported |
|                                                                                                  | Omeprazole     |              |            | S           | Transplacental |                                          |                 | Not Reported |
|                                                                                                  | Oramorph       |              |            | S           | Transplacental | 1 Mg 3-6 Times Daily As<br>Required      |                 | Not Reported |
|                                                                                                  | Tapentadol     |              |            | S           | Transplacental | 100 Mg Once Daily                        |                 | Not Reported |
|                                                                                                  | Daktarin       |              |            | C           | Transplacental |                                          |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 07-Jan-2016              | 11895147      | NON-EXPEDITED    |                    |                 | US-PFIZER INC-<br>2015436814 |                      | 55 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u>   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Hypersensitivity | Morphine Sulfate |              |            | S           |              | Unk                |                 | Pfizer       |
|                       | Lexapro          |              |            | S           |              | Unk                |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|           |   |     |              |
|-----------|---|-----|--------------|
| Klonopin  | S | Unk | Not Reported |
| Robaxin   | S | Unk | Not Reported |
| Methadone | S | Unk | Not Reported |
| Oxycodone | S | Unk | Not Reported |
| Metformin | S | Unk | Not Reported |

| <u>FDA Received Date</u>                                                                                                                                                                                                    | <u>Case #</u>                    | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 07-Jan-2016                                                                                                                                                                                                                 | 11897904                         | DIRECT           |                    | DS, OT          |                      |                      | 44 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                       | <u>Product</u>                   | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Appetite Disorder;<br>Asthenia; Balance<br>Disorder; Dizziness; Drug<br>Ineffective; Drug<br>Withdrawal Syndrome;<br>Fatigue; Head Discomfort;<br>Hypoaesthesia;<br>Hypoaesthesia; Insomnia;<br>Nausea; Weight<br>Decreased | Viibryd - Vilazodone Hcl Tablets |                  |                    | S               |                      | By Mouth; 30 Tablets |                 | Forest       |                |
|                                                                                                                                                                                                                             | Forest Pharmaceuticals Inc.      |                  |                    |                 |                      |                      |                 |              |                |
|                                                                                                                                                                                                                             | Escitalopram 5 Mg Tab. Teva      |                  |                    | S               |                      |                      |                 | Teva         |                |
|                                                                                                                                                                                                                             | Multiple Vitamin                 |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                             | Triamterene                      |                  |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 08-Jan-2016                              | 11232172       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000077780    |                      | 89 YR           | Female       | FRA            |
| <u>Preferred Term</u>                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;<br>Haemorrhagic Stroke | Escitalopram   |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                          | Lovenox        |                    |                    | S               | Subcutaneous         | 12000 Iu             |                 | Not Reported |                |
|                                          | Lasilix        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                          | Morphin        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                          | Oxazepam       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                          | Doliprane      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                          | Calcium        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                          | Vitamin D Nos  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                          | Qvar           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                          | Ventoline      |                    |                    | C               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                             | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|--------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|------------------------------------|---------------------------------|-----------------|-----------------|----------------|
| 08-Jan-2016                                                                          | 11700557               | EXPEDITED (15-DAY) |                    | HO              | GB-WATSON-2015-23608               |                                 | 121 DAY         | Female          | GBR            |
| <u>Preferred Term</u>                                                                | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                       | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>      |                |
| Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Sepsis Neonatal | Azathioprine (Unknown) |                    |                    | S               | Transplacental                     | Unk                             |                 | Not Reported    |                |
|                                                                                      | Co-Dydramol            |                    |                    | S               | Transplacental                     | Unk Unk, Qid (Strength: 10/500) |                 | Not Reported    |                |
|                                                                                      | Escitalopram (Unknown) |                    |                    | S               | Transplacental                     | Unk                             |                 | Not Reported    |                |
|                                                                                      | Omeprazole (Unknown)   |                    |                    | S               | Transplacental                     | Unk                             |                 | Actavis         |                |
|                                                                                      | Oramorph               |                    |                    | S               | Transplacental                     | 15 Mg, 3-6 Per Day              |                 | Not Reported    |                |
|                                                                                      | Oramorph               |                    |                    | S               | Unknown                            | Unk                             |                 | Not Reported    |                |
|                                                                                      | Tapentadol             |                    |                    | S               | Transplacental                     | 100 Mg, Daily                   |                 | Not Reported    |                |
|                                                                                      | Daktarin /00310801/    |                    |                    | C               | Unknown                            | Unk                             |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                             | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 08-Jan-2016                                                                          | 11898672               | EXPEDITED (15-DAY) |                    | DE, OT          | US-GLAXOSMITHKLINE-US2016GSK000903 |                                 | 14 YR           | Male            | USA            |
| <u>Preferred Term</u>                                                                | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                       | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>      |                |
| Completed Suicide                                                                    | Escitalopram           |                    |                    | S               | Oral                               | Unk                             |                 | Glaxosmithkline |                |
|                                                                                      | Metoprolol             |                    |                    | S               | Oral                               | Unk                             |                 | Not Reported    |                |
|                                                                                      | Bupropion              |                    |                    | S               | Oral                               | Unk                             |                 | Glaxosmithkline |                |
| <u>FDA Received Date</u>                                                             | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 08-Jan-2016                                                                          | 11898689               | EXPEDITED (15-DAY) |                    | DE, OT          | US-GLAXOSMITHKLINE-US2016GSK000808 |                                 | 25 YR           | Male            | USA            |
| <u>Preferred Term</u>                                                                | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                       | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>      |                |
| Completed Suicide                                                                    | Bupropion              |                    |                    | S               | Unknown                            | Unk                             |                 | Glaxosmithkline |                |
|                                                                                      | Escitalopram           |                    |                    | S               | Unknown                            | Unk                             |                 | Glaxosmithkline |                |
|                                                                                      | Lamotrigine            |                    |                    | S               | Unknown                            | Unk                             |                 | Glaxosmithkline |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                              |                |                    |                    |                 |                                                 |                      |                 |                      |                |
|----------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|----------------------|----------------|
| Clonazepam                                                                                   |                |                    | S                  | Unknown         | Unk                                             | Glaxosmithkline      |                 |                      |                |
| <u>FDA Received Date</u>                                                                     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 08-Jan-2016                                                                                  | 11904677       | NON-EXPEDITED      |                    |                 | US-ROCHE-1571782                                |                      | 63 YR           | Male                 | USA            |
| <u>Preferred Term</u>                                                                        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Anxiety; Drug Ineffective;<br>Staphylococcal Infection;<br>Therapeutic Response<br>Decreased | Rituxan        |                    |                    | S               | Unknown                                         |                      |                 | Not Reported         |                |
|                                                                                              | Nardil         |                    |                    | S               | Oral                                            |                      |                 | Not Reported         |                |
|                                                                                              | Nardil         |                    |                    | S               |                                                 |                      |                 | Not Reported         |                |
|                                                                                              | Xanax          |                    |                    | S               | Oral                                            |                      |                 | Not Reported         |                |
|                                                                                              | Xanax          |                    |                    | S               |                                                 |                      |                 | Not Reported         |                |
|                                                                                              | Klonopin       |                    |                    | S               | Unknown                                         |                      |                 | Not Reported         |                |
|                                                                                              | Klonopin       |                    |                    | S               |                                                 |                      |                 | Not Reported         |                |
|                                                                                              | Lexapro        |                    |                    | S               | Unknown                                         |                      |                 | Not Reported         |                |
|                                                                                              | Lexapro        |                    |                    | S               |                                                 |                      |                 | Not Reported         |                |
|                                                                                              | Fluconazole    |                    |                    | C               |                                                 |                      |                 | Not Reported         |                |
|                                                                                              | Pepcid         |                    |                    | C               |                                                 |                      |                 | Not Reported         |                |
|                                                                                              | Compazine      |                    |                    | C               |                                                 |                      |                 | Not Reported         |                |
|                                                                                              | Acyclovir      |                    |                    | C               |                                                 |                      |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                                     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 09-Jan-2016                                                                                  | 4122627        | EXPEDITED (15-DAY) |                    | OT              | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>12493342 |                      | 38 YR           | Female               | USA            |
| <u>Preferred Term</u>                                                                        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Foetal Death; Pregnancy                                                                      | Abilify        |                    |                    | S               | Oral                                            | 5 Mg, Qd             |                 | Bristol Myers Squibb |                |
|                                                                                              | Seroquel       |                    |                    | S               | Unknown                                         | 25 Mg, Qd            |                 | Not Reported         |                |
|                                                                                              | Klonopin       |                    |                    | S               | Unknown                                         | .5 Mg, Bid           |                 | Not Reported         |                |
|                                                                                              | Lexapro        |                    |                    | S               | Unknown                                         | 10 Mg, Qd            |                 | Not Reported         |                |
|                                                                                              | Wellbutrin     |                    |                    | S               | Unknown                                         | 300 Mg, Qd           |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                                     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 09-Jan-2016                                                                                  | 11905199       | NON-EXPEDITED      |                    | HO, OT          | US-JNJFOC-<br>20151222951                       |                      | 25 YR           | Male                 | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                             | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|------------------------------------------------|-----------------|--------------|
| Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Off Label Use; Product Use In Unapproved Indication; Rhabdomyolysis | Risperidone    |              |            | S           | Unknown      |                                                |                 | Not Reported |
|                                                                                                                                               | Risperidone    |              |            | S           | Unknown      | Initial Dose Of 0.5 Mg Qhs, Titrated Upto 1 Mg |                 | Not Reported |
|                                                                                                                                               | Risperidone    |              |            | S           | Unknown      | Initial Dose Of 0.5 Mg Qhs, Titrated Upto 1 Mg |                 | Not Reported |
|                                                                                                                                               | Risperidone    |              |            | S           | Unknown      |                                                |                 | Not Reported |
|                                                                                                                                               | Escitalopram   |              |            | S           | Unknown      |                                                |                 | Not Reported |
|                                                                                                                                               | Escitalopram   |              |            | S           | Unknown      |                                                |                 | Not Reported |
|                                                                                                                                               | Mirtazapine    |              |            | C           | Unknown      | 15 Mg Qhs                                      |                 | Not Reported |
|                                                                                                                                               | Mirtazapine    |              |            | C           | Unknown      | 15 Mg Qhs                                      |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 09-Jan-2016              | 11905386      | NON-EXPEDITED    |                    | HO              | US-JNJFOC-20151208764 |                      | 37 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-------------------------------|--------------|------------|-------------|--------------|-----------------------|-----------------|--------------|
| Depression            | Risperdal                     |              |            | S           | Unknown      |                       |                 | Not Reported |
|                       | Mirtazapine                   |              |            | S           | Unknown      |                       |                 | Not Reported |
|                       | Escitalopram                  |              |            | S           | Unknown      |                       |                 | Not Reported |
|                       | Hydroxizine                   |              |            | S           | Unknown      |                       |                 | Not Reported |
|                       | Elvitegravir                  |              |            | S           | Oral         | 1 Df (Dose Factor).   |                 | Not Reported |
|                       | Cobicistat                    |              |            | S           | Oral         | 1 Df (Dose Factor).   |                 | Not Reported |
|                       | Emtricitabine                 |              |            | S           | Oral         | 1 Df (Dosage Factor)  |                 | Not Reported |
|                       | Tenofovir Alafenamide         |              |            | S           | Oral         | 1 Df (Dosage Factor). |                 | Not Reported |
|                       | Tenofovir Disoproxil Fumarate |              |            | S           | Oral         | 1 Df (Dosage Factor). |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 09-Jan-2016              | 11905555      | EXPEDITED (15-DAY) |                    | HO              | FR-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-092977 |                      | 52 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                |          |   |         |             |                      |
|--------------------------------------------------------------------------------|----------|---|---------|-------------|----------------------|
| Axonal Neuropathy;<br>Cyanosis; Livedo<br>Reticularis; Raynaud'S<br>Phenomenon | Abilify  | S | Oral    | 15 Mg, Qd   | Bristol Myers Squibb |
|                                                                                | Abilify  | S |         |             | Bristol Myers Squibb |
|                                                                                | Abilify  | S |         |             | Bristol Myers Squibb |
|                                                                                | Lepticur | S | Unknown | 15 Mg, Unk  | Not Reported         |
|                                                                                | Lepticur | S |         |             | Not Reported         |
|                                                                                | Lepticur | S |         |             | Not Reported         |
|                                                                                | Ritaline | S | Oral    | 100 Mg, Unk | Not Reported         |
|                                                                                | Ritaline | S | Oral    | 110 Mg, Qd  | Not Reported         |
|                                                                                | Ritaline | S |         |             | Not Reported         |
|                                                                                | Xeroquel | S | Oral    | 400 Mg, Qd  | Not Reported         |
|                                                                                | Xeroquel | S |         |             | Not Reported         |
|                                                                                | Xeroquel | S |         |             | Not Reported         |
|                                                                                | Seroplex | S | Oral    | 10 Mg, Qd   | Not Reported         |
|                                                                                | Seroplex | S |         |             | Not Reported         |
|                                                                                | Seroplex | S |         |             | Not Reported         |
|                                                                                | Laroxyl  | S | Unknown | Unk         | Not Reported         |
|                                                                                | Laroxyl  | S |         |             | Not Reported         |
|                                                                                | Laroxyl  | S |         |             | Not Reported         |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Jan-2016              | 11903149      | EXPEDITED (15-DAY) |                    | HO              | PHHY2015US172500     |                      | 25 YR      | Male       | USA            |

| <u>Preferred Term</u>               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction;<br>Rhabdomyolysis | Escitalopram   |              |            | S           | Unknown      | 10 Mg, Qd          |                 | Not Reported |
|                                     | Escitalopram   |              |            | S           |              |                    |                 | Not Reported |
|                                     | Risperidone    |              |            | S           | Unknown      | 0.5 Mg, Qhs        |                 | Novartis     |
|                                     | Risperidone    |              |            | S           | Unknown      | 1 Mg, Unk          |                 | Novartis     |
|                                     | Mirtazapine    |              |            | C           | Unknown      | 15 Mg, Qhs         |                 | Not Reported |
|                                     | Mirtazapine    |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------------------|----------------------|------------|------------|----------------|
| 11-Jan-2016              | 10648647      | EXPEDITED (15-DAY) |                    | HO, OT          | US-<br>GLAXOSMITHKLINE-<br>US2014GSK034688 |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                           |             |   |         |              |                 |
|---------------------------|-------------|---|---------|--------------|-----------------|
| Abnormal Behaviour;       | Lamictal    | S | Oral    | 200 Mg, Qd   | Glaxosmithkline |
| Adverse Drug Reaction;    | Lamictal    | S |         | Unk          | Glaxosmithkline |
| Back Injury; Back Pain;   | Lamictal    | S |         | 100 Unk, Unk | Glaxosmithkline |
| Bipolar Disorder;         | Lamotrigine | S |         | 200 Mg, Qd   | Glaxosmithkline |
| Confusional State; Deep   | Atenolol    | S | Unknown | Unk, U       | Glaxosmithkline |
| Brain Stimulation;        | Atenolol    | S |         |              | Glaxosmithkline |
| Dependence; Depression;   | Aldactone   | S | Unknown | Unk, U       | Glaxosmithkline |
| Drug Hypersensitivity;    | Lasix       | S | Unknown | Unk, U       | Glaxosmithkline |
| Drug Ineffective;         | Effexor     | S | Unknown | Unk, Qd      | Glaxosmithkline |
| Dyspnoea;                 | Lithium     | S |         | 450 Mg, Qd   | Glaxosmithkline |
| Encephalopathy; Essential | Flagyl      | S | Unknown | Unk, U       | Glaxosmithkline |
| Tremor; Fall; Hostility;  | Prozac      | S | Unknown | Unk, U       | Not Reported    |
| Hypersensitivity;         | Lexapro     | S | Unknown | Unk, U       | Not Reported    |
| Hypersensitivity; Ill-    | Serotonin   | S | Unknown | 2 Df, Qd     | Not Reported    |
| Defined Disorder;         | Bioflex     | C |         |              | Not Reported    |
| Impulsive Behaviour;      | Potassium   | C |         |              | Not Reported    |
| Lethargy; Loss Of         | Pepcid      | C |         |              | Not Reported    |
| Personal Independence In  | Theodur     | C |         |              | Not Reported    |
| Daily Activities; Oedema; | Melatonin   | C |         |              | Not Reported    |
| Road Traffic Accident;    | Omeprazol   | C |         |              | Not Reported    |
| Speech Disorder; Spinal   | Doxycycline | C |         |              | Not Reported    |
| Operation; Swelling;      | Oxycodone   | C |         |              | Not Reported    |
| Therapeutic Response      | Norco       | C |         |              | Not Reported    |
| Decreased                 |             |   |         |              |                 |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Jan-2016              | 11442606      | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000079240    |                      | 69 YR      | Female     | FRA            |

  

| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------|----------------|--------------|------------|-------------|--------------|---------------------|-----------------|--------------|
| Cholestasis; Gamma-     | Escitalopram   |              |            | S           | Oral         | Overdose: 30 Mg/Day |                 | Forest       |
| Glutamyltransferase     | Depamide       |              |            | S           | Oral         |                     |                 | Not Reported |
| Increased; Overdose;    | Zyvoxid        |              |            | C           | Unknown      | 1200 Mg             |                 | Not Reported |
| Transaminases Increased | Mirtazapine    |              |            | C           | Oral         | 30 Mg               |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|             |   |      |        |              |
|-------------|---|------|--------|--------------|
| Mysoline    | C | Oral | 500 Mg | Not Reported |
| Paracetamol | C | Oral |        | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|------------|------------|----------------|
| 11-Jan-2016              | 11699778      | EXPEDITED (15-DAY) |                    | HO, OT          | GB-DRREDDYS-GER/UKI/15/0053704 |                      | 121 DAY    | Female     | GBR            |

| <u>Preferred Term</u>                                                                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Sepsis Neonatal | Omeprazole     |              |            | S           | Transplacental |                    |                 | Not Reported |
|                                                                                      | Azathioprine   |              |            | S           | Transplacental |                    |                 | Not Reported |
|                                                                                      | Co-Dydramol    |              |            | S           | Transplacental | Strength: 10/500   |                 | Not Reported |
|                                                                                      | Escitalopram   |              |            | S           | Transplacental |                    |                 | Not Reported |
|                                                                                      | Oramorph       |              |            | S           | Transplacental |                    |                 | Not Reported |
|                                                                                      | Oramorph       |              |            | S           | Unknown        |                    |                 | Not Reported |
|                                                                                      | Tapentadol     |              |            | S           | Transplacental |                    |                 | Not Reported |
|                                                                                      | Daktarin       |              |            | C           | Unknown        |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------------|----------------------|------------|------------|----------------|
| 11-Jan-2016              | 11903167      | EXPEDITED (15-DAY) |                    | DE, HO, OT      | US-GLAXOSMITHKLINE-US2016GSK000816 |                      | 33 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u>   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|-----------------------|------------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Completed Suicide     | Escitalopram     |              |            | S           | Oral         | Unk                |                 | Glaxosmithkline |
|                       | Dextromethorphan |              |            | S           | Oral         | Unk                |                 | Glaxosmithkline |
|                       | Chlorpheniramine |              |            | S           | Oral         | Unk                |                 | Glaxosmithkline |
|                       | Buspirone Hcl    |              |            | S           | Oral         | Unk                |                 | Glaxosmithkline |
|                       | Olanzapine       |              |            | S           | Oral         | Unk                |                 | Glaxosmithkline |
|                       | Sumatriptan      |              |            | S           | Oral         | Unk                |                 | Glaxosmithkline |
|                       | Trazodone        |              |            | S           | Oral         | Unk                |                 | Not Reported    |
|                       | Meloxicam        |              |            | S           | Oral         | Unk                |                 | Glaxosmithkline |
|                       | Benzonatate      |              |            | S           | Oral         | Unk                |                 | Not Reported    |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                 |   |      |     |                 |
|-----------------|---|------|-----|-----------------|
| Topiramate      | S | Oral | Unk | Glaxosmithkline |
| Cyclobenzaprine | S | Oral | Unk | Not Reported    |
| Cyclobenzaprine | S |      | Unk | Not Reported    |

| <u>FDA Received Date</u>                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------|----------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 11-Jan-2016                                | 11906677       | EXPEDITED (15-DAY) |                    | HO, OT          | CH-PFIZER INC-2016002730 |                      | 87 YR           | Female       | CHE            |
| <u>Preferred Term</u>                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Labyrinthitis; Nausea; Pneumonia; Vomiting | Cordarone      |                    |                    | S               | Oral                     | 200 Mg, 3x/Day       |                 | Pfizer       |                |
|                                            | Cordarone      |                    |                    | S               | Oral                     | 200 Mg, 1x/Day       |                 | Pfizer       |                |
|                                            | Cordarone      |                    |                    | S               | Oral                     | 100 Mg, 1x/Day       |                 | Pfizer       |                |
|                                            | Cipralext      |                    |                    | S               | Oral                     | 10 Mg, 2x/Day        |                 | Not Reported |                |
|                                            | Nexium         |                    |                    | C               |                          | Unk                  |                 | Not Reported |                |
|                                            | Enalapril      |                    |                    | C               |                          | Unk                  |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
| 11-Jan-2016                                                                                                                               | 11906808       | EXPEDITED (15-DAY) |                    | OT              | FR-MYLANLABS-2016M1000126 |                      |                 | Unknown      | FRA            |
| <u>Preferred Term</u>                                                                                                                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Depression; Incorrect Dose Administered; Muscle Spasms; Product Packaging Issue; Serotonin Syndrome; Tremor; Withdrawal Syndrome | Escitalopram   |                    |                    | S               |                           | 10 Mg, Unk           |                 | Not Reported |                |
|                                                                                                                                           | Escitalopram   |                    |                    | S               |                           | 15 Mg, Unk           |                 | Not Reported |                |
|                                                                                                                                           | Escitalopram   |                    |                    | S               |                           | 20 Mg, Unk           |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|------------------------------------|----------------------|-----------------|------------|----------------|
| 11-Jan-2016              | 11907504       | EXPEDITED (15-DAY) |                    | DE, HO, OT      | US-GLAXOSMITHKLINE-US2016GSK000847 |                      | 52 YR           | Male       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                       | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                   |              |   |      |     |                 |
|-------------------|--------------|---|------|-----|-----------------|
| Completed Suicide | Escitalopram | S | Oral | Unk | Glaxosmithkline |
|                   | Lamotrigine  | S | Oral | Unk | Glaxosmithkline |
|                   | Atenolol     | S | Oral | Unk | Glaxosmithkline |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Jan-2016              | 11908004      | EXPEDITED (15-DAY) |                    | HO              | PHHY2016FR001625     |                      | 68 YR      | Male       | FRA            |

| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Guillain-Barre Syndrome | Neoral         |              |            | S           | Oral         | 20 Mg, Qd          |                 | Novartis     |
|                         | Neoral         |              |            | S           | Oral         | 80 Mg, Bid         |                 | Novartis     |
|                         | Speciafoldine  |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                         | Seroplex       |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                         | Noxafil        |              |            | S           | Oral         | 200 Mg, Unk        |                 | Not Reported |
|                         | Mecir          |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                         | Zelitrex       |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                         | Alprazolam     |              |            | S           | Unknown      |                    |                 | Not Reported |
|                         | Oracilline     |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                         | Bactrim Forte  |              |            | S           | Oral         | Long Term          |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 11-Jan-2016              | 11908571      | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2016M1000727 |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Dizziness;<br>Rhabdomyolysis | Escitalopram   |              |            | S           | Unknown      | 10mg Daily         |                 | Not Reported |
|                              | Risperidone    |              |            | S           | Unknown      | At Night           |                 | Not Reported |
|                              | Mirtazapine    |              |            | S           |              | At Night           |                 | Not Reported |
|                              | Mirtazapine    |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Jan-2016              | 11910659      | DIRECT           |                    | DS, OT          |                      |                      | 40 YR      | Unknown    | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
|-------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|----------------------|----------------|
| Disease Recurrence;<br>Nausea; Panic Attack;<br>Product Substitution Issue                                                                | Escitalopram   |                    |                    | S               |                                                 |                      |                 | Not Reported         |                |
|                                                                                                                                           | Lexapro        |                    |                    | C               |                                                 |                      |                 | Not Reported         |                |
|                                                                                                                                           | Zanex          |                    |                    | C               |                                                 |                      |                 | Not Reported         |                |
|                                                                                                                                           | Fish Oil       |                    |                    | C               |                                                 |                      |                 | Not Reported         |                |
|                                                                                                                                           | Vitamin D Nos  |                    |                    | C               |                                                 |                      |                 | Not Reported         |                |
|                                                                                                                                           | Vitamin B      |                    |                    | C               |                                                 |                      |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                                                                                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 12-Jan-2016                                                                                                                               | 6929432        | EXPEDITED (15-DAY) |                    | CA, OT          | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>14530828 |                      |                 | Unknown              | USA            |
| <u>Preferred Term</u>                                                                                                                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Cleft Palate; Foetal<br>Exposure During<br>Pregnancy                                                                                      | Abilify        |                    |                    | S               | Transplacental                                  | 20 Mg, Unk           |                 | Bristol Myers Squibb |                |
|                                                                                                                                           | Lexapro        |                    |                    | S               | Transplacental                                  | Unk                  |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                                                                                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 12-Jan-2016                                                                                                                               | 7215369        | EXPEDITED (15-DAY) |                    | OT              | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>14529184 |                      |                 | Female               | USA            |
| <u>Preferred Term</u>                                                                                                                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Gestational Diabetes;<br>Maternal Exposure During<br>Pregnancy                                                                            | Abilify        |                    |                    | S               | Unknown                                         | 20 Mg, Unk           |                 | Bristol Myers Squibb |                |
|                                                                                                                                           | Lexapro        |                    |                    | S               | Unknown                                         |                      |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                                                                                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 12-Jan-2016                                                                                                                               | 7995648        | EXPEDITED (15-DAY) |                    | OT              | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>15705049 |                      |                 | Female               | USA            |
| <u>Preferred Term</u>                                                                                                                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Exposure Via Breast Milk;<br>Failure To Thrive; Foetal<br>Exposure During<br>Pregnancy;<br>Gastrooesophageal Reflux<br>Disease; Menstrual | Abilify        |                    |                    | S               | Transplacental                                  | 2.5 Mg, Qd           |                 | Bristol Myers Squibb |                |
|                                                                                                                                           | Lexapro        |                    |                    | S               | Transplacental                                  | 20 Mg, Qd            |                 | Not Reported         |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Disorder

| <u>FDA Received Date</u>                         | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
|--------------------------------------------------|-----------------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|------------------|----------------|
| 12-Jan-2016                                      | 11031559              | EXPEDITED (15-DAY) |                    | DE, HO          | FR-<br>ELI_LILLY_AND_COMP<br>ANY-FR201504002011 |                      | 76 YR           | Female           | FRA            |
| <u>Preferred Term</u>                            | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |
| Amnesia; Blood Glucose<br>Decreased; Death; Fall | Humalog Lispro        |                    |                    | S               | Subcutaneous                                    | 6 lu, Bid            |                 | Eli Lilly And Co |                |
|                                                  | Avlocardyl /00030001/ |                    |                    | S               | Unknown                                         | 0.25 Df, Tid         |                 | Not Reported     |                |
|                                                  | Lantus                |                    |                    | S               | Subcutaneous                                    | 10 lu, Qd            |                 | Not Reported     |                |
|                                                  | Seroplex              |                    |                    | S               | Oral                                            | 10 Mg, Qd            |                 | Not Reported     |                |
|                                                  | Aldactone /00006201/  |                    |                    | S               | Oral                                            |                      |                 | Not Reported     |                |
|                                                  | Heptaminol            |                    |                    | C               |                                                 | 1 Df, Tid            |                 | Not Reported     |                |
|                                                  | Gaviscon /00237601/   |                    |                    | C               |                                                 | 1 Df, Qd             |                 | Not Reported     |                |
|                                                  | Duphalac /00163401/   |                    |                    | C               |                                                 | 1 Df, Tid            |                 | Not Reported     |                |
|                                                  | Dafalgan              |                    |                    | C               |                                                 | 500 Mg, Prn          |                 | Not Reported     |                |

| <u>FDA Received Date</u>                                                                         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|-------------------------------------|----------------------|-----------------|--------------|----------------|
| 12-Jan-2016                                                                                      | 11695645       | EXPEDITED (15-DAY) |                    | HO              | GB-AUROBINDO-AUR-<br>APL-2015-09841 |                      | 121 DAY         | Female       | GBR            |
| <u>Preferred Term</u>                                                                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Withdrawal<br>Syndrome Neonatal;<br>Foetal Exposure During<br>Pregnancy; Sepsis<br>Neonatal | Escitalopram   |                    |                    | S               | Transplacental                      |                      |                 | Aurobindo    |                |
|                                                                                                  | Escitalopram   |                    |                    | S               |                                     |                      |                 | Aurobindo    |                |
|                                                                                                  | Omeprazole     |                    |                    | S               | Transplacental                      |                      |                 | Aurobindo    |                |
|                                                                                                  | Omeprazole     |                    |                    | S               |                                     |                      |                 | Aurobindo    |                |
|                                                                                                  | Azathioprine   |                    |                    | S               | Transplacental                      |                      |                 | Not Reported |                |
|                                                                                                  | Azathioprine   |                    |                    | S               |                                     |                      |                 | Not Reported |                |
|                                                                                                  | Co-Dydramol    |                    |                    | S               | Transplacental                      | Strength: 10/500     |                 | Not Reported |                |
|                                                                                                  | Co-Dydramol    |                    |                    | S               |                                     |                      |                 | Not Reported |                |
|                                                                                                  | Oramorph       |                    |                    | S               | Transplacental                      | 15 Mg, Unk           |                 | Not Reported |                |
|                                                                                                  | Oramorph       |                    |                    | S               | Unknown                             | Unk                  |                 | Not Reported |                |
|                                                                                                  | Tapentadol     |                    |                    | S               | Transplacental                      | 100 Mg, Once A Day   |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Tapentadol  
Daktarin /00310801/

S  
C Unknown

Not Reported  
Not Reported

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Jan-2016              | 11704053      | EXPEDITED (15-DAY) |                    | HO, OT          | GB-ACCORD-035084     |                      | 121 DAY    | Female     | GBR            |

| <u>Preferred Term</u>                                                                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u>                                                           | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|------------------------------------------------------------------------------|-----------------|--------------|
| Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Sepsis Neonatal | Escitalopram   |              |            | S           | Transplacental |                                                                              |                 | Accord       |
|                                                                                      | Omeprazole     |              |            | S           | Transplacental |                                                                              |                 | Accord       |
|                                                                                      | Azathioprine   |              |            | S           | Transplacental |                                                                              |                 | Not Reported |
|                                                                                      | Co-Dydramol    |              |            | S           | Transplacental | Strength: 10/500                                                             |                 | Not Reported |
|                                                                                      | Oramorph       |              |            | S           | Transplacental | Exposed To Oramorph 15 Mg, 3-6 Times Per Day Via Transplacental As Required. |                 | Not Reported |
|                                                                                      | Tapentadol     |              |            | S           | Transplacental | 100 Mg                                                                       |                 | Not Reported |
|                                                                                      | Daktarin       |              |            | C           | Unknown        |                                                                              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|---------------------------------------------|----------------------|------------|------------|----------------|
| 12-Jan-2016              | 11909775      | NON-EXPEDITED    |                    | OT              | US-ELI_LILLY_AND_COMP<br>ANY-US201601001649 |                      | 19 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>       |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------------|
| Suicidal Behaviour    | Cymbalta       |              |            | S           | Unknown      | Unk, Unknown       |                 | Eli Lilly And Co |
|                       | Viibryd        |              |            | S           | Unknown      | Unk, Unknown       |                 | Not Reported     |
|                       | Lexapro        |              |            | S           | Unknown      | Unk, Unknown       |                 | Not Reported     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 12-Jan-2016              | 11911968      | EXPEDITED (15-DAY) |                    | DE              | US-BAUSCH-BL-2016-000620 |                      | 42 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Diazepam       |              |            | S           | Oral         |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|              |   |      |              |
|--------------|---|------|--------------|
| Zolpidem     | S | Oral | Not Reported |
| Metoprolol   | S | Oral | Not Reported |
| Oxycodone    | S | Oral | Not Reported |
| Escitalopram | S | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------|----------------------|------------|------------|----------------|
| 12-Jan-2016              | 11912129      | NON-EXPEDITED    |                    |                 | US-APOTEX-2015AP014860 |                      | 55 YR      | Male       | USA            |

| <u>Preferred Term</u>                                | <u>Product</u>               | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------|------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Depressed Mood; Product Use In Unapproved Indication | Sertraline Hydrochloride     |              |            | S           | Unknown      | Unk                |                 | Apotex       |
|                                                      | Fluoxetine Oral Solution Usp |              |            | S           | Unknown      | Unk                |                 | Apotex       |
|                                                      | Paroxetine Hydrochloride     |              |            | S           | Unknown      | Unk                |                 | Apotex       |
|                                                      | Citalopram                   |              |            | S           | Unknown      | Unk                |                 | Apotex       |
|                                                      | Escitalopram Oxalate         |              |            | S           | Unknown      | Unk                |                 | Apotex       |
|                                                      | Venlafaxine                  |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                                                      | Amitriptyline                |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                                                      | Imipramine                   |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                                                      | Carbamazepine                |              |            | C           | Unknown      | 600-1400mg Daily   |                 | Not Reported |
|                                                      | Lamotrigine                  |              |            | C           | Unknown      | 300-600mg Daily    |                 | Not Reported |
|                                                      | Clonazepam                   |              |            | C           | Unknown      | 1 Mg, Daily        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Jan-2016              | 11912736      | DIRECT           |                    | DS, OT          |                      |                      | 44 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                  | <u>Product</u>                      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------|------------|-------------|--------------|--------------------------|-----------------|--------------|
| Asthenia; Balance Disorder; Decreased Appetite; Dizziness; Drug Ineffective; Ear Disorder; Fatigue; Feeling Abnormal; Head Discomfort; | Viibryd Vilazodone Hcl Tablets 20mg |              |            | S           | Oral         | 30 Tabs 1 Daily By Mouth |                 | Forest       |
|                                                                                                                                        | Escitalopram 5 Mg Tab Tev           |              |            | S           |              |                          |                 | Walmart      |
|                                                                                                                                        | Triamterene Hctz                    |              |            | C           |              |                          |                 | Not Reported |
|                                                                                                                                        | Multiple Vitamin                    |              |            | C           |              |                          |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Hypoaesthesia;  
Hypoaesthesia;  
Hypoaesthesia Oral;  
Insomnia; Nausea;  
Vertigo; Withdrawal  
Syndrome

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Jan-2016              | 11653421      | EXPEDITED (15-DAY) |                    | HO, OT          | FR-FRI-1000080386    |                      | 95 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abnormal Behaviour;<br>Hallucination, Visual;<br>Mania; Product Use In<br>Unapproved Indication | Escitalopram   |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                                                                                 | Escitalopram   |              |            | S           | Oral         | 20 Mg              |                 | Forest       |
|                                                                                                 | Xanax          |              |            | S           | Oral         | 0.25 Mg            |                 | Not Reported |
|                                                                                                 | Imovane        |              |            | S           | Oral         | 7.5 Mg             |                 | Not Reported |
|                                                                                                 | Risperdal      |              |            | S           | Oral         | 0.5 MI             |                 | Not Reported |
|                                                                                                 | Monuril        |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                                                 | Cardensiel     |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                                                 | Hyperium       |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                                                 | Lercan         |              |            | C           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 13-Jan-2016              | 11913354      | EXPEDITED (15-DAY) |                    | DE              | US-MALLINCKRODT-T201505823 |                      | 34 YR      | Male       | USA            |

| <u>Preferred Term</u>            | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Intentional Product Use<br>Issue | Roxicodone                |              |            | S           | Oral         | Unk                |                 | Mallinckrodt |
|                                  | Oxymorphone Hydrochloride |              |            | S           | Oral         | Unk                |                 | Mallinckrodt |
|                                  | Alprazolam                |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                                  | Gabapentin                |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                                  | Escitalopram              |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                                  | Trazodone                 |              |            | S           | Oral         | Unk                |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                           | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------------|--------------------------------------|-----------------|--------------|----------------|
| 13-Jan-2016                                        | 11913940             | EXPEDITED (15-DAY) |                    | DE              | US-MALLINCKRODT-T201505975 |                                      | 42 YR           | Female       | USA            |
| <u>Preferred Term</u>                              | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                  | Roxicodone           |                    |                    | S               | Oral                       | Unk                                  |                 | Mallinckrodt |                |
|                                                    | Metoprolol           |                    |                    | S               |                            |                                      |                 | Not Reported |                |
|                                                    | Zolpidem             |                    |                    | S               |                            |                                      |                 | Not Reported |                |
|                                                    | Diazepam             |                    |                    | S               |                            |                                      |                 | Not Reported |                |
|                                                    | Escitalopram         |                    |                    | S               |                            |                                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                           | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Jan-2016                                        | 11914318             | EXPEDITED (15-DAY) |                    | OT              | US-APOTEX-2016AP005086     |                                      | 25 YR           | Male         | USA            |
| <u>Preferred Term</u>                              | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Rhabdomyolysis                                     | Escitalopram Oxalate |                    |                    | S               | Unknown                    | 10mg Daily                           |                 | Apotex       |                |
|                                                    | Escitalopram Oxalate |                    |                    | S               |                            |                                      |                 | Apotex       |                |
|                                                    | Risperidone          |                    |                    | S               | Unknown                    | At Night                             |                 | Apotex       |                |
|                                                    | Risperidone          |                    |                    | S               | Unknown                    | 1 Mg, Unk                            |                 | Apotex       |                |
|                                                    | Mirtazapine          |                    |                    | C               | Unknown                    | At Night                             |                 | Not Reported |                |
|                                                    | Mirtazapine          |                    |                    | C               |                            |                                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                           | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Jan-2016                                        | 11698292             | EXPEDITED (15-DAY) |                    | HO              | GB-ASTRAZENECA-2015SF04612 |                                      | 121 DAY         | Female       | GBR            |
| <u>Preferred Term</u>                              | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Withdrawal Syndrome Neonatal; Sepsis Neonatal | Omeprazole           |                    |                    | S               | Transplacental             |                                      |                 | Not Reported |                |
|                                                    | Azathioprine         |                    |                    | S               | Transplacental             |                                      |                 | Not Reported |                |
|                                                    | Oramorph             |                    |                    | S               | Transplacental             | 15 Mg, 3-6 Times Per Day As Required |                 | Not Reported |                |
|                                                    | Oramorph             |                    |                    | S               | Transplacental             | 15 Mg, 3-6 Times Per Day As Required |                 | Not Reported |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|              |   |                |              |
|--------------|---|----------------|--------------|
| Oramorph     | S | Unknown        | Not Reported |
| Co-Dydramol  | S | Transplacental | Not Reported |
| Escitalopram | S | Transplacental | Not Reported |
| Tapentadol   | S | Transplacental | Not Reported |
| Daktarin     | C | Unknown        | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Jan-2016              | 11917137      | EXPEDITED (15-DAY) | HO                 |                 | FR-FRI-1000082053    |                      | 32 YR      | Unknown    | FRA            |

| <u>Preferred Term</u>                                                                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Acute Coronary Syndrome; Chest Pain; Coronary Arterial Stent Insertion; Hypercholesterolaemia | Escitalopram   |              |            | S           | Oral         | 5 Mg               |                 | Forest       |
|                                                                                               | Xeroquel       |              |            | S           | Oral         | 50 Mg              |                 | Not Reported |
|                                                                                               | Xeroquel       |              |            | S           |              |                    |                 | Not Reported |
|                                                                                               | Melatonin      |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                                               | Alimemazine    |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                                               | Digoxine       |              |            | C           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Jan-2016              | 11917539      | EXPEDITED (15-DAY) | HO                 |                 | FR-FRI-1000082072    |                      | 33 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                                                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Acute Coronary Syndrome; Angina Pectoris; Cholestasis; Coronary Arterial Stent Insertion; Hepatocellular Injury | Escitalopram   |              |            | S           | Oral         | 5 Mg               |                 | Forest       |
|                                                                                                                 | Xeroquel       |              |            | S           | Oral         | 50 Mg              |                 | Not Reported |
|                                                                                                                 | Xeroquel       |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                 | Kardegic       |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                                                                 | Brilique       |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                                                                 | Crestor        |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                                                                 | Tenormine      |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                                                                 | Inexium        |              |            | C           | Unknown      |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|           |   |         |              |
|-----------|---|---------|--------------|
| Theralene | C | Unknown | Not Reported |
| Atarax    | C |         | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Jan-2016              | 11917725      | EXPEDITED (15-DAY) |                    | OT              | ES-NSR_02305_2016    |                      | 67 YR      | Female     | ESP            |

| <u>Preferred Term</u> | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blindness; Glaucoma   | Hydrochlorothiazide |              |            | S           |              | Df                 |                 | Not Reported |
|                       | Pantoprazole        |              |            | S           |              | Df                 |                 | Not Reported |
|                       | Irbesartan          |              |            | S           |              | Df                 |                 | Not Reported |
|                       | Quetiapine          |              |            | S           | Oral         | 100 Mg, Unk        |                 | Not Reported |
|                       | Quetiapine          |              |            | S           | Oral         | 100 Mg, Unk        |                 | Not Reported |
|                       | Escitalopram        |              |            | S           |              | Df                 |                 | Not Reported |
|                       | Gemfibrozil         |              |            | S           |              | Df                 |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Jan-2016              | 11918830      | DIRECT           |                    |                 |                      |                      | 58 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                          | <u>Product</u>                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------|--------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Chest Discomfort; Dizziness; Feeling Abnormal; Presyncope; Respiratory Rate Increased; Speech Disorder; Tremor | Risperidone Walmart - Pharmacy |              |            | S           | Oral         |                    |                 | Walmart      |
|                                                                                                                | Escitalopram                   |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 15-Jan-2016              | 11919421      | NON-EXPEDITED    |                    |                 | US-JNJFOC-20151219273 |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Nausea                | Xarelto        |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Xarelto        |              |            | S           | Oral         |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|               |   |         |              |
|---------------|---|---------|--------------|
| Escitalopram  | S | Unknown | Not Reported |
| Donepezil     | S | Unknown | Not Reported |
| Pravastatin   | C | Oral    | Not Reported |
| Fish Oil      | C | Unknown | Not Reported |
| Citracal Plus | C | Unknown | Not Reported |
| Glucosamine   | C | Unknown | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Jan-2016              | 11926802      | DIRECT           |                    | OT              |                      |                      | 44 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Alopecia              | Escitalopram   |              |            | S           | Oral         | 1 1/2 At Bedtime   |                 | Not Reported |
|                       | Adderall Xr    |              |            | C           |              |                    |                 | Not Reported |
|                       | Xanax          |              |            | C           |              |                    |                 | Not Reported |
|                       | Lipitor        |              |            | C           |              |                    |                 | Not Reported |
|                       | Trazodone      |              |            | C           |              |                    |                 | Not Reported |
|                       | Topamax        |              |            | C           |              |                    |                 | Not Reported |
|                       | Colace         |              |            | C           |              |                    |                 | Not Reported |
|                       | Ditopan        |              |            | C           |              |                    |                 | Not Reported |
|                       | Prilosec       |              |            | C           |              |                    |                 | Not Reported |
|                       | Flexeril       |              |            | C           |              |                    |                 | Not Reported |
|                       | Folic Acid     |              |            | C           |              |                    |                 | Not Reported |
|                       | Percocet       |              |            | C           |              |                    |                 | Not Reported |
|                       | Vitamin D Nos  |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 18-Jan-2016              | 11910630      | EXPEDITED (15-DAY) |                    | HO, LT          | FR-ASTRAZENECA-2016SE01934 |                      | 33 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                                                                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Acute Coronary Syndrome; Angina Pectoris; Aortic Valve Incompetence; Cholestasis; Coronary Artery Stenosis; | Xeroquel Sr    |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                             | Xeroquel Sr    |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                             | Crestor        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                             | Crestor        |              |            | S           | Oral         |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                      |           |   |      |              |
|------------------------------------------------------------------------------------------------------|-----------|---|------|--------------|
| Hepatocellular Injury;<br>Hypercholesterolaemia;<br>Myalgia; Product Use In<br>Unapproved Indication | Seroplex  | S | Oral | Not Reported |
|                                                                                                      | Melatonin | C | Oral | Not Reported |
|                                                                                                      | Theralene | C |      | Not Reported |
|                                                                                                      | Atarax    | C |      | Not Reported |
|                                                                                                      | Kardegic  | C |      | Not Reported |
|                                                                                                      | Brilique  | C |      | Not Reported |
|                                                                                                      | Tenormine | C |      | Not Reported |
|                                                                                                      | Inexium   | C |      | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|------------------------------------------------|----------------------|-----------------|------------|----------------|
| 18-Jan-2016              | 11923418       | NON-EXPEDITED    |                    |                 | IL-LUPIN<br>PHARMACEUTICALS<br>INC.-2015-04247 |                      | 28 YR           | Male       | ISR            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Sexual Dysfunction       | Escitalopram   |                  |                    | S               | Unknown                                        | 10 Mg                |                 |            | Not Reported   |

| <u>FDA Received Date</u>                                                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 18-Jan-2016                                                                                    | 11925503       | EXPEDITED (15-DAY) |                    | HO              | SE-TEVA-625739ISR    |                      | 29 YR           | Female     | SWE            |
| <u>Preferred Term</u>                                                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Depressed Level Of<br>Consciousness;<br>Intentional Self-Injury;<br>Toxicity To Various Agents | Escitalopram   |                    |                    | S               |                      |                      |                 |            | Ivax           |
|                                                                                                | Propavan       |                    |                    | S               |                      |                      |                 |            | Not Reported   |

| <u>FDA Received Date</u>                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u>       |
|----------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|------------|----------------------|
| 19-Jan-2016                                                    | 9638581        | EXPEDITED (15-DAY) |                    | OT              | AU-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>16034886 |                      | 40 YR           | Female     | AUS                  |
| <u>Preferred Term</u>                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                      |
| Abortion Spontaneous;<br>Maternal Exposure During<br>Pregnancy | Abilify        |                    |                    | S               | Unknown                                         | 20 Mg, Qd            |                 |            | Bristol Myers Squibb |
|                                                                | Lexapro        |                    |                    | S               | Unknown                                         | 10 Mg, Qd            |                 |            | Not Reported         |

# FDA Adverse Event Reporting System

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| <u>FDA Received Date</u>                                                      | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------|---------------------|--------------------|--------------------|-----------------|---------------------------|------------------------|-----------------|--------------|----------------|
| 19-Jan-2016                                                                   | 11723832            | EXPEDITED (15-DAY) |                    | HO              | GB-MYLANLABS-2015M1037488 |                        |                 | Unknown      | GBR            |
| <u>Preferred Term</u>                                                         | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Withdrawal Syndrome Neonatal; Exposure During Pregnancy; Sepsis Neonatal | Azathioprine        |                    |                    | S               | Transplacental            | Unk                    |                 | Not Reported |                |
|                                                                               | Escitalopram        |                    |                    | S               | Transplacental            | Unk                    |                 | Not Reported |                |
|                                                                               | Omeprazole          |                    |                    | S               | Transplacental            | Unk                    |                 | Not Reported |                |
|                                                                               | Co-Dydramol         |                    |                    | S               | Transplacental            | Unk                    |                 | Mylan        |                |
|                                                                               | Oramorph            |                    |                    | S               | Transplacental            | 15 Mg, (3 - 6 Per Day) |                 | Mylan        |                |
|                                                                               | Oramorph            |                    |                    | S               | Unknown                   | Unk                    |                 | Mylan        |                |
|                                                                               | Tapentadol          |                    |                    | S               | Transplacental            | 100 Mg                 |                 | Mylan        |                |
|                                                                               | Daktarin /00310801/ |                    |                    | C               | Unknown                   | Unk                    |                 | Mylan        |                |
| <u>FDA Received Date</u>                                                      | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Jan-2016                                                                   | 11777505            | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000081157         |                        | 87 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                         | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Hallucination, Visual; Persecutory Delusion                                   | Escitalopram        |                    |                    | S               | Oral                      |                        |                 | Forest       |                |
|                                                                               | Preterax            |                    |                    | C               | Oral                      | 2.5 Mg                 |                 | Not Reported |                |
|                                                                               | Seresta             |                    |                    | C               | Oral                      |                        |                 | Not Reported |                |
|                                                                               | Movicol             |                    |                    | C               | Oral                      | Per Needed             |                 | Not Reported |                |
|                                                                               | Effexor             |                    |                    | C               | Oral                      | 18.75 Mg               |                 | Not Reported |                |
|                                                                               | Uvedose             |                    |                    | C               | Oral                      | 0.2143 Df              |                 | Not Reported |                |
|                                                                               | Doliprane           |                    |                    | C               | Oral                      |                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                      | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Jan-2016                                                                   | 11925915            | EXPEDITED (15-DAY) |                    | HO              | CA-ROCHE-1695785          |                        | 54 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                                         | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |

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|                                                                     |                      |   |      |              |
|---------------------------------------------------------------------|----------------------|---|------|--------------|
| Condition Aggravated;<br>Dehydration; Dysphagia;<br>Mental Disorder | Clonazepam           | S | Oral | Not Reported |
|                                                                     | Cipralax             | S | Oral | Not Reported |
|                                                                     | Domperidone          | S | Oral | Not Reported |
|                                                                     | Ferrous Sulfate      | S | Oral | Not Reported |
|                                                                     | Gabapentin           | S | Oral | Not Reported |
|                                                                     | Gabapentin           | S | Oral | Not Reported |
|                                                                     | Temazepam            | S | Oral | Not Reported |
|                                                                     | Tylenol With Codeine | S | Oral | Not Reported |
|                                                                     | Wellbutrin XL        | S | Oral | Not Reported |

| <u>FDA Received Date</u>  | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------|-----------------------------|--------------------|--------------------|-----------------|------------------------|----------------------|-----------------|--------------|----------------|
| 19-Jan-2016               | 11927844                    | EXPEDITED (15-DAY) |                    | DE              | US-APOTEX-2016AP005275 |                      | 16 YR           | Male         | USA            |
| <u>Preferred Term</u>     | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardio-Respiratory Arrest | Escitalopram Oxalate        |                    |                    | S               |                        |                      |                 | Apotex       |                |
|                           | Aripiprazole Tablets        |                    |                    | S               | Oral                   |                      |                 | Apotex       |                |
|                           | Morphine                    |                    |                    | S               | Oral                   |                      |                 | Not Reported |                |
|                           | Acetaminophen W/Hydrocodone |                    |                    | S               | Oral                   |                      |                 | Not Reported |                |
|                           | Cyclobenzaprine             |                    |                    | S               | Oral                   |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 19-Jan-2016                                                           | 11927862       | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000082202    |                      | 68 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alveolar Lung Disease;<br>Interstitial Lung Disease;<br>Muscle Spasms | Escitalopram   |                    |                    | S               |                      | 7.5 Mg               |                 | Forest       |                |
|                                                                       | Escitalopram   |                    |                    | S               |                      | 7.5 Mg               |                 | Not Reported |                |
|                                                                       | Amiodarone     |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Jan-2016              | 11929468      | DIRECT           |                    |                 |                      |                      | 48 YR      | Female     | USA            |

# FDA Adverse Event Reporting System

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| <u>Preferred Term</u>                                                                           | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
|-------------------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|----------------------|----------------|
| Depression; Dizziness;<br>Dizziness; Product<br>Substitution Issue                              | Escitalopram           |                    |                    | S               | Oral                                            | 1xday                |                 | Mylan                |                |
| <u>FDA Received Date</u>                                                                        | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 20-Jan-2016                                                                                     | 7835256                | EXPEDITED (15-DAY) |                    | DE, OT          | CH-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>15565690 |                      | 1 DAY           | Male                 | CHE            |
| <u>Preferred Term</u>                                                                           | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Death Neonatal; Foetal<br>Exposure During<br>Pregnancy                                          | Abilify                |                    |                    | S               | Transplacental                                  | 15 Mg, Qd            |                 | Bristol Myers Squibb |                |
|                                                                                                 | Cipralax               |                    |                    | S               | Transplacental                                  | 10 Mg, Bid           |                 | Not Reported         |                |
|                                                                                                 | Stilnox                |                    |                    | S               | Transplacental                                  | 12.5 Mg, Qd          |                 | Not Reported         |                |
|                                                                                                 | Temesta (Lorazepam)    |                    |                    | S               | Transplacental                                  | Unk                  |                 | Not Reported         |                |
|                                                                                                 | Zyprexa                |                    |                    | S               | Transplacental                                  | 7.5 Mg, Qd           |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                                        | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 20-Jan-2016                                                                                     | 11929580               | EXPEDITED (15-DAY) |                    | OT              | CA-TEVA-627236ACC                               |                      | 39 YR           | Female               | CAN            |
| <u>Preferred Term</u>                                                                           | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Condition Aggravated;<br>Fatigue; Obsessive<br>Thoughts; Psychomotor<br>Retardation; Somnolence | Citalopram             |                    |                    | S               | Oral                                            | 50 Milligram Daily;  |                 | Pliva                |                |
|                                                                                                 | Citalopram             |                    |                    | S               |                                                 |                      |                 | Pliva                |                |
|                                                                                                 | Escitalopram           |                    |                    | S               |                                                 | 10 Milligram Daily;  |                 | Ivax                 |                |
|                                                                                                 | Escitalopram           |                    |                    | S               |                                                 |                      |                 | Ivax                 |                |
| <u>FDA Received Date</u>                                                                        | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 20-Jan-2016                                                                                     | 11929802               | EXPEDITED (15-DAY) |                    | DE              | US-APOTEX-<br>2016AP005332                      |                      | 34 YR           | Male                 | USA            |
| <u>Preferred Term</u>                                                                           | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Cardio-Respiratory Arrest;<br>Death                                                             | Alprazolam Tablets Usp |                    |                    | S               | Oral                                            |                      |                 | Apotex               |                |
|                                                                                                 | Gabapentin             |                    |                    | S               | Oral                                            |                      |                 | Apotex               |                |
|                                                                                                 | Escitalopram Oxalate   |                    |                    | S               | Oral                                            |                      |                 | Apotex               |                |

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|                                     |                         | Trazodone Hydrochloride | S                  | Oral            |                            |                                                                                     |                 | Apotex       |                |
|-------------------------------------|-------------------------|-------------------------|--------------------|-----------------|----------------------------|-------------------------------------------------------------------------------------|-----------------|--------------|----------------|
|                                     |                         | Oxycodone               | S                  | Oral            |                            |                                                                                     |                 | Not Reported |                |
|                                     |                         | Oxymorphone             | S                  | Oral            |                            |                                                                                     |                 | Not Reported |                |
| <u>FDA Received Date</u>            | <u>Case #</u>           | <u>Case Type</u>        | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                                                                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Jan-2016                         | 11930426                | DIRECT                  | Y                  | LT              |                            |                                                                                     | 66 YR           | Male         | USA            |
| <u>Preferred Term</u>               | <u>Product</u>          | <u>Comp.</u>            | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                                                                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Intolerance; Suicidal Ideation | Escitalopram            |                         |                    | S               | Oral                       |                                                                                     |                 | Not Reported |                |
| <u>FDA Received Date</u>            | <u>Case #</u>           | <u>Case Type</u>        | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                                                                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Jan-2016                         | 11931462                | EXPEDITED (15-DAY)      |                    | OT              | CH-ASTRAZENECA-2016SE03115 |                                                                                     | 37 YR           | Female       | CHE            |
| <u>Preferred Term</u>               | <u>Product</u>          | <u>Comp.</u>            | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                                                                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Anterograde Amnesia; Vomiting       | Inderal                 |                         |                    | S               | Oral                       | 1-1-0-0, I.E. 10 Mg In The Morning And 10 Mg At Midday With Nothing Else After That |                 | Not Reported |                |
|                                     | Sequase                 |                         |                    | S               | Oral                       | 0-1-0-2 Tablets, I.E. 200 Mg At Midday And 400 Mg Before Going To Sleep             |                 | Not Reported |                |
|                                     | Escitalopram            |                         |                    | S               | Oral                       |                                                                                     |                 | Not Reported |                |
|                                     | Lyrica                  |                         |                    | S               | Oral                       | 50 Mg                                                                               |                 | Not Reported |                |
| <u>FDA Received Date</u>            | <u>Case #</u>           | <u>Case Type</u>        | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                                                                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Jan-2016                         | 11932137                | EXPEDITED (15-DAY)      |                    | DE              | US-APOTEX-2016AP005385     |                                                                                     | 14 YR           | Male         | USA            |
| <u>Preferred Term</u>               | <u>Product</u>          | <u>Comp.</u>            | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                                                                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                   | Escitalopram Oxalate    |                         |                    | S               | Oral                       |                                                                                     |                 | Apotex       |                |
|                                     | Bupropion Hydrochloride |                         |                    | S               | Oral                       |                                                                                     |                 | Apotex       |                |
|                                     | Metoprolol              |                         |                    | S               | Oral                       |                                                                                     |                 | Not Reported |                |



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| <u>FDA Received Date</u>                                                 | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u>                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|------------------------|--------------------------------------------|-----------------|--------------|----------------|
| 20-Jan-2016                                                              | 11932145             | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000082203      |                                            | 28 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Antipsychotic Drug Level Above Therapeutic; Intentional Overdose; Tremor | Escitalopram         |                    |                    | S               | Oral                   | Overdose Of Unknown Number Of Tablets Once |                 | Forest       |                |
|                                                                          | Escitalopram         |                    |                    | S               | Oral                   | Overdose Of Unknown Tablets Once           |                 | Forest       |                |
|                                                                          | Teralithe Lp         |                    |                    | S               | Oral                   |                                            |                 | Not Reported |                |
|                                                                          | Teralithe Lp         |                    |                    | S               | Oral                   | Overdose Of Unknown Number Of Tablets Once |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                 | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u>                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Jan-2016                                                              | 11932253             | EXPEDITED (15-DAY) |                    | DE              | US-APOTEX-2016AP005672 |                                            | 64 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                                        | Escitalopram Oxalate |                    |                    | S               | Oral                   |                                            |                 | Apotex       |                |
|                                                                          | Amlodipine Besylate  |                    |                    | S               | Oral                   |                                            |                 | Apotex       |                |
| <u>FDA Received Date</u>                                                 | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u>                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Jan-2016                                                              | 11932254             | EXPEDITED (15-DAY) |                    | DE              | US-APOTEX-2016AP005673 |                                            | 70 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                                        | Escitalopram Oxalate |                    |                    | S               | Oral                   |                                            |                 | Apotex       |                |
|                                                                          | Citalopram           |                    |                    | S               | Oral                   |                                            |                 | Apotex       |                |
| <u>FDA Received Date</u>                                                 | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u>                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Jan-2016                                                              | 11934824             | DIRECT             |                    | OT              |                        |                                            | 49 YR           | Female       |                |
| <u>Preferred Term</u>                                                    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>                         | <u>Duration</u> | <u>Mfr</u>   |                |

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| Depression; Drug Ineffective; Product Substitution Issue                          | Lexapro 10 Mg           |                           | S                           | Oral                     | 1 Pill Daily                             |                               | Not Reported             |                      |                         |
|-----------------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|------------------------------------------|-------------------------------|--------------------------|----------------------|-------------------------|
|                                                                                   | Lexapro                 |                           | C                           |                          |                                          |                               | Not Reported             |                      |                         |
| <a href="#">FDA Received Date</a>                                                 | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>            | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a>  | <a href="#">Country</a> |
| 20-Jan-2016                                                                       | 11937767                | DIRECT                    | Y                           | DS                       |                                          |                               |                          | Unknown              | IND                     |
| <a href="#">Preferred Term</a>                                                    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                    | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a>  |                         |
| Disturbance In Attention; Feeling Abnormal; Memory Impairment                     | Nexito 10mg Sun Pharma  |                           |                             | S                        | Oral                                     |                               | 20 DAY                   | Sun                  |                         |
| <a href="#">FDA Received Date</a>                                                 | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>            | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a>  | <a href="#">Country</a> |
| 21-Jan-2016                                                                       | 7832893                 | EXPEDITED (15-DAY)        |                             | OT                       | CH-BRISTOL-MYERS SQUIBB COMPANY-15571714 |                               | 32 YR                    | Female               | CHE                     |
| <a href="#">Preferred Term</a>                                                    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                    | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a>  |                         |
| Amniotic Cavity Infection; Maternal Exposure During Pregnancy; Premature Delivery | Abilify                 |                           |                             | S                        | Unknown                                  | 15 Mg, Qd                     |                          | Bristol Myers Squibb |                         |
|                                                                                   | Ciprallex               |                           |                             | S                        | Unknown                                  | 10 Mg, Bid                    |                          | Not Reported         |                         |
|                                                                                   | Stilnox                 |                           |                             | S                        | Unknown                                  | 12.5 Mg, Qd                   |                          | Not Reported         |                         |
|                                                                                   | Temesta (Lorazepam)     |                           |                             | S                        | Unknown                                  | Unk                           |                          | Not Reported         |                         |
|                                                                                   | Zyprexa                 |                           |                             | S                        | Unknown                                  | 7.5 Mg, Qd                    |                          | Not Reported         |                         |
| <a href="#">FDA Received Date</a>                                                 | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>            | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a>  | <a href="#">Country</a> |
| 21-Jan-2016                                                                       | 11714074                | NON-EXPEDITED             |                             |                          | US-PFIZER INC-2015375920                 |                               |                          | Male                 | USA                     |
| <a href="#">Preferred Term</a>                                                    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                    | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a>  |                         |
| Drug Screen False Positive                                                        | Amoxicillin             |                           |                             | S                        |                                          | Unk                           |                          | Pfizer               |                         |
|                                                                                   | Chantix                 |                           |                             | S                        |                                          | Unk                           |                          | Pfizer               |                         |
|                                                                                   | Xanax                   |                           |                             | S                        |                                          | Unk                           |                          | Pfizer               |                         |
|                                                                                   | Lexapro                 |                           |                             | S                        |                                          | Unk                           |                          | Not Reported         |                         |

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| <u>FDA Received Date</u> | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|-------------------------------------|--------------------|--------------------|-----------------|------------------------|----------------------|-----------------|--------------|----------------|
| 21-Jan-2016              | 11933812                            | EXPEDITED (15-DAY) |                    | DE, HO          | US-APOTEX-2016AP005366 |                      | 46 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Death                    | Quetiapine Fumarate                 |                    |                    | S               | Oral                   |                      |                 | Apotex       |                |
|                          | Escitalopram Oxalate                |                    |                    | S               | Oral                   |                      |                 | Apotex       |                |
|                          | Sertraline Hydrochloride            |                    |                    | S               | Oral                   |                      |                 | Apotex       |                |
|                          | Buspirone Hydrochloride Tablets Usp |                    |                    | S               | Oral                   |                      |                 | Apotex       |                |
|                          | Acetaminophen                       |                    |                    | S               | Oral                   |                      |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Jan-2016              | 11934178                            | EXPEDITED (15-DAY) |                    | DE              | US-APOTEX-2016AP005576 |                      | 25 YR           | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide        | Lamotrigine                         |                    |                    | S               | Oral                   |                      |                 | Apotex       |                |
|                          | Bupropion Hydrochloride             |                    |                    | S               | Oral                   |                      |                 | Apotex       |                |
|                          | Escitalopram Oxalate                |                    |                    | S               | Oral                   |                      |                 | Apotex       |                |
|                          | Clonazepam Tablets Usp              |                    |                    | S               | Oral                   |                      |                 | Apotex       |                |
| <u>FDA Received Date</u> | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Jan-2016              | 11934183                            | EXPEDITED (15-DAY) |                    | DE              | US-APOTEX-2016AP005580 |                      | 52 YR           | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide        | Lamotrigine                         |                    |                    | S               | Oral                   |                      |                 | Apotex       |                |
|                          | Escitalopram Oxalate                |                    |                    | S               | Oral                   |                      |                 | Apotex       |                |
|                          | Atenolol                            |                    |                    | S               | Oral                   |                      |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Jan-2016              | 11934584                            | EXPEDITED (15-DAY) |                    | DE              | US-APOTEX-2016AP005416 |                      | 25 YR           | Female       | USA            |

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| <u>Preferred Term</u>                           | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| Cardio-Respiratory Arrest;<br>Completed Suicide | Escitalopram Oxalate    |                    |                    | S               | Oral                     |                      |                 | Apotex       |                |
|                                                 | Propranolol             |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                        | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Jan-2016                                     | 11934837                | EXPEDITED (15-DAY) |                    | DE              | US-APOTEX-2016AP005425   |                      | 37 YR           | Female       | USA            |
| <u>Preferred Term</u>                           | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                               | Lisinopril              |                    |                    | S               | Oral                     |                      |                 | Apotex       |                |
|                                                 | Escitalopram Oxalate    |                    |                    | S               | Oral                     |                      |                 | Apotex       |                |
|                                                 | Clonazepam Tablets Usp  |                    |                    | S               | Oral                     |                      |                 | Apotex       |                |
|                                                 | Trazodone Hydrochloride |                    |                    | S               | Oral                     |                      |                 | Apotex       |                |
| <u>FDA Received Date</u>                        | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Jan-2016                                     | 11936414                | EXPEDITED (15-DAY) |                    | DE, OT          | US-BAUSCH-BL-2016-000900 |                      | 22 YR           | Female       | USA            |
| <u>Preferred Term</u>                           | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardio-Respiratory Arrest;<br>Completed Suicide | Diazepam                |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                                                 | Escitalopram            |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                        | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Jan-2016                                     | 11964484                | DIRECT             |                    |                 |                          |                      | 38 YR           | Male         | USA            |
| <u>Preferred Term</u>                           | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Thinking<br>Abnormal                | Lexapro 10mg            |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                                                 | Strattera               |                    |                    | C               |                          |                      |                 | Not Reported |                |
|                                                 | Vit B12                 |                    |                    | C               |                          |                      |                 | Not Reported |                |
|                                                 | Multi Vitamin           |                    |                    | C               |                          |                      |                 | Not Reported |                |
|                                                 | B Complex               |                    |                    | C               |                          |                      |                 | Not Reported |                |
|                                                 | L-Arginine              |                    |                    | C               |                          |                      |                 | Not Reported |                |

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| <u>FDA Received Date</u>   | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|----------------------------|---------------------------|--------------------|--------------------|-----------------|--------------------------------------------------------|----------------------|-----------------|----------------------|----------------|
| 22-Jan-2016                | 11833010                  | EXPEDITED (15-DAY) |                    | HO, OT          | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>BMS-2015-085903 |                      |                 | Female               | USA            |
| <u>Preferred Term</u>      | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Hospitalisation            | Abilify                   |                    |                    | S               | Unknown                                                | Unk, Qd              |                 | Bristol Myers Squibb |                |
|                            | Lexapro                   |                    |                    | S               | Unknown                                                | Unk                  |                 | Not Reported         |                |
| <u>FDA Received Date</u>   | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 22-Jan-2016                | 11842716                  | EXPEDITED (15-DAY) |                    | HO, OT          | ES-ROCHE-1664023                                       |                      |                 | Male                 | ESP            |
| <u>Preferred Term</u>      | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Disorientation;            | Cobimetinib               |                    |                    | S               | Oral                                                   |                      |                 | Not Reported         |                |
| Disorientation; Drug       | Vemurafenib               |                    |                    | S               | Unknown                                                | 240 Mg Per Tablet    |                 | Not Reported         |                |
| Interaction; Psychomotor   | Escitalopram              |                    |                    | S               | Unknown                                                |                      |                 | Not Reported         |                |
| Hyperactivity; Toxicity To | Pristiq                   |                    |                    | S               | Unknown                                                |                      |                 | Not Reported         |                |
| Various Agents             |                           |                    |                    |                 |                                                        |                      |                 |                      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 22-Jan-2016                | 11865954                  | EXPEDITED (15-DAY) |                    | OT              | CA-APOTEX-<br>2015AP015290                             |                      | 56 YR           | Female               | CAN            |
| <u>Preferred Term</u>      | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Nipple Pain; Product       | Apo-Escitalopram          |                    |                    | S               | Unknown                                                | 10 Mg, Qd            |                 | Apotex               |                |
| Contamination; Weight      | Tylenol With Codeine No.3 |                    |                    | C               | Unknown                                                |                      |                 | Not Reported         |                |
| Increased                  |                           |                    |                    |                 |                                                        |                      |                 |                      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 22-Jan-2016                | 11938284                  | EXPEDITED (15-DAY) |                    | DE              | US-ROCHE-1698294                                       |                      | 53 YR           | Female               | USA            |
| <u>Preferred Term</u>      | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Toxicity To Various Agents | Clonazepam                |                    |                    | S               | Oral                                                   |                      |                 | Not Reported         |                |
|                            | Duloxetine                |                    |                    | S               | Oral                                                   |                      |                 | Not Reported         |                |

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|              |   |      |              |
|--------------|---|------|--------------|
| Baclofen     | S | Oral | Not Reported |
| Escitalopram | S | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Jan-2016              | 11939066      | EXPEDITED (15-DAY) | HO                 |                 | FR-FRI-1000082224    |                      | 53 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|---------------------------|-----------------|--------------|
| Intentional Overdose  | Escitalopram   |              |            | S           | Oral         | Overdose:15 Tablets Once  |                 | Forest       |
|                       | Valium         |              |            | S           | Oral         | Overdose: 1 Bottle Once   |                 | Not Reported |
|                       | Theralene      |              |            | S           | Oral         | Overdose: 1 Bottle Once   |                 | Not Reported |
|                       | Theralene      |              |            | S           | Oral         | Overdose: 50 Tablets Once |                 | Not Reported |
|                       | Abilify        |              |            | S           | Oral         | Overdose: 7 Tablets Once  |                 | Not Reported |
|                       | Stilnox        |              |            | S           | Oral         | Overdose: 30 Tablets Once |                 | Not Reported |
|                       | Seresta        |              |            | S           | Oral         | Overdose: 80 Tablets Once |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Jan-2016              | 11939089      | EXPEDITED (15-DAY) | LT                 |                 | FR-FRI-1000082208    |                      | 63 YR      | Male       | FRA            |

| <u>Preferred Term</u>                    | <u>Product</u>  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------|-----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction;<br>Haemorrhagic Stroke | Escitalopram    |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                          | Xarelto         |              |            | S           | Oral         | 10 Mg              |                 | Not Reported |
|                                          | Metformine      |              |            | C           |              | 1700 Mg            |                 | Not Reported |
|                                          | Cyanocobalamine |              |            | C           |              |                    |                 | Not Reported |
|                                          | Folic Acid      |              |            | C           |              | 10 Mg              |                 | Not Reported |
|                                          | Diffu K         |              |            | C           |              | 1800 Mg            |                 | Not Reported |
|                                          | Sotalol         |              |            | C           |              | 40 Mg              |                 | Not Reported |
|                                          | Furosemide      |              |            | C           |              | 40 Mg              |                 | Not Reported |
| Esomeprazole                             |                 |              | C          |             |              |                    | Not Reported    |              |

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|  |              |   |        |              |
|--|--------------|---|--------|--------------|
|  | Prednisone   | C | 7 Mg   | Not Reported |
|  | Simvastatine | C | 10 Mg  | Not Reported |
|  | Tardyferon   | C | 160 Mg | Not Reported |
|  | Zopiclone    | C |        | Not Reported |

| <u>FDA Received Date</u>                         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 22-Jan-2016                                      | 11939159       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000082218    |                      | 72 YR           | Female       | FRA            |
| <u>Preferred Term</u>                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Arrhythmia;<br>Electrocardiogram Qt<br>Prolonged | Escitalopram   |                    |                    | S               | Oral                 |                      |                 | Forest       |                |
|                                                  | Cordarone      |                    |                    | S               | Unknown              |                      |                 | Not Reported |                |
|                                                  | Eliquis        |                    |                    | C               | Unknown              |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                        | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| 22-Jan-2016                                     | 11939693             | EXPEDITED (15-DAY) |                    | DE, OT          | US-APOTEX-<br>2016AP005636 |                      | 22 YR           | Female       | USA            |
| <u>Preferred Term</u>                           | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardio-Respiratory Arrest;<br>Completed Suicide | Escitalopram Oxalate |                    |                    | S               | Oral                       |                      |                 | Apotex       |                |
|                                                 | Diazepam             |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|------------|----------------|
| 22-Jan-2016              | 11939694                | EXPEDITED (15-DAY) |                    | DE              | US-APOTEX-<br>2016AP005640 |                      | 33 YR           | Male       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Completed Suicide        | Escitalopram Oxalate    |                    |                    | S               | Oral                       |                      |                 | Apotex     |                |
|                          | Topiramate              |                    |                    | S               | Oral                       |                      |                 | Apotex     |                |
|                          | Meloxicam               |                    |                    | S               | Oral                       |                      |                 | Apotex     |                |
|                          | Trazodone Hydrochloride |                    |                    | S               | Oral                       |                      |                 | Apotex     |                |
|                          | Olanzapine              |                    |                    | S               | Oral                       |                      |                 | Apotex     |                |
|                          | Sumatriptan Tablets Usp |                    |                    | S               | Oral                       |                      |                 | Apotex     |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                     |   |      |              |
|-------------------------------------|---|------|--------------|
| Buspirone Hydrochloride Tablets Usp | S | Oral | Apotex       |
| Dextromethorfan                     | S | Oral | Not Reported |
| Cyclobenzaprine                     | S | Oral | Not Reported |
| Chlorpheniramine /00072501/         | S | Oral | Not Reported |
| Benzonatate                         | S | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Jan-2016              | 11939824      | EXPEDITED (15-DAY) | HO                 |                 | FR-FRI-1000082212    |                      | 43 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                              | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|-------------------------------------------------|-----------------|--------------|
| Coma; Diarrhoea; Overdose; Prothrombin Time Ratio Decreased | Escitalopram   |              |            | S           | Oral         | Intentional Overdose Of 140 Mg Of Escitalopram. |                 | Forest       |
|                                                             | Colchicine     |              |            | S           | Oral         | Intentional Overdose Of 20 Mg Of Colchicine.    |                 | Not Reported |
|                                                             | Truvada        |              |            | C           | Unknown      |                                                 |                 | Not Reported |
|                                                             | Reyataz        |              |            | C           | Unknown      |                                                 |                 | Not Reported |
|                                                             | Norvir         |              |            | C           | Unknown      |                                                 |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Jan-2016              | 11939890      | EXPEDITED (15-DAY) | HO                 |                 | SE-TEVA-627544ISR    |                      | 59 YR      | Female     | SWE            |

| <u>Preferred Term</u>                                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Heart Rate Decreased; Nausea; Toxicity To Various Agents | Atenolol       |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                          | Cipralext      |              |            | S           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------|----------------------|------------|------------|----------------|
| 22-Jan-2016              | 11939999      | EXPEDITED (15-DAY) |                    | DE              | US-APOTEX-2016AP005444 |                      | 42 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|-------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Completed Suicide     | Zolpidem Tartrate |              |            | S           | Oral         |                    |                 | Apotex     |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |                      |   |      |              |
|--|----------------------|---|------|--------------|
|  | Escitalopram Oxalate | S | Oral | Apotex       |
|  | Metoprolol           | S |      | Not Reported |
|  | Oxycodone            | S |      | Not Reported |
|  | Diazepam             | S |      | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Jan-2016              | 11963352      | DIRECT           |                    | OT              |                      |                      | 33 YR      | Female     | USA            |

| <u>Preferred Term</u>                                               | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Aphasia; Fatigue; Feeling Abnormal; Headache; Mood Altered | Escitalopram 5 Mg Teva |              |            | S           | Oral         | 1 Per Day          |                 | Teva         |
|                                                                     | Zyrtec                 |              |            | C           |              |                    |                 | Not Reported |
|                                                                     | Tums                   |              |            | C           |              |                    |                 | Not Reported |
|                                                                     | Pepto Bismol           |              |            | C           |              |                    |                 | Not Reported |
|                                                                     | Biotin                 |              |            | C           |              |                    |                 | Not Reported |
|                                                                     | Multivitamin           |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------------------|----------------------|------------|------------|----------------|
| 23-Jan-2016              | 7228610       | EXPEDITED (15-DAY) |                    | CA, OT          | FR-BRISTOL-MYERS SQUIBB COMPANY-14901060 |                      | < 1 DAY    | Female     | FRA            |

| <u>Preferred Term</u>                                                                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>           |
|-------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|----------------------|
| Fallot'S Tetralogy; Foetal Exposure During Pregnancy; Foetal Growth Restriction; Premature Baby | Abilify        |              |            | S           | Transplacental | 10 Mg, Unk         |                 | Bristol Myers Squibb |
|                                                                                                 | Seroplex       |              |            | S           | Transplacental | 20 Mg, Unk         |                 | Not Reported         |
|                                                                                                 | Dipiperon      |              |            | S           | Transplacental | 1 Df, Qd           |                 | Not Reported         |
|                                                                                                 | Ikaran         |              |            | S           | Transplacental | 10 Mg, Unk         |                 | Not Reported         |
|                                                                                                 | Seresta        |              |            | S           | Transplacental | 75 Mg, Unk         |                 | Not Reported         |
|                                                                                                 | Havlane        |              |            | S           | Transplacental | Unk Unk, Qd        |                 | Not Reported         |
|                                                                                                 | Tranxene       |              |            | S           | Transplacental | 40 Mg, Unk         |                 | Not Reported         |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------|----------------------|------------|------------|----------------|
| 23-Jan-2016              | 11941685      | EXPEDITED (15-DAY) |                    | DE              | US-APOTEX-2016AP005661 |                      | 53 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                   |                                                   |   |      |              |
|-------------------|---------------------------------------------------|---|------|--------------|
| Completed Suicide | Duloxetine Hydrochloride Delayed-Release Capsules | S | Oral | Apotex       |
|                   | Clonazepam Tablets USP                            | S | Oral | Apotex       |
|                   | Escitalopram Oxalate                              | S | Oral | Apotex       |
|                   | Baclofen                                          | S | Oral | Not Reported |
|                   | Thyroid Preparations                              | S | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Jan-2016              | 11942071      | EXPEDITED (15-DAY) |                    | DE              | US-ROCHE-1698285     |                      | 25 YR      | Male       | USA            |

| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Toxicity To Various Agents | Clonazepam     |              |            | S           | Oral         |                    |                 | Not Reported |
|                            | Bupropion Er   |              |            | S           | Oral         |                    |                 | Not Reported |
|                            | Escitalopram   |              |            | S           | Oral         |                    |                 | Not Reported |
|                            | Lamotrigine    |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Jan-2016              | 11942077      | EXPEDITED (15-DAY) |                    | DE              | US-ROCHE-1698353     |                      | 37 YR      | Female     | USA            |

| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Toxicity To Various Agents | Clonazepam     |              |            | S           | Oral         |                    |                 | Not Reported |
|                            | Lisinopril     |              |            | S           | Oral         |                    |                 | Not Reported |
|                            | Escitalopram   |              |            | S           | Oral         |                    |                 | Not Reported |
|                            | Trazodone      |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------------------|----------------------|------------|------------|----------------|
| 25-Jan-2016              | 7643314       | EXPEDITED (15-DAY) |                    | OT              | AU-BRISTOL-MYERS SQUIBB COMPANY-15352784 |                      | 1 DAY      | Male       | AUS            |

| <u>Preferred Term</u>                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>           |
|--------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|----------------------|
| Foetal Distress Syndrome; Foetal Exposure During | Abilify        |              |            | S           | Transplacental | 30 Mg, Qd          |                 | Bristol Myers Squibb |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                                                                         |                         |                    |                    |                 |                                                 |                      |                 |                      |                |
|---------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|----------------------|----------------|
| Pregnancy; Premature Baby                                                                               |                         | Lexapro            |                    | S               | Transplacental                                  | 10 Mg, Qd            |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                                                | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 25-Jan-2016                                                                                             | 10390937                | EXPEDITED (15-DAY) |                    | OT              | CH-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>21291208 |                      |                 | Female               | CHE            |
| <u>Preferred Term</u>                                                                                   | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Foetal Exposure During Pregnancy; Foetal Macrosomia; Hypoglycaemia Neonatal                             | Abilify                 |                    |                    | S               | Transplacental                                  | Unk                  |                 | Bristol Myers Squibb |                |
|                                                                                                         | Temesta (Lorazepam)     |                    |                    | S               | Transplacental                                  | Unk                  |                 | Not Reported         |                |
|                                                                                                         | Ciprallex               |                    |                    | S               | Transplacental                                  | Unk                  |                 | Not Reported         |                |
|                                                                                                         | Topamax                 |                    |                    | S               | Transplacental                                  | Unk                  |                 | Not Reported         |                |
|                                                                                                         | Seroquel                |                    |                    | S               | Transplacental                                  | Unk                  |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                                                | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 25-Jan-2016                                                                                             | 11706565                | EXPEDITED (15-DAY) |                    | HO              | IT-JNJFOC-<br>20151100729                       |                      | 34 YR           | Female               | ITA            |
| <u>Preferred Term</u>                                                                                   | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Drug Abuse; Dysarthria; Intentional Product Misuse; Self-Medication; Somnolence; Sopor; Speech Disorder | Haldol                  |                    |                    | S               | Oral                                            |                      |                 | Not Reported         |                |
|                                                                                                         | Biperiden Hydrochloride |                    |                    | S               | Oral                                            |                      |                 | Not Reported         |                |
|                                                                                                         | Valium                  |                    |                    | S               | Oral                                            |                      |                 | Not Reported         |                |
|                                                                                                         | Escitalopram            |                    |                    | S               | Oral                                            |                      |                 | Not Reported         |                |
|                                                                                                         | Clonidine Hydrochloride |                    |                    | S               | Oral                                            |                      |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                                                | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 25-Jan-2016                                                                                             | 11942187                | EXPEDITED (15-DAY) |                    | DE              | US-ROCHE-1698283                                |                      | 22 YR           | Female               | USA            |
| <u>Preferred Term</u>                                                                                   | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Cardiac Arrest; Respiratory Arrest; Toxicity To Various Agents                                          | Diazepam                |                    |                    | S               | Oral                                            |                      |                 | Not Reported         |                |
|                                                                                                         | Escitalopram            |                    |                    | S               | Oral                                            |                      |                 | Not Reported         |                |

# FDA Adverse Event Reporting System

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### Detailed Report

| <u>FDA Received Date</u>                                                | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>         | <u>Country</u> |
|-------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|---------------------------------------|----------------------|-----------------|--------------------|----------------|
| 25-Jan-2016                                                             | 11942309               | EXPEDITED (15-DAY) |                    | DE              | US-ROCHE-1698299                      |                      | 42 YR           | Female             | USA            |
| <u>Preferred Term</u>                                                   | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>         |                |
| Toxicity To Various Agents                                              | Diazepam               |                    |                    | S               | Oral                                  |                      |                 | Not Reported       |                |
|                                                                         | Metoprolol             |                    |                    | S               | Oral                                  |                      |                 | Not Reported       |                |
|                                                                         | Oxycodone              |                    |                    | S               | Oral                                  |                      |                 | Not Reported       |                |
|                                                                         | Zolpidem               |                    |                    | S               | Oral                                  |                      |                 | Not Reported       |                |
|                                                                         | Escitalopram           |                    |                    | S               | Oral                                  |                      |                 | Not Reported       |                |
| <u>FDA Received Date</u>                                                | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>         | <u>Country</u> |
| 25-Jan-2016                                                             | 11943173               | EXPEDITED (15-DAY) |                    | OT              | GB-ACCORD-037114                      |                      | 51 YR           | Female             | GBR            |
| <u>Preferred Term</u>                                                   | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>         |                |
| Electrocardiogram Qt Prolonged; Face Oedema; Fatigue; Oedema Peripheral | Escitalopram           |                    |                    | S               | Oral                                  |                      |                 | Accord             |                |
|                                                                         | Atorvastatin           |                    |                    | C               |                                       |                      |                 | Not Reported       |                |
|                                                                         | Diclofenac             |                    |                    | C               |                                       |                      |                 | Not Reported       |                |
|                                                                         | Ezetimibe              |                    |                    | C               |                                       |                      |                 | Not Reported       |                |
| <u>FDA Received Date</u>                                                | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>         | <u>Country</u> |
| 25-Jan-2016                                                             | 11950071               | EXPEDITED (15-DAY) |                    | DE              | US-LEHIGH_VALLEY-USA-POI0580201600017 |                      | 34 YR           | Male               | USA            |
| <u>Preferred Term</u>                                                   | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>         |                |
| Cardiac Arrest; Poisoning Deliberate; Respiratory Arrest                | Oxycodone Hcl Capsules |                    |                    | S               |                                       |                      |                 | Lehigh Valley Tech |                |
|                                                                         | Oxymorphone            |                    |                    | S               |                                       |                      |                 | Not Reported       |                |
|                                                                         | Alprazolam             |                    |                    | S               |                                       |                      |                 | Not Reported       |                |
|                                                                         | Gabapentin             |                    |                    | S               |                                       |                      |                 | Not Reported       |                |
|                                                                         | Escitalopram           |                    |                    | S               |                                       |                      |                 | Not Reported       |                |
|                                                                         | Trazodone              |                    |                    | S               |                                       |                      |                 | Not Reported       |                |
| <u>FDA Received Date</u>                                                | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>         | <u>Country</u> |
| 25-Jan-2016                                                             | 11950139               | EXPEDITED (15-DAY) |                    | DE              | US-LEHIGH_VALLEY-                     |                      | 42 YR           | Female             | USA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

USA-  
POI0580201600062

| <u>Preferred Term</u> | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>         |
|-----------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------------|
| Completed Suicide     | Oxycodone Hcl Capsules |              |            | S           |              |                    |                 | Lehigh Valley Tech |
|                       | Metoprolol             |              |            | S           |              |                    |                 | Not Reported       |
|                       | Zolpidem               |              |            | S           |              |                    |                 | Not Reported       |
|                       | Diazepam               |              |            | S           |              |                    |                 | Not Reported       |
|                       | Escitalopram           |              |            | S           |              |                    |                 | Not Reported       |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Jan-2016              | 11793716      | EXPEDITED (15-DAY) |                    | HO, OT          | PHHY2015IT153835     |                      | 84 YR      | Female     | ITA            |

| <u>Preferred Term</u>                           | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------|--------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Disorientation; Drug Abuse; Fall; Injury; Sopor | Alprazolam         |              |            | S           | Unknown      |                    |                 | Novartis     |
|                                                 | Cardioaspirin      |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                 | Triatec (Ramipril) |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                 | Entact             |              |            | S           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Jan-2016              | 11957436      | EXPEDITED (15-DAY) |                    | HO              | PHHY2016FR006565     |                      | 81 YR      | Female     | FRA            |

| <u>Preferred Term</u>              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------|----------------|--------------|------------|-------------|--------------|-----------------------------|-----------------|--------------|
| Fall; Medication Error; Somnolence | Baclofen       |              |            | S           | Oral         | 8 Df, Qd                    |                 | Not Reported |
|                                    | Amlodipine     |              |            | S           | Oral         | 10 Mg, Once/Single          |                 | Novartis     |
|                                    | Escitalopram   |              |            | S           | Oral         | 5 Mg, Qd                    |                 | Not Reported |
|                                    | Bisoprolol     |              |            | S           | Oral         | 5 Mg, Bid (10 Mg)           |                 | Not Reported |
|                                    | Amitriptyline  |              |            | S           | Oral         | 10 Drp, Single Intake       |                 | Not Reported |
|                                    | Symbicort      |              |            | S           | Unknown      | 1 Df, Bid (2 Df), 100/6/Day |                 | Not Reported |
|                                    | Lormetazepam   |              |            | S           | Oral         | 1 Mg, Once/Single           |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                               |                   |                    |                    |                       |                                                 |                      |                 |                      |                |
|-----------------------------------------------------------------------------------------------|-------------------|--------------------|--------------------|-----------------------|-------------------------------------------------|----------------------|-----------------|----------------------|----------------|
| Oxazepam                                                                                      |                   | S                  | Oral               | 50 Mg, Bid (100 Mg)   |                                                 | Not Reported         |                 |                      |                |
| Potassium                                                                                     |                   | S                  | Oral               | 600 Mg, Bid (1200 Mg) |                                                 | Not Reported         |                 |                      |                |
| <u>FDA Received Date</u>                                                                      | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>       | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 27-Jan-2016                                                                                   | 7975924           | EXPEDITED (15-DAY) | HO                 |                       | DE-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>15152879 |                      |                 | Female               | DEU            |
| <u>Preferred Term</u>                                                                         | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>           | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Abortion Induced;<br>Maternal Exposure During<br>Pregnancy; Premature<br>Rupture Of Membranes | Abilify           |                    |                    | S                     | Unknown                                         | 10 Mg, Qd            |                 | Bristol Myers Squibb |                |
|                                                                                               | Ciprallex         |                    |                    | S                     | Unknown                                         | 10 Mg, Unk           |                 | Not Reported         |                |
|                                                                                               | Neuroleptic Agent |                    |                    | C                     | Unknown                                         |                      |                 | Not Reported         |                |
|                                                                                               | Folsan            |                    |                    | C                     | Unknown                                         | 5 Mg, Unk            |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                                      | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>       | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 27-Jan-2016                                                                                   | 10881233          | EXPEDITED (15-DAY) | HO                 |                       | HR-JNJFOC-<br>20150211176                       |                      |                 | Male                 | HRV            |
| <u>Preferred Term</u>                                                                         | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>           | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Epilepsy; Foetal Exposure<br>During Pregnancy                                                 | Rispolept Consta  |                    |                    | S                     | Transplacental                                  |                      |                 | Not Reported         |                |
|                                                                                               | Xeplion           |                    |                    | S                     | Transplacental                                  |                      |                 | Not Reported         |                |
|                                                                                               | Risperidone       |                    |                    | S                     | Transplacental                                  |                      |                 | Not Reported         |                |
|                                                                                               | Elicea            |                    |                    | S                     | Transplacental                                  |                      |                 | Not Reported         |                |
|                                                                                               | Zoloft            |                    |                    | S                     | Transplacental                                  |                      |                 | Not Reported         |                |
|                                                                                               | Lithium           |                    |                    | S                     | Transplacental                                  |                      |                 | Not Reported         |                |
|                                                                                               | Normabel          |                    |                    | S                     | Transplacental                                  |                      |                 | Not Reported         |                |
|                                                                                               | Seroquel Xr       |                    |                    | S                     | Transplacental                                  |                      |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                                      | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>       | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 27-Jan-2016                                                                                   | 11787651          | EXPEDITED (15-DAY) | HO                 |                       | IT-BAYER-2015-474612                            |                      | 84 YR           | Female               | ITA            |
| <u>Preferred Term</u>                                                                         | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>           | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Disorientation; Drug                                                                          | Cardioaspirin     |                    |                    | S                     |                                                 |                      |                 | Bayer                |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|              |                    |   |              |
|--------------|--------------------|---|--------------|
| Abuse; Sopor | Alprazolam         | S | Not Reported |
|              | Entact             | S | Not Reported |
|              | Triatec (Ramipril) | S | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Jan-2016              | 11951078      | EXPEDITED (15-DAY) |                    | OT              | GB-TEVA-603612ISR    |                      | 43 YR      | Female     | GBR            |

| <u>Preferred Term</u>                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------|----------------|--------------|------------|-------------|--------------|----------------------|-----------------|--------------|
| Drug Interaction; Restless<br>Legs Syndrome | Quetiapine     |              |            | S           | Unknown      | 300 Milligram Daily; |                 | Teva         |
|                                             | Citalopram     |              |            | S           | Unknown      | 20 Milligram Daily;  |                 | Pliva        |
|                                             | Escitalopram   |              |            | S           | Unknown      |                      |                 | Ivax         |
|                                             | Dothieapin     |              |            | S           | Unknown      |                      |                 | Not Reported |
|                                             | Fluoxetine     |              |            | S           | Unknown      |                      |                 | Not Reported |
|                                             | Lofepramine    |              |            | S           | Unknown      |                      |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Jan-2016              | 11965198      | EXPEDITED (15-DAY) |                    | OT              | US-ACCORD-037198     |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|------------------------------------------|-----------------|------------|
| Depersonalisation/Dereali<br>sation Disorder;<br>Disorientation; Headache;<br>Hyperacusis; Impaired<br>Work Ability; Malaise;<br>Migraine; Paraesthesia;<br>Photophobia; Product<br>Substitution Issue;<br>Withdrawal Syndrome | Escitalopram   |              |            | S           |              | Took The Medication For 3<br>Weeks Daily |                 | Accord     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------|----------------------|------------|------------|----------------|
| 27-Jan-2016              | 11965437      | EXPEDITED (15-DAY) |                    | OT              | GB-AUROBINDO-AUR-<br>APL-2016-00430 |                      | 51 YR      | Female     | GBR            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                         |              |   |         |           |              |
|-------------------------|--------------|---|---------|-----------|--------------|
| Electrocardiogram Qt    | Escitalopram | S | Oral    | 5 Mg, Unk | Aurobindo    |
| Prolonged; Face Oedema; | Atorvastatin | C | Unknown |           | Not Reported |
| Fatigue; Oedema         | Diclofenac   | C | Unknown |           | Not Reported |
| Peripheral              | Ezetimibe    | C | Unknown |           | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Jan-2016              | 11965528      | EXPEDITED (15-DAY) |                    | HO              | IT-ROCHE-1699910     |                      | 34 YR      | Female     | ITA            |

| <u>Preferred Term</u>                                                                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|---------------------------------------------------|-----------------|--------------|
| Dysarthria; Intentional Product Misuse; Language Disorder; Self-Medication; Somnolence; Sopor | Valium         |              |            | S           | Oral         | 2 Mg Hard Capsules 30 Capsules                    |                 | Not Reported |
|                                                                                               | Haldol         |              |            | S           | Oral         | 1 Mg Tablets 30 Tablets                           |                 | Not Reported |
|                                                                                               | Akineton       |              |            | S           | Oral         | 2 Mg Tablets 60 Tablets                           |                 | Not Reported |
|                                                                                               | Cipralext      |              |            | S           | Oral         | 28 X 20 Mg Tablets In A White Pvc/Pe/Pvdc/Al Blis |                 | Not Reported |
|                                                                                               | Catapresan     |              |            | S           | Oral         |                                                   |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Jan-2016              | 11966718      | EXPEDITED (15-DAY) |                    | DE, LT          | FR-FRI-1000082310    |                      | 64 YR      | Male       | FRA            |

| <u>Preferred Term</u>                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cerebral Haematoma; Drug Interaction | Escitalopram   |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                      | Kardegic       |              |            | S           | Oral         | 75 Mg              |                 | Not Reported |
|                                      | Lovenox        |              |            | S           | Subcutaneous | 16000 lu           |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Jan-2016              | 11966719      | EXPEDITED (15-DAY) |                    | OT              | NL-FRI-1000082178    |                      |            | Unknown    | NLD            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Seizure               | Escitalopram   |              |            | S           | Unknown      |                    |                 | Forest     |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|----------------------------|----------------------|--------------------|--------------------|-----------------|-------------------------------------------------|--------------------------|-----------------|----------------------|----------------|
| 27-Jan-2016                | 11968853             | DIRECT             |                    |                 |                                                 |                          | 22 YR           | Female               | USA            |
| <u>Preferred Term</u>      | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>           |                |
| Headache;                  | Lexapro Generic 10mg |                    |                    | S               | Oral                                            |                          |                 | Accord               |                |
| Hypersensitivity; Nausea;  | Lorazepam (Ativan)   |                    |                    | C               |                                                 |                          |                 | Not Reported         |                |
| Skin Burning Sensation;    | Bupap                |                    |                    | C               |                                                 |                          |                 | Not Reported         |                |
| Skin Warm                  |                      |                    |                    |                 |                                                 |                          |                 |                      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 28-Jan-2016                | 8167342              | EXPEDITED (15-DAY) |                    | CA, HO, OT      | FR-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>16113003 |                          | 4 DAY           | Male                 | FRA            |
| <u>Preferred Term</u>      | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>           |                |
| Dysmorphism; Foetal        | Abilify              |                    |                    | S               | Transplacental                                  | Unk                      |                 | Bristol Myers Squibb |                |
| Exposure During            | Tercian              |                    |                    | S               | Transplacental                                  | Unk                      |                 | Not Reported         |                |
| Pregnancy; Hypotonia       | Imovane              |                    |                    | S               | Transplacental                                  | Unk                      |                 | Not Reported         |                |
| Neonatal; Large For Dates  | Seroplex             |                    |                    | S               | Transplacental                                  | Unk                      |                 | Not Reported         |                |
| Baby; Respiratory Distress |                      |                    |                    |                 |                                                 |                          |                 |                      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 28-Jan-2016                | 11059319             | EXPEDITED (15-DAY) |                    | DS              | CA-FRI-1000076062                               |                          | 55 YR           | Male                 | CAN            |
| <u>Preferred Term</u>      | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>           |                |
| Abdominal Discomfort;      | Escitalopram         |                    |                    | S               | Oral                                            | Overdose: Escitalopram   |                 | Forest               |                |
| Abnormal Dreams;           |                      |                    |                    |                 |                                                 | 30 Mg Daily              |                 |                      |                |
| Antiandrogen Therapy;      | Zeldox               |                    |                    | C               | Unknown                                         | Daily Dose Not Reported. |                 | Not Reported         |                |
| Arthralgia; Cold Sweat;    |                      |                    |                    |                 |                                                 |                          |                 |                      |                |
| Confusional State;         |                      |                    |                    |                 |                                                 |                          |                 |                      |                |
| Diarrhoea; Flatulence;     |                      |                    |                    |                 |                                                 |                          |                 |                      |                |
| Hunger; Hyperhidrosis;     |                      |                    |                    |                 |                                                 |                          |                 |                      |                |
| Prescribed Overdose;       |                      |                    |                    |                 |                                                 |                          |                 |                      |                |
| Rhinorrhoea; Sleep         |                      |                    |                    |                 |                                                 |                          |                 |                      |                |
| Disorder; Urinary          |                      |                    |                    |                 |                                                 |                          |                 |                      |                |
| Incontinence               |                      |                    |                    |                 |                                                 |                          |                 |                      |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                    | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|---------------------------------------------|---------------------------------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|-----------------|-----------------|----------------|
| 28-Jan-2016                                 | 11885011                              | EXPEDITED (15-DAY) |                    | HO              | US-ACTAVIS-2015-28715           |                      | 25 YR           | Male            | USA            |
| <u>Preferred Term</u>                       | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Dizziness;<br>Rhabdomyolysis                | Risperidone (Watson Laboratories)     |                    |                    | S               | Unknown                         | 1 Mg, Daily          |                 | Watson          |                |
|                                             | Risperidone (Watson Laboratories)     |                    |                    | S               | Unknown                         | 0.5 Mg Qhs           |                 | Watson          |                |
|                                             | Escitalopram (Unknown)                |                    |                    | S               | Unknown                         | 10 Mg, Daily         |                 | Not Reported    |                |
|                                             | Escitalopram (Unknown)                |                    |                    | S               |                                 |                      |                 | Not Reported    |                |
|                                             | Mirtazapine (Actavis Laboratories FI) |                    |                    | S               | Unknown                         | 15 Mg Qhs            |                 | Actavis         |                |
|                                             | Mirtazapine (Actavis Laboratories FI) |                    |                    | S               |                                 |                      |                 | Actavis         |                |
| <u>FDA Received Date</u>                    | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 28-Jan-2016                                 | 11944448                              | EXPEDITED (15-DAY) |                    | HO, OT          | CN-GLAXOSMITHKLINE-CN2015113537 |                      | 56 YR           | Female          | CHN            |
| <u>Preferred Term</u>                       | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Pneumonia                                   | Escitalopram Oxalate                  |                    |                    | S               |                                 | Unk                  |                 | Glaxosmithkline |                |
| <u>FDA Received Date</u>                    | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 28-Jan-2016                                 | 11968828                              | EXPEDITED (15-DAY) |                    | OT              | GB-DRREDDYS-USA/UKI/15/0053339  |                      | 43 YR           | Female          | GBR            |
| <u>Preferred Term</u>                       | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Drug Interaction; Restless<br>Legs Syndrome | Quetiapine                            |                    |                    | S               | Unknown                         |                      |                 | Not Reported    |                |
|                                             | Fluoxetine                            |                    |                    | S               | Unknown                         |                      |                 | Not Reported    |                |
|                                             | Citalopram                            |                    |                    | S               | Unknown                         |                      |                 | Not Reported    |                |
|                                             | Escitalopram                          |                    |                    | S               | Unknown                         |                      |                 | Not Reported    |                |
|                                             | Dothiepin                             |                    |                    | S               | Unknown                         |                      |                 | Not Reported    |                |
|                                             | Lofepamine                            |                    |                    | S               | Unknown                         |                      |                 | Not Reported    |                |

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| <u>FDA Received Date</u>                                                                                | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|------------------------------------------|----------------------|-----------------|----------------------|----------------|
| 28-Jan-2016                                                                                             | 11969517               | EXPEDITED (15-DAY) |                    | OT              | GB-ACTAVIS-2016-01616                    |                      | 43 YR           | Female               | GBR            |
| <u>Preferred Term</u>                                                                                   | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Drug Interaction; Restless Legs Syndrome                                                                | Quetiapine (Unknown)   |                    |                    | S               | Unknown                                  |                      |                 | Actavis              |                |
|                                                                                                         | Escitalopram (Unknown) |                    |                    | S               | Unknown                                  | Unknown              |                 | Not Reported         |                |
|                                                                                                         | Dosulepin              |                    |                    | S               | Unknown                                  | Unknown              |                 | Not Reported         |                |
|                                                                                                         | Fluoxetine (Unknown)   |                    |                    | S               | Unknown                                  | Unknown              |                 | Watson               |                |
|                                                                                                         | Lofepramine (Unknown)  |                    |                    | S               | Unknown                                  | Unknown              |                 | Not Reported         |                |
|                                                                                                         | Citalopram             |                    |                    | C               | Unknown                                  | 20 Mg, Daily         |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                                                | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 28-Jan-2016                                                                                             | 11969913               | EXPEDITED (15-DAY) |                    | OT              | GB-FRI-1000082216                        |                      | 51 YR           | Female               | GBR            |
| <u>Preferred Term</u>                                                                                   | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Electrocardiogram Qt Prolonged; Face Oedema; Fatigue; Oedema Peripheral                                 | Escitalopram           |                    |                    | S               | Oral                                     | 5 Mg Daily           |                 | Forest               |                |
|                                                                                                         | Atorvastatin           |                    |                    | C               | Unknown                                  |                      |                 | Not Reported         |                |
|                                                                                                         | Diclofenac             |                    |                    | C               | Unknown                                  |                      |                 | Not Reported         |                |
|                                                                                                         | Ezetimibe              |                    |                    | C               | Unknown                                  |                      |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                                                | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 28-Jan-2016                                                                                             | 11971729               | EXPEDITED (15-DAY) |                    | OT              | KR-BRISTOL-MYERS SQUIBB COMPANY-15908783 |                      |                 | Female               | KOR            |
| <u>Preferred Term</u>                                                                                   | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Abortion Induced; Exposure During Pregnancy; Pregnancy On Contraceptive; Uterine Dilation And Curettage | Aripiprazole           |                    |                    | S               | Oral                                     | Unk                  |                 | Bristol Myers Squibb |                |
|                                                                                                         | External-Escitalopram  |                    |                    | S               | Oral                                     | 1 Df, Qd             |                 | Unknown              |                |
|                                                                                                         | Mefenamic Acid         |                    |                    | C               | Unknown                                  | Unk                  |                 | Not Reported         |                |
|                                                                                                         | Phazyme                |                    |                    | C               | Unknown                                  | Unk                  |                 | Not Reported         |                |
|                                                                                                         | Domperidone            |                    |                    | C               | Unknown                                  | Unk                  |                 | Not Reported         |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |                      |   |         |     |  |              |
|--|----------------------|---|---------|-----|--|--------------|
|  | Almagate             | C | Unknown | Unk |  | Not Reported |
|  | Ibudilast            | C | Unknown | Unk |  | Not Reported |
|  | Talniflumate         | C | Unknown |     |  | Not Reported |
|  | Diastase             | C | Unknown | Unk |  | Not Reported |
|  | Lipase               | C | Unknown | Unk |  | Not Reported |
|  | Ursodeoxycholic Acid | C | Unknown | Unk |  | Not Reported |
|  | Itopride Hcl         | C | Unknown | Unk |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Jan-2016              | 11973020      | EXPEDITED (15-DAY) |                    | OT              | CA-TEVA-629523USA    |                      |            | Male       | CAN            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                               | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                              | <u>Duration</u> | <u>Mfr</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|--------------|------------|-------------|--------------|-------------------------------------------------|-----------------|------------|
| Adverse Event; Alcohol Use; Dissociation; Dizziness; Emotional Disorder; Emotional Distress; Emotional Poverty; Feeling Abnormal; General Physical Health Deterioration; Hyperhidrosis; Impulsive Behaviour; Insomnia; Job Dissatisfaction; Pain; Paraesthesia; Personality Change; Quality Of Life Decreased; Therapeutic Response Unexpected; Withdrawal Syndrome | Teva-Escitalopram |              |            | S           |              | Started Taking Product Approximately A Year Ago |                 | Ivax       |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Jan-2016              | 11977287      | DIRECT           |                    |                 |                      |                      | 64 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Arthralgia; Libido    | Escitalopram 10 Mg Accord |              |            | S           | Oral         |                    | 1.5 YR          | Accord     |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                             |                                         |        |                              |
|-----------------------------|-----------------------------------------|--------|------------------------------|
| Decreased; Weight Increased | Health<br>Zanax<br>Vit B Complex With C | C<br>C | Not Reported<br>Not Reported |
|-----------------------------|-----------------------------------------|--------|------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 29-Jan-2016              | 6754770       | EXPEDITED (15-DAY) |                    | CA, OT          | CH-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>14326458 |                      | < 1 DAY    | Male       | CHE            |

| <u>Preferred Term</u>                                                                                                                                                                       | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                     | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>                           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|----------------------------------|------------------------|-----------------|--------------------------------------|
| Breech Presentation;<br>Dysmorphism; Ear<br>Malformation; Foetal<br>Exposure During<br>Pregnancy; Hypotonia<br>Neonatal; Multiple<br>Congenital Abnormalities;<br>Selective Eating Disorder | Abilify<br>Ciprallex |              |            | S<br>S      | Transplacental<br>Transplacental | 30 Mg, Qd<br>10 Mg, Qd |                 | Bristol Myers Squibb<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Jan-2016              | 11059709      | EXPEDITED (15-DAY) |                    | OT              | CA-FRI-1000076063    |                      | 62 YR      | Female     | CAN            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                                                      | <u>Product</u>                                                                                                                                    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>                                    | <u>Route</u>                                                                                            | <u>Dosage Text</u>                                                                                                                                                                             | <u>Duration</u> | <u>Mfr</u>                                                                                                                             |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------|--------------|------------|------------------------------------------------|---------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|----------------------------------------------------------------------------------------------------------------------------------------|
| Alopecia; Arthritis; Breath<br>Sounds Abnormal;<br>Bronchitis; Chondropathy;<br>Cough; Depression; Fall;<br>Fatigue; Feeling Of Body<br>Temperature Change;<br>Hyperhidrosis;<br>Inappropriate Schedule Of<br>Product Administration;<br>Incorrect Product<br>Administration Duration;<br>Intervertebral Disc<br>Disorder; Lymphoedema;<br>Lymphoma; Motor<br>Dysfunction; Nausea;<br>Oedema Peripheral; Pain;<br>Panic Attack; Photopsia; | Escitalopram<br>Clorazepate<br>Co Etidrocal<br>Esomeprazole<br>Gabapentin<br>Gabapentin<br>Ibuprofen<br>Morphine<br>Trazodone<br>Voltaren Emulgel |              |            | S<br>S<br>S<br>S<br>S<br>S<br>S<br>S<br>S<br>S | Unknown<br>Oral<br>Unknown<br>Unknown<br>Unknown<br>Unknown<br>Unknown<br>Unknown<br>Unknown<br>Topical | 20 Mg Once Daily At<br>Bedtime<br>45 Mg<br>500 Mg<br>40 Mg<br>Dose Not Reported.<br>Dose Not Reported.<br>100 Mg<br>Dose Not Reported.<br>50 Mg Once Daily At<br>Bedtime<br>3 Squeezes Once Or |                 | Forest<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                         |                                                                    |                  |                    |                                                                             |                                                              |
|-------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------|------------------|--------------------|-----------------------------------------------------------------------------|--------------------------------------------------------------|
| Pneumonia; Respiratory Arrest; Therapeutic Response Changed; Therapeutic Response Decreased; Tremor; Walking Disability | Voltaren Emulgel<br>Voltaren Emulgel<br>Zopiclone<br>Bupropion Hcl | S<br>S<br>S<br>C | Unknown<br>Unknown | Twice A Day And At Night<br>15 Mg Once Daily At Night<br>Dose Not Reported. | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |
|-------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------|------------------|--------------------|-----------------------------------------------------------------------------|--------------------------------------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Jan-2016              | 11069102      | EXPEDITED (15-DAY) | LT                 |                 | CA-FRI-1000076042    |                      | 24 YR      | Male       | CAN            |

| <u>Preferred Term</u>               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------|----------------|--------------|------------|-------------|--------------|---------------------------------------|-----------------|--------------|
| Cardiomyopathy; Prescribed Overdose | Escitalopram   |              |            | S           | Oral         | Overdose: Escitalopram<br>40 Mg Daily |                 | Forest       |
|                                     | Adderall Xr    |              |            | S           | Oral         | 10 Mg                                 |                 | Not Reported |
|                                     | Adderall Xr    |              |            | S           | Oral         | 20 Mg                                 |                 | Not Reported |
|                                     | Dantrium       |              |            | S           | Oral         |                                       |                 | Not Reported |
|                                     | Temazepam      |              |            | S           | Oral         | 15 Mg                                 |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------------------------------|----------------------|------------|------------|----------------|
| 29-Jan-2016              | 11771268      | EXPEDITED (15-DAY) | HO, OT             |                 | CH-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>BMS-2015-080558 |                      | 93 YR      | Female     | CHE            |

| <u>Preferred Term</u>                                                                                                     | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>           |
|---------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------|
| Agitation; Confusional State; Encephalopathy; Enterococcus Test                                                           | Abilify              |              |            | S           | Oral         | Unk                |                 | Bristol Myers Squibb |
| Positive; Extrapyrimalal Disorder; Loss Of Consciousness; Malaise; Renal Failure; Rhabdomyolysis; Urinary Tract Infection | Ciprallex /01588501/ |              |            | S           | Oral         | 20 Mg, Qd          |                 | Not Reported         |
|                                                                                                                           | Ciprallex /01588501/ |              |            | S           | Oral         | 10 Mg, Qd          |                 | Not Reported         |
|                                                                                                                           | Keppra               |              |            | S           | Oral         | 250 Mg, Bid        |                 | Not Reported         |
|                                                                                                                           | Keppra               |              |            | S           | Oral         | 250 Mg, Qd         |                 | Not Reported         |
|                                                                                                                           | Amoxicillin Sodium   |              |            | S           | Oral         | 500 Mg, Bid        |                 | Not Reported         |
|                                                                                                                           | Valdoxan             |              |            | C           | Oral         | 25 Mg, Qd          |                 | Not Reported         |
|                                                                                                                           | Xanax                |              |            | C           | Oral         | 0.25 Mg, Qd        |                 | Not Reported         |
|                                                                                                                           | Xanax                |              |            | C           | Oral         | 0.125 Mg, Qd       |                 | Not Reported         |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                    |   |              |             |              |
|--------------------|---|--------------|-------------|--------------|
| Temesta /00273201/ | C | Oral         | 0.5 Mg, Qd  | Not Reported |
| Aspirin Cardio     | C | Unknown      | 100 Mg, Unk | Not Reported |
| Nexium /01479302/  | C | Oral         | 20 Mg, Qd   | Not Reported |
| Anxiolit           | C | Oral         | 15 Mg, Qid  | Not Reported |
| Anxiolit           | C | Oral         | 15 Mg, Qid  | Not Reported |
| Anxiolit           | C | Oral         | 7.5 Mg, Qid | Not Reported |
| Prednisone         | C | Oral         | 2.5 Mg, Qd  | Not Reported |
| Prednisone         | C | Oral         | 5 Mg, Qd    | Not Reported |
| Valtrex            | C | Oral         | 500 Mg, Qd  | Not Reported |
| Vitamine B6        | C | Oral         | 40 Mg, Qd   | Not Reported |
| Metoject           | C | Subcutaneous | 15 Mg, Qwk  | Not Reported |
| Laxoberon          | C | Oral         | 5 Mg, Unk   | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Jan-2016              | 11803534      | EXPEDITED (15-DAY) | HO                 |                 | IT-TEVA-613107ACC    |                      | 84 YR      | Female     | ITA            |

| <u>Preferred Term</u>                                          | <u>Product</u>                                                  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------|-----------------------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Disorientation; Drug Abuse; Fall; Head Injury; Overdose; Sopor | Alprazolam                                                      |              |            | S           |              | 1 Bottle           |                 | Teva         |
|                                                                | Cardioaspirin - 100 Mg Comprese Gastroresistenti - Bayer S.P.A. |              |            | S           |              |                    |                 | Not Reported |
|                                                                | Triatec - 2.5 Mg Comprese - Programmi Sanitari Integrati S.R.L. |              |            | S           |              |                    |                 | Not Reported |
|                                                                | Entact - Comprese Rivestite Con Film - H. Lundbeck A/S          |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------------------|----------------------|------------|------------|----------------|
| 29-Jan-2016              | 11977844      | EXPEDITED (15-DAY) |                    | OT              | FR-BRISTOL-MYERS SQUIBB COMPANY-21650262 |                      |            | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>           |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------|
| Caesarean Section;    | Abilify        |              |            | S           | Unknown      | 15 Mg, Unk         |                 | Bristol Myers Squibb |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                 |                                      |   |         |                       |              |
|---------------------------------------------------------------------------------|--------------------------------------|---|---------|-----------------------|--------------|
| Delirium; Hypertension;<br>Maternal Exposure During<br>Pregnancy; Off Label Use | Seroplex                             | S | Unknown | Unk                   | Not Reported |
|                                                                                 | Parkinane                            | S | Unknown | Unk                   | Not Reported |
|                                                                                 | Tenoretic                            | S | Unknown | 1 Df, Qd              | Not Reported |
|                                                                                 | Tercian                              | S | Unknown | 1 Df, Qd              | Not Reported |
|                                                                                 | Loxen (Nicardipine<br>Hydrochloride) | C | Unknown | Unk                   | Not Reported |
|                                                                                 | Loxapac                              | C | Unknown | Unk Unk, Intermittent | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 29-Jan-2016              | 11980648      | EXPEDITED (15-DAY) |                    | OT              | US-JNJFOC-<br>20160116550 |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>                                  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction;<br>Electrocardiogram Qt<br>Prolonged | Domperidone    |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                        | Levofloxacin   |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                        | Erythromycin   |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                        | Haloperidol    |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                        | Risperidone    |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                        | Itraconazole   |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                        | Ketoconazole   |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                        | Miconazole     |              | Y          | S           | Unknown      |                    |                 | Not Reported |
|                                                        | Miconazole     |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                        | Droperidol     |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                        | Desipramine    |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                        | Doxepin        |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                        | Dronedarone    |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                        | Clomipramine   |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                        | Azithromycin   |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                        | Escitalopram   |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                        | Flecainide     |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                        | Fluoxetine     |              |            | S           | Unknown      |                    |                 | Not Reported |



**FDA Adverse Event Reporting System  
Freedom of Information Act (FOIA)  
Detailed Report**

|                |   |         |              |
|----------------|---|---------|--------------|
| Amitriptyline  | S | Unknown | Not Reported |
| Ibutilide      | S | Unknown | Not Reported |
| Imipramine     | S | Unknown | Not Reported |
| Methadone      | S | Unknown | Not Reported |
| Moxifloxacin   | S | Unknown | Not Reported |
| Norfloxacin    | S | Unknown | Not Reported |
| Nortriptyline  | S | Unknown | Not Reported |
| Octreotide     | S | Unknown | Not Reported |
| Ondansetron    | S | Unknown | Not Reported |
| Perflutren     | S | Unknown | Not Reported |
| Propafenone    | S | Unknown | Not Reported |
| Ranolazine     | S | Unknown | Not Reported |
| Ciprofloxacin  | S | Unknown | Not Reported |
| Sotalol        | S | Unknown | Not Reported |
| Quetiapine     | S | Unknown | Not Reported |
| Voriconazole   | S | Unknown | Not Reported |
| Aprepitant     | S | Unknown | Not Reported |
| Cyclosporine   | S | Unknown | Not Reported |
| Diltiazem      | S | Unknown | Not Reported |
| Isoniazid      | S | Unknown | Not Reported |
| Citalopram     | S | Unknown | Not Reported |
| Clarithromycin | S | Unknown | Not Reported |
| Metronidazole  | S | Unknown | Not Reported |
| Nicardipine    | S | Unknown | Not Reported |
| Sertraline     | S | Unknown | Not Reported |
| Tetracaine     | S | Unknown | Not Reported |
| Tetracycline   | S | Unknown | Not Reported |
| Verapamil      | S | Unknown | Not Reported |
| Tacrolimus     | S | Unknown | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|              |   |         |              |
|--------------|---|---------|--------------|
| Amidarone    | S | Unknown | Not Reported |
| Clindamycin  | S | Unknown | Not Reported |
| Fluconazole  | S | Unknown | Not Reported |
| Clotrimazole | S | Unknown | Not Reported |
| Lidocaine    | S | Unknown | Not Reported |

| <u>FDA Received Date</u>                                                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|---------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|---------------------------------------------------------------|----------------------|-----------------|----------------------|----------------|
| 29-Jan-2016                                                                           | 11981096       | EXPEDITED (15-DAY) |                    | HO              | IT-B.I.<br>PHARMACEUTICALS,I<br>NC./RIDGEFIELD-2016-<br>BI-04 |                      | 34 YR           | Female               | ITA            |
| <u>Preferred Term</u>                                                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Dysarthria; Intentional<br>Product Misuse; Language<br>Disorder; Somnolence;<br>Sopor | Catapresan     |                    |                    | S               | Oral                                                          |                      |                 | Boehringer Ingelheim |                |
|                                                                                       | Haldol         |                    |                    | S               | Oral                                                          | Strength: 1 Mg       |                 | Not Reported         |                |
|                                                                                       | Akineton       |                    |                    | S               | Oral                                                          | Strength: 2 Mg       |                 | Not Reported         |                |
|                                                                                       | Valium         |                    |                    | S               | Oral                                                          | Strength: 2 Mg       |                 | Not Reported         |                |
|                                                                                       | Ciprallex      |                    |                    | S               | Oral                                                          | Strength: 20 Mg      |                 | Not Reported         |                |

| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                | <u>Case #</u>      | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 29-Jan-2016                                                                                                                                                                                                                                                                                                                             | 11982681           | DIRECT           |                    | DS, OT          |                      |                      | 66 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                   | <u>Product</u>     | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Discomfort;<br>Abdominal Distension;<br>Agitation; Anal<br>Incontinence; Defaecation<br>Urgency; Depression;<br>Discomfort; Emotional<br>Disorder; Eructation;<br>Feeling Abnormal;<br>Flatulence; Flatulence;<br>Gastrointestinal Motility<br>Disorder; Hallucination,<br>Auditory; Hallucination,<br>Visual; Hyperhidrosis; | Escitalopram 10 Mg |                  |                    | S               |                      | Taken By Mouth       |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                         | Spironolactone     |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                         | Nattokinase        |                  |                    | C               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Hypoaesthesia; Irritability;  
Lethargy; Nervousness;  
Overdose; Pain;  
Paraesthesia; Pruritus;  
Somnolence; Tremor;  
Withdrawal Syndrome

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------|----------------------|------------|------------|----------------|
| 30-Jan-2016              | 11981447      | EXPEDITED (15-DAY) |                    | HO              | IT-AUROBINDO-AUR-<br>APL-2016-00527 |                      | 17 YR      | Male       | ITA            |

| <u>Preferred Term</u>                                                                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Electrocardiogram Qt<br>Prolonged; Intentional<br>Overdose; Intentional Self-<br>Injury | Escitalopram   |              |            | S           | Oral         | 190 Mg, Unk        |                 | Aurobindo  |
|                                                                                         | Olanzapine     |              |            | S           | Oral         | 22.5 Mg, Daily     |                 | Aurobindo  |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Feb-2016              | 11714569      | EXPEDITED (15-DAY) |                    | HO              | GB-TEVA-605523ACC    |                      | 121 DAY    | Female     | GBR            |

| <u>Preferred Term</u>                                                                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|----------------------|-----------------|--------------|
| Drug Withdrawal<br>Syndrome Neonatal;<br>Foetal Exposure During<br>Pregnancy; Sepsis<br>Neonatal | Azathioprine   |              |            | S           | Transplacental |                      |                 | Not Reported |
|                                                                                                  | Escitalopram   |              |            | S           | Transplacental |                      |                 | Ivax         |
|                                                                                                  | Omeprazole     |              |            | S           | Transplacental |                      |                 | Not Reported |
|                                                                                                  | Co-Dydramol    |              |            | S           | Transplacental | Strength: 10/500     |                 | Not Reported |
|                                                                                                  | Oramorph       |              |            | S           | Transplacental | 3-6 Per Day          |                 | Not Reported |
|                                                                                                  | Oramorph       |              |            | S           | Unknown        |                      |                 | Not Reported |
|                                                                                                  | Tapentadol     |              |            | S           | Transplacental | 100 Milligram Daily; |                 | Not Reported |
|                                                                                                  | Daktarin       |              |            | C           | Unknown        |                      |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------------------------------------|----------------------|------------|------------|----------------|
| 01-Feb-2016              | 11801512      | EXPEDITED (15-DAY) |                    | HO              | IT-SUN<br>PHARMACEUTICAL<br>INDUSTRIES LTD-<br>2015RR-107113 |                      |            | Unknown    | ITA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                          | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|----------------------------------------------------------------|--------------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
| Disorientation; Drug Abuse; Somnolence                         | Alprazolam                     |                    |                    | S               | Unknown                   |                      |                 | Sun          |                |
|                                                                | Cardioasprin                   |                    |                    | S               | Unknown                   |                      |                 | Not Reported |                |
|                                                                | Triatec (Ramipril)             |                    |                    | S               | Unknown                   |                      |                 | Not Reported |                |
|                                                                | Entact                         |                    |                    | S               | Unknown                   |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Feb-2016                                                    | 11805233                       | EXPEDITED (15-DAY) |                    | HO              | IT-MYLANLABS-2015M1042207 |                      |                 | Unknown      | ITA            |
| <u>Preferred Term</u>                                          | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Disorientation; Drug Abuse; Fall; Head Injury; Overdose; Sopor | Alprazolam                     |                    |                    | S               |                           | 1 Bottle             |                 | Not Reported |                |
|                                                                | Cardioaspirin                  |                    |                    | S               |                           | Unk                  |                 | Mylan        |                |
|                                                                | Triatec /00885601/             |                    |                    | S               |                           | Unk                  |                 | Mylan        |                |
|                                                                | Entact                         |                    |                    | S               |                           | 1 Bottle             |                 | Mylan        |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Feb-2016                                                    | 11982399                       | EXPEDITED (15-DAY) |                    | OT              | GB-ALKEM-001067           |                      | 43 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                          | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Restless Legs Syndrome                       | Quetiapine/Quetiapine Fumarate |                    |                    | S               |                           |                      |                 | Alkem        |                |
|                                                                | Escitalopram                   |                    |                    | S               |                           |                      |                 | Not Reported |                |
|                                                                | Dosulepin                      |                    |                    | S               |                           |                      |                 | Not Reported |                |
|                                                                | Fluoxetine                     |                    |                    | S               |                           |                      |                 | Not Reported |                |
|                                                                | Lofepramine                    |                    |                    | S               |                           |                      |                 | Not Reported |                |
|                                                                | Citalopram                     |                    |                    | C               |                           |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Feb-2016                                                    | 11982942                       | NON-EXPEDITED      |                    |                 | US-APOTEX-2015AP013833    |                      | 37 YR           | Male         | USA            |
| <u>Preferred Term</u>                                          | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Somnolence; Therapy Non-Responder                              | Trazodone Hydrochloride        |                    |                    | S               | Unknown                   | 100 Mg, Unk          |                 | Apotex       |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                         |   |         |                 |        |
|-------------------------|---|---------|-----------------|--------|
| Escitalopram Oxalate    | S | Unknown | 40 Mg, Unk      | Apotex |
| Bupropion Hydrochloride | S |         | Up To 375mg/Day | Apotex |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Feb-2016              | 11983812      | EXPEDITED (15-DAY) |                    | HO              | FR-SA-2016SA015041   |                      | 48 YR      | Male       | FRA            |

| <u>Preferred Term</u>          | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------|----------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Electrocardiogram Qt Prolonged | Cyamemazine          |              |            | S           | Oral         | Form Drops                    |                 | Not Reported |
|                                | Cyamemazine          |              |            | S           | Oral         | Form Unknown                  |                 | Not Reported |
|                                | Zolpidem Tartrate    |              |            | S           | Oral         |                               |                 | Not Reported |
|                                | Temesta (Lorazepam)  |              |            | S           | Oral         | Form Divisible Tablet         |                 | Not Reported |
|                                | Temesta (Lorazepam)  |              |            | S           | Oral         | Form Divisible Tablet         |                 | Not Reported |
|                                | Olanzapine           |              |            | S           | Oral         |                               |                 | Not Reported |
|                                | Olanzapine           |              |            | S           | Oral         |                               |                 | Not Reported |
|                                | Escitalopram Oxalate |              |            | S           | Oral         | Film-Coated Divisible Tablets |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 02-Feb-2016              | 7414202       | EXPEDITED (15-DAY) |                    | OT              | CH-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>15135338 |                      | < 1 DAY    | Male       | CHE            |

| <u>Preferred Term</u>                                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>           |
|-----------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|----------------------|
| Foetal Exposure During Pregnancy; Respiratory Disorder Neonatal | Buspar         |              |            | S           | Transplacental | 10 Mg, Tid         |                 | Bristol Myers Squibb |
|                                                                 | Trittico       |              |            | S           | Transplacental | 50 Mg, Qd          |                 | Not Reported         |
|                                                                 | Cipralext      |              |            | S           | Transplacental | 5 Mg, Qd           |                 | Not Reported         |
|                                                                 | Effexor        |              |            | S           | Transplacental | 75 Mg, Qd          |                 | Not Reported         |
|                                                                 | Seresta        |              |            | S           | Transplacental | 15 Mg, Qd          |                 | Not Reported         |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Feb-2016              | 8662921       | EXPEDITED (15-DAY) |                    | OT              | IT-FRI-1000037024    |                      |            | Unknown    | ITA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                       | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                 | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------------------------------|--------------------|--------------------|--------------------|-----------------|--------------------------------------------------------------|------------------------|-----------------|--------------|----------------|
| Foetal Exposure During Pregnancy; Foetal Growth Restriction | Escitalopram       |                    |                    | S               | Transplacental                                               | 10 Mg                  |                 | Forest       |                |
|                                                             | Pasaden [Etizolam] |                    |                    | C               | Transplacental                                               | 0.5 Mg                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                    | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                         | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Feb-2016                                                 | 11796894           | EXPEDITED (15-DAY) |                    | HO, OT          | IT-FRI-1000081294                                            |                        | 84 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                       | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                 | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Disorientation; Drug Abuse; Overdose; Sopor                 | Escitalopram       |                    |                    | S               | Unknown                                                      | Unknown                |                 | Forest       |                |
|                                                             | Escitalopram       |                    |                    | S               | Unknown                                                      | Overdose: One Package  |                 | Forest       |                |
|                                                             | Triatec (Ramipril) |                    |                    | S               | Unknown                                                      | Unknown                |                 | Not Reported |                |
|                                                             | Triatec            |                    |                    | S               | Unknown                                                      | Overdose: Unknown Dose |                 | Not Reported |                |
|                                                             | Cardioaspirin      |                    |                    | S               | Unknown                                                      | Unknown                |                 | Not Reported |                |
|                                                             | Cardioaspirin      |                    |                    | S               | Unknown                                                      | Overdose: Unknown Dose |                 | Not Reported |                |
|                                                             | Alprazolam         |                    |                    | S               | Unknown                                                      | Unknown                |                 | Not Reported |                |
|                                                             | Alprazolam         |                    |                    | S               | Unknown                                                      | Overdose: A Flacon     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                    | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                         | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Feb-2016                                                 | 11891852           | EXPEDITED (15-DAY) |                    | HO, OT          | US-SUN<br>PHARMACEUTICAL<br>INDUSTRIES LTD-<br>2015US-108711 |                        | 25 YR           | Male         | USA            |
| <u>Preferred Term</u>                                       | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                 | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Rhabdomyolysis                            | Risperidone        |                    |                    | S               | Unknown                                                      | Titrated Upto 1 Mg     |                 | Ranbaxy      |                |
|                                                             | Risperidone        |                    |                    | S               | Unknown                                                      | 0.5 Mg, Qd (Qhs)       |                 | Ranbaxy      |                |
|                                                             | Escilatopram       |                    |                    | S               | Unknown                                                      | 10 Mg, Daily           |                 | Not Reported |                |
|                                                             | Escilatopram       |                    |                    | S               |                                                              |                        |                 | Not Reported |                |
|                                                             | Mirtazapine        |                    |                    | C               | Unknown                                                      | 15 Mg, Qd(Qhs)         |                 | Not Reported |                |
|                                                             | Mirtazapine        |                    |                    | C               |                                                              | 15 Mg Qhs              |                 | Not Reported |                |
|                                                             | Mirtazapine        |                    |                    | C               |                                                              | 15 Mg Qhs              |                 | Not Reported |                |
|                                                             | Mirtazapine        |                    |                    | C               |                                                              |                        |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                    | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|-------------------------------------------------|---------------------------------------|-----------------|--------------|----------------|
| 02-Feb-2016                                                                 | 11957821       | NON-EXPEDITED      |                    |                 | US-ABBVIE-15K-163-1343478-00                    |                                       |                 | Male         | USA            |
| <u>Preferred Term</u>                                                       | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Heart Rate Irregular;<br>Middle Insomnia;<br>Nervousness; Panic<br>Reaction | Humira         |                    |                    | S               | Unknown                                         |                                       |                 | Not Reported |                |
|                                                                             | Lexapro        |                    |                    | S               | Unknown                                         |                                       |                 | Not Reported |                |
|                                                                             | Lexapro        |                    |                    | S               | Unknown                                         | Dose Decreased                        |                 | Not Reported |                |
|                                                                             | Xanax          |                    |                    | C               |                                                 | Wean Off                              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                    | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Feb-2016                                                                 | 11991024       | EXPEDITED (15-DAY) |                    | HO              | NL-ASTRAZENECA-2016SE09175                      |                                       | 55 YR           | Male         | NLD            |
| <u>Preferred Term</u>                                                       | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;<br>Pulmonary Embolism                                     | Seroquel Xr    |                    |                    | S               | Oral                                            |                                       |                 | Astrazeneca  |                |
|                                                                             | Seroquel Xr    |                    |                    | S               | Oral                                            |                                       |                 | Astrazeneca  |                |
|                                                                             | Seroquel Xr    |                    |                    | S               | Oral                                            | Dose Reduced                          |                 | Astrazeneca  |                |
|                                                                             | Lexapro        |                    |                    | S               | Oral                                            |                                       |                 | Not Reported |                |
|                                                                             | Lexapro        |                    |                    | S               | Oral                                            |                                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                    | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Feb-2016                                                                 | 11992660       | DIRECT             |                    |                 |                                                 |                                       | 47 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                       | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Fatigue;<br>Nausea                                               | Lexapro 10 Mg  |                    |                    | S               | Oral                                            | 1 Pill, Once Daily, Taken<br>By Mouth |                 | Not Reported |                |
|                                                                             | Cozaar         |                    |                    | C               |                                                 |                                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                    | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Feb-2016                                                                 | 9749853        | EXPEDITED (15-DAY) |                    | OT              | CH-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>19873413 |                                       | 33 YR           | Female       | CHE            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                    | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>           |
|------------------------------------------------------------------------------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------|
| Live Birth; Maternal Exposure During Pregnancy; Off Label Use; Oligohydramnios; Vomiting | Abilify             |              |            | S           | Unknown      | 10 Mg, Qd          |                 | Bristol Myers Squibb |
|                                                                                          | Cipralex /01588501/ |              |            | S           | Unknown      | 29jan13 29jan13    |                 | Not Reported         |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Feb-2016              | 11996053      | EXPEDITED (15-DAY) |                    | CA, OT          | DE-TEVA-630183GER    |                      | 1 DAY      | Male       | DEU            |

| <u>Preferred Term</u>                                               | <u>Product</u>                       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u>                                    | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------|--------------------------------------|--------------|------------|-------------|----------------|-------------------------------------------------------|-----------------|--------------|
| Foetal Exposure During Pregnancy; Hypospadias; Small For Dates Baby | Dominal (Prothipendyl Hydrochloride) |              |            | S           | Transplacental | 240 Mg /Day / Dosage Reduction To 40mg/D Step By Step |                 | Not Reported |
|                                                                     | Escitalopram                         |              |            | S           | Transplacental | 10 Milligram Daily;                                   |                 | Ivax         |
|                                                                     | Tavor (Lorazepam)                    |              |            | C           | Transplacental |                                                       |                 | Not Reported |
|                                                                     | Lyrica                               |              |            | C           | Transplacental | 300 Milligram Daily;                                  |                 | Not Reported |
|                                                                     | Metamizol                            |              |            | C           | Transplacental | 500 Milligram Daily;                                  |                 | Not Reported |
|                                                                     | Femaform Natal                       |              |            | C           | Transplacental |                                                       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                              | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------------------------|----------------------|------------|------------|----------------|
| 03-Feb-2016              | 11998301      | EXPEDITED (15-DAY) |                    | DE              | US-NORTHSTAR HEALTHCARE HOLDINGS-US-2016NSR000296 |                      | 53 YR      | Female     | USA            |

| <u>Preferred Term</u>                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide; Toxicity To Various Agents | Baclofen       |              |            | S           | Oral         | Unk Df, Unk        |                 | Northstar    |
|                                               | Duloxetine     |              |            | S           | Oral         | Unk Df, Unk        |                 | Not Reported |
|                                               | Clonazepam     |              |            | S           | Oral         | Unk Df, Unk        |                 | Not Reported |
|                                               | Escitalopram   |              |            | S           | Oral         | Unk Df, Unk        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Feb-2016              | 11999434      | DIRECT           |                    |                 |                      |                      |            | Unknown    | USA            |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                         | <u>Product</u>                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                     | <u>Dosage Text</u>                                   | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------------------------------------------------|--------------------------------------------|--------------------|--------------------|-----------------|--------------------------------------------------|------------------------------------------------------|-----------------|--------------|----------------|
| Intercepted Medication Error; Product Dispensing Error                        | Escitalopram Oxalate (Escitalopram) Tablet |                    |                    | S               |                                                  |                                                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                      | <u>Case #</u>                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u>                                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Feb-2016                                                                   | 11951240                                   | EXPEDITED (15-DAY) |                    | HO              | PHHY2016IT006036                                 |                                                      | 17 YR           | Male         | ITA            |
| <u>Preferred Term</u>                                                         | <u>Product</u>                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                     | <u>Dosage Text</u>                                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Electrocardiogram Qt Prolonged; Intentional Overdose; Intentional Self-Injury | Olanzapine                                 |                    |                    | S               | Oral                                             | 22.5 Mg, Qd                                          |                 | Novartis     |                |
|                                                                               | Escitalopram                               |                    |                    | S               | Oral                                             | 190 Mg, Once/Single                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                      | <u>Case #</u>                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u>                                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Feb-2016                                                                   | 11999264                                   | EXPEDITED (15-DAY) |                    | CA, OT          | DE-MACLEODS PHARMACEUTICALS US LTD-MAC2014002387 |                                                      |                 | Unknown      | DEU            |
| <u>Preferred Term</u>                                                         | <u>Product</u>                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                     | <u>Dosage Text</u>                                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Foetal Exposure During Pregnancy; Hypospadias; Small For Dates Baby           | Escitalopram                               |                    |                    | S               | Transplacental                                   | 10 Mg ,Qd ( 0.0- 38.4. Gestational Week)             |                 | Macleods     |                |
|                                                                               | Dominal (Prothipendyl Hydrochloride)       |                    |                    | S               | Transplacental                                   | 240 Mg, Qd ( 0.0 - 38.4. Gestational Week)           |                 | Not Reported |                |
|                                                                               | Dominal (Prothipendyl Hydrochloride)       |                    |                    | S               | Transplacental                                   | 40 Mg, Qd (0.-38.4. Gestational Week)                |                 | Not Reported |                |
|                                                                               | Dominal (Prothipendyl Hydrochloride)       |                    |                    | S               |                                                  | Unk                                                  |                 | Not Reported |                |
|                                                                               | Tavor (Lorazepam)                          |                    |                    | C               | Transplacental                                   | On Demand (0.0 - 38.4. Gestational Week)             |                 | Not Reported |                |
|                                                                               | Lyrica                                     |                    |                    | C               | Transplacental                                   | 300 Mg, Qd (0.0 - 7. Gestational Week)               |                 | Not Reported |                |
|                                                                               | Metamizol                                  |                    |                    | C               | Transplacental                                   | 500 Mg, Qd / On Demand (0.0 -38.4. Gestational Week) |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Femaform Natal C Transplacental Unk, (5.0 -38.5. Gestatiaonal Week) Not Reported

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 04-Feb-2016              | 12000711      | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2016007250 |                      |            | Unknown    | USA            |

| <u>Preferred Term</u> | <u>Product</u>   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Hypersensitivity | Morphine Sulfate |              |            | S           |              | Unk                |                 | Pfizer       |
|                       | Vistaril         |              |            | S           |              | Unk                |                 | Pfizer       |
|                       | Spiriva          |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Celexa           |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Advair           |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Proair           |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Prilosec         |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Lisinopril       |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Zyloprim         |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Lexapro          |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Colace           |              |            | S           |              | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                              | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------------------------|----------------------|------------|------------|----------------|
| 04-Feb-2016              | 12004144      | EXPEDITED (15-DAY) |                    | DE              | US-NORTHSTAR HEALTHCARE HOLDINGS-US-2016NSR000284 |                      | 52 YR      | Male       | USA            |

| <u>Preferred Term</u>                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide; Toxicity To Various Agents | Atenolol       |              |            | S           | Oral         | Unk Df, Unk        |                 | Northstar    |
|                                               | Escitalopram   |              |            | S           | Oral         | Unk Df, Unk        |                 | Not Reported |
|                                               | Lamotrigine    |              |            | S           | Oral         | Unk Df, Unk        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Feb-2016              | 12007719      | EXPEDITED (15-DAY) |                    | HO              | JP-FRI-1000081929    |                      | 78 YR      | Female     | JPN            |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                          | <u>Product</u>                                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>           |                |
|------------------------------------------------|-------------------------------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|-----------------------|-----------------|----------------------|----------------|
| Seizure                                        | Lexapro                                         |                    |                    | S               | Oral                                            | 10 Mg                 |                 | Forest               |                |
|                                                | Edirol (Eldcalcitol)                            |                    |                    | C               | Oral                                            | Unknown               |                 | Not Reported         |                |
|                                                | Arimidex (Anastrozole)                          |                    |                    | C               | Oral                                            | Unknown               |                 | Not Reported         |                |
|                                                | Mevalotin (Pravastatin Sodium)                  |                    |                    | C               | Oral                                            | Unknown               |                 | Not Reported         |                |
|                                                | Trazenta (Linagliptin)                          |                    |                    | C               | Oral                                            | Unknown               |                 | Not Reported         |                |
|                                                | Depas (Etizolam)                                |                    |                    | C               | Oral                                            | Unknown               |                 | Not Reported         |                |
|                                                | Mohrus Tape (Ketoprofen)                        |                    |                    | C               | Cutaneous                                       | Unknown               |                 | Not Reported         |                |
|                                                | Naboal (Diclofenac Sodium)                      |                    |                    | C               | Unknown                                         | Unknown               |                 | Not Reported         |                |
|                                                | Ruefrien (Sodium Gualenate Hydrate/L-Glutamine) |                    |                    | C               | Oral                                            | Unknown               |                 | Not Reported         |                |
|                                                | Claritin (Loratadine)                           |                    |                    | C               | Oral                                            | Unknown               |                 | Not Reported         |                |
|                                                | Hirudoid (Heparinoid)                           |                    |                    | C               | Cutaneous                                       | Unknown               |                 | Not Reported         |                |
| <u>FDA Received Date</u>                       | <u>Case #</u>                                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 05-Feb-2016                                    | 8793808                                         | EXPEDITED (15-DAY) |                    | OT              | BE-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>16699746 |                       | 28 YR           | Female               | BEL            |
| <u>Preferred Term</u>                          | <u>Product</u>                                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>           |                |
| Off Label Use; Systemic<br>Lupus Erythematosus | Abilify                                         |                    |                    | S               | Unknown                                         | 2.5 Mg, Unk           |                 | Bristol Myers Squibb |                |
|                                                | Escitalopram                                    |                    |                    | S               | Unknown                                         |                       |                 | Not Reported         |                |
| <u>FDA Received Date</u>                       | <u>Case #</u>                                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 05-Feb-2016                                    | 11442989                                        | EXPEDITED (15-DAY) |                    | HO              | RU-FRI-1000079224                               |                       | 43 YR           | Male                 | RUS            |
| <u>Preferred Term</u>                          | <u>Product</u>                                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>           |                |
| Drug Withdrawal<br>Syndrome                    | Escitalopram                                    |                    |                    | S               | Oral                                            | 20 Mg, Qd             |                 | Forest               |                |
|                                                | Escitalopram                                    |                    |                    | S               | Oral                                            | 10 Mg, Qd             |                 | Forest               |                |
|                                                | Escitalopram                                    |                    |                    | S               | Oral                                            | 20 Mg, In The Morning |                 | Not Reported         |                |
|                                                | Luaf41156                                       |                    |                    | S               | Oral                                            | 1 Mg, Qd (At Night)   |                 | Not Reported         |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Feb-2016              | 11616157      | EXPEDITED (15-DAY) |                    | HO, OT          | PHEH2015US020054     |                      | 42 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Alopecia; Anxiety;<br>Arthralgia; Back Pain;<br>Bone Pain; Burning<br>Sensation; Chills;<br>Cytogenetic Abnormality;<br>Decreased Appetite;<br>Diarrhoea; Dry Mouth;<br>Dysgeusia; Facial Pain;<br>Fatigue; Feeling<br>Abnormal; Halo Vision;<br>Headache;<br>Hypometabolism;<br>Hypotension;<br>Immunoglobulins<br>Increased; Influenza;<br>Influenza Like Illness;<br>Myalgia; Nervousness;<br>Pain; Pain In Jaw;<br>Palpitations; Photophobia;<br>Spinal Pain; Tongue Dry;<br>Toxicity To Various<br>Agents; Urinary Tract<br>Infection; Vision Blurred;<br>White Blood Cell Count<br>Decreased | Gilenya        |              |            | S           | Oral         | 0.5 Mg, Qd         |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Prednisone     |              |            | S           | Unknown      |                    |                 | Novartis     |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Lexapro        |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Vit D          |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Xanax          |              |            | C           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Feb-2016              | 11702902      | EXPEDITED (15-DAY) |                    | DE, HO          | PA-FRI-1000080649    |                      | 89 YR      | Female     | PAN            |

| <u>Preferred Term</u>                                                                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Acute Hepatic Failure;<br>Asthenia; Drug-Induced<br>Liver Injury;<br>Hepatomegaly; Intestinal | Escitalopram   |              |            | S           | Oral         |                    |                 | Forest     |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Haemorrhage; Jaundice;  
Nausea

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 05-Feb-2016              | 11977318      | EXPEDITED (15-DAY) |                    | HO, OT          | IT-<br>ELI_LILLY_AND_COMP<br>ANY-IT201601006788 |                      | 17 YR      | Male       | ITA            |

| <u>Preferred Term</u>                                                                                 | <u>Product</u>  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>       |
|-------------------------------------------------------------------------------------------------------|-----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------------|
| Electrocardiogram Qt Prolonged; Intentional Overdose; Intentional Self-Injury; Malaise; Off Label Use | Olanzapine      |              |            | S           | Oral         | 2.5 Mg, Qd         |                 | Eli Lilly And Co |
|                                                                                                       | Olanzapine      |              |            | S           | Oral         | 22.5 Mg, Single    |                 | Eli Lilly And Co |
|                                                                                                       | Escitalopram Eg |              |            | S           | Oral         | Unk, Unknown       |                 | Not Reported     |
|                                                                                                       | Escitalopram Eg |              |            | S           | Oral         | 190 Mg, Total      |                 | Not Reported     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Feb-2016              | 12010008      | EXPEDITED (15-DAY) |                    | DE              | US-DEP_13495_2016    |                      | 34 YR      | Male       | USA            |

| <u>Preferred Term</u>                                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardio-Respiratory Arrest; Drug Abuse; Toxicity To Various Agents | Gabapentin     |              |            | S           | Oral         | Df                 |                 | Not Reported |
|                                                                   | Alprazolam     |              |            | S           | Oral         | Df                 |                 | Not Reported |
|                                                                   | Oxycodone      |              |            | S           | Oral         | Df                 |                 | Not Reported |
|                                                                   | Oxymorphone    |              |            | S           | Oral         | Df                 |                 | Not Reported |
|                                                                   | Escitalopram   |              |            | S           | Oral         | Df                 |                 | Not Reported |
|                                                                   | Trazodone      |              |            | S           | Oral         | Df                 |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Feb-2016              | 12010629      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000082429    |                      | 45 YR      | Female     | FRA            |

| <u>Preferred Term</u>            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------|----------------|--------------|------------|-------------|--------------|-------------------------|-----------------|--------------|
| Intentional Overdose; Somnolence | Escitalopram   |              |            | S           | Oral         | 20 Mg                   |                 | Forest       |
|                                  | Dafalgan       |              |            | S           | Oral         | Overdose: 18 Grams Once |                 | Not Reported |
|                                  | Spifen         |              |            | S           | Oral         | Overdose: 8 Grams Once  |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                        | Lysanxia                  |                    | S                  | Oral            |                                                   | 30 Mg                             |                 |              | Not Reported   |
|----------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|---------------------------------------------------|-----------------------------------|-----------------|--------------|----------------|
|                                                                                        | Noctamide                 |                    | S                  | Oral            |                                                   | 1 Df                              |                 |              | Not Reported   |
| <u>FDA Received Date</u>                                                               | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                              | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Feb-2016                                                                            | 11952593                  | EXPEDITED (15-DAY) |                    | HO              | IT-TEVA-627470ACC                                 |                                   | 17 YR           | Male         | ITA            |
| <u>Preferred Term</u>                                                                  | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                      | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |                |
| Electrocardiogram Qt Prolonged; Intentional Overdose; Intentional Self-Injury; Malaise | Olanzapine                |                    |                    | S               | Oral                                              | 2.5 Milligram Daily; 2.5 Mg Daily |                 | Teva         |                |
|                                                                                        | Escitalopram              |                    |                    | S               | Oral                                              | 10 Mg Total                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                               | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                              | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Feb-2016                                                                            | 12034572                  | EXPEDITED (15-DAY) |                    | DE              | US-NORTHSTAR HEALTHCARE HOLDINGS-US-2016NSR000325 |                                   | 25 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                  | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                      | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardio-Respiratory Arrest; Completed Suicide; Toxicity To Various Agents               | Propranolol Hydrochloride |                    |                    | S               | Oral                                              | Unk Df, Unk                       |                 | Northstar    |                |
|                                                                                        | Escitalopram              |                    |                    | S               | Oral                                              | Unk Df, Unk                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                               | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                              | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Feb-2016                                                                            | 11987850                  | EXPEDITED (15-DAY) |                    | DS, HO          | IT-ACCORD-037393                                  |                                   | 17 YR           | Male         | ITA            |
| <u>Preferred Term</u>                                                                  | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                      | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |                |
| Electrocardiogram Qt Prolonged; Intentional Overdose; Intentional Self-Injury; Malaise | Escitalopram              |                    |                    | S               | Oral                                              |                                   |                 | Accord       |                |
|                                                                                        | Olanzapine                |                    |                    | S               | Oral                                              |                                   |                 | Accord       |                |
| <u>FDA Received Date</u>                                                               | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                              | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Feb-2016                                                                            | 12036827                  | EXPEDITED (15-DAY) |                    | OT              | DE-ROCHE-1706615                                  |                                   | 36 YR           | Male         | DEU            |
| <u>Preferred Term</u>                                                                  | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                      | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                         |                |   |      |              |              |
|-------------------------|----------------|---|------|--------------|--------------|
| Myalgia; Rhabdomyolysis | Cellcept       | S | Oral | 750-0-500 Mg | Not Reported |
|                         | Cipralex       | S | Oral |              | Not Reported |
|                         | Cipralex       | S | Oral |              | Not Reported |
|                         | Ramipril       | C | Oral |              | Not Reported |
|                         | Amlodipin      | C | Oral |              | Not Reported |
|                         | Pantoprazol    | C | Oral |              | Not Reported |
|                         | Colecalciferol | C | Oral |              | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------|----------------------|------------|------------|----------------|
| 08-Feb-2016              | 12037351      | NON-EXPEDITED    |                    |                 | US-APOTEX-2015AP006456 |                      |            | Female     | USA            |

| <u>Preferred Term</u>           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Skin Exfoliation; Swelling Face | Paxil Tablets  |              |            | S           | Unknown      |                    |                 | Apotex       |
|                                 | Lexapro        |              |            | S           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------|----------------------|------------|------------|----------------|
| 08-Feb-2016              | 12037630      | NON-EXPEDITED    |                    |                 | US-APOTEX-2015AP011279 |                      | 77 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Ineffective      | Paxil Tablets     |              |            | S           | Unknown      | Unk                |                 | Apotex       |
|                       | Lexapro           |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                       | Celexa /00582602/ |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                       | Wellbutrin        |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                       | Prozac            |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                       | Remeron           |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                       | Pristiq           |              |            | C           | Unknown      | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|------------|------------|----------------|
| 08-Feb-2016              | 12039859      | EXPEDITED (15-DAY) |                    | CA, OT          | DE-AUROBINDO-AUR-APL-2016-00961 |                      | 1 DAY      | Male       | DEU            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                               | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------|----------------------|--------------|------------|-------------|----------------|---------------------------|-----------------|--------------|
| Foetal Exposure During Pregnancy; Hypospadias; Small For Dates Baby | Escitalopram 10 Mg   |              |            | S           | Transplacental | 10 Mg, Daily              |                 | Aurobindo    |
|                                                                     | Dominal /00002701/   |              |            | S           | Transplacental | 240 Mg, Daily             |                 | Not Reported |
|                                                                     | Dominal /00002701/   |              |            | S           | Transplacental | 40 Mg, Daily Step To Step |                 | Not Reported |
|                                                                     | Tavor /00273201/     |              |            | C           | Transplacental | On Demand                 |                 | Not Reported |
|                                                                     | Lyrica               |              |            | C           | Transplacental | 300 Mg, Daily             |                 | Not Reported |
|                                                                     | Metamizol /06276702/ |              |            | C           | Transplacental | 500 Mg, Daily             |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|------------|------------|----------------|
| 08-Feb-2016              | 12040373      | EXPEDITED (15-DAY) |                    |                 | US-GLAXOSMITHKLINE-US2016012009 |                      | 81 YR      | Female     | USA            |

  

| <u>Preferred Term</u>                                                                                          | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|----------------------------------------------------------------------------------------------------------------|--------------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Dizziness; Drug Ineffective; Hypertension; Insulin Resistance; Labelled Drug-Drug Interaction Medication Error | Lamotrigine Tablet |              |            | S           | Oral         | 100 Mg, 1d         |                 | Glaxosmithkline |
|                                                                                                                | Lamotrigine Tablet |              |            | S           | Oral         | 50 Mg, Qd          |                 | Glaxosmithkline |
|                                                                                                                | Lexapro            |              |            | S           |              | 100 Mg, Qd         |                 | Not Reported    |
|                                                                                                                | Hydroxyz Pam       |              |            | S           | Oral         | 25 Mg, Unk         |                 | Not Reported    |
|                                                                                                                | Levothyroxin       |              |            | C           |              |                    |                 | Not Reported    |
|                                                                                                                | Doxepine           |              |            | C           |              | Unk                |                 | Not Reported    |
|                                                                                                                | Xanax              |              |            | C           |              |                    |                 | Not Reported    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------|----------------------|------------|------------|----------------|
| 08-Feb-2016              | 12041717      | NON-EXPEDITED    |                    |                 | US-APOTEX-2015AP013620 |                      |            | Male       | USA            |

  

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Ineffective      | Paxil Tablets  |              |            | S           | Unknown      |                    |                 | Apotex       |
|                       | Lexapro        |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Effexor        |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Cymbalta       |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Prozac         |              |            | S           | Unknown      |                    |                 | Not Reported |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                     |                              |                    |                    |                 |                                                          |                      |                 |              |                |
|---------------------------------------------------------------------|------------------------------|--------------------|--------------------|-----------------|----------------------------------------------------------|----------------------|-----------------|--------------|----------------|
| Zoloft                                                              |                              |                    | S                  |                 | Unknown                                                  |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                            | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Feb-2016                                                         | 12042548                     | EXPEDITED (15-DAY) |                    | DE              | US-ARBOR<br>PHARMACEUTICALS,<br>LLC-US-<br>2016ARB000059 |                      | 25 YR           | Male         | USA            |
| <u>Preferred Term</u>                                               | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Toxicity To Various Agents                    | Lamotrigine                  |                    |                    | S               |                                                          | Unk Df, Unk          |                 | Arbor        |                |
|                                                                     | Bupropion (Extended Release) |                    |                    | S               |                                                          | Unk Df, Unk          |                 | Not Reported |                |
|                                                                     | Escitalopram                 |                    |                    | S               |                                                          | Unk Df, Unk          |                 | Not Reported |                |
|                                                                     | Clonazepam                   |                    |                    | S               |                                                          | Unk Df, Unk          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                            | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Feb-2016                                                         | 12042562                     | EXPEDITED (15-DAY) |                    | DE              | US-ARBOR<br>PHARMACEUTICALS,<br>LLC-US-<br>2016ARB000063 |                      | 52 YR           | Male         | USA            |
| <u>Preferred Term</u>                                               | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Toxicity To Various Agents                    | Lamotrigine                  |                    |                    | S               | Oral                                                     | Unk Df, Unk          |                 | Arbor        |                |
|                                                                     | Escitalopram                 |                    |                    | S               | Oral                                                     | Unk Df, Unk          |                 | Not Reported |                |
|                                                                     | Atenolol                     |                    |                    | S               | Oral                                                     | Unk Df, Unk          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                            | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Feb-2016                                                         | 11515477                     | EXPEDITED (15-DAY) |                    | HO              | CA-FRI-1000079541                                        |                      | 54 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                               | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated;<br>Dehydration; Dysphagia;<br>Mental Disorder | Escitalopram                 |                    |                    | S               | Oral                                                     |                      |                 | Forest       |                |
|                                                                     | Clonazepam                   |                    |                    | S               | Oral                                                     | 1.5 Mg               |                 | Not Reported |                |
|                                                                     | Domperidone                  |                    |                    | S               | Oral                                                     | 20 Mg                |                 | Not Reported |                |
|                                                                     | Ferrous Sulphate             |                    |                    | S               | Oral                                                     | 900 Mg               |                 | Not Reported |                |
|                                                                     | Gabapentin                   |                    |                    | S               | Oral                                                     | 1200 Mg              |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                 |   |      |                         |              |
|---------------------------------|---|------|-------------------------|--------------|
| Gabapentin                      | S | Oral | 300 Mg                  | Not Reported |
| Temazepam                       | S | Oral | 30 Mg                   | Not Reported |
| Tylenol/Codeine No.3            | S | Oral | 6 Df                    | Not Reported |
| Vitalux                         | S | Oral | Daily Dose Not Reported | Not Reported |
| Wellbutrin XL                   | S | Oral | 300 Mg                  | Not Reported |
| Acetaminophen/Codeine Phosphate | S | Oral | 6 Df                    | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Feb-2016              | 11831792      | EXPEDITED (15-DAY) |                    | LT              | JP-FRI-1000081115    |                      | 73 YR      | Female     | JPN            |

| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Intentional Self-Injury | Lexapro        |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                         | Lunesta        |              |            | C           | Oral         | 1 Mg               |                 | Not Reported |
|                         | Myslee         |              |            | C           | Oral         | 10 Mg              |                 | Not Reported |
|                         | Rohypnol       |              |            | C           | Oral         | 1 Mg               |                 | Not Reported |
|                         | Amlodipine     |              |            | C           | Oral         | 5 Mg               |                 | Not Reported |
|                         | Reminyl        |              |            | C           | Oral         | 16 Mg              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 09-Feb-2016              | 11938747      | EXPEDITED (15-DAY) |                    | HO              | IT-MYLANLABS-2016M1002890 |                      |            | Unknown    | ITA            |

| <u>Preferred Term</u>                                                                  | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------|--------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Electrocardiogram Qt Prolonged; Intentional Overdose; Intentional Self-Injury; Malaise | Olanzapine         |              |            | S           |              | Unk                |                 | Not Reported |
|                                                                                        | Olanzapine         |              |            | S           | Oral         | 22.5 Mg, Qd        |                 | Not Reported |
|                                                                                        | Escitalopram Mylan |              |            | S           |              | Unk                |                 | Mylan        |
|                                                                                        | Escitalopram Mylan |              |            | S           | Oral         | 190 Mg, Total      |                 | Mylan        |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Feb-2016              | 11994845      | EXPEDITED (15-DAY) |                    | HO              | IT-FRI-1000082405    |                      | 34 YR      | Female     | ITA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Dysarthria; Intentional Product Misuse; Medication Error; Somnolence; Sopor; Speech Disorder | Escitalopram   |              |            | S           | Oral         |                    |                 | Forest       |
|                                                                                              | Catapresan     |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                              | Haldol         |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                              | Akineton       |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                              | Valium         |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------------------|----------------------|------------|------------|----------------|
| 09-Feb-2016              | 12052909      | EXPEDITED (15-DAY) |                    | HO, OT          | US-ELI_LILLY_AND_COMP<br>ANY-US200602005208 |                      | 1 DAY      | Unknown    | USA            |

| <u>Preferred Term</u>                                                                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>       |
|------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|------------------|
| Exposure During Pregnancy; Exposure Via Breast Milk; Sedation; Selective Eating Disorder | Zyprexa        |              |            | S           | Transplacental |                    |                 | Eli Lilly And Co |
|                                                                                          | Topamax        |              |            | S           | Transplacental |                    |                 | Not Reported     |
|                                                                                          | Lexapro /Usa/  |              |            | S           | Transplacental |                    |                 | Not Reported     |
|                                                                                          | Abilify        |              |            | S           | Transplacental |                    |                 | Not Reported     |
|                                                                                          | Remeron /Net/  |              |            | S           | Transplacental |                    |                 | Not Reported     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 09-Feb-2016              | 12055842      | EXPEDITED (15-DAY) |                    | OT              | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>15298680 |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                                                                  | <u>Product</u>                        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                          | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>           |
|--------------------------------------------------------------------------------------------------------|---------------------------------------|--------------|------------|-------------|---------------------------------------|--------------------|-----------------|----------------------|
| Maternal Exposure During Pregnancy; Pre-Eclampsia; Pregnancy On Oral Contraceptive; Premature Delivery | Abatacept                             |              |            | S           | Intravenous (not otherwise specified) | 10 Mg/Kg, Q4wk     |                 | Bristol Myers Squibb |
|                                                                                                        | Metformin Hydrochloride               |              |            | S           | Oral                                  | 500 Mg, Bid        |                 | Bristol Myers Squibb |
|                                                                                                        | External-Mycophenolate Mofetil        |              |            | S           | Oral                                  | 1000 Mg, Qd        |                 | Unknown              |
|                                                                                                        | External-Prednisone                   |              |            | S           | Oral                                  | 5 Mg, Qd           |                 | Unknown              |
|                                                                                                        | External-Hydroxychloroquine Sulfate   |              |            | S           | Oral                                  | 200 Mg, Bid        |                 | Unknown              |
|                                                                                                        | External-Ethinylestradiol+Desogestrel |              |            | S           | Oral                                  | 20 Mg, Qd          |                 | Not Reported         |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                               |   |      |            |              |
|-------------------------------|---|------|------------|--------------|
| External-Levothyroxine        | S | Oral | 150 Mg, Qd | Not Reported |
| External-Iron                 | S | Oral | 1 Df, Qd   | Not Reported |
| External-Esomeprazole         | S | Oral | 40 Mg, Qd  | Not Reported |
| External-Escitalopram Oxalate | S | Oral | 10 Mg, Qd  | Unknown      |

| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------------|------------------|--------------------|-----------------|----------------------|----------------------------|-----------------|--------------|----------------|
| 09-Feb-2016              | 12058429             | DIRECT           |                    | OT              |                      |                            |                 | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Fatigue      | Escitalopram Oxalate |                  |                    | S               | Oral                 | 20mg 90 One Po Qd By Mouth |                 | Not Reported |                |
|                          | Lexapro              |                  |                    | C               |                      |                            |                 | Not Reported |                |
|                          | Premarin             |                  |                    | C               |                      |                            |                 | Not Reported |                |

| <u>FDA Received Date</u>                                   | <u>Case #</u>     | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------|-------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 09-Feb-2016                                                | 12059163          | DIRECT           |                    | OT              |                      |                      | 43 YR           | Female       | USA            |
| <u>Preferred Term</u>                                      | <u>Product</u>    | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Disease Recurrence; Product Substitution Issue | Escitalopram 20mg |                  |                    | S               | Oral                 |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                 | <u>Case #</u>             | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------|---------------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 09-Feb-2016                                                                              | 12059201                  | DIRECT           |                    | OT              |                      |                      | 54 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                    | <u>Product</u>            | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Condition Aggravated; Crying; Depression; Nightmare; Product Substitution Issue | Escitalopram 20mg Unknown |                  |                    | S               | Oral                 |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Feb-2016              | 12059555      | DIRECT           |                    | LT              |                      |                      | 41 YR      | Male       | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                             | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                       | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------------------------------------|-------------------------------|-----------------|--------------|----------------|
| Drug Intolerance; Suicidal Ideation                                                               | Escitalopram   |                    |                    | S               | Oral                                               |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                          | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                               | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Feb-2016                                                                                       | 11969912       | EXPEDITED (15-DAY) |                    | HO              | IT-FRI-1000082343                                  |                               | 17 YR           | Male         | ITA            |
| <u>Preferred Term</u>                                                                             | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                       | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Electrocardiogram Qt Prolonged; Intentional Overdose; Intentional Self-Injury; Product Use Issue  | Escitalopram   |                    |                    | S               | Oral                                               | 10 Mg                         |                 | Forest       |                |
|                                                                                                   | Escitalopram   |                    |                    | S               | Oral                                               | Overdose: 20 Tablets Of 10 Mg |                 | Forest       |                |
|                                                                                                   | Olanzapine     |                    |                    | S               | Oral                                               | 2.5 Mg                        |                 | Not Reported |                |
|                                                                                                   | Olanzapine     |                    |                    | S               | Oral                                               | Overdose: 9 Tablets Of 2.5 Mg |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                          | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                               | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Feb-2016                                                                                       | 11975681       | EXPEDITED (15-DAY) |                    | HO              | IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2016RR-110257 |                               |                 | Unknown      | ITA            |
| <u>Preferred Term</u>                                                                             | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                       | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Electrocardiogram Qt Prolonged; Intentional Overdose; Intentional Self-Injury                     | Olanzapine     |                    |                    | S               | Oral                                               | 22.5 Mg, Daily                |                 | Sun          |                |
|                                                                                                   | Escitalopram   |                    |                    | S               | Oral                                               | 190 Mg, Total                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                          | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                               | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Feb-2016                                                                                       | 12057395       | EXPEDITED (15-DAY) |                    | OT              | AT-PFIZER INC-2016065418                           |                               | 33 YR           | Female       | AUT            |
| <u>Preferred Term</u>                                                                             | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                       | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Diarrhoea; Disturbance In Attention; Eye Pain; Gait Disturbance; Headache; Impaired Work Ability; | Lyrica         |                    |                    | S               |                                                    | 125 Mg, Daily (25-25-25-50)   |                 | Pfizer       |                |
|                                                                                                   | Lyrica         |                    |                    | S               |                                                    |                               |                 | Pfizer       |                |
|                                                                                                   | Lyrica         |                    |                    | S               |                                                    |                               |                 | Pfizer       |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                                                                                                                                                                 |                      |   |           |              |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|---|-----------|--------------|
| Intentional Product Use Issue; Mental Impairment; Migraine; Nausea; Neck Pain; Night Sweats; Peripheral Coldness; Pruritus Generalised; Rash; Tremor; Vertigo; Vision Blurred; Weight Increased | Escitalopram Oxalate | S | 5 Mg, Unk | Not Reported |
|                                                                                                                                                                                                 | Escitalopram Oxalate | S |           | Not Reported |
|                                                                                                                                                                                                 | Escitalopram Oxalate | S |           | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 10-Feb-2016              | 12059537      | EXPEDITED (15-DAY) |                    | CA, OT          | DE-MYLANLABS-2016M1004610 |                      |            | Unknown    | DEU            |

| <u>Preferred Term</u>                                               | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u>                                   | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------|--------------------|--------------|------------|-------------|----------------|------------------------------------------------------|-----------------|--------------|
| Foetal Exposure During Pregnancy; Hypospadias; Small For Dates Baby | Escitalopram       |              |            | S           | Transplacental | 10 [Mg/D ]                                           |                 | Not Reported |
|                                                                     | Dominal /00018902/ |              |            | S           | Transplacental | 240 [Mg/D ]/ Dosage Reduction To 40mg/D Step By Step |                 | Mylan        |
|                                                                     | Tavor /00273201/   |              |            | C           | Transplacental | On Demand                                            |                 | Mylan        |
|                                                                     | Lyrica             |              |            | C           | Transplacental | 300 [Mg/D ]                                          |                 | Mylan        |
|                                                                     | Metamizol          |              |            | C           | Transplacental | 500 [Mg/D ]/ On Demand                               |                 | Mylan        |
|                                                                     | Folic Acid         |              |            | C           | Transplacental | Unk                                                  |                 | Mylan        |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>              | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------------------|----------------------|------------|------------|----------------|
| 10-Feb-2016              | 12060148      | EXPEDITED (15-DAY) |                    | DE              | US-EGALET US INC-US-2016EGA000033 |                      | 34 YR      | Male       | USA            |

| <u>Preferred Term</u>                                             | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardio-Respiratory Arrest; Drug Abuse; Toxicity To Various Agents | Oxycodone Hydrochloride |              |            | S           | Oral         | Unk Df, Unk        |                 | Egalet       |
|                                                                   | Oxymorphone             |              |            | S           | Oral         | Unk Df, Unk        |                 | Not Reported |
|                                                                   | Alprazolam              |              |            | S           | Oral         | Unk Df, Unk        |                 | Not Reported |
|                                                                   | Gabapentin              |              |            | S           | Oral         | Unk Df, Unk        |                 | Not Reported |
|                                                                   | Escitalopram            |              |            | S           | Oral         | Unk Df, Unk        |                 | Not Reported |
|                                                                   | Trazodone               |              |            | S           | Oral         | Unk Df, Unk        |                 | Not Reported |

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| <u>FDA Received Date</u>                         | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|---------------------------------------|----------------------|-----------------|--------------|----------------|
| 10-Feb-2016                                      | 12060391                      | EXPEDITED (15-DAY) |                    | DE              | US-EGALET US INC-<br>US-2016EGA000079 |                      | 42 YR           | Female       | USA            |
| <u>Preferred Term</u>                            | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Toxicity To Various Agents | Oxycodone Hydrochloride       |                    |                    | S               | Oral                                  | Unk Df, Unk          |                 | Egalet       |                |
|                                                  | Metoprolol                    |                    |                    | S               | Oral                                  | Unk Df, Unk          |                 | Not Reported |                |
|                                                  | Zolpidem                      |                    |                    | S               | Oral                                  | Unk Df, Unk          |                 | Not Reported |                |
|                                                  | Diazepam                      |                    |                    | S               | Oral                                  | Unk Df, Unk          |                 | Not Reported |                |
|                                                  | Escitalopram                  |                    |                    | S               | Oral                                  | Unk Df, Unk          |                 | Not Reported |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Feb-2016                                      | 12061097                      | EXPEDITED (15-DAY) |                    | DE              | US-PERRIGO-<br>16US001189             |                      | 16 YR           | Male         | USA            |
| <u>Preferred Term</u>                            | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Death                                            | Morphine Sulfate 20 Mg/ML 018 |                    |                    | S               | Oral                                  | Unk                  |                 | Perrigo      |                |
|                                                  | Acetaminophen W/Hydrocodone   |                    |                    | S               | Oral                                  | Unk                  |                 | Not Reported |                |
|                                                  | Escitalopram                  |                    |                    | S               | Oral                                  | Unk                  |                 | Not Reported |                |
|                                                  | Cyclobenzaprine               |                    |                    | S               | Oral                                  | Unk                  |                 | Not Reported |                |
|                                                  | Aripiprazole                  |                    |                    | S               | Oral                                  | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Feb-2016                                      | 12066354                      | DIRECT             | Y                  |                 |                                       |                      | 60 YR           | Female       | USA            |
| <u>Preferred Term</u>                            | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Nausea; Tremor                                   | Escitalopram                  |                    |                    | S               | Oral                                  |                      |                 | Not Reported |                |
|                                                  | Escitalopram                  |                    |                    | S               | Oral                                  |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Feb-2016                                      | 11792317                      | NON-EXPEDITED      |                    |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-   |                      |                 | Unknown      | USA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

BMS-2015-083829

| <u>Preferred Term</u>                                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>           |
|---------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------|
| Therapeutic Product Effect Incomplete; Weight Increased | Abilify        |              |            | S           | Unknown      | Unk                |                 | Bristol Myers Squibb |
|                                                         | Lexapro        |              |            | S           | Unknown      | Unk                |                 | Not Reported         |
|                                                         | Remeron        |              |            | S           | Unknown      | Unk                |                 | Not Reported         |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 11-Feb-2016              | 12065940      | EXPEDITED (15-DAY) |                    | HO              | US-ASTRAZENECA-2016SE12105 |                      | 46 YR      | Male       | TWN            |

| <u>Preferred Term</u>                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction; Restless Legs Syndrome | Quetiapine     |              |            | S           | Oral         |                    |                 | Zeneca       |
|                                          | Escitalopram   |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                          | Lithium        |              |            | S           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Feb-2016              | 12070328      | EXPEDITED (15-DAY) |                    | OT              | CA-SA-2016SA021353   |                      | 67 YR      | Female     | CAN            |

| <u>Preferred Term</u>                                                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Electrocardiogram Qt Prolonged; Electrolyte Imbalance; Torsade De Pointes | Furosemide     |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                           | Cipralext      |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                           | Cipralext      |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                           | Quetiapine     |              |            | S           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Feb-2016              | 12070476      | EXPEDITED (15-DAY) |                    | HO              | CA-SA-2016SA021401   |                      | 83 YR      | Female     | CAN            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                           |                         |   |             |              |
|---------------------------|-------------------------|---|-------------|--------------|
| Anxiety; Depressed Mood;  | Furosemide              | S | Unknown     | Not Reported |
| Dizziness; Fall;          | Amlodipine              | S | Unknown     | Not Reported |
| Hypotension; Orthostatic  | Escitalopram            | S | Unknown     | Not Reported |
| Hypotension; Pain; Visual | Escitalopram            | S | Unknown     | Not Reported |
| Acuity Reduced            | Metoprolol              | S | Unknown     | Not Reported |
|                           | Metoprolol              | S | Unknown     | Not Reported |
|                           | Oxazepam                | S | Unknown     | Not Reported |
|                           | Nitroglycerine          | S | Transdermal | Not Reported |
|                           | Zopiclone               | S | Unknown     | Not Reported |
|                           | Acetaminophen           | C |             | Not Reported |
|                           | Acetaminophen W/Codeine | C |             | Not Reported |
|                           | Atorvastatin Calcium    | C |             | Not Reported |
|                           | Clopidogrel             | C |             | Not Reported |
|                           | Hydroxychloroquine      | C |             | Not Reported |
|                           | Nitroglycerine          | C |             | Not Reported |
|                           | Pantoprazole            | C |             | Not Reported |
|                           | Polyethylene Glycol     | C |             | Not Reported |
|                           | Ramipril                | C |             | Not Reported |
|                           | Vitamin D Nos           | C |             | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------------------------------|----------------------|------------|------------|----------------|
| 11-Feb-2016              | 12070683      | EXPEDITED (15-DAY) |                    | OT              | AT-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>BMS-2016-010026 |                      | 47 YR      | Female     | AUT            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>           |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------|
| Galactorrhoea         | Abilify        |              |            | S           | Unknown      | 2.5 Mg, Unk        |                 | Bristol Myers Squibb |
|                       | Abilify        |              |            | S           | Unknown      | 5 Mg, Unk          |                 | Bristol Myers Squibb |
|                       | Risperdal      |              |            | S           | Unknown      | 1 Mg, Qd           |                 | Not Reported         |
|                       | Gewacalm       |              |            | S           | Unknown      | 30 Mg, Qd          |                 | Not Reported         |
|                       | Gewacalm       |              |            | S           | Unknown      | 20 Mg, Qd          |                 | Not Reported         |
|                       | Gewacalm       |              |            | S           | Unknown      | 10 Mg, Qd          |                 | Not Reported         |
|                       | Gewacalm       |              |            | S           | Unknown      | 5 Mg, Qd           |                 | Not Reported         |
|                       | Seroquel       |              |            | S           | Unknown      | 50 Mg, Qd          |                 | Not Reported         |

**FDA Adverse Event Reporting System  
Freedom of Information Act (FOIA)  
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|                       |   |         |             |              |
|-----------------------|---|---------|-------------|--------------|
| Seroquel              | S | Unknown | 1 Df, Qd    | Not Reported |
| Seroquel              | S | Unknown | 100 Mg, Qd  | Not Reported |
| Seroquel              | S | Unknown | 75 Mg, Qd   | Not Reported |
| Seroquel              | S | Unknown | 50 Mg, Qd   | Not Reported |
| Seroquel              | S | Unknown | 25 Mg, Qd   | Not Reported |
| Anafranil             | S | Unknown | 75 Mg, Qd   | Not Reported |
| Cipralex /01588501/   | S | Unknown | 20 Mg, Qd   | Not Reported |
| Cipralex /01588501/   | S | Unknown | 30 Mg, Qd   | Not Reported |
| Trittico              | S | Unknown | 150 Mg, Qd  | Not Reported |
| Trittico              | S | Unknown | 150 Mg, Qd  | Not Reported |
| Trittico              | S | Unknown | 300 Mg, Qd  | Not Reported |
| Trittico              | S | Unknown | 200 Mg, Qd  | Not Reported |
| Trittico              | S | Unknown | 300 Mg, Qd  | Not Reported |
| Trittico              | S | Unknown | 250 Mg, Qd  | Not Reported |
| Trittico              | S | Unknown | 200 Mg, Qd  | Not Reported |
| Trittico              | S | Unknown | 250 Mg, Qd  | Not Reported |
| Rivotril              | S | Unknown | 2 Mg, Qd    | Not Reported |
| Rivotril              | S | Unknown | 2.5 Mg, Qd  | Not Reported |
| Rivotril              | S | Unknown | 1.5 Mg, Qd  | Not Reported |
| Rivotril              | S | Unknown | 1.25 Mg, Qd | Not Reported |
| Rivotril              | S | Unknown | 1 Mg, Qd    | Not Reported |
| Rivotril              | S | Unknown | 0.5 Mg, Qd  | Not Reported |
| Cymbalta              | S | Unknown | 60 Mg, Qd   | Not Reported |
| Ixel                  | S | Unknown | 50 Mg, Qd   | Not Reported |
| Ixel                  | S | Unknown | 100 Mg, Qd  | Not Reported |
| Ixel                  | S | Unknown | 150 Mg, Qd  | Not Reported |
| Ixel                  | S | Unknown | 200 Mg, Qd  | Not Reported |
| Paroxetine /00830801/ | S | Unknown | 40 Mg, Qd   | Not Reported |
| Molaxole              | S | Unknown | Unk         | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Oleovit D3 S Unknown 30 G, Qwk Not Reported

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Feb-2016              | 12071067      | EXPEDITED (15-DAY) | OT                 |                 | AT-FRI-1000082623    |                      | 47 YR      | Female     | AUT            |

| <u>Preferred Term</u>              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------|----------------|--------------|------------|-------------|--------------|------------------------------|-----------------|--------------|
| Galactorrhoea; Prescribed Overdose | Escitalopram   |              |            | S           | Unknown      | 20 Mg                        |                 | Forest       |
|                                    | Escitalopram   |              |            | S           | Unknown      | Overdose: 30 Mg Daily        |                 | Forest       |
|                                    | Rivotril       |              |            | S           | Unknown      | 2 Mg                         |                 | Not Reported |
|                                    | Rivotril       |              |            | S           | Unknown      | 2.5 Mg                       |                 | Not Reported |
|                                    | Rivotril       |              |            | S           | Unknown      | 1.5 Mg                       |                 | Not Reported |
|                                    | Rivotril       |              |            | S           | Unknown      | 1.25 Mg                      |                 | Not Reported |
|                                    | Rivotril       |              |            | S           | Unknown      | 1 Mg                         |                 | Not Reported |
|                                    | Rivotril       |              |            | S           | Unknown      | 0.5 Mg                       |                 | Not Reported |
|                                    | Cymbalta       |              |            | S           | Unknown      | 60 Mg                        |                 | Not Reported |
|                                    | Risperdal      |              |            | S           | Unknown      | 1 Mg                         |                 | Not Reported |
|                                    | Oleovit D3     |              |            | S           | Unknown      | 4.2857 Df                    |                 | Not Reported |
|                                    | Seroquel       |              |            | S           | Unknown      | 50 Mg                        |                 | Not Reported |
|                                    | Seroquel       |              |            | S           | Unknown      | 50 Mg                        |                 | Not Reported |
|                                    | Seroquel       |              |            | S           | Unknown      | Unit Dose: 100-200 Milligram |                 | Not Reported |
|                                    | Seroquel       |              |            | S           | Unknown      | 100 Mg                       |                 | Not Reported |
|                                    | Seroquel       |              |            | S           | Unknown      | 75 Mg                        |                 | Not Reported |
|                                    | Seroquel       |              |            | S           | Unknown      | 50 Mg                        |                 | Not Reported |
|                                    | Seroquel       |              |            | S           | Unknown      | 25 Mg                        |                 | Not Reported |
|                                    | Gewacalm       |              |            | C           | Unknown      | 30 Mg                        |                 | Not Reported |
|                                    | Gewacalm       |              |            | C           | Unknown      | 20 Mg                        |                 | Not Reported |
| Gewacalm                           |                |              | C          | Unknown     | 10 Mg        |                              | Not Reported    |              |
| Gewacalm                           |                |              | C          | Unknown     | 5 Mg         |                              | Not Reported    |              |
| Anafranil Retard                   |                |              | C          | Unknown     | 75 Mg        |                              | Not Reported    |              |

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|                 |   |         |        |              |
|-----------------|---|---------|--------|--------------|
| Trittico Retard | C | Unknown | 150 Mg | Not Reported |
| Trittico Retard | C | Unknown | 150 Mg | Not Reported |
| Trittico Retard | C | Unknown | 300 Mg | Not Reported |
| Trittico Retard | C | Unknown | 200 Mg | Not Reported |
| Trittico Retard | C | Unknown | 300 Mg | Not Reported |
| Trittico Retard | C | Unknown | 250 Mg | Not Reported |
| Trittico Retard | C | Unknown | 200 Mg | Not Reported |
| Trittico Retard | C | Unknown | 250 Mg | Not Reported |
| Ixel            | C | Unknown | 50 Mg  | Not Reported |
| Ixel            | C | Unknown | 100 Mg | Not Reported |
| Ixel            | C | Unknown | 150 Mg | Not Reported |
| Ixel            | C | Unknown | 200 Mg | Not Reported |
| Abilify         | C | Unknown | 2.5 Mg | Not Reported |
| Abilify         | C | Unknown | 5 Mg   | Not Reported |
| Seroquel Xr     | C | Unknown | 200 Mg | Not Reported |
| Paroxetine      | C | Unknown | 40 Mg  | Not Reported |
| Molaxole        | C | Unknown | 3 Df   | Not Reported |
| Molaxole        | C | Unknown | 4 Df   | Not Reported |
| Molaxole        | C | Unknown | 2 Df   | Not Reported |
| Molaxole        | C | Unknown | 3 Df   | Not Reported |
| Molaxole        | C | Unknown | 2 Df   | Not Reported |
| Molaxole        | C | Unknown | 1 Df   | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 12-Feb-2016              | 10233287      | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2014160718 |                      | 57 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                               | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|------------------------------------------------------------------|-----------------|------------|
| Drug Ineffective      | Pristiq        |              |            | S           | Oral         | 100 Mg, 2x/Day (100 Mg In The Morning And 100 Mg In The Evening) |                 | Pfizer     |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                       |   |      |                |              |
|-----------------------|---|------|----------------|--------------|
| Pristiq               | S | Oral | 25 Mg, 1x/Day  | Pfizer       |
| Effexor               | S |      | Unk            | Pfizer       |
| Zoloft                | S |      | Unk            | Pfizer       |
| Prozac                | S |      | Unk            | Not Reported |
| Citalopram            | S |      | Unk            | Not Reported |
| Lexapro               | S |      | Unk            | Not Reported |
| Wellbutrin            | S |      | Unk            | Not Reported |
| Tegretol              | C |      | Unk            | Not Reported |
| Klonopin              | C |      | Unk            | Not Reported |
| Levothyroxine         | C |      | Unk            | Not Reported |
| Lidocaine             | C |      | Unk            | Not Reported |
| Lidocaine             | C |      | Unk            | Not Reported |
| Zofran                | C |      | Unk            | Not Reported |
| Oxycodone             | C |      | Unk            | Not Reported |
| Benzotropine Mesilate | C |      | Unk            | Not Reported |
| Vicoprofen            | C |      | Unk            | Not Reported |
| Ibuprofen             | C |      | Unk, As Needed | Not Reported |
| Tylenol               | C |      | Unk            | Not Reported |
| Botox                 | C |      | Unk            | Not Reported |

| <u>FDA Received Date</u>                   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------|--------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 12-Feb-2016                                | 11940126                 | EXPEDITED (15-DAY) |                    | OT              | IT-<br>ELI_LILLY_AND_COMP<br>ANY-IT201601008195 |                      | 26 YR           | Male         | ITA            |
| <u>Preferred Term</u>                      | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Depression;<br>Drug Ineffective | Fluoxetine Hydrochloride |                    |                    | S               | Unknown                                         | 40 Mg, Qd            |                 | Unknown      |                |
|                                            | Clomipramine             |                    |                    | S               | Unknown                                         | 75 Mg, Qd            |                 | Not Reported |                |
|                                            | Amitriptyne              |                    |                    | S               | Unknown                                         | 25 Mg, Qd            |                 | Not Reported |                |
|                                            | Venlafaxine              |                    |                    | S               | Unknown                                         | 75 Mg, Qd            |                 | Not Reported |                |
|                                            | Escitalopram             |                    |                    | S               | Unknown                                         | 10 Mg, Qd            |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                            | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------|--------------------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 12-Feb-2016                                                         | 12071616                             | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-2016077466 |                      | 38 YR           | Female       | USA            |
| <u>Preferred Term</u>                                               | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bronchitis; Lower Respiratory Tract Infection; Sinusitis            | Lyrica                               |                    |                    | S               |                          | 200 Mg, 2x/Day       |                 | Pfizer       |                |
|                                                                     | Duloxetine                           |                    |                    | S               |                          | 60 Mg, 1x/Day        |                 | Not Reported |                |
|                                                                     | Escitalopram                         |                    |                    | S               |                          | 20 Mg, 1x/Day        |                 | Not Reported |                |
|                                                                     | Benadryl                             |                    |                    | S               |                          | 25 Mg, 1x/Day        |                 | Not Reported |                |
|                                                                     | Celexa                               |                    |                    | S               |                          | 40 Mg, 1x/Day        |                 | Not Reported |                |
|                                                                     | Ginger Root/Vitamin B6               |                    |                    | S               |                          | 150 Mg, 1x/Day       |                 | Not Reported |                |
|                                                                     | Turmeric                             |                    |                    | S               |                          | 500 Mg, 1x/Day       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                            | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Feb-2016                                                         | 12073194                             | EXPEDITED (15-DAY) |                    | CA, OT          | DE-FRI-1000082466        |                      | 1 DAY           | Male         | DEU            |
| <u>Preferred Term</u>                                               | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Foetal Exposure During Pregnancy; Hypospadias; Small For Dates Baby | Escitalopram                         |                    |                    | S               | Transplacental           | 10 Mg                |                 | Forest       |                |
|                                                                     | Tavor (Lorazepam)                    |                    |                    | S               | Transplacental           |                      |                 | Not Reported |                |
|                                                                     | Lyrica                               |                    |                    | S               | Transplacental           | 300 Mg               |                 | Not Reported |                |
|                                                                     | Metamizol                            |                    |                    | S               | Transplacental           | 500 Mg               |                 | Not Reported |                |
|                                                                     | Dominal (Prothipendyl Hydrochloride) |                    |                    | S               | Transplacental           | 240 Mg               |                 | Not Reported |                |
|                                                                     | Femaform Natal                       |                    |                    | S               | Unknown                  |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                            | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Feb-2016                                                         | 12073883                             | EXPEDITED (15-DAY) |                    | DE              | US-PERRIGO-16US001328    |                      | 45 YR           | Male         | USA            |
| <u>Preferred Term</u>                                               | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Death                                                               | Acetaminophen                        |                    |                    | S               | Oral                     | Unknown, Unknown     |                 | Perrigo      |                |
|                                                                     | Quetiapine                           |                    |                    | S               | Oral                     | Unknown, Unknown     |                 | Not Reported |                |

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|                                                              | Escitalopram   |                    | S                  | Oral            |                              | Unknown, Unknown     |                 | Not Reported |                |
|--------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
|                                                              | Sertraline     |                    | S                  | Oral            |                              | Unknown, Unknown     |                 | Not Reported |                |
|                                                              | Buspirone      |                    | S                  | Oral            |                              | Unknown, Unknown     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Feb-2016                                                  | 12077091       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000082587            |                      | 83 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;<br>Haematoma Muscle                        | Escitalopram   |                    |                    | S               | Oral                         |                      |                 | Forest       |                |
|                                                              | Xarelto        |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                              | Modopar        |                    |                    | C               |                              |                      |                 | Not Reported |                |
|                                                              | Levothyrox     |                    |                    | C               |                              |                      |                 | Not Reported |                |
|                                                              | Zestoretic     |                    |                    | C               |                              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Feb-2016                                                  | 12077390       | EXPEDITED (15-DAY) |                    | OT              | ZA-FRI-1000081546            |                      |                 | Female       | ZAF            |
| <u>Preferred Term</u>                                        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Pressure<br>Inadequately Controlled                    | Escitalopram   |                    |                    | S               | Oral                         |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Feb-2016                                                  | 12078701       | EXPEDITED (15-DAY) |                    | OT              | US-ACCORD-037691             |                      | 37 YR           | Female       | USA            |
| <u>Preferred Term</u>                                        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Chills; Hot Flush; Myalgia;<br>Nausea; Night Sweats;<br>Pain | Escitalopram   |                    |                    | S               | Oral                         | Strength: 10 Mg      |                 | Accord       |                |
|                                                              | Ativan         |                    |                    | C               |                              | Prn                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Feb-2016                                                  | 12078982       | NON-EXPEDITED      |                    |                 | US-PFIZER INC-<br>2016028112 |                      | 38 YR           | Unknown      | USA            |
| <u>Preferred Term</u>                                        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

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|                       |            |   |     |              |
|-----------------------|------------|---|-----|--------------|
| Drug Hypersensitivity | Zoloft     | S | Unk | Pfizer       |
|                       | Effexor Xr | S | Unk | Pfizer       |
|                       | Paxil      | S | Unk | Not Reported |
|                       | Prozac     | S | Unk | Not Reported |
|                       | Demerol    | S | Unk | Not Reported |
|                       | Bactrim    | S | Unk | Not Reported |
|                       | Viibryd    | S | Unk | Not Reported |
|                       | Lexapro    | S | Unk | Not Reported |

| <u>FDA Received Date</u>            | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------|-------------------|--------------------|--------------------|-----------------|--------------------------|------------------------|-----------------|--------------|----------------|
| 16-Feb-2016                         | 12080654          | EXPEDITED (15-DAY) |                    | OT              | FR-ASTELLAS-2016US004941 |                        | 73 YR           | Male         | FRA            |
| <u>Preferred Term</u>               | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Ascites; Pancytopenia; Splenomegaly | Advagraf          |                    |                    | S               | Oral                     |                        |                 | Astellas     |                |
|                                     | Mecir Lp          |                    |                    | S               | Unknown                  | 0.4 Mg, Unknown Freq.  |                 | Not Reported |                |
|                                     | Imurel /00001501/ |                    |                    | S               | Oral                     |                        |                 | Not Reported |                |
|                                     | Seroplex          |                    |                    | S               | Unknown                  |                        |                 | Not Reported |                |
|                                     | Kardegic          |                    |                    | C               | Unknown                  |                        |                 | Not Reported |                |
|                                     | Lantus            |                    |                    | C               | Unknown                  | Unk Unk, Unknown Freq. |                 | Not Reported |                |
|                                     | Imodium           |                    |                    | C               | Unknown                  |                        |                 | Not Reported |                |
|                                     | Aprovel           |                    |                    | C               | Unknown                  |                        |                 | Not Reported |                |
|                                     | Lercan            |                    |                    | C               | Unknown                  |                        |                 | Not Reported |                |

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|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 16-Feb-2016              | 12080668       | EXPEDITED (15-DAY) |                    | HO              | FR-SA-2016SA024952   |                      | 87 YR           | Female       | FRA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyponatraemia            | Aprovel        |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                          | Seroplex       |                    |                    | S               | Oral                 | 10 Mg                |                 | Not Reported |                |
|                          | Plavix         |                    |                    | C               | Oral                 | Strength: 75 Mg      |                 | Not Reported |                |



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|           |   |      |                                   |              |
|-----------|---|------|-----------------------------------|--------------|
| Lipanthyl | C | Oral | Strength: 160 Mg                  | Not Reported |
| Tenormin  | C | Oral | Strength: 50 Mg, Divisible Tablet | Not Reported |
| Amlor     | C | Oral | Strength: 5 Mg                    | Not Reported |
| Atarax    | C | Oral | Strength: 25 Mg, Divisible        | Not Reported |

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|--------------------------------|----------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|-----------------|--------------|----------------|
| 16-Feb-2016                    | 12080943       | EXPEDITED (15-DAY) |                    | HO              | US-AUROBINDO-AUR-APL-2016-01098 |                      | 60 YR           | Male         | USA            |
| <u>Preferred Term</u>          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Neuroleptic Malignant Syndrome | Divalproex     |                    |                    | S               | Unknown                         | Unk                  |                 | Aurobindo    |                |
|                                | Escitalopram   |                    |                    | S               | Unknown                         | Unk                  |                 | Aurobindo    |                |
|                                | Risperidone    |                    |                    | S               | Unknown                         | Unk                  |                 | Aurobindo    |                |
|                                | Fentanyl       |                    |                    | S               | Unknown                         | Unk                  |                 | Not Reported |                |
|                                | Atorvastatin   |                    |                    | C               | Unknown                         | Unk                  |                 | Not Reported |                |
|                                | Bupropion      |                    |                    | S               | Unknown                         | Unk                  |                 | Not Reported |                |

| <u>FDA Received Date</u>                                      | <u>Case #</u>                           | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------|-----------------------------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 16-Feb-2016                                                   | 12082815                                | DIRECT           |                    | OT              |                      |                      | 38 YR           | Male         | USA            |
| <u>Preferred Term</u>                                         | <u>Product</u>                          | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Depressed Mood; Headache; Product Substitution Issue | Lexapro 10mg Tablet Aurobindo           |                  |                    | S               | Oral                 |                      |                 | Aurobindo    |                |
|                                                               | Vyvanse                                 |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                               | Fish Oil                                |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                               | Vit D                                   |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                               | Multivitamin                            |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                               | Lexapro 10mg Tablet Aurobindo (Generic) |                  |                    | S               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Feb-2016              | 12083698      | DIRECT           |                    |                 |                      |                      | 58 YR      | Male       | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                 | <u>Product</u>                        | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|------------------|--------------------|-----------------|----------------------|-------------------------------------|-----------------|--------------|----------------|
| Facial Bones Fracture;<br>Fall; Syncope                                                                                                               | Lexapro                               |                  |                    | S               |                      |                                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                              | <u>Case #</u>                         | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Feb-2016                                                                                                                                           | 12084156                              | DIRECT           |                    | OT              |                      |                                     | 57 YR           | Unknown      | USA            |
| <u>Preferred Term</u>                                                                                                                                 | <u>Product</u>                        | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Alopecia; Alopecia                                                                                                                                    | Escitalopram                          |                  |                    | S               | Oral                 | 1 Daily Once Daily                  |                 | Mylan        |                |
|                                                                                                                                                       | Lostratan                             |                  |                    | C               |                      |                                     |                 | Not Reported |                |
|                                                                                                                                                       | Norvasc                               |                  |                    | C               |                      |                                     |                 | Not Reported |                |
|                                                                                                                                                       | Hydrochlorizide                       |                  |                    | C               |                      |                                     |                 | Not Reported |                |
|                                                                                                                                                       | D3                                    |                  |                    | C               |                      |                                     |                 | Not Reported |                |
|                                                                                                                                                       | Fish Oil                              |                  |                    | C               |                      |                                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                              | <u>Case #</u>                         | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Feb-2016                                                                                                                                           | 12084207                              | DIRECT           |                    | LT, OT          |                      |                                     | 37 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                 | <u>Product</u>                        | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Anger; Depression; Drug<br>Withdrawal Syndrome;<br>Headache; Muscle<br>Twitching; Nausea; Panic<br>Attack; Product<br>Substitution Issue;<br>Vomiting | Escitalopram 20 Mg                    |                  |                    | S               | Oral                 |                                     | 12 DAY          | Not Reported |                |
|                                                                                                                                                       | Lexapro                               |                  |                    | C               |                      |                                     |                 | Not Reported |                |
|                                                                                                                                                       | Alprazolam Extended Release           |                  |                    | C               |                      |                                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                              | <u>Case #</u>                         | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Feb-2016                                                                                                                                           | 12084244                              | DIRECT           |                    | DS              |                      |                                     | 36 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                 | <u>Product</u>                        | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Eye Irritation;<br>Headache; Nausea; Panic<br>Attack; Product<br>Substitution Issue                                                       | Escitalopram 5mg Accord<br>Healthcare |                  |                    | S               | Oral                 | 1 Pill Once Daily Taken By<br>Mouth |                 | Accord       |                |
|                                                                                                                                                       | Synthroid                             |                  |                    | C               |                      |                                     |                 | Not Reported |                |
|                                                                                                                                                       | Vit. D3                               |                  |                    | C               |                      |                                     |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| Probiotic                |                      |                    | C                  |                 |                                                              | Not Reported         |                 |                      |                |
|--------------------------|----------------------|--------------------|--------------------|-----------------|--------------------------------------------------------------|----------------------|-----------------|----------------------|----------------|
| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 17-Feb-2016              | 12082529             | EXPEDITED (15-DAY) |                    | HO              | FR-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>BMS-2016-010535       |                      | 89 YR           | Male                 | FRA            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Dyskinesia               | Eliquis              |                    |                    | S               | Oral                                                         | 2.5 Mg, Unk          |                 | Bristol Myers Squibb |                |
|                          | Seroplex             |                    |                    | S               | Oral                                                         | 10 Mg, Qd            |                 | Not Reported         |                |
|                          | Atenolol             |                    |                    | C               | Unknown                                                      | 20 Mg, Unk           |                 | Not Reported         |                |
|                          | Coversyl /00790702/  |                    |                    | C               | Unknown                                                      | 5 Mg, Unk            |                 | Not Reported         |                |
|                          | Adenuric             |                    |                    | C               | Unknown                                                      | 80 Mg, Unk           |                 | Not Reported         |                |
|                          | Lescol               |                    |                    | C               | Unknown                                                      | 80 Mg, Unk           |                 | Not Reported         |                |
|                          | Seresta              |                    |                    | C               | Unknown                                                      | 10 Mg, Unk           |                 | Not Reported         |                |
|                          | Betaseric /00141801/ |                    |                    | C               | Unknown                                                      |                      |                 | Not Reported         |                |
|                          | Mecir                |                    |                    | C               | Unknown                                                      | 0.4 Mg, Unk          |                 | Not Reported         |                |
|                          | Inexium /01479302/   |                    |                    | C               | Unknown                                                      |                      |                 | Not Reported         |                |
| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 17-Feb-2016              | 12083882             | EXPEDITED (15-DAY) |                    | HO              | TW-SUN<br>PHARMACEUTICAL<br>INDUSTRIES LTD-<br>2016RR-111707 |                      |                 | Unknown              | TWN            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Restless Legs Syndrome   | Quetiapine           |                    |                    | S               | Unknown                                                      | 100 Mg, Daily        |                 | Sun                  |                |
|                          | Quetiapine           |                    |                    | S               |                                                              |                      |                 | Sun                  |                |
|                          | Quetiapine           |                    |                    | S               | Unknown                                                      | 150 Mg, Daily        |                 | Sun                  |                |
|                          | Escitalopram         |                    |                    | S               | Unknown                                                      | 20 Mg, Daily         |                 | Not Reported         |                |
|                          | Lithium              |                    |                    | S               | Unknown                                                      | 600 Mg, Daily        |                 | Sun                  |                |
| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 17-Feb-2016              | 12084644             | EXPEDITED (15-DAY) |                    | HO              | PHHY2016FR019470                                             |                      | 67 YR           | Male                 | FRA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                      | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>   |                |
|--------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|---------------------------------|--------------------------------------|-----------------|--------------|----------------|
| Acute Kidney Injury;<br>Metabolic Acidosis                                                                                                 | Eucreas                |                    |                    | S               | Oral                            | 1 Df, Bid (Morning And Evening)      |                 | Not Reported |                |
|                                                                                                                                            | Enalapril              |                    |                    | S               | Oral                            | 20 Mg, Qd (In Morning)               |                 | Novartis     |                |
|                                                                                                                                            | Escitalopram           |                    |                    | S               | Oral                            | 20 Mg, Qd (In Morning)               |                 | Not Reported |                |
|                                                                                                                                            | Zolpidem               |                    |                    | S               | Oral                            | Unk, Prn (In Evening)                |                 | Not Reported |                |
|                                                                                                                                            | Alprazolam             |                    |                    | S               | Oral                            | 0.5 Mg, Bid (In Morning And Evening) |                 | Not Reported |                |
|                                                                                                                                            | Amarel                 |                    |                    | S               | Oral                            | 2 Mg, Qd (In Morning)                |                 | Not Reported |                |
|                                                                                                                                            | Trimebutine            |                    |                    | C               | Unknown                         |                                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                   | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u>                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Feb-2016                                                                                                                                | 12085547               | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-2016064354        |                                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                                                                                      | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Abuse; Malaise                                                                                                                        | Robitussin             |                    | Y                  | S               |                                 | Unk                                  |                 | Pfizer       |                |
|                                                                                                                                            | Lexapro                |                    |                    | S               |                                 | Unk                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                   | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u>                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Feb-2016                                                                                                                                | 12087835               | NON-EXPEDITED      |                    |                 | US-AUROBINDO-AUR-APL-2014-12673 |                                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                      | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Contusion;<br>Cough; Drug<br>Hypersensitivity; Memory<br>Impairment; Myalgia;<br>Psychomotor<br>Hyperactivity; Rash;<br>Urticaria | Penicillin V Potassium |                    |                    | S               | Unknown                         |                                      |                 | Aurobindo    |                |
|                                                                                                                                            | Amoxicillin            |                    |                    | S               | Unknown                         |                                      |                 | Aurobindo    |                |
|                                                                                                                                            | Atenolol               |                    |                    | S               | Unknown                         |                                      |                 | Aurobindo    |                |
|                                                                                                                                            | Simvastatin            |                    |                    | S               | Unknown                         |                                      |                 | Aurobindo    |                |
|                                                                                                                                            | Celexa /00582602/      |                    |                    | S               | Unknown                         |                                      |                 | Not Reported |                |
|                                                                                                                                            | Cipro /00697201/       |                    |                    | S               | Unknown                         |                                      |                 | Not Reported |                |
|                                                                                                                                            | Keflex /00145501/      |                    |                    | S               | Unknown                         |                                      |                 | Not Reported |                |
|                                                                                                                                            | Lexapro                |                    |                    | S               | Unknown                         |                                      |                 | Not Reported |                |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                      |   |         |                                                          |              |
|----------------------|---|---------|----------------------------------------------------------|--------------|
| Lipitor              | S | Unknown |                                                          | Not Reported |
| Paxil /00500401/     | S | Unknown |                                                          | Not Reported |
| Trazodone Hcl        | S | Unknown |                                                          | Not Reported |
| Vicodin              | S | Unknown |                                                          | Not Reported |
| Metoprolol           | C | Oral    | Unk, Once A Day                                          | Not Reported |
| Lasix /00032601/     | C | Oral    | 1 Df, Two Times A Day                                    | Not Reported |
| Aldactone /00006201/ | C | Oral    | 1 Df, Once A Day                                         | Not Reported |
| Digoxin              | C | Oral    | 1 Tablet On Monday,<br>Wednesday And Friday              | Not Reported |
| Amiodarone           | C | Oral    | Half Tablets Once A Day                                  | Not Reported |
| Pravastatin Sodium   | C | Oral    | 1 Df, Once A Day                                         | Not Reported |
| Omeprazole           | C | Oral    | 1 Df, Once A Day                                         | Not Reported |
| Lyrica               | C | Unknown | 1 Df, 3 Times A Day                                      | Not Reported |
| Lorazepam            | C | Oral    | 1 Df, As Necessary                                       | Not Reported |
| Aspirin              | C | Oral    | 1 Df, Once A Day                                         | Not Reported |
| Flonase              | C | Nasal   | 50 Mcg/Act 2 Puffs, Twice<br>A Day                       | Not Reported |
| Warfarin Sodium      | C | Unknown | 2 Tablets On Friday, 1<br>Tablet The Rest Of The<br>Week | Not Reported |
| Vitamin B-12         | C | Oral    | 1 Df, Once A Day                                         | Not Reported |
| Nortriptyline        | C | Unknown | 1 At Bed Time                                            | Not Reported |
| Spironolactone       | C | Unknown | 25 Mg, Once A Day                                        | Not Reported |
| Sulfa /00076401/     | C | Unknown |                                                          | Not Reported |

| <u>FDA Received Date</u>                  | <u>Case #</u>                              | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>     | <u>Country</u> |
|-------------------------------------------|--------------------------------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|----------------|----------------|
| 17-Feb-2016                               | 12089178                                   | DIRECT           |                    | DS, LT          |                      |                      | 29 YR           | Female         | HUN            |
| <u>Preferred Term</u>                     | <u>Product</u>                             | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>     |                |
| Alopecia; Anhedonia;<br>Apathy; Asthenia; | Escitalopram 10 Mg Richter<br>Gedeon Nyrt. |                  |                    | S               | Oral                 |                      |                 | Gedeon Richter |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |         |   |              |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|---|--------------|
| Cognitive Disorder;<br>Decreased Appetite;<br>Depression; Diffuse<br>Alopecia; Disturbance In<br>Attention; Drug Withdrawal<br>Syndrome; Emotional<br>Disorder; Fatigue; Feeling<br>Abnormal; Gastrointestinal<br>Disorder; Genital<br>Hypoaesthesia; Genital<br>Paraesthesia; Head<br>Discomfort; Hypotension;<br>Influenza Like Illness;<br>Insomnia; Loss Of<br>Employment; Loss Of<br>Libido; Memory<br>Impairment; Menstruation<br>Irregular; Palpitations;<br>Peripheral Coldness;<br>Sexual Dysfunction; Sleep<br>Disorder; Tremor; Weight<br>Decreased | Omega 3 | C | Not Reported |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|---|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Feb-2016              | 12092362      | DIRECT           | Y                  |                 |                      |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|----------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Depression; Drug<br>Ineffective; Product<br>Substitution Issue | Escitalopram   |              |            | S           |              |                    |                 | Unknown    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 18-Feb-2016              | 9232851       | EXPEDITED (15-DAY) |                    | DS              | FR-JNJFOC-<br>20130404027 |                      | 48 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Blood Creatine<br>Phosphokinase Increased;<br>Drug Interaction; Myalgia; | Intelence      |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                   | Norvir         |              |            | S           | Oral         |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                       |           |   |      |              |
|-----------------------|-----------|---|------|--------------|
| Neuropathy Peripheral | Seroplex  | S | Oral | Not Reported |
|                       | Prezista  | C | Oral | Not Reported |
|                       | Isentress | C | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 18-Feb-2016              | 11154636      | EXPEDITED (15-DAY) |                    | HO, LT, OT      | FR-AMGEN-FRASP2015051933 |                      | 56 YR      | Female     | FRA            |

| <u>Preferred Term</u>      | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|----------------------|--------------|------------|-------------|--------------|-----------------------|-----------------|--------------|
| Bundle Branch Block Left;  | Procoralan           |              |            | S           | Oral         | 5 Mg, Bid             |                 | Amgen        |
| Cardio-Respiratory Arrest; | Plaquenil /00072602/ |              |            | S           | Oral         | 200 Mg, Bid           |                 | Not Reported |
| Chest Pain; Diarrhoea;     | Seroplex             |              |            | S           | Oral         | 5 Mg, Qd              |                 | Not Reported |
| Electrocardiogram Qt       | Atacand              |              |            | C           |              | 4 Mg, Daily           |                 | Not Reported |
| Prolonged; Hypokalaemia;   | Aldactone /00006201/ |              |            | C           |              | 25 Mg, Unkevery Other |                 | Not Reported |
| Lactic Acidosis; Malaise;  |                      |              |            |             |              | Day                   |                 |              |
| Nausea; Torsade De         |                      |              |            |             |              |                       |                 |              |
| Pointes; Ventricular       |                      |              |            |             |              |                       |                 |              |
| Dyssynchrony               |                      |              |            |             |              |                       |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Feb-2016              | 11669235      | EXPEDITED (15-DAY) |                    | CA, DE, HO, OT  | US-FRI-1000080399    |                      | < 1 DAY    | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|------------|
| Anuria; Aqueductal<br>Stenosis; Atrial Septal<br>Defect; Bradycardia;<br>Cardiomegaly; Cerebral<br>Ventricle Dilatation;<br>Congenital<br>Hydrocephalus;<br>Congenital<br>Hydronephrosis;<br>Congenital Spinal Fusion;<br>Hemivertebra;<br>Hyponatraemia;<br>Hypotension; Irritability;<br>Limb Malformation;<br>Macrocephaly; | Lexapro        |              |            | S           | Transplacental | 10mg               |                 | Forest     |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Malnutrition; Maternal  
Condition Affecting  
Foetus; Microtia; Multiple  
Congenital Abnormalities;  
Neonatal Respiratory  
Distress Syndrome;  
Premature Baby;  
Pulmonary Oedema;  
Pulmonary Vascular  
Disorder; Renal Failure;  
Seizure; Sepsis; Sepsis  
Neonatal; Shock;  
Tachypnoea; Truncus  
Arteriosus Persistent

| <u>FDA Received Date</u> | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|------------------------|-----------------|--------------|----------------|
| 18-Feb-2016              | 11889844               | EXPEDITED (15-DAY) |                    | HO              | JP-FRI-1000081968    |                        | 57 YR           | Female       | JPN            |
| <u>Preferred Term</u>    | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Activation Syndrome      | Lexapro                |                    |                    | S               | Oral                 | 10 Mg                  |                 | Forest       |                |
|                          | Myslee                 |                    |                    | C               | Oral                 | 5 Mg                   |                 | Not Reported |                |
|                          | Saikokaryukotsuboreito |                    |                    | C               | Oral                 |                        |                 | Not Reported |                |
|                          | Melex                  |                    |                    | C               | Oral                 | 0.5 Mg                 |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Feb-2016              | 11917151               | EXPEDITED (15-DAY) |                    | HO              | FR-UCBSA-2016000712  |                        | 40 YR           | Female       | FRA            |
| <u>Preferred Term</u>    | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Ventricular Arrhythmia   | Cimzia                 |                    |                    | S               |                      | Unk                    |                 | Ucb          |                |
|                          | Seroplex               |                    |                    | S               | Oral                 | 10 Mg, Once Daily (Qd) |                 | Not Reported |                |
|                          | Havlane                |                    |                    | C               |                      | Unk                    |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Feb-2016              | 12089126               | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000082646    |                        | 73 YR           | Male         | FRA            |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Pancytopenia          | Escitalopram   |              |            | S           | Oral         |                    |                 | Forest       |
|                       | Imurel         |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Advagraf       |              |            | S           | Oral         | 1.5 Mg             |                 | Not Reported |
|                       | Kardegic       |              |            | C           | Oral         |                    |                 | Not Reported |
|                       | Lantus         |              |            | C           | Unknown      |                    |                 | Not Reported |
|                       | Imodium        |              |            | C           | Oral         |                    |                 | Not Reported |
|                       | Aprovel        |              |            | C           | Oral         |                    |                 | Not Reported |
|                       | Lercan         |              |            | C           | Oral         |                    |                 | Not Reported |
|                       | Mecir          |              |            | C           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------------------------------------|----------------------|------------|------------|----------------|
| 18-Feb-2016              | 12091544      | EXPEDITED (15-DAY) |                    | OT              | FR-B.I.<br>PHARMACEUTICALS,I<br>NC./RIDGEFIELD-2016-<br>BI-09 |                      | 73 YR      | Male       | FRA            |

| <u>Preferred Term</u>                  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>           |
|----------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------|
| Ascites; Pancytopenia;<br>Splenomegaly | Mecir          |              |            | S           | Unknown      | 0.4 Mg             |                 | Boehringer Ingelheim |
|                                        | Advagraf       |              |            | S           | Oral         | 1.5 Mg             |                 | Not Reported         |
|                                        | Imurel         |              |            | S           | Oral         | 50 Mg              |                 | Not Reported         |
|                                        | Seroplex       |              |            | S           | Unknown      | 5 Mg               |                 | Not Reported         |
|                                        | Kardegic       |              |            | C           | Unknown      | 75 Mg              |                 | Not Reported         |
|                                        | Lantus         |              |            | C           | Unknown      |                    |                 | Not Reported         |
|                                        | Imodium        |              |            | C           | Unknown      | 2 Mg               |                 | Not Reported         |
|                                        | Aprovel        |              |            | C           | Unknown      | 300 Mg             |                 | Not Reported         |
|                                        | Lercan         |              |            | C           | Unknown      | 10 Mg              |                 | Not Reported         |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Feb-2016              | 12091775      | EXPEDITED (15-DAY) |                    | HO              | US-FRI-1000080395    |                      | 29 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                            |             |   |      |          |              |
|----------------------------|-------------|---|------|----------|--------------|
| Complication Of            | Lexapro     | S | Oral | 10mg     | Forest       |
| Pregnancy; Cough;          | Relion      | C |      |          | Not Reported |
| Diabetes Mellitus          | Relion      | C |      |          | Not Reported |
| Inadequate Control;        | Novolog     | C |      | 30 Units | Not Reported |
| Diabetic Ketoacidosis;     | Neurontin   | C | Oral | 600mg    | Not Reported |
| Exposure During            | Zofran      | C | Oral | 24mg     | Not Reported |
| Pregnancy; Menstruation    | Ultram      | C | Oral |          | Not Reported |
| Delayed; Nausea;           | Albuterol   | C |      |          | Not Reported |
| Oropharyngeal Pain;        | Albuterol   | C |      |          | Not Reported |
| Rhinorrhoea; Urinary Tract | Zithromax   | C | Oral | 500mg    | Not Reported |
| Infection; Vaginal         | Zithromax   | C | Oral | 250mg    | Not Reported |
| Haemorrhage; Vomiting      | Mucinex     | C | Oral |          | Not Reported |
|                            | Concept Dha | C | Oral |          | Not Reported |
|                            | Rocephin    | C |      |          | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Feb-2016              | 12092721      | DIRECT           |                    | OT              |                      |                      | 51 YR      | Female     | USA            |

| <u>Preferred Term</u>                  | <u>Product</u>                                       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------|------------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Depression; Product Substitution Issue | Lexapro Generic 20mg<br>Generic---I Do Not Know More |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 19-Feb-2016              | 12095152      | EXPEDITED (15-DAY) |                    | DS              | FR-ABBVIE-13P-056-1076954-00 |                      | 48 YR      | Male       | FRA            |

| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Creatine           | Norvir         |              |            | S           | Oral         |                    |                 | Not Reported |
| Phosphokinase Increased; | Intelence      |              |            | S           | Oral         |                    |                 | Not Reported |
| Myalgia; Neuropathy      | Seroplex       |              |            | S           | Oral         |                    |                 | Not Reported |
| Peripheral               | Isentress      |              |            | C           |              |                    |                 | Not Reported |
|                          | Prezista       |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Feb-2016              | 12099596      | DIRECT           | Y                  |                 |                      |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                           | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Incorrect Dose Administered; Insomnia; Product Dispensing Error | Escitalopram Oxalate |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 22-Feb-2016              | 10480274      | EXPEDITED (15-DAY) |                    | HO              | FR-009507513-1409FRA009458 |                      | 67 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                                                                                                                | <u>Product</u>                     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abdominal Pain; Body Temperature Abnormal; C-Reactive Protein Increased; Diarrhoea; Duodenitis; Gastritis; General Physical Condition Abnormal; Nausea; Oesophagitis | Victrelis                          |              |            | S           | Unknown      | 800 Mg, Tid        |                 | Merck        |
|                                                                                                                                                                      | Ribavirin                          |              |            | S           | Unknown      | 400 Mg, Bid        |                 | Merck        |
|                                                                                                                                                                      | Norfloxacin                        |              |            | S           | Oral         | Unk                |                 | Merck        |
|                                                                                                                                                                      | Peginterferon Alfa-2a              |              |            | S           | Unknown      | 180 Microgram, Qw  |                 | Not Reported |
|                                                                                                                                                                      | Inexium (Esomeprazole Sodium)      |              |            | S           | Unknown      | 40 Mg, Qd          |                 | Not Reported |
|                                                                                                                                                                      | Seroplex                           |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                                                                                                                                                                      | Loxen (Niacardipine Hydrochloride) |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                                                                                                                                                                      | Esomeprazole                       |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                                                                                                                                                                      | Kardegic                           |              |            | S           | Unknown      | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Feb-2016              | 12055656      | EXPEDITED (15-DAY) |                    | OT              | SI-FRI-1000082430    |                      | 49 YR      | Male       | SVN            |

| <u>Preferred Term</u>                                                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Asthenia; Impaired Work Ability; Malaise; Nerve Conduction Studies Abnormal; Radiculopathy | Escitalopram   |              |            | S           | Oral         |                    |                 | Forest     |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                           | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------|---------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 22-Feb-2016                                                                                        | 12099241            | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2016102369 |                      | 39 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                              | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated;<br>Depression; Irritability;<br>Mood Altered; Nausea;<br>Withdrawal Syndrome | Effexor             |                    |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                                                                                                    | Lexapro             |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                                                                                                    | Wellbutrin          |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                                                                                                    | Paxil               |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                                                                                                    | Prozac              |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                           | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Feb-2016                                                                                        | 12100989            | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000082674        |                      | 22 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                              | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Transaminases Increased                                                                            | Escitalopram        |                    |                    | S               | Oral                     |                      |                 | Forest       |                |
|                                                                                                    | Temesta (Lorazepam) |                    |                    | S               | Oral                     | 6 Mg                 |                 | Not Reported |                |
|                                                                                                    | Loxapac             |                    |                    | S               | Oral                     | 50 Mg                |                 | Not Reported |                |
|                                                                                                    | Loxapac             |                    |                    | S               | Oral                     | 100 Mg               |                 | Not Reported |                |
|                                                                                                    | Olanzapine          |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                                                                                                    | Olanzapine          |                    |                    | S               | Oral                     | 20 Mg                |                 | Not Reported |                |
|                                                                                                    | Xeroquel            |                    |                    | C               | Oral                     |                      |                 | Not Reported |                |
|                                                                                                    | Seresta             |                    |                    | C               | Oral                     |                      |                 | Not Reported |                |
|                                                                                                    | Risperdal           |                    |                    | C               | Oral                     | 2 Mg                 |                 | Not Reported |                |
|                                                                                                    | Risperdal           |                    |                    | C               | Oral                     | 6 Mg                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                           | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Feb-2016                                                                                        | 12101463            | EXPEDITED (15-DAY) |                    | HO              | FR-SA-2016SA029056       |                      | 67 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                              | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                     |                   |   |         |                         |              |
|---------------------|-------------------|---|---------|-------------------------|--------------|
| Acute Kidney Injury | Enalapril Maleate | S | Oral    |                         | Not Reported |
|                     | Amarel            | S | Oral    | Morning                 | Not Reported |
|                     | Alprazolam        | S | Oral    | Morning And Evening     | Not Reported |
|                     | Zolpidem          | S | Oral    | If Necessary On Evening | Not Reported |
|                     | Escitalopram      | S | Oral    |                         | Not Reported |
|                     | Eucreas           | S | Oral    | Morning End Evening     | Not Reported |
|                     | Trimebutine       | C | Unknown |                         | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Feb-2016              | 12102313      | EXPEDITED (15-DAY) |                    | HO, OT          | ALCN2016CA001392     |                      | 54 YR      | Female     | CAN            |

| <u>Preferred Term</u>                                               | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Condition Aggravated;<br>Dehydration; Dysphagia;<br>Mental Disorder | Vitalux                   |              |            | S           | Oral         | 2 Tablets, Qd      |                 | Not Reported |
|                                                                     | Wellbutrin                |              |            | S           | Oral         | 150 Mg, Bid        |                 | Not Reported |
|                                                                     | Tylenol With Codeine No.3 |              |            | S           | Oral         | 2 Tablets, Tid     |                 | Not Reported |
|                                                                     | Temazepam                 |              |            | S           | Oral         | 30 Mg, Qd          |                 | Not Reported |
|                                                                     | Gabapentin                |              |            | S           | Oral         | 600 Mg, Bid        |                 | Not Reported |
|                                                                     | Gabapentin                |              |            | S           | Oral         | 300 Mg, Qd         |                 | Not Reported |
|                                                                     | Ferrous Sulphate          |              |            | S           | Unknown      | 300 Mg, Tid        |                 | Not Reported |
|                                                                     | Domperidone               |              |            | S           | Oral         | 10 Mg, Bid         |                 | Not Reported |
|                                                                     | Clonazepam                |              |            | S           | Oral         | 0.5 Mg, Tid        |                 | Not Reported |
|                                                                     | Ciprallex//Escitalopram   |              |            | S           | Oral         | 20 Mg, Unk         |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-------------------------------|----------------------|------------|------------|----------------|
| 22-Feb-2016              | 12102866      | NON-EXPEDITED    |                    |                 | US-ACORDA-<br>ACO_112554_2015 |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                                                              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Energy Increased;<br>Inappropriate Schedule Of<br>Product Administration;<br>Insomnia; Logorrhoea; | Ampyra         |              |            | S           | Oral         | 10 Mg, Bid         |                 | Acorda       |
|                                                                                                    | Escitalopram   |              |            | S           | Oral         | 10 Mg, Qd          |                 | Not Reported |
|                                                                                                    | Gilenya        |              |            | C           |              | 0.5 Mg, Unk        |                 | Not Reported |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                 |               |   |              |              |
|---------------------------------|---------------|---|--------------|--------------|
| Psychomotor                     | Amantadine    | C | 100 Mg, Unk  | Not Reported |
| Hyperactivity; Weight Increased | Vitamin D Nos | C | 4000 Iu, Unk | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 22-Feb-2016              | 12103098      | EXPEDITED (15-DAY) |                    | OT              | AU-MYLANLABS-2016M1006967 |                      |            | Unknown    | AUS            |

| <u>Preferred Term</u>                                         | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------|--------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Akathisia; Confusional State; Drug Interaction; Hyponatraemia | Escitalopram       |              |            | S           | Unknown      | 30 Mg Daily        |                 | Not Reported |
|                                                               | Dosulepin          |              |            | S           | Unknown      | 225mg              |                 | Not Reported |
|                                                               | Dosulepin          |              |            | S           | Unknown      | 175mg              |                 | Not Reported |
|                                                               | Bupropion          |              |            | S           | Oral         | 75mg               |                 | Not Reported |
|                                                               | Quetiapine         |              |            | C           | Unknown      | At Night           |                 | Mylan        |
|                                                               | Lamotrigine        |              |            | C           | Unknown      |                    |                 | Mylan        |
|                                                               | Estradiol          |              |            | C           | Unknown      |                    |                 | Mylan        |
|                                                               | Ramipril           |              |            | C           | Unknown      |                    |                 | Mylan        |
|                                                               | Glipizide          |              |            | C           | Unknown      |                    |                 | Mylan        |
|                                                               | Metformin          |              |            | C           | Unknown      |                    |                 | Mylan        |
|                                                               | Lantus             |              |            | C           | Unknown      |                    |                 | Mylan        |
|                                                               | Atorvastatin       |              |            | C           | Unknown      |                    |                 | Mylan        |
|                                                               | Aspirin /00002701/ |              |            | C           | Unknown      |                    |                 | Mylan        |
|                                                               | Norfloxacin        |              |            | C           | Unknown      |                    |                 | Mylan        |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Feb-2016              | 12108815      | DIRECT           |                    |                 |                      |                      | 35 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Dizziness             | Lexapro 5 Mg   |              |            | S           | Oral         | Taken By Mouth     |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Feb-2016              | 12109193      | DIRECT           | Y                  | OT              |                      |                      | 61 YR      | Female     | USA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u> | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|--------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Diarrhoea             | Escitalopram 20 Mg |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------|----------------------|------------|------------|----------------|
| 23-Feb-2016              | 12104455      | EXPEDITED (15-DAY) |                    | OT              | GB-AUROBINDO-AUR-<br>APL-2016-01806 |                      | 54 YR      | Female     | GBR            |

| <u>Preferred Term</u>                                   | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>     | <u>Dosage Text</u>                                    | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------|----------------------|--------------|------------|-------------|------------------|-------------------------------------------------------|-----------------|--------------|
| Drug Ineffective; Nausea;<br>Product Substitution Issue | Escitalopram         |              |            | S           | Unknown          |                                                       |                 | Aurobindo    |
|                                                         | Ciprallex /01588501/ |              |            | C           | Unknown          | Use As Directed                                       |                 | Not Reported |
|                                                         | Diazepam             |              |            | C           | Unknown          | 1 Df, Unk                                             |                 | Not Reported |
|                                                         | Dihydrocodeine       |              |            | C           | Unknown          | 1 Df, Unk                                             |                 | Not Reported |
|                                                         | Lansoprazole         |              |            | C           | Unknown          | 1 Df, Once A Day                                      |                 | Not Reported |
|                                                         | Loperamide           |              |            | C           | Unknown          | Use As Directed                                       |                 | Not Reported |
|                                                         | Metronidazole        |              |            | C           | Unknown          | 5 MI, 3 Times A Day                                   |                 | Not Reported |
|                                                         | Oramorph             |              |            | C           | Unknown          | 5mls To Be Taken Four<br>Times Daily When<br>Required |                 | Not Reported |
|                                                         | Paracetamol          |              |            | C           | Unknown          | 2 Df, Four Times/Day                                  |                 | Not Reported |
| Zopiclone                                               |                      |              | C          | Unknown     | 1 Df, Once A Day |                                                       | Not Reported    |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 23-Feb-2016              | 12105091      | EXPEDITED (15-DAY) |                    | OT              | FR-JNJFOC-<br>20160215328 |                      |            | Female     | FRA            |

| <u>Preferred Term</u>                                                                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                  | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|---------------------------------------------------------------------|-----------------|--------------|
| Exposure During<br>Pregnancy; Off Label Use;<br>Product Use In<br>Unapproved Indication | Risperdal      |              |            | S           | Oral         | One Tablet Per Day                                                  |                 | Not Reported |
|                                                                                         | Depakote       |              |            | S           | Oral         |                                                                     |                 | Not Reported |
|                                                                                         | Tercian        |              |            | S           | Oral         | Dose Strength 25 Mg<br>Frequency Half A Tablet<br>Per Day If Needed |                 | Not Reported |
|                                                                                         | Seresta        |              |            | S           | Oral         | One Tablet Per Day                                                  |                 | Not Reported |

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| Seropam                                                                         |                |                    | S                  |                 | Oral                  |                                                                       |                 | Not Reported |                |
|---------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|-----------------------|-----------------------------------------------------------------------|-----------------|--------------|----------------|
| <u>FDA Received Date</u>                                                        | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>                                                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Feb-2016                                                                     | 12105092       | EXPEDITED (15-DAY) |                    | CA, DE          | FR-JNJFOC-20160215490 |                                                                       |                 | Unknown      | FRA            |
| <u>Preferred Term</u>                                                           | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>                                                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Foetal Exposure During Pregnancy; Maternal Drugs Affecting Foetus; Spina Bifida | Risperdal      |                    |                    | S               | Transplacental        | Mother'S Dose, 1 Tablet Per Day, On Demand                            |                 | Not Reported |                |
|                                                                                 | Depakote       |                    |                    | S               | Transplacental        | Mother'S Dose 500 Mg 2 Tablets Per Day                                |                 | Not Reported |                |
|                                                                                 | Tercian        |                    |                    | S               | Transplacental        | Mother'S Dose Strength 25 Mgfrequency Half A Tablet Per Day If Needed |                 | Not Reported |                |
|                                                                                 | Seresta        |                    |                    | S               | Transplacental        | Mother'S Dose, Frequency One Tablet Per Day On Demand                 |                 | Not Reported |                |
|                                                                                 | Seropam        |                    |                    | S               | Transplacental        | Mother'S Dose,Strength 20 Mg Frequency Half A Tablet Per Day          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                        | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>                                                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Feb-2016                                                                     | 12107292       | EXPEDITED (15-DAY) |                    | DE              | CA-TEVA-637120ACC     |                                                                       | 41 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                                           | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>                                                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Arrhythmia; Death                                                               | Quetiapine     |                    |                    | S               | Unknown               | 100 Milligram Daily;                                                  |                 | Teva         |                |
|                                                                                 | Ciprallex      |                    |                    | S               | Oral                  | 20 Milligram Daily;                                                   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                        | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>                                                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Feb-2016                                                                     | 12109389       | DIRECT             |                    |                 |                       |                                                                       | 37 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                           | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>                                                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Anhedonia; Dizziness; Fatigue; Feeling                                          | Lexapro 10 Mg  |                    |                    | S               | Oral                  | 1 Pill A Day, Once Daily, Taken By Mouth                              |                 | Not Reported |                |



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Abnormal; Headache;  
Impaired Work Ability;  
Libido Decreased;  
Nausea; Night Sweats;  
Sleep Disorder; Weight  
Increased

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Feb-2016              | 12109454      | DIRECT           |                    |                 |                      |                      | 44 YR      | Female     | USA            |

| <u>Preferred Term</u>                              | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anger; Anxiety; Headache;<br>Product Quality Issue | Escitalopram 20mg Teva |              |            | S           | Oral         |                    |                 | Teva         |
|                                                    | Lunesta                |              |            | C           |              |                    |                 | Not Reported |
|                                                    | Welchol                |              |            | C           |              |                    |                 | Not Reported |
|                                                    | Omeprazole             |              |            | C           |              |                    |                 | Not Reported |
|                                                    | Amlodipine             |              |            | C           |              |                    |                 | Not Reported |
|                                                    | Motrin                 |              |            | C           |              |                    |                 | Not Reported |
|                                                    | Melatonin              |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Feb-2016              | 12109464      | DIRECT           |                    |                 |                      |                      | 33 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                               | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------|---------------------------|--------------|------------|-------------|--------------|-------------------------------------|-----------------|--------------|
| Palpitations; Paraesthesia;<br>Product Formulation<br>Issue; Withdrawal<br>Syndrome | Escitalopram 20 Mg Camber |              |            | S           | Oral         | 1 Pill Once Daily Taken By<br>Mouth |                 | Camber       |
|                                                                                     | Adderall                  |              |            | C           |              |                                     |                 | Not Reported |
|                                                                                     | Magnesium                 |              |            | C           |              |                                     |                 | Not Reported |
|                                                                                     | Escitalopram              |              |            | C           |              |                                     |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Feb-2016              | 12109488      | DIRECT           |                    | DS, OT          |                      |                      | 29 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Anxiety; Drug Ineffective;<br>Panic Attack; Product<br>Substitution Issue | Escitalopram   |              |            | S           | Oral         | 1 Pill             |                 | Accord     |
|                                                                           | Escitalopram   |              |            | S           |              |                    |                 | Camber     |

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| <u>FDA Received Date</u>                                                                                                                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
| 24-Feb-2016                                                                                                                                           | 10097131       | EXPEDITED (15-DAY) |                    | OT              | CA-FRI-1000066734         |                      | 38 YR           | Male         | CAN            |
| <u>Preferred Term</u>                                                                                                                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Impulsive Behaviour                                                                                                                       | Escitalopram   |                    |                    | S               | Oral                      | 5 Mg                 |                 | Forest       |                |
|                                                                                                                                                       | Escitalopram   |                    |                    | S               | Oral                      | 10 Mg                |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Feb-2016                                                                                                                                           | 12094795       | EXPEDITED (15-DAY) |                    | OT              | FI-FRI-1000082667         |                      |                 | Female       | FIN            |
| <u>Preferred Term</u>                                                                                                                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Haemorrhage In Pregnancy; Pregnancy                                                                                                                   | Escitalopram   |                    |                    | S               | Oral                      | 7.5 Mg               |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Feb-2016                                                                                                                                           | 12108789       | EXPEDITED (15-DAY) |                    | HO              | US-CIPLA LTD.-2016US01305 |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                                                                                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Chest Discomfort; Dizziness; Drug Interaction; Palpitations; Rhabdomyolysis | Risperidone    |                    |                    | S               | Unknown                   | 0.5 Mg, Qhs          |                 | Cipla        |                |
|                                                                                                                                                       | Risperidone    |                    |                    | S               | Unknown                   | 1 Mg, Qhs            |                 | Cipla        |                |
|                                                                                                                                                       | Escitalopram   |                    |                    | S               | Unknown                   | 10 Mg, Qd            |                 | Teva         |                |
|                                                                                                                                                       | Escitalopram   |                    |                    | S               |                           |                      |                 | Teva         |                |
|                                                                                                                                                       | Mirtazapine    |                    |                    | S               | Unknown                   | 15 Mg, Qhs           |                 | Not Reported |                |
|                                                                                                                                                       | Mirtazapine    |                    |                    | S               |                           |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Feb-2016                                                                                                                                           | 12110397       | EXPEDITED (15-DAY) |                    | LT              | FR-FRI-1000082737         |                      | 42 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Respiratory Distress;                                                                                                                 | Escitalopram   |                    |                    | S               |                           | 20 Mg                |                 | Forest       |                |

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|              |                  |   |        |              |
|--------------|------------------|---|--------|--------------|
| Sudden Death | Nebivolol        | S | 5 Mg   | Forest       |
|              | Flecaine         | S | 200 Mg | Not Reported |
|              | Atarax           | S |        | Not Reported |
|              | Paroxetine       | C |        | Not Reported |
|              | Lexomil          | C |        | Not Reported |
|              | Lexomil          | C |        | Not Reported |
|              | Mianserine       | C |        | Not Reported |
|              | Valium           | C |        | Not Reported |
|              | Subutex          | C |        | Not Reported |
|              | Suboxone         | C |        | Not Reported |
|              | Inexium          | C |        | Not Reported |
|              | Thiocolchicoside | C |        | Not Reported |
|              | Tiorfan          | C |        | Not Reported |
|              | Doliprane        | C |        | Not Reported |
|              | Ibuprofene       | C |        | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Feb-2016              | 12110398      | EXPEDITED (15-DAY) |                    | OT              | GB-FRI-1000082757    |                      | 54 YR      | Female     | GBR            |

| <u>Preferred Term</u>                                   | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------|-------------------------------|--------------|------------|-------------|--------------|-----------------------------------|-----------------|--------------|
| Drug Ineffective; Nausea;<br>Product Substitution Issue | Escitalopram                  |              |            | S           | Unknown      |                                   |                 | Forest       |
|                                                         | Cipralext Film-Coated Tablets |              |            | C           | Unknown      |                                   |                 | Not Reported |
|                                                         | Diazepam                      |              |            | C           | Unknown      | One Dosage Form As Necessary      |                 | Not Reported |
|                                                         | Dihydrocodeine                |              |            | C           | Unknown      | One Dosage Form Daily             |                 | Not Reported |
|                                                         | Lansoprazole                  |              |            | C           | Unknown      | One Dosage Form Daily             |                 | Not Reported |
|                                                         | Loperamide                    |              |            | C           | Unknown      |                                   |                 | Not Reported |
|                                                         | Metronidazole                 |              |            | C           | Unknown      | 5 MI Three Times Daily            |                 | Not Reported |
|                                                         | Oramorph                      |              |            | C           | Unknown      | 5ml As Necessary                  |                 | Not Reported |
|                                                         | Paracetamol                   |              |            | C           | Unknown      | Two Dosage Forms Four Times Daily |                 | Not Reported |
|                                                         | Zopiclone                     |              |            | C           | Unknown      | One Dosage Form Daily             |                 | Not Reported |

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| <u>FDA Received Date</u>                                                                                                                           | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|-------------------------|----------------------|-----------------|--------------|----------------|
| 24-Feb-2016                                                                                                                                        | 12110406       | EXPEDITED (15-DAY) |                    | OT              | SE-FRI-1000082759       |                      | 22 YR           | Female       | SWE            |
| <u>Preferred Term</u>                                                                                                                              | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Intentional Overdose; Lethargy; Nausea; Toxicity To Various Agents                                                                      | Escitalopram   |                    |                    | S               | Unknown                 | 100 Mg               |                 | Forest       |                |
|                                                                                                                                                    | Atarax         |                    |                    | S               | Unknown                 | 150 Mg               |                 | Not Reported |                |
|                                                                                                                                                    | Sertraline     |                    |                    | S               | Unknown                 | 1 G                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                           | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Feb-2016                                                                                                                                        | 12111283       | EXPEDITED (15-DAY) |                    | OT              | US-FRI-1000082763       |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                              | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Asthenia; Choking; Confusional State; Dysphagia; Muscle Spasms; Rib Fracture; Transient Ischaemic Attack; Tremor; Urinary Tract Infection | Lexapro        |                    |                    | S               |                         |                      |                 | Forest       |                |
|                                                                                                                                                    | Synthroid      |                    |                    | C               |                         |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                           | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Feb-2016                                                                                                                                        | 12111737       | EXPEDITED (15-DAY) |                    | OT              | US-TAKEDA-2016TUS002961 |                      | 31 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                              | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Restless Legs Syndrome; Serotonin Syndrome; Sinus Operation; Tachycardia                                                                           | Brintellix     |                    |                    | S               | Unknown                 | Unk                  |                 | Takeda       |                |
|                                                                                                                                                    | Lexapro        |                    |                    | S               | Unknown                 | 40 Mg, Unk           |                 | Not Reported |                |
|                                                                                                                                                    | Buspar         |                    |                    | S               | Unknown                 | 60 Mg, Unk           |                 | Not Reported |                |
|                                                                                                                                                    | Tramadol       |                    |                    | S               | Unknown                 | Unk                  |                 | Not Reported |                |
|                                                                                                                                                    | Requip         |                    |                    | S               | Unknown                 | Unk                  |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                          | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|---------------------------------------------------------------------------------------------------|---------------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|----------------------|----------------|
| 25-Feb-2016                                                                                       | 9240596             | EXPEDITED (15-DAY) |                    | DS              | FR-FRI-1000044444                               |                      | 48 YR           | Male                 | FRA            |
| <u>Preferred Term</u>                                                                             | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Blood Creatine<br>Phosphokinase Increased;<br>Drug Interaction; Myalgia;<br>Neuropathy Peripheral | Escitalopram        |                    |                    | S               | Oral                                            |                      |                 | Forest               |                |
|                                                                                                   | Intelence           |                    |                    | S               | Oral                                            | 400 Mg               |                 | Not Reported         |                |
|                                                                                                   | Norvir              |                    |                    | S               | Oral                                            | 200 Mg               |                 | Not Reported         |                |
|                                                                                                   | Isentress           |                    |                    | C               |                                                 | 400 Mg               |                 | Not Reported         |                |
|                                                                                                   | Prezista            |                    |                    | C               |                                                 | 1200 Mg              |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                                          | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 25-Feb-2016                                                                                       | 9880262             | EXPEDITED (15-DAY) |                    | OT              | JP-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>19068535 |                      | 36 YR           | Female               | JPN            |
| <u>Preferred Term</u>                                                                             | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Caesarean Section; Live<br>Birth; Maternal Exposure<br>During Pregnancy; Off<br>Label Use         | Abilify             |                    |                    | S               | Oral                                            | 3 Mg, Qd             |                 | Bristol Myers Squibb |                |
|                                                                                                   | Abilify             |                    |                    | S               | Oral                                            | 6 Mg, Qd             |                 | Bristol Myers Squibb |                |
|                                                                                                   | Abilify             |                    |                    | S               | Oral                                            | 9 Mg, Qd             |                 | Bristol Myers Squibb |                |
|                                                                                                   | Abilify             |                    |                    | S               | Oral                                            | 15 Mg, Qd            |                 | Bristol Myers Squibb |                |
|                                                                                                   | Abilify             |                    |                    | S               | Oral                                            | 12 Mg, Qd            |                 | Bristol Myers Squibb |                |
|                                                                                                   | Lexapro             |                    |                    | S               | Oral                                            | Tabs                 |                 | Not Reported         |                |
|                                                                                                   | Silece              |                    |                    | S               | Oral                                            | Tabs.                |                 | Not Reported         |                |
|                                                                                                   | Contomin            |                    |                    | S               | Oral                                            | 25 Mg, Bid           |                 | Not Reported         |                |
|                                                                                                   | Seroquel            |                    |                    | S               | Oral                                            | 25 Mg, Qd            |                 | Not Reported         |                |
|                                                                                                   | Cymbalta            |                    |                    | S               | Oral                                            | Capsule.             |                 | Not Reported         |                |
|                                                                                                   | Pyrethia /00033002/ |                    |                    | C               | Unknown                                         | 25 Mg, Unk           |                 | Not Reported         |                |
|                                                                                                   | Tasmolin /00079501/ |                    |                    | C               | Unknown                                         | 1 Mg, Unk            |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                                          | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 25-Feb-2016                                                                                       | 10097126            | EXPEDITED (15-DAY) |                    | OT              | CA-FRI-1000066732                               |                      | 41 YR           | Female               | CAN            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                                                                                                                                                        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                              | <u>Duration</u> | <u>Mfr</u>   |                |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|-------------------------------------------------|-----------------|--------------|----------------|
| Affect Lability; Anxiety; Crying; Dizziness; Dizziness Postural; Halo Vision; Insomnia; Muscle Spasms; Muscle Tightness; Myalgia; Panic Attack; Paraesthesia; Paraesthesia Oral; Photophobia; Sleep Disorder | Escitalopram   |                    |                    | S               | Oral                 | 10 Mg                                           |                 | Forest       |                |
|                                                                                                                                                                                                              | Cymbalta       |                    |                    | S               | Oral                 |                                                 |                 | Not Reported |                |
|                                                                                                                                                                                                              | Zomig          |                    |                    | C               |                      | Daily Dose Not Reported.                        |                 | Not Reported |                |
|                                                                                                                                                                                                              |                |                    |                    |                 |                      |                                                 |                 |              |                |
| <u>FDA Received Date</u>                                                                                                                                                                                     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Feb-2016                                                                                                                                                                                                  | 12113578       | EXPEDITED (15-DAY) |                    | OT              | GB-ACCORD-037987     |                                                 | 54 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                                                                                                                                                        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                              | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective; Nausea; Product Substitution Issue                                                                                                                                                         | Escitalopram   |                    |                    | S               |                      |                                                 |                 | Accord       |                |
|                                                                                                                                                                                                              | Cipralext      |                    |                    | C               |                      | Use As Directed                                 |                 | Not Reported |                |
|                                                                                                                                                                                                              | Diazepam       |                    |                    | C               |                      | Take One As Needed                              |                 | Not Reported |                |
|                                                                                                                                                                                                              | Dihydrocodeine |                    |                    | C               |                      | Take One Every 4-6 Hrs                          |                 | Not Reported |                |
|                                                                                                                                                                                                              | Lansoprazole   |                    |                    | C               |                      |                                                 |                 | Not Reported |                |
|                                                                                                                                                                                                              | Loperamide     |                    |                    | C               |                      | Use As Directed                                 |                 | Not Reported |                |
|                                                                                                                                                                                                              | Metronidazole  |                    |                    | C               |                      |                                                 |                 | Not Reported |                |
|                                                                                                                                                                                                              | Oramorph       |                    |                    | C               |                      | 5mls To Be Taken Four Times Daily When Required |                 | Not Reported |                |
|                                                                                                                                                                                                              | Paracetamol    |                    |                    | C               |                      |                                                 |                 | Not Reported |                |
|                                                                                                                                                                                                              | Zopiclone      |                    |                    | C               |                      | At Night                                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Feb-2016                                                                                                                                                                                                  | 12114448       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000082756    |                                                 | 67 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                                        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                              | <u>Duration</u> | <u>Mfr</u>   |                |
| Acute Kidney Injury                                                                                                                                                                                          | Escitalopram   |                    |                    | S               | Oral                 | 20 Mg                                           |                 | Forest       |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|             |   |      |            |              |
|-------------|---|------|------------|--------------|
| Enalapril   | S | Oral | 20 Mg      | Not Reported |
| Eucreas     | S | Oral | 1 Df       | Not Reported |
| Amarel      | S | Oral | 2 Mg       | Not Reported |
| Alprazolam  | S | Oral | 0.5 Mg     | Not Reported |
| Zolpidem    | S | Oral | On Evening | Not Reported |
| Trimebutine | C |      |            | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Feb-2016              | 12114577      | EXPEDITED (15-DAY) | HO                 |                 | FR-FRI-1000082791    |                      | 69 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                   | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anaemia; Drug Interaction;<br>Subcutaneous<br>Haematoma | Escitalopram           |              |            | S           | Oral         | 5 Mg               |                 | Forest       |
|                                                         | Previscan (Fluindione) |              |            | S           | Oral         | 20 Mg              |                 | Not Reported |
|                                                         | Kardegic               |              |            | S           | Oral         | 75 Mg              |                 | Not Reported |
|                                                         | Olmesartan             |              |            | C           | Unknown      | 10 Mg              |                 | Not Reported |
|                                                         | Sotalol                |              |            | C           | Unknown      | 180 Mg             |                 | Not Reported |
|                                                         | Amlodipine             |              |            | C           | Unknown      | 10 Mg              |                 | Not Reported |
|                                                         | Befizal Lp             |              |            | C           | Unknown      | 400 Mg             |                 | Not Reported |
|                                                         | Forlax                 |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                         | Lumigan                |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                         | Azarga                 |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                         | Iopidine               |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                         | Celluvisc              |              |            | C           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Feb-2016              | 12114741      | EXPEDITED (15-DAY) |                    | OT              | CH-SA-2016SA034629   |                      | 32 YR      | Female     | CHE            |

| <u>Preferred Term</u>                                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hallucination,<br>Synaesthetic;<br>Hallucination, Visual | Zolpidem       |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                          | Zolpidem       |              |            | S           | Oral         |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|              |   |      |              |
|--------------|---|------|--------------|
| Escitalopram | S | Oral | Not Reported |
| Escitalopram | S | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Feb-2016              | 12115669      | NON-EXPEDITED    |                    |                 | US-TORRENT-00001101  |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Constipation          | Escitalopram Tablets, Usp |              |            | S           |              |                    |                 | Torrent    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 25-Feb-2016              | 12116494      | EXPEDITED (15-DAY) |                    | OT              | GB-MYLANLABS-2016M1006909 |                      |            | Unknown    | GBR            |

| <u>Preferred Term</u>                                | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                      | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|---------------------------------------------------------|-----------------|--------------|
| Drug Ineffective; Nausea; Product Substitution Issue | Escitalopram         |              |            | S           |              | Unk                                                     |                 | Not Reported |
|                                                      | Ciprallex /01588501/ |              |            | C           |              | Use As Directed                                         |                 | Mylan        |
|                                                      | Diazepam             |              |            | C           |              | 1 Df, (Take One As Needed)                              |                 | Mylan        |
|                                                      | Dihydrocodeine       |              |            | C           |              | 1 Df, (Take One Every 4-6 Hrs)                          |                 | Mylan        |
|                                                      | Lansoprazole         |              |            | C           |              | 1 Df, Qd                                                |                 | Mylan        |
|                                                      | Loperamide           |              |            | C           |              | Use As Directed                                         |                 | Mylan        |
|                                                      | Metronidazole        |              |            | C           |              | 5 MI, Tid                                               |                 | Mylan        |
|                                                      | Oramorph             |              |            | C           |              | 5 MI, (5mls To Be Taken Four Times Daily When Required) |                 | Mylan        |
|                                                      | Paracetamol          |              |            | C           |              | 2 Df, Qid                                               |                 | Mylan        |
|                                                      | Zopiclone            |              |            | C           |              | 1 Df, Qd (At Night)                                     |                 | Mylan        |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Feb-2016              | 10094557      | EXPEDITED (15-DAY) |                    | OT              | CA-FRI-1000066660    |                      | 85 YR      | Female     | CAN            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|



## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                            |                              |   |      |                |              |
|----------------------------|------------------------------|---|------|----------------|--------------|
| Blood Potassium Decreased; | Escitalopram                 | S | Oral | 10mg           | Forest       |
| Gastrointestinal Disorder  | Losartan/Hydrochlorothiazide | C |      | 100/25mg Daily | Not Reported |
|                            | Nifedipine                   | C |      |                | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Feb-2016              | 10097135      | EXPEDITED (15-DAY) |                    | HO              | CA-FRI-1000066738    |                      | 29 YR      | Male       | CAN            |

| <u>Preferred Term</u>                                                              | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------|---------------------|--------------|------------|-------------|--------------|----------------------|-----------------|--------------|
| Abdominal Discomfort;                                                              | Escitalopram        |              |            | S           | Oral         | 20 Mg In The Morning |                 | Forest       |
| Dizziness; Drug Interaction;                                                       | Escitalopram        |              |            | S           | Oral         | 10 Mg                |                 | Forest       |
| Electrocardiogram Qt Interval; Loss Of Consciousness; Nausea; Presyncope; Vomiting | Pms-Methylphenidate |              |            | S           | Oral         | 20 Mg                |                 | Not Reported |
|                                                                                    | Ethanol             |              |            | S           |              |                      |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------------------------|----------------------|------------|------------|----------------|
| 26-Feb-2016              | 12118092      | EXPEDITED (15-DAY) |                    | HO              | AU-LUPIN<br>PHARMACEUTICALS<br>INC.-2016-00766 |                      | 70 YR      | Female     | AUS            |

| <u>Preferred Term</u>           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction; Hyponatraemia | Escitalopram   |              |            | S           | Unknown      | 30 Mg              |                 | Not Reported |
|                                 | Escitalopram   |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                 | Bupropion      |              |            | S           | Oral         |                    |                 | Not Reported |
|                                 | Bupropion      |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                 | Dothiepin      |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                 | Dothiepin      |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                 | Oestradiol     |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                 | Glipizide      |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                 | Metformin      |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                 | Lantus Insulin |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                 | Atorvastatin   |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                 | Quetiapine     |              |            | C           | Unknown      | At Night           |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|             |   |         |              |
|-------------|---|---------|--------------|
| Lamotrigine | C | Unknown | Not Reported |
| Aspirin     | C | Unknown | Not Reported |
| Ramipril    | C | Unknown | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------------------------------------|----------------------|------------|------------|----------------|
| 26-Feb-2016              | 12120470      | EXPEDITED (15-DAY) |                    | DE              | FR-B.I.<br>PHARMACEUTICALS,I<br>NC./RIDGEFIELD-2016-<br>BI-11 |                      | 92 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>           |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------|
| Subdural Haematoma    | Pradaxa        |              |            | S           | Oral         |                    |                 | Boehringer Ingelheim |
|                       | Seroplex       |              |            | S           | Oral         |                    |                 | Not Reported         |
|                       | Irbesartan     |              |            | C           | Unknown      |                    |                 | Not Reported         |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Feb-2016              | 12120774      | EXPEDITED (15-DAY) |                    | OT              | KR-FRI-1000082812    |                      | 82 YR      | Female     | KOR            |

| <u>Preferred Term</u>                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Delirium; Nervousness;<br>Sleep Disorder | Escitalopram   |              |            | S           | Oral         |                    |                 | Forest       |
|                                          | Clonazepam     |              |            | C           | Oral         |                    |                 | Not Reported |
|                                          | Donepezil      |              |            | C           | Oral         |                    |                 | Not Reported |
|                                          | Zolpidem       |              |            | C           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Feb-2016              | 12121183      | EXPEDITED (15-DAY) |                    | CA, OT          | DE-TEVA-636413GER    |                      | < 1 DAY    | Female     | DEU            |

| <u>Preferred Term</u>                                                                                                   | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------|-------------------|--------------|------------|-------------|----------------|----------------------|-----------------|--------------|
| Coordination Abnormal;<br>Developmental Hip<br>Dysplasia; Foetal<br>Exposure During<br>Pregnancy; Hypotonia;<br>Seizure | Escitalopram      |              |            | S           | Transplacental | 15 Milligram Daily;  |                 | Ivax         |
|                                                                                                                         | Venlafaxin Retard |              |            | C           | Transplacental | 225 Milligram Daily; |                 | Not Reported |
|                                                                                                                         | Euthyrox          |              |            | C           | Transplacental | 100 Microgram Daily; |                 | Not Reported |
|                                                                                                                         | Cyanocobalamin    |              |            | C           | Transplacental |                      |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| Folsaeure                                                                                                                                                                              |                        |                    | C                  |                 | Transplacental       |                      |                 | Not Reported |                |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| <u>FDA Received Date</u>                                                                                                                                                               | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Feb-2016                                                                                                                                                                            | 12121341               | EXPEDITED (15-DAY) |                    | OT              | US-TEVA-636955USA    |                      | 37 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                  | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bronchitis; Lower Respiratory Tract Infection; Sinusitis                                                                                                                               | Escitalopram           |                    |                    | S               | Unknown              | 20 Milligram Daily;  |                 | Ivax         |                |
|                                                                                                                                                                                        | Duloxetine             |                    |                    | S               | Unknown              |                      |                 | Teva         |                |
|                                                                                                                                                                                        | Probiotic              |                    |                    | S               | Unknown              |                      |                 | Not Reported |                |
|                                                                                                                                                                                        | Lyrica                 |                    |                    | S               | Unknown              |                      |                 | Not Reported |                |
|                                                                                                                                                                                        | Celexa                 |                    |                    | S               | Unknown              | 40 Milligram Daily;  |                 | Not Reported |                |
|                                                                                                                                                                                        | Ginger Root/Vitamin B6 |                    |                    | S               | Unknown              | 150 Milligram Daily; |                 | Not Reported |                |
|                                                                                                                                                                                        | Turmeric               |                    |                    | S               | Unknown              | 500 Milligram Daily; |                 | Not Reported |                |
|                                                                                                                                                                                        | Benadryl               |                    |                    | S               | Unknown              | 25 Milligram Daily;  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                               | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Feb-2016                                                                                                                                                                            | 12124060               | EXPEDITED (15-DAY) |                    | OT              | CA-TEVA-637991ACC    |                      | 35 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                                                                                                                                                  | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Urine Present; Chills; Condition Aggravated; Dizziness; Dyspnoea; Fatigue; Heart Rate Increased; Heart Rate Irregular; Hyperhidrosis; Loss Of Consciousness; Nausea; Photophobia | Escitalopram           |                    |                    | S               | Oral                 | 10 Milligram Daily;  |                 | Ivax         |                |
|                                                                                                                                                                                        | Dayquil                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                        | Diclofenac Sodium      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                        | Ferrous Sulphate       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                        | Misoprostol            |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                        | Multivitamine(S)       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                        | Vitamin C              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                        |                        |                    |                    |                 |                      |                      |                 |              |                |
| <u>FDA Received Date</u>                                                                                                                                                               | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Feb-2016                                                                                                                                                                            | 12124063               | EXPEDITED (15-DAY) |                    | OT              | CA-TEVA-638431ACC    |                      | 67 YR           | Male         | CAN            |
| <u>Preferred Term</u>                                                                                                                                                                  | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                               |                                         |             |      |                                      |
|---------------------------------------------------------------------------------------------------------------|-----------------------------------------|-------------|------|--------------------------------------|
| Condition Aggravated;<br>Product Substitution Issue;<br>Restlessness; Therapeutic<br>Product Effect Decreased | Escitalopram<br>Lorazepam<br>Olanzapine | S<br>C<br>C | Oral | Ivax<br>Not Reported<br>Not Reported |
|---------------------------------------------------------------------------------------------------------------|-----------------------------------------|-------------|------|--------------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Feb-2016              | 12124064      | EXPEDITED (15-DAY) |                    | LT              | CA-TEVA-638487ACC    |                      | 65 YR      | Female     | CAN            |

| <u>Preferred Term</u>                                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Condition Aggravated;<br>Depression; Suicidal<br>Ideation | Escitalopram   |              |            | S           |              |                    |                 | Ivax       |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Feb-2016              | 12124066      | EXPEDITED (15-DAY) |                    | HO, LT          | CA-TEVA-637986ACC    |                      | 55 YR      | Female     | CAN            |

| <u>Preferred Term</u>                                                                                                                                     | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|--------------|------------|-------------|--------------|---------------------|-----------------|------------|
| Burning Sensation;<br>Feeling Hot; Flushing;<br>Nausea; Paraesthesia<br>Oral; Pharyngeal Oedema;<br>Pruritus; Rash<br>Generalised; Urticaria;<br>Vomiting | Teva-Escitalopram |              |            | S           | Oral         | 10 Milligram Daily; |                 | Ivax       |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Feb-2016              | 12124173      | EXPEDITED (15-DAY) |                    | OT              | CA-TEVA-638457ACC    |                      | 55 YR      | Male       | CAN            |

| <u>Preferred Term</u>                                                                                                   | <u>Product</u>                              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u>                           |
|-------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|--------------|------------|-------------|--------------|---------------------|-----------------|--------------------------------------|
| Abdominal Discomfort;<br>Anxiety; Emotional<br>Distress; Palpitations;<br>Panic Reaction; Product<br>Substitution Issue | Teva-Escitalopram<br>Clonazepam<br>Seroquel |              |            | S<br>C<br>C | Unknown      | 25 Milligram Daily; |                 | Ivax<br>Not Reported<br>Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                    | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                       | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|--------------------|--------------------|-----------------|------------------------------------------------------------|---------------------------------------|-----------------|----------------------|----------------|
| 28-Feb-2016                                                                                                                                 | 12124174                       | EXPEDITED (15-DAY) |                    | OT              | CA-TEVA-638464ACC                                          |                                       | 69 YR           | Female               | CAN            |
| <u>Preferred Term</u>                                                                                                                       | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                               | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>           |                |
| Back Pain; Headache; Hot Flush; Lymph Node Pain; Musculoskeletal Pain; Nausea; Neck Pain; Suicidal Ideation; Tinnitus                       | Teva-Escitalopram<br>Synthroid |                    |                    | S<br>C          | Oral                                                       | 10 Milligram Daily;                   |                 | Ivax<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                    | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                       | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 29-Feb-2016                                                                                                                                 | 10097134                       | EXPEDITED (15-DAY) |                    | DE              | CA-FRI-1000066735                                          |                                       | 62 YR           | Male                 | CAN            |
| <u>Preferred Term</u>                                                                                                                       | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                               | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>           |                |
| Agitation; Anxiety; Completed Suicide; Product Use In Unapproved Indication; Tinnitus                                                       | Escitalopram                   |                    |                    | S               | Oral                                                       | 1 Df                                  |                 | Forest               |                |
| <u>FDA Received Date</u>                                                                                                                    | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                       | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 29-Feb-2016                                                                                                                                 | 12124947                       | EXPEDITED (15-DAY) |                    | CA, HO, OT      | DE-MACLEODS<br>PHARMACEUTICALS<br>US LTD-<br>MAC2014002444 |                                       |                 | Unknown              | DEU            |
| <u>Preferred Term</u>                                                                                                                       | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                               | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>           |                |
| Coordination Abnormal; Developmental Hip Dysplasia; Dyspnoea; Foetal Exposure During Pregnancy; Hypotonia; Muscle Rigidity; Seizure; Tremor | Escitalopram                   |                    |                    | S               | Transplacental                                             | 15 Mg, Qd (8 - 38.5 Gestational Week) |                 | Macleods             |                |
|                                                                                                                                             | Euthyrox                       |                    |                    | C               | Transplacental                                             | 100 Mg, Qd (0 -38.5 Gestational Week) |                 | Not Reported         |                |
|                                                                                                                                             | Venlafaxin Retard              |                    |                    | C               | Transplacental                                             | 225 Mg, Qd (0- 8 Gestational Week)    |                 | Not Reported         |                |
|                                                                                                                                             | Cyanocobalamin                 |                    |                    | C               | Transplacental                                             | Unk (0-38.5gestational Week)          |                 | Not Reported         |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                           |                |                    |                    |                 |                                            |                      |                 |                 |                |  |
|---------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|--------------------------------------------|----------------------|-----------------|-----------------|----------------|--|
| Folsaure                                                                                                                  |                |                    | C                  |                 | Transplacental                             |                      | Unk             |                 | Not Reported   |  |
| <u>FDA Received Date</u>                                                                                                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |  |
| 29-Feb-2016                                                                                                               | 12126297       | NON-EXPEDITED      |                    |                 | US-FRI-1000079270                          |                      |                 | Male            | USA            |  |
| <u>Preferred Term</u>                                                                                                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |  |
| Diarrhoea; Dizziness;<br>Drug Ineffective;<br>Intentional Product<br>Misuse; Nausea; Off Label<br>Use; Sexual Dysfunction | Viibryd        |                    |                    | S               |                                            |                      |                 | Forest          |                |  |
|                                                                                                                           | Lexapro        |                    |                    | S               |                                            |                      |                 | Forest          |                |  |
| <u>FDA Received Date</u>                                                                                                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |  |
| 29-Feb-2016                                                                                                               | 12126665       | EXPEDITED (15-DAY) |                    |                 | US-<br>GLAXOSMITHKLINE-<br>US2016GSK028175 |                      |                 | Unknown         | USA            |  |
| <u>Preferred Term</u>                                                                                                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |  |
| Chest Discomfort; Drug<br>Ineffective; Emotional<br>Disorder; Tremor                                                      | Wellbutrin     |                    |                    | S               |                                            |                      |                 | Glaxosmithkline |                |  |
|                                                                                                                           | Pristiq        |                    |                    | S               |                                            |                      |                 | Not Reported    |                |  |
|                                                                                                                           | Lexapro        |                    |                    | S               |                                            |                      |                 | Not Reported    |                |  |
| <u>FDA Received Date</u>                                                                                                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |  |
| 29-Feb-2016                                                                                                               | 12126945       | EXPEDITED (15-DAY) |                    | OT              | US-FRI-1000082886                          |                      | 31 YR           | Female          | USA            |  |
| <u>Preferred Term</u>                                                                                                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |  |
| Prescribed Overdose;<br>Restless Legs Syndrome;<br>Serotonin Syndrome;<br>Sinus Operation;<br>Tachycardia                 | Escitalopram   |                    |                    | S               | Unknown                                    | 40 Mg, Unk           |                 | Forest          |                |  |
|                                                                                                                           | Brintellix     |                    |                    | S               | Unknown                                    | Unk                  |                 | Not Reported    |                |  |
|                                                                                                                           | Buspar         |                    |                    | S               | Unknown                                    | 60 Mg, Unk           |                 | Not Reported    |                |  |
|                                                                                                                           | Tramadol       |                    |                    | S               | Unknown                                    | Unk                  |                 | Not Reported    |                |  |
|                                                                                                                           | Requip         |                    |                    | S               | Unknown                                    | Unk                  |                 | Not Reported    |                |  |
| <u>FDA Received Date</u>                                                                                                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |  |
| 29-Feb-2016                                                                                                               | 12126969       | EXPEDITED (15-DAY) |                    | HO              | PT-MYLANLABS-<br>2016M1007997              |                      |                 | Unknown         | PRT            |  |

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| <u>Preferred Term</u>                                                                                                                                          | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| Apathy; Asthenia; Confusional State; Death Of Relative; Decreased Appetite; Depression; Diet Refusal; Expired Product Administered; Gait Disturbance; Insomnia | Escitalopram 10 Mg Film-Coated Tablets |                    |                    | S               | Unknown                  | 10 Mg, Qd            |                 | Mylan        |                |
|                                                                                                                                                                | Concor                                 |                    |                    | C               |                          | Unk                  |                 | Mylan        |                |
|                                                                                                                                                                | Lorazepam                              |                    |                    | C               |                          | Unk                  |                 | Mylan        |                |
| <u>FDA Received Date</u>                                                                                                                                       | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Feb-2016                                                                                                                                                    | 12127237                               | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000082874        |                      |                 | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                                          | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; International Normalised Ratio Increased; Muscle Haemorrhage                                                                                 | Escitalopram                           |                    |                    | S               | Oral                     |                      |                 | Forest       |                |
|                                                                                                                                                                | Previscan (Fluindione)                 |                    |                    | S               | Oral                     | 15 Mg                |                 | Not Reported |                |
|                                                                                                                                                                | Amoxicillin Clavulanic Acid            |                    |                    | C               | Unknown                  |                      |                 | Not Reported |                |
|                                                                                                                                                                | Diffu K                                |                    |                    | C               | Unknown                  |                      |                 | Not Reported |                |
|                                                                                                                                                                | Fumafer                                |                    |                    | C               | Unknown                  |                      |                 | Not Reported |                |
|                                                                                                                                                                | Lasilix                                |                    |                    | C               | Unknown                  |                      |                 | Not Reported |                |
|                                                                                                                                                                | Loxapac                                |                    |                    | C               | Unknown                  |                      |                 | Not Reported |                |
|                                                                                                                                                                | Mecir                                  |                    |                    | C               | Unknown                  |                      |                 | Not Reported |                |
|                                                                                                                                                                | Movicol                                |                    |                    | C               | Unknown                  |                      |                 | Not Reported |                |
|                                                                                                                                                                | Alprazolam                             |                    |                    | C               | Unknown                  |                      |                 | Not Reported |                |
|                                                                                                                                                                | Mirtazapine                            |                    |                    | C               | Unknown                  |                      |                 | Not Reported |                |
|                                                                                                                                                                | Risperidone                            |                    |                    | C               | Unknown                  |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                       | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Feb-2016                                                                                                                                                    | 12128141                               | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-2016116979 |                      | 52 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                          | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Migraine                                                                                                                                                       | Lyrica                                 |                    |                    | S               |                          | Unk                  |                 | Pfizer       |                |

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|                  |   |     |              |
|------------------|---|-----|--------------|
| Paxil /00830802/ | S | Unk | Not Reported |
| Cymbalta         | S | Unk | Not Reported |
| Lexapro          | S | Unk | Not Reported |
| Prozac           | S | Unk | Not Reported |
| Naltrexone       | S | Unk | Not Reported |
| Savella          | S | Unk | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Feb-2016              | 12129964      | DIRECT           |                    |                 |                      |                      | 35 YR      | Female     |                |

| <u>Preferred Term</u>                                                                             | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u> |
|---------------------------------------------------------------------------------------------------|-------------------|--------------|------------|-------------|--------------|------------------------------------------|-----------------|------------|
| Dizziness; Paraesthesia;<br>Product Substitution Issue;<br>Vision Blurred; Withdrawal<br>Syndrome | Escitalopram 10mg |              |            | S           | Oral         | 1 1/2 Pills Once Daily<br>Taken By Mouth |                 | Unknown    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Feb-2016              | 12130677      | DIRECT           | Y                  | LT              |                      |                      | 45 YR      | Female     | USA            |

| <u>Preferred Term</u>                            | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------|-------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Product Substitution Issue;<br>Suicidal Ideation | Escitalopram 10mg |              |            | S           | Oral         | 1/2 Qd Oral        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Feb-2016              | 12132904      | DIRECT           |                    |                 |                      |                      | 53 YR      | Female     | USA            |

| <u>Preferred Term</u>          | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------|--------------------|--------------|------------|-------------|--------------|---------------------------------------------|-----------------|--------------|
| Muscle Twitching;<br>Myoclonus | Escitalopram 10 Mg |              |            | S           | Oral         | 10 Mg (1 Pill) Once Daily<br>Taken By Mouth |                 | Not Reported |
|                                | Red Yeast Rice     |              |            | C           |              |                                             |                 | Not Reported |
|                                | Fish Oil           |              |            | C           |              |                                             |                 | Not Reported |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                      | <u>Case #</u>    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------|------------------|--------------------|--------------------|-----------------|----------------------|-------------------------|-----------------|--------------|----------------|
| 01-Mar-2016                                                                                   | 10094552         | EXPEDITED (15-DAY) |                    | OT              | CA-FRI-1000066659    |                         |                 | Female       | CAN            |
| <u>Preferred Term</u>                                                                         | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Chills; Depressed Level Of Consciousness; Dizziness; Drug Withdrawal Syndrome; Sleep Disorder | Escitalopram     |                    |                    | S               |                      |                         |                 | Forest       |                |
|                                                                                               | Gilenya          |                    |                    | S               | Oral                 | 0.5 Mg                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                      | <u>Case #</u>    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Mar-2016                                                                                   | 10096741         | EXPEDITED (15-DAY) |                    | HO              | CA-FRI-1000066733    |                         | 54 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                                                         | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Extrapyramidal Disorder; Large Intestine Operation                                            | Escitalopram     |                    |                    | S               | Oral                 | 20mg Every Dinner       |                 | Forest       |                |
|                                                                                               | Zeldox           |                    |                    | S               | Oral                 | 5.7143 Mg               |                 | Not Reported |                |
|                                                                                               | Zeldox           |                    |                    | S               | Oral                 | 160 Mg                  |                 | Not Reported |                |
|                                                                                               | Clonazepam       |                    |                    | C               |                      | Daily Dose Not Reported |                 | Not Reported |                |
|                                                                                               | Cogentin         |                    |                    | C               |                      | Daily Dose Not Reported |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                      | <u>Case #</u>    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Mar-2016                                                                                   | 11920341         | EXPEDITED (15-DAY) |                    | HO              | JP-FRI-1000082118    |                         | < 1 DAY         | Female       | JPN            |
| <u>Preferred Term</u>                                                                         | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy                           | Lexapro          |                    |                    | S               | Transplacental       | 10 Mg                   |                 | Forest       |                |
|                                                                                               | Depas (Etizolam) |                    |                    | S               | Transplacental       | 1.5 Mg                  |                 | Not Reported |                |
|                                                                                               | Magmitt          |                    |                    | C               | Transplacental       | 1500 Mg                 |                 | Not Reported |                |
|                                                                                               | Famotidine       |                    |                    | C               | Transplacental       |                         |                 | Not Reported |                |
|                                                                                               | Ritodrine        |                    |                    | C               | Transplacental       | Unknown                 |                 | Not Reported |                |
|                                                                                               | Racol            |                    |                    | C               | Transplacental       | Unknown                 |                 | Not Reported |                |
|                                                                                               | Medicon          |                    |                    | C               | Transplacental       |                         |                 | Not Reported |                |

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| <u>FDA Received Date</u>    | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|-----------------------------|-----------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|--------------------------|-----------------|----------------------|----------------|
| 01-Mar-2016                 | 12131243                    | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2015389052                        |                          | 44 YR           | Female               | USA            |
| <u>Preferred Term</u>       | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>           |                |
| Drug Hypersensitivity       | Piperacillin And Tazobactam |                    |                    | S               |                                                 | Unk                      |                 | Unknown              |                |
|                             | Escitalopram                |                    |                    | S               |                                                 | Unk                      |                 | Not Reported         |                |
| <u>FDA Received Date</u>    | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 02-Mar-2016                 | 12138879                    | EXPEDITED (15-DAY) |                    | CA, OT          | DE-MYLANLABS-2016M1008247                       |                          |                 | Unknown              | DEU            |
| <u>Preferred Term</u>       | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>           |                |
| Coordination Abnormal;      | Escitalopram                |                    |                    | S               | Transplacental                                  | 15 Mg, Qd                |                 | Not Reported         |                |
| Developmental Hip           | Venlafaxin                  |                    |                    | C               | Transplacental                                  | 225 Mg, Qd (225 [Mg/D ]) |                 | Mylan                |                |
| Dysplasia; Foetal           | Euthyrox                    |                    |                    | C               | Transplacental                                  | 100 Mg, Qd (100 [Mg/D ]) |                 | Mylan                |                |
| Exposure During             | Cyanocobalamin              |                    |                    | C               | Transplacental                                  | Unk                      |                 | Mylan                |                |
| Pregnancy; Hypotonia;       | Folsaeure                   |                    |                    | C               | Transplacental                                  | Unk                      |                 | Mylan                |                |
| Seizure                     |                             |                    |                    |                 |                                                 |                          |                 |                      |                |
| <u>FDA Received Date</u>    | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 03-Mar-2016                 | 11915171                    | NON-EXPEDITED      |                    |                 | US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-085896 |                          |                 | Female               | USA            |
| <u>Preferred Term</u>       | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>           |                |
| Breast Feeding; Live Birth; | Abilify                     |                    |                    | S               | Unknown                                         | Unk                      |                 | Bristol Myers Squibb |                |
| Maternal Exposure During    | Lexapro                     |                    |                    | S               | Unknown                                         |                          |                 | Not Reported         |                |
| Pregnancy                   |                             |                    |                    |                 |                                                 |                          |                 |                      |                |
| <u>FDA Received Date</u>    | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 03-Mar-2016                 | 12126995                    | EXPEDITED (15-DAY) |                    | OT              | US-JNJFOC-20160217307                           |                          |                 | Female               | USA            |
| <u>Preferred Term</u>       | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>           |                |
| Bronchitis; Lower           | Benadryl                    |                    | Y                  | S               | Unknown                                         | Taking For Years         |                 | Not Reported         |                |

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|                                        |                                |   |         |                                      |              |
|----------------------------------------|--------------------------------|---|---------|--------------------------------------|--------------|
| Respiratory Tract Infection; Sinusitis | Lyrica                         | S | Unknown | Started Taking 4 Months Ago.         | Not Reported |
|                                        | Duloxetine                     | S | Unknown | Started Taking 4 Months Ago.         | Not Reported |
|                                        | Celexa                         | S | Unknown | Started Taking 3 Weeks Ago.          | Not Reported |
|                                        | Escitalopram                   | S | Unknown |                                      | Not Reported |
|                                        | Ginger                         | S | Unknown | Started Taking 3 Months Ago.         | Not Reported |
|                                        | Turmeric                       | S | Unknown | Started Taking 3 Months Ago.         | Not Reported |
|                                        | Probiotics Nos                 | S | Unknown | Started Taking About Two Months Ago. | Not Reported |
|                                        | All Other Therapeutic Products | C | Unknown |                                      | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 03-Mar-2016              | 12142036      | EXPEDITED (15-DAY) | HO                 |                 | CH-ASTRAZENECA-2016SE19681 |                      | 94 YR      | Female     | CHE            |

| <u>Preferred Term</u>                                                                                                                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>             | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------------------|--------------------|-----------------|--------------|
| Acute Kidney Injury;<br>Cardiac Failure Acute;<br>Cholestatic Liver Injury;<br>Escherichia Sepsis;<br>Pancreatitis; Respiratory Failure | Nexium         |              |            | S           | Oral                     |                    |                 | Not Reported |
|                                                                                                                                         | Beloc-Zok      |              |            | S           | Oral                     |                    |                 | Not Reported |
|                                                                                                                                         | Ceftriaxon     |              |            | S           | Intravenous bolus        |                    |                 | Not Reported |
|                                                                                                                                         | Lasix          |              |            | S           | Intravenous bolus        |                    |                 | Not Reported |
|                                                                                                                                         | Amlodipin      |              |            | S           | Oral                     |                    |                 | Not Reported |
|                                                                                                                                         | Escitalopram   |              |            | S           | Oral                     |                    |                 | Not Reported |
|                                                                                                                                         | Metronidazole  |              |            | S           | Intravenous bolus        |                    |                 | Not Reported |
|                                                                                                                                         | Calciparine    |              |            | S           | Subcutaneous             |                    |                 | Not Reported |
|                                                                                                                                         | Propycil       |              |            | S           | Oral                     |                    |                 | Not Reported |
|                                                                                                                                         | Ipramol        |              |            | C           | Respiratory (inhalation) |                    |                 | Not Reported |

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| <u>FDA Received Date</u>                                                                                                         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|-------------------------------------|----------------------|-----------------|--------------|----------------|
| 03-Mar-2016                                                                                                                      | 12142050       | EXPEDITED (15-DAY) |                    | OT              | US-FRI-1000082888                   |                      |                 | Male         | USA            |
| <u>Preferred Term</u>                                                                                                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Failure<br>Congestive; Intentional<br>Product Misuse;<br>Intentional Product<br>Misuse; Pneumonia;<br>Serotonin Syndrome | Viibryd        |                    |                    | S               | Oral                                |                      |                 | Forest       |                |
|                                                                                                                                  | Lexapro        |                    |                    | S               | Oral                                |                      |                 | Forest       |                |
|                                                                                                                                  | Tramadol       |                    |                    | S               | Oral                                |                      |                 | Not Reported |                |
|                                                                                                                                  |                |                    |                    |                 |                                     |                      |                 |              |                |
| <u>FDA Received Date</u>                                                                                                         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Mar-2016                                                                                                                      | 12142769       | EXPEDITED (15-DAY) |                    | HO, OT          | ES-FRI-1000082915                   |                      |                 | Male         | ESP            |
| <u>Preferred Term</u>                                                                                                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Disorientation; Drug<br>Interaction; Psychomotor<br>Hyperactivity; Toxicity To<br>Various Agents                                 | Escitalopram   |                    |                    | S               | Unknown                             | 20mg                 |                 | Forest       |                |
|                                                                                                                                  | Vemurafenib    |                    |                    | S               | Unknown                             | 1920mg               |                 | Not Reported |                |
|                                                                                                                                  | Cobimetinib    |                    |                    | S               | Oral                                | 60mg                 |                 | Not Reported |                |
|                                                                                                                                  | Cobimetinib    |                    |                    | S               | Oral                                |                      |                 | Not Reported |                |
|                                                                                                                                  | Pristiq        |                    |                    | S               | Unknown                             | 50mg                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Mar-2016                                                                                                                      | 12153256       | EXPEDITED (15-DAY) |                    | CA, OT          | DE-AUROBINDO-AUR-<br>APL-2016-02032 |                      |                 | Female       | DEU            |
| <u>Preferred Term</u>                                                                                                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Coordination Abnormal;<br>Developmental Hip<br>Dysplasia; Foetal<br>Exposure During<br>Pregnancy; Hypotonia;<br>Seizure          | Escitalopram   |                    |                    | S               | Transplacental                      | 15 Mg, Daily         |                 | Aurobindo    |                |
|                                                                                                                                  | Venlafaxine    |                    |                    | C               | Transplacental                      | 225 Mg, Daily        |                 | Not Reported |                |
|                                                                                                                                  | Euthyrox       |                    |                    | C               | Transplacental                      | 100 Mcg, Daily       |                 | Not Reported |                |
|                                                                                                                                  | Cyanocobalamin |                    |                    | C               | Transplacental                      | Unk                  |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                                                          | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|-----------------|--------------|----------------|
| 06-Mar-2016                                                                                                       | 12153260       | EXPEDITED (15-DAY) |                    | OT              | DE-AUROBINDO-AUR-APL-2016-02033 |                      | 29 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                                                                             | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Exposure During Pregnancy; Haemorrhoids Thrombosed                                                                | Escitalopram   |                    |                    | S               | Oral                            | 15 Mg, Daily         |                 | Aurobindo    |                |
|                                                                                                                   | Venlafaxine    |                    |                    | C               | Oral                            | 225 Mg, Daily        |                 | Not Reported |                |
|                                                                                                                   | Euthyrox       |                    |                    | C               | Oral                            | 100 Mcg, Daily       |                 | Not Reported |                |
|                                                                                                                   | Cyanocobalamin |                    |                    | C               | Oral                            | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                          | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Mar-2016                                                                                                       | 12153315       | EXPEDITED (15-DAY) |                    | DE, OT          | US-AUROBINDO-AUR-APL-2016-02095 |                      | 26 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                             | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Drug Abuse; Respiratory Arrest                                                                    | Escitalopram   |                    |                    | S               | Unknown                         |                      |                 | Aurobindo    |                |
|                                                                                                                   | Oxycodone      |                    |                    | S               | Unknown                         |                      |                 | Aurobindo    |                |
|                                                                                                                   | Ethanol        |                    |                    | S               | Unknown                         |                      |                 | Not Reported |                |
|                                                                                                                   | Methocarbamol  |                    |                    | S               | Unknown                         |                      |                 | Not Reported |                |
|                                                                                                                   | Lorazepam      |                    |                    | S               | Unknown                         |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                          | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Mar-2016                                                                                                       | 11885634       | EXPEDITED (15-DAY) |                    | HO              | US-APOTEX-2015AP011284          |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                             | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Adverse Drug Reaction; Aggression; Condition Aggravated; Drug Ineffective; Product Complaint; Psychiatric Symptom | Paxil Tablets  |                    |                    | S               | Unknown                         |                      |                 | Apotex       |                |
|                                                                                                                   | Lexapro        |                    |                    | S               | Unknown                         | Unk                  |                 | Not Reported |                |
|                                                                                                                   | Serzone        |                    |                    | S               | Unknown                         | Unk                  |                 | Not Reported |                |
|                                                                                                                   | Lorazepam      |                    |                    | C               | Unknown                         | Unk                  |                 | Not Reported |                |
|                                                                                                                   | Pristiq        |                    |                    | C               | Unknown                         | Unk                  |                 | Not Reported |                |

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| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 07-Mar-2016              | 12041724      | EXPEDITED (15-DAY) |                    | OT              | US-JNJFOC-20160105241 |                      | 8 YR       | Male       | USA            |

| <u>Preferred Term</u>                                                  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|-------------------------------------|-----------------|--------------|
| Emotional Distress;<br>Gynaecomastia;<br>Hyperinsulinaemia;<br>Obesity | Risperdal      |              |            | S           | Oral         |                                     |                 | Not Reported |
|                                                                        | Risperdal      |              |            | S           | Oral         | In Varying Doses Of 0.5 Mg And 1 Mg |                 | Not Reported |
|                                                                        | Risperdal      |              |            | S           | Oral         |                                     |                 | Not Reported |
|                                                                        | Risperdal      |              |            | S           | Oral         | In Varying Doses Of 0.5 Mg And 1 Mg |                 | Not Reported |
|                                                                        | Risperdal      |              |            | S           | Oral         |                                     |                 | Not Reported |
|                                                                        | Risperdal      |              |            | S           | Oral         | In Varying Doses Of 0.5 Mg And 1 Mg |                 | Not Reported |
|                                                                        | Risperdal      |              |            | S           | Oral         | In Varying Doses Of 0.5 Mg And 1 Mg |                 | Not Reported |
|                                                                        | Risperdal      |              |            | S           | Oral         |                                     |                 | Not Reported |
|                                                                        | Zoloft         |              |            | S           | Unknown      |                                     |                 | Not Reported |
|                                                                        | Zoloft         |              |            | S           | Unknown      |                                     |                 | Not Reported |
|                                                                        | Lexapro        |              |            | S           | Unknown      |                                     |                 | Not Reported |
|                                                                        | Lexapro        |              |            | S           | Unknown      |                                     |                 | Not Reported |
|                                                                        | Focalin        |              |            | S           | Unknown      |                                     |                 | Not Reported |
|                                                                        | Focalin        |              |            | S           | Unknown      |                                     |                 | Not Reported |
|                                                                        | Sertraline     |              |            | C           |              |                                     |                 | Not Reported |
|                                                                        | Abilify        |              |            | C           | Unknown      |                                     |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|------------|------------|----------------|
| 07-Mar-2016              | 12154311      | EXPEDITED (15-DAY) |                    | DE, OT          | US-AUROBINDO-AUR-APL-2016-02690 |                      | 48 YR      | Female     | USA            |

| <u>Preferred Term</u>                        | <u>Product</u>  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|----------------------------------------------|-----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Cardiac Arrest; Death;<br>Respiratory Arrest | Cyclobenzaprine |              |            | S           | Unknown      |                    |                 | Aurobindo  |

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|                       |   |         |              |
|-----------------------|---|---------|--------------|
| Escitalopram          | S | Unknown | Aurobindo    |
| Lisinopril            | S | Unknown | Aurobindo    |
| Metoprolol            | S | Unknown | Aurobindo    |
| Oxycodone             | S | Unknown | Aurobindo    |
| Cephalexin /00145501/ | S | Unknown | Not Reported |
| Clonidine             | S | Unknown | Not Reported |
| Nitroglycerin         | S | Unknown | Not Reported |
| Ibuprofen             | S | Unknown | Not Reported |
| Diclofenac            | S | Unknown | Not Reported |
| Azithromycin          | S | Unknown | Not Reported |
| Doxycycline           | S | Unknown | Not Reported |
| Methylprednisolone    | S | Unknown | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------|----------------------|------------|------------|----------------|
| 07-Mar-2016              | 12154351      | EXPEDITED (15-DAY) |                    | DE, HO          | US-AUROBINDO-AUR-<br>APL-2016-02737 |                      | 37 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Escitalopram   |              |            | S           | Oral         |                    |                 | Aurobindo    |
|                       | Meloxicam      |              |            | S           | Oral         |                    |                 | Aurobindo    |
|                       | Loperamide     |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 07-Mar-2016              | 12156306      | EXPEDITED (15-DAY) |                    | HO, OT          | US-APOTEX-<br>2016AP005594 |                      | 15 YR      | Female     | USA            |

| <u>Preferred Term</u>                            | <u>Product</u>               | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--------------------------------------------------|------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Blood Prolactin Increased;                       | Fluoxetine Oral Solution Usp |              |            | S           | Unknown      | 10 Mg, Unknown     |                 | Apotex     |
| Blunted Affect; Drug                             | Escitalopram Oxalate         |              |            | S           | Unknown      | Unk Unk, Unknown   |                 | Apotex     |
| Ineffective;                                     | Aripiprazole Tablets         |              |            | S           | Unknown      | 2 Mg, Unknown      |                 | Apotex     |
| Gastrointestinal Disorder;                       | Aripiprazole Tablets         |              |            | S           | Unknown      | 5 Mg, Unk          |                 | Apotex     |
| Homicidal Ideation;                              | Risperidone                  |              |            | S           | Unknown      | 0.5 Mg, Bid        |                 | Apotex     |
| Intentional Overdose; Pre-<br>Existing Condition |                              |              |            |             |              |                    |                 |            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                             |             |   |         |              |              |
|-----------------------------|-------------|---|---------|--------------|--------------|
| Improved; Suicidal Ideation | Lamotrigine | S | Unknown | 25mg Daily   | Apotex       |
|                             | Paracetamol | C | Unknown | Unk, Unknown | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Mar-2016              | 12158143      | DIRECT           |                    | HO, OT          |                      |                      | 17 YR      | Male       | USA            |

| <u>Preferred Term</u>                                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Depression; Drug Ineffective; Paraesthesia; Suicidal Ideation | Lexapro        |              |            | S           | Oral         |                    | 3 MTH           | Lundbeck   |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Mar-2016              | 11421202      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000079090    |                      | 44 YR      | Female     | FRA            |

| <u>Preferred Term</u>        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Behaviour Disorder; Delirium | Escitalopram   |              |            | S           | Oral         | 5 Mg               |                 | Forest       |
|                              | Tecfidera      |              |            | S           | Oral         | 480 Mg             |                 | Not Reported |
|                              | Bromazepam     |              |            | S           | Oral         | 0.5 Dosage Forms   |                 | Not Reported |
|                              | Kardegic       |              |            | C           | Unknown      | 160 Mg             |                 | Not Reported |
|                              | Levothyrox     |              |            | C           | Unknown      | 75 Microgram       |                 | Not Reported |
|                              | Tardyferon     |              |            | C           | Unknown      | 80 Mg              |                 | Not Reported |
|                              | Avlocardyl     |              |            | C           | Unknown      | 40 Mg              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Mar-2016              | 12142429      | EXPEDITED (15-DAY) |                    | CA, OT          | DE-FRI-1000082865    |                      |            | Female     | DEU            |

| <u>Preferred Term</u>                                                                                    | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------|-------------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Coordination Abnormal; Developmental Hip Dysplasia; Foetal Exposure During Pregnancy; Hypotonia; Seizure | Escitalopram      |              |            | S           | Transplacental | 15 Mg              |                 | Forest       |
|                                                                                                          | Venlafaxin Retard |              |            | C           | Transplacental | 225 Mg             |                 | Not Reported |
|                                                                                                          | Euthyrox          |              |            | C           | Transplacental | 100 Mcg            |                 | Not Reported |
|                                                                                                          | Cyanocobalamin    |              |            | C           | Transplacental |                    |                 | Not Reported |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                |                 |                    |                    |                 |                                                |                      |                 |            |                |  |
|----------------------------------------------------------------|-----------------|--------------------|--------------------|-----------------|------------------------------------------------|----------------------|-----------------|------------|----------------|--|
| Folic Acid                                                     |                 |                    | C                  |                 |                                                | Transplacental       |                 |            | Not Reported   |  |
| <u>FDA Received Date</u>                                       | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |  |
| 08-Mar-2016                                                    | 12157381        | EXPEDITED (15-DAY) |                    | OT              | US-LUPIN<br>PHARMACEUTICALS<br>INC.-2016-00917 |                      |                 | Female     | USA            |  |
| <u>Preferred Term</u>                                          | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |  |
| Bronchitis; Lower<br>Respiratory Tract<br>Infection; Sinusitis | Duloxetine      |                    |                    | S               | Unknown                                        |                      |                 |            | Not Reported   |  |
|                                                                | Escitalopram    |                    |                    | S               | Unknown                                        |                      |                 |            | Not Reported   |  |
|                                                                | Lyrica          |                    |                    | S               | Unknown                                        |                      |                 |            | Not Reported   |  |
|                                                                | Celexa          |                    |                    | S               | Unknown                                        |                      |                 |            | Not Reported   |  |
|                                                                | Turmeric        |                    |                    | S               | Unknown                                        |                      |                 |            | Not Reported   |  |
|                                                                | Benadryl        |                    |                    | S               | Unknown                                        |                      |                 |            | Not Reported   |  |
| <u>FDA Received Date</u>                                       | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |  |
| 08-Mar-2016                                                    | 12157434        | EXPEDITED (15-DAY) |                    | DE              | US-AUROBINDO-AUR-<br>APL-2016-02717            |                      | 32 YR           | Male       | USA            |  |
| <u>Preferred Term</u>                                          | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |  |
| Completed Suicide                                              | Escitalopram    |                    |                    | S               | Oral                                           |                      |                 |            | Aurobindo      |  |
|                                                                | Carbon Monoxide |                    |                    | S               | Oral                                           |                      |                 |            | Not Reported   |  |
|                                                                | Ethanol         |                    |                    | S               | Oral                                           |                      |                 |            | Not Reported   |  |
|                                                                | Methamphetamine |                    |                    | S               | Oral                                           |                      |                 |            | Not Reported   |  |
|                                                                | Zolpidem        |                    |                    | S               | Oral                                           |                      |                 |            | Not Reported   |  |
| <u>FDA Received Date</u>                                       | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |  |
| 08-Mar-2016                                                    | 12159586        | EXPEDITED (15-DAY) |                    | OT              | CA-FRI-1000082962                              |                      |                 | Female     | CAN            |  |
| <u>Preferred Term</u>                                          | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |  |
| Negative Thoughts;<br>Suicide Attempt                          | Escitalopram    |                    |                    | S               | Oral                                           |                      |                 |            | Forest         |  |
|                                                                | Escitalopram    |                    |                    | S               | Oral                                           |                      |                 |            | Forest         |  |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 08-Mar-2016                                                    | 12160995       | EXPEDITED (15-DAY) |                    | DE              | FR-FRI-1000083022    |                      | 92 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Product Use In<br>Unapproved Indication;<br>Subdural Haematoma | Escitalopram   |                    |                    | S               | Oral                 |                      |                 | Forest       |                |
|                                                                | Pradaxa        |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                | Irbesartan     |                    |                    | C               | Unknown              |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                   | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------|---------------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|----------------------|----------------|
| 09-Mar-2016                                                                                                | 9880259             | EXPEDITED (15-DAY) |                    | HO, OT          | JP-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>20161428 |                      | < 1 DAY         | Male                 | JPN            |
| <u>Preferred Term</u>                                                                                      | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Foetal Distress Syndrome;<br>Foetal Exposure During<br>Pregnancy; Neonatal<br>Asphyxia; Tremor<br>Neonatal | Abilify             |                    |                    | S               | Transplacental                                  | 3 Mg, Qd             |                 | Bristol Myers Squibb |                |
|                                                                                                            | Abilify             |                    |                    | S               | Transplacental                                  | 6 Mg, Qd             |                 | Bristol Myers Squibb |                |
|                                                                                                            | Abilify             |                    |                    | S               | Transplacental                                  | 9 Mg, Qd             |                 | Bristol Myers Squibb |                |
|                                                                                                            | Abilify             |                    |                    | S               | Transplacental                                  | 15 Mg, Qd            |                 | Bristol Myers Squibb |                |
|                                                                                                            | Abilify             |                    |                    | S               | Transplacental                                  | 12 Mg, Qd            |                 | Bristol Myers Squibb |                |
|                                                                                                            | Lexapro             |                    |                    | S               | Transplacental                                  | 10 Mg, Bid           |                 | Not Reported         |                |
|                                                                                                            | Silece              |                    |                    | S               | Transplacental                                  | Tabs                 |                 | Not Reported         |                |
|                                                                                                            | Contomin            |                    |                    | S               | Transplacental                                  | 25 Mg, Bid           |                 | Not Reported         |                |
|                                                                                                            | Seroquel            |                    |                    | S               | Transplacental                                  | 25 Mg, Qd            |                 | Not Reported         |                |
|                                                                                                            | Cymbalta            |                    |                    | S               | Transplacental                                  | Caps                 |                 | Not Reported         |                |
|                                                                                                            | Pyrethia /00033002/ |                    |                    | C               | Transplacental                                  | 25 Mg, Unk           |                 | Not Reported         |                |
|                                                                                                            | Tasmolin /00079501/ |                    |                    | C               | Transplacental                                  | 1 Mg, Unk            |                 | Not Reported         |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|--------------------------------|----------------------|-----------------|------------|----------------|
| 09-Mar-2016              | 12165417       | NON-EXPEDITED    |                    |                 | US-009507513-<br>1602USA011844 |                      | 74 YR           | Male       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|               |                          |   |      |                   |              |
|---------------|--------------------------|---|------|-------------------|--------------|
| Gynaecomastia | Proscar                  | S | Oral | 5 Mg, Unk         | Merck        |
|               | Lexapro                  | S | Oral | 5 Mg, Qd          | Not Reported |
|               | Lexapro                  | S | Oral | 10 Mg, Qd         | Not Reported |
|               | Lexapro                  | S | Oral | 5 Mg, Qd          | Not Reported |
|               | Spironolactone           | S | Oral | 25 Mg, Qd         | Not Reported |
|               | Cholecalciferol          | C |      |                   | Not Reported |
|               | Lisinopril               | C |      | 2.5 Mg, Q12h      | Merck        |
|               | Imdur                    | C | Oral | 30 Mg, Qd         | Merck        |
|               | Lasix (Furosemide)       | C | Oral | 20 Mg, Qid        | Not Reported |
|               | Metoprolol               | C | Oral | 100 Mg, Qd        | Not Reported |
|               | Digoxin                  | C | Oral | 125 Microgram, Qd | Not Reported |
|               | Loratadine               | C | Oral | 10 Mg, Unk        | Merck        |
|               | Vytorin                  | C | Oral | 20 Mg, Qd         | Merck        |
|               | Tamsulosin Hydrochloride | C | Oral | 0.4 Mg, Qd        | Not Reported |

| <u>FDA Received Date</u>                                                  | <u>Case #</u>                                                                                 | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------|------------------|--------------------|-----------------|----------------------|-----------------------------|-----------------|--------------|----------------|
| 09-Mar-2016                                                               | 12167043                                                                                      | DIRECT           |                    | DE              |                      |                             | 23 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                     | <u>Product</u>                                                                                | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Partner Stress; Prescribed Overdose; Thinking Abnormal | Escitalopram (Generic For Lexapro) 1st Prescription 10mg. 7/15/15 Doubled To 20 Mg. 8/25/15 . |                  |                    | S               | Oral                 | 10mg 7/10/15 15mg 8/25/2015 |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|-------------------|--------------------|--------------------|-----------------|----------------------|------------------------------------|-----------------|------------|----------------|
| 10-Mar-2016              | 11118739          | EXPEDITED (15-DAY) |                    | OT              | IE-TEVA-563141ISR    |                                    | 38 YR           | Female     | IRL            |
| <u>Preferred Term</u>    | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u> |                |
| Galactorrhoea            | Escitalopram Teva |                    |                    | S               | Oral                 | Increased From 5mg Daily Initially |                 | Ivax       |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                | <u>503B Facility</u>                      | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|--------------------|--------------------|-----------------|-----------------------------------------------------|-------------------------------------------|-----------------|-----------------|----------------|
| 10-Mar-2016                                                                                                                                                                                             | 12167540                                  | EXPEDITED (15-DAY) |                    |                 | US-<br>GLAXOSMITHKLINE-<br>US2016GSK032154          |                                           | 24 YR           | Male            | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                   | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                        | <u>Dosage Text</u>                        | <u>Duration</u> | <u>Mfr</u>      |                |
| Condition Aggravated;<br>Disturbance In Sexual<br>Arousal; Ejaculation<br>Disorder; Erectile<br>Dysfunction; Erection<br>Increased; Loss Of Libido;<br>Prescription Drug Used<br>Without A Prescription | Lamictal Tablet                           |                    |                    | S               | Oral                                                | Two 200 Mg Tablets Once<br>Daily By Mouth |                 | Glaxosmithkline |                |
|                                                                                                                                                                                                         | Viagra                                    |                    |                    | S               | Oral                                                | 1 Tablet Once By Mouth<br>At Night        |                 | Not Reported    |                |
|                                                                                                                                                                                                         | Viagra                                    |                    |                    | S               |                                                     |                                           |                 | Not Reported    |                |
|                                                                                                                                                                                                         | Latuda                                    |                    |                    | S               | Oral                                                | 120 Mg Tablet 1d Orally                   |                 | Not Reported    |                |
|                                                                                                                                                                                                         | Risperdal                                 |                    |                    | S               | Oral                                                | 0.5 Mg, 1d Orally                         |                 | Not Reported    |                |
|                                                                                                                                                                                                         | Lithium                                   |                    |                    | S               | Oral                                                | 30 Mg, 1d                                 |                 | Not Reported    |                |
|                                                                                                                                                                                                         | Lithium                                   |                    |                    | S               |                                                     |                                           |                 | Not Reported    |                |
|                                                                                                                                                                                                         | Lexapro                                   |                    |                    | S               |                                                     | 40 Mg 1d At Night                         |                 | Not Reported    |                |
|                                                                                                                                                                                                         | Nicotine                                  |                    |                    | S               |                                                     | 1 Pack Per Day Of E-<br>Cigarettes        |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                                                                                                | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                | <u>503B Facility</u>                      | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 10-Mar-2016                                                                                                                                                                                             | 12168575                                  | NON-EXPEDITED      |                    |                 | US-ROXANE<br>LABORATORIES, INC.-<br>2016-RO-00496RO |                                           |                 | Male            | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                   | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                        | <u>Dosage Text</u>                        | <u>Duration</u> | <u>Mfr</u>      |                |
| Erectile Dysfunction; Loss<br>Of Libido                                                                                                                                                                 | Lithium Carbonate Capsules<br>Usp, 150 Mg |                    |                    | S               | Oral                                                | 30 Mg                                     |                 | Roxane          |                |
|                                                                                                                                                                                                         | Lithium Carbonate Capsules<br>Usp, 150 Mg |                    |                    | S               |                                                     |                                           |                 | Roxane          |                |
|                                                                                                                                                                                                         | Lamictal                                  |                    |                    | S               | Oral                                                | 400 Mg                                    |                 | Not Reported    |                |
|                                                                                                                                                                                                         | Latuda                                    |                    |                    | S               | Oral                                                | 120 Mg                                    |                 | Not Reported    |                |
|                                                                                                                                                                                                         | Risperdal                                 |                    |                    | S               | Oral                                                | 0.5 Mg                                    |                 | Not Reported    |                |
|                                                                                                                                                                                                         | Lexapro                                   |                    |                    | S               | Unknown                                             | 40 Mg                                     |                 | Not Reported    |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                                                                                  | <u>Case #</u>                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 10-Mar-2016                                                                                                                                                                                                                                                               | 12168793                                    | EXPEDITED (15-DAY) |                    | CA, OT          | CH-SA-2016SA043387   |                      |                 | Male         | CHE            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                     | <u>Product</u>                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Congenital Ureteric Anomaly; Exposure During Pregnancy                                                                                                                                                                                                                    | Cipralext                                   |                    |                    | S               | Transplacental       |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                           | Tranxilium                                  |                    |                    | S               | Transplacental       |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                           | Zolpidem                                    |                    |                    | S               | Transplacental       |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                  | <u>Case #</u>                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Mar-2016                                                                                                                                                                                                                                                               | 12169014                                    | EXPEDITED (15-DAY) |                    | HO, OT          | US-FRI-1000083118    |                      | 32 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                     | <u>Product</u>                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety Disorder; Asthenia; Asthenia; Chest Pain; Diarrhoea; Ecg Signs Of Myocardial Ischaemia; Electrocardiogram Abnormal; Fatigue; Fear; Gastrointestinal Disorder; Limb Discomfort; Muscle Spasms; Nausea; Paraesthesia; Unevaluable Event; Vomiting; Weight Decreased | Lexapro                                     |                    |                    | S               | Oral                 | 20mg                 |                 | Forest       |                |
|                                                                                                                                                                                                                                                                           | Lexapro                                     |                    |                    | S               | Oral                 | 10mg                 |                 | Forest       |                |
|                                                                                                                                                                                                                                                                           | Lexapro                                     |                    |                    | S               | Oral                 | 5mg                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                           | Lexapro                                     |                    |                    | S               |                      | One Dose             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                  | <u>Case #</u>                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Mar-2016                                                                                                                                                                                                                                                               | 12170991                                    | DIRECT             |                    |                 |                      |                      | 36 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                     | <u>Product</u>                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Decreased Activity; Depression; Dizziness; Drug Dependence; Nausea; Withdrawal                                                                                                                                                                                            | Lexapro 20mg - Generic                      |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                           | Celexa 20mg Forest Laboratories/ Meijer#205 |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                           | Apap                                        |                    |                    | C               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                        |                |                    |                    |                 |                                     |                      |                 |              |                |
|----------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|-------------------------------------|----------------------|-----------------|--------------|----------------|
| Syndrome                                                                               | Cetirizine     |                    | C                  |                 | Not Reported                        |                      |                 |              |                |
| <u>FDA Received Date</u>                                                               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Mar-2016                                                                            | 12170917       | EXPEDITED (15-DAY) |                    | DE, HO          | US-AUROBINDO-AUR-<br>APL-2016-02416 |                      | 62 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                                                      | Lamotrigine    |                    |                    | S               | Oral                                |                      |                 | Aurobindo    |                |
|                                                                                        | Escitalopram   |                    |                    | S               | Oral                                |                      |                 | Aurobindo    |                |
|                                                                                        | Benzatropine   |                    |                    | S               | Oral                                |                      |                 | Not Reported |                |
|                                                                                        | Lorazepam      |                    |                    | S               | Oral                                |                      |                 | Not Reported |                |
|                                                                                        | Primidone      |                    |                    | S               | Oral                                |                      |                 | Not Reported |                |
|                                                                                        | Temazepam      |                    |                    | S               | Oral                                |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Mar-2016                                                                            | 12171612       | EXPEDITED (15-DAY) |                    | OT              | AU-EDGEMONT-<br>2016EDG00007        |                      | 70 YR           | Female       | AUS            |
| <u>Preferred Term</u>                                                                  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;<br>Hyponatraemia;<br>Inappropriate Antidiuretic<br>Hormone Secretion | Bupropion      |                    |                    | S               | Oral                                | 75 Mg, "Po Mane"     |                 | Edgemont     |                |
|                                                                                        | Dothiepin      |                    |                    | S               | Unknown                             | Unk                  |                 | Not Reported |                |
|                                                                                        | Dothiepin      |                    |                    | S               | Unknown                             | 225 Mg, Unk          |                 | Not Reported |                |
|                                                                                        | Dothiepin      |                    |                    | S               | Unknown                             | 175 Mg, Unk          |                 | Not Reported |                |
|                                                                                        | Escitalopram   |                    |                    | S               | Unknown                             | 30 Mg, 1x/Day        |                 | Not Reported |                |
|                                                                                        | Ramipril       |                    |                    | S               | Unknown                             |                      |                 | Not Reported |                |
|                                                                                        | Quetiapine     |                    |                    | C               | Unknown                             | 400 Mg, At Night     |                 | Not Reported |                |
|                                                                                        | Lamotrigine    |                    |                    | C               | Unknown                             | 75 Mg, 2x/Day        |                 | Not Reported |                |
|                                                                                        | Estradiol      |                    |                    | C               |                                     |                      |                 | Not Reported |                |
|                                                                                        | Glipizide      |                    |                    | C               |                                     |                      |                 | Not Reported |                |
|                                                                                        | Metformin      |                    |                    | C               |                                     |                      |                 | Not Reported |                |
|                                                                                        | Lantus         |                    |                    | C               |                                     |                      |                 | Not Reported |                |
|                                                                                        | Atorvastatin   |                    |                    | C               |                                     |                      |                 | Not Reported |                |
|                                                                                        | Aspirin        |                    |                    | C               |                                     |                      |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                               | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                               | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                 | <u>Country</u> |
|----------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------------------------------------|----------------------|-----------------|----------------------------|----------------|
| 11-Mar-2016                                                                            | 12173174                | EXPEDITED (15-DAY) |                    | OT              | AU-PRINSTON<br>PHARMACEUTICAL<br>INC.-2016PRN00038 |                      | 70 YR           | Female                     | AUS            |
| <u>Preferred Term</u>                                                                  | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                       | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                 |                |
| Drug Interaction;<br>Hyponatraemia;<br>Inappropriate Antidiuretic<br>Hormone Secretion | Bupropion Hydrochloride |                    |                    | S               | Oral                                               | 75 Mg, "Po Mane"     |                 | Prinston<br>Pharmaceutical |                |
|                                                                                        | Escitalopram            |                    |                    | S               | Unknown                                            | 30 Mg, 1x/Day        |                 | Prinston<br>Pharmaceutical |                |
|                                                                                        | Dothiepin               |                    |                    | S               | Unknown                                            |                      |                 | Not Reported               |                |
|                                                                                        | Dothiepin               |                    |                    | S               | Unknown                                            | 225 Mg, Unk          |                 | Not Reported               |                |
|                                                                                        | Dothiepin               |                    |                    | S               | Unknown                                            | 175 Mg, Unk          |                 | Not Reported               |                |
|                                                                                        | Ramipril                |                    |                    | S               | Unknown                                            |                      |                 | Not Reported               |                |
|                                                                                        | Quetiapine              |                    |                    | C               |                                                    | 400 Mg, At Night     |                 | Not Reported               |                |
|                                                                                        | Lamotrigine             |                    |                    | C               | Unknown                                            | 75 Mg, 2x/Day        |                 | Not Reported               |                |
|                                                                                        | Estradiol               |                    |                    | C               |                                                    |                      |                 | Not Reported               |                |
|                                                                                        | Glipizide               |                    |                    | C               |                                                    |                      |                 | Not Reported               |                |
|                                                                                        | Metformin               |                    |                    | C               |                                                    |                      |                 | Not Reported               |                |
|                                                                                        | Lantus                  |                    |                    | C               |                                                    |                      |                 | Not Reported               |                |
|                                                                                        | Atorvastatin            |                    |                    | C               |                                                    |                      |                 | Not Reported               |                |
|                                                                                        | Aspirin                 |                    |                    | C               |                                                    |                      |                 | Not Reported               |                |
| <u>FDA Received Date</u>                                                               | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                               | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                 | <u>Country</u> |
| 12-Mar-2016                                                                            | 12174574                | EXPEDITED (15-DAY) |                    | DE, HO          | US-AUROBINDO-AUR-<br>APL-2016-03284                |                      | 36 YR           | Female                     | USA            |
| <u>Preferred Term</u>                                                                  | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                       | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                 |                |
| Completed Suicide                                                                      | Escitalopram            |                    |                    | S               | Unknown                                            |                      |                 | Aurobindo                  |                |
|                                                                                        | Topiramate              |                    |                    | S               | Unknown                                            |                      |                 | Aurobindo                  |                |
|                                                                                        | Verapamil               |                    |                    | S               | Unknown                                            |                      |                 | Not Reported               |                |
|                                                                                        | Codeine                 |                    |                    | S               | Unknown                                            |                      |                 | Not Reported               |                |
| <u>FDA Received Date</u>                                                               | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                               | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                 | <u>Country</u> |
| 13-Mar-2016                                                                            | 12174442                | EXPEDITED (15-DAY) |                    | DE              | SE-CIPLA LTD.-<br>2016SE02266                      |                      |                 | Unknown                    | SWE            |

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| <u>Preferred Term</u>                                     | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|-----------------------------------------------------------|-----------------------|--------------------|--------------------|-----------------|------------------------------------------------------------|----------------------|-----------------|--------------|----------------|
| Completed Suicide;<br>Poisoning                           | Citalopram            |                    |                    | S               | Unknown                                                    | Unk                  |                 | Cipla        |                |
|                                                           | Escitalopram          |                    |                    | S               | Unknown                                                    | Unk                  |                 | Not Reported |                |
|                                                           | Promethazine          |                    |                    | S               | Unknown                                                    | Unk                  |                 | Not Reported |                |
|                                                           | Desmethylpromethazine |                    |                    | S               | Unknown                                                    | Unk                  |                 | Not Reported |                |
|                                                           | Diazepam              |                    |                    | S               | Unknown                                                    | Unk                  |                 | Not Reported |                |
|                                                           | Nordiazepam           |                    |                    | S               | Unknown                                                    | Unk                  |                 | Not Reported |                |
|                                                           | Hydroxyzine           |                    |                    | S               | Unknown                                                    | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                  | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Mar-2016                                               | 11983931              | EXPEDITED (15-DAY) |                    | OT              | FR-GILEAD-2016-0194053                                     |                      | 32 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                     | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Weight Increased                                          | Eviplera              |                    |                    | S               | Unknown                                                    | Unk                  |                 | Gilead       |                |
|                                                           | Seroplex              |                    |                    | S               | Unknown                                                    | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                  | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Mar-2016                                               | 12174800              | EXPEDITED (15-DAY) |                    | HO, OT          | IT-MACLEODS<br>PHARMACEUTICALS<br>US LTD-<br>MAC2016002506 |                      |                 | Unknown      | ITA            |
| <u>Preferred Term</u>                                     | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blister; Dermatitis;<br>Erythema; Pemphigoid;<br>Pruritus | Escitalopram          |                    |                    | S               | Unknown                                                    | 10 Mg, Qd            |                 | Macleods     |                |
| <u>FDA Received Date</u>                                  | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Mar-2016                                               | 12176866              | EXPEDITED (15-DAY) |                    | HO              | FR-SYMLMED<br>PHARMACEUTICALS-<br>2016SYMLMED00016<br>9    |                      |                 | Unknown      | FRA            |
| <u>Preferred Term</u>                                     | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |



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|                          |              |   |      |                       |              |
|--------------------------|--------------|---|------|-----------------------|--------------|
| Accidental Overdose;     | Perindopril  | S | Oral | 2.5 Mg, Unk           | Unknown      |
| Amnesia; Asthenia;       | Perindopril  | S | Oral | 10 Mg-17.5 Mg, Single | Unknown      |
| Bradycardia; Coma Scale  | Procoralan   | S | Oral | 5 Mg, Unk             | Not Reported |
| Abnormal; Confusional    | Procoralan   | S | Oral | 70 Mg, Single         | Not Reported |
| State; Disorientation;   | Zopiclone    | S | Oral | 7.5 Mg, Unk           | Not Reported |
| Ejection Fraction        | Zopiclone    | S | Oral | 37.5 Mg, Single       | Not Reported |
| Decreased;               | Coumadine    | S | Oral | 10 Mg, Unk            | Not Reported |
| Electrocardiogram Qt     | Coumadine    | S | Oral | 100 Mg-140 Mg, Single | Not Reported |
| Prolonged; Fall;         | Escitalopram | S | Oral | 10 Mg, Unk            | Not Reported |
| Hypotonia; International | Escitalopram | S | Oral | 70 Mg, Single         | Not Reported |
| Normalised Ratio         | Montelukast  | S | Oral | 10 Mg, Unk            | Not Reported |
| Increased; Medication    | Montelukast  | S | Oral | 40 Mg-70 Mg, Single   | Not Reported |
| Error; Mydriasis;        | Cetirizine   | S | Oral | 10 Mg, Unk            | Not Reported |
| Somnolence               | Cetirizine   | S | Oral | 40 Mg-70 Mg, Single   | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|------------|------------|----------------|
| 14-Mar-2016              | 12176933      | EXPEDITED (15-DAY) | DE                 |                 | SE-CIPLA LTD.-<br>2016SE02277 |                      |            | Unknown    | SWE            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Myocardial Fibrosis   | Citalopram           |              |            | S           | Unknown      | Unk                |                 | Cipla        |
|                       | Escitalopram         |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                       | Paracetamol          |              |            | S           | Unknown      | Unk                |                 | Cipla        |
|                       | Nortriptyline        |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                       | Diazepam             |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                       | Nordiazepam          |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                       | Tramadol             |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                       | O-Desmethyiltramadol |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                       | Caffeine             |              |            | S           | Unknown      | Unk                |                 | Not Reported |

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| <u>FDA Received Date</u>             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------|----------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|-----------------|--------------|----------------|
| 14-Mar-2016                          | 12176935       | EXPEDITED (15-DAY) |                    | DE              | SE-CIPLA LTD.-<br>2016SE02275 |                      |                 | Unknown      | SWE            |
| <u>Preferred Term</u>                | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Accident; Myocardial<br>Fibrosis     | Citalopram     |                    |                    | S               | Unknown                       | Unk                  |                 | Cipla        |                |
|                                      | Escitalopram   |                    |                    | S               | Unknown                       | Unk                  |                 | Not Reported |                |
|                                      | Paracetamol    |                    |                    | S               | Unknown                       | Unk                  |                 | Cipla        |                |
| <u>FDA Received Date</u>             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Mar-2016                          | 12176942       | EXPEDITED (15-DAY) |                    | DE              | SE-CIPLA LTD.-<br>2016SE02276 |                      |                 | Unknown      | SWE            |
| <u>Preferred Term</u>                | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Poisoning      | Citalopram     |                    |                    | S               | Unknown                       | Unk                  |                 | Cipla        |                |
|                                      | Escitalopram   |                    |                    | S               | Unknown                       | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Mar-2016                          | 12176958       | EXPEDITED (15-DAY) |                    | DE              | SE-CIPLA LTD.-<br>2016SE02274 |                      |                 | Unknown      | SWE            |
| <u>Preferred Term</u>                | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Gun<br>Shot Wound | Citalopram     |                    |                    | S               | Unknown                       | Unk                  |                 | Cipla        |                |
|                                      | Escitalopram   |                    |                    | S               | Unknown                       | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Mar-2016                          | 12177068       | EXPEDITED (15-DAY) |                    | DE              | SE-CIPLA LTD.-<br>2016SE02278 |                      |                 | Unknown      | SWE            |
| <u>Preferred Term</u>                | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                    | Citalopram     |                    |                    | S               | Unknown                       | Unk                  |                 | Cipla        |                |
|                                      | Escitalopram   |                    |                    | S               | Unknown                       | Unk                  |                 | Not Reported |                |
|                                      | Zopiclone      |                    |                    | S               | Unknown                       | Unk                  |                 | Cipla        |                |

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| <u>FDA Received Date</u>        | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------|-------------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|-----------------|--------------|----------------|
| 14-Mar-2016                     | 12177080          | EXPEDITED (15-DAY) |                    | DE              | SE-CIPLA LTD.-<br>2016SE02279 |                      |                 | Unknown      | SWE            |
| <u>Preferred Term</u>           | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Poisoning | Citalopram        |                    |                    | S               | Unknown                       | Unk                  |                 | Cipla        |                |
|                                 | Escitalopram      |                    |                    | S               | Unknown                       | Unk                  |                 | Not Reported |                |
|                                 | Nortriptyline     |                    |                    | S               | Unknown                       | Unk                  |                 | Not Reported |                |
|                                 | 7-Aminonitrazepam |                    |                    | S               | Unknown                       | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>        | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Mar-2016                     | 12177119          | EXPEDITED (15-DAY) |                    | DE              | SE-CIPLA LTD.-<br>2016SE02298 |                      |                 | Unknown      | SWE            |
| <u>Preferred Term</u>           | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Accident; Poisoning             | Citalopram        |                    |                    | S               | Unknown                       | Unk                  |                 | Cipla        |                |
|                                 | Escitalopram      |                    |                    | S               | Unknown                       | Unk                  |                 | Not Reported |                |
|                                 | Ethanol           |                    |                    | S               | Unknown                       | Unk                  |                 | Not Reported |                |
|                                 | Carbon Monoxide   |                    |                    | S               | Unknown                       | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>        | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Mar-2016                     | 12177224          | EXPEDITED (15-DAY) |                    | DE              | SE-CIPLA LTD.-<br>2016SE02301 |                      |                 | Unknown      | SWE            |
| <u>Preferred Term</u>           | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Disorder                | Citalopram        |                    |                    | S               | Unknown                       | Unk                  |                 | Cipla        |                |
|                                 | Escitalopram      |                    |                    | S               | Unknown                       | Unk                  |                 | Not Reported |                |
|                                 | Ethanol           |                    |                    | S               | Unknown                       | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>        | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Mar-2016                     | 12177229          | EXPEDITED (15-DAY) |                    | DE              | SE-CIPLA LTD.-<br>2016SE02307 |                      |                 | Unknown      | SWE            |
| <u>Preferred Term</u>           | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                     |              |   |         |     |              |
|---------------------|--------------|---|---------|-----|--------------|
| Accident; Poisoning | Citalopram   | S | Unknown | Unk | Cipla        |
|                     | Escitalopram | S | Unknown | Unk | Not Reported |
|                     | Zopiclone    | S | Unknown | Unk | Cipla        |

| <u>FDA Received Date</u>        | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------|----------------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|-----------------|--------------|----------------|
| 14-Mar-2016                     | 12177237             | EXPEDITED (15-DAY) |                    | DE              | SE-CIPLA LTD.-<br>2016SE02320 |                      |                 | Unknown      | SWE            |
| <u>Preferred Term</u>           | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Poisoning | Citalopram           |                    |                    | S               | Unknown                       | Unk                  |                 | Cipla        |                |
|                                 | Escitalopram         |                    |                    | S               | Unknown                       | Unk                  |                 | Not Reported |                |
|                                 | Ethanol              |                    |                    | S               | Unknown                       | Unk                  |                 | Not Reported |                |
|                                 | Alimemazine          |                    |                    | S               | Unknown                       | Unk                  |                 | Not Reported |                |
|                                 | Desmethyralimemazine |                    |                    | S               | Unknown                       | Unk                  |                 | Not Reported |                |
|                                 | Carbamazepin         |                    |                    | S               | Unknown                       | Unk                  |                 | Not Reported |                |
|                                 | Hydroxyzine          |                    |                    | S               | Unknown                       | Unk                  |                 | Not Reported |                |

| <u>FDA Received Date</u>                                 | <u>Case #</u>              | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------|----------------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 14-Mar-2016                                              | 12178830                   | DIRECT           |                    | OT              |                      |                      | 60 YR           | Female       | USA            |
| <u>Preferred Term</u>                                    | <u>Product</u>             | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Dreams;<br>Hypertension; Sensory<br>Disturbance | Escitalopram Oxalate 10 Mg |                  |                    | S               | Oral                 |                      |                 | Aurobindo    |                |
|                                                          | Aurobindo Pharma           |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                          | Baby Aspirin               |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                          | Effexor                    |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                          | Pravastatin                |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                          | Centrum Silver             |                  |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>        | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|-----------------------------|----------------------|-----------------|------------|----------------|
| 14-Mar-2016              | 12179818       | EXPEDITED (15-DAY) |                    | HO              | SE-TAKEDA-<br>2016TUS004248 |                      | 37 YR           | Female     | SWE            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Abdominal Pain;          | Brintellix     |                    |                    | S               | Unknown                     | 5 Mg, Qd             |                 | Takeda     |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                         |                           |   |         |     |              |
|---------------------------------------------------------|---------------------------|---|---------|-----|--------------|
| Diarrhoea; Drug Interaction; Feeling Abnormal; Vomiting | Escitalopram-Form_Unknown | S | Unknown | Unk | Not Reported |
|---------------------------------------------------------|---------------------------|---|---------|-----|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------------------|----------------------|------------|------------|----------------|
| 15-Mar-2016              | 12177202      | NON-EXPEDITED    |                    | OT              | US-LUPIN PHARMACEUTICALS INC.-2016-00013 |                      | 31 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Hypersensitivity | Erythromycin      |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Doxycycline       |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Imitrex           |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Biaxin            |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Suprax (Cefixime) |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Lexapro           |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Augmentin         |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Zoloft            |              |            | S           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|------------|------------|----------------|
| 15-Mar-2016              | 12177486      | EXPEDITED (15-DAY) |                    | DE              | US-AUROBINDO-AUR-APL-2016-02540 |                      | 41 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Olanzapine     |              |            | S           | Unknown      |                    |                 | Aurobindo    |
|                       | Lisinopril     |              |            | S           | Unknown      |                    |                 | Aurobindo    |
|                       | Escitalopram   |              |            | S           | Unknown      |                    |                 | Aurobindo    |
|                       | Prednisone     |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Warfarin       |              |            | S           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 15-Mar-2016              | 12177722      | EXPEDITED (15-DAY) |                    | DE              | SE-CIPLA LTD.-2016SE02322 |                      |            | Unknown    | SWE            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                        |                |                    |                    |                 |                                             |                      |                 |              |                |
|----------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|---------------------------------------------|----------------------|-----------------|--------------|----------------|
| Acute Myocardial Infarction                                                            | Citalopram     | S                  | Unknown            | Unk             | Cipla                                       |                      |                 |              |                |
|                                                                                        | Escitalopram   | S                  | Unknown            | Unk             | Not Reported                                |                      |                 |              |                |
| <u>FDA Received Date</u>                                                               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Mar-2016                                                                            | 12178099       | EXPEDITED (15-DAY) | DE                 |                 | SE-CIPLA LTD.-<br>2016SE02306               |                      |                 | Unknown      | SWE            |
| <u>Preferred Term</u>                                                                  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Disorder; Cold Exposure Injury                                                 | Citalopram     |                    |                    | S               | Unknown                                     |                      |                 | Cipla        |                |
|                                                                                        | Escitalopram   |                    |                    | S               | Unknown                                     | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Mar-2016                                                                            | 12178215       | EXPEDITED (15-DAY) |                    | OT              | GB-AUROBINDO-AUR-<br>APL-2016-03185         |                      | 24 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                                  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alopecia Areata                                                                        | Escitalopram   |                    |                    | S               | Oral                                        | 15 Mg                |                 | Aurobindo    |                |
| <u>FDA Received Date</u>                                                               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Mar-2016                                                                            | 12178365       | EXPEDITED (15-DAY) |                    | DE              | SE-CIPLA LTD.-<br>2016SE02321               |                      |                 | Unknown      | SWE            |
| <u>Preferred Term</u>                                                                  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Accident; Fat Embolism                                                                 | Citalopram     |                    |                    | S               | Unknown                                     | Unk                  |                 | Cipla        |                |
|                                                                                        | Escitalopram   |                    |                    | S               | Unknown                                     | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Mar-2016                                                                            | 12178785       | EXPEDITED (15-DAY) |                    | OT              | AU-JUBILANT<br>GENERICS LIMITED-<br>1049038 |                      | 70 YR           | Female       | AUS            |
| <u>Preferred Term</u>                                                                  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;<br>Hyponatraemia;<br>Inappropriate Antidiuretic<br>Hormone Secretion | Bupropion      |                    |                    | S               |                                             |                      |                 | Jubilant     |                |
|                                                                                        | Escitalopram   |                    |                    | S               |                                             |                      |                 | Not Reported |                |
|                                                                                        | Dothiepin      |                    |                    | S               |                                             |                      |                 | Not Reported |                |
|                                                                                        | Ramipril       |                    |                    | S               |                                             |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                      |   |              |
|----------------------|---|--------------|
| Quetiapine Fumarate  | C | Not Reported |
| Lamotrogine          | C | Not Reported |
| Oestradiol           | C | Not Reported |
| Glipizide            | C | Not Reported |
| Metformin            | C | Not Reported |
| Lantus Brand Insulin | C | Not Reported |
| Atorvastatin Calcium | C | Not Reported |
| Aspirin              | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Mar-2016              | 11893805      | EXPEDITED (15-DAY) |                    | HO              | TR-FRI-1000081967    |                      | 59 YR      | Male       | TUR            |

| <u>Preferred Term</u>                                                                                         | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Confusional State; Drug Interaction; Dyspnoea; Hallucination; Hypercapnia; Hyponatraemia; Hypoxia; Somnolence | Escitalopram         |              |            | S           | Unknown      | 10 Mg Qd           |                 | Forest       |
|                                                                                                               | Acetylsalicylic Acid |              |            | C           | Unknown      | 300 Mg             |                 | Not Reported |
|                                                                                                               | Metoprolol           |              |            | C           | Unknown      | 25 Mg              |                 | Not Reported |
|                                                                                                               | Perindopril          |              |            | C           | Unknown      | 5 Mg               |                 | Not Reported |
|                                                                                                               | Amiodarone           |              |            | C           | Unknown      | 200 Mg             |                 | Not Reported |
|                                                                                                               | Spironolactone       |              |            | C           | Unknown      | 50 Mg              |                 | Not Reported |
|                                                                                                               | Aldactazide          |              |            | C           | Unknown      | 50 Mg              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Mar-2016              | 12175431      | EXPEDITED (15-DAY) |                    | OT              | GB-FRI-1000083125    |                      | 24 YR      | Female     | GBR            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Alopecia Areata       | Escitalopram   |              |            | S           | Oral         | 15 Mg Daily        |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 16-Mar-2016              | 12182326      | EXPEDITED (15-DAY) |                    | OT              | CZ-CIPLA LTD.-2016CZ02380 |                      |            | Unknown    | CZE            |

| <u>Preferred Term</u>                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Exposure During Pregnancy; Stillbirth | Sertraline     |              |            | S           | Unknown      | Unk                |                 | Cipla      |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|              |   |         |     |              |
|--------------|---|---------|-----|--------------|
| Citalopram   | S | Unknown | Unk | Cipla        |
| Escitalopram | S | Unknown | Unk | Not Reported |
| Fluoxetine   | S | Unknown | Unk | Cipla        |
| Paroxetine   | S | Unknown | Unk | Not Reported |
| Fluvoxamin   | S | Unknown | Unk | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|-----------------|--------------|----------------|
| 16-Mar-2016              | 12182731       | EXPEDITED (15-DAY) |                    | DE, HO          | US-AUROBINDO-AUR-APL-2016-02834 |                      | 74 YR           | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Death                    | Atenolol       |                    |                    | S               | Unknown                         |                      |                 | Aurobindo    |                |
|                          | Escitalopram   |                    |                    | S               | Unknown                         |                      |                 | Aurobindo    |                |
|                          | Primidone      |                    |                    | S               | Oral                            |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|-----------------|--------------|----------------|
| 16-Mar-2016              | 12182875       | EXPEDITED (15-DAY) |                    | DE, HO          | US-AUROBINDO-AUR-APL-2016-02839 |                      | 69 YR           | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide        | Escitalopram   |                    |                    | S               | Oral                            |                      |                 | Aurobindo    |                |
|                          | Finasteride    |                    |                    | S               | Oral                            |                      |                 | Aurobindo    |                |
|                          | Lamotrigine    |                    |                    | S               | Oral                            |                      |                 | Aurobindo    |                |
|                          | Quetiapine     |                    |                    | S               |                                 |                      |                 | Aurobindo    |                |
|                          | Clonazepam     |                    |                    | S               | Oral                            |                      |                 | Not Reported |                |
|                          | Oxybutynin     |                    |                    | S               | Oral                            |                      |                 | Not Reported |                |
|                          | Trazodone      |                    |                    | S               | Oral                            |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|------------|----------------|
| 16-Mar-2016              | 12183015       | EXPEDITED (15-DAY) |                    | CA, OT          | DE-HETERO LABS LTD-1049139 |                      | 10 YR           | Male       | DEU            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                     |                            |   |                |              |
|---------------------------------------------------------------------|----------------------------|---|----------------|--------------|
| Foetal Exposure During Pregnancy; Hypospadias; Small For Dates Baby | Escitalopram               | S | Transplacental | Hetero       |
|                                                                     | Prothipendyl Hydrochloride | S | Transplacental | Not Reported |
|                                                                     | Lorazepam                  | C | Transplacental | Not Reported |
|                                                                     | Magnesium Chloride         | C | Transplacental | Not Reported |
|                                                                     | Pregabalin                 | C | Transplacental | Not Reported |
|                                                                     | Folic Acid                 | C | Transplacental | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------------|----------------------|------------|------------|----------------|
| 16-Mar-2016              | 12183129      | EXPEDITED (15-DAY) |                    | OT              | JP-XENOPORT, INC.-<br>2016JP002362 |                      | 80 YR      | Male       | JPN            |

| <u>Preferred Term</u>                                                                                              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|---------------------|-----------------|--------------|
| Blood Glucose Increased;<br>Blood Pressure Decreased;<br>Depressive Symptom; Malaise;<br>Nausea; Oedema Peripheral | Regnite        |              |            | S           | Oral         | Unk                 |                 | Xenoport     |
|                                                                                                                    | Neupro         |              |            | S           | Transdermal  | 2.25 Mg, Once Daily |                 | Not Reported |
|                                                                                                                    | Neupro         |              |            | S           | Transdermal  | 2.25 Mg, Once Daily |                 | Not Reported |
|                                                                                                                    | Neupro         |              |            | S           | Transdermal  | 2.25 Mg, Once Daily |                 | Not Reported |
|                                                                                                                    | Neupro         |              |            | S           | Transdermal  | 4.5 Mg, Once Daily  |                 | Not Reported |
|                                                                                                                    | Neupro         |              |            | S           | Transdermal  | 9 Mg, Once Daily    |                 | Not Reported |
|                                                                                                                    | Mohrus         |              |            | S           |              |                     |                 | Not Reported |
|                                                                                                                    | Irbetan        |              |            | S           |              |                     |                 | Not Reported |
|                                                                                                                    | Amlodin        |              |            | S           |              |                     |                 | Not Reported |
|                                                                                                                    | Urief          |              |            | S           |              |                     |                 | Not Reported |
|                                                                                                                    | Lantus         |              |            | S           |              |                     |                 | Not Reported |
|                                                                                                                    | Novorapid      |              |            | S           |              |                     |                 | Not Reported |
|                                                                                                                    | Opalmon        |              |            | S           |              |                     |                 | Not Reported |
|                                                                                                                    | Lexapro        |              |            | S           |              |                     |                 | Not Reported |
|                                                                                                                    | Meilax         |              |            | S           |              |                     |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Mar-2016              | 12184826      | EXPEDITED (15-DAY) |                    | HO              | SE-FRI-1000083207    |                      | 37 YR      | Female     | SWE            |

| <u>Preferred Term</u>              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Abdominal Pain;<br>Diarrhoea; Drug | Escitalopram   |              |            | S           | Unknown      |                    |                 | Forest     |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                           |                               |                    |                    |                 |                               |                      |                 |              |                |
|-------------------------------------------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|-----------------|--------------|----------------|
| Interaction; Vomiting                                                                     |                               | Brintellix         |                    | S               | Unknown                       |                      | 5 Mg            | Not Reported |                |
| <u>FDA Received Date</u>                                                                  | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Mar-2016                                                                               | 12187563                      | DIRECT             |                    | OT              |                               |                      | 26 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                     | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Crying; Dyspnoea;<br>Madarosis; Madarosis;<br>Panic Attack; Product<br>Substitution Issue | Excitalopram Oxalate          |                    |                    | S               | Oral                          |                      |                 | Not Reported |                |
|                                                                                           | Ocella (Birth Control)        |                    |                    | C               |                               |                      |                 | Not Reported |                |
|                                                                                           | Diazepam                      |                    |                    | C               |                               |                      |                 | Not Reported |                |
|                                                                                           | Lexapro                       |                    |                    | C               |                               |                      |                 | Not Reported |                |
|                                                                                           | Fish Oil                      |                    |                    | C               |                               |                      |                 | Not Reported |                |
|                                                                                           | Multi Vitamin                 |                    |                    | C               |                               |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                  | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Mar-2016                                                                               | 12063207                      | EXPEDITED (15-DAY) |                    | HO              | FR-SA-2016SA019940            |                      | 86 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                     | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depressed Level Of<br>Consciousness;<br>Disorientation;<br>Hyponatraemia                  | Coaprovel                     |                    |                    | S               | Unknown                       |                      |                 | Not Reported |                |
|                                                                                           | Seroplex                      |                    |                    | S               | Oral                          |                      |                 | Not Reported |                |
|                                                                                           | Temesta (Lorazepam)           |                    |                    | S               | Oral                          |                      |                 | Not Reported |                |
|                                                                                           | Inexium                       |                    |                    | S               | Oral                          |                      |                 | Not Reported |                |
|                                                                                           | Monocrixo                     |                    |                    | S               | Oral                          |                      |                 | Not Reported |                |
|                                                                                           | Lexomil                       |                    |                    | S               | Oral                          |                      |                 | Not Reported |                |
|                                                                                           | Levothyrox                    |                    |                    | C               |                               | 50 Mcg Tablets       |                 | Not Reported |                |
|                                                                                           | Avlocardyl                    |                    |                    | C               |                               | 40 Mg Tablets        |                 | Not Reported |                |
|                                                                                           | Dedrogyl                      |                    |                    | C               |                               |                      |                 | Not Reported |                |
|                                                                                           | Calcidose [Calcium Carbonate] |                    |                    | C               |                               |                      |                 | Not Reported |                |
|                                                                                           | Trophigil                     |                    |                    | C               |                               |                      |                 | Not Reported |                |
|                                                                                           | Flector                       |                    |                    | C               |                               | 1% Gel               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                  | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Mar-2016                                                                               | 12185907                      | EXPEDITED (15-DAY) |                    | CA, OT          | DE-HETERO LABS<br>LTD-1049230 |                      |                 | Female       | DEU            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                           | <u>Product</u>                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------------------------------------|---------------------------------------------|--------------------|--------------------|-----------------|-------------------------------------|----------------------|-----------------|--------------|----------------|
| Coordination Abnormal;<br>Developmental Hip<br>Dysplasia; Hypotonia;<br>Seizure | Escitalopram                                |                    |                    | S               | Transplacental                      |                      |                 | Hetero       |                |
|                                                                                 | Venlafaxine Hydrochloride                   |                    |                    | C               | Transplacental                      |                      |                 | Not Reported |                |
|                                                                                 | Levothyroxine Sodium                        |                    |                    | C               | Transplacental                      |                      |                 | Not Reported |                |
|                                                                                 | Cyanocobalamin                              |                    |                    | C               | Transplacental                      |                      |                 | Not Reported |                |
|                                                                                 | Folic Acid                                  |                    |                    | C               | Transplacental                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                        | <u>Case #</u>                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Mar-2016                                                                     | 12186291                                    | EXPEDITED (15-DAY) |                    | OT              | IT-ACCORD-038883                    |                      | 78 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                           | <u>Product</u>                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Pemphigoid                                                                      | Escitalopram                                |                    |                    | S               |                                     |                      |                 | Accord       |                |
| <u>FDA Received Date</u>                                                        | <u>Case #</u>                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Mar-2016                                                                     | 12186477                                    | EXPEDITED (15-DAY) |                    | DE              | US-AUROBINDO-AUR-<br>APL-2016-03105 |                      | 67 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                           | <u>Product</u>                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                                               | Lamotrigine                                 |                    |                    | S               | Unknown                             |                      |                 | Aurobindo    |                |
|                                                                                 | Escitalopram                                |                    |                    | S               | Unknown                             |                      |                 | Aurobindo    |                |
|                                                                                 | Zonisamide                                  |                    |                    | S               | Unknown                             |                      |                 | Not Reported |                |
|                                                                                 | Lorazepam                                   |                    |                    | S               | Unknown                             |                      |                 | Not Reported |                |
|                                                                                 | Lovastatin                                  |                    |                    | S               | Unknown                             |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                        | <u>Case #</u>                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Mar-2016                                                                     | 12186572                                    | EXPEDITED (15-DAY) |                    | DE, HO, OT      | US-AUROBINDO-AUR-<br>APL-2016-03145 |                      | 34 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                           | <u>Product</u>                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Completed<br>Suicide; Respiratory Arrest                        | Hydrocodone Bitartrate And<br>Acetaminophen |                    |                    | S               | Unknown                             |                      |                 | Aurobindo    |                |
|                                                                                 | Gabapentin                                  |                    |                    | S               | Unknown                             |                      |                 | Aurobindo    |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|               |   |         |              |
|---------------|---|---------|--------------|
| Escitalopram  | S | Unknown | Aurobindo    |
| Ondansetron   | S | Unknown | Aurobindo    |
| Zolpidem      | S | Unknown | Aurobindo    |
| Amitriptyline | S | Unknown | Not Reported |
| Tramadol      | S | Unknown | Not Reported |
| Linaclotide   | S | Unknown | Not Reported |
| Diclofenac    | S | Unknown | Not Reported |
| Lubiprostone  | S | Unknown | Not Reported |
| Liothyronine  | S | Unknown | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|------------|------------|----------------|
| 17-Mar-2016              | 12186652      | EXPEDITED (15-DAY) |                    | DE              | US-AUROBINDO-AUR-APL-2016-03162 |                      | 43 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Death                 | Escitalopram   |              |            | S           | Unknown      |                    |                 | Aurobindo    |
|                       | Sertraline     |              |            | S           | Unknown      |                    |                 | Aurobindo    |
|                       | Atomoxetine    |              |            | S           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 17-Mar-2016              | 12187326      | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2016108272 |                      | 74 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Gynaecomastia         | Spironolactone |              |            | S           | Oral         | 25 Mg, 1x/Day      |                 | Pfizer       |
|                       | Lexapro        |              |            | S           | Oral         | 5 Mg, 1x/Day       |                 | Not Reported |
|                       | Lexapro        |              |            | S           | Oral         | 10 Mg, 1x/Day      |                 | Not Reported |
|                       | Lexapro        |              |            | S           | Oral         | 5 Mg, 1x/Day       |                 | Not Reported |
|                       | Finasteride    |              |            | S           | Oral         | 5 Mg, Unk          |                 | Not Reported |
|                       | Vitamin D3     |              |            | C           |              |                    |                 | Not Reported |
|                       | Lisinopril     |              |            | C           |              | 2.5 Mg, 2x/Day     |                 | Not Reported |
|                       | Imdur          |              |            | C           | Oral         | 30 Mg, 1x/Day      |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|             |   |      |                |              |
|-------------|---|------|----------------|--------------|
| Lasix       | C | Oral | 20 Mg, 4x/Day  | Not Reported |
| Metoprolol  | C | Oral | 100 Mg, 1x/Day | Not Reported |
| Digoxin     | C | Oral | 125 Ug, 1x/Day | Not Reported |
| Loratadine  | C | Oral | 10 Mg, Daily   | Not Reported |
| Simvastatin | C | Oral | 20 Mg, 1x/Day  | Not Reported |
| Tamsulosin  | C | Oral | 0.4 Mg, 1x/Day | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Mar-2016              | 12188306      | EXPEDITED (15-DAY) | CA, OT             |                 | CH-FRI-1000083227    |                      |            | Male       | CHE            |

| <u>Preferred Term</u>                                                                          | <u>Product</u>                       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------|--------------------------------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Congenital Ureteric Anomaly; Foetal Exposure During Pregnancy; Maternal Drugs Affecting Foetus | Escitalopram                         |              |            | S           | Transplacental |                    |                 | Forest       |
|                                                                                                | Tranxilium (Clorazepate Dipotassium) |              |            | S           | Transplacental | 10 Mg              |                 | Not Reported |
|                                                                                                | Zolpidem (Zolpidem)                  |              |            | S           | Transplacental | 0.5 Cp Daily       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 17-Mar-2016              | 12188399      | EXPEDITED (15-DAY) | HO, OT             |                 | FR-AMGEN-FRASP2016031851 |                      | 46 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|----------------------|-----------------|--------------|
| Amnesia; Asthenia; Bradycardia; Coma Scale Abnormal; Confusional State; Disorientation; Ejection Fraction Decreased; Electrocardiogram Qt Prolonged; Fall; Hypotonia; International Normalised Ratio Increased; Medication Error; Mydriasis; Overdose; Somnolence | Procoralan     |              |            | S           | Oral         | Unk                  |                 | Amgen        |
|                                                                                                                                                                                                                                                                   | Procoralan     |              |            | S           | Oral         | 70 Mg, Qd            |                 | Amgen        |
|                                                                                                                                                                                                                                                                   | Perindopril    |              |            | S           | Oral         | Unk                  |                 | Not Reported |
|                                                                                                                                                                                                                                                                   | Perindopril    |              |            | S           | Oral         | 10 Mg - 17.5 Mg,, Qd |                 | Not Reported |
|                                                                                                                                                                                                                                                                   | Zopiclone      |              |            | S           | Oral         | Unk                  |                 | Not Reported |
|                                                                                                                                                                                                                                                                   | Zopiclone      |              |            | S           | Oral         | 37.5 Mg, Qd          |                 | Not Reported |
|                                                                                                                                                                                                                                                                   | Coumadine      |              |            | S           | Oral         | Unk                  |                 | Not Reported |
|                                                                                                                                                                                                                                                                   | Coumadine      |              |            | S           | Oral         | 100 Mg - 140 Mg, Qd  |                 | Not Reported |
|                                                                                                                                                                                                                                                                   | Escitalopram   |              |            | S           | Oral         | Unk                  |                 | Not Reported |
|                                                                                                                                                                                                                                                                   | Escitalopram   |              |            | S           | Oral         | 70 Mg, Qd            |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|             |   |      |                   |              |
|-------------|---|------|-------------------|--------------|
| Montelukast | S | Oral | Unk               | Not Reported |
| Montelukast | S | Oral | 40 Mg - 70 Mg, Qd | Not Reported |
| Cetirizine  | S | Oral | Unk               | Not Reported |
| Cetirizine  | S | Oral | 40 Mg - 70 Mg, Qd | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------------------------------|----------------------|------------|------------|----------------|
| 17-Mar-2016              | 12189324      | EXPEDITED (15-DAY) |                    | HO              | FR-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>BMS-2016-017428 |                      | 46 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                                                                                                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>           |
|--------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------|
| Bradycardia; Confusional State; Disorientation; Fall; Hypotonia; International Normalised Ratio Increased; Medication Error; Mydriasis; Overdose | Coumadine      |              |            | S           | Unknown      | 10 Tab, Unk        |                 | Bristol Myers Squibb |
|                                                                                                                                                  | Zopiclone      |              |            | S           | Oral         | 5 Tab, Unk         |                 | Not Reported         |
|                                                                                                                                                  | Procoralan     |              |            | S           | Unknown      | 5 Mg, Unk          |                 | Not Reported         |
|                                                                                                                                                  | Escitalopram   |              |            | S           | Unknown      | 7 Tab, Unk         |                 | Not Reported         |
|                                                                                                                                                  | Perindopril    |              |            | S           | Unknown      | 1 Df, Unk          |                 | Not Reported         |
|                                                                                                                                                  | Montelukast    |              |            | S           | Unknown      | 10 Mg, Unk         |                 | Not Reported         |
|                                                                                                                                                  | Cetirizine     |              |            | S           | Unknown      | 10 Mg, Unk         |                 | Not Reported         |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Mar-2016              | 12190534      | DIRECT           |                    | HO, LT, OT      |                      |                      | 54 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                  | <u>Product</u>                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------|--------------------------------|--------------|------------|-------------|--------------|-----------------------------------|-----------------|--------------|
| Blood Pressure Fluctuation; Confusional State; Dyspnoea; Feeling Abnormal; Hyperhidrosis; Palpitations | Escitalopram 10 Mg Generic/Cvs |              |            | S           | Oral         | 1 10 Mg Once Daily Taken By Mouth |                 | Cvs Caremark |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Mar-2016              | 12190969      | DIRECT           | Y                  | OT              |                      |                      | 35 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                         |                           |   |      |              |
|-----------------------------------------|---------------------------|---|------|--------------|
| Nausea; Suicidal Ideation;<br>Urticaria | Escitalopram 20mg Unknown | S | Oral | Unknown      |
|                                         | Metformin                 | C |      | Not Reported |
|                                         | Singulair                 | C |      | Not Reported |
|                                         | Zofran                    | C |      | Not Reported |
|                                         | Xoponex Neb               | C |      | Not Reported |
|                                         | Lantus                    | C |      | Not Reported |
|                                         | Ibuprofen                 | C |      | Not Reported |
|                                         | Loratadine                | C |      | Not Reported |
|                                         | Januvia                   | C |      | Not Reported |
|                                         | Requip                    | C |      | Not Reported |
|                                         | Amaryl                    | C |      | Not Reported |
|                                         | Trilipex                  | C |      | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 18-Mar-2016              | 12056824      | EXPEDITED (15-DAY) |                    | HO, OT          | FR-ASTRAZENECA-2016SE12531 |                      | 86 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                                                                                                                                                    | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|--------------|------------|-------------|--------------|--------------------------|-----------------|--------------|
| Bronchitis; Depressed<br>Level Of Consciousness;<br>Disorientation; Faecal<br>Vomiting; Fall;<br>Hypertension;<br>Hyponatraemia;<br>Inappropriate Antidiuretic<br>Hormone Secretion;<br>Productive Cough | Inexium                       |              |            | S           | Oral         |                          |                 | Not Reported |
|                                                                                                                                                                                                          | Lexomil                       |              |            | S           | Oral         | (Roche) 1 Tablet Per Day |                 | Not Reported |
|                                                                                                                                                                                                          | Seroplex                      |              |            | S           | Oral         |                          |                 | Not Reported |
|                                                                                                                                                                                                          | Coaprovel                     |              |            | S           | Unknown      | 300 Mg + 12.5 Mg Daily   |                 | Not Reported |
|                                                                                                                                                                                                          | Temesta (Lorazepam)           |              |            | S           | Oral         |                          |                 | Not Reported |
|                                                                                                                                                                                                          | Monocrixo                     |              |            | S           | Oral         |                          |                 | Not Reported |
|                                                                                                                                                                                                          | Levothyrox                    |              |            | C           |              |                          |                 | Not Reported |
|                                                                                                                                                                                                          | Avlocardyl                    |              |            | C           |              |                          |                 | Not Reported |
|                                                                                                                                                                                                          | Dedrogyl                      |              |            | C           |              |                          |                 | Not Reported |
|                                                                                                                                                                                                          | Calcidose [Calcium Carbonate] |              |            | C           |              | 500                      |                 | Not Reported |
|                                                                                                                                                                                                          | Trophigil                     |              |            | C           |              |                          |                 | Not Reported |
|                                                                                                                                                                                                          | Flector                       |              |            | C           |              |                          |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Mar-2016              | 12167913      | NON-EXPEDITED    |                    |                 | PHHY2016US028926     |                      | 74 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|        |                     |   |             |               |              |
|--------|---------------------|---|-------------|---------------|--------------|
| Tremor | Lioresal Intratecal | S | Intrathecal | 128.78 Ug, Qd | Not Reported |
|        | Lioresal Intratecal | S | Intrathecal | 183.77 Ug, Qd | Not Reported |
|        | Simvastatin         | S | Unknown     |               | Novartis     |
|        | Lexapro             | S | Unknown     | Unk           | Not Reported |
|        | Keppra              | S | Unknown     | Unk           | Not Reported |
|        | Plavix              | S | Unknown     |               | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------|----------------------|------------|------------|----------------|
| 18-Mar-2016              | 12189651      | EXPEDITED (15-DAY) |                    | DE              | US-AUROBINDO-AUR-<br>APL-2016-03256 |                      | 51 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>                              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|---------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Escitalopram                                |              |            | S           | Unknown      |                    |                 | Aurobindo    |
|                       | Hydrocodone Bitartrate And<br>Acetaminophen |              |            | S           | Unknown      |                    |                 | Aurobindo    |
|                       | Topiramate                                  |              |            | S           | Unknown      |                    |                 | Aurobindo    |
|                       | Promethazine                                |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Verapamil                                   |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Diazepam                                    |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Esomeprazole                                |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Diclofenac                                  |              |            | S           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|------------|------------|----------------|
| 18-Mar-2016              | 12189694      | EXPEDITED (15-DAY) |                    | LT              | FR-009507513-<br>1603FRA007070 |                      | 65 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                 | <u>Product</u>                           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------|------------------------------------------|--------------|------------|-------------|--------------|--------------------------------|-----------------|--------------|
| Acute Respiratory Distress<br>Syndrome; Lung Disorder | Sinemet 250 Mg/25 Mg<br>Comprime Secable |              |            | S           | Oral         | Currently 5 Tablets Per<br>Day |                 | Merck        |
|                                                       | Apomorphine Hydrochloride                |              |            | S           | Subcutaneous | Unk                            |                 | Not Reported |
|                                                       | Mantadix                                 |              |            | S           | Oral         | 100 Mg, Qd                     |                 | Not Reported |
|                                                       | Modopar                                  |              |            | S           | Oral         | If Required                    |                 | Not Reported |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|          |   |      |             |              |
|----------|---|------|-------------|--------------|
| Seroplex | S | Oral | 15 Mg, Qd   | Not Reported |
| Imovane  | S | Oral | 7.5 Mg, Qd  | Not Reported |
| Sifrol   | S | Oral | 1.05 Mg, Qd | Not Reported |
| Azilect  | S | Oral | 1 Mg, Qd    | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Mar-2016              | 12194504      | DIRECT           | Y                  | OT              |                      |                      | 54 YR      | Female     | USA            |

| <u>Preferred Term</u>       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Headache;                   | Lexapro        |              |            | S           | Oral         |                    |                 | Not Reported |
| Hypoaesthesia;              | Topamax        |              |            | S           |              |                    |                 | Not Reported |
| Hypoaesthesia; Nausea;      |                |              |            |             |              |                    |                 |              |
| Product Substitution Issue; |                |              |            |             |              |                    |                 |              |
| Rash; Throat Tightness;     |                |              |            |             |              |                    |                 |              |
| Vision Blurred; Vomiting    |                |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------------------|----------------------|------------|------------|----------------|
| 21-Mar-2016              | 12093822      | EXPEDITED (15-DAY) |                    | OT              | DE-<br>GLAXOSMITHKLINE-<br>DE2016GSK023831 |                      | 48 YR      | Male       | DEU            |

| <u>Preferred Term</u> | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|-----------------------|--------------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Rectal Haemorrhage    | Omacor             |              |            | S           | Oral         | 1000 Mg, Bid       |                 | Glaxosmithkline |
|                       | Cipralext          |              |            | S           | Oral         | 10 Mg, 1d          |                 | Glaxosmithkline |
|                       | Concor Cor         |              |            | C           |              | Unk                |                 | Not Reported    |
|                       | Xanef              |              |            | C           |              | Unk                |                 | Not Reported    |
|                       | Tromcardin Complex |              |            | C           |              | Unk                |                 | Not Reported    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Mar-2016              | 12126947      | EXPEDITED (15-DAY) |                    | HO              | JP-FRI-1000082856    |                      | 72 YR      | Female     | JPN            |

| <u>Preferred Term</u>                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Drug Interaction;<br>Inappropriate Antidiuretic | Lexapro        |              |            | S           | Oral         | 5 Mg               |                 | Forest     |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                   |                   |   |             |                                                                                                      |              |
|-------------------|-------------------|---|-------------|------------------------------------------------------------------------------------------------------|--------------|
| Hormone Secretion | Lexapro           | S | Oral        | 10 Mg                                                                                                | Forest       |
|                   | Nexium            | S | Oral        | 20 Mg                                                                                                | Not Reported |
|                   | Mecobalamin       | C | Oral        | 2 Tablets Divided Into 2 Doses/Day                                                                   | Not Reported |
|                   | Juvela            | C | Oral        | 400 Mg                                                                                               | Not Reported |
|                   | Depas (Etizolam)  | C | Oral        | 0.5 Mg                                                                                               | Not Reported |
|                   | Limaprost Alfadex | C | Oral        | 15 Mcg                                                                                               | Not Reported |
|                   | Cravit            | C | Oral        | (Prescribed 1 Tablet At Night) 2 Tablets Was Taken For Symptom Of Suspected Cystitis From The Second | Not Reported |
|                   | Kallidinogenase   | C | Oral        | 50 Units, 1 Tablet, 1 Dose/Day                                                                       | Not Reported |
|                   | Loxonin           | C | Transdermal |                                                                                                      | Not Reported |
|                   | Fluvastatin       | C | Oral        |                                                                                                      | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------------------------|----------------------|------------|------------|----------------|
| 21-Mar-2016              | 12194426      | EXPEDITED (15-DAY) |                    | HO              | FR-LUPIN<br>PHARMACEUTICALS<br>INC.-2016-01015 |                      | 55 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                  | <u>Product</u>  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>  | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------|-----------------|--------------|------------|-------------|---------------|---------------------------|-----------------|--------------|
| Drug Interaction;<br>Neuroleptic Malignant<br>Syndrome | Risperdalconsta |              |            | S           | Intramuscular |                           |                 | Not Reported |
|                                                        | Risperdalconsta |              |            | S           | Intramuscular |                           |                 | Not Reported |
|                                                        | Risperdalconsta |              |            | S           |               |                           |                 | Not Reported |
|                                                        | Escitalopram    |              |            | S           | Intramuscular | 20 Mg                     |                 | Not Reported |
|                                                        | Escitalopram    |              |            | S           |               |                           |                 | Not Reported |
|                                                        | Theralene       |              |            | C           | Intramuscular | 20 Drops At Night If Need |                 | Not Reported |
|                                                        | Theralene       |              |            | C           |               |                           |                 | Not Reported |
|                                                        | Siresta         |              |            | C           | Intramuscular | 10 Mg                     |                 | Not Reported |
|                                                        | Siresta         |              |            | C           |               |                           |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <a href="#">FDA Received Date</a>                                                                                              | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|--------------------------------------------------------------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 21-Mar-2016                                                                                                                    | 12195061                | NON-EXPEDITED             |                             |                          | US-TEVA-640507USA             |                               |                          | Male                | USA                     |
| <a href="#">Preferred Term</a>                                                                                                 | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Somnolence                                                                                                                     | Escitalopram            |                           |                             | S                        | Unknown                       |                               |                          | Ivax                |                         |
| <a href="#">FDA Received Date</a>                                                                                              | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 21-Mar-2016                                                                                                                    | 12195062                | NON-EXPEDITED             |                             |                          | US-TEVA-572570USA             |                               | 54 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                                                                 | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Pruritus                                                                                                                       | Escitalopram            |                           |                             | S                        | Unknown                       |                               |                          | Ivax                |                         |
| <a href="#">FDA Received Date</a>                                                                                              | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 21-Mar-2016                                                                                                                    | 12195064                | NON-EXPEDITED             |                             |                          | US-TEVA-554096USA             |                               |                          | Male                | USA                     |
| <a href="#">Preferred Term</a>                                                                                                 | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Confusional State;<br>Dizziness; Drug<br>Ineffective; Mental<br>Disorder; Product<br>Substitution Issue; Urinary<br>Hesitation | Escitalopram            |                           |                             | S                        | Unknown                       | Frequency Not Provided        |                          | Ivax                |                         |
| <a href="#">FDA Received Date</a>                                                                                              | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 21-Mar-2016                                                                                                                    | 12195065                | NON-EXPEDITED             |                             |                          | US-TEVA-558205USA             |                               | 63 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>                                                                                                 | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Therapeutic Product Effect<br>Decreased                                                                                        | Generic Lexapro         |                           |                             | S                        | Unknown                       | 20 Milligram Daily;           |                          | Ivax                |                         |
|                                                                                                                                | Generic Lexapro         |                           |                             | S                        |                               |                               |                          | Ivax                |                         |
|                                                                                                                                | Nardil                  |                           |                             | S                        | Unknown                       | 60 Milligram Daily;           |                          | Not Reported        |                         |
|                                                                                                                                | Nardil                  |                           |                             | S                        | Unknown                       | 60 Milligram Daily;           |                          | Not Reported        |                         |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |          |   |         |                      |              |
|--|----------|---|---------|----------------------|--------------|
|  | Xanax    | S | Unknown | 1.5 Milligram Daily; | Not Reported |
|  | Xanax    | S | Unknown | 3 Milligram Daily;   | Not Reported |
|  | Klonopin | S | Unknown |                      | Not Reported |
|  | Klonopin | S |         |                      | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Mar-2016              | 12195067      | NON-EXPEDITED    |                    |                 | US-TEVA-578801USA    |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|---------------------|-----------------|--------------|
| Energy Increased;<br>Inappropriate Schedule Of<br>Product Administration;<br>Insomnia; Logorrhoea;<br>Psychomotor<br>Hyperactivity; Weight<br>Increased | Escitalopram   |              |            | S           | Oral         | 10 Milligram Daily; |                 | Ivax         |
|                                                                                                                                                         | Ampyra         |              |            | S           | Oral         | 20 Milligram Daily; |                 | Not Reported |
|                                                                                                                                                         | Gilenya        |              |            | C           |              |                     |                 | Not Reported |
|                                                                                                                                                         | Amantadine     |              |            | C           |              |                     |                 | Not Reported |
|                                                                                                                                                         | Vitamin D Nos  |              |            | C           |              |                     |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Mar-2016              | 12195068      | NON-EXPEDITED    |                    |                 | US-TEVA-568938USA    |                      |            | Male       | USA            |

| <u>Preferred Term</u>            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|----------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Muscular Weakness;<br>Somnolence | Escitalopram   |              |            | S           | Unknown      |                    |                 | Ivax       |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Mar-2016              | 12195069      | NON-EXPEDITED    |                    |                 | US-TEVA-630736USA    |                      |            | Male       | USA            |

| <u>Preferred Term</u>                                                                                                  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Decreased Appetite; Drug<br>Ineffective; Nausea; Panic<br>Attack; Product<br>Substitution Issue;<br>Retching; Vomiting | Escitalopram   |              |            | S           | Unknown      |                    |                 | Ivax       |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 21-Mar-2016                                                                                                                             | 12195070       | NON-EXPEDITED    |                    |                 | US-TEVA-630086USA    |                      |                 | Female     | USA            |
| <u>Preferred Term</u>                                                                                                                   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Asthenia                                                                                                                                | Escitalopram   |                  |                    | S               | Unknown              | 5 Milligram Daily;   |                 | Ivax       |                |
| <u>FDA Received Date</u>                                                                                                                | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 21-Mar-2016                                                                                                                             | 12195071       | NON-EXPEDITED    |                    |                 | US-TEVA-610345USA    |                      |                 | Female     | USA            |
| <u>Preferred Term</u>                                                                                                                   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Anxiety; Crying; Feeling Abnormal; Heart Rate Increased; Nausea; Panic Attack; Product Substitution Issue; Somnolence; Tremor; Vomiting | Escitalopram   |                  |                    | S               | Unknown              |                      |                 | Ivax       |                |
|                                                                                                                                         | Escitalopram   |                  |                    | S               |                      |                      |                 | Ivax       |                |
| <u>FDA Received Date</u>                                                                                                                | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 21-Mar-2016                                                                                                                             | 12195072       | NON-EXPEDITED    |                    |                 | US-TEVA-591715USA    |                      |                 | Female     | USA            |
| <u>Preferred Term</u>                                                                                                                   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Malaise                                                                                                                                 | Escitalopram   |                  |                    | S               | Unknown              |                      |                 | Ivax       |                |
| <u>FDA Received Date</u>                                                                                                                | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 21-Mar-2016                                                                                                                             | 12195073       | NON-EXPEDITED    |                    |                 | US-TEVA-569593USA    |                      |                 | Female     | USA            |
| <u>Preferred Term</u>                                                                                                                   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective; Product Substitution Issue                                                                                            | Escitalopram   |                  |                    | S               | Unknown              |                      |                 | Ivax       |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                             | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|-------------------------|-----------------|--------------|----------------|
| 21-Mar-2016                                                                                                                                          | 12195074       | NON-EXPEDITED    |                    |                 | US-TEVA-623213USA    |                         | 45 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Dry Mouth; Dyspnoea;<br>Movement Disorder                                                                                                            | Escitalopram   |                  |                    | S               | Oral                 | 40 Milligram Daily;     |                 | Ivax         |                |
|                                                                                                                                                      | Escitalopram   |                  |                    | S               |                      |                         |                 | Ivax         |                |
|                                                                                                                                                      | Buspar         |                  |                    | C               |                      | 10 Mg In Am, 5 Mg In Pm |                 | Not Reported |                |
|                                                                                                                                                      | Phentermine    |                  |                    | C               |                      | 1/2 Daily               |                 | Not Reported |                |
|                                                                                                                                                      | Trazodone      |                  |                    | C               |                      |                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                             | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Mar-2016                                                                                                                                          | 12195075       | NON-EXPEDITED    |                    |                 | US-TEVA-593199USA    |                         |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective                                                                                                                                     | Escitalopram   |                  |                    | S               |                      |                         |                 | Ivax         |                |
| <u>FDA Received Date</u>                                                                                                                             | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Mar-2016                                                                                                                                          | 12195076       | NON-EXPEDITED    |                    |                 | US-TEVA-553201USA    |                         |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety                                                                                                                                              | Escitalopram   |                  |                    | S               | Unknown              |                         |                 | Ivax         |                |
| <u>FDA Received Date</u>                                                                                                                             | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Mar-2016                                                                                                                                          | 12195077       | NON-EXPEDITED    |                    |                 | US-TEVA-564394USA    |                         | 48 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Apathy; Depressed Mood;<br>Depression; Fatigue;<br>Irritability; Menopausal<br>Symptoms; Negative<br>Thoughts; Off Label Use;<br>Poor Quality Sleep; | Escitalopram   |                  |                    | S               | Oral                 |                         |                 | Ivax         |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Product Substitution Issue;  
Product Use In  
Unapproved Indication

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 21-Mar-2016                       | 12195088                | NON-EXPEDITED             |                             | HO                       | US-TEVA-584675USA             |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Hypersensitivity                  | Generic Lexapro         |                           |                             | S                        | Unknown                       |                               |                          | Ivax                |                         |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 21-Mar-2016                       | 12195089                | NON-EXPEDITED             |                             |                          | US-TEVA-611022USA             |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Hypersensitivity             | Escitalopram            |                           |                             | S                        | Unknown                       |                               |                          | Ivax                |                         |

| <a href="#">FDA Received Date</a>                   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 21-Mar-2016                                         | 12195090                | NON-EXPEDITED             |                             |                          | US-TEVA-610420USA             |                               | 48 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                      | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Extrapyramidal Disorder;<br>Salivary Hypersecretion | Escitalopram            |                           |                             | S                        | Unknown                       |                               |                          |                     | Ivax                    |
|                                                     | Abilify                 |                           |                             | S                        |                               |                               |                          |                     | Not Reported            |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 21-Mar-2016                       | 12195091                | NON-EXPEDITED             |                             |                          | US-TEVA-586053USA             |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Sleep Disorder                    | Escitalopram            |                           |                             | S                        | Unknown                       |                               |                          | Ivax                |                         |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 21-Mar-2016                       | 12195092               | NON-EXPEDITED             |                             |                          | US-TEVA-614233USA             |                               | 77 YR               | Female              | USA                     |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|----------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|------------------------------------------|----------------------|-----------------|--------------|----------------|
| Depressed Mood; Feeling Abnormal; Intentional Product Use Issue; Product Dispensing Error; Product Dose Omission; Product Substitution Issue | Escitalopram   |                    |                    | S               | Oral                                     | 20 Milligram Daily;  |                 | Ivax         |                |
|                                                                                                                                              | Escitalopram   |                    |                    | S               |                                          |                      |                 | Ivax         |                |
|                                                                                                                                              | Diazepam       |                    |                    | C               | Oral                                     | Take 1/2 When Needed |                 | Not Reported |                |
|                                                                                                                                              | Atenolol       |                    |                    | C               | Oral                                     | 50 Milligram Daily;  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Mar-2016                                                                                                                                  | 12195093       | NON-EXPEDITED      |                    |                 | US-TEVA-631831USA                        |                      | 74 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bladder Pain; Intentional Product Use Issue; Vulvovaginal Dryness; Wrong Technique In Product Usage Process                                  | Escitalopram   |                    |                    | S               |                                          |                      |                 | Ivax         |                |
| <u>FDA Received Date</u>                                                                                                                     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Mar-2016                                                                                                                                  | 12195094       | NON-EXPEDITED      |                    |                 | US-TEVA-591113USA                        |                      |                 | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Erectile Dysfunction                                                                                                                         | Escitalopram   |                    |                    | S               | Unknown                                  | 20 Milligram Daily;  |                 | Ivax         |                |
|                                                                                                                                              | Lisinopril     |                    |                    | S               | Unknown                                  | 40 Milligram Daily;  |                 | Ivax         |                |
| <u>FDA Received Date</u>                                                                                                                     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Mar-2016                                                                                                                                  | 12196017       | EXPEDITED (15-DAY) |                    | HO              | FR-EISAI MEDICAL RESEARCH-EC-2016-015399 |                      | 84 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Inappropriate Antidiuretic Hormone Secretion                                                                                                 | Pariet         |                    |                    | S               | Oral                                     | Unknown              |                 | Not Reported |                |
|                                                                                                                                              | Seroplex       |                    |                    | S               | Oral                                     | Unknown              |                 | Not Reported |                |
|                                                                                                                                              | Ogastoro       |                    |                    | S               | Oral                                     | Unknown              |                 | Not Reported |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                     |   |         |         |              |
|---------------------|---|---------|---------|--------------|
| Coaprovel           | C | Oral    | Unknown | Not Reported |
| Lercan              | C | Oral    | Unknown | Not Reported |
| Ideos               | C | Oral    | Unknown | Not Reported |
| Temesta (Lorazepam) | C | Unknown | Unknown | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 22-Mar-2016              | 12072825      | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2016021554 |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Hypersensitivity | Effexor Xr     |              |            | S           |              | Unk                |                 | Pfizer       |
|                       | Effexor        |              |            | S           |              |                    |                 | Pfizer       |
|                       | Lithium        |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Risperdal      |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Topamax        |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Lexapro        |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Paxil          |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Cymbalta       |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Celexa         |              |            | S           |              | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 22-Mar-2016              | 12197811      | NON-EXPEDITED    |                    |                 | US-JNJFOC-20160305018 |                      |            | Male       | USA            |

| <u>Preferred Term</u>                                                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                   | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|------------------------------------------------------|-----------------|--------------|
| Erectile Dysfunction; Off Label Use; Product Use In Unapproved Indication | Risperdal      |              |            | S           | Oral         | Started It 5 Years Ago                               |                 | Not Reported |
|                                                                           | Lamictal       |              |            | S           | Oral         | Two Tablets Of 200 Mg Once A Day (Since 5 Years Ago) |                 | Not Reported |
|                                                                           | Latuda         |              |            | S           | Oral         | Started It 4 Years                                   |                 | Not Reported |
|                                                                           | Lithium        |              |            | S           | Oral         | Started It 2 Months Ago                              |                 | Not Reported |
|                                                                           | Lithium        |              |            | S           | Oral         | Started It 2 Months Ago                              |                 | Not Reported |
|                                                                           |                |              |            |             |              |                                                      |                 |              |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|         |   |         |                                    |              |
|---------|---|---------|------------------------------------|--------------|
| Lexapro | S | Unknown | Once At Night, Started 2 Years Ago | Not Reported |
|---------|---|---------|------------------------------------|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Mar-2016              | 12200159      | EXPEDITED (15-DAY) |                    | OT              | CN-FRI-1000083331    |                      | 63 YR      | Male       | CHN            |

| <u>Preferred Term</u>                                                                                                                                                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Cerebral Atrophy; Chromaturia; Cold Sweat; Dry Mouth; Dysgeusia; Liver Function Test Abnormal | Lexapro        |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                                                                                                                                                         | Lexapro        |              |            | S           | Oral         |                    |                 | Forest       |
|                                                                                                                                                                         | Lexapro        |              |            | S           | Oral         | 10 Mg              |                 | Not Reported |
|                                                                                                                                                                         | Citalopram     |              |            | S           | Unknown      | 40 Mg              |                 | Forest       |
|                                                                                                                                                                         | Citalopram     |              |            | S           | Unknown      |                    |                 | Forest       |
|                                                                                                                                                                         | Citalopram     |              |            | S           | Unknown      | 20 Mg              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Mar-2016              | 10101748      | EXPEDITED (15-DAY) |                    | OT              | SE-FRI-1000066765    |                      | 35 YR      | Female     | SWE            |

| <u>Preferred Term</u>                                                                               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|-----------------------------|-----------------|--------------|
| Anxiety; Confusional State; Decreased Appetite; Dizziness; Nausea; Paranoia; Sleep Disorder; Tremor | Escitalopram   |              |            | S           | Unknown      | 1 Tablet Daily At Ovulation |                 | Forest       |
|                                                                                                     | Propavan       |              |            | C           | Unknown      |                             |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Mar-2016              | 12075341      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000082561    |                      | 86 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                           | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Depressed Level Of Consciousness; Disorientation; Hyponatraemia | Escitalopram        |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                                                 | Coaprovel           |              |            | S           | Oral         | 300 Mg             |                 | Not Reported |
|                                                                 | Temesta (Lorazepam) |              |            | S           | Oral         | 1 Mg               |                 | Not Reported |
|                                                                 | Inexium             |              |            | S           | Oral         | 20 Mg              |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |                               |   |      |        |              |
|--|-------------------------------|---|------|--------|--------------|
|  | Monocrixo                     | S | Oral | 100 Mg | Not Reported |
|  | Lexomil Roche                 | S | Oral | 1 Df   | Not Reported |
|  | Levothyrox                    | C |      |        | Not Reported |
|  | Avlocardyl                    | C |      |        | Not Reported |
|  | Dedrogyl                      | C |      |        | Not Reported |
|  | Calcidose [Calcium Carbonate] | C |      |        | Not Reported |
|  | Trophigil                     | C |      |        | Not Reported |
|  | Flector                       | C |      |        | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 23-Mar-2016              | 12184496      | EXPEDITED (15-DAY) |                    | OT              | US-ASTRAZENECA-2016SE26666 |                      |            | Male       | DEU            |

| <u>Preferred Term</u>                                                                 | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Choking; Depression;<br>Drug Ineffective;<br>Oesophageal Pain;<br>Sensory Disturbance | Nexium               |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                       | Nexium               |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                       | Nexium               |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                       | Nexium               |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                       | Escitalopram Oxalate |              |            | S           | Unknown      | Unknown            |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Mar-2016              | 12204247      | EXPEDITED (15-DAY) |                    | HO              | BE-FRI-1000083428    |                      |            | Female     | BEL            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|-------------------------|-----------------|--------------|
| Cerebral Haemorrhage  | Escitalopram         |              |            | S           | Oral         |                         |                 | Forest       |
|                       | Escitalopram         |              |            | S           | Oral         |                         |                 | Forest       |
|                       | Escitalopram         |              |            | S           | Oral         |                         |                 | Not Reported |
|                       | Abilify/Aripiprazole |              |            | C           | Oral         | (1/2 Of Tablet Of 10mg) |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Mar-2016              | 12204661      | EXPEDITED (15-DAY) |                    | HO, LT          | FR-FRI-1000083453    |                      | 52 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                          |                                             |   |      |                         |              |
|--------------------------------------------------------------------------|---------------------------------------------|---|------|-------------------------|--------------|
| Coma; Depressed Level Of Consciousness; Intentional Overdose; Somnolence | Escitalopram                                | S | Oral | Overdose Of 280 Mg Once | Forest       |
|                                                                          | Tranxene                                    | S | Oral | Overdose Of 560 Mg Once | Not Reported |
|                                                                          | Laroxyl                                     | S | Oral |                         | Not Reported |
|                                                                          | Meteospasmyl (Alverine Citrate\Dimethicone) | S | Oral | Overdose Of 3 Df        | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 23-Mar-2016              | 12204765      | EXPEDITED (15-DAY) |                    | OT              | GB-ASTRAZENECA-2016SE30930 |                      |            | Female     | GBR            |

  

| <u>Preferred Term</u>                           | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Emotional Distress; Suicidal Ideation; Tinnitus | Quetiapine Fumarate  |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                 | Escitalopram Oxalate |              |            | S           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Mar-2016              | 12204800      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000083408    |                      | 87 YR      | Male       | FRA            |

  

| <u>Preferred Term</u>           | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Dysphagia; Pneumonia Aspiration | Escitalopram         |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                 | Escitalopram         |              |            | S           | Oral         | 20 Mg              |                 | Forest       |
|                                 | Seresta              |              |            | S           | Oral         | 40 Mg              |                 | Not Reported |
|                                 | Risperdal            |              |            | S           | Oral         | 1 Mg               |                 | Not Reported |
|                                 | Plavix               |              |            | C           | Oral         | 75 Mg              |                 | Not Reported |
|                                 | Pravastatine Sodique |              |            | C           | Oral         | 1 Df               |                 | Not Reported |
|                                 | Amlor                |              |            | C           | Oral         | 10 Mg              |                 | Not Reported |
|                                 | Vogalene             |              |            | C           | Oral         |                    |                 | Not Reported |
|                                 | Duphalac             |              |            | C           | Oral         | 1 Df               |                 | Not Reported |
|                                 | Pantoprazole         |              |            | C           | Oral         | 1 Df               |                 | Not Reported |
|                                 | Spasfon Lyoc         |              |            | C           | Oral         | 1 To 3 Df          |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                     | <u>Case #</u>                 | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------|-------------------------------|------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| 23-Mar-2016                                  | 12207359                      | DIRECT           | Y                  | HO              |                              |                      | 71 YR           | Female       | USA            |
| <u>Preferred Term</u>                        | <u>Product</u>                | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Hyponatraemia;<br>Nausea; Vomiting | Escitalopram                  |                  |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                              | Aspirin                       |                  |                    | C               |                              |                      |                 | Not Reported |                |
|                                              | Fluticasone                   |                  |                    | C               |                              |                      |                 | Not Reported |                |
|                                              | Metoprolol                    |                  |                    | C               |                              |                      |                 | Not Reported |                |
|                                              | Omeprazole                    |                  |                    | C               |                              |                      |                 | Not Reported |                |
|                                              | Tiotropium                    |                  |                    | C               |                              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                     | <u>Case #</u>                 | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Mar-2016                                  | 10621751                      | NON-EXPEDITED    |                    |                 | US-PFIZER INC-<br>2014328455 |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                        | <u>Product</u>                | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity                        | Zithromax                     |                  |                    | S               |                              | Unk                  |                 | Pfizer       |                |
|                                              | Arthrotec                     |                  |                    | S               |                              | Unk                  |                 | Pfizer       |                |
|                                              | Lexapro                       |                  |                    | S               |                              | Unk                  |                 | Not Reported |                |
|                                              | Vitamin D Nos                 |                  |                    | S               |                              | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                     | <u>Case #</u>                 | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Mar-2016                                  | 12206514                      | NON-EXPEDITED    |                    |                 | US-PFIZER INC-<br>2016143628 |                      | 67 YR           | Female       | USA            |
| <u>Preferred Term</u>                        | <u>Product</u>                | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity                        | Effexor                       |                  |                    | S               |                              | Unk                  |                 | Pfizer       |                |
|                                              | Sulfamethoxazole/Trimethoprim |                  |                    | S               |                              | Unk                  |                 | Pfizer       |                |
|                                              | Crestor                       |                  |                    | S               |                              | Unk                  |                 | Not Reported |                |
|                                              | Cymbalta                      |                  |                    | S               |                              | Unk                  |                 | Not Reported |                |
|                                              | E-Mycin                       |                  |                    | S               |                              | Unk                  |                 | Not Reported |                |
|                                              | Fenofibrate                   |                  |                    | S               |                              | Unk                  |                 | Not Reported |                |
|                                              | Lexapro                       |                  |                    | S               |                              | Unk                  |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                    |   |     |              |
|--------------------|---|-----|--------------|
| Livalo             | S | Unk | Not Reported |
| Lovastatin         | S | Unk | Not Reported |
| Niacin             | S | Unk | Not Reported |
| Paxil              | S | Unk | Not Reported |
| Pravastatin Sodium | S | Unk | Not Reported |
| Zetia              | S | Unk | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                 | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------------------------------|----------------------|------------|------------|----------------|
| 24-Mar-2016              | 12206605      | EXPEDITED (15-DAY) |                    | HO              | TR-SCIEGEN<br>PHARMACEUTICALS<br>INC-2016SCILIT00045 |                      | 59 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                                       | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Confusional State;<br>Dyspnoea; Hallucination;<br>Hypercapnia;<br>Hyponatraemia; Hypoxia;<br>Inappropriate Antidiuretic<br>Hormone Secretion;<br>Somnolence | Hydrochlorothiazide Tablets |              |            | S           | Unknown      | 50 Mg, Unk         |                 | Sciegen      |
|                                                                                                                                                             | Spirolonolactone            |              |            | S           | Unknown      | 50 Mg, Unk         |                 | Not Reported |
|                                                                                                                                                             | Escitalopram                |              |            | S           | Unknown      | 10 Mg, Qd          |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Mar-2016              | 12209031      | EXPEDITED (15-DAY) |                    | LT              | FR-TEVA-644762ISR    |                      | 65 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                 | <u>Product</u>                           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                            | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------|------------------------------------------|--------------|------------|-------------|--------------|---------------------------------------------------------------|-----------------|--------------|
| Acute Respiratory Distress<br>Syndrome; Lung Disorder | Azilect                                  |              |            | S           | Oral         | 1 Milligram Daily;                                            |                 | Teva         |
|                                                       | Apokionon                                |              |            | S           | Subcutaneous |                                                               |                 | Not Reported |
|                                                       | Mantadix 100 Mg                          |              |            | S           | Oral         | 100 Milligram Daily;                                          |                 | Not Reported |
|                                                       | Sinemet 250 Mg/25 Mg                     |              |            | S           | Oral         | Carbidopa 25 Mg +<br>Levodopa 250 Mg                          |                 | Not Reported |
|                                                       | Sinemet 250 Mg/25 Mg<br>Comprime Secable |              |            | S           | Oral         | 5 Dosage Forms Daily;<br>Carbidopa 25 Mg +<br>Levodopa 250 Mg |                 | Not Reported |
|                                                       | Modopar 125 (100 Mg/25 Mg)               |              |            | S           | Oral         | Benserazide 25 Mg +<br>Levodopa 100 Mg                        |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |                   |   |      |              |
|--|-------------------|---|------|--------------|
|  | Seroplex          | S | Oral | Not Reported |
|  | Imovane 7.5 Mg    | S | Oral | Not Reported |
|  | Sifrol Lp 1.05 Mg | S | Oral | Not Reported |
|  | Alprazolam        | C |      | Not Reported |
|  | Apomorphine       | C |      | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Mar-2016              | 12210570      | DIRECT           |                    |                 |                      |                      | 34 YR      | Female     |                |

| <u>Preferred Term</u>                                                               | <u>Product</u>                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                     | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------|--------------------------------|--------------|------------|-------------|--------------|--------------------------------------------------------|-----------------|--------------|
| Muscle Rigidity;<br>Myoclonus; Nausea;<br>Restlessness; Stress;<br>Weight Decreased | Hydromorphone Contin 3mg & 6mg |              |            | S           | Oral         | One 3mg & 6mg Capsule<br>Twice Daily Taken By<br>Mouth |                 | Not Reported |
|                                                                                     | Cipralext 20 Mg                |              |            | S           | Oral         | 20mg / One Tablet Hs<br>Once Daily Taken By<br>Mouth   |                 | Not Reported |
|                                                                                     | Sodium Oxybate                 |              |            | C           |              |                                                        |                 | Not Reported |
|                                                                                     | Celebrex                       |              |            | C           |              |                                                        |                 | Not Reported |
|                                                                                     | Hydromorphone                  |              |            | C           |              |                                                        |                 | Not Reported |
|                                                                                     | Lansoprazole                   |              |            | C           |              |                                                        |                 | Not Reported |
|                                                                                     | Ciprolex                       |              |            | C           |              |                                                        |                 | Not Reported |
|                                                                                     | Clonazepam                     |              |            | C           |              |                                                        |                 | Not Reported |
|                                                                                     | Lactulose                      |              |            | C           |              |                                                        |                 | Not Reported |
|                                                                                     | Dexedrine                      |              |            | C           |              |                                                        |                 | Not Reported |
|                                                                                     | Lorazepam                      |              |            | C           |              |                                                        |                 | Not Reported |
|                                                                                     | Vitamin B Complex              |              |            | C           |              |                                                        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Mar-2016              | 11865333      | EXPEDITED (15-DAY) |                    | OT              | FR-SA-2015SA212838   |                      | 93 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                                          | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Bradypnoea; Depressed<br>Level Of Consciousness;<br>Disorientation;<br>Hypotension; Somnolence | Mianserin Hydrochloride |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                | Alprazolam              |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                | Pregabalin              |              |            | S           | Unknown      |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |               |   |         |              |
|--|---------------|---|---------|--------------|
|  | Tramadol Base | S | Unknown | Not Reported |
|  | Valsartan     | S | Unknown | Not Reported |
|  | Lasilix       | S | Unknown | Not Reported |
|  | Seroplex      | S | Unknown | Not Reported |
|  | Pantoprazole  | C |         | Not Reported |

| <u>FDA Received Date</u>                                                      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|-------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 25-Mar-2016                                                                   | 12210818       | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000083426    |                      | 45 YR           | Female     | FRA            |
| <u>Preferred Term</u>                                                         | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Aneurysm; Arrhythmia;<br>Cardiac Arrest;<br>Electrocardiogram Qt<br>Prolonged | Escitalopram   |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest     |                |

| <u>FDA Received Date</u>                                                                                                                                                             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 25-Mar-2016                                                                                                                                                                          | 12211277       | EXPEDITED (15-DAY) |                    | CA              | US-FRI-1000083382    |                      |                 | Female     | USA            |
| <u>Preferred Term</u>                                                                                                                                                                | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Anal Atresia; Congenital<br>Pulmonary Hypertension;<br>Kidney Malformation;<br>Patent Ductus Arteriosus;<br>Tethered Cord Syndrome;<br>Vaginal Fistula; Ventricular<br>Septal Defect | Lexapro        |                    |                    | S               | Transplacental       |                      |                 | Forest     |                |

| <u>FDA Received Date</u>                                                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|-----------------|--------------|----------------|
| 25-Mar-2016                                                               | 12212053       | EXPEDITED (15-DAY) |                    | HO              | CH-ASTRAZENECA-<br>2016SE30259 |                      | 93 YR           | Female       | CHE            |
| <u>Preferred Term</u>                                                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;<br>Hyponatraemia;<br>Normochromic Normocytic<br>Anaemia | Nexium         |                    |                    | S               | Oral                           |                      |                 | Astrazeneca  |                |
|                                                                           | Cipralext      |                    |                    | S               | Oral                           |                      |                 | Not Reported |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                               |   |      |              |
|-------------------------------|---|------|--------------|
| Co Irbesan                    | S | Oral | Not Reported |
| Amlodipin                     | C | Oral | Not Reported |
| Seresta                       | C | Oral | Not Reported |
| Venoruton                     | C |      | Not Reported |
| Aspirin Cardio                | C | Oral | Not Reported |
| Novalgine (Metamizole Sodium) | C |      | Not Reported |
| Celecoxib                     | C | Oral | Not Reported |
| Furadantin                    | C | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 25-Mar-2016              | 12212370      | EXPEDITED (15-DAY) |                    | HO              | CA-TAKEDA-2016TUS002433AA |                      |            | Female     | CAN            |

| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Crying; Suicidal Ideation | Trintellix     |              |            | S           | Oral         | 10 Mg, Unk         |                 | Takeda       |
|                           | Escitalopram   |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                           | Clonazepam     |              |            | C           |              | Unk                |                 | Not Reported |
|                           | Amitriptyline  |              |            | C           |              | Unk                |                 | Not Reported |
|                           | Seroquel       |              |            | C           |              | Unk                |                 | Not Reported |
|                           | Lorazepam      |              |            | C           |              | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 28-Mar-2016              | 12207624      | NON-EXPEDITED    |                    | HO, LT, OT      | US-MDT-ADR-2016-00550 |                      | 71 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Sedation Complication | Compounded Baclofen      |              |            | S           | Intrathecal  | 195.14 Mcg/Day     |                 | Not Reported |
|                       | Dilaudid (Hydromorphone) |              |            | S           | Intrathecal  | 9.006 Mg/Day       |                 | Not Reported |
|                       | Dilaudid (Hydromorphone) |              |            | S           | Intrathecal  | 12.008mg/Day       |                 | Not Reported |
|                       | Cymbalta                 |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Escitalopram             |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Baclofen                 |              |            | S           | Oral         |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                     |   |             |               |
|---------------------|---|-------------|---------------|
| Norco               | S | Oral        | Not Reported  |
| Lasix               | S | Oral        | Not Reported  |
| Ondansetron         | S | Oral        | Not Reported  |
| Compounded Baclofen | S | Intrathecal | 360.18mcg/Day |
| Gabapentin          | S | Oral        | Not Reported  |

| <u>FDA Received Date</u>    | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------|-------------------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 28-Mar-2016                 | 12213929                      | EXPEDITED (15-DAY) |                    | OT              | GB-ACTAVIS-2016-06247 |                      |                 | Female       | GBR            |
| <u>Preferred Term</u>       | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Emotional Distress;         | Escitalopram (Unknown)        |                    |                    | S               | Unknown               | Unk                  |                 | Not Reported |                |
| Suicidal Ideation; Tinnitus | Quetiapine Fumarate (Unknown) |                    |                    | S               | Unknown               | Unk                  |                 | Actavis      |                |

| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------|--------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 28-Mar-2016                | 12213932                 | EXPEDITED (15-DAY) |                    | LT, OT          | ES-WATSON-2016-06488 |                      | 85 YR           | Female       | ESP            |
| <u>Preferred Term</u>      | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bundle Branch Block Left;  | Metoclopramide (Unknown) |                    |                    | S               | Unknown              | Unk                  |                 | Watson       |                |
| Cardio-Respiratory Arrest; | Metoclopramide (Unknown) |                    |                    | S               |                      |                      |                 | Watson       |                |
| Electrocardiogram Qt       | Amiodarone (Unknown)     |                    |                    | S               | Unknown              | Unk                  |                 | Not Reported |                |
| Prolonged; Torsade De      | Escitalopram (Unknown)   |                    |                    | S               | Unknown              | Unk                  |                 | Not Reported |                |
| Pointes                    | Losartan                 |                    |                    | C               | Unknown              | Unk                  |                 | Not Reported |                |
|                            | Betahistine              |                    |                    | C               | Unknown              | Unk                  |                 | Not Reported |                |
|                            | Simvastatin              |                    |                    | C               | Unknown              | Unk                  |                 | Not Reported |                |
|                            | Bisoprolol               |                    |                    | C               | Unknown              | Unk                  |                 | Not Reported |                |
|                            | Acenocoumarol            |                    |                    | C               | Unknown              | Unk                  |                 | Not Reported |                |
|                            | Metformin                |                    |                    | C               | Unknown              | Unk                  |                 | Not Reported |                |
|                            | Ferrous Sulfate          |                    |                    | C               | Unknown              | Unk                  |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                               | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------|-----------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
| 28-Mar-2016                                                                                                                            | 12214228        | EXPEDITED (15-DAY) |                    | HO              | IT-MYLANLABS-2016M1012543 |                      |                 | Unknown      | ITA            |
| <u>Preferred Term</u>                                                                                                                  | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bradyphrenia; Drug Abuse; Intentional Overdose; Sopor                                                                                  | Escitalopram    |                    |                    | S               |                           | 100 Mg, Total        |                 | Not Reported |                |
|                                                                                                                                        | Flurazepam      |                    |                    | S               | Oral                      | 150 Mg, Total        |                 | Mylan        |                |
| <u>FDA Received Date</u>                                                                                                               | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Mar-2016                                                                                                                            | 12214389        | EXPEDITED (15-DAY) |                    | LT, OT          | ES-TEVA-647343ISR         |                      | 85 YR           | Female       | ESP            |
| <u>Preferred Term</u>                                                                                                                  | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bundle Branch Block Left; Cardio-Respiratory Arrest; Electrocardiogram Qt Prolonged; Hypokalaemia; Hypomagnesaemia; Torsade De Pointes | Escitalopram    |                    |                    | S               |                           |                      |                 | Ivax         |                |
|                                                                                                                                        | Metoclopramide  |                    |                    | S               |                           |                      |                 | Not Reported |                |
|                                                                                                                                        | Metoclopramide  |                    |                    | S               |                           |                      |                 | Not Reported |                |
|                                                                                                                                        | Amiodarone      |                    |                    | S               |                           |                      |                 | Not Reported |                |
|                                                                                                                                        | Losartan        |                    |                    | C               |                           |                      |                 | Not Reported |                |
|                                                                                                                                        | Betahistine     |                    |                    | C               |                           |                      |                 | Not Reported |                |
|                                                                                                                                        | Simvastatin     |                    |                    | C               |                           |                      |                 | Not Reported |                |
|                                                                                                                                        | Bisoprolol      |                    |                    | C               |                           |                      |                 | Not Reported |                |
|                                                                                                                                        | Acenocoumarol   |                    |                    | C               |                           |                      |                 | Not Reported |                |
|                                                                                                                                        | Metformin       |                    |                    | C               |                           |                      |                 | Not Reported |                |
|                                                                                                                                        | Ferrous Sulfate |                    |                    | C               |                           |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                               | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Mar-2016                                                                                                                            | 12217878        | DIRECT             | Y                  |                 |                           |                      | 57 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                  | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Nightmare                                                                                                                              | Escitalopram    |                    |                    | S               | Oral                      |                      |                 | Camber       |                |
|                                                                                                                                        | Victoza         |                    |                    | C               |                           |                      |                 | Not Reported |                |
|                                                                                                                                        | Tizanidine      |                    |                    | C               |                           |                      |                 | Not Reported |                |
|                                                                                                                                        | Pioglitazone    |                    |                    | C               |                           |                      |                 | Not Reported |                |
|                                                                                                                                        | Montelukast     |                    |                    | C               |                           |                      |                 | Not Reported |                |
|                                                                                                                                        | Metformin       |                    |                    | C               |                           |                      |                 | Not Reported |                |
|                                                                                                                                        | Levemir         |                    |                    | C               |                           |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|             |   |              |
|-------------|---|--------------|
| Latanoprost | C | Not Reported |
| Advair      | C | Not Reported |
| Baclofen    | C | Not Reported |
| Coreg       | C | Not Reported |
| Crestor     | C | Not Reported |
| Docusate    | C | Not Reported |
| Fluticasone | C | Not Reported |
| Furosemide  | C | Not Reported |
| Gabapentin  | C | Not Reported |
| Glimepiride | C | Not Reported |
| Norco       | C | Not Reported |
| Invokana    | C | Not Reported |
| Januvia     | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------------------|----------------------|------------|------------|----------------|
| 29-Mar-2016              | 12194788      | EXPEDITED (15-DAY) |                    | HO, LT, OT      | ZA-<br>GLAXOSMITHKLINE-<br>ZA2016GSK039240 |                      | 47 YR      | Female     | ZAF            |

| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>      |
|---------------------------|----------------|--------------|------------|-------------|--------------|---------------------------------------|-----------------|-----------------|
| Overdose; Suicide Attempt | Wellbutrin XL  |              |            | S           | Oral         | 300 Mg, Daily For The<br>Past 3 Years |                 | Glaxosmithkline |
|                           | Trazadone      |              |            | S           | Oral         | 150 Mg, Daily For The<br>Past 3 Years |                 | Not Reported    |
|                           | Lexamil        |              |            | S           | Oral         | 10 Mg, Daily For The Past<br>3 Years  |                 | Not Reported    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Mar-2016              | 12216289      | EXPEDITED (15-DAY) |                    | HO, LT, OT      | ES-HOSPIRA-3228942   |                      | 84 YR      | Female     | ESP            |

| <u>Preferred Term</u>                                                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                             | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|------------------------------------------|--------------------|-----------------|--------------|
| Electrocardiogram Qt<br>Prolonged; Hypokalaemia;<br>Hypomagnesaemia;<br>Torsade De Pointes | Solifenacin    |              |            | S           | Intravenous (not<br>otherwise specified) |                    |                 | Not Reported |
|                                                                                            | Furosemide     |              |            | C           |                                          |                    |                 | Not Reported |
|                                                                                            | Digoxin        |              |            | S           |                                          |                    |                 | Not Reported |
|                                                                                            | Levofloxacin   |              |            | S           |                                          |                    |                 | Not Reported |
|                                                                                            | Amiodarone     |              |            | S           |                                          |                    |                 | Not Reported |
|                                                                                            | Sulpiride      |              |            | S           |                                          |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                |                              | Escitalopram       |                    | S               |                                            |                      |                 |              | Not Reported   |
|----------------------------------------------------------------|------------------------------|--------------------|--------------------|-----------------|--------------------------------------------|----------------------|-----------------|--------------|----------------|
|                                                                |                              | Candesartan        |                    | C               |                                            |                      |                 |              | Not Reported   |
|                                                                |                              | Acenocoumarol      |                    | C               |                                            |                      |                 |              | Not Reported   |
|                                                                |                              | Simvastatin        |                    | C               |                                            |                      |                 |              | Not Reported   |
| <u>FDA Received Date</u>                                       | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Mar-2016                                                    | 12218007                     | EXPEDITED (15-DAY) |                    | HO              | IT-TEVA-646318ACC                          |                      | 48 YR           | Male         | ITA            |
| <u>Preferred Term</u>                                          | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bradyphrenia; Drug Abuse; Product Administration Error; Sopor  | Escitalopram Oxalate         |                    |                    | S               |                                            | 100 Mg Total         |                 | Ivax         |                |
|                                                                | Flurazepam Monohydrochloride |                    |                    | S               | Oral                                       | 150 Mg Total         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Mar-2016                                                    | 12218180                     | EXPEDITED (15-DAY) |                    | HO              | FR-TAKEDA-2016TEU002081                    |                      | 85 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                          | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Inappropriate Antidiuretic Hormone Secretion                   | Ogastoro                     |                    |                    | S               | Oral                                       | Unk                  |                 | Takeda       |                |
|                                                                | Ideos                        |                    |                    | S               | Unknown                                    | Unk                  |                 | Not Reported |                |
|                                                                | Pariet                       |                    |                    | S               | Unknown                                    | Unk                  |                 | Not Reported |                |
|                                                                | Coaprovel                    |                    |                    | S               | Unknown                                    | Unk                  |                 | Not Reported |                |
|                                                                | Lercan                       |                    |                    | S               | Unknown                                    | Unk                  |                 | Not Reported |                |
|                                                                | Seroplex                     |                    |                    | S               | Unknown                                    | Unk                  |                 | Not Reported |                |
|                                                                | Temesta /00273201/           |                    |                    | C               | Oral                                       | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Mar-2016                                                    | 12219079                     | EXPEDITED (15-DAY) |                    | HO              | AU-IMPAX LABORATORIES, INC-2016-IPXL-00179 |                      | 70 YR           | Female       | AUS            |
| <u>Preferred Term</u>                                          | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Inappropriate Antidiuretic Hormone Secretion | Bupropion Hydrochloride Sr   |                    |                    | S               | Oral                                       | 75 Mg, Unk           |                 | Impax        |                |
|                                                                | Dothiepin Hydrochloride      |                    |                    | S               | Unknown                                    | Unk                  |                 | Not Reported |                |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                         |   |         |               |              |
|-------------------------|---|---------|---------------|--------------|
| Dothiepin Hydrochloride | S | Unknown | 225 Mg, Unk   | Not Reported |
| Dothiepin Hydrochloride | S | Unknown | 175 Mg, Unk   | Not Reported |
| Escitalopram            | S | Unknown | 30 Mg, Daily  | Not Reported |
| Lamotrigine             | C | Unknown | 75 Mg, 2 /Day | Not Reported |
| Oestradiol              | C | Unknown | Unk           | Not Reported |
| Ramipril                | C | Unknown | Unk           | Not Reported |
| Glipizide               | C | Unknown | Unk           | Not Reported |
| Metformin               | C | Unknown | Unk           | Not Reported |
| Atorvastatin            | C | Unknown | Unk           | Not Reported |
| Lantus                  | C | Unknown | Unk           | Not Reported |
| Aspirin                 | C | Unknown | Unk           | Not Reported |
| Norfloxacin             | S | Unknown | 400 Mg, Daily | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 29-Mar-2016              | 12219339      | EXPEDITED (15-DAY) |                    | LT, OT          | ES-BAUSCH-BL-2016-007173 |                      | 85 YR      | Female     | ESP            |

| <u>Preferred Term</u>                                                                                                                                 | <u>Product</u>  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Bundle Branch Block Left;<br>Cardio-Respiratory Arrest;<br>Electrocardiogram Qt<br>Prolonged; Hypokalaemia;<br>Hypomagnesaemia;<br>Torsade De Pointes | Metoclopramide  |              |            | S           | Unknown      |                    |                 | Valeant      |
|                                                                                                                                                       | Metoclopramide  |              |            | S           |              |                    |                 | Valeant      |
|                                                                                                                                                       | Escitalopram    |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                                       | Amiodarone      |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                                       | Losartan        |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                       | Betahistine     |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                       | Simvastatin     |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                       | Bisoprolol      |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                       | Acenocoumarol   |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                       | Metformin       |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                       | Ferrous Sulfate |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 30-Mar-2016              | 11812043      | EXPEDITED (15-DAY) |                    | HO              | FR-JNJFOC-20151205280 |                      | 51 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                    |            |   |             |     |              |
|------------------------------------|------------|---|-------------|-----|--------------|
| Dyskinesia; Muscle Spasms; Myalgia | Xarelto    | S | Oral        |     | Not Reported |
|                                    | Pazopanib  | S | Oral        |     | Not Reported |
|                                    | Durogesic  | S | Transdermal | 200 | Not Reported |
|                                    | Actiskenan | S | Oral        |     | Not Reported |
|                                    | Lyrica     | S | Oral        |     | Not Reported |
|                                    | Laroxyl    | S | Oral        |     | Not Reported |
|                                    | Seroplex   | S | Oral        |     | Not Reported |

| <u>FDA Received Date</u>                                                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|-------------------------|-----------------|--------------|----------------|
| 30-Mar-2016                                                                           | 11859339       | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000081819    |                         | 93 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Bradypnoea; Depressed Level Of Consciousness; Disorientation; Hypotension; Somnolence | Escitalopram   |                    |                    | S               |                      | Daily Dose Not Reported |                 | Forest       |                |
|                                                                                       | Mianserine     |                    |                    | S               |                      | Daily Dose Not Reported |                 | Not Reported |                |
|                                                                                       | Alprazolam     |                    |                    | S               |                      | Daily Dose Not Reported |                 | Not Reported |                |
|                                                                                       | Pregabalin     |                    |                    | S               |                      | Daily Dose Not Reported |                 | Not Reported |                |
|                                                                                       | Tramadol Base  |                    |                    | S               |                      | Daily Dose Not Reported |                 | Not Reported |                |
|                                                                                       | Valsartan      |                    |                    | S               |                      | Daily Dose Not Reported |                 | Not Reported |                |
|                                                                                       | Lasilix        |                    |                    | S               |                      | Daily Dose Not Reported |                 | Not Reported |                |
|                                                                                       | Pantoprazole   |                    |                    | C               |                      | Daily Dose Not Reported |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                        | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------|-----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 30-Mar-2016                                                                                                     | 11893342        | EXPEDITED (15-DAY) |                    | HO              | JP-FRI-1000082049    |                      | 60 YR           | Female       | JPN            |
| <u>Preferred Term</u>                                                                                           | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Altered State Of Consciousness; Electrocardiogram Qt Prolonged; Hepatic Steatosis; Parkinsonism; Rhabdomyolysis | Lexapro         |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                                                                                                 | Amoxan          |                    |                    | C               | Oral                 | 30 Mg                |                 | Not Reported |                |
|                                                                                                                 | Meilax          |                    |                    | C               | Oral                 | 3 Mg                 |                 | Not Reported |                |
|                                                                                                                 | Magnesium Oxide |                    |                    | C               | Oral                 | 1980 Mg              |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 30-Mar-2016                                                                                                                                              | 11895922       | EXPEDITED (15-DAY) |                    | HO, OT          | FR-PFIZER INC-2015423120 |                      | 51 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bone Marrow Tumour Cell Infiltration; Dyskinesia; Muscle Spasms; Myalgia; Paraplegia; Phlebitis; Pulmonary Embolism; Renal Failure; Ureteric Obstruction | Lyrica         |                    |                    | S               | Oral                     | Unk                  |                 | Pfizer       |                |
|                                                                                                                                                          | Votrient       |                    |                    | S               | Oral                     | 400 Mg, 1x/Day       |                 | Not Reported |                |
|                                                                                                                                                          | Durogesic      |                    |                    | S               | Transdermal              | 200 Daily            |                 | Not Reported |                |
|                                                                                                                                                          | Actiskenan     |                    |                    | S               | Oral                     | Unk                  |                 | Not Reported |                |
|                                                                                                                                                          | Laroxyl        |                    |                    | S               | Oral                     | Unk                  |                 | Not Reported |                |
|                                                                                                                                                          | Xarelto        |                    |                    | S               | Oral                     | 10 Mg, 1x/Day        |                 | Not Reported |                |
|                                                                                                                                                          | Seroplex       |                    |                    | S               | Oral                     | 10 Mg, 1x/Day        |                 | Not Reported |                |

| <u>FDA Received Date</u>                                    | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------|-------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 30-Mar-2016                                                 | 12159787          | EXPEDITED (15-DAY) |                    | HO, LT          | JP-FRI-1000082992    |                      | 47 YR           | Female       | JPN            |
| <u>Preferred Term</u>                                       | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depressed Level Of Consciousness; Overdose; Suicide Attempt | Lexapro           |                    |                    | S               | Oral                 |                      |                 | Forest       |                |
|                                                             | Lexapro           |                    |                    | S               | Oral                 | Overdose: 300 Mg     |                 | Forest       |                |
|                                                             | Flunitrazepam     |                    |                    | S               | Oral                 | 2 Mg                 |                 | Not Reported |                |
|                                                             | Flunitrazepam     |                    |                    | S               | Oral                 | Overdose: 36 Mg      |                 | Not Reported |                |
|                                                             | Ethyl Loflazepate |                    |                    | S               | Oral                 | 2 Mg                 |                 | Not Reported |                |
|                                                             | Ethyl Loflazepate |                    |                    | S               | Oral                 | Overdose: 34 Mg      |                 | Not Reported |                |
|                                                             | Gasmotin          |                    |                    | S               | Oral                 | 5 Mg                 |                 | Not Reported |                |
|                                                             | Gasmotin          |                    |                    | S               | Oral                 | Overdose: 150 Mg     |                 | Not Reported |                |
|                                                             | Podonin-S         |                    |                    | S               | Oral                 | 0.5 Mg               |                 | Not Reported |                |
|                                                             | Podonin-S         |                    |                    | S               | Oral                 | Overdose: 15 Mg      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 30-Mar-2016              | 12193452      | EXPEDITED (15-DAY) |                    | LT              | FR-B.I. PHARMACEUTICALS,I |                      | 65 YR      | Female     | FRA            |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

NC./RIDGEFIELD-2016-  
BI-16

| <u>Preferred Term</u>                              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>           |
|----------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------|
| Acute Respiratory Distress Syndrome; Lung Disorder | Sifrol         |              |            | S           | Oral         | 1.05 Mg            |                 | Boehringer Ingelheim |
|                                                    | Apokinin       |              |            | S           | Subcutaneous |                    |                 | Not Reported         |
|                                                    | Mantadix       |              |            | S           | Oral         | 100 Mg             |                 | Not Reported         |
|                                                    | Sinemet        |              |            | S           | Oral         | 1250 Anz           |                 | Not Reported         |
|                                                    | Modopar        |              |            | S           | Oral         | Strength: 125      |                 | Not Reported         |
|                                                    | Seroplex       |              |            | S           | Oral         | 15 Mg              |                 | Not Reported         |
|                                                    | Imovane        |              |            | S           | Oral         | 7.5 Mg             |                 | Not Reported         |
|                                                    | Azilect        |              |            | S           | Oral         | 1 Mg               |                 | Not Reported         |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 30-Mar-2016              | 12213258      | NON-EXPEDITED    |                    | DE, OT          | US-JNJFOC-20160314012 |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>     | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|-------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abdominal Pain; Acidosis; | Tylenol                       |              | Y          | S           | Unknown      |                    |                 | Not Reported |
| Anion Gap Increased;      | Tylenol                       |              |            | S           | Unknown      |                    |                 | Not Reported |
| Arrhythmia; Blood         | Benadryl                      |              | Y          | S           | Unknown      |                    |                 | Not Reported |
| Creatine Phosphokinase    | Motrin                        |              | Y          | S           | Unknown      |                    |                 | Not Reported |
| Increased; Blood          | Motrin                        |              |            | S           | Unknown      |                    |                 | Not Reported |
| Creatinine Increased;     | Pseudoephedrine Hydrochloride |              | Y          | S           | Unknown      |                    |                 | Not Reported |
| Bradycardia; Cardiac      | Ibuprofen                     |              | Y          | S           | Unknown      |                    |                 | Not Reported |
| Arrest; Cardiac Arrest;   | Ibuprofen                     |              |            | S           | Unknown      |                    |                 | Not Reported |
| Coma; Conduction          | Aspirin                       |              |            | S           | Unknown      |                    |                 | Not Reported |
| Disorder; Confusional     | Seroquel                      |              |            | S           | Unknown      |                    |                 | Not Reported |
| State; Cyanosis;          | Adderall                      |              |            | S           | Unknown      |                    |                 | Not Reported |
| Diarrhoea; Dizziness;     | Amitriptyline                 |              |            | S           | Unknown      |                    |                 | Not Reported |
| Electrocardiogram         |                               |              |            |             |              |                    |                 |              |
| Change; Hyperglycaemia;   |                               |              |            |             |              |                    |                 |              |
| Hyperhidrosis;            |                               |              |            |             |              |                    |                 |              |
| Hypertension;             |                               |              |            |             |              |                    |                 |              |
| Hyperventilation;         |                               |              |            |             |              |                    |                 |              |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                                                                                |                                |   |         |              |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|---|---------|--------------|
| Hypotension; Intentional Self-Injury; Lethargy; Liver Function Test Abnormal; Mydriasis; Nausea; Non-Cardiac Chest Pain; Respiratory Arrest; Respiratory Depression; Seizure; Somnolence; Syncope; Tachycardia; Tachypnoea; Tinnitus; Vomiting; X-Ray Abnormal | Anafranil                      | S | Unknown | Not Reported |
|                                                                                                                                                                                                                                                                | Benicar                        | S | Unknown | Not Reported |
|                                                                                                                                                                                                                                                                | Cartia Xt                      | S | Unknown | Not Reported |
|                                                                                                                                                                                                                                                                | Depakote                       | S | Unknown | Not Reported |
|                                                                                                                                                                                                                                                                | Effexor                        | S | Unknown | Not Reported |
|                                                                                                                                                                                                                                                                | All Other Therapeutic Products | S | Unknown | Not Reported |
|                                                                                                                                                                                                                                                                | Flecainide                     | S | Unknown | Not Reported |
|                                                                                                                                                                                                                                                                | Flexeril                       | S | Unknown | Not Reported |
|                                                                                                                                                                                                                                                                | Geodon                         | S | Unknown | Not Reported |
|                                                                                                                                                                                                                                                                | Lamictal                       | S | Unknown | Not Reported |
|                                                                                                                                                                                                                                                                | Lexapro                        | S | Unknown | Not Reported |
|                                                                                                                                                                                                                                                                | Methadone                      | S | Unknown | Not Reported |
|                                                                                                                                                                                                                                                                | Methamphetamine                | S | Unknown | Not Reported |
|                                                                                                                                                                                                                                                                | Opioids                        | S | Unknown | Not Reported |
|                                                                                                                                                                                                                                                                | Paxil                          | S | Unknown | Not Reported |
|                                                                                                                                                                                                                                                                | Potassium                      | S | Unknown | Not Reported |
|                                                                                                                                                                                                                                                                | Trazodone                      | S | Unknown | Not Reported |
|                                                                                                                                                                                                                                                                | Strattera                      | S | Unknown | Not Reported |
|                                                                                                                                                                                                                                                                | Wellbutrin                     | S | Unknown | Not Reported |
|                                                                                                                                                                                                                                                                | Vicodin                        | S | Unknown | Not Reported |
|                                                                                                                                                                                                                                                                | Xanax                          | S | Unknown | Not Reported |

| <u>FDA Received Date</u>         | <u>Case #</u>                                    | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|----------------------------------|--------------------------------------------------|------------------|--------------------|-----------------|------------------------------------------------|----------------------|-----------------|------------|----------------|
| 30-Mar-2016                      | 12220119                                         | NON-EXPEDITED    |                    |                 | US-LUPIN<br>PHARMACEUTICALS<br>INC.-2015-04518 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>            | <u>Product</u>                                   | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Feeling Abnormal;<br>Hypersomnia | Duloxetine Delayed-Release 30<br>Mg Capsules Usp |                  |                    | S               | Oral                                           |                      |                 |            | Not Reported   |
|                                  | Duloxetine Delayed-Release 30<br>Mg Capsules Usp |                  |                    | S               | Oral                                           |                      |                 |            | Not Reported   |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                        |   |         |              |
|------------------------|---|---------|--------------|
| Lexapro                | S | Unknown | Not Reported |
| Women'S Centrum Silver | C | Unknown | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------------------------------------|----------------------|------------|------------|----------------|
| 30-Mar-2016              | 12220254      | EXPEDITED (15-DAY) |                    | LT, OT          | ES-MACLEODS<br>PHARMACEUTICALS<br>US LTD-<br>MAC2016002563 |                      |            | Unknown    | ESP            |

| <u>Preferred Term</u>                                                                                                                                 | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Bundle Branch Block Left;<br>Cardio-Respiratory Arrest;<br>Electrocardiogram Qt<br>Prolonged; Hypokalaemia;<br>Hypomagnesaemia;<br>Torsade De Pointes | Escitalopram Oxalate    |              |            | S           | Unknown      | Unk                |                 | Macleods     |
|                                                                                                                                                       | Metoclopramide          |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                                                                                                                                                       | Metoclopramide          |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                       | Amiodarone              |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                                       | Metformin Hydrochloride |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                                       | Losartan Potassium      |              |            | C           | Unknown      |                    |                 | Macleods     |
|                                                                                                                                                       | Betahistine             |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                                       | Simvastatin             |              |            | C           | Unknown      | Unk                |                 | Not Reported |
|                                                                                                                                                       | Bisoprolol              |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                                       | Acenocoumarol           |              |            | C           | Unknown      |                    |                 | Not Reported |
| Ferrous Sulfate                                                                                                                                       |                         |              | C          | Unknown     |              |                    | Not Reported    |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------------------------|----------------------|------------|------------|----------------|
| 30-Mar-2016              | 12220426      | EXPEDITED (15-DAY) |                    | HO, LT, OT      | ES-MACLEODS<br>PHARMA UK LTD-<br>MAC2016002564 |                      |            | Unknown    | ESP            |

| <u>Preferred Term</u>                                                                                                                                              | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                             | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|------------------------------------------|--------------------|-----------------|--------------|
| Electrocardiogram Qt<br>Prolonged;<br>Haemodynamic Instability;<br>Hypokalaemia;<br>Hypomagnesaemia;<br>Syncope; Torsade De<br>Pointes; Ventricular<br>Tachycardia | Escitalopram Oxalate |              |            | S           | Unknown                                  | Unk                |                 | Macleods     |
|                                                                                                                                                                    | Levofloxacin         |              |            | S           | Unknown                                  | Unk                |                 | Macleods     |
|                                                                                                                                                                    | Sulpiride            |              |            | S           | Unknown                                  | Unk                |                 | Not Reported |
|                                                                                                                                                                    | Solifenacin          |              |            | S           | Unknown                                  | Unk                |                 | Not Reported |
|                                                                                                                                                                    | Amiodarone           |              |            | S           | Intravenous (not<br>otherwise specified) | Unk                |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|               |   |         |     |              |
|---------------|---|---------|-----|--------------|
| Digoxin       | S | Unknown | Unk | Not Reported |
| Candesartan   | C | Unknown | Unk | Not Reported |
| Furosemide    | C | Unknown | Unk | Not Reported |
| Acenocoumarol | C | Unknown | Unk | Not Reported |
| Simvastatin   | C | Unknown | Unk | Not Reported |

| <u>FDA Received Date</u>                                                                                             | <u>Case #</u>                                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>        | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------|------------------------------------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|-------------------|----------------|
| 30-Mar-2016                                                                                                          | 12220979                                       | EXPEDITED (15-DAY) |                    | OT              | US-ACTAVIS-2016-06695 |                      | 71 YR           | Female            | USA            |
| <u>Preferred Term</u>                                                                                                | <u>Product</u>                                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>        |                |
| Agitation; Condition Aggravated; Dystonia; Hallucinations, Mixed; Therapeutic Response Unexpected; Unevaluable Event | Escitalopram (Unknown)                         |                    |                    | S               | Unknown               | Unk                  |                 | Not Reported      |                |
|                                                                                                                      | Duloxetine Hydrochloride (Aellc)               |                    |                    | S               | Unknown               | Unk                  |                 | Actavis Elizabeth |                |
|                                                                                                                      | Fluoxetine Hydrochloride (Watson Laboratories) |                    |                    | S               | Unknown               | 30 Mg, Unk           |                 | Watson            |                |
|                                                                                                                      | Fluvoxamine Maleate (Aellc)                    |                    |                    | S               | Unknown               | 25 Mg, Daily         |                 | Watson            |                |
|                                                                                                                      | Venlafaxine (Unknown)                          |                    |                    | S               | Unknown               | Unk                  |                 | Not Reported      |                |
|                                                                                                                      | Quetiapine (Agptc)                             |                    |                    | S               | Unknown               | Unk                  |                 | Actavis           |                |
|                                                                                                                      | Donepezil Hydrochloride (Apmp)                 |                    |                    | S               | Unknown               | Unk                  |                 | Actavis           |                |
|                                                                                                                      | Olanzapine (Unknown)                           |                    |                    | S               | Unknown               | Unk                  |                 | Not Reported      |                |
|                                                                                                                      | Sertraline                                     |                    |                    | C               | Unknown               | Unk                  |                 | Not Reported      |                |
|                                                                                                                      | Memantine                                      |                    |                    | C               | Unknown               | Unk                  |                 | Not Reported      |                |

| <u>FDA Received Date</u>                                                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------------------|-----------------|--------------|----------------|
| 30-Mar-2016                                                               | 12222083       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000083522    |                                  | 45 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Coma; Suicide Attempt; Tonic Clonic Movements; Toxicity To Various Agents | Escitalopram   |                    |                    | S               | Oral                 | Only One Intake (Doses Unknown). |                 | Forest       |                |
|                                                                           | Baclofene      |                    |                    | S               | Oral                 | Only One Intake (Doses Unknown). |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                     | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>                             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|------------------------------------------|--------------------------------------------------|-----------------|--------------|----------------|
| 30-Mar-2016                                                                                  | 12223662                    | EXPEDITED (15-DAY) |                    | OT              | GB-MYLANLABS-2016M1012322                |                                                  |                 | Unknown      | GBR            |
| <u>Preferred Term</u>                                                                        | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>                               | <u>Duration</u> | <u>Mfr</u>   |                |
| Emotional Distress;<br>Suicidal Ideation; Tinnitus                                           | Escitalopram                |                    |                    | S               |                                          | Unk                                              |                 | Not Reported |                |
|                                                                                              | Quetiapine                  |                    |                    | S               |                                          | Unk                                              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                     | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>                             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Mar-2016                                                                                  | 12224196                    | EXPEDITED (15-DAY) |                    | DS              | NO-FRI-1000083461                        |                                                  | 35 YR           | Male         | NOR            |
| <u>Preferred Term</u>                                                                        | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>                               | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain Upper;<br>Asthenia; Insomnia;<br>Nausea; Pain; Sleep<br>Disorder; Yellow Skin | Escitalopram                |                    |                    | S               | Unknown                                  |                                                  |                 | Forest       |                |
|                                                                                              | Escitalopram                |                    |                    | S               | Unknown                                  | 180 G                                            |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                     | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>                             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Mar-2016                                                                                  | 12228415                    | DIRECT             | Y                  | HO              |                                          |                                                  | 57 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                        | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>                               | <u>Duration</u> | <u>Mfr</u>   |                |
| Renal Failure; Toxicity To<br>Various Agents                                                 | Vancomycin                  |                    |                    | S               | Intravenous (not<br>otherwise specified) | 2 G Bid Intravenous (Not<br>Otherwise Specified) | 11 DAY          | Not Reported |                |
|                                                                                              | Atorvastatin                |                    |                    | C               |                                          |                                                  |                 | Not Reported |                |
|                                                                                              | Cyclobenzaprine             |                    |                    | C               |                                          |                                                  |                 | Not Reported |                |
|                                                                                              | Enalapril                   |                    |                    | C               |                                          |                                                  |                 | Not Reported |                |
|                                                                                              | Escitalopram                |                    |                    | S               |                                          |                                                  |                 | Not Reported |                |
|                                                                                              | Acetaminophen\Hydrocodone   |                    |                    | C               |                                          |                                                  |                 | Not Reported |                |
|                                                                                              | Bitartrate<br>Mydromorphone |                    |                    | C               |                                          |                                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                     | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>                             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-Mar-2016                                                                                  | 10554493                    | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2014298019                 |                                                  |                 | Female       | USA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u> | <u>Product</u>   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Hypersensitivity | Effexor          |              |            | S           |              | Unk                |                 | Pfizer       |
|                       | Morphine Sulfate |              |            | S           |              | Unk                |                 | Pfizer       |
|                       | Ativan           |              |            | S           |              | Unk                |                 | Pfizer       |
|                       | Keflex           |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Lexapro          |              |            | S           |              | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-Mar-2016              | 10950824      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000075415    |                      | 94 YR      | Male       | FRA            |

| <u>Preferred Term</u> | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|------------------------|--------------|------------|-------------|--------------|---------------------------------|-----------------|--------------|
| Subdural Haematoma    | Escitalopram           |              |            | S           | Oral         | 1 Df                            |                 | Forest       |
|                       | Previscan (Fluindione) |              |            | S           |              | 0.5 Mg                          |                 | Not Reported |
|                       | Tahor                  |              |            | C           | Oral         | 1 Df                            |                 | Not Reported |
|                       | Seresta                |              |            | C           | Oral         | 1 Df                            |                 | Not Reported |
|                       | Dafalgan               |              |            | C           | Oral         | On Request (Up To 4 Tab. Daily) |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 31-Mar-2016              | 12223681      | EXPEDITED (15-DAY) |                    | HO, OT          | IT-MYLANLABS-2016M1013042 |                      |            | Unknown    | ITA            |

| <u>Preferred Term</u>                                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Foetal Exposure During Pregnancy; Neonatal Tachypnoea | Lorazepam      |              |            | S           | Transplacental | 0.25 Mg, Qd        |                 | Not Reported |
|                                                       | Escitalopram   |              |            | S           | Transplacental | 5 Gtt, Qd          |                 | Not Reported |
|                                                       | Adalat         |              |            | S           | Transplacental | 60 Mg, Qd          |                 | Mylan        |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-Mar-2016              | 12224564      | EXPEDITED (15-DAY) |                    | OT              | GB-ACCORD-039210     |                      |            | Female     | GBR            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                   |                                                |                    |                    |                 |                                                 |                                           |                 |                                                  |                  |
|-----------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|-------------------------------------------|-----------------|--------------------------------------------------|------------------|
| Emotional Distress;<br>Suicidal Ideation; Tinnitus                                                                                | Escitalopram<br>Quetiapine                     |                    |                    | S<br>S          |                                                 |                                           |                 |                                                  | Accord<br>Accord |
| <u>FDA Received Date</u>                                                                                                          | <u>Case #</u>                                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                      | <u>Age</u>      | <u>Sex</u>                                       | <u>Country</u>   |
| 31-Mar-2016                                                                                                                       | 12224577                                       | EXPEDITED (15-DAY) |                    | OT              | GB-ALKEM-001550                                 |                                           |                 | Female                                           | GBR              |
| <u>Preferred Term</u>                                                                                                             | <u>Product</u>                                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                        | <u>Duration</u> | <u>Mfr</u>                                       |                  |
| Emotional Distress;<br>Suicidal Ideation; Tinnitus                                                                                | Quetiapine/Quetiapine Fumarate<br>Escitalopram |                    |                    | S<br>S          |                                                 |                                           |                 | Alkem<br>Not Reported                            |                  |
| <u>FDA Received Date</u>                                                                                                          | <u>Case #</u>                                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                      | <u>Age</u>      | <u>Sex</u>                                       | <u>Country</u>   |
| 31-Mar-2016                                                                                                                       | 12225897                                       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000083618                               |                                           | 43 YR           | Male                                             | FRA              |
| <u>Preferred Term</u>                                                                                                             | <u>Product</u>                                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                        | <u>Duration</u> | <u>Mfr</u>                                       |                  |
| Tonic Convulsion                                                                                                                  | Escitalopram<br>Atarax                         |                    |                    | S<br>S          | Oral<br>Oral                                    | 5 Mg<br>25 Mg                             |                 | Forest<br>Not Reported                           |                  |
| <u>FDA Received Date</u>                                                                                                          | <u>Case #</u>                                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                      | <u>Age</u>      | <u>Sex</u>                                       | <u>Country</u>   |
| 31-Mar-2016                                                                                                                       | 12226316                                       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000083616                               |                                           | 77 YR           | Female                                           | FRA              |
| <u>Preferred Term</u>                                                                                                             | <u>Product</u>                                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                        | <u>Duration</u> | <u>Mfr</u>                                       |                  |
| Confusional State;<br>Hypertonia; Tremor                                                                                          | Escitalopram                                   |                    |                    | S               | Oral                                            |                                           |                 | Forest                                           |                  |
| <u>FDA Received Date</u>                                                                                                          | <u>Case #</u>                                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                      | <u>Age</u>      | <u>Sex</u>                                       | <u>Country</u>   |
| 31-Mar-2016                                                                                                                       | 12226378                                       | EXPEDITED (15-DAY) |                    | OT              | US-<br>ELI_LILLY_AND_COMP<br>ANY-US201603007950 |                                           | 62 YR           | Male                                             | USA              |
| <u>Preferred Term</u>                                                                                                             | <u>Product</u>                                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                        | <u>Duration</u> | <u>Mfr</u>                                       |                  |
| Device Occlusion; Gingival<br>Bleeding; Intervertebral<br>Disc Protrusion;<br>Myocardial Infarction;<br>Platelet Count Decreased; | Effient<br>Aspirin /00002701/<br>Lexapro       |                    |                    | S<br>S<br>S     | Unknown<br>Unknown<br>Unknown                   | 10 Mg, Qd<br>Unk, Unknown<br>Unk, Unknown |                 | Eli Lilly And Co<br>Not Reported<br>Not Reported |                  |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                    |                        |   |         |              |              |
|------------------------------------|------------------------|---|---------|--------------|--------------|
| Platelet Function Test<br>Abnormal | Buspar                 | S | Unknown | Unk, Unknown | Not Reported |
|                                    | Janumet                | C |         |              | Not Reported |
|                                    | Carvedilol             | C |         |              | Not Reported |
|                                    | Potassium              | C |         |              | Not Reported |
|                                    | Lyrica                 | C |         |              | Not Reported |
|                                    | Isosorbide Mononitrate | C |         |              | Not Reported |
|                                    | Lasix /00032601/       | C |         |              | Not Reported |
|                                    | Clonidine              | C |         |              | Not Reported |
|                                    | Losartan               | C |         |              | Not Reported |
|                                    | Lantus                 | C |         |              | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 31-Mar-2016              | 12226885      | NON-EXPEDITED    |                    |                 | US-<br>ELI_LILLY_AND_COMP<br>ANY-US201603010762 |                      | 39 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                      | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abdominal Discomfort;<br>Agitation; Chest Pain;<br>Diarrhoea; Dizziness;<br>Dyspepsia; Euphoric<br>Mood; Fatigue; Headache;<br>Hypersensitivity; Pain;<br>Sedation; Therapeutic<br>Reaction Time Decreased | Zyprexa           |              |            | S           | Unknown      | Unk, Unknown       |                 | Unknown      |
|                                                                                                                                                                                                            | Baclofen          |              |            | S           | Unknown      | Unk, Unknown       |                 | Not Reported |
|                                                                                                                                                                                                            | Carbatrol         |              |            | S           | Unknown      | Unk, Unknown       |                 | Not Reported |
|                                                                                                                                                                                                            | Daypro            |              |            | S           | Unknown      | Unk, Unknown       |                 | Not Reported |
|                                                                                                                                                                                                            | Escitalopram      |              |            | S           | Unknown      | Unk, Unknown       |                 | Not Reported |
|                                                                                                                                                                                                            | Eszopiclone       |              |            | S           | Unknown      | Unk, Unknown       |                 | Not Reported |
|                                                                                                                                                                                                            | Levoxyl           |              |            | S           | Unknown      | Unk, Unknown       |                 | Not Reported |
|                                                                                                                                                                                                            | Oxycodone         |              |            | S           | Unknown      | Unk, Unknown       |                 | Not Reported |
|                                                                                                                                                                                                            | Seroquel          |              |            | S           | Unknown      | Unk, Unknown       |                 | Not Reported |
|                                                                                                                                                                                                            | Ultram /00599202/ |              |            | S           | Unknown      | Unk, Unknown       |                 | Not Reported |
|                                                                                                                                                                                                            | Vicodin           |              |            | S           | Unknown      | Unk, Unknown       |                 | Not Reported |
|                                                                                                                                                                                                            | Wellbutrin        |              |            | S           | Unknown      | Unk, Unknown       |                 | Not Reported |
|                                                                                                                                                                                                            | Zantac            |              |            | S           | Unknown      | Unk, Unknown       |                 | Not Reported |
|                                                                                                                                                                                                            | Zithromax         |              |            | S           | Unknown      | Unk, Unknown       |                 | Not Reported |
|                                                                                                                                                                                                            | Zolpidem          |              |            | S           | Unknown      | Unk, Unknown       |                 | Not Reported |
|                                                                                                                                                                                                            | Sertraline        |              |            | C           | Unknown      | Unk, Unknown       |                 | Not Reported |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                          | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|-------------------------|-----------------|--------------|----------------|
| 31-Mar-2016                                       | 12227556       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000083615    |                         | 17 YR           | Female       | FRA            |
| <u>Preferred Term</u>                             | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Suicidal Behaviour;<br>Toxicity To Various Agents | Escitalopram   |                    |                    | S               | Oral                 | 5 Mg                    |                 | Forest       |                |
|                                                   | Escitalopram   |                    |                    | S               | Oral                 | 10 Mg                   |                 | Forest       |                |
|                                                   | Escitalopram   |                    |                    | S               | Oral                 | 15 Mg                   |                 | Not Reported |                |
|                                                   | Escitalopram   |                    |                    | S               | Oral                 | Overdose Of 600 Mg Once |                 | Not Reported |                |
| <u>FDA Received Date</u>                          | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Apr-2016                                       | 11822952       | EXPEDITED (15-DAY) |                    | HO              | PHHY2015FR160511     |                         | 51 YR           | Female       | FRA            |
| <u>Preferred Term</u>                             | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Dyskinesia; Muscle<br>Spasms; Myalgia             | Votrient       |                    |                    | S               | Oral                 | 400 Mg, Qd              |                 | Novartis     |                |
|                                                   | Durogesic      |                    |                    | S               | Transdermal          | 200 Ot, Unk             |                 | Not Reported |                |
|                                                   | Actiskenan     |                    |                    | S               | Oral                 | Unk                     |                 | Not Reported |                |
|                                                   | Lyrica         |                    |                    | S               | Oral                 | Unk                     |                 | Not Reported |                |
|                                                   | Laroxyl        |                    |                    | S               | Oral                 |                         |                 | Not Reported |                |
|                                                   | Xarelto        |                    |                    | S               | Oral                 | 10 Mg, Qd               |                 | Not Reported |                |
|                                                   | Seroplex       |                    |                    | S               | Oral                 | 10 Mg, Qd               |                 | Not Reported |                |
| <u>FDA Received Date</u>                          | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Apr-2016                                       | 11930502       | EXPEDITED (15-DAY) |                    |                 | BE-FRI-1000082116    |                         |                 | Unknown      | BEL            |
| <u>Preferred Term</u>                             | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Foetal Exposure During<br>Pregnancy               | Escitalopram   |                    |                    | S               | Transplacental       |                         |                 | Forest       |                |
| <u>FDA Received Date</u>                          | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Apr-2016                                       | 12227952       | NON-EXPEDITED      |                    |                 | US-TORRENT-00001141  |                         |                 | Female       | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                              | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|----------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|--------------|----------------|
| Off Label Use; Tinnitus                            | Escitalopram Tablets, Usp |                    |                    | S               | Oral                                            |                      |                 | Torrent      |                |
| <u>FDA Received Date</u>                           | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Apr-2016                                        | 12227983                  | EXPEDITED (15-DAY) |                    | OT              | GB-DRREDDYS-GER/UKI/16/0078246                  |                      |                 | Female       | GBR            |
| <u>Preferred Term</u>                              | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Emotional Distress;<br>Suicidal Ideation; Tinnitus | Quetiapine                |                    |                    | S               |                                                 |                      |                 | Not Reported |                |
|                                                    | Escitalopram Oxalate      |                    |                    | S               |                                                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                           | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Apr-2016                                        | 12228098                  | EXPEDITED (15-DAY) |                    | HO              | IT-ACCORD-039277                                |                      | 48 YR           | Male         | ITA            |
| <u>Preferred Term</u>                              | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bradyphrenia; Sopor                                | Escitalopram              |                    |                    | S               |                                                 |                      |                 | Accord       |                |
|                                                    | Flurazepam                |                    |                    | S               | Oral                                            |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                           | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Apr-2016                                        | 12231045                  | NON-EXPEDITED      |                    |                 | US-009507513-1603USA011907                      |                      |                 | Male         | USA            |
| <u>Preferred Term</u>                              | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective                                   | Remeron                   |                    |                    | S               | Oral                                            | Unk                  |                 | Merck        |                |
|                                                    | Trazodone Hydrochloride   |                    |                    | S               |                                                 |                      |                 | Not Reported |                |
|                                                    | Escitalopram              |                    |                    | S               |                                                 | Unk                  |                 | Not Reported |                |
|                                                    | Bupropion Hydrochloride   |                    |                    | S               |                                                 | Unk                  |                 | Not Reported |                |
|                                                    | Lamotrigine               |                    |                    | S               |                                                 |                      |                 | Not Reported |                |
|                                                    | Aripiprazole              |                    |                    | S               |                                                 | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                           | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Apr-2016                                        | 12232613                  | EXPEDITED (15-DAY) |                    | OT              | FR-VALIDUS PHARMACEUTICALS LLC-FR-2016VAL000680 |                      | 93 YR           | Female       | FRA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                 | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Bradypnoea; Depressed Level Of Consciousness; Disorientation; Hypotension; Somnolence | Furosemide              |              |            | S           |              | Unk                |                 | Validus      |
|                                                                                       | Mianserin Hydrochloride |              |            | S           |              | Unk                |                 | Not Reported |
|                                                                                       | Alprazolam              |              |            | S           |              | Unk                |                 | Not Reported |
|                                                                                       | Pregabalin              |              |            | S           |              | Unk                |                 | Not Reported |
|                                                                                       | Tramadol Hydrochloride  |              |            | S           |              | Unk                |                 | Not Reported |
|                                                                                       | Valsartan               |              |            | S           |              | Unk                |                 | Not Reported |
|                                                                                       | Seroplex                |              |            | S           |              | Unk                |                 | Not Reported |
|                                                                                       | Pantoprazole            |              |            | C           |              | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 04-Apr-2016              | 10238976      | EXPEDITED (15-DAY) |                    | OT              | US-009507513-1406USA006221 |                      |            | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Acute Sinusitis; Arthralgia; Attention Deficit/Hyperactivity Disorder; Carpal Tunnel Syndrome; Cholecystectomy; Conjunctivitis; Dermatitis Contact; Diarrhoea; Epididymitis; Erectile Dysfunction; Essential Hypertension; Generalised Anxiety Disorder; Hair Disorder; Headache; Hypertriglyceridaemia; Insomnia; Liver Function Test Abnormal; Loss Of Libido; Lyme Disease; Major Depression; Migraine; Obesity; Orchitis; Osteoarthritis; Palpitations; Panic Disorder; Plantar Fascial | Propecia       |              |            | S           | Oral         | 1 Mg, Qd           |                 | Merck        |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Lexapro        |              |            | S           | Unknown      | Unk                |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Fibromatosis; Pruritus;  
Rash; Sexual Dysfunction;  
Sexually Transmitted  
Disease; Skin Texture  
Abnormal; Tachycardia;  
Vitamin D Deficiency

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------|----------------------|------------|------------|----------------|
| 04-Apr-2016              | 12233465      | EXPEDITED (15-DAY) |                    | OT              | GB-AUROBINDO-AUR-<br>APL-2016-03998 |                      |            | Female     | GBR            |

| <u>Preferred Term</u>       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Emotional Distress;         | Escitalopram   |              |            | S           | Unknown      | Unk                |                 | Aurobindo  |
| Suicidal Ideation; Tinnitus | Quetiapine     |              |            | S           | Unknown      | Unk                |                 | Aurobindo  |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------------------------------------|----------------------|------------|------------|----------------|
| 04-Apr-2016              | 12233589      | EXPEDITED (15-DAY) |                    | OT              | ES-PAR<br>PHARMACEUTICAL<br>COMPANIES-<br>2016SCPR015307 |                      |            | Unknown    | ESP            |

| <u>Preferred Term</u>                                                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Bundle Branch Block Left;<br>Cardio-Respiratory Arrest;<br>Torsade De Pointes | Metoclopramide |              |            | S           | Unknown      | Unk Unk, Unknown   |                 | Par          |
|                                                                               | Metoclopramide |              |            | S           |              |                    |                 | Par          |
|                                                                               | Losartan       |              |            | S           | Unknown      | Unk, Unknown       |                 | Not Reported |
|                                                                               | Betahistine    |              |            | S           | Unknown      | Unk, Unknown       |                 | Not Reported |
|                                                                               | Simvastatin    |              |            | S           | Unknown      | Unk, Unknown       |                 | Not Reported |
|                                                                               | Amiodarone     |              |            | S           | Unknown      | Unk, Unknown       |                 | Not Reported |
|                                                                               | Bisoprolol     |              |            | S           | Unknown      | Unk Unk, Unknown   |                 | Not Reported |
|                                                                               | Acenocoumarol  |              |            | S           | Unknown      | Unk, Unknown       |                 | Not Reported |
|                                                                               | Metformin      |              |            | S           | Unknown      | Unk, Unknown       |                 | Not Reported |
|                                                                               | Iron Sulfate   |              |            | S           | Unknown      | Unk, Unknown       |                 | Not Reported |
|                                                                               | Escitalopram   |              |            | S           | Unknown      | Unk, Unknown       |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                        | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------|-----------------------------------------|--------------------|--------------------|-----------------|--------------------------------------------|----------------------|-----------------|--------------|----------------|
| 04-Apr-2016                                     | 12233671                                | EXPEDITED (15-DAY) |                    | HO              | IT-AUROBINDO-AUR-APL-2016-04100            |                      | 48 YR           | Male         | ITA            |
| <u>Preferred Term</u>                           | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bradyphrenia; Drug Abuse; Sopor                 | Escitalopram                            |                    |                    | S               | Unknown                                    | 100 Mg, Unk          |                 | Aurobindo    |                |
|                                                 | Flurazepam                              |                    |                    | S               | Oral                                       | 150 Mg, Unk          |                 | Not Reported |                |
| <u>FDA Received Date</u>                        | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Apr-2016                                     | 12234006                                | EXPEDITED (15-DAY) |                    | OT              | GB-LUPIN PHARMACEUTICALS INC.-E2B_00005183 |                      |                 | Female       | GBR            |
| <u>Preferred Term</u>                           | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Emotional Distress; Suicidal Ideation; Tinnitus | Escitalopram                            |                    |                    | S               | Unknown                                    |                      |                 | Not Reported |                |
|                                                 | Quetiapine                              |                    |                    | S               | Unknown                                    |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                        | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Apr-2016                                     | 12235739                                | EXPEDITED (15-DAY) |                    | OT              | GB-FRI-1000083625                          |                      |                 | Female       | GBR            |
| <u>Preferred Term</u>                           | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Emotional Distress; Suicidal Ideation; Tinnitus | Escitalopram                            |                    |                    | S               | Oral                                       |                      |                 | Forest       |                |
|                                                 | Quetiapine Fumarate                     |                    |                    | S               | Unknown                                    |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                        | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Apr-2016                                     | 12237389                                | DIRECT             |                    |                 |                                            |                      | 32 YR           | Female       | USA            |
| <u>Preferred Term</u>                           | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Product Substitution Issue          | Escitalopram: Oral Tablet (10mg), 10 Mg |                    |                    | S               | Oral                                       |                      |                 | Teva         |                |
|                                                 | Lexapro                                 |                    |                    | C               |                                            |                      |                 | Not Reported |                |
|                                                 | Welbutrin                               |                    |                    | C               |                                            |                      |                 | Not Reported |                |
|                                                 | Lamictal                                |                    |                    | C               |                                            |                      |                 | Not Reported |                |
|                                                 | Buspirone                               |                    |                    | C               |                                            |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| Vitamin D Nos              |                                    |                    | C                  |                 |                                       | Not Reported         |                 |              |                |
|----------------------------|------------------------------------|--------------------|--------------------|-----------------|---------------------------------------|----------------------|-----------------|--------------|----------------|
| <u>FDA Received Date</u>   | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Apr-2016                | 12237003                           | EXPEDITED (15-DAY) |                    | HO, LT, OT      | ES-ACCORD-039374                      |                      | 84 YR           | Female       | ESP            |
| <u>Preferred Term</u>      | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Electrocardiogram Qt       | Sulpiride/Sulpiride                |                    |                    | S               |                                       |                      |                 | Not Reported |                |
| Prolonged; Hypokalaemia;   | Adamantanecarboxylat               |                    |                    | S               |                                       |                      |                 | Accord       |                |
| Hypomagnesaemia;           | Escitalopram                       |                    |                    | S               |                                       |                      |                 | Accord       |                |
| Torsade De Pointes         | Levofloxacin/Levofloxacin Mesylate |                    |                    | S               |                                       |                      |                 |              |                |
|                            | Solifenacin/Solifenacin Succinate  |                    |                    | S               |                                       |                      |                 | Not Reported |                |
|                            | Amiodarone                         |                    |                    | S               | Intravenous (not otherwise specified) |                      |                 | Not Reported |                |
|                            | Digoxin                            |                    |                    | S               |                                       |                      |                 | Not Reported |                |
|                            | Candesartan                        |                    |                    | C               |                                       |                      |                 | Not Reported |                |
|                            | Furosemide                         |                    |                    | C               |                                       |                      |                 | Not Reported |                |
|                            | Acenocoumarol                      |                    |                    | C               |                                       |                      |                 | Not Reported |                |
|                            | Simvastatin                        |                    |                    | C               |                                       |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Apr-2016                | 12237004                           | EXPEDITED (15-DAY) |                    | HO, LT, OT      | ES-ACCORD-039376                      |                      | 85 YR           | Female       | ESP            |
| <u>Preferred Term</u>      | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bundle Branch Block Left;  | Metoclopramide                     |                    |                    | S               |                                       |                      |                 | Accord       |                |
| Cardio-Respiratory Arrest; | Escitalopram                       |                    |                    | S               |                                       |                      |                 | Accord       |                |
| Electrocardiogram Qt       | Amiodarone                         |                    |                    | S               |                                       |                      |                 | Not Reported |                |
| Prolonged; Hypokalaemia;   | Losartan                           |                    |                    | C               |                                       |                      |                 | Not Reported |                |
| Hypomagnesaemia;           | Betahistine                        |                    |                    | C               |                                       |                      |                 | Not Reported |                |
| Torsade De Pointes         | Simvastatin                        |                    |                    | C               |                                       |                      |                 | Not Reported |                |
|                            | Bisoprolol                         |                    |                    | C               |                                       |                      |                 | Not Reported |                |
|                            | Acenocoumarol                      |                    |                    | C               |                                       |                      |                 | Not Reported |                |
|                            | Metformin                          |                    |                    | C               |                                       |                      |                 | Not Reported |                |
|                            | Iron                               |                    |                    | C               |                                       |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                       | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|--------------------|--------------------|-----------------|---------------------------------|--------------------------------|-----------------|--------------|----------------|
| 05-Apr-2016                                                                                                                                                                                    | 12237023            | EXPEDITED (15-DAY) |                    | HO, OT          | IT-AUROBINDO-AUR-APL-2016-02458 |                                |                 | Unknown      | ITA            |
| <u>Preferred Term</u>                                                                                                                                                                          | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Macule; Papule; Skin Lesion; Telangiectasia                                                                                                                                                    | Escitalopram 10 Mg  |                    |                    | S               | Oral                            | 10 Mg, Daily                   |                 | Aurobindo    |                |
| <u>FDA Received Date</u>                                                                                                                                                                       | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Apr-2016                                                                                                                                                                                    | 12237907            | EXPEDITED (15-DAY) |                    | OT              | CN-FRI-1000083735               |                                | 67 YR           | Female       | CHN            |
| <u>Preferred Term</u>                                                                                                                                                                          | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Acute Leukaemia                                                                                                                                                                                | Lexapro             |                    |                    | S               | Oral                            | 5 Mg                           |                 | Forest       |                |
|                                                                                                                                                                                                | Lexapro             |                    |                    | S               | Oral                            | 10 Mg                          |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                                                                                       | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Apr-2016                                                                                                                                                                                    | 12241340            | DIRECT             |                    | HO, LT, RI, OT  |                                 |                                | 56 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                          | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Anion Gap Decreased; Blood Creatinine Decreased; Blood Potassium Decreased; Blood Urine Present; Chromaturia; Dehydration; Platelet Count Decreased; Seizure; White Blood Cells Urine Positive | Haldol              |                    |                    | S               |                                 | Misdiagnosis/Drug Forced On Me |                 | Unknown      |                |
|                                                                                                                                                                                                | Trazodone           |                    |                    | S               |                                 |                                |                 | Not Reported |                |
|                                                                                                                                                                                                | Escitalopram        |                    |                    | S               |                                 |                                |                 | Not Reported |                |
|                                                                                                                                                                                                | Bupropion           |                    |                    | S               |                                 |                                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                       | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Apr-2016                                                                                                                                                                                    | 9555126             | NON-EXPEDITED      |                    | HO, OT          | ADR-2012-02307                  |                                | 54 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                          | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Arthralgia; Arthritis;                                                                                                                                                                         | Compounded Baclofen |                    |                    | S               |                                 |                                |                 | Not Reported |                |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                            |                |   |                                                                 |              |
|----------------------------|----------------|---|-----------------------------------------------------------------|--------------|
| Decreased Activity; Device | Symbicort      | S | 160-4.5mcg/Act Aero                                             | Not Reported |
| Defective; Pain; Therapy   | Imitrex        | S | 20mg/Act Soln                                                   | Not Reported |
| Non-Responder;             | Transderm-Scop | S | 1.5mg Pt72 As Needed                                            | Not Reported |
| Unevaluable Event          | Flector        | S | 1.3% Patch To Left Knee<br>For Pain Flare Up Every<br>12 Hours  | Not Reported |
|                            | Nasonex        | S | 50mcg/Act Susp                                                  | Not Reported |
|                            | Medrol Pak     | S | 4mg Tabs - Use As<br>Directed                                   | Not Reported |
|                            | Robaxin        | S | 500mg Twice Daily As<br>Needed For Spasms                       | Not Reported |
|                            | Neurotin       | S | 400mg 3 Times Daily                                             | Not Reported |
|                            | Flexeril       | S | 10mg Tabs As Needed<br>For Spasms                               | Not Reported |
|                            | Vesicare       | S | 5mg Tabs                                                        | Not Reported |
|                            | Lortab         | S | 7.5-500mg Tabs; 1 Tab 3-<br>4 Times Daily As Needed<br>For Pain | Not Reported |
|                            | Albuterol      | S | 90mcg/Act Aers                                                  | Not Reported |
|                            | Lexapro        | S | 1.5 Tabs Daily                                                  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 06-Apr-2016              | 12171456      | EXPEDITED (15-DAY) |                    | HO, OT          | US-PFIZER INC-<br>2016125599 |                      | 62 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Euphoric Mood;                                                        | Lyrice         |              |            | S           |              | 75 Mg, Daily       |                 | Pfizer       |
| Intervertebral Disc<br>Protrusion; Nerve Injury;<br>Pain In Extremity | Lexapro        |              |            | S           |              | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Apr-2016              | 12240815      | EXPEDITED (15-DAY) |                    | HO, OT          | TH-ACCORD-039246     |                      | 77 YR      | Male       | THA            |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                    | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>                                      | <u>Duration</u> | <u>Mfr</u>   |                |
|--------------------------------------------------------------------------|-----------------------------------------|--------------------|--------------------|-----------------|---------------------------------|---------------------------------------------------------|-----------------|--------------|----------------|
| Acute Kidney Injury; Drug Interaction; Haemodialysis; Serotonin Syndrome | Escitalopram                            |                    |                    | S               |                                 |                                                         |                 | Accord       |                |
|                                                                          | Rasagiline/Rasagiline Mesylate          |                    |                    | S               |                                 |                                                         |                 | Not Reported |                |
|                                                                          | Ticlopidine                             |                    |                    | C               |                                 |                                                         |                 | Not Reported |                |
|                                                                          | Atorvastatin                            |                    |                    | C               |                                 |                                                         |                 | Not Reported |                |
|                                                                          | Gemfibrozil                             |                    |                    | C               |                                 |                                                         |                 | Not Reported |                |
|                                                                          | Piribedil/Piribedil                     |                    |                    | C               |                                 |                                                         |                 | Not Reported |                |
|                                                                          | Monomethanesulfonate                    |                    |                    |                 |                                 |                                                         |                 |              |                |
|                                                                          | Rivastigmine/Rivastigmine Tartrate      |                    |                    | C               |                                 | Patch 10 Cm2                                            |                 | Not Reported |                |
|                                                                          | Stalevo                                 |                    |                    | C               |                                 | Levodopa 100 Mg, Carbidopa 25 Mg, And Entacapone 200 Mg |                 | Not Reported |                |
|                                                                          | Pramipexole/Pramipexole Dihydrochloride |                    |                    | C               |                                 |                                                         |                 | Not Reported |                |
| Melatonin                                                                |                                         |                    | C                  |                 |                                 |                                                         | Not Reported    |              |                |
| Clonazepam                                                               |                                         |                    | C                  |                 |                                 |                                                         | Not Reported    |              |                |
| <u>FDA Received Date</u>                                                 | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u>                                    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Apr-2016                                                              | 12241619                                | EXPEDITED (15-DAY) |                    | HO, OT          | IT-AUROBINDO-AUR-APL-2016-04247 |                                                         | < 1 DAY         | Male         | ITA            |
| <u>Preferred Term</u>                                                    | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>                                      | <u>Duration</u> | <u>Mfr</u>   |                |
| Foetal Exposure During Pregnancy; Neonatal Tachypnoea                    | Lorazepam                               |                    |                    | S               | Transplacental                  | Unk                                                     |                 | Not Reported |                |
|                                                                          | Escitalopram 5 Mg                       |                    |                    | S               | Transplacental                  | 5 Gtt, Unk                                              |                 | Aurobindo    |                |
|                                                                          | Adalat                                  |                    |                    | S               | Unknown                         | Unk                                                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                 | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u>                                    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Apr-2016                                                              | 12191790                                | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2016143391        |                                                         | 50 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                    | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>                                      | <u>Duration</u> | <u>Mfr</u>   |                |
| Therapeutic Product Effect Decreased                                     | Zoloft                                  |                    |                    | S               |                                 | Unk                                                     |                 | Pfizer       |                |
|                                                                          | Effexor Xr                              |                    |                    | S               |                                 | Unk                                                     |                 | Pfizer       |                |
|                                                                          | Paxil                                   |                    |                    | S               |                                 | Unk                                                     |                 | Not Reported |                |
|                                                                          | Buspar                                  |                    |                    | S               |                                 | Unk                                                     |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|            |   |     |              |
|------------|---|-----|--------------|
| Wellbutrin | S | Unk | Not Reported |
| Lexapro    | S | Unk | Not Reported |
| Cymbalta   | S | Unk | Not Reported |
| Prozac     | S | Unk | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 08-Apr-2016              | 12247668      | EXPEDITED (15-DAY) | HO                 |                 | US-ABBVIE-16K-163-1597728-00 |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                 | <u>Product</u>                        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------|---------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Limb Discomfort; Liver Disorder; Pruritus Generalised | Humira 40mg/0.8ml                     |              |            | S           | Subcutaneous |                    |                 | Not Reported |
|                                                       | Advair                                |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                       | Albuterol                             |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                       | Cyclobenzaprine                       |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                       | Amoxicillin And Clavulanate Potassium |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                       | Escitalopram                          |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                       | Hydrochlorothiazide                   |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                       | Lisinopril                            |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                       | Lovastatin                            |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                       | Losartan Potassium                    |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                       | Meclizine                             |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                       | Methotrexate                          |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                       | Norco                                 |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                       | Pantoprazole Sodium                   |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                       | Prednisone                            |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                       | Tramadol                              |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                       | Ranitidine                            |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                       | Ventolin                              |              |            | S           | Unknown      |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                    | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|---------------------------------------|----------------------|-----------------|--------------|----------------|
| 08-Apr-2016                                                                                                                                 | 12249979                      | EXPEDITED (15-DAY) |                    | HO, OT          | ES-APOTEX-2016AP007532                |                      | 84 YR           | Female       | ESP            |
| <u>Preferred Term</u>                                                                                                                       | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Electrocardiogram Qt Prolonged; Electrolyte Imbalance;                                                                                      | Escitalopram Apotex           |                    |                    | S               | Unknown                               | Unk Unk, Unknown     |                 | Apotex       |                |
| Haemodynamic Instability; Hypokalaemia;                                                                                                     | Levofloxacin                  |                    |                    | S               | Unknown                               | Unk Unk, Unknown     |                 | Apotex       |                |
| Hypomagnesaemia; Multiple Drug Therapy; Respiratory Tract Infection; Torsade De Pointes; Ventricular Extrasystoles; Ventricular Tachycardia | Sulpiride                     |                    |                    | S               | Unknown                               | Unk, Unknown         |                 | Not Reported |                |
|                                                                                                                                             | Solifenacin                   |                    |                    | S               | Unknown                               | Unk, Unknown         |                 | Not Reported |                |
|                                                                                                                                             | Amiodarone                    |                    |                    | S               | Intravenous (not otherwise specified) | Unk Unk, Unknown     |                 | Not Reported |                |
|                                                                                                                                             | Furosemide                    |                    |                    | C               | Unknown                               | Unk, Unknown         |                 | Not Reported |                |
|                                                                                                                                             | Acenocoumarol                 |                    |                    | C               | Unknown                               | Unk, Unknown         |                 | Not Reported |                |
|                                                                                                                                             | Candesartan                   |                    |                    | C               | Unknown                               | Unk, Unknown         |                 | Not Reported |                |
|                                                                                                                                             | Digoxin                       |                    |                    | C               | Unknown                               | Unk, Unknown         |                 | Not Reported |                |
|                                                                                                                                             | Simvastatin                   |                    |                    | C               | Unknown                               | Unk, Unknown         |                 | Not Reported |                |
|                                                                                                                                             | Magnesium Sulphate /01097001/ |                    |                    | C               | Unknown                               |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                      | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------------------------|-----------------|--------------|----------------|
| 08-Apr-2016                                                                                                   | 12252606       | DIRECT           |                    | OT              |                      |                                        | 35 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                         | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Chest Discomfort; Confusional State; Dizziness; Fatigue; Feeling Abnormal; Quality Of Life Decreased | Lexapro, 20 Mg |                  |                    | S               | Oral                 | 30 Tablet(S) At Bedtime Taken By Mouth |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|------------|----------------|
| 11-Apr-2016              | 11717283       | EXPEDITED (15-DAY) |                    | OT              | US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-077201 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                          |                     |   |         |            |                      |
|--------------------------|---------------------|---|---------|------------|----------------------|
| Conjunctival Haemorrhage | Eliquis             | S | Unknown | 5 Mg, Unk  | Bristol Myers Squibb |
|                          | Lipitor             | S | Unknown | 20 Mg, Qd  | Not Reported         |
|                          | Hydrochlorothiazide | S | Unknown | 25 Mg, Qd  | Not Reported         |
|                          | Losartan            | S | Unknown | 100 Mg, Qd | Not Reported         |
|                          | Lexapro             | S | Unknown | 10 Mg, Qd  | Not Reported         |
|                          | Acetyl-L-Carnitine  | C | Unknown | Unk        | Not Reported         |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 11-Apr-2016              | 12216780      | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2016179799 |                      | 70 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Tremor                | Pristiq        |              |            | S           | Oral         | 50 Mg, 1x/Day      |                 | Pfizer       |
|                       | Lexapro        |              |            | S           | Oral         | 30 Mg, 1x/Day      |                 | Not Reported |
|                       | Benicar        |              |            | C           |              | 10 Mg              |                 | Not Reported |
|                       | Zocor          |              |            | C           |              | 40 Mg              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 11-Apr-2016              | 12253804      | NON-EXPEDITED    |                    |                 | US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-027591 |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>                           | <u>Product</u>  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>           |
|-------------------------------------------------|-----------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------|
| Labelled Drug-Drug Interaction Medication Error | Warfarin Sodium |              |            | S           | Unknown      |                    |                 | Bristol Myers Squibb |
|                                                 | Escitalopram    |              |            | S           | Unknown      |                    |                 | Not Reported         |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 11-Apr-2016              | 12254462      | EXPEDITED (15-DAY) |                    | OT              | CZ-MYLANLABS-2016M1014465 |                      |            | Unknown    | CZE            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Deep Vein Thrombosis  | Lamotrigine    |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Olanzapine     |              |            | S           |              | 20 Mg, Unk         |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                       | Escitalopram       |                  | S                  |                 | 10 Mg, Unk                                             |                      | Not Reported    |                      |                |
|-------------------------------------------------------|--------------------|------------------|--------------------|-----------------|--------------------------------------------------------|----------------------|-----------------|----------------------|----------------|
|                                                       | Trazodone          |                  | S                  |                 | 150 Mg, Unk                                            |                      | Not Reported    |                      |                |
|                                                       | Oxazepam           |                  | C                  |                 | 15 Mg, Unk                                             |                      | Mylan           |                      |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>      | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 11-Apr-2016                                           | 12254505           | NON-EXPEDITED    |                    |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>BMS-2016-027592 |                      |                 | Unknown              | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u>     | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Labelled Drug-Drug<br>Interaction Medication<br>Error | Warfarin Sodium    |                  |                    | S               | Unknown                                                |                      |                 | Bristol Myers Squibb |                |
|                                                       | Escitalopram       |                  |                    | S               | Unknown                                                |                      |                 | Not Reported         |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>      | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 11-Apr-2016                                           | 12256862           | DIRECT           | Y                  |                 |                                                        |                      | 60 YR           | Male                 | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u>     | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Therapy Cessation;<br>Tinnitus                        | Escitalopram, 5 Mg |                  |                    | S               |                                                        |                      |                 | Not Reported         |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>      | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 12-Apr-2016                                           | 12088145           | NON-EXPEDITED    |                    |                 | US-AUROBINDO-AUR-<br>APL-2014-07108                    |                      |                 | Female               | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u>     | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Drug Hypersensitivity                                 | Metformin          |                  |                    | S               | Unknown                                                |                      |                 | Aurobindo            |                |
|                                                       | Amoxicillin        |                  |                    | S               | Unknown                                                |                      |                 | Aurobindo            |                |
|                                                       | Zoloft             |                  |                    | S               | Unknown                                                | Unk                  |                 | Not Reported         |                |
|                                                       | Ibuprofen          |                  |                    | S               | Unknown                                                |                      |                 | Not Reported         |                |
|                                                       | Advil /00044201/   |                  |                    | S               | Unknown                                                |                      |                 | Not Reported         |                |
|                                                       | Pristiq            |                  |                    | S               | Unknown                                                |                      |                 | Not Reported         |                |
|                                                       | Pce                |                  |                    | S               | Unknown                                                |                      |                 | Not Reported         |                |
|                                                       | Biaxin             |                  |                    | S               | Unknown                                                | Unk                  |                 | Not Reported         |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                            |   |         |     |              |
|----------------------------|---|---------|-----|--------------|
| Benadryl /00000402/        | S | Unknown |     | Not Reported |
| Tylenol With Codeine       | S |         |     | Not Reported |
| Novocain                   | S | Unknown |     | Not Reported |
| Actos                      | S |         |     | Not Reported |
| Cipro /00697201/           | S | Unknown |     | Not Reported |
| Macrochantin               | S | Unknown | Unk | Not Reported |
| Albuterol /00139501/       | S | Unknown | Unk | Not Reported |
| Elavil /00002202/          | S | Unknown | Unk | Not Reported |
| Prozac                     | S | Unknown |     | Not Reported |
| Lexapro                    | S | Unknown |     | Not Reported |
| Lithobid                   | S | Unknown | Unk | Not Reported |
| Remeron                    | S | Unknown | Unk | Not Reported |
| Risperdal                  | S | Unknown | Unk | Not Reported |
| Xylocaine /00033401/       | S | Unknown | Unk | Not Reported |
| Paxil /00500401/           | S | Unknown | Unk | Not Reported |
| St. John'S Wort /01166801/ | S | Unknown | Unk | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Apr-2016              | 12205506      | EXPEDITED (15-DAY) |                    | DS, HO          | GXKR2016DE001457     |                      | 43 YR      | Male       | DEU            |

  

| <u>Preferred Term</u>                                                                                                | <u>Product</u>  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------|-----------------|--------------|------------|-------------|--------------|---------------------------------------------------|-----------------|--------------|
| Acute Stress Disorder;<br>Akathisia; Dyskinesia;<br>Impaired Work Ability;<br>Nervousness; Restless<br>Legs Syndrome | Quetiapin Hexal |              |            | S           | Oral         | 50 Mg In The Morning And<br>200 Mg In The Evening |                 | Novartis     |
|                                                                                                                      | Quetiapin Hexal |              |            | S           | Oral         | 50 Mg, Bid                                        |                 | Novartis     |
|                                                                                                                      | Risperidone     |              |            | S           |              | Unk Ukn, Unk                                      |                 | Not Reported |
|                                                                                                                      | Mirtazapine     |              |            | S           | Oral         | Unk Ukn, Unk                                      |                 | Not Reported |
|                                                                                                                      | Melperone       |              |            | S           | Oral         | Unk Ukn, Unk                                      |                 | Not Reported |
|                                                                                                                      | Melneurin       |              |            | S           | Oral         | Variable Dosages                                  |                 | Not Reported |
|                                                                                                                      | Zyprexa         |              |            | S           | Oral         | Variable Dosages                                  |                 | Not Reported |
|                                                                                                                      | Risperidon Atid |              |            | S           | Oral         | Unk Ukn, Unk                                      |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                    |                                    |                    |                    |                 |                                     |                        |                 |              |                |
|--------------------------------------------------------------------|------------------------------------|--------------------|--------------------|-----------------|-------------------------------------|------------------------|-----------------|--------------|----------------|
| Escitalopram Basics                                                |                                    |                    | S                  |                 | Unk Unk, Unk                        |                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                           | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Apr-2016                                                        | 12215354                           | EXPEDITED (15-DAY) |                    | HO, OT          | CZ-TEVA-644392ISR                   |                        | 82 YR           | Female       | CZE            |
| <u>Preferred Term</u>                                              | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                        | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Chest Wall Haematoma;<br>Dehydration; Fall; Fall;<br>Hyponatraemia | Atorvastatin                       |                    |                    | S               | Oral                                | 10 Milligram Daily;    |                 | Teva         |                |
|                                                                    | Escitalopram 10 Mg                 |                    |                    | S               | Oral                                | 10 Milligram Daily;    |                 | Ivax         |                |
|                                                                    | Levothyroxin 75 Mcg Unknown        |                    |                    | S               | Oral                                | 75 Microgram Daily;    |                 | Not Reported |                |
|                                                                    | Furosemid 40 Mg                    |                    |                    | S               | Oral                                | 40 Milligram Daily;    |                 | Ivax         |                |
|                                                                    | Omeprazol 20 Mg                    |                    |                    | S               | Oral                                | 20 Milligram Daily;    |                 | Not Reported |                |
|                                                                    | Nitrendipin 10 Mg                  |                    |                    | S               | Oral                                | 10 Milligram Daily;    |                 | Not Reported |                |
|                                                                    | Perindopril 5 Mg                   |                    |                    | S               | Oral                                | 10 Milligram Daily;    |                 | Not Reported |                |
|                                                                    | Isosorbid 20 Mg                    |                    |                    | S               | Oral                                | 40 Milligram Daily;    |                 | Not Reported |                |
|                                                                    | Tiaprid 100 Mg                     |                    |                    | S               | Oral                                | 100 Milligram Daily;   |                 | Not Reported |                |
|                                                                    | Fentanyl 25 Mcg/H Actavis          |                    |                    | S               | Transdermal                         |                        |                 | Cephalon     |                |
|                                                                    | Metamizol 500 Mg                   |                    |                    | S               | Oral                                | 3000 Milligram Daily;  |                 | Not Reported |                |
|                                                                    | Tramadol 150 Mg Sr                 |                    |                    | S               | Oral                                | 300 Milligram Daily;   |                 | Not Reported |                |
|                                                                    | Rivoxaban 20 Mg                    |                    |                    | S               | Oral                                | 20 Milligram Daily;    |                 | Not Reported |                |
|                                                                    | Bromazepam 3 Mg                    |                    |                    | S               | Oral                                | .5 Dosage Forms Daily; |                 | Not Reported |                |
|                                                                    | Chlortalidon/Amilorid 25 Mg/2.5 Mg |                    |                    | S               | Oral                                | 2 Dosage Forms Daily;  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                           | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Apr-2016                                                        | 12255809                           | NON-EXPEDITED      |                    |                 | US-AUROBINDO-AUR-<br>APL-2015-02405 |                        |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                              | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                        | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity                                              | Metformin                          |                    |                    | S               | Unknown                             | Unk                    |                 | Aurobindo    |                |
|                                                                    | Oxycodone                          |                    |                    | S               | Unknown                             | Unk                    |                 | Aurobindo    |                |
|                                                                    | Tramadol                           |                    |                    | S               | Unknown                             | Unk                    |                 | Aurobindo    |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                     |   |         |     |              |
|---------------------|---|---------|-----|--------------|
| Cymbalta            | S | Unknown | Unk | Not Reported |
| Neurontin           | S | Unknown | Unk | Not Reported |
| Celebrex            | S | Unknown | Unk | Not Reported |
| Dilantin /00017401/ | S | Unknown | Unk | Not Reported |
| Lexapro             | S | Unknown | Unk | Not Reported |
| Methadone           | S | Unknown | Unk | Not Reported |
| Stadol              | S | Unknown | Unk | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|---------------------------------|----------------------|------------|------------|----------------|
| 12-Apr-2016              | 12256432      | NON-EXPEDITED    |                    |                 | US-AUROBINDO-AUR-APL-2015-07526 |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>                                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-----------------------------------------------|--------------|------------|-------------|--------------|-------------------------|-----------------|--------------|
| Abdominal Discomfort  | Metformin Hydrochloride Tablets<br>Usp 500 Mg |              |            | S           | Unknown      | 500 Mg, Two Times A Day |                 | Aurobindo    |
|                       | Benazepril 10 Mg                              |              |            | S           | Unknown      | 10 Mg, Once A Day       |                 | Aurobindo    |
|                       | Tramadol Hydrochloride Tablets<br>Usp 50 Mg   |              |            | S           | Unknown      | 50 Mg, Every 8 Hours    |                 | Aurobindo    |
|                       | Abilify                                       |              |            | S           | Unknown      | 2 Mg, Every Morning     |                 | Not Reported |
|                       | Ativan                                        |              |            | S           | Unknown      | 1 Mg, Two Times A Day   |                 | Not Reported |
|                       | Lasix /00032601/                              |              |            | S           | Unknown      | 40 Mg, Two Times A Day  |                 | Not Reported |
|                       | Lexapro                                       |              |            | S           | Unknown      | 20 Mg, Every Morning    |                 | Not Reported |
|                       | Nitro /00003201/                              |              |            | S           | Unknown      | 0.4 Mg, Unk             |                 | Not Reported |
|                       | Proair Hfa                                    |              |            | S           | Unknown      | 90 Mcg, Two Times A Day |                 | Not Reported |
|                       | Proventil /00139501/                          |              |            | S           | Unknown      |                         |                 | Not Reported |
|                       | Spiriva                                       |              |            | S           | Unknown      | 1 Df, Daily             |                 | Not Reported |
|                       | Zocor                                         |              |            | S           | Unknown      | 40 Mg, At Bed Time      |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 12-Apr-2016              | 12257137      | EXPEDITED (15-DAY) |                    | OT              | IT-JNJFOC-20160406024 |                      |            | Female     | ITA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|



## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                  |                        |   |              |              |
|----------------------------------|------------------------|---|--------------|--------------|
| Insomnia; Restless Legs Syndrome | Serenase (Haloperidol) | S | Oral         | Not Reported |
|                                  | Rivotril               | S | Oral         | Not Reported |
|                                  | Cipralelex             | S | Oral         | Not Reported |
|                                  | Cipralelex             | S | Oral         | Not Reported |
|                                  | Insulin                | C | Subcutaneous | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 12-Apr-2016              | 12257823       | NON-EXPEDITED    |                    | HO              | TH-FRI-1000083761    |                      | 77 YR           | Male         | THA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Serotonin Syndrome       | Escitalopram   |                  |                    | S               | Unknown              | Unknown              |                 | Forest       |                |
|                          | Rasagiline     |                  |                    | S               | Unknown              | Unknown              |                 | Not Reported |                |

| <u>FDA Received Date</u>                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|------------------------|-----------------|--------------|----------------|
| 13-Apr-2016                                           | 12231820       | EXPEDITED (15-DAY) |                    | HO              | PHHY2016IT040639     |                        | < 1 DAY         | Male         | ITA            |
| <u>Preferred Term</u>                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Foetal Exposure During Pregnancy; Neonatal Tachypnoea | Escitalopram   |                    |                    | S               | Transplacental       | 5 Drp, Qd              |                 | Not Reported |                |
|                                                       | Lorazepam      |                    |                    | S               | Transplacental       | Mother Took 2.5 Mg, Qd |                 | Novartis     |                |
|                                                       | Adalat         |                    |                    | S               | Transplacental       | Mother Took 60mg, Qd   |                 | Not Reported |                |

| <u>FDA Received Date</u>     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|-------------------------------------------|-----------------|--------------|----------------|
| 13-Apr-2016                  | 12262487       | EXPEDITED (15-DAY) |                    | OT              | US-ACCORD-039534     |                                           | 18 YR           | Female       | USA            |
| <u>Preferred Term</u>        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                        | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Drug Ineffective | Escitalopram   |                    |                    | S               | Oral                 | Strength: 20 Mg Initially Received 10 Mg. |                 | Accord       |                |
|                              | Melatonin      |                    |                    | C               |                      | Otc Melatonin                             |                 | Not Reported |                |
|                              | Ibuprofen      |                    |                    | C               |                      | Frequently                                |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Apr-2016              | 12263383      | EXPEDITED (15-DAY) |                    | HO              | CH-SA-2016SA069553   |                      | 74 YR      | Male       | CHE            |

| <u>Preferred Term</u>                                              | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------|--------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Bladder Tamponade;<br>Haematuria; Potentiating<br>Drug Interaction | Plavix             |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                    | Escitalopram       |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                    | Xarelto            |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                    | Aspirin            |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                    | Sequase            |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                    | Prograf            |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                    | Torem              |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                    | Atorvastatin       |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                    | Concor             |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                    | Triatec (Ramipril) |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                    | Aldactone          |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                    | Pantozol           |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                    | Zyloric            |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                    | Euthyrox           |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                    | Levemir            |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                    | Movicol            |              |            | C           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Apr-2016              | 12265407      | EXPEDITED (15-DAY) |                    | HO              | CH-BAYER-2016-064710 |                      | 74 YR      | Male       | CHE            |

| <u>Preferred Term</u>                                              | <u>Product</u>                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------|--------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Bladder Tamponade;<br>Haematuria; Potentiating<br>Drug Interaction | Xarelto                        |              |            | S           |              | 10 Mg, Qd          |                 | Unknown      |
|                                                                    | Acetylsalicylic Acid(<=100 Mg) |              | Y          | S           |              | 100 Mg, Qd         |                 | Bayer        |
|                                                                    | Plavix                         |              |            | S           |              | 75 Mg, Qd          |                 | Not Reported |
|                                                                    | Escitalopram                   |              |            | S           |              | 20 Mg, Qd          |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                     |   |              |              |
|---------------------|---|--------------|--------------|
| Quetiapine Fumarate | C | 50 Mg, Qd    | Not Reported |
| Prograf             | C | 1 Mg, Bid    | Not Reported |
| Torem               | C | 10 Mg, Qd    | Not Reported |
| Atorvastatin        | C | 10 Mg, Qd    | Not Reported |
| Concor              | C | 2.5 Mg, Qd   | Not Reported |
| Triatec (Ramipril)  | C | 2.5 Mg, Qd   | Not Reported |
| Aldactone A         | C | 25 Mg, Qd    | Not Reported |
| Pantozol            | C | 40 Mg, Qd    | Not Reported |
| Zyloric             | C | 300 Mg, Qd   | Not Reported |
| Euthyrox            | C | 0.075 Mg, Qd | Not Reported |
| Levemir             | C | 6 Iu, Qd     | Not Reported |
| Movicol             | C | 1 Df, Bid    | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Apr-2016              | 12266165      | DIRECT           | Y                  |                 |                      |                      | 54 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Headache              | Generic Lexapro |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 14-Apr-2016              | 12088526      | EXPEDITED (15-DAY) |                    | HO              | US-BAUSCH-BL-2016-003730 |                      | 67 YR      | Female     | USA            |

| <u>Preferred Term</u>                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|-----------------------------------------------|-----------------|--------------|
| Apparent Death; Drug Ineffective; Tremor; Weight Decreased | Wellbutrin XI  |              |            | S           | Oral         |                                               |                 | Not Reported |
|                                                            | Bupropion      |              |            | S           | Oral         |                                               |                 | Not Reported |
|                                                            | Lorazepam      |              |            | S           | Oral         |                                               |                 | Not Reported |
|                                                            | Lorazepam      |              |            | S           | Oral         | ½ Tablet In The Morning And 1 Tablet At Night |                 | Not Reported |
|                                                            | Lexapro        |              |            | S           | Oral         |                                               |                 | Not Reported |
|                                                            | Lexapro        |              |            | S           | Oral         |                                               |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|---------------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|-----------------|--------------|----------------|
| 14-Apr-2016              | 12257026            | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-2015376027        |                      | 59 YR           | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Conjunctival Haemorrhage | Eliquis             |                    |                    | S               | Unknown                         | 5 Mg, 2x/Day         |                 | Not Reported |                |
|                          | Lipitor             |                    |                    | S               | Unknown                         | 20 Mg, 1x/Day        |                 | Pfizer       |                |
|                          | Losartan            |                    |                    | S               |                                 | 100 Mg, 1x/Day       |                 | Not Reported |                |
|                          | Hydrochloorthiazide |                    |                    | S               |                                 | 25 Mg, 1x/Day        |                 | Not Reported |                |
|                          | Lexapro             |                    |                    | S               |                                 | 10 Mg, Daily         |                 | Not Reported |                |
|                          | Acetyl L Carnitin   |                    |                    | C               |                                 | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Apr-2016              | 12266937            | EXPEDITED (15-DAY) |                    | HO, OT          | FR-AUROBINDO-AUR-APL-2016-04437 |                      |                 | Unknown      | FRA            |
| <u>Preferred Term</u>    | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Treatment Failure        | Escitalopram        |                    |                    | S               | Unknown                         | Unk                  |                 | Aurobindo    |                |
|                          | Escitalopram        |                    |                    | S               |                                 |                      |                 | Aurobindo    |                |
|                          | Sertraline          |                    |                    | S               | Unknown                         | Unk                  |                 | Aurobindo    |                |
|                          | Sertraline          |                    |                    | S               |                                 |                      |                 | Aurobindo    |                |
|                          | Venlafaxine         |                    |                    | S               | Unknown                         | Unk                  |                 | Aurobindo    |                |
|                          | Venlafaxine         |                    |                    | S               |                                 |                      |                 | Aurobindo    |                |
|                          | Risperidone         |                    |                    | S               | Unknown                         | 2 Mg/Day             |                 | Aurobindo    |                |
|                          | Risperidone         |                    |                    | S               |                                 | 2 Mg/Day             |                 | Aurobindo    |                |
|                          | Paroxetine          |                    |                    | S               |                                 |                      |                 | Aurobindo    |                |
|                          | Paroxetine          |                    |                    | S               |                                 |                      |                 | Aurobindo    |                |
| <u>FDA Received Date</u> | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Apr-2016              | 12269586            | EXPEDITED (15-DAY) |                    | HO              | SE-TEVA-651584ISR               |                      | 37 YR           | Female       | SWE            |
| <u>Preferred Term</u>    | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain;          | Escitalopram        |                    |                    | S               |                                 |                      |                 | Ivax         |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                              |                         |                    |                    |                 |                                    |                      |                 |                 |                |
|------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|------------------------------------|----------------------|-----------------|-----------------|----------------|
| Diarrhoea; Drug Interaction; Vomiting                                        |                         | Brintellix         |                    | S               |                                    | Not Reported         |                 |                 |                |
| <u>FDA Received Date</u>                                                     | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 14-Apr-2016                                                                  | 12270415                | DIRECT             |                    | OT              |                                    |                      | 46 YR           | Male            | USA            |
| <u>Preferred Term</u>                                                        | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                       | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Arrhythmia; Therapy Change                                                   | Escitalopram            |                    |                    | S               | Oral                               |                      |                 | Mylan           |                |
|                                                                              | Omeprazole              |                    |                    | C               |                                    |                      |                 | Not Reported    |                |
|                                                                              | Fenofibrate             |                    |                    | C               |                                    |                      |                 | Not Reported    |                |
|                                                                              | Lopo-Flavonoid          |                    |                    | C               |                                    |                      |                 | Not Reported    |                |
|                                                                              | Omega 3 Fish Oil        |                    |                    | C               |                                    |                      |                 | Not Reported    |                |
|                                                                              | Fibercon                |                    |                    | C               |                                    |                      |                 | Not Reported    |                |
|                                                                              | Glucosamine Chondroitin |                    |                    | C               |                                    |                      |                 | Not Reported    |                |
|                                                                              | Aspirin                 |                    |                    | C               |                                    |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                     | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 14-Apr-2016                                                                  | 12270580                | DIRECT             |                    | OT              |                                    |                      | 51 YR           | Male            | USA            |
| <u>Preferred Term</u>                                                        | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                       | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Anxiety; Chest Pain; Chills; Dehydration; Heart Rate Irregular; Hypertension | Escitalopram            | Y                  |                    | S               | Oral                               |                      | 1 DAY           | Not Reported    |                |
|                                                                              | Atenolol                |                    |                    | C               |                                    |                      |                 | Not Reported    |                |
|                                                                              | Lexapro                 |                    |                    | C               |                                    |                      |                 | Not Reported    |                |
|                                                                              | Extra Strength Tylenol  |                    |                    | C               |                                    |                      |                 | Not Reported    |                |
|                                                                              | Pepcid Ac               |                    |                    | C               |                                    |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                     | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 15-Apr-2016                                                                  | 12109629                | EXPEDITED (15-DAY) |                    | HO, OT          | US-GLAXOSMITHKLINE-US2016GSK025468 |                      | 67 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                        | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                       | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Apparent Death; Drug Ineffective; Tremor; Weight Decreased                   | Wellbutrin XI           |                    |                    | S               | Oral                               | 300 Mg, Qd           |                 | Glaxosmithkline |                |
|                                                                              | Bupropion               |                    |                    | S               | Oral                               | 600 Mg, Qd           |                 | Glaxosmithkline |                |
|                                                                              | Lorazepam               |                    |                    | S               | Oral                               | 0.5 Df, Qd           |                 | Not Reported    |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|           |   |      |          |              |
|-----------|---|------|----------|--------------|
| Lorazepam | S | Oral | 1 Df, Qd | Not Reported |
| Lexapro   | S | Oral | Unk      | Not Reported |
| Lexapro   | S | Oral | 3 Df, 1d | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Apr-2016              | 12227503      | EXPEDITED (15-DAY) | HO                 |                 | ES-FRI-1000083691    |                      | 85 YR      | Female     | ESP            |

| <u>Preferred Term</u>                                                                                                                                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Biliary Colic; Bundle Branch Block Left; Cardio-Respiratory Arrest; Electrocardiogram Qt Prolonged; Hypokalaemia; Hypomagnesaemia; Torsade De Pointes | Escitalopram   |              |            | S           | Unknown      | Unknown            |                 | Forest       |
|                                                                                                                                                       | Amiodarone     |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                                       | Metoclopramide |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                                       | Metoclopramide |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                       | Losartan       |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                                       | Betahistine    |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                                       | Simvastatin    |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                                       | Bisoprolol     |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                                       | Acenocoumarol  |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                                       | Metformin      |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                                       | Iron Sulfate   |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Apr-2016              | 12256057      | EXPEDITED (15-DAY) | OT                 |                 | IT-ROCHE-1738422     |                      | 67 YR      | Female     | ITA            |

| <u>Preferred Term</u>            | <u>Product</u>   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                              | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------|------------------|--------------|------------|-------------|--------------|-------------------------------------------------|-----------------|--------------|
| Insomnia; Restless Legs Syndrome | Rivotril         |              |            | S           | Oral         | '2.5 Mg/MI Oral Drops, Solution' 10 MI Bottle   |                 | Not Reported |
|                                  | Serenase (Italy) |              |            | S           | Oral         | '2 Mg/MI Oral Drops, Solution' 1 X 15 MI Bottle |                 | Not Reported |
|                                  | Cipralext        |              |            | S           | Oral         | 28 X 20 Mg Tablets                              |                 | Not Reported |
|                                  | Insulin          |              |            | C           | Subcutaneous |                                                 |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 15-Apr-2016                                                   | 12270239       | EXPEDITED (15-DAY) |                    | HO              | SE-TEVA-650536ISR    |                      | 22 YR           | Female       | SWE            |
| <u>Preferred Term</u>                                         | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Lethargy;<br>Nausea; Toxicity To<br>Various Agents | Sertralin      |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                               | Atarax         |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                               | Cipralext      |                    |                    | S               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                           | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 15-Apr-2016                                                        | 12273368             | EXPEDITED (15-DAY) |                    | HO              | CH-JNJFOC-20160410963 |                      | 74 YR           | Male         | CHE            |
| <u>Preferred Term</u>                                              | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bladder Tamponade;<br>Haematuria; Potentiating<br>Drug Interaction | Xarelto              |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                    | Plavix               |                    |                    | S               | Unknown               |                      |                 | Not Reported |                |
|                                                                    | Acetylsalicylic Acid |                    |                    | S               | Unknown               |                      |                 | Not Reported |                |
|                                                                    | Escitalopram         |                    |                    | S               | Unknown               |                      |                 | Not Reported |                |
|                                                                    | Prograf              |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |
|                                                                    | Aldactone A          |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |
|                                                                    | Pantozol             |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |
|                                                                    | Zyloric              |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |
|                                                                    | Euthyrox             |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |
|                                                                    | Levemir              |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |
|                                                                    | Triatec (Ramipril)   |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |
|                                                                    | Movicol              |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |
|                                                                    | Atorvastatin         |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |
|                                                                    | Torem                |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |
|                                                                    | Quetiapine Fumarate  |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |
|                                                                    | Concor               |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                           | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|------------------------------------|-----------------|------------|----------------|
| 15-Apr-2016                                                        | 12273619       | EXPEDITED (15-DAY) |                    | OT              | DE-FRI-1000083829    |                                    |                 | Female     | DEU            |
| <u>Preferred Term</u>                                              | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u> |                |
| Alopecia; Decreased Appetite; Fatigue; Insomnia; Mental Impairment | Escitalopram   |                    |                    | S               | Unknown              | 10-25 Milligram Daily For 10 Years |                 | Forest     |                |
|                                                                    | Escitalopram   |                    |                    | S               | Unknown              | 20 Mg                              |                 | Forest     |                |

| <u>FDA Received Date</u> | <u>Case #</u>       | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|---------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 15-Apr-2016              | 12273731            | NON-EXPEDITED    |                    |                 | ADR-2015-01197       |                      | 84 YR           | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u>      | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Urinary Retention        | Lioresal            |                  |                    | S               | Intrathecal          | 39.95 Mc/Gday        |                 | Not Reported |                |
|                          | Percocet            |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                          | Tylenol             |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                          | Aspirin             |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                          | Insulin Lispro      |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                          | Levothyroxine       |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                          | Magneisum Hydroxide |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                          | Metformin           |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                          | Pravastatin         |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                          | Warfarin            |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                          | Lotrisine Topical   |                  |                    | S               | Topical              |                      |                 | Not Reported |                |
|                          | Benazepril          |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                          | Vitaqmin D3         |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                          | Lexapro             |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                          | Insulin Glargine    |                  |                    | S               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|----------------------|----------------|
| 15-Apr-2016              | 12274844       | EXPEDITED (15-DAY) |                    | HO, OT          | FR-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-028691 |                      | 85 YR           | Male                 | FRA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Fall; Off Label Use;     | Abilify        |                    |                    | S               | Oral                                            | 5 Mg, Qd             |                 | Bristol Myers Squibb |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                     |                      |   |         |               |              |
|-------------------------------------|----------------------|---|---------|---------------|--------------|
| Respiratory Distress;<br>Somnolence | Temesta /00273201/   | S | Unknown | 2.5 Mg, Unk   | Not Reported |
|                                     | Seroplex             | S | Oral    | 20 Mg, Qd     | Not Reported |
|                                     | Kardegic             | C | Unknown | 75 Mg, Unk    | Not Reported |
|                                     | Flodil /00641902/    | C | Unknown | 5 Mg, Unk     | Not Reported |
|                                     | Tegretol             | C | Unknown | 400 Mg, Unk   | Not Reported |
|                                     | Gardenal /00023201/  | C | Unknown | 100 Mg, Unk   | Not Reported |
|                                     | Inegy                | C | Unknown | 1 Df, Unk     | Not Reported |
|                                     | Bisoce               | C | Unknown | 2.5 Mg, Unk   | Not Reported |
|                                     | Omexel               | C | Unknown | 0.4 Mg, Unk   | Not Reported |
|                                     | Uvedose              | C | Unknown | 100000 U, Unk | Not Reported |
|                                     | Dafalgan             | C | Unknown | 1 G, Unk      | Not Reported |
|                                     | Avodart              | C | Unknown | 0.5 Mg, Unk   | Not Reported |
|                                     | Vesicare             | C | Unknown | 10 Mg, Unk    | Not Reported |
|                                     | Topalgic /00599202/  | C | Unknown | 150 Mg, Unk   | Not Reported |
|                                     | Allopurinol          | C | Unknown |               | Not Reported |
|                                     | Pantoprazole         | C | Unknown |               | Not Reported |
|                                     | Domperidone          | C | Unknown |               | Not Reported |
|                                     | Loperamide           | C | Unknown |               | Not Reported |
|                                     | Spasfon /00765801/   | C | Unknown |               | Not Reported |
|                                     | Ventoline /00139501/ | C | Unknown |               | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 18-Apr-2016              | 12090135      | NON-EXPEDITED    |                    | OT              | US-ACTAVIS-2015-25380 |                      | 66 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                    | <u>Product</u>                                     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------|--------------|------------|-------------|--------------|------------------------|-----------------|--------------|
| Blood Potassium Increased; Cough; Decreased Appetite; Dyspnoea; Ear Pain; Haemoptysis; Headache; Lung Cancer Metastatic; | Benazepril Hydrochloride (Actavis Laboratories FI) |              |            | S           | Oral         | 10 Mg, Daily           |                 | Actavis      |
|                                                                                                                          | Lexapro /01588501/                                 |              |            | S           | Oral         | 10 Mg, Daily           |                 | Not Reported |
|                                                                                                                          | Boniva                                             |              |            | C           | Oral         | 1 Tablet, Once A Month |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Night Sweats; Pain;  
Weight Decreased

| <u>FDA Received Date</u>                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|-------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 18-Apr-2016                               | 12222084       | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000083491    |                      | 50 YR           | Male       | FRA            |
| <u>Preferred Term</u>                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Headache; Vertigo;<br>Withdrawal Syndrome | Escitalopram   |                    |                    | S               | Oral                 | 20 Mg                |                 | Forest     |                |

| <u>FDA Received Date</u> | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 18-Apr-2016              | 12279983               | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000083870    |                      | 91 YR           | Female       | FRA            |
| <u>Preferred Term</u>    | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Traumatic Haematoma      | Escitalopram           |                    |                    | S               | Oral                 | 5 Mg                 |                 | Forest       |                |
|                          | Previscan (Fluindione) |                    |                    | S               | Oral                 | 10 Mg                |                 | Not Reported |                |
|                          | Lasilix                |                    |                    | C               | Oral                 | 40 Mg                |                 | Not Reported |                |
|                          | Lasilix Retard         |                    |                    | C               | Oral                 | 60 Mg                |                 | Not Reported |                |
|                          | Nebivolol              |                    |                    | C               | Oral                 | 5 Mg                 |                 | Not Reported |                |
|                          | Bromazepam             |                    |                    | C               | Oral                 | 3 Mg                 |                 | Not Reported |                |

| <u>FDA Received Date</u>                              | <u>Case #</u>             | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------|---------------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 18-Apr-2016                                           | 12281298                  | DIRECT           |                    | HO              |                      |                      | 17 YR           | Male         | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u>            | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depressed Mood; Mental<br>Disorder; Suicidal Ideation | Escitalopram, 10 Mg, Teva |                  |                    | S               | Oral                 |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|-------------------------------------|----------------------|-----------------|------------|----------------|
| 19-Apr-2016              | 12280631       | EXPEDITED (15-DAY) |                    | HO              | SE-AUROBINDO-AUR-<br>APL-2016-04869 |                      |                 | Unknown    | SWE            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                               |                      |   |         |            |              |
|---------------------------------------------------------------|----------------------|---|---------|------------|--------------|
| Dizziness; Lethargy;<br>Nausea; Toxicity To<br>Various Agents | Sertraline           | S | Unknown | Unk        | Aurobindo    |
|                                                               | Atarax /00058401/    | S | Unknown | 25 Mg, Unk | Not Reported |
|                                                               | Cipralext /01588501/ | S | Unknown | Unk        | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Apr-2016              | 12285044      | DIRECT           | Y                  | OT              |                      |                      | 56 YR      | Female     | USA            |

| <u>Preferred Term</u>        | <u>Product</u>             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------|----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Insomnia; Nightmare;<br>Rash | Escitalopram Oxalate, 20mg |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|------------|------------|----------------|
| 20-Apr-2016              | 12287835      | EXPEDITED (15-DAY) |                    | HO              | IT-MYLANLABS-<br>2016M1016181 |                      |            | Unknown    | ITA            |

| <u>Preferred Term</u>                                                                               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Abuse; Hypokinesia;<br>Intentional Overdose;<br>Speech Disorder; Toxicity<br>To Various Agents | Escitalopram   |              |            | S           | Oral         | 1 Df, Total        |                 | Not Reported |
|                                                                                                     | Escitalopram   |              |            | S           | Oral         | 28 Df Total        |                 | Not Reported |
|                                                                                                     | Xanax          |              |            | S           | Oral         | 2 Df, Total        |                 | Mylan        |
|                                                                                                     | Xanax          |              |            | S           | Oral         | 60 Df Total        |                 | Mylan        |
|                                                                                                     | Neurontin      |              |            | C           | Oral         | Unk                |                 | Mylan        |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Apr-2016              | 12288278      | NON-EXPEDITED    |                    |                 | ADR-2015-01442       |                      | 47 YR      | Female     | USA            |

| <u>Preferred Term</u>                                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Gait Disturbance; Muscle<br>Spasms; Nerve<br>Compression | Lioresal       |              |            | S           | Intrathecal  | 257.4 Mcg/Day      |                 | Not Reported |
|                                                          | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Apr-2016              | 12290330      | DIRECT           | Y                  | OT              |                      |                      | 30 YR      | Female     | USA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                                                                                         | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |
|-----------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|--------------------|--------------------|-----------------|---------------------------------------------|----------------------|-----------------|------------------|----------------|
| Anxiety; Malaise; Product Substitution Issue                                                                                                  | Escitalopram Oxalate 10mg Accord Hlthcare |                    |                    | S               | Oral                                        |                      |                 | Accord           |                |
| <u>FDA Received Date</u>                                                                                                                      | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 21-Apr-2016                                                                                                                                   | 12289450                                  | NON-EXPEDITED      |                    |                 | US-ELI_LILLY_AND_COMP<br>ANY-US201604005259 |                      |                 | Male             | USA            |
| <u>Preferred Term</u>                                                                                                                         | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |
| Retrograde Ejaculation                                                                                                                        | Strattera                                 |                    |                    | S               | Oral                                        | Unk, Unknown         |                 | Eli Lilly And Co |                |
|                                                                                                                                               | Lexapro                                   |                    |                    | S               | Unknown                                     | Unk, Unknown         |                 | Not Reported     |                |
| <u>FDA Received Date</u>                                                                                                                      | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 22-Apr-2016                                                                                                                                   | 12238414                                  | EXPEDITED (15-DAY) |                    | LT, OT          | ES-PFIZER INC-2016174192                    |                      | 85 YR           | Female           | ESP            |
| <u>Preferred Term</u>                                                                                                                         | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |
| Bundle Branch Block Left; Cardio-Respiratory Arrest; Contraindicated Product Administered; Electrocardiogram Qt Prolonged; Torsade De Pointes | Amiodarone Hcl                            |                    |                    | S               | Unknown                                     | Unk                  |                 | Pfizer           |                |
|                                                                                                                                               | Escitalopram Oxalate                      |                    |                    | S               | Unknown                                     | Unk                  |                 | Not Reported     |                |
|                                                                                                                                               | Metoclopramide                            |                    |                    | S               | Unknown                                     | Unk                  |                 | Not Reported     |                |
|                                                                                                                                               | Metoclopramide                            |                    |                    | S               |                                             |                      |                 | Not Reported     |                |
|                                                                                                                                               | Losartan                                  |                    |                    | C               |                                             | Unk                  |                 | Not Reported     |                |
|                                                                                                                                               | Betahistine                               |                    |                    | C               |                                             | Unk                  |                 | Not Reported     |                |
|                                                                                                                                               | Simvastatin                               |                    |                    | C               |                                             | Unk                  |                 | Not Reported     |                |
|                                                                                                                                               | Bisoprolol                                |                    |                    | C               |                                             | Unk                  |                 | Not Reported     |                |
|                                                                                                                                               | Acenocoumarol                             |                    |                    | C               |                                             | Unk                  |                 | Not Reported     |                |
|                                                                                                                                               | Acenocoumarol                             |                    |                    | C               |                                             | Unk                  |                 | Not Reported     |                |
|                                                                                                                                               | Metformin                                 |                    |                    | C               |                                             | Unk                  |                 | Not Reported     |                |
|                                                                                                                                               | Ferrous Sulfate                           |                    |                    | C               |                                             | Unk                  |                 | Not Reported     |                |
| <u>FDA Received Date</u>                                                                                                                      | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 22-Apr-2016                                                                                                                                   | 12245363                                  | EXPEDITED (15-DAY) |                    | HO              | IT-SUN<br>PHARMACEUTICAL                    |                      | < 1 DAY         | Male             | ITA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

INDUSTRIES LTD-  
2016RR-114544

| <u>Preferred Term</u>                                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Foetal Exposure During Pregnancy; Neonatal Tachypnoea | Lorazepam      |              |            | S           | Transplacental | 0.25 Mg Daily      |                 | Sun          |
|                                                       | Escitalopram   |              |            | S           | Transplacental | 5 Gtt Daily        |                 | Not Reported |
|                                                       | Adalat         |              |            | S           | Transplacental | 60 Mg Daily        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Apr-2016              | 12247383      | EXPEDITED (15-DAY) |                    | HO, OT          | IT-FRI-1000083756    |                      | < 1 DAY    | Male       | ITA            |

| <u>Preferred Term</u>                                 | <u>Product</u>             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------|----------------------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Foetal Exposure During Pregnancy; Neonatal Tachypnoea | Escitalopram Oral Solution |              |            | S           | Transplacental | 5 Gtt              |                 | Forest       |
|                                                       | Adalat/ Nifedipine         |              |            | S           | Transplacental | 60 Mg              |                 | Not Reported |
|                                                       | Lorazepam                  |              |            | S           | Transplacental | 0.25 Mg            |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 22-Apr-2016              | 12294796      | NON-EXPEDITED    |                    |                 | US-PFIZER INC-<br>2016212046 |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Ineffective      | Effexor        |              |            | S           |              | Unk                |                 | Pfizer       |
|                       | Lexapro        |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Celexa         |              |            | S           |              | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Apr-2016              | 12295637      | EXPEDITED (15-DAY) |                    | HO              | IT-TEVA-653750ACC    |                      | 66 YR      | Female     | ITA            |

| <u>Preferred Term</u>                              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|----------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Drug Abuse; Hypokinesia; Speech Disorder; Toxicity | Escitalopram   |              |            | S           | Oral         | 28 Df Total        |                 | Ivax       |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                   |                             |   |      |             |              |
|-------------------|-----------------------------|---|------|-------------|--------------|
| To Various Agents | Xanax - 0.25 Mg Compresse - | S | Oral | 60 Df Total | Not Reported |
|                   | 4pharma S.R.L.              |   |      |             |              |
|                   | Neurontin                   | C | Oral |             | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Apr-2016              | 12296114      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000084003    |                      | 63 YR      | Male       | FRA            |

| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hyponatraemia; Seizure | Escitalopram   |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                        | Tramadol       |              |            | S           | Oral         |                    |                 | Not Reported |
|                        | Iperten        |              |            | C           |              |                    |                 | Not Reported |
|                        | Lamictal       |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 25-Apr-2016              | 12298633      | EXPEDITED (15-DAY) |                    | HO, OT          | FR-AMGEN-FRASP2016049782 |                      | 40 YR      | Female     | FRA            |

| <u>Preferred Term</u>            | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                        | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------|------------------------|--------------|------------|-------------|--------------|-------------------------------------------|-----------------|--------------|
| Cholecystitis Infective; Colitis | Xgeva                  |              |            | S           | Subcutaneous | 120 Mg, Q4wk                              |                 | Amgen        |
|                                  | Coversyl /00790702/    |              |            | S           | Oral         | 10 Mg, Qd                                 |                 | Not Reported |
|                                  | Fenofibrate            |              |            | S           | Oral         | 100 Mg, Qd                                |                 | Not Reported |
|                                  | Previscan (Fluindione) |              |            | S           | Oral         | 20 Mg, Dividable Pill                     |                 | Not Reported |
|                                  | Cortancyl              |              |            | S           | Oral         | 20 Mg, Qd                                 |                 | Not Reported |
|                                  | Monuril                |              |            | S           | Oral         | 3 G, Granules For Oral Solution In Sachet |                 | Not Reported |
|                                  | Inexium                |              |            | S           | Oral         | 20 Mg, Gastro-Resistant Pill Qd           |                 | Not Reported |
|                                  | Amlor                  |              |            | S           | Oral         | 50 Mg, Qd                                 |                 | Not Reported |
|                                  | Zopiclone              |              |            | S           | Oral         | Unk                                       |                 | Not Reported |
|                                  | Seroplex               |              |            | S           | Oral         | 10 Mg, Dividable Coated Pill              |                 | Not Reported |
|                                  | Levothyrox             |              |            | S           | Oral         | 125 Mug, Dividable, Pill                  |                 | Not Reported |
|                                  | Dafalgan               |              |            | S           | Oral         | Unk                                       |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                                                                                                        |                                           |                  |                    |                 |                      |                                                                  |                 |              |                |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|------------------|--------------------|-----------------|----------------------|------------------------------------------------------------------|-----------------|--------------|----------------|
| Tramadol Basi                                                                                                                                                                                                                                                                          |                                           |                  | S                  | Oral            | Unk                  | Not Reported                                                     |                 |              |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                               | <u>Case #</u>                             | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Apr-2016                                                                                                                                                                                                                                                                            | 12300173                                  | NON-EXPEDITED    |                    | HO, OT          | ADR-2015-00661       |                                                                  | 46 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                  | <u>Product</u>                            | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                               | <u>Duration</u> | <u>Mfr</u>   |                |
| Autonomic Dysreflexia;<br>Blood Pressure Increased;<br>Blood Test Abnormal;<br>Device Breakage; Drug<br>Withdrawal Syndrome;<br>Headache; Heart Rate<br>Increased; Hypertonia;<br>Muscle Spasms; Muscle<br>Spasticity; Pyrexia; Rash;<br>Tremor; Urine Analysis<br>Abnormal; Urticaria | Ascorbic Acid                             |                  |                    | S               | Oral                 |                                                                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                        | Escitalopram Lexapro                      |                  |                    | S               | Oral                 |                                                                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                        | Ketoconazole 2 Percent Topical Cream      |                  |                    | S               | Topical              |                                                                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                        | Detrol La                                 |                  |                    | S               | Oral                 |                                                                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                        | Hydrocortisone 2.5% Ointment              |                  |                    | S               | Topical              |                                                                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                        | Potassium                                 |                  |                    | S               | Oral                 |                                                                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                        | Normal Saline                             |                  |                    | S               | Topical              |                                                                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                        | Minocycline (Minocin)                     |                  |                    | S               | Oral                 |                                                                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                        | Rifampin                                  |                  |                    | S               | Oral                 |                                                                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                        | Docusate Sodium                           |                  |                    | S               | Oral                 |                                                                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                        | Clonidine Transdermal Patch               |                  |                    | S               | Transdermal          | 0.2 Mg/24 Hr Weekly<br>Transdermal Patch One<br>Patch Every Week |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                        | Clonidine Hcl                             |                  |                    | S               | Oral                 | 0.1 Mg Tablet One Tablet<br>By Mouth Every Other Day             |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                        | Dakins 0.025% Solution                    |                  |                    | S               | Unknown              |                                                                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                        | Citrucel Fiber                            |                  |                    | S               | Oral                 |                                                                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                        | Lioresal Intrathecal (Baclofen Injection) |                  |                    | S               | Intrathecal          | 879.8mcg/Day                                                     |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                        | Baclofen                                  |                  |                    | S               | Intrathecal          |                                                                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                        | Baclofen                                  |                  |                    | S               | Intrathecal          |                                                                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                        | Levothyroxine Synthroid                   |                  |                    | S               | Oral                 |                                                                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                        | Aspirin                                   |                  |                    | S               | Oral                 |                                                                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                        | Nystatin 100,00 Unit/Gram Topical Powder  |                  |                    | S               | Topical              |                                                                  |                 | Not Reported |                |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                     |   |             |                                                                                             |              |
|-----------------------------------------------------|---|-------------|---------------------------------------------------------------------------------------------|--------------|
| Tolterodine Detrol La                               | S | Oral        |                                                                                             | Not Reported |
| Imipramine                                          | S | Oral        |                                                                                             | Not Reported |
| Ciclopirox                                          | S | Topical     | Apply To Scalp Every Other Day                                                              | Not Reported |
| Betamethasone Dipropionate 0.05% Lotion             | S | Topical     |                                                                                             | Not Reported |
| Juven                                               | S | Oral        |                                                                                             | Not Reported |
| Gentamicin 0.1% Topical Ointment                    | S | Topical     |                                                                                             | Not Reported |
| Clindamycin Phosphate 1% Topical                    | S | Topical     |                                                                                             | Not Reported |
| Sulfamethoxazole Trimethoprim (Bactrim Ds)          | S | Oral        | Sulfamethoxazole 800 Mg Trimethoprim 160 Mg Tablet One Tablet By Mouth Daily                | Not Reported |
| Sulfacetamide Sodium-Sulfur 10%-5% Topical Cleanser | S | Topical     |                                                                                             | Not Reported |
| Baclofen                                            | S | Oral        |                                                                                             | Not Reported |
| Diazepam (Valium)                                   | S | Oral        |                                                                                             | Not Reported |
| Acetaminophen\Hydrocodone Bitartrate                | S | Oral        | Hydrocodone 10 Mg Acetaminophen 325 Mg Tablet One Tablet By Mouth Every Six Hours As Needed | Not Reported |
| Escitalopram Lexapro                                | S | Oral        |                                                                                             | Not Reported |
| Baclofen                                            | S | Intrathecal | 900.2 Mcg/Day                                                                               | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|------------|----------------|
| 25-Apr-2016              | 12300464       | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2016203303 |                      | 41 YR           | Female     | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective         | Zoloft         |                  |                    | S               |                          | Unk                  |                 | Pfizer     |                |
|                          | Alprazolam     |                  |                    | S               |                          | Unk                  |                 | Pfizer     |                |
|                          | Lorazepam      |                  |                    | S               |                          | Unk                  |                 | Pfizer     |                |



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|            |   |     |              |
|------------|---|-----|--------------|
| Clonazepam | S | Unk | Not Reported |
| Wellbutrin | S | Unk | Not Reported |
| Lexapro    | S | Unk | Not Reported |

| <u>FDA Received Date</u>                              | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 25-Apr-2016                                           | 12301195               | EXPEDITED (15-DAY) |                    | HO              | IT-WATSON-2016-06928 |                      | < 1 DAY         | Male         | ITA            |
| <u>Preferred Term</u>                                 | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Foetal Exposure During Pregnancy; Neonatal Tachypnoea | Lorazepam (Unknown)    |                    |                    | S               | Transplacental       | Unk                  |                 | Watson       |                |
|                                                       | Escitalopram (Unknown) |                    |                    | S               | Transplacental       | Unk                  |                 | Not Reported |                |
|                                                       | Adalat                 |                    |                    | S               | Transplacental       | Unk                  |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                         | <u>Case #</u>             | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------|---------------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 25-Apr-2016                                                                      | 12304237                  | DIRECT           |                    | OT              |                      |                      | 48 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                            | <u>Product</u>            | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Dysgeusia; Fall; Feeling Hot; Flushing; Head Injury; Headache; Nausea | Escitalopram Oxalate, 5mg |                  |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                  | Sumatriptan               |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                  | Fluticasone               |                  |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                     | <u>Case #</u>                     | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------|-----------------------------------|------------------|--------------------|-----------------|----------------------|----------------------------------------|-----------------|--------------|----------------|
| 25-Apr-2016                                                  | 12304378                          | DIRECT           |                    | HO              |                      |                                        | 34 YR           | Female       | USA            |
| <u>Preferred Term</u>                                        | <u>Product</u>                    | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Dystonia; Pain In Jaw; Serotonin Syndrome; Suicidal Ideation | Escitalopram 10mg Aurobindo Pharm |                  |                    | S               | Oral                 | 10mg 1 Tablet 1 A Day In Morning Mouth |                 | Aurobindo    |                |
|                                                              | Prilosec                          |                  |                    | C               |                      |                                        |                 | Not Reported |                |
|                                                              | Motrin                            |                  |                    | C               |                      |                                        |                 | Not Reported |                |
|                                                              | Xanax                             |                  |                    | C               |                      |                                        |                 | Not Reported |                |
|                                                              | Benadryl                          |                  |                    | C               |                      |                                        |                 | Not Reported |                |
|                                                              | Multivitamin                      |                  |                    | C               |                      |                                        |                 | Not Reported |                |

# FDA Adverse Event Reporting System

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### Detailed Report

| <u>FDA Received Date</u>         | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------|--------------------------|--------------------|--------------------|-----------------|------------------------------------------|---------------------------|-----------------|--------------|----------------|
| 25-Apr-2016                      | 12304677                 | DIRECT             |                    | DS, HO          |                                          |                           | 61 YR           | Male         | USA            |
| <u>Preferred Term</u>            | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |                |
| Amnesia; Arthralgia;             | Escitalopram - Lexipro   |                    |                    | S               | Oral                                     | 1 Pill 1 Time Daily Mouth |                 | Camber       |                |
| Dyspnoea; Erectile               | Metformin                |                    |                    | C               |                                          |                           |                 | Not Reported |                |
| Dysfunction; Malaise;            | Previcid                 |                    |                    | C               |                                          |                           |                 | Not Reported |                |
| Myalgia; Nausea; Tinnitus;       | Oxycodone                |                    |                    | C               |                                          |                           |                 | Not Reported |                |
| Vision Blurred; Weight Decreased |                          |                    |                    |                 |                                          |                           |                 |              |                |
| <u>FDA Received Date</u>         | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Apr-2016                      | 12253858                 | EXPEDITED (15-DAY) |                    | OT              | US-MDT-ADR-2016-00648                    |                           | 44 YR           | Female       | USA            |
| <u>Preferred Term</u>            | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |                |
| Catheter Site Swelling;          | Bupivacaine              |                    |                    | S               | Intrathecal                              | 7.6 Mg/Day                |                 | Not Reported |                |
| Drug Withdrawal                  | Compounded Baclofen      |                    |                    | S               | Intrathecal                              | 70 Mcg/Day                |                 | Not Reported |                |
| Syndrom; Fall; Loss Of           | Dilaudid (Hydromorphone) |                    |                    | S               | Intrathecal                              | 3.78 Mg/Day               |                 | Not Reported |                |
| Consciousness; Malaise;          | Fentanyl                 |                    |                    | S               | Intrathecal                              | 630 Mg/Day                |                 | Not Reported |                |
| Post Lumbar Puncture             | Tizanidine               |                    |                    | S               |                                          | 2 Mg                      |                 | Not Reported |                |
| Syndrom; Toxicity To             | Baclofen                 |                    |                    | S               |                                          | 10 Mg                     |                 | Not Reported |                |
| Various Agents                   | Topamax                  |                    |                    | S               |                                          | 100 Mg                    |                 | Not Reported |                |
|                                  | Remeron                  |                    |                    | S               |                                          | 115 Mg                    |                 | Not Reported |                |
|                                  | Synthroid                |                    |                    | S               |                                          | 200 Mcg                   |                 | Not Reported |                |
|                                  | Midrin                   |                    |                    | S               |                                          |                           |                 | Not Reported |                |
|                                  | Adderall                 |                    |                    | S               |                                          | 10 Mg                     |                 | Not Reported |                |
|                                  | Lexapro                  |                    |                    | S               |                                          | 20 Mg                     |                 | Not Reported |                |
| <u>FDA Received Date</u>         | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Apr-2016                      | 12304456                 | EXPEDITED (15-DAY) |                    | HO              | TH-LUPIN PHARMACEUTICALS INC.-2016-01613 |                           | 77 YR           | Male         | THA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                     | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------|--------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Acute Kidney Injury; Drug Interaction; Serotonin Syndrome | Escitalopram       |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                           | Rasagiline         |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                           | Ticlopidine        |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                           | Atorvastatin       |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                           | Gemfibrozil        |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                           | Piribidil          |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                           | Rivastigmine Patch |              |            | C           | Unknown      | 10 Cm2             |                 | Not Reported |
|                                                           | Stalevo 100        |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                           | Pramiprexole       |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                           | Melatonin          |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                           | Clonazepam         |              |            | C           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Apr-2016              | 12306899      | EXPEDITED (15-DAY) |                    | DS              | AU-FRI-1000084025    |                      | 45 YR      | Female     | AUS            |

| <u>Preferred Term</u>                                                                                               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Delirium; Depression; Dizziness; Food Intolerance; Histamine Intolerance; Suicidal Ideation; Tachycardia; Urticaria | Escitalopram   |              |            | S           | Unknown      | 20 Mg              |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 26-Apr-2016              | 12308243      | EXPEDITED (15-DAY) |                    | HO              | FR-ASTRAZENECA-2016SE43033 |                      | 40 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|---------------------------------------|-----------------|--------------|
| Chemical Peritonitis; Cholecystitis Infective; Colitis; Lung Disorder; Melaena; Sciatica | Inexium        |              |            | S           | Oral         |                                       |                 | Not Reported |
|                                                                                          | Cortancyl      |              |            | S           | Oral         | From 20mg To 60mg Once In The Morning |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |                        |   |              |              |
|--|------------------------|---|--------------|--------------|
|  | Xgeva                  | S | Subcutaneous | Not Reported |
|  | Fenofibrate            | S | Oral         | Not Reported |
|  | Previscan (Fluindione) | S | Oral         | Not Reported |
|  | Monuril                | S | Oral         | Not Reported |
|  | Amlor                  | S | Oral         | Not Reported |
|  | Coversyl               | S | Oral         | Not Reported |
|  | Zopiclone              | S | Oral         | Not Reported |
|  | Seroplex               | S | Oral         | Not Reported |
|  | Levothyrox             | S | Unknown      | Not Reported |
|  | Dafalgan               | S | Oral         | Not Reported |
|  | Tramadol               | C | Oral         | Not Reported |

  

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Apr-2016              | 12308919      | DIRECT           | Y                  | OT              |                      |                      | 51 YR      | Female     | USA            |

  

| <u>Preferred Term</u>                              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------|----------------|--------------|------------|-------------|--------------|------------------------|-----------------|--------------|
| Anxiety; Depression;<br>Product Substitution Issue | Escitalopram   |              |            | S           | Oral         | Prior To Up To 7/14/15 |                 | Not Reported |

  

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Apr-2016              | 12309189      | DIRECT           |                    |                 |                      |                      | 58 YR      | Female     |                |

  

| <u>Preferred Term</u>           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Intolerance;<br>Somnolence | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

  

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Apr-2016              | 12309217      | DIRECT           |                    | OT              |                      |                      | 24 YR      | Male       |                |

  

| <u>Preferred Term</u>         | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                   |
|-------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------------------------|
| Food Interaction;<br>Headache | Lexapro<br>Lamotragine |              |            | S<br>C      |              |                    |                 | Not Reported<br>Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                        | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------|---------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 27-Apr-2016                                                                     | 10991392            | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2015117628 |                      | 54 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                           | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity                                                           | Effexor Xr          |                    |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                                                                                 | Cipro               |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                                                                                 | Depakote            |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                                                                                 | Lexapro             |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                                                                                 | Trileptal           |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                                                                                 | Bee Venom, Standard |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                                                                                 | Losartan            |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                        | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Apr-2016                                                                     | 12188498            | EXPEDITED (15-DAY) |                    | HO, OT          | US-JNJFOC-20160226890    |                      | 20 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                           | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Adverse Event; Breast Enlargement; Confusional State; Headache; Hospitalisation | Risperdal Consta    |                    |                    | S               | Intramuscular            |                      |                 | Not Reported |                |
|                                                                                 | Risperdal Consta    |                    |                    | S               | Intramuscular            |                      |                 | Not Reported |                |
|                                                                                 | Risperidone         |                    |                    | S               | Unknown                  |                      |                 | Not Reported |                |
|                                                                                 | Lexapro             |                    |                    | S               | Unknown                  |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                        | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Apr-2016                                                                     | 12204477            | EXPEDITED (15-DAY) |                    | CA, HO          | FR-FRI-1000083392        |                      |                 | Female       | FRA            |
| <u>Preferred Term</u>                                                           | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Exposure During Pregnancy; Foetal Growth Restriction                            | Escitalopram        |                    |                    | S               | Transplacental           | Not Specified        |                 | Forest       |                |
|                                                                                 | Baclofene           |                    |                    | S               | Transplacental           |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                                                                          | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|------------------------------|------------------------------------------------------------|-----------------|--------------|----------------|
| 27-Apr-2016                                                                                                                                                                                                                                                       | 12308861             | EXPEDITED (15-DAY) |                    | OT              | BR-SHIRE-<br>BR201604799     |                                                            | 13 YR           | Male         | BRA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                             | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Cardiac Arrest;<br>Condition Aggravated;<br>Depression; Oxygen<br>Consumption Decreased;<br>Panic Disorder; Poor<br>Venous Access; Pulse<br>Abnormal; Social Avoidant<br>Behaviour; Tooth<br>Disorder; Vascular Access<br>Complication; Vein<br>Disorder | Elaprase             |                    |                    | S               | Intravenous drip             | 18 Mg (3 Vials), 1x/Week                                   |                 | Shire        |                |
|                                                                                                                                                                                                                                                                   | Escitalopram Oxalate |                    |                    | S               | Unknown                      | 20 Mg (10 Mg, 2 Tablets),<br>1x/Day:Qd (In The<br>Morning) |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                   | Escitalopram Oxalate |                    |                    | S               |                              |                                                            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                          | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Apr-2016                                                                                                                                                                                                                                                       | 12309331             | EXPEDITED (15-DAY) |                    | HO              | IT-ACCORD-039984             |                                                            | 66 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                             | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Abuse; Hypokinesia;<br>Speech Disorder; Toxicity<br>To Various Agents                                                                                                                                                                                        | Escitalopram         |                    |                    | S               | Oral                         |                                                            |                 | Accord       |                |
|                                                                                                                                                                                                                                                                   | Xanax                |                    |                    | S               | Oral                         | Strength: 0.25 Mg Mah:<br>4pharma S.R.L.                   |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                   | Neurontin            |                    |                    | C               | Oral                         |                                                            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                          | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Apr-2016                                                                                                                                                                                                                                                       | 12310423             | EXPEDITED (15-DAY) |                    | HO              | FR-PFIZER INC-<br>2016220488 |                                                            | 40 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                             | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Cholecystitis Infective;<br>Colitis                                                                                                                                                                                                                               | Amlor                |                    |                    | S               | Oral                         | 5 Mg, 1x/Day                                               |                 | Pfizer       |                |
|                                                                                                                                                                                                                                                                   | Inexium              |                    |                    | S               | Oral                         | 20 Mg, 1x/Day                                              |                 | Unknown      |                |
|                                                                                                                                                                                                                                                                   | Xgeva                |                    |                    | S               | Subcutaneous                 | 120 Mg Every 4 Weeks                                       |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                   | Fenofibrate          |                    |                    | S               | Oral                         | 100 Mg, 1x/Day                                             |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                        |   |      |                 |              |
|------------------------|---|------|-----------------|--------------|
| Previscan /00789001/   | S | Oral | Strenght 20 Mg  | Not Reported |
| Cortancyl              | S | Oral | 20 Mg, 1x/Day   | Not Reported |
| Monuril Adultes        | S | Oral | 3 G, Single     | Not Reported |
| Coversyl /00790703/    | S | Oral | 10 Mg, 1x/Day   | Not Reported |
| Zopiclone              | S | Oral | 1 Df, 1x/Day    | Not Reported |
| Seroplex               | S | Oral | 10 Mg, 2x/Day   | Not Reported |
| Levothyrox             | S | Oral | 62.5 Ug, 1x/Day | Not Reported |
| Dafalgan               | S | Oral | Unk             | Not Reported |
| Tramadol Hydrochloride | C | Oral | Unk             | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                    | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------------------------------|----------------------|------------|------------|----------------|
| 27-Apr-2016              | 12311398      | EXPEDITED (15-DAY) |                    | HO              | FR-SYMLMED<br>PHARMACEUTICALS-<br>2016SYMLMED00020<br>2 |                      |            | Unknown    | FRA            |

| <u>Preferred Term</u>                                                                                                                                                                                                  | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|-----------------------|-----------------|--------------|
| Chemical Peritonitis;<br>Cholecystitis Infective;<br>Colitis; Diarrhoea;<br>Enterobacter Infection;<br>Melaena; Pneumonia;<br>Pyrexia; Sciatica; Septic<br>Shock; Tachycardia;<br>Urinary Tract Infection;<br>Vomiting | Coversyl             |              |            | S           | Oral         | 10 Mg, Qd             |                 | Unknown      |
|                                                                                                                                                                                                                        | Xgeva                |              |            | S           | Subcutaneous | 120 Mg, Every 4 Weeks |                 | Not Reported |
|                                                                                                                                                                                                                        | Fenofibrate          |              |            | S           | Oral         | 100 Mg, Qd            |                 | Not Reported |
|                                                                                                                                                                                                                        | Previscan /00789001/ |              |            | S           | Oral         | 20 Mg, Unk            |                 | Not Reported |
|                                                                                                                                                                                                                        | Cortancyl            |              |            | S           | Oral         | 20 Mg, Qd             |                 | Not Reported |
|                                                                                                                                                                                                                        | Monuril              |              |            | S           | Oral         | 3 Gram, Once          |                 | Not Reported |
|                                                                                                                                                                                                                        | Inexium /01479302/   |              |            | S           | Oral         | 20 Mg, Qd             |                 | Not Reported |
|                                                                                                                                                                                                                        | Amlor                |              |            | S           | Oral         | 5 Mg, Qd              |                 | Not Reported |
|                                                                                                                                                                                                                        | Zopiclone            |              |            | S           | Oral         | 1 Df, Qd              |                 | Not Reported |
|                                                                                                                                                                                                                        | Seroplex             |              |            | S           | Oral         | 10 Mg, Bid            |                 | Not Reported |
|                                                                                                                                                                                                                        | Levothyrox           |              |            | S           | Oral         | 62.5 Mg, Qd           |                 | Not Reported |
|                                                                                                                                                                                                                        | Dafalgan             |              |            | S           | Oral         | Unk                   |                 | Not Reported |
|                                                                                                                                                                                                                        | Tramadol             |              |            | C           | Oral         | Unk                   |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------|----------------|--------------------|--------------------|-----------------|------------------------------------------|--------------------------|-----------------|--------------|----------------|
| 27-Apr-2016                               | 12311620       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000084148                        |                          | 74 YR           | Male         | FRA            |
| <u>Preferred Term</u>                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Hepatitis; Jaundice;<br>Product Use Issue | Escitalopram   |                    |                    | S               | Oral                                     | 5 Mg                     |                 | Forest       |                |
|                                           | Zelitrex       |                    |                    | C               |                                          |                          |                 | Not Reported |                |
|                                           | Wellvone       |                    |                    | C               |                                          |                          |                 | Not Reported |                |
|                                           | Alprazolam     |                    |                    | C               |                                          |                          |                 | Not Reported |                |
|                                           | Cortancyl      |                    |                    | C               |                                          |                          |                 | Not Reported |                |
|                                           | Nasonex        |                    |                    | C               |                                          |                          |                 | Not Reported |                |
|                                           | Movicol        |                    |                    | C               |                                          |                          |                 | Not Reported |                |
|                                           | Gaviscon       |                    |                    | C               |                                          |                          |                 | Not Reported |                |
|                                           | Tercian        |                    |                    | C               |                                          |                          |                 | Not Reported |                |
|                                           | Permixon       |                    |                    | C               |                                          |                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Apr-2016                               | 12311716       | EXPEDITED (15-DAY) |                    | OT              | FR-UCBSA-2016014716                      |                          | 62 YR           | Female       | FRA            |
| <u>Preferred Term</u>                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Thrombocytopenia                          | Xyzall         |                    |                    | S               | Oral                                     | Unk Unk, As Needed (Prn) |                 | Ucb          |                |
|                                           | Istodax        |                    |                    | S               |                                          | Unk                      |                 | Not Reported |                |
|                                           | Istodax        |                    |                    | S               | Intravenous (not<br>otherwise specified) | 24 Mg, Unk               |                 | Not Reported |                |
|                                           | Inexium        |                    |                    | S               | Oral                                     | 20 Mg, Once Daily (Qd)   |                 | Not Reported |                |
|                                           | Gaviscon       |                    |                    | S               | Oral                                     | 1 Df, 3x/Day (Tid)       |                 | Not Reported |                |
|                                           | Seroplex       |                    |                    | S               | Oral                                     | 10 Mg, Once Daily (Qd)   |                 | Not Reported |                |
|                                           | Bactrim        |                    |                    | C               |                                          | Unk                      |                 | Not Reported |                |
|                                           | Zelitrex       |                    |                    | C               |                                          |                          |                 | Not Reported |                |
|                                           | Neorecormon    |                    |                    | C               |                                          |                          |                 | Not Reported |                |
|                                           | Granocyte      |                    |                    | C               |                                          |                          |                 | Not Reported |                |
|                                           | Dexamethasone  |                    |                    | C               |                                          | Unk                      |                 | Not Reported |                |
|                                           | Bendamustine   |                    |                    | C               |                                          | Unk                      |                 | Not Reported |                |
|                                           | Brentuximab    |                    |                    | C               |                                          | Unk                      |                 | Not Reported |                |



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|                                                                             | Revlimid                                                              |                    | C                  |                 |                      | Unk                           |                 |              | Not Reported   |
|-----------------------------------------------------------------------------|-----------------------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------|-----------------|--------------|----------------|
|                                                                             | Endoxan                                                               |                    | C                  |                 |                      | Unk                           |                 |              | Not Reported   |
| <u>FDA Received Date</u>                                                    | <u>Case #</u>                                                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Apr-2016                                                                 | 12313522                                                              | DIRECT             |                    | OT              |                      |                               | 76 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                       | <u>Product</u>                                                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Pain In Extremity                                                           | Escitalopram (Subet For Lexapro) 10 Mg Tablet Accord Healthca (Lblr.) |                    |                    | S               | Oral                 | 10 Mg Tab 30 1 X Day By Mouth |                 | Accord       |                |
|                                                                             | Losartan                                                              |                    |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                             | Saphris                                                               |                    |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                             | 50 + Vitamins                                                         |                    |                    | C               |                      |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                    | <u>Case #</u>                                                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Apr-2016                                                                 | 12314260                                                              | DIRECT             | Y                  | CA              |                      |                               | < 1 DAY         | Female       | USA            |
| <u>Preferred Term</u>                                                       | <u>Product</u>                                                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Dental Alveolar Anomaly; Gingival Disorder; Maternal Drugs Affecting Foetus | Lexapro                                                               |                    |                    | S               |                      |                               |                 | Not Reported |                |
|                                                                             | Marijuana                                                             |                    |                    | S               |                      |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                    | <u>Case #</u>                                                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Apr-2016                                                                 | 12217176                                                              | EXPEDITED (15-DAY) |                    | LT              | FR-FRI-1000083489    |                               | 65 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                       | <u>Product</u>                                                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Acute Respiratory Distress Syndrome; Lung Disorder                          | Escitalopram                                                          |                    |                    | S               | Oral                 | 15 Mg                         |                 | Forest       |                |
|                                                                             | Apokinon                                                              |                    |                    | S               | Subcutaneous         |                               |                 | Not Reported |                |
|                                                                             | Mantadix                                                              |                    |                    | S               | Oral                 | 100 Mg                        |                 | Not Reported |                |
|                                                                             | Sinemet                                                               |                    |                    | S               | Oral                 | 1250 Mg                       |                 | Not Reported |                |
|                                                                             | Modopar                                                               |                    |                    | S               | Oral                 |                               |                 | Not Reported |                |
|                                                                             | Imovane                                                               |                    |                    | S               | Oral                 | 7.5 Mg                        |                 | Not Reported |                |

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|  |             |   |      |         |  |              |
|--|-------------|---|------|---------|--|--------------|
|  | Sifrol      | S | Oral | 1.05 Mg |  | Not Reported |
|  | Azilect     | S | Oral | 1 Mg    |  | Not Reported |
|  | Alprazolam  | S |      |         |  | Not Reported |
|  | Apomorphine | S |      |         |  | Not Reported |

| <u>FDA Received Date</u>                                                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|-----------------|--------------|----------------|
| 28-Apr-2016                                                                | 12312735       | EXPEDITED (15-DAY) | HO                 |                 | IT-CIPLA LTD.-<br>2016IT03999 |                      |                 | Unknown      | ITA            |
| <u>Preferred Term</u>                                                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Abuse; Hypokinesia;<br>Speech Disorder; Toxicity<br>To Various Agents | Escitalopram   |                    |                    | S               | Oral                          | 28 Df Total          |                 | Invagen      |                |
|                                                                            | Xanax          |                    |                    | S               | Oral                          | 60 Df, Total         |                 | Not Reported |                |
|                                                                            | Neurontin      |                    |                    | C               | Oral                          | Unk                  |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                   | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------|-------------------------------------|--------------------|--------------------|-----------------|-------------------------------------|----------------------|-----------------|--------------|----------------|
| 28-Apr-2016                                                                | 12313139                            | EXPEDITED (15-DAY) | HO                 |                 | IT-AUROBINDO-AUR-<br>APL-2016-05070 |                      | 66 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                      | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Abuse; Hypokinesia;<br>Speech Disorder; Toxicity<br>To Various Agents | Escitalopram Film-Coated<br>Tablets |                    |                    | S               | Oral                                | 28 Df, Total         |                 | Aurobindo    |                |
|                                                                            | Xanax                               |                    |                    | S               | Oral                                | 60 Df, Total         |                 | Not Reported |                |
|                                                                            | Neurontin                           |                    |                    | C               | Oral                                |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|----------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 28-Apr-2016                                              | 12314561       | EXPEDITED (15-DAY) | OT                 |                 | IE-FRI-1000084107    |                      | 62 YR           | Male       | IRL            |
| <u>Preferred Term</u>                                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Dyspnoea; Headache;<br>Heart Rate Increased;<br>Insomnia | Lexapro        |                    |                    | S               | Oral                 | 5 Mg                 |                 | Forest     |                |
|                                                          | Lexapro        |                    |                    | S               |                      |                      |                 | Forest     |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Apr-2016              | 12314566      | EXPEDITED (15-DAY) | HO                 |                 | IT-FRI-1000084116    |                      | 66 YR      | Female     | ITA            |

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| <u>Preferred Term</u>                                                                                                        | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                        | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|-------------------------------------------|-----------------|--------------|
| Drug Abuse; Hypokinesia;<br>Intentional Overdose;<br>Intentional Overdose;<br>Speech Disorder; Toxicity<br>To Various Agents | Escitalopram            |              |            | S           | Oral         | 10 Mg                                     |                 | Forest       |
|                                                                                                                              | Escitalopram            |              |            | S           | Oral         | Overdose: 28 Df (10 Mg X<br>28 = 280mg)   |                 | Forest       |
|                                                                                                                              | Xanax "0,25mg Compresse |              |            | S           | Oral         |                                           |                 | Not Reported |
|                                                                                                                              | Xanax "0,25mg Compresse |              |            | S           | Oral         | Overdose: 60 Df ((0.25 Mg<br>X 60= 15 Mg) |                 | Not Reported |
|                                                                                                                              | Neurontin/ Gabapentin   |              |            | C           | Oral         |                                           |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|------------|------------|----------------|
| 28-Apr-2016              | 12315298      | EXPEDITED (15-DAY) |                    | OT              | FR-ASTRAZENECA-<br>2016SE44029 |                      | 62 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                             | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------|----------------|--------------|------------|-------------|------------------------------------------|--------------------|-----------------|--------------|
| Malignant Neoplasm<br>Progression;<br>Thrombocytopenia | Inexium        |              |            | S           | Oral                                     |                    |                 | Astrazeneca  |
|                                                        | Xyzall         |              |            | S           | Oral                                     | If Needed          |                 | Not Reported |
|                                                        | Istodax        |              |            | S           | Intravenous (not<br>otherwise specified) |                    |                 | Not Reported |
|                                                        | Istodax        |              |            | S           | Intravenous (not<br>otherwise specified) |                    |                 | Not Reported |
|                                                        | Gaviscon       |              |            | S           | Oral                                     |                    |                 | Not Reported |
|                                                        | Seroplex       |              |            | S           | Oral                                     |                    |                 | Not Reported |
|                                                        | Bactrim        |              |            | C           |                                          |                    |                 | Not Reported |
|                                                        | Zelitrex       |              |            | C           |                                          |                    |                 | Not Reported |
|                                                        | Neorecormon    |              |            | C           |                                          |                    |                 | Not Reported |
|                                                        | Granocyte      |              |            | C           |                                          |                    |                 | Not Reported |
|                                                        | Dexamethasone  |              |            | C           |                                          |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Apr-2016              | 12217185      | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000083487    |                      | 47 YR      | Male       | FRA            |

| <u>Preferred Term</u>                  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|----------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Ejaculation Failure;<br>Product Use In | Escitalopram   |              |            | S           | Oral         | 5 Mg               |                 | Forest     |

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|                       |              |   |         |       |              |
|-----------------------|--------------|---|---------|-------|--------------|
| Unapproved Indication | Escitalopram | S | Oral    | 10 Mg | Forest       |
|                       | Bromazepam   | C | Unknown |       | Not Reported |
|                       | Meteoxane    | C | Unknown |       | Not Reported |
|                       | Pantoprazole | C | Unknown |       | Not Reported |

| <u>FDA Received Date</u>                          | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------|---------------------|--------------------|--------------------|-----------------|----------------------|-----------------------|-----------------|--------------|----------------|
| 29-Apr-2016                                       | 12317145            | EXPEDITED (15-DAY) |                    | OT              | SE-ACCORD-039976     |                       | 51 YR           | Male         | SWE            |
| <u>Preferred Term</u>                             | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Depressive Symptom;<br>Product Substitution Issue | Escitalopram Accord |                    |                    | S               | Oral                 |                       |                 | Accord       |                |
|                                                   | Propavan Sanofi Ab  |                    |                    | C               |                      | Propavan 25 Mg Tablet |                 | Not Reported |                |
|                                                   | Oxascand            |                    |                    | C               |                      | Oxascand 10 Mg Tablet |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u>                             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|-------------------------------|--------------------------------------------------|-----------------|--------------|----------------|
| 29-Apr-2016                                                                   | 12317457       | EXPEDITED (15-DAY) |                    | HO, OT          | US-CIPLA LTD.-<br>2016US03823 |                                                  |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                         | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>                               | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Fatigue;<br>Myocardial Infarction;<br>Ventricular Tachycardia | Gemcitabine    |                    |                    | S               |                               | 1000 Mg/M2 On 2 Weeks<br>On, 1 Week Off Schedule |                 | Cipla        |                |
|                                                                               | Gemcitabine    |                    |                    | S               |                               | 1000 Mg/M2, Infused Over<br>30 Mins              |                 | Cipla        |                |
|                                                                               | Gabapentin     |                    |                    | S               | Unknown                       | 600 Mg, Qd                                       |                 | Invagen      |                |
|                                                                               | Escitalopram   |                    |                    | S               | Unknown                       | 10 Mg, Qd                                        |                 | Invagen      |                |
|                                                                               | Docetaxel      |                    |                    | S               |                               | 40 Mg/M2, Unk                                    |                 | Cipla        |                |
|                                                                               | Nifedipine     |                    |                    | S               | Unknown                       | 10 Mg, Qd                                        |                 | Cipla        |                |
|                                                                               | Digoxin        |                    |                    | S               | Unknown                       | 0.25 Mg, Qd                                      |                 | Not Reported |                |
|                                                                               | Spirolactone   |                    |                    | S               | Unknown                       | 25 Mg, Qd                                        |                 | Not Reported |                |
|                                                                               | Rabeprazole    |                    |                    | S               | Unknown                       | 20 Mg, Qd                                        |                 | Not Reported |                |
|                                                                               | Rofecoxib      |                    |                    | S               | Unknown                       | 25 Mg, Qd                                        |                 | Not Reported |                |
|                                                                               | Aspirin        |                    |                    | S               | Unknown                       | 81 Mg, Qd                                        |                 | Not Reported |                |

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|                                                                                                                                                                                                                                                                                              |                                                                                                              |                    |                    |                                     |                      |                                          |                 |            |                                                                                              |  |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------|--------------------|--------------------|-------------------------------------|----------------------|------------------------------------------|-----------------|------------|----------------------------------------------------------------------------------------------|--|
| Nitroglycerin                                                                                                                                                                                                                                                                                |                                                                                                              |                    | S                  |                                     | Unknown              |                                          | 0.4 Mg, Prn     |            | Not Reported                                                                                 |  |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                     | <u>Case #</u>                                                                                                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>                     | <u>Mfr Control #</u> | <u>503B Facility</u>                     | <u>Age</u>      | <u>Sex</u> | <u>Country</u>                                                                               |  |
| 29-Apr-2016                                                                                                                                                                                                                                                                                  | 12318687                                                                                                     | EXPEDITED (15-DAY) |                    | OT                                  | TR-FRI-1000084337    |                                          |                 | Unknown    | TUR                                                                                          |  |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                        | <u>Product</u>                                                                                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                         | <u>Route</u>         | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u> |                                                                                              |  |
| Asthenia; Cold Sweat;<br>Dizziness; Drug<br>Ineffective;<br>Hypoaesthesia;<br>Hypoaesthesia; Nausea;<br>Seizure                                                                                                                                                                              | Escitalopram                                                                                                 |                    |                    | S                                   | Unknown              |                                          |                 | Forest     |                                                                                              |  |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                     | <u>Case #</u>                                                                                                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>                     | <u>Mfr Control #</u> | <u>503B Facility</u>                     | <u>Age</u>      | <u>Sex</u> | <u>Country</u>                                                                               |  |
| 29-Apr-2016                                                                                                                                                                                                                                                                                  | 12321152                                                                                                     | DIRECT             |                    |                                     |                      |                                          | 32 YR           | Male       | USA                                                                                          |  |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                        | <u>Product</u>                                                                                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                         | <u>Route</u>         | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u> |                                                                                              |  |
| Pollakiuria                                                                                                                                                                                                                                                                                  | Lexapro                                                                                                      |                    |                    | S                                   |                      |                                          |                 |            | Not Reported                                                                                 |  |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                     | <u>Case #</u>                                                                                                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>                     | <u>Mfr Control #</u> | <u>503B Facility</u>                     | <u>Age</u>      | <u>Sex</u> | <u>Country</u>                                                                               |  |
| 29-Apr-2016                                                                                                                                                                                                                                                                                  | 12321162                                                                                                     | DIRECT             |                    | OT                                  |                      |                                          | 72 YR           | Female     | USA                                                                                          |  |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                        | <u>Product</u>                                                                                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                         | <u>Route</u>         | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u> |                                                                                              |  |
| Amnesia; Burning<br>Sensation; Burning<br>Sensation; Discomfort;<br>Disturbance In Attention;<br>Dry Skin; Dry Skin; Flank<br>Pain; Gait Disturbance;<br>Oedema; Oedema<br>Peripheral; Pain In<br>Extremity; Pruritus; Rash;<br>Rash; Rash<br>Erythematous; Swelling;<br>Withdrawal Syndrome | Escitalopram, 20 Mg Teva Usa<br><br>Levothyroxine<br>Warfarin<br>Multi Vit/Mineral<br>Calc<br>D3<br>Fish Oil |                    |                    | S<br><br>C<br>C<br>C<br>C<br>C<br>C | Oral                 | 1 Tablet(S) Once A Day<br>Taken By Mouth |                 | Teva       | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |  |

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| <a href="#">FDA Received Date</a>                                                   | <a href="#">Case #</a>                    | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-------------------------------------------------------------------------------------|-------------------------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 29-Apr-2016                                                                         | 12321864                                  | DIRECT                    | Y                           | OT                       |                               |                               | 30 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                      | <a href="#">Product</a>                   | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Anxiety; Feeling Abnormal                                                           | Escitalopram Oxalate 10mg Accord Hlthcare |                           |                             | S                        | Oral                          |                               |                          | Accord              |                         |
| <a href="#">FDA Received Date</a>                                                   | <a href="#">Case #</a>                    | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 02-May-2016                                                                         | 12268590                                  | EXPEDITED (15-DAY)        |                             | HO                       | CN-FRI-1000083840             |                               | 53 YR                    | Female              | CHN                     |
| <a href="#">Preferred Term</a>                                                      | <a href="#">Product</a>                   | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Alanine Aminotransferase Increased                                                  | Lexapro                                   |                           |                             | S                        | Unknown                       | 10 Mg                         |                          | Forest              |                         |
|                                                                                     | Mirtazapine                               |                           |                             | C                        | Unknown                       |                               |                          | Not Reported        |                         |
|                                                                                     | Dexzopiclone Tablets                      |                           |                             | C                        | Unknown                       |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                   | <a href="#">Case #</a>                    | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 02-May-2016                                                                         | 12321675                                  | EXPEDITED (15-DAY)        |                             | OT                       | US-TORRENT-00001202           |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                      | <a href="#">Product</a>                   | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Abdominal Discomfort; Emotional Distress; Nasopharyngitis; Surgery; Tension; Tremor | Escitalopram Tablets, Usp                 |                           |                             | S                        |                               | 1/2 Tablet Daily (20mg)       |                          | Torrent             |                         |
| <a href="#">FDA Received Date</a>                                                   | <a href="#">Case #</a>                    | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 03-May-2016                                                                         | 12326856                                  | EXPEDITED (15-DAY)        |                             | OT                       | FR-FRI-1000084321             |                               | 28 YR                    | Female              | FRA                     |
| <a href="#">Preferred Term</a>                                                      | <a href="#">Product</a>                   | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Suicidal Behaviour; Toxicity To Various Agents                                      | Escitalopram                              |                           |                             | S                        | Oral                          |                               |                          | Forest              |                         |
|                                                                                     | Escitalopram                              |                           |                             | S                        | Oral                          |                               |                          | Forest              |                         |
|                                                                                     | Escitalopram                              |                           |                             | S                        | Oral                          |                               |                          | Not Reported        |                         |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|            |   |      |              |
|------------|---|------|--------------|
| Bromazepam | S | Oral | Not Reported |
| Bromazepam | S | Oral | Not Reported |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>        | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|--------------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 03-May-2016                       | 12329334               | EXPEDITED (15-DAY)        |                             | OT                       | US-INDIVIOR LIMITED-INDV-090134-2016 |                               | < 1 DAY             | Female              | USA                     |

| <a href="#">Preferred Term</a>                                                                                 | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a>               | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|----------------------------------------------------------------------------------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-------------------------------------------|--------------------------|---------------------|
| Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Premature Baby; Psychomotor Hyperactivity | Suboxone                |                       |                     | S                    | Transplacental        | 8 Mg, Qd                                  |                          | Reckitt Benckiser   |
|                                                                                                                | Subutex                 |                       |                     | S                    | Transplacental        | Unk                                       |                          | Reckitt Benckiser   |
|                                                                                                                | Lexapro                 |                       |                     | S                    | Transplacental        | 10 Mg, Qd                                 |                          | Not Reported        |
|                                                                                                                | Clonidine               |                       |                     | S                    | Transplacental        | 0.1 Mg, Tid                               |                          | Not Reported        |
|                                                                                                                | Ativan                  |                       |                     | S                    | Transplacental        | 0.5 Mg Two Times A Day And When Necessary |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 03-May-2016                       | 12329723               | EXPEDITED (15-DAY)        |                             | HO                       | BR-TAKEDA-2016TUS007550       |                               | 30 YR               | Female              | BRA                     |

| <a href="#">Preferred Term</a>         | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|----------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Colitis; Diarrhoea; Headache; Vomiting | Brintellix              |                       |                     | S                    | Oral                  | 5 Mg, Qd                    |                          | Takeda              |
|                                        | Escitalopram            |                       |                     | S                    | Unknown               | Unknown                     |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 03-May-2016                       | 12331411               | DIRECT                    |                             |                          |                               |                               |                     | Female              | USA                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Drug Ineffective               | Lexapro                 |                       |                     | S                    |                       |                             |                          | Forest              |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 04-May-2016                       | 12266408               | EXPEDITED (15-DAY)        |                             | HO, OT                   | ES-APOTEX-2016AP007534        |                               | 85 YR               | Female              | ESP                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                        |                           |   |         |              |
|----------------------------------------------------------------------------------------|---------------------------|---|---------|--------------|
| Cardio-Respiratory Arrest;<br>Electrocardiogram Qt<br>Prolonged; Torsade De<br>Pointes | Escitalopram Apotex       | S | Unknown | Apotex       |
|                                                                                        | Amiodarone                | S | Unknown | Not Reported |
|                                                                                        | Metoclopramide /00041902/ | S | Unknown | Not Reported |
|                                                                                        | Metoclopramide /00041902/ | S |         | Not Reported |
|                                                                                        | Losartan                  | C | Unknown | Not Reported |
|                                                                                        | Betahistine               | C | Unknown | Not Reported |
|                                                                                        | Simvastatin               | C | Unknown | Not Reported |
|                                                                                        | Bisoprolol                | C | Unknown | Not Reported |
|                                                                                        | Acenocoumarol             | C | Unknown | Not Reported |
|                                                                                        | Metformin                 | C | Unknown | Not Reported |
|                                                                                        | Iron Sulfate              | C | Unknown | Not Reported |

| <u>FDA Received Date</u>           | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------|---------------------|--------------------|--------------------|-----------------|------------------------------|------------------------|-----------------|--------------|----------------|
| 04-May-2016                        | 12330992            | EXPEDITED (15-DAY) |                    | OT              | US-ASTELLAS-<br>2016US017094 |                        | 46 YR           | Male         | USA            |
| <u>Preferred Term</u>              | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Coronary Artery Disease;<br>Tremor | Prograf             |                    |                    | S               | Unknown                      |                        |                 | Astellas     |                |
|                                    | Cellcept /01275102/ |                    |                    | S               | Unknown                      | Unk, Unknown Freq.     |                 | Not Reported |                |
|                                    | Sirolimus           |                    |                    | S               | Unknown                      | 0.5 Mg, Unknown Freq.  |                 | Not Reported |                |
|                                    | Lexapro /01588501/  |                    |                    | S               | Unknown                      | Unk Unk, Unknown Freq. |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 04-May-2016              | 12331205       | NON-EXPEDITED    |                    |                 | US-ENDO<br>PHARMACEUTICALS<br>INC.-2016-001887 |                      |                 | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Road Traffic Accident    | Diazepam 5mg   |                  |                    | S               | Oral                                           |                      |                 | Not Reported |                |
|                          | Lexapro        |                  |                    | S               | Unknown                                        |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-May-2016              | 12336314      | DIRECT           |                    | OT              |                      |                      | 52 YR      | Female     | USA            |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                   | <u>Product</u>             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------|----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Contusion; Drug Ineffective; Haemorrhage; Pruritus Generalised; Scratch | Escitalopram, 10mg Walmart |              |            | S           | Oral         |                    |                 | Walmart      |
|                                                                         | Prozac                     |              |            | C           |              |                    |                 | Not Reported |
|                                                                         | Clonazepam                 |              |            | C           |              |                    |                 | Not Reported |
|                                                                         | Skelaxin                   |              |            | C           |              |                    |                 | Not Reported |
|                                                                         | Suboxone                   |              |            | C           |              |                    |                 | Not Reported |
|                                                                         | Tylenol                    |              |            | C           |              |                    |                 | Not Reported |
|                                                                         | Excedrin                   |              |            | C           |              |                    |                 | Not Reported |
|                                                                         | Zyrtec                     |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-May-2016              | 12242569      | EXPEDITED (15-DAY) |                    | HO, OT          | US-FRI-1000083662    |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                                                 | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Arthralgia; Balance Disorder; Blindness Unilateral; Blood Pressure Increased; Dehydration; Depressed Mood; Diarrhoea; Eye Swelling; Fatigue; Furuncle; Hair Colour Changes; Hair Texture Abnormal; Headache; Infection; Intestinal Obstruction; Liver Abscess; Muscular Weakness; Nausea; Neovascular Age-Related Macular Degeneration; Nervousness; Oral Pain; Pruritus; Swelling Face; Vision Blurred; Vomiting; Weight Fluctuation | Escitalopram                  |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                       | Sutent                        |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                       | Levothyroxine                 |              |            | S           |              | 100 Mcg            |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                       | Losartan                      |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                       | Amlodipine Besylate           |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                       | Trazodone                     |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                       | Vitamin D3                    |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                       | Probiotic                     |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                       | Ergocalciferol                |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                       | Cyclobenzaprine Hydrochloride |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                       | Meloxicam                     |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                       |                               |              |            |             |              |                    |                 |              |
|                                                                                                                                                                                                                                                                                                                                                                                                                                       |                               |              |            |             |              |                    |                 |              |
|                                                                                                                                                                                                                                                                                                                                                                                                                                       |                               |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 05-May-2016              | 12336785      | EXPEDITED (15-DAY) |                    | LT              | CH-ACTAVIS-2016-08978 |                      | 86 YR      | Female     | CHE            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                    |                        |   |                  |               |              |
|--------------------------------------------------------------------------------------------------------------------|------------------------|---|------------------|---------------|--------------|
| Agitation; Clonus; Drug Interaction; Hyperhidrosis; Hyperreflexia; Hypertonia; Pyrexia; Serotonin Syndrome; Tremor | Escitalopram (Unknown) | S | Oral             | 10 Mg, Daily  | Not Reported |
|                                                                                                                    | Mirtazapine            | S | Oral             | 15 Mg, Daily  | Actavis      |
|                                                                                                                    | Fentanyl (Unknown)     | S | Intravenous drip | 12 Mg, Daily  | Watson       |
|                                                                                                                    | Oxycodone (Unknown)    | S | Oral             | 20 Mg, Daily  | Watson       |
|                                                                                                                    | Pethidine              | S | Intravenous drip | 768 Mg, Daily | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 05-May-2016              | 12337345      | EXPEDITED (15-DAY) |                    | OT              | FR-PFIZER INC-2016237608 |                      | 62 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Condition Aggravated; Movement Disorder; Myoclonus; Tinnitus; Tremor; Vertigo | Effexor        |              |            | S           | Oral         | 37.5 Mg, Unk       |                 | Pfizer       |
|                                                                               | Effexor        |              |            | S           | Oral         | 75 Mg, Unk         |                 | Pfizer       |
|                                                                               | Escitalopram   |              |            | S           | Oral         | 10 Mg, Unk         |                 | Not Reported |
|                                                                               | Escitalopram   |              |            | S           | Oral         | 5 Mg, Daily        |                 | Not Reported |
|                                                                               | Tranxene       |              |            | C           | Oral         | Unk                |                 | Not Reported |
|                                                                               | Plavix         |              |            | C           |              | Unk                |                 | Not Reported |
|                                                                               | Zocor          |              |            | C           |              | Unk                |                 | Not Reported |
|                                                                               | Cotareg        |              |            | C           |              | Unk                |                 | Not Reported |
|                                                                               | Levothyrox     |              |            | C           |              | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-May-2016              | 12339229      | EXPEDITED (15-DAY) |                    | HO              | US-FRI-1000084339    |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Asthenopia; Asthenopia; Headache; Headache; Influenza Like Illness; Influenza Like Illness; Product Administration Error; Pyrexia; Streptococcal Infection; Streptococcal Sepsis | Lexapro        |              |            | S           | Oral         |                    |                 | Forest       |
|                                                                                                                                                                                  | Lexapro        |              |            | S           | Oral         |                    |                 | Forest       |
|                                                                                                                                                                                  | Escitalopram   |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                                                  | Escitalopram   |              |            | S           | Oral         |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                             | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| 05-May-2016                                                                                                                                                                          | 12339233               | EXPEDITED (15-DAY) |                    | HO              | US-ASTRAZENECA-2016SE45931 |                      | 40 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Chemical Peritonitis;<br>Cholecystitis Infective;<br>Colitis; Enterobacter<br>Infection; Large Intestinal<br>Obstruction; Large<br>Intestine Perforation;<br>Pneumonia; Septic Shock | Inexium                |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                                                                                                                                                      | Amlor                  |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                                                                                                                                                      | Xgeva                  |                    |                    | S               | Subcutaneous               |                      |                 | Not Reported |                |
|                                                                                                                                                                                      | Fenofibrate            |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                                                                                                                                                      | Previscan (Fluindione) |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                                                                                                                                                      | Cortancyl              |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                                                                                                                                                      | Monuril Adultes        |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                                                                                                                                                      | Coversyl               |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                                                                                                                                                      | Zopiclone              |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                                                                                                                                                      | Seroplex               |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                                                                                                                                                      | Levothyrox             |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                                                                                                                                                      | Dafalgan               |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                                                                                                                                                      | Tramadol Hydrochloride |                    |                    | C               | Oral                       | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                             | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-May-2016                                                                                                                                                                          | 12340970               | DIRECT             |                    |                 |                            |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective                                                                                                                                                                     | Prozac                 |                    |                    | S               |                            |                      |                 | Not Reported |                |
|                                                                                                                                                                                      | Zoloft                 |                    |                    | S               |                            |                      |                 | Not Reported |                |
|                                                                                                                                                                                      | Lexapro                |                    |                    | S               |                            |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                             | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-May-2016                                                                                                                                                                          | 12341010               | DIRECT             |                    |                 |                            |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                                                                                                                                | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                          |                        |                    |                    |                 |                      |                                                                                                      |                 |              |                |
|----------------------------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|------------------------------------------------------------------------------------------------------|-----------------|--------------|----------------|
| Drug Ineffective                                                                                         |                        | Lexapro            |                    | S               |                      | Not Reported                                                                                         |                 |              |                |
| <u>FDA Received Date</u>                                                                                 | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-May-2016                                                                                              | 12333239               | EXPEDITED (15-DAY) |                    | OT              | CN-FRI-1000084324    |                                                                                                      | 35 YR           | Female       | CHN            |
| <u>Preferred Term</u>                                                                                    | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Drug Dependence; Drug Ineffective; Exposure During Pregnancy; Feeling Abnormal               | Escitalopram           |                    |                    | S               | Unknown              | 0.5 Tablet, 1 Tablet, 1.5 Tablets And 2 Tablets (Step Increased For 2 Months). Then Step Decreased F |                 | Forest       |                |
|                                                                                                          | Escitalopram           |                    |                    | S               | Unknown              | Step Increased To 1.5 Tablets                                                                        |                 | Forest       |                |
|                                                                                                          | Escitalopram           |                    |                    | S               | Unknown              | 1 Tablet Per Day                                                                                     |                 | Not Reported |                |
|                                                                                                          | Elevit Vitamin Complex |                    |                    | C               | Unknown              |                                                                                                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                 | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-May-2016                                                                                              | 12340046               | EXPEDITED (15-DAY) |                    | OT              | US-ACCORD-040129     |                                                                                                      | 59 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                    | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anger; Anxiety; Depression; Drug Ineffective; Fatigue; Feeling Abnormal; Frustration Tolerance Decreased | Accord Escitalopram    |                    |                    | S               | Oral                 | Pt. Took 5 Mg (Half Tablet) For A Month Then Dose Was Increased To 10 Mg (Whole Tablet)              |                 | Accord       |                |
| <u>FDA Received Date</u>                                                                                 | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-May-2016                                                                                              | 12341362               | EXPEDITED (15-DAY) |                    | CA, DE          | FR-FRI-1000084377    |                                                                                                      |                 | Unknown      | FRA            |
| <u>Preferred Term</u>                                                                                    | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Congenital Central Nervous System Anomaly; Foetal Exposure During Pregnancy; Microcephaly                | Escitalopram           |                    |                    | S               | Transplacental       |                                                                                                      |                 | Forest       |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------|-------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| 06-May-2016                                                             | 12341745          | EXPEDITED (15-DAY) |                    | HO, LT          | FR-JNJFOC-20160503132        |                      | 45 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                   | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bradycardia; Toxicity To Various Agents                                 | Risperdal         |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                                         | Seroplex          |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                                         | Subutex           |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                                         | Ethanol           |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                                         | Valium            |                    |                    | C               | Unknown                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-May-2016                                                             | 12343416          | EXPEDITED (15-DAY) |                    | OT              | US-ABBVIE-16K-163-1620631-00 |                      | 34 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                   | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Generalised Tonic-Clonic Seizure                               | Humira 40mg/0.8ml |                    |                    | S               | Subcutaneous                 |                      |                 | Not Reported |                |
|                                                                         | Lexapro           |                    |                    | S               | Unknown                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-May-2016                                                             | 12343640          | EXPEDITED (15-DAY) |                    | HO              | FR-TAKEDA-2016TUS007740      |                      | 36 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                   | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bradypnoea; Mydriasis; Somnolence; Toxicity To Various Agents; Vomiting | Adenuric          |                    |                    | S               | Oral                         | Unk                  |                 | Takeda       |                |
|                                                                         | Adenuric          |                    |                    | S               | Oral                         | 80 Mg, Qd            |                 | Takeda       |                |
|                                                                         | Nebivolol         |                    |                    | S               | Oral                         | Unk                  |                 | Not Reported |                |
|                                                                         | Nebivolol         |                    |                    | S               | Oral                         | 5 Mg, Qd             |                 | Not Reported |                |
|                                                                         | Seroplex          |                    |                    | S               | Oral                         | Unk                  |                 | Not Reported |                |
|                                                                         | Seroplex          |                    |                    | S               | Oral                         | 10 Mg, Qd            |                 | Not Reported |                |
|                                                                         | Atarax /00058401/ |                    |                    | S               | Oral                         | Unk                  |                 | Not Reported |                |
|                                                                         | Atarax /00058401/ |                    |                    | S               | Oral                         | Unk, Qd              |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                    | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------|----------------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------------------------------------------|-----------------|--------------|----------------|
| 06-May-2016                                                                                                 | 12346057                         | DIRECT             |                    |                 |                          |                                                          | 58 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                       | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                                       | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective; Headache; Product Substitution Issue                                                      | Escitalopram Oxalate 20mg, 20 Mg |                    |                    | S               | Oral                     | 30 Tablet(S) In The Morning Taken By Mouth               |                 | Lupin        |                |
|                                                                                                             | Lexapro                          |                    |                    | C               |                          |                                                          |                 | Not Reported |                |
|                                                                                                             | Trazodone                        |                    |                    | C               |                          |                                                          |                 | Not Reported |                |
|                                                                                                             | Clonazepam                       |                    |                    | C               |                          |                                                          |                 | Not Reported |                |
|                                                                                                             | Vitamin D3                       |                    |                    | C               |                          |                                                          |                 | Not Reported |                |
|                                                                                                             | Fish Oil                         |                    |                    | C               |                          |                                                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                    | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-May-2016                                                                                                 | 12224877                         | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2016186319 |                                                          | 56 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                       | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                                       | <u>Duration</u> | <u>Mfr</u>   |                |
| Head Discomfort                                                                                             | Zoloft                           |                    |                    | S               |                          | Unk                                                      |                 | Pfizer       |                |
|                                                                                                             | Wellbutrin                       |                    |                    | S               |                          | Unk                                                      |                 | Not Reported |                |
|                                                                                                             | Lexapro                          |                    |                    | S               |                          | Unk                                                      |                 | Not Reported |                |
|                                                                                                             | Celexa                           |                    |                    | S               |                          | Unk                                                      |                 | Not Reported |                |
|                                                                                                             | Levothyroxine                    |                    |                    | C               |                          | Unk                                                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                    | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-May-2016                                                                                                 | 12348694                         | EXPEDITED (15-DAY) |                    | HO              | FR-SA-2016SA089512       |                                                          |                 | Female       | FRA            |
| <u>Preferred Term</u>                                                                                       | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                                       | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Drug Interaction; Electrocardiogram Qt Prolonged; Hypokalaemia; Malaise; Torsade De Pointes | Lasilix                          |                    |                    | S               | Oral                     |                                                          |                 | Not Reported |                |
|                                                                                                             | Cordarone                        |                    |                    | S               | Oral                     | Dose And Frequency:1/2 In The Morning Except On Weekends |                 | Not Reported |                |
|                                                                                                             | Seroplex                         |                    |                    | S               | Oral                     |                                                          |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                        |   |      |                         |              |
|------------------------|---|------|-------------------------|--------------|
| Temesta (Lorazepam)    | S | Oral |                         | Not Reported |
| Previscan (Fluindione) | S | Oral | Dose:1/4 In The Evening | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------------|----------------------|------------|------------|----------------|
| 09-May-2016              | 12348729      | EXPEDITED (15-DAY) | HO, LT             |                 | FR-INDIVIOR LIMITED-INDV-090262-2016 |                      | 45 YR      | Male       | FRA            |

| <u>Preferred Term</u>                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>        |
|---------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|-------------------|
| Alcohol Abuse;                                    | Subutex        |              |            | S           | Oral         | Unk                |                 | Reckitt Benckiser |
| Atrioventricular Block First Degree; Bradycardia; | Seroplex       |              |            | S           | Oral         | Unk                |                 | Not Reported      |
| Intentional Product Use Issue; Poisoning          | Risperdal      |              |            | S           | Oral         | Unk                |                 | Not Reported      |
| Deliberate; Toxicity To Various Agents            | Seresta        |              |            | S           | Oral         | Unk                |                 | Not Reported      |
|                                                   | Alcohol        |              |            | S           | Oral         | Unk                |                 | Not Reported      |
|                                                   | Valium         |              |            | C           | Unknown      | Unk                |                 | Not Reported      |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-May-2016              | 12351412      | DIRECT           | Y                  |                 |                      |                      | 36 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Suicidal Ideation     | Lexapro        |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Tylenol        |              |            | C           |              |                    |                 | Not Reported |
|                       | Depakote Er    |              |            | C           |              |                    |                 | Not Reported |
|                       | Ativan         |              |            | C           |              |                    |                 | Not Reported |
|                       | Seroquel       |              |            | C           |              |                    |                 | Not Reported |
|                       | Clonidin       |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                               | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------------------------------|----------------------|------------|------------|----------------|
| 10-May-2016              | 12225106      | EXPEDITED (15-DAY) | LT, OT             |                 | ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2016RR-114116 |                      | 85 YR      | Female     | ESP            |

| <u>Preferred Term</u>                                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Bundle Branch Block Left; Cardio-Respiratory Arrest; | Metoclopramide |              |            | S           | Unknown      |                    |                 | Mutual     |
|                                                      | Metoclopramide |              |            | S           |              |                    |                 | Mutual     |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                   |                 |   |         |              |
|-----------------------------------------------------------------------------------|-----------------|---|---------|--------------|
| Electrocardiogram Qt Prolonged; Hypokalaemia; Hypomagnesaemia; Torsade De Pointes | Amiodarone      | S | Unknown | Taro         |
|                                                                                   | Escitalopram    | S | Unknown | Not Reported |
|                                                                                   | Losartan        | C | Unknown | Not Reported |
|                                                                                   | Betahistine     | C | Unknown | Not Reported |
|                                                                                   | Simvastatin     | C | Unknown | Not Reported |
|                                                                                   | Bisoprolol      | C | Unknown | Not Reported |
|                                                                                   | Acenocoumarol   | C | Unknown | Not Reported |
|                                                                                   | Metformin       | C | Unknown | Not Reported |
|                                                                                   | Ferrous Sulfate | C | Unknown | Not Reported |

| <u>FDA Received Date</u>                                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 10-May-2016                                                              | 12277938       | EXPEDITED (15-DAY) |                    | OT              | IT-JNJFOC-20160414366 |                      | 24 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Overdose; Intentional Self-Injury; Sluggishness; Tachycardia | Risperdal      |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                          | Invega         |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                          | Depakin        |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                          | Neoduplamox    |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                          | Escitalopram   |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                         | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>              | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------|-----------------------------------------|--------------------|--------------------|-----------------|-----------------------------------|----------------------|-----------------|--------------|----------------|
| 10-May-2016                                                                      | 12351182                                | EXPEDITED (15-DAY) |                    | HO              | US-PURDUE PHARMA-CAN-2016-0006668 |                      | 94 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                            | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                      | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Adverse Drug Reaction; Drug Ineffective For Unapproved Indication; Off Label Use | Methylphenidate Hcl (Similar To 205831) |                    |                    | S               | Unknown                           | Unk                  |                 | Rhodes       |                |
|                                                                                  | Sertraline                              |                    |                    | S               | Unknown                           | Unk                  |                 | Not Reported |                |
|                                                                                  | Escitalopram                            |                    |                    | S               | Unknown                           | Unk                  |                 | Not Reported |                |
|                                                                                  | Venlafaxine                             |                    |                    | S               | Unknown                           | Unk                  |                 | Not Reported |                |
|                                                                                  | Mirtazapine                             |                    |                    | S               | Unknown                           | Unk                  |                 | Not Reported |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |             |   |         |     |              |
|--|-------------|---|---------|-----|--------------|
|  | Bupropion   | S | Unknown | Unk | Not Reported |
|  | Trazodone   | S | Unknown | Unk | Not Reported |
|  | Lorazepam   | S | Unknown | Unk | Not Reported |
|  | Clonazepam  | S | Unknown | Unk | Not Reported |
|  | Donepezil   | S | Unknown | Unk | Not Reported |
|  | Memantine   | S | Unknown | Unk | Not Reported |
|  | Lamotrigine | S | Unknown | Unk | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 10-May-2016              | 12352739      | EXPEDITED (15-DAY) |                    | HO              | FR-JNJFOC-20160503256 |                      | 90 YR      | Female     | FRA            |

| <u>Preferred Term</u>                         | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------|-----------------------------|--------------|------------|-------------|--------------|----------------------------|-----------------|--------------|
| Disturbance In Attention;<br>Nausea; Vomiting | Durogesic                   |              |            | S           | Transdermal  |                            |                 | Not Reported |
|                                               | Lyrica                      |              |            | S           | Oral         |                            |                 | Not Reported |
|                                               | Seroplex                    |              |            | S           | Oral         | 0.5 Tablet                 |                 | Not Reported |
|                                               | Lasilix                     |              |            | C           | Oral         |                            |                 | Not Reported |
|                                               | Kardegic                    |              |            | C           | Oral         |                            |                 | Not Reported |
|                                               | Pravastatin Sodium          |              |            | C           | Oral         |                            |                 | Not Reported |
|                                               | Lercan                      |              |            | C           | Oral         |                            |                 | Not Reported |
|                                               | Renitec [Enalapril Maleate] |              |            | C           | Oral         |                            |                 | Not Reported |
|                                               | Cardensiel                  |              |            | C           | Oral         |                            |                 | Not Reported |
|                                               | Lantus                      |              |            | C           | Subcutaneous | 12 To 14 lu In The Evening |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|------------|------------|----------------|
| 11-May-2016              | 12218019      | EXPEDITED (15-DAY) |                    | OT              | DE-DRREDDYS-GER/GER/16/0078135 |                      | 57 YR      | Female     | DEU            |

| <u>Preferred Term</u> | <u>Product</u>  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Haematochezia         | Ciprallex 40 Mg |              |            | S           | Oral         |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                              | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                         | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|--------------------------------------------------------------|------------------------------------|-----------------|--------------|----------------|
| 11-May-2016                                                           | 12354187                 | EXPEDITED (15-DAY) |                    | HO              | CZ-CIPLA LTD.-<br>2016CZ04875                                |                                    |                 | Unknown      | CZE            |
| <u>Preferred Term</u>                                                 | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                 | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Chest Wall Haematoma;<br>Dehydration; Fall;<br>Hyponatraemia; Syncope | Escitalopram             |                    |                    | S               | Unknown                                                      | 10 Mg, Qd                          |                 | Invagen      |                |
|                                                                       | Perindopril              |                    |                    | S               | Unknown                                                      | 5 Mg, Bid                          |                 | Not Reported |                |
|                                                                       | Omeprazole               |                    |                    | S               | Unknown                                                      | 20 Mg, Qd                          |                 | Cipla        |                |
|                                                                       | Atorvastatin             |                    |                    | S               | Unknown                                                      | 10 Mg, 1/2 Once Daily              |                 | Not Reported |                |
|                                                                       | Chlorthalidone/Amiloride |                    |                    | S               | Unknown                                                      | 25 Mg / 2.5 Mg, Bid                |                 | Not Reported |                |
|                                                                       | Levothyroxine            |                    |                    | S               | Unknown                                                      | 75 Mcg, Qd                         |                 | Not Reported |                |
|                                                                       | Furosemide               |                    |                    | S               | Unknown                                                      | 40 Mg, Qd                          |                 | Not Reported |                |
|                                                                       | Bromazepam               |                    |                    | S               | Unknown                                                      | 3 Mg, 1/2 Once Daily               |                 | Not Reported |                |
|                                                                       | Nitrendipine             |                    |                    | S               | Unknown                                                      | 10 Mg, Qd                          |                 | Not Reported |                |
|                                                                       | Isosorbide Dinitrate     |                    |                    | S               | Unknown                                                      | 20 Mg, Bid                         |                 | Not Reported |                |
|                                                                       | Tramadol                 |                    |                    | S               | Unknown                                                      | 150 Mg, Bid                        |                 | Not Reported |                |
|                                                                       | Tiaprider                |                    |                    | S               | Unknown                                                      | 100 Mg, Qd                         |                 | Not Reported |                |
|                                                                       | Rivaroxaban              |                    |                    | S               | Unknown                                                      | 20 Mg, Qd                          |                 | Not Reported |                |
|                                                                       | Fentanyl                 |                    |                    | S               | Unknown                                                      | 25 Mcg/H                           |                 | Not Reported |                |
|                                                                       | Metamizole               |                    |                    | S               | Unknown                                                      | 500 Mg, Two Doses,<br>Thrice Daily |                 | Not Reported |                |
| <u>FDA Received Date</u>                                              | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                         | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-May-2016                                                           | 12354217                 | EXPEDITED (15-DAY) |                    | OT              | TR-SUN<br>PHARMACEUTICAL<br>INDUSTRIES LTD-<br>2016RR-116210 |                                    | 26 YR           | Female       | TUR            |
| <u>Preferred Term</u>                                                 | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                 | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Contraindicated Product<br>Administered; Exposure<br>During Pregnancy | Thiocolchicoside         |                    |                    | S               | Oral                                                         | 16 Mg, Daily                       |                 | Not Reported |                |
|                                                                       | Escitalopram             |                    |                    | S               | Unknown                                                      |                                    |                 | Not Reported |                |
|                                                                       | Dexketoprofen            |                    |                    | S               | Unknown                                                      |                                    |                 | Not Reported |                |

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|               |   |         |         |
|---------------|---|---------|---------|
| Etodolac      | S | Unknown | Ranbaxy |
| Desloratadine | S | Unknown | Sun     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-May-2016              | 12355802      | NON-EXPEDITED    |                    |                 | US-FRI-1000083115    |                      | 47 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Decreased Appetite;<br>Libido Decreased; Off<br>Label Use; Urinary<br>Retention | Fetzima        |              |            | S           | Oral         | 40mg               |                 | Forest     |
|                                                                                 | Fetzima        |              |            | S           | Oral         | 20mg               |                 | Forest     |
|                                                                                 | Lexapro        |              |            | S           | Oral         | 20mg               |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-May-2016              | 12357417      | NON-EXPEDITED    |                    |                 | US-TEVA-653051ACC    |                      | 23 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Menstruation Delayed  | Paragard 380a  |              |            | S           |              |                    |                 | Duramed      |
|                       | Lexapro        |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-May-2016              | 12358862      | DIRECT           |                    | DS, HO          |                      |                      | 33 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Burning Sensation;<br>Discomfort; Dizziness;<br>Head Discomfort;<br>Headache; Heart Rate<br>Increased; Impaired Work<br>Ability; Pain; Paraesthesia | Lexapro        |              |            | S           | Oral         |                    |                 | Forest       |
|                                                                                                                                                     | Multi Vitamin  |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                     | Omega 3        |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                     | Vitamin C      |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                     | Vitamin E      |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 12-May-2016              | 12351863      | NON-EXPEDITED    |                    | OT              | US-PFIZER INC-<br>2016241950 |                      | 11 YR      | Male       | USA            |

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| <u>Preferred Term</u>                                                                  | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
|----------------------------------------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|------------------------------|--------------------------|-----------------|--------------|----------------|
| Chest Discomfort; Rash<br>Erythematous; Rash<br>Papular; Rash Pruritic                 | Geodon                        |                    |                    | S               |                              | 40 Unk, Unk              |                 | Pfizer       |                |
|                                                                                        | Geodon                        |                    |                    | S               |                              | 60 Unk, Unk              |                 | Pfizer       |                |
|                                                                                        | Lexapro                       |                    |                    | S               |                              | Unk                      |                 | Not Reported |                |
|                                                                                        | Lexapro                       |                    |                    | S               |                              | 30 Unk, Unk              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                               | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-May-2016                                                                            | 12362285                      | EXPEDITED (15-DAY) |                    | OT              | IT-ABBVIE-16P-083-1624323-00 |                          | 24 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                                  | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Overdose;<br>Intentional Self-Injury;<br>Sluggishness;<br>Tachycardia      | Depakin                       |                    |                    | S               | Oral                         |                          |                 | Not Reported |                |
|                                                                                        | Risperdal                     |                    |                    | S               | Oral                         |                          |                 | Not Reported |                |
|                                                                                        | Invega                        |                    |                    | S               | Oral                         | Tablet, Extended Release |                 | Not Reported |                |
|                                                                                        | Neoduplamox                   |                    |                    | S               | Oral                         |                          |                 | Not Reported |                |
|                                                                                        | Escitalopram                  |                    |                    | S               | Oral                         |                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                               | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-May-2016                                                                            | 12364703                      | EXPEDITED (15-DAY) |                    | OT              | ES-ANIPHARMA-2016-ES-000006  |                          | 85 YR           | Female       | ESP            |
| <u>Preferred Term</u>                                                                  | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardio-Respiratory Arrest;<br>Electrocardiogram Qt<br>Prolonged; Torsade De<br>Pointes | Metoclopramide (Non-Specific) |                    |                    | S               | Unknown                      | Unknown                  |                 | Ani          |                |
|                                                                                        | Iron Sulfate                  |                    |                    | C               |                              |                          |                 | Not Reported |                |
|                                                                                        | Amiodarone                    |                    |                    | S               | Unknown                      | Unknown                  |                 | Not Reported |                |
|                                                                                        | Escitalopram                  |                    |                    | S               | Unknown                      | Unknown                  |                 | Not Reported |                |
|                                                                                        | Losartan                      |                    |                    | C               |                              |                          |                 | Not Reported |                |
|                                                                                        | Betahistine                   |                    |                    | C               |                              |                          |                 | Not Reported |                |
|                                                                                        | Simvastatin                   |                    |                    | C               |                              |                          |                 | Not Reported |                |
|                                                                                        | Bisoprolol                    |                    |                    | C               |                              |                          |                 | Not Reported |                |
|                                                                                        | Acenocoumarol                 |                    |                    | C               |                              |                          |                 | Not Reported |                |
| Metformin                                                                              |                               |                    | C                  |                 |                              |                          | Not Reported    |              |                |

# FDA Adverse Event Reporting System

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| <u>FDA Received Date</u>                                                                                                                                                           | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|--------------------------|-----------------------------------------------------------|-----------------|--------------|----------------|
| 13-May-2016                                                                                                                                                                        | 12365375               | EXPEDITED (15-DAY) |                    | HO, OT          | FR-PFIZER INC-2016251966 |                                                           |                 | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                                                              | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                                        | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardio-Respiratory Arrest;<br>Drug Interaction;<br>Electrocardiogram Qt<br>Prolonged; Hypokalaemia;<br>International Normalised<br>Ratio Increased; Malaise;<br>Torsade De Pointes | Cordarone              |                    |                    | S               | Oral                     | At A Dose Of Half In The<br>Morning Except On<br>Weekends |                 | Pfizer       |                |
|                                                                                                                                                                                    | Temesta (Lorazepam)    |                    |                    | S               | Oral                     | Unk, Daily                                                |                 | Pfizer       |                |
|                                                                                                                                                                                    | Lasilix                |                    |                    | S               | Oral                     | Unk                                                       |                 | Not Reported |                |
|                                                                                                                                                                                    | Seroplex               |                    |                    | S               | Oral                     | Unk                                                       |                 | Not Reported |                |
|                                                                                                                                                                                    | Previscan (Fluindione) |                    |                    | S               | Oral                     | At A Dose Of One-Fourth<br>In The Evening                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                           | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-May-2016                                                                                                                                                                        | 12367789               | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000084556        |                                                           | 17 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                                                                                              | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                                        | <u>Duration</u> | <u>Mfr</u>   |                |
| Arthralgia; Erythema;<br>Prescribed Overdose;<br>Product Use Issue;<br>Pruritus; Pyrexia; Rash<br>Pustular; Tachycardia                                                            | Escitalopram           |                    |                    | S               | Oral                     | Overdose: Escitalopram<br>30 Mg Daily                     |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                                                                           | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-May-2016                                                                                                                                                                        | 12368265               | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000084572        |                                                           | 94 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                                                                                              | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                                        | <u>Duration</u> | <u>Mfr</u>   |                |
| Dyspnoea; Iron Deficiency<br>Anaemia; Oesophageal<br>Ulcer                                                                                                                         | Escitalopram           |                    |                    | S               | Oral                     | 10 Mg                                                     |                 | Forest       |                |
|                                                                                                                                                                                    | Kardegic               |                    |                    | S               | Oral                     | 1 Df                                                      |                 | Not Reported |                |
|                                                                                                                                                                                    | Rivastigmine           |                    |                    | C               | Unknown                  |                                                           |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                                                                                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|-------------------------------------|----------------------|-----------------|--------------|----------------|
| 13-May-2016                                                                                                                                           | 12368708       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000084504                   |                      | 36 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                                                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bradypnoea; Mydriasis;<br>Somnolence; Toxicity To<br>Various Agents; Vomiting                                                                         | Nebivolol      |                    |                    | S               | Oral                                | 30 To 40 Mg          |                 | Forest       |                |
|                                                                                                                                                       | Nebivolol      |                    |                    | S               | Oral                                | 5 Mg                 |                 | Forest       |                |
|                                                                                                                                                       | Escitalopram   |                    |                    | S               | Oral                                | 40 To 50 Mg          |                 | Forest       |                |
|                                                                                                                                                       | Escitalopram   |                    |                    | S               | Oral                                | 10 Mg                |                 | Forest       |                |
|                                                                                                                                                       | Adenuric       |                    |                    | S               | Oral                                | 320 To 480 Mg        |                 | Not Reported |                |
|                                                                                                                                                       | Adenuric       |                    |                    | S               | Oral                                | 80 Mg                |                 | Not Reported |                |
|                                                                                                                                                       | Atarax         |                    |                    | S               | Oral                                | 5 To 6 Tablets       |                 | Not Reported |                |
|                                                                                                                                                       | Atarax         |                    |                    | S               | Oral                                | 1 Dosage Form        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-May-2016                                                                                                                                           | 12369137       | EXPEDITED (15-DAY) |                    | HO              | ES-AUROBINDO-AUR-<br>APL-2016-05963 |                      | 85 YR           | Female       | ESP            |
| <u>Preferred Term</u>                                                                                                                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bundle Branch Block Left;<br>Cardio-Respiratory Arrest;<br>Electrocardiogram Qt<br>Prolonged; Hypokalaemia;<br>Hypomagnesaemia;<br>Torsade De Pointes | Escitalopram   |                    |                    | S               | Unknown                             |                      |                 | Aurobindo    |                |
|                                                                                                                                                       | Amiodarone     |                    |                    | S               | Unknown                             |                      |                 | Not Reported |                |
|                                                                                                                                                       | Metoclopramide |                    |                    | S               | Unknown                             |                      |                 | Not Reported |                |
|                                                                                                                                                       | Metoclopramide |                    |                    | S               |                                     |                      |                 | Not Reported |                |
|                                                                                                                                                       | Losartan       |                    |                    | C               | Unknown                             |                      |                 | Not Reported |                |
|                                                                                                                                                       | Betahistine    |                    |                    | C               | Unknown                             |                      |                 | Not Reported |                |
|                                                                                                                                                       | Simvastatin    |                    |                    | C               | Unknown                             |                      |                 | Not Reported |                |
|                                                                                                                                                       | Bisoprolol     |                    |                    | C               | Unknown                             |                      |                 | Not Reported |                |
|                                                                                                                                                       | Acenocoumarol  |                    |                    | C               | Unknown                             |                      |                 | Not Reported |                |
|                                                                                                                                                       | Metformin      |                    |                    | C               | Unknown                             |                      |                 | Not Reported |                |
|                                                                                                                                                       | Iron Sulfate   |                    |                    | C               | Unknown                             |                      |                 | Not Reported |                |

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| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 16-May-2016              | 12351870      | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2016224051 |                      | 84 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                 | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                               | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------------------------------------|-----------------|--------------|
| Drug Hypersensitivity;<br>Drug Hypersensitivity;<br>Food Allergy;<br>Hypersensitivity | Celebrex               |              |            | S           |              | Unk                                              |                 | Pfizer       |
|                                                                                       | Tessalon               |              |            | S           |              | Unk                                              |                 | Pfizer       |
|                                                                                       | Aleve                  |              |            | S           |              | Unk                                              |                 | Not Reported |
|                                                                                       | Codeine                |              |            | S           |              | Unk                                              |                 | Not Reported |
|                                                                                       | Lortab                 |              |            | S           |              | Unk (Hydrocodone Bitartrate 7.5/Paracetamol 7.5) |                 | Not Reported |
|                                                                                       | Ultram                 |              |            | S           |              | Unk                                              |                 | Not Reported |
|                                                                                       | Isosorbide Mononitrate |              |            | S           |              | Unk                                              |                 | Not Reported |
|                                                                                       | Parafon Forte          |              |            | S           |              | Unk                                              |                 | Not Reported |
|                                                                                       | Lexapro                |              |            | S           |              | Unk                                              |                 | Not Reported |
|                                                                                       | Ultracet               |              |            | S           |              | Unk                                              |                 | Not Reported |
|                                                                                       | Darvon                 |              |            | S           |              | Unk                                              |                 | Not Reported |
|                                                                                       | Duragesic              |              |            | S           |              | Unk                                              |                 | Not Reported |
|                                                                                       | Hydrocodone/Ibuprofen  |              |            | S           |              | Unk                                              |                 | Not Reported |
|                                                                                       | Gluten                 |              |            | S           |              | Unk                                              |                 | Not Reported |
|                                                                                       | Nitrofurantoin         |              |            | S           |              | Unk                                              |                 | Not Reported |
|                                                                                       | Cimzia                 |              |            | S           |              | Unk                                              |                 | Not Reported |

| <u>FDA Received Date</u>                                         | <u>Case #</u>                                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------|-------------------------------------------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|-----------------|--------------|----------------|
| 16-May-2016                                                      | 12369555                                        | EXPEDITED (15-DAY) |                    | OT              | IT-AUROBINDO-AUR-APL-2016-05849 |                      |                 | Unknown      | ITA            |
| <u>Preferred Term</u>                                            | <u>Product</u>                                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Product Misuse; Intentional Self-Injury; Tachycardia | Escitalopram Aurobindo Film-Coated Tablets 10mg |                    |                    | S               | Oral                            | 20 Df, Total         |                 | Aurobindo    |                |
|                                                                  | Depakin                                         |                    |                    | S               | Oral                            | 3 Df, Total          |                 | Not Reported |                |

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|                                                  | Invega /05724801/  |                    | S                  | Oral            |                                              | Unk                  |                 |              | Not Reported   |
|--------------------------------------------------|--------------------|--------------------|--------------------|-----------------|----------------------------------------------|----------------------|-----------------|--------------|----------------|
|                                                  | Neoduplamox        |                    | S                  | Oral            |                                              | 3 Df, Total          |                 |              | Not Reported   |
|                                                  | Risperdal          |                    | S                  | Oral            |                                              | Unk                  |                 |              | Not Reported   |
| <u>FDA Received Date</u>                         | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-May-2016                                      | 12371202           | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2016224646                     |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                            | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity                            | Diflucan           |                    |                    | S               |                                              | Unk                  |                 | Pfizer       |                |
|                                                  | Prednisolone       |                    |                    | S               |                                              | Unk                  |                 | Not Reported |                |
|                                                  | Lexapro            |                    |                    | S               |                                              | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-May-2016                                      | 12371595           | EXPEDITED (15-DAY) |                    | OT              | CA-APOTEX-2016AP008324                       |                      | 16 YR           | Female       | CAN            |
| <u>Preferred Term</u>                            | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Loss Of Consciousness; Seizure | Apo-Escitalopram   |                    |                    | S               | Oral                                         | 5 Mg, Qd             |                 | Apotex       |                |
|                                                  | Dayquil Sinus      |                    |                    | S               | Unknown                                      | 2 Df, Single         |                 | Not Reported |                |
|                                                  | Dalacin /00166002/ |                    |                    | S               | Unknown                                      | Unk                  |                 | Not Reported |                |
|                                                  | Stieva-A           |                    |                    | S               | Unknown                                      | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-May-2016                                      | 12373090           | EXPEDITED (15-DAY) |                    | HO              | TW-SIGMAPHARM LABORATORIES, LLC-2016SIG00014 |                      | 38 YR           | Male         | TWN            |
| <u>Preferred Term</u>                            | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Delirium; Drug Interaction                       | Disulfiram         |                    |                    | S               | Unknown                                      | 200 Mg, 1x/Day       |                 | Sigmapharm   |                |
|                                                  | Griseofulvin       |                    |                    | S               | Oral                                         | 500 Mg, 1x/Day       |                 | Sigmapharm   |                |
|                                                  | Escitalopram       |                    |                    | S               | Unknown                                      | 10 Mg, 1x/Day        |                 | Not Reported |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                               | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------|------------------------------|--------------------|--------------------|-----------------|-----------------------------------------------|----------------------|-----------------|--------------|----------------|
| 16-May-2016                                                                            | 12373369                     | EXPEDITED (15-DAY) |                    | HO              | FR-JNJFOC-20160511203                         |                      | 79 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                  | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrioventricular Block First Degree; Balance Disorder; Sinus Bradycardia               | Reminyl                      |                    |                    | S               | Oral                                          |                      |                 | Not Reported |                |
|                                                                                        | Seroplex                     |                    |                    | S               | Unknown                                       |                      |                 | Not Reported |                |
|                                                                                        | Seroplex                     |                    |                    | S               | Unknown                                       |                      |                 | Not Reported |                |
|                                                                                        | Diacerein                    |                    |                    | C               | Unknown                                       |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                               | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-May-2016                                                                            | 12373519                     | EXPEDITED (15-DAY) |                    | HO              | ES-IPCA LABORATORIES LIMITED-IPC201605-000412 |                      | 85 YR           | Female       | ESP            |
| <u>Preferred Term</u>                                                                  | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardio-Respiratory Arrest; Hypokalaemia; Hypomagnesaemia; Torsade De Pointes           | Metoclopramide Hydrochloride |                    |                    | S               |                                               |                      |                 | Ipca         |                |
|                                                                                        | Metoclopramide Hydrochloride |                    |                    | S               |                                               |                      |                 | Ipca         |                |
|                                                                                        | Amiodarone                   |                    |                    | S               |                                               |                      |                 | Not Reported |                |
|                                                                                        | Escitalopram                 |                    |                    | S               |                                               |                      |                 | Not Reported |                |
|                                                                                        | Losartan                     |                    |                    | C               |                                               |                      |                 | Not Reported |                |
|                                                                                        | Betahistine                  |                    |                    | C               |                                               |                      |                 | Not Reported |                |
|                                                                                        | Simvastatin                  |                    |                    | C               |                                               |                      |                 | Not Reported |                |
|                                                                                        | Bisoprolol                   |                    |                    | C               |                                               |                      |                 | Not Reported |                |
|                                                                                        | Acenocoumarol                |                    |                    | C               |                                               |                      |                 | Not Reported |                |
|                                                                                        | Metformin                    |                    |                    | C               |                                               |                      |                 | Not Reported |                |
|                                                                                        | Iron Sulfate                 |                    |                    | C               |                                               |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                               | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-May-2016                                                                            | 12374272                     | DIRECT             |                    |                 |                                               |                      | 39 YR           | Male         |                |
| <u>Preferred Term</u>                                                                  | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Restless Legs Syndrome; Sleep Disorder Due To General Medical Condition, Insomnia Type | Escitalopram                 |                    |                    | S               | Oral                                          |                      |                 | Camber       |                |
|                                                                                        | Lamictal                     |                    |                    | C               |                                               |                      |                 | Not Reported |                |
|                                                                                        | Clonazepam                   |                    |                    | C               |                                               |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                         |                                                                                                           |                    |                    |                                      |                                                               |                                              |                 |                                                                                                                        |                |
|-------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------|--------------------|--------------------|--------------------------------------|---------------------------------------------------------------|----------------------------------------------|-----------------|------------------------------------------------------------------------------------------------------------------------|----------------|
| Vit-D                                                                   |                                                                                                           |                    | C                  |                                      |                                                               | Not Reported                                 |                 |                                                                                                                        |                |
| <u>FDA Received Date</u>                                                | <u>Case #</u>                                                                                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>                      | <u>Mfr Control #</u>                                          | <u>503B Facility</u>                         | <u>Age</u>      | <u>Sex</u>                                                                                                             | <u>Country</u> |
| 16-May-2016                                                             | 12375428                                                                                                  | DIRECT             |                    | DS, HO, LT                           |                                                               |                                              |                 | Female                                                                                                                 |                |
| <u>Preferred Term</u>                                                   | <u>Product</u>                                                                                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                          | <u>Route</u>                                                  | <u>Dosage Text</u>                           | <u>Duration</u> | <u>Mfr</u>                                                                                                             |                |
| Apparent Death; Transient Ischaemic Attack; Vaginal Haemorrhage         | Cipralex<br>Celexa                                                                                        |                    |                    | S<br>S                               |                                                               |                                              |                 | Not Reported<br>Not Reported                                                                                           |                |
| <u>FDA Received Date</u>                                                | <u>Case #</u>                                                                                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>                      | <u>Mfr Control #</u>                                          | <u>503B Facility</u>                         | <u>Age</u>      | <u>Sex</u>                                                                                                             | <u>Country</u> |
| 17-May-2016                                                             | 10680921                                                                                                  | EXPEDITED (15-DAY) |                    | HO                                   | TR-B.I.<br>PHARMACEUTICALS,I<br>NC./RIDGEFIELD-2014-<br>BI-62 |                                              | 68 YR           | Male                                                                                                                   | TUR            |
| <u>Preferred Term</u>                                                   | <u>Product</u>                                                                                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                          | <u>Route</u>                                                  | <u>Dosage Text</u>                           | <u>Duration</u> | <u>Mfr</u>                                                                                                             |                |
| Depression; Drug Interaction; Sleep Disorder; Social Avoidant Behaviour | Pradaxa<br>Escitalopram                                                                                   |                    |                    | S<br>S                               | Unknown<br>Unknown                                            | 110 Mg<br>10 Mg                              |                 | Boehringer Ingelheim<br>Not Reported                                                                                   |                |
| <u>FDA Received Date</u>                                                | <u>Case #</u>                                                                                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>                      | <u>Mfr Control #</u>                                          | <u>503B Facility</u>                         | <u>Age</u>      | <u>Sex</u>                                                                                                             | <u>Country</u> |
| 17-May-2016                                                             | 11698410                                                                                                  | EXPEDITED (15-DAY) |                    | DE                                   | CH-FRI-1000080610                                             |                                              | 89 YR           | Female                                                                                                                 | CHE            |
| <u>Preferred Term</u>                                                   | <u>Product</u>                                                                                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                          | <u>Route</u>                                                  | <u>Dosage Text</u>                           | <u>Duration</u> | <u>Mfr</u>                                                                                                             |                |
| Cardiac Failure; General Physical Health Deterioration                  | Escitalopram<br>Seroquel<br>Risperdal<br>Risperdal<br>Risperdal<br>Coversum<br>Coversum<br>Aspirin Cardio |                    |                    | S<br>S<br>S<br>S<br>S<br>C<br>C<br>C | Oral<br>Other<br>Oral<br>Oral<br>Oral<br>Oral<br>Oral<br>Oral | 5 Mg<br><br><br>1 Mg<br>0.5 Mg<br><br>100 Mg |                 | Forest<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                               |   |                                       |         |              |
|-------------------------------|---|---------------------------------------|---------|--------------|
| Euthyrox                      | C | Oral                                  |         | Not Reported |
| Temesta (Lorazepam)           | C | Oral                                  |         | Not Reported |
| Temesta (Lorazepam)           | C | Oral                                  |         | Not Reported |
| Temesta (Lorazepam)           | C | Oral                                  |         | Not Reported |
| Morphin                       | C | Oral                                  |         | Not Reported |
| Atorvastatin                  | C | Oral                                  | 10 Mg   | Not Reported |
| Novalgine (Metamizole Sodium) | C | Oral                                  | 0.5 Mg  | Not Reported |
| Adalat                        | C | Oral                                  | 20 Mg   | Not Reported |
| Ringer Lactat                 | C | Intravenous (not otherwise specified) | 1000 MI | Not Reported |
| Exelon                        | C | Transdermal                           | 4.6 Mg  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-May-2016              | 12195283      | EXPEDITED (15-DAY) | HO                 |                 | FR-FRI-1000083361    |                      | < 1 DAY    | Male       | FRA            |

| <u>Preferred Term</u>                                                                                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|------------|
| Electrocardiogram Qt Prolonged; Exposure During Pregnancy; Hypotonia Neonatal; Supraventricular Tachycardia | Escitalopram   |              |            | S           | Transplacental | 10 Mg              |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-May-2016              | 12370525      | EXPEDITED (15-DAY) | HO                 |                 | PHHY2016FR065744     |                      | 62 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                    | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------|-------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Confusional State; Disorientation; Fall; Gait Disturbance; Hyponatraemia | Voltarene (Diclofenac Sodium) |              |            | S           | Parenteral   | 1 Df, Bid          |                 | Not Reported |
|                                                                          | Escitalopram                  |              |            | S           | Oral         | 1 Df, Qd           |                 | Not Reported |
|                                                                          | Perindopril                   |              |            | S           | Oral         | 1 Df, Qd           |                 | Not Reported |
|                                                                          | Alprazolam                    |              |            | S           | Oral         | 1.5 Df, Qd         |                 | Novartis     |
|                                                                          | Nebivolol                     |              |            | S           | Oral         | 1 Df, Qd           |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                |   |            |           |              |
|------------------------------------------------|---|------------|-----------|--------------|
| Acupan                                         | S | Parenteral | 1 Df, Bid | Not Reported |
| Lamaline<br>(Acetaminophen\Caffeine\Opium<br>) | S | Oral       |           | Not Reported |
| Lyrica                                         | S | Oral       |           | Not Reported |
| Lantus                                         | C | Unknown    |           | Not Reported |
| Metformin                                      | C | Unknown    |           | Not Reported |
| Pravastatine                                   | C | Unknown    |           | Not Reported |
| Kardegic                                       | C | Unknown    |           | Not Reported |
| Vesicare                                       | C | Unknown    |           | Not Reported |

| <u>FDA Received Date</u>           | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------------------------|-----------------|--------------|----------------|
| 17-May-2016                        | 12374341       | EXPEDITED (15-DAY) |                    | OT              | US-ROCHE-1757972     |                                        | 48 YR           | Male         | USA            |
| <u>Preferred Term</u>              | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Coronary Artery Disease;<br>Tremor | Cellcept       |                    |                    | S               | Unknown              |                                        |                 | Not Reported |                |
|                                    | Prograf        |                    |                    | S               | Unknown              | 1mg In The Morning And<br>1mg At Night |                 | Not Reported |                |
|                                    | Sirolimus      |                    |                    | S               | Unknown              |                                        |                 | Not Reported |                |
|                                    | Lexapro        |                    |                    | S               | Unknown              |                                        |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|--------------------------------------------------------|----------------------|-----------------|----------------------|----------------|
| 17-May-2016              | 12375196       | NON-EXPEDITED    |                    |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>BMS-2016-036910 |                      |                 | Female               | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Hypertension             | Eliquis        |                  |                    | S               | Unknown                                                | 5 Mg, Bid            |                 | Bristol Myers Squibb |                |
|                          | Lexapro        |                  |                    | S               | Unknown                                                | Unk                  |                 | Not Reported         |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------------------|----------------------|------------|------------|----------------|
| 17-May-2016              | 12375863      | EXPEDITED (15-DAY) |                    | HO              | FR-<br>GLAXOSMITHKLINE-<br>FR2016GSK069619 |                      | 62 YR      | Female     | FRA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                             | <u>Product</u>                                 | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
|-----------------------------------------------------------------------------------|------------------------------------------------|------------------|--------------------|-----------------|------------------------|----------------------|-----------------|-----------------|----------------|
| Confusional State;<br>Disorientation; Fall; Gait<br>Disturbance;<br>Hyponatraemia | Voltarene (Diclofenac Sodium)                  |                  |                    | S               | Parenteral             | 1 Df, Bid            |                 | Glaxosmithkline |                |
|                                                                                   | Escitalopram                                   |                  |                    | S               |                        | 1 Df, Qd             |                 | Glaxosmithkline |                |
|                                                                                   | Alprazolam                                     |                  |                    | S               | Oral                   | 1.5 Df, Qd           |                 | Glaxosmithkline |                |
|                                                                                   | Nebivolol                                      |                  |                    | S               | Oral                   | 1 Df, Qd             |                 | Glaxosmithkline |                |
|                                                                                   | Perindopril                                    |                  |                    | S               | Oral                   | 1 Df, Qd             |                 | Not Reported    |                |
|                                                                                   | Acupan                                         |                  |                    | S               | Parenteral             | 1 Df, Bid            |                 | Not Reported    |                |
|                                                                                   | Lamaline<br>(Acetaminophen\Caffeine\Opium<br>) |                  |                    | S               | Oral                   | Unk                  |                 | Not Reported    |                |
|                                                                                   | Lyrica                                         |                  |                    | S               | Oral                   |                      |                 | Not Reported    |                |
|                                                                                   | Lantus                                         |                  |                    | C               |                        |                      |                 | Not Reported    |                |
|                                                                                   | Metformin                                      |                  |                    | C               |                        |                      |                 | Glaxosmithkline |                |
|                                                                                   | Pravastatine                                   |                  |                    | C               |                        |                      |                 | Not Reported    |                |
|                                                                                   | Kardegic                                       |                  |                    | C               |                        |                      |                 | Not Reported    |                |
|                                                                                   | Vesicare                                       |                  |                    | C               |                        |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                          | <u>Case #</u>                                  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 17-May-2016                                                                       | 12376016                                       | NON-EXPEDITED    |                    |                 | US-JAZZ-2015-US-014265 |                      | 47 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                             | <u>Product</u>                                 | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Hyperhidrosis; Sensation<br>Of Foreign Body                                       | Xyrem                                          |                  |                    | S               | Oral                   | 2.25 G, Bid          |                 | Jazz            |                |
|                                                                                   | Xyrem                                          |                  |                    | S               | Oral                   | Dose Adjustements    |                 | Jazz            |                |
|                                                                                   | Xyrem                                          |                  |                    | S               | Oral                   | 4.5 G, Bid           |                 | Jazz            |                |
|                                                                                   | Lexapro                                        |                  |                    | S               |                        | Unk                  |                 | Not Reported    |                |
|                                                                                   | Levothyroxine                                  |                  |                    | C               |                        | Unk                  |                 | Not Reported    |                |
|                                                                                   | Provigil                                       |                  |                    | C               |                        | Unk                  |                 | Not Reported    |                |
|                                                                                   | Adderall                                       |                  |                    | C               |                        | Unk                  |                 | Not Reported    |                |
|                                                                                   | Aspirin                                        |                  |                    | C               |                        | Unk                  |                 | Not Reported    |                |
|                                                                                   | Fish Oil                                       |                  |                    | C               |                        | Unk                  |                 | Not Reported    |                |
|                                                                                   | Multivitamins                                  |                  |                    | C               |                        | Unk                  |                 | Not Reported    |                |

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|                          |   |     |              |
|--------------------------|---|-----|--------------|
| Methylphenidate Hcl      | C | Unk | Not Reported |
| Modafinil                | C | Unk | Not Reported |
| Meloxicam                | C | Unk | Not Reported |
| Escitalopram             | C | Unk | Not Reported |
| Tizanidine Hydrochloride | C | Unk | Not Reported |
| Xanax                    | C | Unk | Not Reported |

| <u>FDA Received Date</u>                                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
|------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|------------------|----------------|
| 17-May-2016                                                | 12376100       | EXPEDITED (15-DAY) | LT                 |                 | ES-<br>ELI_LILLY_AND_COMP<br>ANY-ES201605004547 |                      | 35 YR           | Male             | ESP            |
| <u>Preferred Term</u>                                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |
| Blastic Plasmacytoid<br>Dendritic Cell Neoplasia;<br>Cough | Zyprexa        |                    |                    | S               | Oral                                            | 10 Mg, Unknown       |                 | Eli Lilly And Co |                |
|                                                            | Escitalopram   |                    |                    | S               | Unknown                                         | 15 Mg, Unknown       |                 | Not Reported     |                |

| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------------|------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
| 17-May-2016              | 12377614             | NON-EXPEDITED    |                    |                 | US-JNJFOC-<br>20140611274 |                      | 69 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity    | Benadryl             |                  | Y                  | S               | Unknown                   |                      |                 | Not Reported |                |
|                          | Ibuprofen            |                  |                    | S               | Unknown                   |                      |                 | Not Reported |                |
|                          | Risperdal            |                  |                    | S               | Unknown                   |                      |                 | Not Reported |                |
|                          | Tylenol With Codeine |                  |                    | S               | Unknown                   |                      |                 | Not Reported |                |
|                          | Pristiq              |                  |                    | S               | Unknown                   |                      |                 | Not Reported |                |
|                          | Metformin Hcl        |                  |                    | S               | Unknown                   |                      |                 | Not Reported |                |
|                          | Amoxicillin          |                  |                    | S               | Unknown                   |                      |                 | Not Reported |                |
|                          | Pce                  |                  |                    | S               | Unknown                   |                      |                 | Not Reported |                |
|                          | Biaxin               |                  |                    | S               | Unknown                   |                      |                 | Not Reported |                |
|                          | Novocain             |                  |                    | S               | Unknown                   |                      |                 | Not Reported |                |
|                          | Actos                |                  |                    | S               | Unknown                   |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                 |   |         |              |
|-----------------|---|---------|--------------|
| Cipro           | S | Unknown | Not Reported |
| Macrodantin     | S | Unknown | Not Reported |
| Albuterol       | S | Unknown | Not Reported |
| Elavil          | S | Unknown | Not Reported |
| Prozac          | S | Unknown | Not Reported |
| Lexapro         | S | Unknown | Not Reported |
| Paxil           | S | Unknown | Not Reported |
| Xylocaine       | S | Unknown | Not Reported |
| Glucotrol XL    | S | Unknown | Not Reported |
| St. John'S Wort | S | Unknown | Not Reported |
| Lithobid        | S | Unknown | Not Reported |
| Remeron         | S | Unknown | Not Reported |
| Zoloft          | S | Unknown | Not Reported |
| Advil           | S | Unknown | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                        | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------------------|----------------------|------------|------------|----------------|
| 17-May-2016              | 12377642      | EXPEDITED (15-DAY) |                    | HO, OT          | ES-NORTHSTAR<br>HEALTHCARE<br>HOLDINGS-ES-<br>2016NSR001398 |                      |            | Unknown    | ESP            |

| <u>Preferred Term</u>                                                                                                                                                       | <u>Product</u>               | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Bundle Branch Block Left;<br>Cardiac Disorder; Cardio-<br>Respiratory Arrest;<br>Electrocardiogram Qt<br>Prolonged; Hypokalaemia;<br>Hypomagnesaemia;<br>Torsade De Pointes | Metoclopramide Hydrochloride |              |            | S           |              | Unk                |                 | Northstar    |
|                                                                                                                                                                             | Metoclopramide Hydrochloride |              |            | S           |              |                    |                 | Northstar    |
|                                                                                                                                                                             | Amiodarone                   |              |            | S           |              | Unk                |                 | Not Reported |
|                                                                                                                                                                             | Escitalopram                 |              |            | S           |              | Unk                |                 | Not Reported |
|                                                                                                                                                                             | Losartan                     |              |            | C           |              | Unk                |                 | Not Reported |
|                                                                                                                                                                             | Betahistine                  |              |            | C           |              | Unk                |                 | Not Reported |
|                                                                                                                                                                             | Simvastatin                  |              |            | C           |              | Unk                |                 | Not Reported |
|                                                                                                                                                                             | Bisoprolol                   |              |            | C           |              | Unk                |                 | Not Reported |
|                                                                                                                                                                             | Acenocoumarol                |              |            | C           |              | Unk                |                 | Not Reported |
|                                                                                                                                                                             | Metformin                    |              |            | C           |              | Unk                |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| Iron Sulfate                                                                                                               |                      |                    | C                  |                 | Unk                                                       |                      |                 | Not Reported |                |
|----------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|-----------------------------------------------------------|----------------------|-----------------|--------------|----------------|
| <u>FDA Received Date</u>                                                                                                   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-May-2016                                                                                                                | 12378432             | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000084607                                         |                      | 81 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                      | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Haematuria                                                                                                                 | Escitalopram         |                    |                    | S               | Oral                                                      | 1 Df                 |                 | Forest       |                |
|                                                                                                                            | Kardegic             |                    |                    | S               | Oral                                                      | 1 Df                 |                 | Not Reported |                |
|                                                                                                                            | Atarax               |                    |                    | C               |                                                           |                      |                 | Not Reported |                |
|                                                                                                                            | Melaxose             |                    |                    | C               |                                                           |                      |                 | Not Reported |                |
|                                                                                                                            | Celluvisc            |                    |                    | C               |                                                           |                      |                 | Not Reported |                |
|                                                                                                                            | Crestor              |                    |                    | C               |                                                           |                      |                 | Not Reported |                |
|                                                                                                                            | Triatec (Ramipril)   |                    |                    | C               |                                                           |                      |                 | Not Reported |                |
|                                                                                                                            | Levothyrox           |                    |                    | C               |                                                           |                      |                 | Not Reported |                |
|                                                                                                                            | Trimebutine          |                    |                    | C               |                                                           |                      |                 | Not Reported |                |
|                                                                                                                            | Baclofene            |                    |                    | C               |                                                           |                      |                 | Not Reported |                |
|                                                                                                                            | Noctamide            |                    |                    | C               |                                                           |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-May-2016                                                                                                                | 12378590             | EXPEDITED (15-DAY) |                    | HO              | FR-VALIDUS<br>PHARMACEUTICALS<br>LLC-FR-<br>2016VAL001543 |                      |                 | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                      | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Drug<br>Interaction;<br>Electrocardiogram Qt<br>Prolonged; Hypokalaemia;<br>Malaise; Torsade De<br>Pointes | Furosemide           |                    |                    | S               | Oral                                                      | Unk                  |                 | Validus      |                |
|                                                                                                                            | Cordarone            |                    |                    | S               | Oral                                                      | Unk                  |                 | Not Reported |                |
|                                                                                                                            | Seroplex             |                    |                    | S               | Oral                                                      | Unk                  |                 | Not Reported |                |
|                                                                                                                            | Temesta /00273201/   |                    |                    | S               | Oral                                                      | Unk                  |                 | Not Reported |                |
|                                                                                                                            | Previscan /00789001/ |                    |                    | S               | Oral                                                      | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-May-2016                                                                                                                | 12378659             | EXPEDITED (15-DAY) |                    |                 | CA-PERNIX<br>THERAPEUTICS-<br>2016PT000017                |                      |                 | Unknown      | CAN            |
| <u>Preferred Term</u>                                                                                                      | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                               |                     |   |      |                  |              |
|-------------------------------------------------------------------------------|---------------------|---|------|------------------|--------------|
| Drug Ineffective; Drug Interaction; Incoherent; Somnambulism; Speech Disorder | Silenor             | S | Oral | 3 Mg, At Bedtime | Pernix       |
|                                                                               | Cipralex /01588501/ | S |      |                  | Not Reported |
|                                                                               | Warfarin            | C |      | 4 Mg, Unk        | Not Reported |
|                                                                               | Simvastatin         | C |      | 20 Mg, Unk       | Not Reported |
|                                                                               | Ursodiol            | C |      |                  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-May-2016              | 12378863      | EXPEDITED (15-DAY) | HO                 |                 | BE-FRI-1000083903    |                      |            | Female     | BEL            |

| <u>Preferred Term</u>                                                  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Diabetes Insipidus; Hypophysitis; Langerhans' Cell Histiocytosis; Rash | Escitalopram   |              |            | S           | Oral         | 10 Mg              |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-May-2016              | 12378899      | EXPEDITED (15-DAY) |                    | OT              | TR-FRI-1000084335    |                      | 34 YR      | Male       | TUR            |

| <u>Preferred Term</u>                                                                                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Angina Pectoris; Arrhythmia; Chest Discomfort; Dizziness; Dizziness; Hypoaesthesia; Nightmare; Panic Attack | Escitalopram   |              |            | S           | Oral         |                    |                 | Forest       |
|                                                                                                             | Escitalopram   |              |            | S           | Unknown      |                    |                 | Forest       |
|                                                                                                             | Escitalopram   |              |            | S           | Oral         |                    |                 | Forest       |
|                                                                                                             | Depakin        |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                                                             | Depakin        |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-May-2016              | 12378900      | EXPEDITED (15-DAY) |                    | DS              | FR-FRI-1000084614    |                      | 37 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Amenorrhoea           | Escitalopram   |              |            | S           | Oral         | 10 Mg              |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-May-2016              | 12379012      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000084611    |                      |            | Female     | FRA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                 | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiac Arrest;<br>Electrocardiogram Qt<br>Prolonged; Hypokalaemia;<br>Malaise; Torsade De<br>Pointes | Escitalopram           |              |            | S           | Oral         |                    |                 | Forest       |
|                                                                                                       | Temesta (Lorazepam)    |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                       | Previscan (Fluindione) |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                       | Lasilix                |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                       | Cordarone              |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-May-2016              | 11626629      | NON-EXPEDITED    |                    | OT              | ADR-2015-01093       |                      | 39 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Device Dislocation; Device<br>Inversion; Device Kink;<br>Pain; Therapeutic<br>Response Decreased | Lioresal       |              |            | S           | Intrathecal  |                    |                 | Not Reported |
|                                                                                                  | Albuterol      |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                  | Lexapro        |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                  | Els II         |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                  | Vitamin D Nos  |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                  | Allegra        |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                  | Lisinopril     |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-May-2016              | 12380682      | NON-EXPEDITED    |                    | OT              | ADR-2015-01116       |                      | 29 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Adverse Drug Reaction;<br>Muscle Spasticity; Pain;<br>Therapeutic Response<br>Decreased | Baclofen       |              |            | S           | Intrathecal  |                    |                 | Not Reported |
|                                                                                         | Lexapro        |              |            | S           |              |                    |                 | Not Reported |
|                                                                                         | Ortho Evra     |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 18-May-2016              | 12380940      | EXPEDITED (15-DAY) |                    | HO, OT          | FR-PFIZER INC-<br>2016254939 |                      | 62 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                                                                      |                               |   |            |                |              |
|------------------------------------------------------------------------------------------------------|-------------------------------|---|------------|----------------|--------------|
| Confusional State;<br>Disorientation; Fall; Gait<br>Disturbance;<br>Hyponatraemia; Mixed<br>Dementia | Perindopril                   | S | Oral       | 1 Df, 1x/Day   | Not Reported |
|                                                                                                      | Alprazolam                    | S | Oral       | 1.5 Df, 1x/Day | Pfizer       |
|                                                                                                      | Lyrica                        | S | Oral       | Unk            | Pfizer       |
|                                                                                                      | Escitalopram                  | S | Oral       | 1 Df, 1x/Day   | Not Reported |
|                                                                                                      | Acupan                        | S | Parenteral | 1 Df, 2x/Day   | Not Reported |
|                                                                                                      | Lamaline (France)             | S | Oral       | Unk            | Not Reported |
|                                                                                                      | Voltarene (Diclofenac Sodium) | S | Parenteral | 1 Df, 2x/Day   | Not Reported |
|                                                                                                      | Nebivolol                     | S | Oral       | 1 Df, 1x/Day   | Not Reported |
|                                                                                                      | Lantus                        | C |            | Unk            | Not Reported |
|                                                                                                      | Metformin                     | C |            | Unk            | Not Reported |
|                                                                                                      | Pravastatin Sodium            | C |            | Unk            | Not Reported |
|                                                                                                      | Kardegic                      | C |            | Unk            | Not Reported |
|                                                                                                      | Vesicare                      | C |            | Unk            | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-May-2016              | 12381278      | EXPEDITED (15-DAY) | HO                 |                 | FR-FRI-1000084660    |                      | 90 YR      | Female     | FRA            |

| <u>Preferred Term</u>                         | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------|-----------------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Disturbance In Attention;<br>Nausea; Vomiting | Escitalopram                |              |            | S           | Oral         | 5 Mg                          |                 | Forest       |
|                                               | Lyrica                      |              |            | S           | Oral         | 150 Mg                        |                 | Not Reported |
|                                               | Durogesic                   |              |            | S           | Transdermal  | 25 Mcg/Hour (4.2 Mg/10.5 Cm2) |                 | Not Reported |
|                                               | Lantus                      |              |            | C           | Subcutaneous | 12 To 14 Iu                   |                 | Not Reported |
|                                               | Cardensiel                  |              |            | C           | Oral         |                               |                 | Not Reported |
|                                               | Kardegic                    |              |            | C           | Oral         |                               |                 | Not Reported |
|                                               | Lasilix                     |              |            | C           | Oral         | 80 Mg                         |                 | Not Reported |
|                                               | Pravastatine                |              |            | C           | Oral         |                               |                 | Not Reported |
|                                               | Renitec [Enalapril Maleate] |              |            | C           | Oral         |                               |                 | Not Reported |
|                                               | Lercan                      |              |            | C           | Oral         |                               |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|--------------------------|---------------------------------------------------|-----------------|--------------|----------------|
| 18-May-2016                                                                                                                                      | 12381475       | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-2016254823 |                                                   | 46 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                                | <u>Duration</u> | <u>Mfr</u>   |                |
| Coronary Artery Disease;<br>Product Use In<br>Unapproved Indication;<br>Tremor                                                                   | Sirolimus      |                    |                    | S               |                          | 0.5 Mg, Unk                                       |                 | Pfizer       |                |
|                                                                                                                                                  | Prograf        |                    |                    | S               |                          | 1 Mg, 2x/Day (1 Mg In The Morning And 1 Mg Night) |                 | Not Reported |                |
|                                                                                                                                                  | Prograf        |                    |                    | S               |                          |                                                   |                 | Not Reported |                |
|                                                                                                                                                  | Cellcept       |                    |                    | S               |                          | Unk                                               |                 | Not Reported |                |
|                                                                                                                                                  | Lexapro        |                    |                    | S               |                          | Unk                                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-May-2016                                                                                                                                      | 12381854       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000084618        |                                                   | 78 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                                | <u>Duration</u> | <u>Mfr</u>   |                |
| Dysarthria; Hallucination;<br>Hypertonia                                                                                                         | Escitalopram   |                    |                    | S               | Oral                     |                                                   |                 | Forest       |                |
|                                                                                                                                                  | Veratran       |                    |                    | S               | Oral                     |                                                   |                 | Not Reported |                |
|                                                                                                                                                  | Temerit        |                    |                    | C               |                          |                                                   |                 | Not Reported |                |
|                                                                                                                                                  | Esomeprazole   |                    |                    | C               |                          |                                                   |                 | Not Reported |                |
|                                                                                                                                                  | Pravastatine   |                    |                    | C               |                          |                                                   |                 | Not Reported |                |
|                                                                                                                                                  | Cetornan       |                    |                    | C               |                          |                                                   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-May-2016                                                                                                                                      | 12381855       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000084656        |                                                   | 24 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                                                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                                | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated;<br>Delirium; Disease<br>Recurrence; Hallucination;<br>Loss Of Consciousness;<br>Malaise; Tonic Clonic<br>Movements; Tremor | Escitalopram   |                    |                    | S               | Oral                     | 1 Df                                              |                 | Forest       |                |
|                                                                                                                                                  | Zyprexa        |                    |                    | S               | Oral                     |                                                   |                 | Not Reported |                |
|                                                                                                                                                  | Zyprexa        |                    |                    | S               | Oral                     |                                                   |                 | Not Reported |                |
|                                                                                                                                                  | Haldol         |                    |                    | S               | Oral                     | 6 Df                                              |                 | Not Reported |                |
|                                                                                                                                                  | Clozapine      |                    |                    | S               | Oral                     | 400 Mg                                            |                 | Not Reported |                |

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|              |   |      |        |              |
|--------------|---|------|--------|--------------|
| Tercian      | S | Oral | 200 Mg | Not Reported |
| Theralene 4% | S | Oral |        | Not Reported |
| Noctamide    | C |      | 1 Df   | Not Reported |
| Parkinane    | C |      | 3 Df   | Not Reported |
| Hept A Myl   | C | Oral | 1 Df   | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-May-2016              | 12381856      | EXPEDITED (15-DAY) |                    | HO, LT          | FR-FRI-1000084662    |                      | 45 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Bradycardia; Poisoning<br>Deliberate; Toxicity To<br>Various Agents | Escitalopram   |              |            | S           | Oral         |                    |                 | Forest       |
|                                                                     | Risperdal      |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                     | Seresta        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                     | Subutex        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                     | Ethanol        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                     | Valium         |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-May-2016              | 12382022      | EXPEDITED (15-DAY) |                    | LT              | FR-FRI-1000084617    |                      | 84 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiogenic Shock     | Escitalopram           |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                       | Flecaine Lp            |              |            | S           | Oral         | 50 Mg              |                 | Not Reported |
|                       | Bisoprolol             |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Inexium                |              |            | C           |              |                    |                 | Not Reported |
|                       | Valsartan              |              |            | C           |              |                    |                 | Not Reported |
|                       | Previscan (Fluindione) |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-May-2016              | 12384789      | DIRECT           | Y                  | OT              |                      |                      | 29 YR      | Female     | USA            |

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| <u>Preferred Term</u>                                                                                                                                            | <u>Product</u>                                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>        |                |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------|--------------------|--------------------|-----------------|--------------------------|-----------------------|-----------------|-------------------|----------------|
| Agitation; Anxiety;<br>Decreased Appetite;<br>Diarrhoea; Dyspnoea;<br>Feeling Abnormal;<br>Headache; Nausea;<br>Restlessness; Suicidal<br>Ideation; Tachyphrenia | Escitalopram 5mg                                       |                    |                    | S               | Oral                     | 1/2 Tablet Daily Oral |                 | Not Reported      |                |
| <u>FDA Received Date</u>                                                                                                                                         | <u>Case #</u>                                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>        | <u>Country</u> |
| 19-May-2016                                                                                                                                                      | 11788931                                               | EXPEDITED (15-DAY) |                    | HO, OT          | KR-WATSON-2015-<br>18655 |                       | 56 YR           | Female            | KOR            |
| <u>Preferred Term</u>                                                                                                                                            | <u>Product</u>                                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>        |                |
| Dry Mouth; Dystonia;<br>Nausea; Tardive<br>Dyskinesia; Vision Blurred                                                                                            | Amitriptyline                                          |                    |                    | S               | Unknown                  | 10 Mg, Daily          |                 | Not Reported      |                |
|                                                                                                                                                                  | Amitriptyline                                          |                    |                    | S               |                          | 10 Mg, Daily          |                 | Not Reported      |                |
|                                                                                                                                                                  | Trazodone Hydrochloride<br>(Watson Laboratories)       |                    |                    | S               | Unknown                  | 25 Mg, Daily          |                 | Watson            |                |
|                                                                                                                                                                  | Escitalopram (Unknown)                                 |                    |                    | S               | Unknown                  | 5 Mg, Daily           |                 | Not Reported      |                |
|                                                                                                                                                                  | Trihexyphenidyl Hydrochloride<br>(Watson Laboratories) |                    |                    | S               | Unknown                  | 2 Mg, Daily           |                 | Watson            |                |
|                                                                                                                                                                  | Carbidopa/Levodopa (Aellc)                             |                    |                    | S               | Unknown                  | Unk, 50/200mg/Day     |                 | Actavis Elizabeth |                |
|                                                                                                                                                                  | Benztropine                                            |                    |                    | S               | Unknown                  | 2 Mg, Daily           |                 | Not Reported      |                |
|                                                                                                                                                                  | Benztropine                                            |                    |                    | S               | Unknown                  | 2 Mg, Daily           |                 | Not Reported      |                |
|                                                                                                                                                                  | Benztropine                                            |                    |                    | S               |                          | Unk                   |                 | Not Reported      |                |
|                                                                                                                                                                  | Baclofen                                               |                    |                    | C               | Unknown                  | 20 Mg, Daily          |                 | Not Reported      |                |
|                                                                                                                                                                  | Flurazepam                                             |                    |                    | C               | Unknown                  | Unk, 15-30mg/Day      |                 | Not Reported      |                |
|                                                                                                                                                                  | Lorazepam                                              |                    |                    | C               | Unknown                  | 2 Mg, Daily           |                 | Not Reported      |                |
|                                                                                                                                                                  | Clonazepam                                             |                    |                    | C               | Unknown                  | 1.5 Mg, Daily         |                 | Not Reported      |                |
|                                                                                                                                                                  | Clonazepam                                             |                    |                    | C               |                          | 1.5 Mg, Daily         |                 | Not Reported      |                |
|                                                                                                                                                                  | Vitamin E /00110501/                                   |                    |                    | C               | Unknown                  | 1000 Iu, Daily        |                 | Not Reported      |                |

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| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-May-2016              | 12289866      | NON-EXPEDITED    |                    |                 | PHEH2016US009725     |                      | 70 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                            | <u>Product</u>               | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------|------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Dizziness; Drug Interaction; Fatigue; Hypotension; Malaise; Product Use In Unapproved Indication; Vision Blurred | Entresto                     |              |            | S           | Oral         | 24/26 Mg, Bid      |                 | Novartis     |
|                                                                                                                  | Lexapro                      |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                                  | Oxybutin                     |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                                                                  | Coreg                        |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                                                                  | Furosemide                   |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                                                                  | Senna                        |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                                                                  | Levothyroxine                |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                                                                  | Omeprazole                   |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                                                                  | Razadyne                     |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                                                                  | Pradaxa//Dabigatran Etxilate |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                                                                  | Tambocor                     |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                                                                  | Calcium                      |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                                                                  | Multi Vitamin                |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                                                                  | Vitamin D Nos                |              |            | C           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 19-May-2016              | 12384648      | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2016242377 |                      | 79 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Hypersensitivity | Zoloft         |              |            | S           |              | Unk                |                 | Pfizer       |
|                       | Amitriptyline  |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Ditropan       |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Lexapro        |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Paxil          |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Prednisone     |              |            | S           |              | Unk                |                 | Not Reported |

# FDA Adverse Event Reporting System

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| Spectracef                                                                    |                          |                    | S                  |                 | Unk                                         |                      |                 | Not Reported     |                |
|-------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|---------------------------------------------|----------------------|-----------------|------------------|----------------|
| <u>FDA Received Date</u>                                                      | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 19-May-2016                                                                   | 12385568                 | EXPEDITED (15-DAY) |                    | DS              | IT-ASTRAZENECA-2016SE53153                  |                      | 61 YR           | Male             | ITA            |
| <u>Preferred Term</u>                                                         | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |
| Anxiety; Dysgraphia; Dyskinesia; Therapeutic Product Effect Decreased; Tremor | Quetiapine Fumarate      |                    |                    | S               | Oral                                        |                      |                 | Zeneca           |                |
|                                                                               | Sertraline Hydrochloride |                    |                    | S               | Unknown                                     |                      |                 | Not Reported     |                |
|                                                                               | Sertraline Hydrochloride |                    |                    | S               | Unknown                                     |                      |                 | Not Reported     |                |
|                                                                               | Mirtazapine              |                    |                    | S               | Unknown                                     |                      |                 | Not Reported     |                |
|                                                                               | Venlafaxine              |                    |                    | S               | Unknown                                     |                      |                 | Not Reported     |                |
|                                                                               | Valproic Acid            |                    |                    | S               | Unknown                                     |                      |                 | Not Reported     |                |
|                                                                               | Escitalopram             |                    |                    | S               | Unknown                                     |                      |                 | Not Reported     |                |
| <u>FDA Received Date</u>                                                      | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 19-May-2016                                                                   | 12386126                 | EXPEDITED (15-DAY) |                    | DE              | SK-ELI_LILLY_AND_COMP<br>ANY-SK201605005622 |                      | 31 YR           | Female           | SVK            |
| <u>Preferred Term</u>                                                         | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |
| Completed Suicide; Parent-Child Problem                                       | Zypadhera                |                    |                    | S               | Intramuscular                               | 405 Mg, Unknown      |                 | Eli Lilly And Co |                |
|                                                                               | Zalasta                  |                    |                    | S               | Unknown                                     | 10 Mg, Unknown       |                 | Not Reported     |                |
|                                                                               | Elicea /01588501/        |                    |                    | S               | Unknown                                     | 10 Mg, Unknown       |                 | Not Reported     |                |
|                                                                               | Stilnox                  |                    |                    | S               | Unknown                                     | 10 Mg, Unknown       |                 | Not Reported     |                |
|                                                                               | Rivotril                 |                    |                    | S               | Unknown                                     | 0.5 Mg, Unknown      |                 | Not Reported     |                |
|                                                                               | Alcohol                  |                    |                    | S               | Unknown                                     | Unk, Unknown         |                 | Not Reported     |                |
| <u>FDA Received Date</u>                                                      | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 19-May-2016                                                                   | 12386127                 | EXPEDITED (15-DAY) |                    | HO, OT          | FR-ELI_LILLY_AND_COMP<br>ANY-FR201605004133 |                      |                 | Male             | FRA            |
| <u>Preferred Term</u>                                                         | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |



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|                          |                    |   |      |                     |                  |
|--------------------------|--------------------|---|------|---------------------|------------------|
| Delirium;                | Zyprexa            | S | Oral | Unk Unk, Unknown    | Eli Lilly And Co |
| Electroencephalogram     | Zyprexa            | S | Oral | 10 Mg, Qd           | Eli Lilly And Co |
| Abnormal; Hallucination; | Seroplex           | S | Oral | 10 Mg, Each Morning | Not Reported     |
| Hyporeflexia; Loss Of    | Haldol /00027401/  | S | Oral | 5 Mg, Other         | Not Reported     |
| Consciousness; Malaise;  | Clozapine          | S | Oral | 100 Mg, Qid         | Not Reported     |
| Seizure; Tonic Clonic    | Clozapine          | S | Oral | 300 Mg, Qd          | Not Reported     |
| Movements; Tremor        | Clozapine          | S | Oral | 400 Mg, Qd          | Not Reported     |
|                          | Clozapine          | S | Oral | Unk, Unknown        | Not Reported     |
|                          | Theralene          | S | Oral | 20 Df, Prn          | Not Reported     |
|                          | Tercian /00759301/ | S | Oral | 50 Mg, Qid          | Not Reported     |
|                          | Noctamide          | C | Oral | 2 Mg, Unknown       | Not Reported     |
|                          | Parkinane          | C | Oral | 5 Mg, Tid           | Not Reported     |
|                          | Hept-A-Myl         | C | Oral | 184.8 Mg, Tid       | Not Reported     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 19-May-2016              | 12386952      | EXPEDITED (15-DAY) |                    | OT              | DK-MYLANLABS-2016M1019746 |                      |            | Unknown    | DNK            |

| <u>Preferred Term</u>                                  | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--------------------------------------------------------|-----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Dental Caries; Dry Mouth;<br>Periodontitis; Tooth Loss | Clomipramine Mylan    |              |            | S           | Oral         | Unk                |                 | Mylan      |
|                                                        | Citalopram "Orion"    |              |            | S           | Oral         | Unk                |                 | Mylan      |
|                                                        | Mirtazapin Hexal      |              |            | S           | Oral         | Unk                |                 | Mylan      |
|                                                        | Lyrica                |              |            | S           | Oral         | Unk                |                 | Mylan      |
|                                                        | Stadaquel             |              |            | S           | Oral         | Unk                |                 | Mylan      |
|                                                        | Olanzapin Sandoz      |              |            | S           | Oral         | Unk                |                 | Mylan      |
|                                                        | Risperidon Krka       |              |            | S           | Oral         | Unk                |                 | Mylan      |
|                                                        | Zonoct                |              |            | S           | Oral         | Unk                |                 | Mylan      |
|                                                        | Escitalopram Glenmark |              |            | S           | Oral         | Unk                |                 | Mylan      |

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| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|--------------------------|----------------------------------------|-----------------|--------------|----------------|
| 20-May-2016              | 11658950       | EXPEDITED (15-DAY) |                    | HO              | FR-ROCHE-1649277         |                                        | 55 YR           | Female       | FRA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Hemiparesis              | Roactemra      |                    |                    | S               | Intravenous drip         |                                        |                 | Not Reported |                |
|                          | Metoject       |                    |                    | S               | Unknown                  |                                        |                 | Not Reported |                |
|                          | Tercian        |                    |                    | S               | Unknown                  |                                        |                 | Not Reported |                |
|                          | Seroplex       |                    |                    | S               | Unknown                  |                                        |                 | Not Reported |                |
|                          | Alprazolam     |                    |                    | S               | Unknown                  |                                        |                 | Not Reported |                |
|                          | Haldol         |                    |                    | S               | Unknown                  |                                        |                 | Not Reported |                |
|                          | Speciafoldine  |                    |                    | C               |                          |                                        |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-May-2016              | 12373455       | EXPEDITED (15-DAY) |                    | OT              | SE-JNJFOC-20160503099    |                                        | 37 YR           | Female       | SWE            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Benign Breast Neoplasm   | Xeplion        |                    |                    | S               | Intramuscular            |                                        |                 | Not Reported |                |
|                          | Xeplion        |                    |                    | S               | Intramuscular            |                                        |                 | Not Reported |                |
|                          | Escitalopram   |                    |                    | S               | Unknown                  |                                        |                 | Not Reported |                |
|                          | Singulair      |                    |                    | S               | Unknown                  |                                        |                 | Not Reported |                |
|                          | Innovair       |                    |                    | S               | Respiratory (inhalation) |                                        |                 | Not Reported |                |
|                          | Dymista        |                    |                    | S               | Nasal                    |                                        |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-May-2016              | 12388056       | EXPEDITED (15-DAY) |                    | HO              | TN-ACCORD-040741         |                                        | 33 YR           | Male         | TUN            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Treatment Failure        | Escitalopram   |                    |                    | S               |                          | Received As Anti-Depressive Treatments |                 | Accord       |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                       |   |                                        |              |
|---------------------------------------|---|----------------------------------------|--------------|
| Clomipramine                          | S | Received As Anti-Depressive Treatments | Not Reported |
| Sertraline                            | S | Received As Anti-Depressive Treatments | Not Reported |
| Venlafaxine/Venlafaxine Hydrochloride | S | Received As Anti-Depressive Treatments | Not Reported |
| Paroxetine                            | S | Received As Anti-Depressive Treatments | Not Reported |
| Lithium                               | S | Received As Mood Stabilizers           | Not Reported |
| Lamotrigine                           | S | Received As Mood Stabilizers           | Not Reported |
| Olanzapine                            | S | Received As Mood Stabilizers           | Not Reported |
| Risperidone                           | S | Received As Mood Stabilizers           | Not Reported |
| Amisulpride                           | S | Received As Mood Stabilizers           | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-May-2016              | 12389861      | EXPEDITED (15-DAY) |                    | LT              | SI-FRI-1000084621    |                      |            | Male       | SVN            |

| <u>Preferred Term</u>                                                              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Altered State Of Consciousness; Cheyne-Stokes Respiration; Epilepsy; Hyponatraemia | Escitalopram   |              |            | S           | Oral         | 1 Df               |                 | Forest       |
|                                                                                    | Insulin        |              |            | C           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 20-May-2016              | 12391121      | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2016260848 |                      | 86 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Drug Hypersensitivity | Celebrex       |              |            | S           |              | Unk                |                 | Pfizer     |
|                       | Toviaz         |              |            | S           |              | Unk                |                 | Pfizer     |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|             |   |     |              |
|-------------|---|-----|--------------|
| Bextra      | S | Unk | Pfizer       |
| Amoxicillin | S | Unk | Pfizer       |
| Boniva      | S | Unk | Not Reported |
| Lexapro     | S | Unk | Not Reported |
| Fosamax     | S | Unk | Not Reported |
| Mobic       | S | Unk | Not Reported |
| Enablex     | S | Unk | Not Reported |
| Bactrim     | S | Unk | Not Reported |
| Oxybutynin  | S | Unk | Not Reported |
| Mirtazapine | S | Unk | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 23-May-2016              | 11683573      | EXPEDITED (15-DAY) |                    | HO              | FR-JNJFOC-20151016961 |                      | 55 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                          | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|---------------------------------------|--------------------|-----------------|--------------|
| Hemiparesis           | Haldol         |              |            | S           | Oral                                  |                    |                 | Not Reported |
|                       | Roactemra      |              |            | S           | Intravenous (not otherwise specified) |                    |                 | Not Reported |
|                       | Metoject       |              |            | S           | Subcutaneous                          |                    |                 | Not Reported |
|                       | Tercian        |              |            | S           | Unknown                               |                    |                 | Not Reported |
|                       | Seroplex       |              |            | S           | Unknown                               |                    |                 | Not Reported |
|                       | Alprazolam     |              |            | S           | Unknown                               |                    |                 | Not Reported |
|                       | Speciafoldine  |              |            | C           | Unknown                               |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-May-2016              | 11693564      | EXPEDITED (15-DAY) |                    | HO              | IT-FRI-1000080518    |                      | 37 YR      | Male       | ITA            |

| <u>Preferred Term</u>        | <u>Product</u>             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|------------------------------|----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Drug Abuse; Drug Ineffective | Escitalopram Oral Solution |              |            | S           | Oral         | 15 MI              |                 | Forest     |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------|---------------------|--------------------|--------------------|-----------------|-------------------------------------|----------------------|-----------------|--------------|----------------|
| 23-May-2016                             | 12392086            | NON-EXPEDITED      |                    |                 | US-AUROBINDO-AUR-<br>APL-2015-10733 |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                   | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity                   | Escitalopram        |                    |                    | S               | Unknown                             |                      |                 | Aurobindo    |                |
|                                         | Hydrochlorothiazide |                    |                    | S               | Unknown                             |                      |                 | Aurobindo    |                |
|                                         | Celebrex            |                    |                    | S               | Unknown                             |                      |                 | Not Reported |                |
|                                         | Crestor             |                    |                    | S               | Unknown                             |                      |                 | Not Reported |                |
|                                         | Erythromycin        |                    |                    | S               | Unknown                             |                      |                 | Not Reported |                |
|                                         | Nexium /01479302/   |                    |                    | S               | Unknown                             |                      |                 | Not Reported |                |
|                                         | Toprol XL           |                    |                    | S               | Unknown                             |                      |                 | Not Reported |                |
|                                         | Ventolin /00139501/ |                    |                    | S               | Unknown                             |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-May-2016                             | 12393278            | NON-EXPEDITED      |                    |                 | US-PFIZER INC-<br>2016244212        |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                   | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity                   | Morphine Sulfate    |                    |                    | S               |                                     | Unk                  |                 | Pfizer       |                |
|                                         | Lexapro             |                    |                    | S               |                                     | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-May-2016                             | 12395442            | EXPEDITED (15-DAY) |                    | OT              | IT-MYLANLABS-<br>2016M1020768       |                      |                 | Unknown      | ITA            |
| <u>Preferred Term</u>                   | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Therapeutic Product Effect<br>Decreased | Escitalopram        |                    |                    | S               |                                     |                      |                 | Not Reported |                |
|                                         | Quetiapine          |                    |                    | S               |                                     |                      |                 | Not Reported |                |
|                                         | Venlafaxine         |                    |                    | S               |                                     |                      |                 | Not Reported |                |
|                                         | Valproic Acid       |                    |                    | S               |                                     |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

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| <u>FDA Received Date</u> | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|-------------------------------------|--------------------|--------------------|-----------------|----------------------|--------------------------|-----------------|--------------|----------------|
| 23-May-2016              | 12398298                            | DIRECT             | Y                  | LT              |                      |                          | 71 YR           | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Alkaline           | Risperidone, 0.5 Mg                 |                    |                    | S               | Oral                 |                          |                 | Not Reported |                |
| Phosphatase Increased;   | Escitalopram, 10 Mg, Teva           |                    |                    | S               | Oral                 |                          |                 | Not Reported |                |
| Blood Glucose Increased; |                                     |                    |                    |                 |                      |                          |                 |              |                |
| Electrocardiogram Qt     |                                     |                    |                    |                 |                      |                          |                 |              |                |
| Prolonged; Lymphocyte    |                                     |                    |                    |                 |                      |                          |                 |              |                |
| Count Decreased; Protein |                                     |                    |                    |                 |                      |                          |                 |              |                |
| Total Decreased          |                                     |                    |                    |                 |                      |                          |                 |              |                |
| <u>FDA Received Date</u> | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-May-2016              | 12073734                            | EXPEDITED (15-DAY) |                    | CA              | IT-TEVA-633360ACC    |                          |                 | Unknown      | ITA            |
| <u>Preferred Term</u>    | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Foetal Exposure During   | Carbolithium - Teva Italia S.R.L.   |                    |                    | S               | Transplacental       | 750 Milligram Daily; 750 |                 | Barr         |                |
| Pregnancy; Foetal        |                                     |                    |                    |                 |                      | Mg Daily                 |                 |              |                |
| Malformation;            | Tasigna - Novartis Europharm        |                    |                    | S               | Transplacental       | 400 Milligram Daily; 400 |                 | Not Reported |                |
| Univentricular Heart     | Ltd                                 |                    |                    |                 |                      | Mg Daily                 |                 |              |                |
|                          | Ciprallex - H. Lundbeck A/S         |                    |                    | S               | Transplacental       | 1 Dosage Forms Daily; 1  |                 | Not Reported |                |
|                          |                                     |                    |                    |                 |                      | Df Daily                 |                 |              |                |
|                          | Tavor - Pfizer Italia S.R.L.        |                    |                    | S               | Transplacental       | 1 Dosage Forms Daily; 1  |                 | Not Reported |                |
|                          |                                     |                    |                    |                 |                      | Df Daily                 |                 |              |                |
|                          | Tirosint - Ibsa Farmaceutici Italia |                    |                    | S               | Transplacental       | 150 Microgram Daily; 150 |                 | Not Reported |                |
|                          | S.R.L.                              |                    |                    |                 |                      | Ug Daily                 |                 |              |                |
| <u>FDA Received Date</u> | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-May-2016              | 12329735                            | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000084341    |                          | 40 YR           | Female       | FRA            |
| <u>Preferred Term</u>    | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Cholecystitis Infective; | Escitalopram                        |                    |                    | S               | Oral                 | 2 Df                     |                 | Forest       |                |
| Colitis                  | Monurol                             |                    |                    | S               | Oral                 |                          |                 | Forest       |                |

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|                        |   |              |           |              |
|------------------------|---|--------------|-----------|--------------|
| Xgeva                  | S | Subcutaneous | 0.0013 Df | Not Reported |
| Xgeva                  | S | Subcutaneous |           | Not Reported |
| Fenofibrate            | S | Oral         | 100 Mg    | Not Reported |
| Previscan (Fluindione) | S | Oral         |           | Not Reported |
| Cortancyl              | S | Oral         | 1 Df      | Not Reported |
| Inexium                | S | Oral         | 1 Df      | Not Reported |
| Amlor                  | S | Oral         | 1 Df      | Not Reported |
| Coversyl               | S | Oral         | 1 Df      | Not Reported |
| Zopiclone              | S | Oral         | 1 Df      | Not Reported |
| Levothyrox             | S | Oral         | 62.5 Mcg  | Not Reported |
| Dafalgan               | S | Oral         |           | Not Reported |
| Tramadol Base          | C | Oral         |           | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-May-2016              | 12396441      | EXPEDITED (15-DAY) | HO                 |                 | FR-ROCHE-1761805     |                      | 59 YR      | Male       | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                          | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|---------------------------------------|--------------------|-----------------|--------------|
| Myoclonus             | Cellcept       |              |            | S           | Oral                                  |                    |                 | Not Reported |
|                       | Laroxyl        |              |            | S           | Intravenous (not otherwise specified) |                    |                 | Not Reported |
|                       | Seroplex       |              |            | S           | Oral                                  |                    |                 | Not Reported |
|                       | Tramadol       |              |            | S           | Oral                                  |                    |                 | Not Reported |
|                       | Tramadol       |              |            | S           | Intravenous (not otherwise specified) |                    |                 | Not Reported |
|                       | Novorapid      |              |            | S           | Subcutaneous                          |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-May-2016              | 12398250      | EXPEDITED (15-DAY) | OT                 |                 | DE-FRI-1000084805    |                      | 41 YR      | Female     | DEU            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                           |                          |   |      |         |              |
|---------------------------|--------------------------|---|------|---------|--------------|
| Dermatitis Allergic; Rash | Escitalopram             | S | Oral |         | Forest       |
|                           | Escitalopram             | S | Oral |         | Forest       |
|                           | Escitalopram             | S | Oral |         | Not Reported |
|                           | Escitalopram             | S | Oral |         | Not Reported |
|                           | Escitalopram             | S | Oral |         | Not Reported |
|                           | Escitalopram             | S | Oral |         | Not Reported |
|                           | Mirtazapin / Mirtazapine | C | Oral |         | Not Reported |
|                           | Mirtazapin / Mirtazapine | C | Oral |         | Not Reported |
|                           | Mirtazapin / Mirtazapine | C | Oral | 3.75 Mg | Not Reported |
|                           | Mirtazapin / Mirtazapine | C | Oral |         | Not Reported |
|                           | Mirtazapin / Mirtazapine | C | Oral |         | Not Reported |

| <u>FDA Received Date</u>  | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------|-------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 24-May-2016               | 12398251          | EXPEDITED (15-DAY) |                    | OT              | DE-FRI-1000084806    |                      | 29 YR           | Female       | DEU            |
| <u>Preferred Term</u>     | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dermatitis Allergic; Rash | Escitalopram      |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                           | Escitalopram      |                    |                    | S               | Oral                 | 20 Mg                |                 | Forest       |                |
|                           | Vitamine B1       |                    |                    | C               | Oral                 | 600 Mg               |                 | Not Reported |                |
|                           | Tavor (Lorazepam) |                    |                    | C               | Oral                 | 4 Mg                 |                 | Not Reported |                |
|                           | Tavor / Lorazepam |                    |                    | C               | Oral                 | 3 Mg                 |                 | Not Reported |                |
|                           | Tavor / Lorazepam |                    |                    | C               | Oral                 | 2 Mg                 |                 | Not Reported |                |
|                           | Tavor / Lorazepam |                    |                    | C               | Oral                 | 1 Mg                 |                 | Not Reported |                |

| <u>FDA Received Date</u>            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|-------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 24-May-2016                         | 12398999       | EXPEDITED (15-DAY) |                    | HO              | AU-FRI-1000084743    |                      | 26 YR           | Male       | AUS            |
| <u>Preferred Term</u>               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Body Temperature Increased; Nausea; | Escitalopram   |                    |                    | S               | Unknown              |                      |                 | Forest     |                |
|                                     | Escitalopram   |                    |                    | S               | Unknown              |                      |                 | Forest     |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                              |              |   |         |        |
|----------------------------------------------|--------------|---|---------|--------|
| Serotonin Syndrome;<br>Tachycardia; Vomiting | Escitalopram | S | Unknown | Forest |
|                                              | Escitalopram | S | Unknown | Forest |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-May-2016              | 12316610      | EXPEDITED (15-DAY) |                    | OT              | PHHY2014US122251     |                      | 60 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                                                                     | <u>Product</u>                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|--------------|------------|-------------|--------------|-------------------------|-----------------|--------------|
| Decubitus Ulcer; Diastolic Dysfunction; Headache; Incision Site Pain; Mitral Valve Stenosis; Myalgia; Myoclonus; Pain; Peripheral Swelling; Procedural Pain; Supraventricular Tachycardia | Baclofen                       |              |            | S           |              | 100 Ug, Qd (2000 Ug/MI) |                 | Not Reported |
|                                                                                                                                                                                           | Diovan                         |              |            | S           | Unknown      |                         |                 | Not Reported |
|                                                                                                                                                                                           | Metformin Hydrochloride Sandoz |              |            | S           | Unknown      |                         |                 | Novartis     |
|                                                                                                                                                                                           | Escitalopram Oxalate           |              |            | S           | Unknown      |                         |                 | Not Reported |
|                                                                                                                                                                                           | Amlodipine Besylate            |              |            | S           | Unknown      |                         |                 | Not Reported |
|                                                                                                                                                                                           | Baclofen                       |              |            | S           | Unknown      |                         |                 | Not Reported |
|                                                                                                                                                                                           | Foltx                          |              |            | S           | Unknown      |                         |                 | Not Reported |
|                                                                                                                                                                                           | Norvasc /Grc/                  |              |            | S           | Unknown      |                         |                 | Not Reported |
|                                                                                                                                                                                           | Pioglitazone Hcl               |              |            | S           | Unknown      |                         |                 | Not Reported |
|                                                                                                                                                                                           | Centrum Silver                 |              |            | S           | Unknown      |                         |                 | Not Reported |
|                                                                                                                                                                                           | Senna S                        |              |            | S           | Unknown      |                         |                 | Not Reported |
|                                                                                                                                                                                           | Crestor                        |              |            | S           | Unknown      |                         |                 | Not Reported |
|                                                                                                                                                                                           | Aggrenox                       |              |            | S           | Unknown      |                         |                 | Not Reported |
|                                                                                                                                                                                           | Folbee                         |              |            | S           | Unknown      |                         |                 | Not Reported |
|                                                                                                                                                                                           | Fish Oil                       |              |            | S           | Unknown      |                         |                 | Not Reported |
|                                                                                                                                                                                           | Morphine                       |              |            | S           | Unknown      |                         |                 | Not Reported |
|                                                                                                                                                                                           | Oxycodone                      |              |            | S           | Unknown      |                         |                 | Not Reported |
|                                                                                                                                                                                           | Tylenol                        |              |            | S           | Unknown      |                         |                 | Not Reported |
|                                                                                                                                                                                           | Sensi Care Protective Barrier  |              |            | S           | Unknown      |                         |                 | Not Reported |
|                                                                                                                                                                                           | Toprol                         |              |            | S           | Unknown      |                         |                 | Not Reported |
|                                                                                                                                                                                           | Baby Aspirin                   |              |            | S           | Unknown      |                         |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                 | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|--------------------------------------------|----------------------|-----------------|--------------|----------------|
| 25-May-2016                                                              | 12404564                      | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2016275535                   |                      | 19 YR           | Unknown      | USA            |
| <u>Preferred Term</u>                                                    | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity                                                    | Celebrex                      |                    |                    | S               |                                            | Unk                  |                 | Pfizer       |                |
|                                                                          | Premarin                      |                    |                    | S               |                                            | Unk                  |                 | Pfizer       |                |
|                                                                          | Ibuprofen                     |                    |                    | S               |                                            | Unk                  |                 | Pfizer       |                |
|                                                                          | Norco                         |                    |                    | S               |                                            | Unk                  |                 | Not Reported |                |
|                                                                          | Klonopin                      |                    |                    | S               |                                            | Unk                  |                 | Not Reported |                |
|                                                                          | Synthroid                     |                    |                    | S               |                                            | Unk                  |                 | Not Reported |                |
|                                                                          | Pravastatin                   |                    |                    | S               |                                            | Unk                  |                 | Not Reported |                |
|                                                                          | Flexeril                      |                    |                    | S               |                                            | Unk                  |                 | Not Reported |                |
|                                                                          | Lexapro                       |                    |                    | S               |                                            | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                 | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-May-2016                                                              | 12404766                      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000084897                          |                      | 79 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                    | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrioventricular Block First Degree; Balance Disorder; Sinus Bradycardia | Escitalopram                  |                    |                    | S               | Oral                                       | 1 Dosage Form        |                 | Forest       |                |
|                                                                          | Reminyl                       |                    |                    | S               | Oral                                       | 1 Dosage Forms       |                 | Not Reported |                |
|                                                                          | Art                           |                    |                    | C               | Unknown                                    | 50                   |                 | Not Reported |                |
|                                                                          | Piascledine                   |                    |                    | C               | Unknown                                    |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                 | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-May-2016                                                              | 12405522                      | EXPEDITED (15-DAY) |                    | HO, OT          | US-LUPIN PHARMACEUTICALS INC.-E2B_00005450 |                      | 34 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                    | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Insomnia; Mania; Sinusitis; Sleep Paralysis; Tachyphrenia     | Escitalopram Tablets Usp 10mg |                    |                    | S               | Oral                                       |                      |                 | Not Reported |                |
|                                                                          | Escitalopram Tablets Usp 10mg |                    |                    | S               | Oral                                       |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |                               |   |      |  |  |  |  |  |              |
|--|-------------------------------|---|------|--|--|--|--|--|--------------|
|  | Escitalopram Tablets Usp 10mg | S | Oral |  |  |  |  |  | Not Reported |
|  | Escitalopram Tablets Usp 10mg | S | Oral |  |  |  |  |  | Not Reported |
|  | Virtprex                      | C | Oral |  |  |  |  |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-May-2016              | 12091271      | EXPEDITED (15-DAY) |                    | CA              | IT-FRI-1000082656    |                      |            | Unknown    | ITA            |

| <u>Preferred Term</u>                                                       | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------|-------------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Foetal Exposure During Pregnancy; Foetal Malformation; Univentricular Heart | Escitalopram      |              |            | S           | Transplacental | 1 Df               |                 | Forest       |
|                                                                             | Tasigna           |              |            | S           | Transplacental | 400mg              |                 | Not Reported |
|                                                                             | Carbolithium      |              |            | S           | Transplacental | 750mg              |                 | Not Reported |
|                                                                             | Tavor [Lorazepam] |              |            | S           | Transplacental | 1 Df               |                 | Not Reported |
|                                                                             | Tirosint          |              |            | S           | Transplacental | 150mcg             |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|------------|------------|----------------|
| 26-May-2016              | 12406009      | EXPEDITED (15-DAY) |                    | DE, HO          | US-AUROBINDO-AUR-APL-2016-06668 |                      | 46 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Death                 | Quetiapine     |              |            | S           |              |                    |                 | Aurobindo    |
|                       | Escitalopram   |              |            | S           | Oral         | Unk                |                 | Aurobindo    |
|                       | Sertraline     |              |            | S           | Oral         | Unk                |                 | Aurobindo    |
|                       | Acetaminophen  |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                       | Buspirone      |              |            | S           | Oral         | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 26-May-2016              | 12407235      | EXPEDITED (15-DAY) |                    | DE, HO, OT      | FR-JNJFOC-20160522458 |                      | 66 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                            | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardio-Respiratory Arrest; Death; Intentional Overdose; Overdose | Tramadol Hydrochloride |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                  | Methotrexate           |              |            | S           | Oral         |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |            |   |      |              |
|--|------------|---|------|--------------|
|  | Xatral     | S | Oral | Not Reported |
|  | Seroplex   | S | Oral | Not Reported |
|  | Baclofene  | S | Oral | Not Reported |
|  | Dafalgan   | S | Oral | Not Reported |
|  | Folic Acid | S | Oral | Not Reported |

| <u>FDA Received Date</u>       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|-----------------------------------------------------|-----------------|--------------|----------------|
| 26-May-2016                    | 12408043       | EXPEDITED (15-DAY) |                    |                 | DE-UCBSA-2016016292  |                                                     | 33 YR           | Male         | DEU            |
| <u>Preferred Term</u>          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Accidental Exposure To Product | Vimpat         |                    |                    | S               | Oral                 | 150 Mg, Total                                       |                 | Ucb          |                |
|                                | Valproic Acid  |                    |                    | S               | Oral                 | 600 Mg, Total                                       |                 | Not Reported |                |
|                                | Oxcarbazepine  |                    |                    | S               | Oral                 | 1050mg, Total (600 Mg 1 Tablet + 300 Mg 1.5 Tablet) |                 | Not Reported |                |
|                                | Escitalopram   |                    |                    | S               | Oral                 | 20 Mg, Total                                        |                 | Not Reported |                |
|                                | Salt           |                    |                    | S               | Oral                 | 4000 Mg, Total                                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                            | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------|--------------------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 26-May-2016                                                         | 12408975                       | EXPEDITED (15-DAY) |                    | DE, HO, OT      | FR-MDT-ADR-2016-00955 |                      | 41 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                               | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Brain Death; Coma; Drug Screen Positive; Toxicity To Various Agents | Paracetamol (Ngx)              |                    |                    | S               |                       |                      |                 | Not Reported |                |
|                                                                     | Seroplex (Escitaloprm Oxalate) |                    |                    | S               |                       |                      |                 | Not Reported |                |
|                                                                     | Depamide (Valpromide)          |                    |                    | S               |                       |                      |                 | Not Reported |                |
|                                                                     | Dextropropoxyphene             |                    |                    | S               |                       |                      |                 | Not Reported |                |
|                                                                     | Baclofen                       |                    |                    | S               |                       |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|------------|----------------|
| 26-May-2016              | 12409335       | EXPEDITED (15-DAY) |                    | DE, HO, OT      | FR-MDT-ADR-2016-00958 |                      | 53 YR           | Male       | FRA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                            |                                 |   |              |
|----------------------------|---------------------------------|---|--------------|
| Cardiac Arrest; Coma;      | Lopressor (Metoprolol Tartrate) | S | Not Reported |
| Drug Screen Positive;      | Seroplex (Escitalopram Oxalate) | S | Not Reported |
| Toxicity To Various Agents | Baclofen                        | S | Not Reported |
|                            | Coversyl (Perindopril Arginine) | S | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-May-2016              | 12411161      | DIRECT           |                    |                 |                      |                      | 60 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                   | <u>Product</u>             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------|--------------|------------|-------------|--------------|-----------------------------|-----------------|--------------|
| Agitation; Disturbance In Attention; Irritability; Loss Of Dreaming; Rapid Eye Movements Sleep Abnormal; Sleep Disorder | Lexapro                    |              |            | S           | Oral         | One Pill Once, Daily Orally |                 | Not Reported |
|                                                                                                                         | Concerta (Methylphenidate) |              |            | C           |              |                             |                 | Not Reported |
|                                                                                                                         | Klonopin (Clonazepam)      |              |            | C           |              |                             |                 | Not Reported |
|                                                                                                                         | Alprazolam (Xanax)         |              |            | C           |              |                             |                 | Not Reported |
|                                                                                                                         | Crestor (Rosuvastatin)     |              |            | C           |              |                             |                 | Not Reported |
|                                                                                                                         | Zetia (Ezetimibe)          |              |            | C           |              |                             |                 | Not Reported |
|                                                                                                                         | Riboflavin (B2)            |              |            | C           |              |                             |                 | Not Reported |
|                                                                                                                         | Trintellix (Vortioxetine)  |              |            | C           |              |                             |                 | Not Reported |
|                                                                                                                         | Androgel (Testosterone)    |              |            | C           |              |                             |                 | Not Reported |
|                                                                                                                         | Synthroid (Levothyroxine)  |              |            | C           |              |                             |                 | Not Reported |
|                                                                                                                         | Vit D3                     |              |            | C           |              |                             |                 | Not Reported |
|                                                                                                                         | Meclizine                  |              |            | C           |              |                             |                 | Not Reported |
|                                                                                                                         | Afo Brace                  |              |            | C           |              |                             |                 | Not Reported |
|                                                                                                                         | Flonase                    |              |            | C           |              |                             |                 | Not Reported |
|                                                                                                                         | Ibuprofen                  |              |            | C           |              |                             |                 | Not Reported |
|                                                                                                                         | Metamucil                  |              |            | C           |              |                             |                 | Not Reported |
|                                                                                                                         | Glucosamine Chondroitin    |              |            | C           |              |                             |                 | Not Reported |
|                                                                                                                         | Saline Nasal Rinse         |              |            | C           |              |                             |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|------------|------------|----------------|
| 27-May-2016              | 12409756      | EXPEDITED (15-DAY) |                    | DE, HO, OT      | US-AUROBINDO-AUR-APL-2016-06706 |                      | 16 YR      | Male       | USA            |

| <u>Preferred Term</u>                     | <u>Product</u>                           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------|------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiac Arrest; Death; Respiratory Arrest | Cyclobenzaprine                          |              |            | S           | Unknown      |                    |                 | Aurobindo    |
|                                           | Escitalopram                             |              |            | S           | Oral         |                    |                 | Aurobindo    |
|                                           | Hydrocodone Bitartrate And Acetaminophen |              |            | S           | Oral         |                    |                 | Aurobindo    |
|                                           | Aripiprazol                              |              |            | S           | Oral         |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| Morphine                                |                      |                    | S                  |                 | Oral                                     |                      |                 | Not Reported |                |
|-----------------------------------------|----------------------|--------------------|--------------------|-----------------|------------------------------------------|----------------------|-----------------|--------------|----------------|
| <u>FDA Received Date</u>                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-May-2016                             | 12410069             | EXPEDITED (15-DAY) |                    | DE              | US-AUROBINDO-AUR-<br>APL-2016-06833      |                      | 25 YR           | Male         | USA            |
| <u>Preferred Term</u>                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                       | Escitalopram         |                    |                    | S               | Oral                                     |                      |                 | Aurobindo    |                |
|                                         | Escitalopram         |                    |                    | S               |                                          | Unk                  |                 | Aurobindo    |                |
|                                         | Lamotrigine          |                    |                    | S               | Oral                                     |                      |                 | Aurobindo    |                |
|                                         | Lamotrigine          |                    |                    | S               |                                          | Unk                  |                 | Aurobindo    |                |
|                                         | Bupropion            |                    |                    | S               | Oral                                     |                      |                 | Not Reported |                |
|                                         | Bupropion            |                    |                    | S               |                                          | Unk                  |                 | Not Reported |                |
|                                         | Clonazepam           |                    |                    | S               | Oral                                     |                      |                 | Not Reported |                |
|                                         | Clonazepam           |                    |                    | S               |                                          | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-May-2016                             | 12410452             | EXPEDITED (15-DAY) |                    | OT              | CA-SHIRE-<br>CA201606199                 |                      |                 | Male         | CAN            |
| <u>Preferred Term</u>                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;<br>Serotonin Syndrome | Vyvanse              |                    |                    | S               | Oral                                     | Unk, Unknown         |                 | Shire        |                |
|                                         | Ciprallex /01588501/ |                    |                    | S               | Unknown                                  | Unk, Unknown         |                 | Not Reported |                |
| <u>FDA Received Date</u>                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-May-2016                             | 12412660             | EXPEDITED (15-DAY) |                    | HO, OT          | FR-NOVOPROD-<br>493493                   |                      | 59 YR           | Male         | FRA            |
| <u>Preferred Term</u>                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Myoclonus                               | Novorapid            |                    |                    | S               | Unknown                                  | Unk                  |                 | Novo Nordisk |                |
|                                         | Cellcept /01275102/  |                    |                    | S               | Oral                                     | 500 Mg, Qd           |                 | Not Reported |                |
|                                         | Laroxyl              |                    |                    | S               | Intravenous (not<br>otherwise specified) | Unk                  |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|          |   |                                       |          |              |
|----------|---|---------------------------------------|----------|--------------|
| Seroplex | S | Oral                                  | 1 Df, Qd | Not Reported |
| Rivotril | S | Intravenous (not otherwise specified) | Unk      | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 27-May-2016              | 12414150       | NON-EXPEDITED    |                    |                 | US-MDT-ADR-2016-00407 |                      | 74 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Tremor                   | Lioresal       |                  |                    | S               | Intrathecal           | 183.77mcg/Day        |                 | Not Reported |                |
|                          | Lioresal       |                  |                    | S               | Intrathecal           | 128.78mcg/Day        |                 | Not Reported |                |
|                          | Lexapro        |                  |                    | S               |                       |                      |                 | Not Reported |                |
|                          | Keppra         |                  |                    | S               |                       |                      |                 | Not Reported |                |
|                          | Plavix         |                  |                    | S               |                       |                      |                 | Not Reported |                |
|                          | Simvastatin    |                  |                    | S               |                       |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                    | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 28-May-2016                                                                                                                 | 12350156       | EXPEDITED (15-DAY) |                    | HO, OT          | ES-ZYDUS-010988      |                      | 85 YR           | Female       | ESP            |
| <u>Preferred Term</u>                                                                                                       | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Biliary Colic; Cardio-Respiratory Arrest; Electrocardiogram Qt Prolonged; Hypokalaemia; Hypomagnesaemia; Torsade De Pointes | Escitalopram   |                    |                    | S               | Unknown              |                      |                 | Zydus Pharm  |                |
|                                                                                                                             | Losartan       |                    |                    | S               | Unknown              |                      |                 | Not Reported |                |
|                                                                                                                             | Simvastatin    |                    |                    | S               | Unknown              |                      |                 | Not Reported |                |
|                                                                                                                             | Metformin      |                    |                    | S               | Unknown              |                      |                 | Not Reported |                |
|                                                                                                                             | Amiodarone     |                    |                    | S               | Unknown              |                      |                 | Not Reported |                |
|                                                                                                                             | Metoclopramide |                    |                    | S               | Unknown              |                      |                 | Not Reported |                |
|                                                                                                                             | Betahistine    |                    |                    | C               | Unknown              |                      |                 | Not Reported |                |
|                                                                                                                             | Bisoprolol     |                    |                    | C               | Unknown              |                      |                 | Not Reported |                |
|                                                                                                                             | Acenocoumarol  |                    |                    | C               | Unknown              |                      |                 | Not Reported |                |
|                                                                                                                             | Iron           |                    |                    | C               | Unknown              |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-May-2016              | 12350178      | EXPEDITED (15-DAY) |                    | HO, OT          | ES-ZYDUS-010987      |                      | 84 YR      | Female     | ESP            |

| <u>Preferred Term</u>                                                                                                                                      | <u>Product</u>                       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                             | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|--------------|------------|-------------|------------------------------------------|--------------------|-----------------|--------------|
| Atrial Fibrillation;<br>Electrocardiogram Qt<br>Prolonged; Hypokalaemia;<br>Hypomagnesaemia;<br>Syncope; Torsade De<br>Pointes; Ventricular<br>Tachycardia | Escitalopram                         |              |            | S           | Unknown                                  |                    |                 | Zybus Pharm  |
|                                                                                                                                                            | Levofloxacin                         |              |            | S           | Unknown                                  |                    |                 | Zybus Pharm  |
|                                                                                                                                                            | Solifenacin/Solifenacin<br>Succinate |              |            | S           | Unknown                                  |                    |                 | Not Reported |
|                                                                                                                                                            | Amiodarone                           |              |            | S           | Intravenous (not<br>otherwise specified) |                    |                 | Not Reported |
|                                                                                                                                                            | Sulpiride/Sulpiride                  |              |            | S           | Unknown                                  |                    |                 | Not Reported |
|                                                                                                                                                            | Adamantanecarboxylat                 |              |            |             |                                          |                    |                 |              |
|                                                                                                                                                            | Acenocoumarol                        |              |            | C           | Unknown                                  |                    |                 | Not Reported |
|                                                                                                                                                            | Furosemide                           |              |            | C           | Unknown                                  |                    |                 | Not Reported |
|                                                                                                                                                            | Candesartan                          |              |            | C           | Unknown                                  |                    |                 | Not Reported |
|                                                                                                                                                            | Digoxin                              |              |            | C           | Unknown                                  |                    |                 | Not Reported |
|                                                                                                                                                            | Simvastatin                          |              |            | C           | Unknown                                  |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------|----------------------|------------|------------|----------------|
| 28-May-2016              | 12414243      | EXPEDITED (15-DAY) |                    | DE              | US-AUROBINDO-AUR-<br>APL-2016-06920 |                      | 64 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Completed Suicide     | Amlodipine     |              |            | S           | Oral         |                    |                 | Aurobindo  |
|                       | Escitalopram   |              |            | S           | Oral         |                    |                 | Aurobindo  |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------|----------------------|------------|------------|----------------|
| 28-May-2016              | 12414320      | EXPEDITED (15-DAY) |                    | DE, HO, OT      | US-AUROBINDO-AUR-<br>APL-2016-06832 |                      | 34 YR      | Male       | USA            |

| <u>Preferred Term</u>                        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|----------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Cardiac Arrest; Death;<br>Respiratory Arrest | Alprazolam     |              |            | S           | Oral         | Unk                |                 | Aurobindo  |
|                                              | Escitalopram   |              |            | S           | Oral         | Unk                |                 | Aurobindo  |



## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |             |   |      |     |              |
|--|-------------|---|------|-----|--------------|
|  | Gabapentin  | S | Oral | Unk | Aurobindo    |
|  | Oxycodone   | S | Oral | Unk | Aurobindo    |
|  | Trazodone   | S | Oral | Unk | Aurobindo    |
|  | Oxymorphone | S | Oral | Unk | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|-----------------|--------------|----------------|
| 28-May-2016              | 12414353       | EXPEDITED (15-DAY) |                    | DE              | US-AUROBINDO-AUR-APL-2016-06939 |                      | 14 YR           | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide        | Escitalopram   |                    |                    | S               | Oral                            |                      |                 | Aurobindo    |                |
|                          | Bupropion      |                    |                    | S               | Oral                            |                      |                 | Not Reported |                |
|                          | Metoprolol     |                    |                    | S               | Unknown                         |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|-----------------|------------|----------------|
| 28-May-2016              | 12414414       | EXPEDITED (15-DAY) |                    | DE, HO          | US-AUROBINDO-AUR-APL-2016-07022 |                      | 70 YR           | Female     | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Completed Suicide        | Escitalopram   |                    |                    | S               | Oral                            |                      |                 | Aurobindo  |                |
|                          | Citalopram     |                    |                    | S               | Oral                            |                      |                 | Aurobindo  |                |

| <u>FDA Received Date</u>                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------|----------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|-----------------|--------------|----------------|
| 28-May-2016                                           | 12414416       | EXPEDITED (15-DAY) |                    | DE, HO          | US-AUROBINDO-AUR-APL-2016-07067 |                      | 25 YR           | Female       | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Completed Suicide; Respiratory Arrest | Escitalopram   |                    |                    | S               | Oral                            |                      |                 | Aurobindo    |                |
|                                                       | Propranolol    |                    |                    | S               | Oral                            |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|-----------------|------------|----------------|
| 28-May-2016              | 12414419       | EXPEDITED (15-DAY) |                    | DE, HO          | US-AUROBINDO-AUR-APL-2016-07012 |                      | 33 YR           | Male       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                   |                  |   |      |              |
|-------------------|------------------|---|------|--------------|
| Completed Suicide | Cyclobenzaprine  | S | Oral | Aurobindo    |
|                   | Chlorpheniramine | S | Oral | Aurobindo    |
|                   | Escitalopram     | S | Oral | Aurobindo    |
|                   | Meloxicam        | S | Oral | Aurobindo    |
|                   | Olanzapine       | S | Oral | Aurobindo    |
|                   | Sumatriptan      | S | Oral | Aurobindo    |
|                   | Trazodone        | S | Oral | Aurobindo    |
|                   | Topiramate       | S | Oral | Aurobindo    |
|                   | Venlafaxine      | S | Oral | Aurobindo    |
|                   | Buspirone        | S | Oral | Not Reported |
|                   | Benzonatate      | S | Oral | Not Reported |
|                   | Dextromethorphan | S | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------|----------------------|------------|------------|----------------|
| 28-May-2016              | 12414428      | EXPEDITED (15-DAY) |                    | DE              | US-AUROBINDO-AUR-<br>APL-2016-07092 |                      | 37 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Lisinopril     |              |            | S           | Oral         |                    |                 | Aurobindo    |
|                       | Escitalopram   |              |            | S           | Oral         |                    |                 | Aurobindo    |
|                       | Trazodone      |              |            | S           | Oral         |                    |                 | Aurobindo    |
|                       | Clonazepam     |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------|----------------------|------------|------------|----------------|
| 28-May-2016              | 12414440      | EXPEDITED (15-DAY) |                    | DE, HO          | US-AUROBINDO-AUR-<br>APL-2016-07084 |                      | 52 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Completed Suicide     | Atenolol       |              |            | S           | Oral         | Unk                |                 | Aurobindo  |
|                       | Escitalopram   |              |            | S           | Oral         |                    |                 | Aurobindo  |
|                       | Lamotrigine    |              |            | S           | Oral         |                    |                 | Aurobindo  |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|-----------------|--------------|----------------|
| 28-May-2016                                                    | 12414482       | EXPEDITED (15-DAY) |                    | DE, HO          | US-AUROBINDO-AUR-APL-2016-07110 |                      | 42 YR           | Female       | USA            |
| <u>Preferred Term</u>                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                              | Metoprolol     |                    |                    | S               | Oral                            |                      |                 | Aurobindo    |                |
|                                                                | Oxycodone      |                    |                    | S               | Oral                            |                      |                 | Aurobindo    |                |
|                                                                | Zolpidem       |                    |                    | S               | Oral                            |                      |                 | Aurobindo    |                |
|                                                                | Escitalopram   |                    |                    | S               | Oral                            |                      |                 | Aurobindo    |                |
|                                                                | Diazepam       |                    |                    | S               | Oral                            |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-May-2016                                                    | 12414562       | EXPEDITED (15-DAY) |                    | OT              | KR-ACCORD-041012                |                      | 56 YR           | Female       | KOR            |
| <u>Preferred Term</u>                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Tardive Dyskinesia                                             | Escitalopram   |                    |                    | S               |                                 |                      |                 | Accord       |                |
|                                                                | Clonazepam     |                    |                    | S               |                                 |                      |                 | Accord       |                |
|                                                                | Benzatropine   |                    |                    | S               |                                 |                      |                 | Not Reported |                |
|                                                                | Trazodone      |                    |                    | S               |                                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-May-2016                                                    | 12416678       | EXPEDITED (15-DAY) |                    | HO, OT          | FR-JNJFOC-20140711999           |                      | 73 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Extrapyramidal Disorder;<br>Frontotemporal Dementia;<br>Tremor | Risperdal      |                    |                    | S               | Oral                            |                      |                 | Not Reported |                |
|                                                                | Seroplex       |                    |                    | S               | Unknown                         |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-May-2016                                                    | 12416788       | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-2016276555        |                      | 16 YR           | Female       | USA            |
| <u>Preferred Term</u>                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Gene Mutation; Product                                         | Xanax          |                    |                    | S               |                                 |                      |                 | Pfizer       |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                   |         |   |              |
|---------------------------------------------------|---------|---|--------------|
| Use Issue; Serotonin Syndrome; Suicidal Behaviour | Lexapro | S | Not Reported |
|---------------------------------------------------|---------|---|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 31-May-2016              | 10364762      | EXPEDITED (15-DAY) |                    | OT              | US-JNJFOC-20140800604 |                      |            | Male       | USA            |

| <u>Preferred Term</u>                                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Behaviour Disorder; Homicidal Ideation; Suicidal Ideation | Risperdal      |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                           | Invega         |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                           | Concerta       |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                           | Lexapro        |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                           | Clonidine      |              |            | S           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-May-2016              | 11129464      | EXPEDITED (15-DAY) |                    | DE              | CH-FRI-1000076821    |                      |            | Male       | CHE            |

| <u>Preferred Term</u>                                        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|------------|
| Exomphalos; Foetal Exposure During Pregnancy; Premature Baby | Escitalopram   |              |            | S           | Transplacental |                    |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------------------|----------------------|------------|------------|----------------|
| 31-May-2016              | 11643342      | EXPEDITED (15-DAY) |                    |                 | JP-ELI_LILLY_AND_COMP<br>ANY-JP201510005334 |                      | 22 YR      | Female     | JPN            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>       |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------------|
| Abnormal Behaviour    | Strattera      |              |            | S           | Oral         | 80 Mg, Qd          |                 | Eli Lilly And Co |
|                       | Lexapro        |              |            | S           | Oral         | 20 Mg, Qd          |                 | Not Reported     |
|                       | Sulpiride      |              |            | C           | Oral         | 50 Mg, Qd          |                 | Not Reported     |
|                       | Merislon       |              |            | C           | Oral         | 18 Mg, Qd          |                 | Not Reported     |
|                       | Seroquel       |              |            | C           | Oral         | 25 Mg, Qd          |                 | Not Reported     |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 31-May-2016              | 12421914      | NON-EXPEDITED    |                    | OT              | US-MDT-ADR-2016-00220 |                      | 50 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                   | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|------------------------------------------------------|-----------------|--------------|
| Abdominal Rigidity    | Lioresal       |              |            | S           | Intrathecal  |                                                      |                 | Not Reported |
|                       | Wellbutrin Xr  |              |            | S           | Oral         |                                                      |                 | Not Reported |
|                       | Lexapro        |              |            | S           | Oral         |                                                      |                 | Not Reported |
|                       | Glucose        |              |            | S           | Oral         | 4 G Chew Tab; 8 Tablets By Mouth As Needed           |                 | Not Reported |
|                       | Hiprex         |              |            | S           | Oral         | 1 G Tab                                              |                 | Not Reported |
|                       | Zantac         |              |            | S           |              |                                                      |                 | Not Reported |
|                       | Cialis         |              |            | S           |              |                                                      |                 | Not Reported |
|                       | Baclofen       |              |            | S           | Intrathecal  | 500.5 Mcg/Day                                        |                 | Not Reported |
|                       | Baclofen       |              |            | S           | Intrathecal  | 549.5 Mcg/Day                                        |                 | Not Reported |
|                       | Lioresal       |              |            | S           | Oral         | 10 Mg Tab; 1-2 Tabs By Mouth Every 4 Hours As Needed |                 | Not Reported |
|                       | Albuterol Hfa  |              |            | S           |              |                                                      |                 | Not Reported |
|                       | Eliquis        |              |            | S           |              |                                                      |                 | Not Reported |
|                       | Valium         |              |            | S           |              |                                                      |                 | Not Reported |
|                       | Glucophage     |              |            | S           | Oral         |                                                      |                 | Not Reported |
|                       | Dilaudid       |              |            | S           |              |                                                      |                 | Not Reported |
|                       | Baclofen       |              |            | S           | Intrathecal  | 99.9 Mcg/Day                                         |                 | Not Reported |
|                       | Baclofen       |              |            | S           | Intrathecal  |                                                      |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Jun-2016              | 11697429      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000080654    |                      | 55 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                          | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|---------------------------------------|--------------------|-----------------|--------------|
| Hemiparesis           | Escitalopram   |              |            | S           | Unknown                               |                    |                 | Forest       |
|                       | Roactemra      |              |            | S           | Intravenous (not otherwise specified) | 16 Mg              |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |               |   |              |       |              |
|--|---------------|---|--------------|-------|--------------|
|  | Metoject      | S | Subcutaneous | 10 Mg | Not Reported |
|  | Tercian       | S | Unknown      |       | Not Reported |
|  | Alprazolam    | S | Unknown      |       | Not Reported |
|  | Haldol        | S | Unknown      |       | Not Reported |
|  | Gutron        | C | Unknown      |       | Not Reported |
|  | Speciafoldine | C | Unknown      |       | Not Reported |

| <u>FDA Received Date</u>                               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------|----------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|-----------------|--------------|----------------|
| 01-Jun-2016                                            | 12422201       | EXPEDITED (15-DAY) |                    | OT              | IT-CIPLA LTD.-<br>2016IT06035 |                      |                 | Unknown      | ITA            |
| <u>Preferred Term</u>                                  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective;<br>Dysgraphia; Dyskinesia;<br>Tremor | Sertraline     |                    |                    | S               | Unknown                       | 50 Mg, Qd            |                 | Invagen      |                |
|                                                        | Sertraline     |                    |                    | S               | Unknown                       | 200 Mg, Qd           |                 | Invagen      |                |
|                                                        | Sertraline     |                    |                    | S               | Unknown                       | 50 Mg, Qd            |                 | Invagen      |                |
|                                                        | Escitalopram   |                    |                    | S               | Unknown                       | Unk                  |                 | Invagen      |                |
|                                                        | Quetiapine     |                    |                    | S               | Oral                          | Unk                  |                 | Not Reported |                |
|                                                        | Venlafaxine    |                    |                    | S               | Unknown                       | Unk                  |                 | Cipla        |                |
|                                                        | Valproic Acid  |                    |                    | S               | Unknown                       | Unk                  |                 | Cipla        |                |
|                                                        | Mirtazapine    |                    |                    | S               | Unknown                       | Unk                  |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>                                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|---------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|------------------------------|-----------------|--------------|----------------|
| 01-Jun-2016              | 12424923                                                | EXPEDITED (15-DAY) |                    | OT              | IT-FRI-1000084954    |                              | 21 YR           | Female       | ITA            |
| <u>Preferred Term</u>    | <u>Product</u>                                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Abuse               | Escitalopram                                            |                    |                    | S               | Oral                 | Overdose: 14 Dosage<br>Forms |                 | Forest       |                |
|                          | Zoloft "50mg Comprese<br>Rivestite Con Film"/Sertraline |                    |                    | C               | Oral                 |                              |                 | Not Reported |                |
|                          | Abilify "5mg Comprese"/<br>Aripiprazole                 |                    |                    | C               | Oral                 |                              |                 | Not Reported |                |
|                          | Abilify "5mg Comprese"/<br>Aripiprazole                 |                    |                    | C               | Oral                 |                              |                 | Not Reported |                |
|                          |                                                         |                    |                    |                 |                      |                              |                 |              |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                   | <u>Case #</u>                                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|-----------------------------------------------------------|-----------------|--------------|----------------|
| 01-Jun-2016                                                                                                                                | 12425677                                          | EXPEDITED (15-DAY) |                    | DS              | NL-FRI-1000085034                               |                                                           |                 | Female       | NLD            |
| <u>Preferred Term</u>                                                                                                                      | <u>Product</u>                                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                        | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypersensitivity; Product Use In Unapproved Indication; Therapeutic Response Unexpected; Tooth Disorder                                    | Citalopram                                        |                    |                    | S               | Oral                                            | 1 Times Per Day 1 Piece                                   |                 | Forest       |                |
|                                                                                                                                            | Escitalopram                                      |                    |                    | S               | Oral                                            | 10 Mg                                                     |                 | Forest       |                |
|                                                                                                                                            | Omeprazol Rp Capsule Msr 10mg - Non-Current Drug  |                    |                    | C               | Oral                                            | Extra Info: Only When I Am Taking For Example Antibiotics |                 | Not Reported |                |
|                                                                                                                                            | Paracetamol/Ascorbinezuur Poeder V Drank 500/50mg |                    |                    | C               | Oral                                            | Extra Info: Now And Then For (Head)Ache                   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                   | <u>Case #</u>                                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Jun-2016                                                                                                                                | 12426105                                          | EXPEDITED (15-DAY) |                    | DE, HO          | FR-VALIDUS PHARMACEUTICALS LLC-FR-2016VAL001623 |                                                           | 53 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                                                      | <u>Product</u>                                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                        | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Coma; Toxicity To Various Agents                                                                                           | Lopressor                                         |                    |                    | S               |                                                 | Unk                                                       |                 | Validus      |                |
|                                                                                                                                            | Baclofen                                          |                    |                    | S               |                                                 | Unk                                                       |                 | Not Reported |                |
|                                                                                                                                            | Seroplex                                          |                    |                    | S               |                                                 | Unk                                                       |                 | Not Reported |                |
|                                                                                                                                            | Coversyl /00790702/                               |                    |                    | S               |                                                 | Unk                                                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                   | <u>Case #</u>                                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Jun-2016                                                                                                                                | 12427809                                          | DIRECT             |                    | DS, OT          |                                                 |                                                           | 62 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                      | <u>Product</u>                                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                        | <u>Duration</u> | <u>Mfr</u>   |                |
| Coordination Abnormal; Depression; Fatigue; Infection; Loss Of Consciousness; Product Packaging Quantity Issue; Suicidal Ideation; Tremor; | Escitalopram 10 Mg Tablet, 10                     |                    |                    | S               |                                                 |                                                           |                 | Lupin        |                |
|                                                                                                                                            | Mg Lupin Pharmaceuticals                          |                    |                    |                 |                                                 |                                                           |                 |              |                |
|                                                                                                                                            | Lexapro                                           |                    |                    | C               |                                                 |                                                           |                 | Not Reported |                |
|                                                                                                                                            | Clonazepam                                        |                    |                    | C               |                                                 |                                                           |                 | Not Reported |                |
|                                                                                                                                            | Estrace                                           |                    |                    | C               |                                                 |                                                           |                 | Not Reported |                |
|                                                                                                                                            | Losartan                                          |                    |                    | C               |                                                 |                                                           |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                 |                                        |   |      |                       |              |
|-----------------|----------------------------------------|---|------|-----------------------|--------------|
| Viral Infection | Nexium                                 | S |      |                       | Not Reported |
|                 | Singular                               | C |      |                       | Not Reported |
|                 | Myrbetriq Er                           | C |      |                       | Not Reported |
|                 | Fosamax                                | C |      |                       | Not Reported |
|                 | Flonase                                | C |      |                       | Not Reported |
|                 | Xopenex Prn                            | C |      |                       | Not Reported |
|                 | Hydrocodone                            | C |      |                       | Not Reported |
|                 | Alleve                                 | C |      |                       | Not Reported |
|                 | Colace                                 | C |      |                       | Not Reported |
|                 | Centrum Silver Womens 50 Plus (Pfizer) | C |      |                       | Not Reported |
|                 | Tylenol Prn                            | C |      |                       | Not Reported |
|                 | Magnesium Prn                          | C | Oral | 90 Tablets Once A Day | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Jun-2016              | 12428606      | DIRECT           | Y                  |                 |                      |                      | 38 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Headache     | Escitalopram   |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Jun-2016              | 12429052      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000085035    |                      | 81 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Spontaneous Haematoma | Escitalopram   |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                       | Kardegic       |              |            | S           | Oral         | 160 Mg             |                 | Not Reported |
|                       | Calciparine    |              |            | S           | Subcutaneous |                    |                 | Not Reported |
|                       | Inexium        |              |            | C           |              |                    |                 | Not Reported |
|                       | Nefopam        |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Jun-2016              | 12429706      | NON-EXPEDITED    |                    |                 | US-TARO-2016TAR00178 |                      | 41 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                   |                              |   |      |                |              |
|-------------------|------------------------------|---|------|----------------|--------------|
| Diarrhoea; Nausea | Escitalopram Oral Solution   | S | Oral | 1 Mg, 1x/Day   | Taro         |
|                   | Escitalopram Oral Solution   | S | Oral | 2.5 Mg, 1x/Day | Taro         |
|                   | Probiotic                    | C |      |                | Not Reported |
|                   | Vitamin D Nos                | C |      |                | Not Reported |
|                   | Unspecified Digestive Enzyme | C |      |                | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------|----------------------|------------|------------|----------------|
| 03-Jun-2016              | 12433879      | EXPEDITED (15-DAY) |                    | LT              | FR-B. BRAUN MEDICAL<br>INC.-1053209 |                      | 77 YR      | Female     | FRA            |

| <u>Preferred Term</u>     | <u>Product</u>                        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                             | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|---------------------------------------|--------------|------------|-------------|------------------------------------------|--------------------|-----------------|--------------|
| Interstitial Lung Disease | Metronidazole                         |              |            | S           | Intravenous (not<br>otherwise specified) |                    |                 | B Braun      |
|                           | Rifadine (Rifampicin)                 |              |            | S           | Intravenous (not<br>otherwise specified) |                    |                 | Not Reported |
|                           | Simvastatin                           |              |            | C           |                                          |                    |                 | Not Reported |
|                           | Cubicin                               |              |            | S           | Intravenous (not<br>otherwise specified) |                    |                 | Not Reported |
|                           | Azactam                               |              |            | S           | Intravenous (not<br>otherwise specified) |                    |                 | Not Reported |
|                           | Pravastatin                           |              |            | S           | Oral                                     |                    |                 | Not Reported |
|                           | Escitalopram                          |              |            | S           | Oral                                     |                    |                 | Not Reported |
|                           | Allopurinol                           |              |            | S           | Oral                                     |                    |                 | Not Reported |
|                           | Calciparine (Heparin Calcium)         |              |            | S           | Subcutaneous                             |                    |                 | Not Reported |
|                           | Nebivolol                             |              |            | S           | Oral                                     |                    |                 | Not Reported |
|                           | Irbesartan And<br>Hydrochlorothiazide |              |            | S           | Oral                                     |                    |                 | Not Reported |
|                           | Seresta (Oxazepam)                    |              |            | C           |                                          |                    |                 | Not Reported |
|                           | Inexium (Esomeprazole)                |              |            | C           |                                          |                    |                 | Not Reported |
|                           | Voltarene (Diclofenac Sodium)         |              |            | C           |                                          |                    |                 | Not Reported |
|                           | Rimactan (Rifampicin)                 |              |            | S           | Oral                                     |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 06-Jun-2016              | 12240158      | EXPEDITED (15-DAY) |                    | HO, OT          | US-PFIZER INC-<br>2016187117 |                      | 31 YR      | Female     | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                                    | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                             | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|--------------|------------|-------------|--------------|----------------------------------------------------------------|-----------------|--------------|
| Abnormal Behaviour;<br>Blood Alcohol Increased;<br>Fatigue; Loss Of<br>Consciousness; Muscle<br>Twitching; Neuroleptic<br>Malignant Syndrome;<br>Overdose; Pain; Seizure | Geodon            |              |            | S           | Oral         | 20 Mg At Dinner                                                |                 | Pfizer       |
|                                                                                                                                                                          | Geodon            |              |            | S           | Oral         | 60 Mg Per Day (20 Mg In<br>The Morning And 40 Mg At<br>Dinner) |                 | Pfizer       |
|                                                                                                                                                                          | Geodon            |              |            | S           | Oral         | 420 Mg, Single                                                 |                 | Pfizer       |
|                                                                                                                                                                          | Alprazolam        |              |            | S           | Oral         | 0.5 Mg Tablets, 3 Times<br>Per Day, As Needed                  |                 | Pfizer       |
|                                                                                                                                                                          | Zolpidem Tartrate |              |            | S           | Oral         | 10 Mg Tablets Per Day                                          |                 | Not Reported |
|                                                                                                                                                                          | Lexapro           |              |            | S           | Oral         | 20 Mg Tablet, Once Per<br>Day                                  |                 | Not Reported |
|                                                                                                                                                                          | Lexapro           |              |            | S           | Oral         | 140 Mg, Single                                                 |                 | Not Reported |
|                                                                                                                                                                          | Lamotrigine       |              |            | S           | Oral         | Unk                                                            |                 | Not Reported |
|                                                                                                                                                                          | Lamotrigine       |              |            | S           | Oral         | 150 Mg Tablets Once Per<br>Day In The Morning                  |                 | Not Reported |
|                                                                                                                                                                          | Lamotrigine       |              |            | S           | Oral         | 1050 Mg, Single                                                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------|----------------------|------------|------------|----------------|
| 06-Jun-2016              | 12437441      | EXPEDITED (15-DAY) |                    | DE, HO          | US-AUROBINDO-AUR-<br>APL-2016-07094 |                      | 53 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Duloxetine     |              |            | S           | Oral         |                    |                 | Aurobindo    |
|                       | Escitalopram   |              |            | S           | Oral         |                    |                 | Aurobindo    |
|                       | Baclofen       |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Clonazepam     |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                    | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------------------------------|----------------------|------------|------------|----------------|
| 06-Jun-2016              | 12439931      | EXPEDITED (15-DAY) |                    | HO              | CA-IPCA<br>LABORATORIES<br>LIMITED-IPC201605-<br>000479 |                      | 77 YR      | Female     | CAN            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                            |                     |   |              |
|----------------------------|---------------------|---|--------------|
| Confusional State;         | Hydrochlorothiazide | S | Ipca         |
| Hyponatraemia;             | Escitalopram        | S | Not Reported |
| Inappropriate Antidiuretic | Gliclazide          | C | Not Reported |
| Hormone Secretion          | Insulin             | C | Not Reported |
|                            | L-Thyroxine         | C | Not Reported |
|                            | Telmisartan         | C | Not Reported |
|                            | Trazadone           | C | Not Reported |
|                            | Metformin           | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Jun-2016              | 12442878      | DIRECT           |                    | DS, HO, LT, OT  |                      |                      | 51 YR      | Female     | USA            |

| <u>Preferred Term</u>                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                           | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------|----------------|--------------|------------|-------------|--------------|----------------------------------------------|-----------------|--------------|
| Atrioventricular Block<br>Second Degree | Bupropn Hcl    |              |            | S           | Oral         | 1 Tablet(S) In The Morning<br>Taken By Mouth |                 | Not Reported |
|                                         | Escitalopram   |              |            | S           | Oral         | 1 Tablet(S) In The Morning<br>Taken By Mouth |                 | Not Reported |
|                                         | Calcium        |              |            | C           |              |                                              |                 | Not Reported |
|                                         | Magnesium      |              |            | C           |              |                                              |                 | Not Reported |
|                                         | Vitamin D Nos  |              |            | C           |              |                                              |                 | Not Reported |
|                                         | Epsom          |              |            | C           |              |                                              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Jun-2016              | 12227568      | EXPEDITED (15-DAY) |                    | HO              | IT-FRI-1000083529    |                      | 48 YR      | Male       | ITA            |

| <u>Preferred Term</u>                        | <u>Product</u>               | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------|------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Bradyphrenia; Intentional<br>Overdose; Sopor | Escitalopram                 |              |            | S           | Unknown      | Overdose: 100 Mg   |                 | Forest       |
|                                              | Flurazepam Monohydrochloride |              |            | S           | Oral         | Overdose: 150 Mg   |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Jun-2016              | 12302245      | EXPEDITED (15-DAY) |                    | HO              | JP-FRI-1000084103    |                      | 33 YR      | Female     | JPN            |

| <u>Preferred Term</u>                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Drug Reaction With<br>Eosinophilia And Systemic | Lexapro        |              |            | S           | Oral         | 15 Mg              |                 | Forest     |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|          |           |   |      |              |
|----------|-----------|---|------|--------------|
| Symptoms | Lexapro   | S | Oral | Forest       |
|          | Cyanamide | S | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 07-Jun-2016              | 12356433                | EXPEDITED (15-DAY) |                    | OT              | JP-FRI-1000084393    |                      | 42 YR           | Female       | JPN            |
| <u>Preferred Term</u>    | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Eruption            | Lexapro                 |                    |                    | S               | Oral                 | 5 Mg                 |                 | Forest       |                |
|                          | Paxil                   |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |
|                          | Lexotan                 |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |
|                          | Benzalin (Nitrazepam)   |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |
|                          | Keishikaryukotsuboreito |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                        | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|--------------------------------------------------------|----------------------|-----------------|----------------------|----------------|
| 07-Jun-2016                                                                                                     | 12441313       | EXPEDITED (15-DAY) |                    | HO, OT          | FR-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>BMS-2016-043165 |                      |                 | Male                 | FRA            |
| <u>Preferred Term</u>                                                                                           | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Confusional State;<br>Dissociation; Labelled<br>Drug-Drug Interaction<br>Medication Error; Suicidal<br>Ideation | Daklinza       |                    |                    | S               | Oral                                                   | 60 Mg, Qd            |                 | Bristol Myers Squibb |                |
|                                                                                                                 | Sovaldi        |                    |                    | S               | Oral                                                   | 400 Mg, Qd           |                 | Not Reported         |                |
|                                                                                                                 | Seroplex       |                    |                    | S               | Oral                                                   | Unk, Qd              |                 | Not Reported         |                |
|                                                                                                                 | Xanax          |                    |                    | C               | Unknown                                                |                      |                 | Not Reported         |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| 07-Jun-2016              | 12443682       | NON-EXPEDITED    |                    |                 | US-PFIZER INC-<br>2016274697 |                      |                 | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity    | Skelaxin       |                  |                    | S               |                              |                      |                 | Pfizer       |                |
|                          | Pristiq        |                  |                    | S               |                              |                      |                 | Pfizer       |                |
|                          | Lexapro        |                  |                    | S               |                              |                      |                 | Not Reported |                |
|                          | Ambien         |                  |                    | S               |                              |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
|---------------------------------------------|----------------------|--------------------|--------------------|-----------------|---------------------------------------------|----------------------|-----------------|------------------|----------------|
| 07-Jun-2016                                 | 12445076             | EXPEDITED (15-DAY) |                    | OT              | US-BAUSCH-BL-2016-012785                    |                      | 29 YR           | Female           | USA            |
| <u>Preferred Term</u>                       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |
| Off Label Use; Weight Increased             | Xenazine             |                    |                    | S               | Oral                                        |                      |                 | Not Reported     |                |
|                                             | Lexapro              |                    |                    | S               | Unknown                                     |                      |                 | Not Reported     |                |
| <u>FDA Received Date</u>                    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 08-Jun-2016                                 | 12074823             | EXPEDITED (15-DAY) |                    | HO, OT          | AT-ELI_LILLY_AND_COMP<br>ANY-AT201602000133 |                      | 47 YR           | Female           | AUT            |
| <u>Preferred Term</u>                       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |
| Drug Interaction; Hepatic Enzyme Increased; | Cymbalta             |                    |                    | S               | Oral                                        | 60 Mg, Unknown       |                 | Eli Lilly And Co |                |
| Hepatic Steato-Fibrosis;                    | Cymbalta             |                    |                    | S               |                                             |                      |                 | Eli Lilly And Co |                |
| Hyperprolactinaemia;                        | Risperdal            |                    |                    | S               | Unknown                                     | 1 Mg, Unk            |                 | Not Reported     |                |
| Leiomyoma; Renal Cyst                       | Seroquel             |                    |                    | S               | Unknown                                     | 50 Mg, Qd            |                 | Not Reported     |                |
|                                             | Seroquel             |                    |                    | S               |                                             | Unk                  |                 | Not Reported     |                |
|                                             | Seroquel             |                    |                    | S               | Oral                                        | 100 Mg, Qd           |                 | Not Reported     |                |
|                                             | Seroquel             |                    |                    | S               | Unknown                                     | 75 Mg, Qd            |                 | Not Reported     |                |
|                                             | Seroquel             |                    |                    | S               | Unknown                                     | 50 Mg, Qd            |                 | Not Reported     |                |
|                                             | Seroquel             |                    |                    | S               | Unknown                                     | 25 Mg, Qd            |                 | Not Reported     |                |
|                                             | Trittico             |                    |                    | S               | Unknown                                     | 150 Mg, Qd           |                 | Not Reported     |                |
|                                             | Trittico             |                    |                    | S               | Unknown                                     | 150 Mg, Qd           |                 | Not Reported     |                |
|                                             | Trittico             |                    |                    | S               | Oral                                        | 300 Mg, Qd           |                 | Not Reported     |                |
|                                             | Trittico             |                    |                    | S               | Unknown                                     | 300 Mg, Qd           |                 | Not Reported     |                |
|                                             | Trittico             |                    |                    | S               | Unknown                                     | 250 Mg, Qd           |                 | Not Reported     |                |
|                                             | Trittico             |                    |                    | S               | Unknown                                     | 200 Mg, Qd           |                 | Not Reported     |                |
|                                             | Trittico             |                    |                    | S               | Unknown                                     | 150 Mg, Qd           |                 | Not Reported     |                |
|                                             | Cipralext /01588501/ |                    |                    | S               | Unknown                                     | 20 Mg, Qd            |                 | Not Reported     |                |
|                                             | Cipralext /01588501/ |                    |                    | S               | Unknown                                     | 30 Mg, Unknown       |                 | Not Reported     |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                    |   |         |                      |              |
|--------------------|---|---------|----------------------|--------------|
| Gewacalm           | S | Unknown | 30 Mg, Qd            | Not Reported |
| Gewacalm           | S | Unknown | 20 Mg, Qd            | Not Reported |
| Gewacalm           | S | Unknown | 10 Mg, Qd            | Not Reported |
| Gewacalm           | S | Unknown | 5 Mg, Qd             | Not Reported |
| Rivotril           | C | Unknown | 2 Mg, Qd             | Not Reported |
| Rivotril           | C | Unknown | 2.5 Mg, Qd           | Not Reported |
| Rivotril           | C | Unknown | 1.5 Mg, Qd           | Not Reported |
| Rivotril           | C | Unknown | 1.25 Mg, Qd          | Not Reported |
| Rivotril           | C | Unknown | 1 Mg, Qd             | Not Reported |
| Rivotril           | C | Unknown | 0.5 Mg, Qd           | Not Reported |
| Molaxole           | C | Unknown | Unk, Unknown         | Not Reported |
| Oleovit D3         | C | Unknown | 30 Gtt, Weekly (1/W) | Not Reported |
| Cevitol /00008001/ | C | Unknown | Unk Unk, Unknown     | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------------------------|----------------------|------------|------------|----------------|
| 09-Jun-2016              | 12450010      | EXPEDITED (15-DAY) |                    | DE, HO, OT      | US-STRIDES ARCOLAB<br>LIMITED-<br>2016SP004432 |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>                                                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiac Arrest; Completed<br>Suicide; Respiratory<br>Arrest; Toxicity To Various<br>Agents | Meloxicam      |              |            | S           | Oral         | Unk                |                 | Strides      |
|                                                                                            | Meloxicam      |              |            | S           | Oral         | Unk                |                 | Strides      |
|                                                                                            | Lamotrigine    |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                                                                                            | Lamotrigine    |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                                                                                            | Escitalopram   |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                                                                                            | Escitalopram   |              |            | S           | Oral         | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Jun-2016              | 12453096      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000085203    |                      | 84 YR      | Male       | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|              |                           |   |      |       |              |
|--------------|---------------------------|---|------|-------|--------------|
| Haematemesis | Escitalopram              | S | Oral | 10 Mg | Forest       |
|              | Previscan (Fluindione)    | S | Oral |       | Not Reported |
|              | Ebixa Film-Coated Tablets | C |      |       | Not Reported |
|              | Zymad                     | C |      |       | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Jun-2016              | 12455659      | DIRECT           |                    |                 |                      |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>                                                                         | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------|-------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Product Dispensing Error;<br>Transcription Medication<br>Error; Wrong Product<br>Administered | Lexapro           |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                               | Enalapril Maleate |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 10-Jun-2016              | 12455523      | NON-EXPEDITED    |                    | HO              | FR-EISAI MEDICAL<br>RESEARCH-EC-2016-<br>017555 |                      | 83 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u>                    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-----------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hyponatraemia         | Aricept                           |              |            | S           | Oral         | Unknown            |                 | Not Reported |
|                       | Desloratadine                     |              |            | S           | Oral         | 5 Mg               |                 | Not Reported |
|                       | Pantoprazole                      |              |            | S           | Oral         | 20 Mg              |                 | Not Reported |
|                       | Escitalopram                      |              |            | S           | Oral         | 10 Mg              |                 | Not Reported |
|                       | Furosemide                        |              |            | S           | Oral         | 40 Mg              |                 | Not Reported |
|                       | Alteis                            |              |            | S           | Oral         | 40 Mg              |                 | Not Reported |
|                       | Aspegic [Acetylsalicylate Lysine] |              |            | C           |              | Unknown            |                 | Not Reported |
|                       | Nebivolol                         |              |            | C           |              | Unknown            |                 | Not Reported |
|                       | Levothyrox                        |              |            | C           |              | Unknown            |                 | Not Reported |
|                       | Alepsal (Caffeine\Phenobarbital)  |              |            | C           |              | Unknown            |                 | Not Reported |
|                       | Nerisone                          |              |            | C           |              | Unknown            |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                              | <u>Case #</u>                                                                                                                                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| 10-Jun-2016                                                                                                                                                                                                           | 12456239                                                                                                                                             | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000085209            |                      | 65 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                                                 | <u>Product</u>                                                                                                                                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anaemia; Drug Reaction<br>With Eosinophilia And<br>Systemic Symptoms                                                                                                                                                  | Escitalopram                                                                                                                                         |                    |                    | S               | Oral                         |                      |                 | Forest       |                |
|                                                                                                                                                                                                                       | Zeclar                                                                                                                                               |                    |                    | S               | Oral                         | 500 Mg               |                 | Not Reported |                |
|                                                                                                                                                                                                                       | Josacine                                                                                                                                             |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                       | Alprazolam                                                                                                                                           |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                       | Mucothiol                                                                                                                                            |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                       | Polery (Aconite<br>Tincture\Belladonna<br>Leaf\Codeine\Ethylmorphine<br>Hydrochloride\Polygala<br>Tenuifolia Root\Sodium<br>Benzoate\Sodium Bromide) |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                              | <u>Case #</u>                                                                                                                                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Jun-2016                                                                                                                                                                                                           | 12279906                                                                                                                                             | EXPEDITED (15-DAY) |                    | HO, OT          | US-TEVA-652224USA            |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                 | <u>Product</u>                                                                                                                                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain Upper;<br>Anaemia; Decreased<br>Appetite; Haemorrhage;<br>Hallucination; Intentional<br>Self-Injury; Loss Of<br>Consciousness; Malaise;<br>Nausea; Treatment<br>Noncompliance; Urinary<br>Incontinence | Clonazepam                                                                                                                                           |                    |                    | S               | Unknown                      |                      |                 | Teva         |                |
|                                                                                                                                                                                                                       | Escitalopram                                                                                                                                         |                    |                    | S               | Unknown                      |                      |                 | Ivax         |                |
|                                                                                                                                                                                                                       | Tramadol                                                                                                                                             |                    |                    | S               | Unknown                      |                      |                 | Teva         |                |
| <u>FDA Received Date</u>                                                                                                                                                                                              | <u>Case #</u>                                                                                                                                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Jun-2016                                                                                                                                                                                                           | 12313299                                                                                                                                             | NON-EXPEDITED      |                    |                 | US-PFIZER INC-<br>2016219314 |                      | 39 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                 | <u>Product</u>                                                                                                                                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                       |             |   |     |              |
|-----------------------|-------------|---|-----|--------------|
| Drug Hypersensitivity | Chantix     | S | Unk | Pfizer       |
|                       | Colestid    | S | Unk | Pfizer       |
|                       | Codeine     | S | Unk | Not Reported |
|                       | Hydrocodone | S | Unk | Not Reported |
|                       | Citalopram  | S | Unk | Not Reported |
|                       | Zocor       | S | Unk | Not Reported |
|                       | Lexapro     | S | Unk | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|------------|------------|----------------|
| 13-Jun-2016              | 12458987      | EXPEDITED (15-DAY) |                    | OT              | DE-DRREDDYS-GER/GER/16/0080267 |                      | 53 YR      | Male       | DEU            |

| <u>Preferred Term</u>                                                                                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Ejaculation Disorder;<br>Erectile Dysfunction;<br>Fatigue; Urinary<br>Retention; Urinary<br>Straining | Venlafaxine    |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                       | Venlafaxine    |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                       | Escitalopram   |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                       | Pantoprazole   |              |            | C           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 13-Jun-2016              | 12460139      | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2016291495 |                      |            | Female     | USA            |

| <u>Preferred Term</u>                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Asthenia; Crying; Drug<br>Ineffective | Zoloft         |              |            | S           |              | Unk                |                 | Pfizer       |
|                                       | Lexapro        |              |            | S           |              | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------------------------------------|----------------------|------------|------------|----------------|
| 13-Jun-2016              | 12460206      | EXPEDITED (15-DAY) |                    | HO, OT          | US-WEST-WARD<br>PHARMACEUTICALS<br>CORP.-US-H14001-16-00 |                      | 47 YR      | Female     | USA            |

| <u>Preferred Term</u>                                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Aphasia; Drug Interaction;<br>Mental Status Changes; | Doxycycline    |              |            | S           | Unknown      |                    |                 | Hikma      |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                         |              |   |         |              |
|-------------------------|--------------|---|---------|--------------|
| Nephrogenic Diabetes    | Lithium      | S | Unknown | Roxane       |
| Insipidus; Renal        | Aripiprazole | S | Unknown | Not Reported |
| Impairment; Toxicity To | Escitalopram | S | Unknown | Not Reported |
| Various Agents; Tremor  | Klonopin     | S | Unknown | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Jun-2016              | 12464119      | DIRECT           |                    | HO, LT, OT      |                      |                      | 27 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                            | <u>Product</u>                          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------|-----------------------------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Anxiety; Depressed Mood; Hallucination, Auditory; Product Substitution Issue; Suicidal Behaviour | Escitalopram                            |              |            | S           | Oral         | In The Morning Taken By Mouth |                 | Not Reported |
|                                                                                                  | Lamotrigine                             |              |            | C           |              |                               |                 | Not Reported |
|                                                                                                  | Norethindrone                           |              |            | C           |              |                               |                 | Not Reported |
|                                                                                                  | Nifedipine                              |              |            | C           |              |                               |                 | Not Reported |
|                                                                                                  | Aripiprazole                            |              |            | C           |              |                               |                 | Not Reported |
|                                                                                                  | Levothyroxine                           |              |            | C           |              |                               |                 | Not Reported |
|                                                                                                  | Gabapentin                              |              |            | C           |              |                               |                 | Not Reported |
|                                                                                                  | Nortriptyline                           |              |            | C           |              |                               |                 | Not Reported |
|                                                                                                  | Trazodone                               |              |            | C           |              |                               |                 | Not Reported |
|                                                                                                  | Vistaril                                |              |            | C           |              |                               |                 | Not Reported |
|                                                                                                  | Proair                                  |              |            | C           |              |                               |                 | Not Reported |
|                                                                                                  | Hyoscyamine                             |              |            | C           |              |                               |                 | Not Reported |
|                                                                                                  | B12                                     |              |            | C           |              |                               |                 | Not Reported |
|                                                                                                  | Ferrix                                  |              |            | C           |              |                               |                 | Not Reported |
|                                                                                                  | Vitamin With Iron                       |              |            | C           |              |                               |                 | Not Reported |
|                                                                                                  | Calcium Citrate With Zinc And Magnesium |              |            | C           |              |                               |                 | Not Reported |
|                                                                                                  | Melatonin                               |              |            | C           |              |                               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|------------|------------|----------------|
| 14-Jun-2016              | 12463468      | EXPEDITED (15-DAY) |                    | HO, OT          | US-DRREDDYS-USA/USA/16/0080426 |                      | 50 YR      | Female     | USA            |

| <u>Preferred Term</u>             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Dizziness; Fall; Long Qt Syndrome | Levofloxacin   |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                   | Escitalopram   |              |            | S           | Unknown      |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                  | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|--------------------------|---------------------------------------|-----------------|--------------|----------------|
| 14-Jun-2016                                               | 12463701                  | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2016295155 |                                       |                 | Female       | USA            |
| <u>Preferred Term</u>                                     | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Malaise; Nausea; Tremor                          | Zoloft                    |                    |                    | S               |                          | Unk, Less Than Four Doses             |                 | Pfizer       |                |
|                                                           | Escitalopram              |                    |                    | S               |                          | Unk, Less Than Four Doses             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                  | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Jun-2016                                               | 12463809                  | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2016289950 |                                       |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                     | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity                                     | Lipitor                   |                    |                    | S               |                          | Unk                                   |                 | Pfizer       |                |
|                                                           | Lexapro                   |                    |                    | S               |                          | Unk                                   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                  | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Jun-2016                                               | 12464719                  | NON-EXPEDITED      |                    |                 | US-TORRENT-00001195      |                                       |                 | Female       | USA            |
| <u>Preferred Term</u>                                     | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypersensitivity                                          | Escitalopram Tablets, Usp |                    |                    | S               |                          |                                       |                 | Torrent      |                |
| <u>FDA Received Date</u>                                  | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Jun-2016                                               | 12465512                  | EXPEDITED (15-DAY) |                    | HO              | FR-SA-2016SA108290       |                                       | 58 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                     | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Bradypnoea; Hypercapnia; Respiratory Acidosis; Somnolence | Stilnox                   |                    |                    | S               | Oral                     |                                       |                 | Not Reported |                |
|                                                           | Skenan                    |                    |                    | S               | Oral                     | 70 Mg In Morning And 50 Mg In Evening |                 | Not Reported |                |
|                                                           | Actiskenan                |                    |                    | S               | Oral                     |                                       |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                        |   |         |              |
|------------------------|---|---------|--------------|
| Domperidone Arrow      | S | Oral    | Not Reported |
| Seroplex               | S | Oral    | Not Reported |
| Lysanxia               | S | Oral    | Not Reported |
| Clamoxyl (Amoxicillin) | C | Unknown | Not Reported |
| Novorapid              | C | Unknown | Not Reported |
| Lantus                 | C | Unknown | Not Reported |
| Lovenox                | C | Unknown | Not Reported |
| Macrogol               | C | Unknown | Not Reported |
| Eupantol               | C | Unknown | Not Reported |
| Adrovanse              | C | Unknown | Not Reported |
| Amoxicillin            | C | Unknown | Not Reported |
| Vitamin D3             | C | Unknown | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 14-Jun-2016              | 12465904      | EXPEDITED (15-DAY) |                    | OT              | IT-ABBVIE-16P-083-1650601-00 |                      | 31 YR      | Female     | ITA            |

| <u>Preferred Term</u>             | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Sopor; Toxicity To Various Agents | Depakin              |              |            | S           | Oral         |                    |                 | Not Reported |
|                                   | Escitalopram Oxalate |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Jun-2016              | 12009330      | EXPEDITED (15-DAY) |                    | OT              | IT-ACCORD-037384     |                      | 51 YR      | Female     | ITA            |

| <u>Preferred Term</u> | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-------------------|--------------|------------|-------------|--------------|----------------------|-----------------|--------------|
| Clonus                | Escitalopram      |              |            | S           |              | Dose Reduced To 10mg |                 | Accord       |
|                       | Eutirox           |              |            | C           | Oral         |                      |                 | Not Reported |
|                       | Cardioaspirin     |              |            | C           | Oral         |                      |                 | Not Reported |
|                       | Tavor [Lorazepam] |              |            | C           |              |                      |                 | Not Reported |
|                       | Surmontil         |              |            | C           |              |                      |                 | Not Reported |
|                       | Lyrica            |              |            | C           |              |                      |                 | Not Reported |

# FDA Adverse Event Reporting System

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| <u>FDA Received Date</u>                                                | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------|---------------------------------------|--------------------|--------------------|-----------------|-------------------------|----------------------|-----------------|--------------|----------------|
| 15-Jun-2016                                                             | 12456802                              | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000085204       |                      | 75 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                   | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Coma; Hyponatraemia;<br>Inappropriate Antidiuretic<br>Hormone Secretion | Escitalopram                          |                    |                    | S               | Oral                    | 1 Df                 |                 | Forest       |                |
|                                                                         | Prozac                                |                    |                    | C               | Unknown                 |                      |                 | Not Reported |                |
|                                                                         | Imovane                               |                    |                    | C               | Unknown                 |                      |                 | Not Reported |                |
|                                                                         | Athymil                               |                    |                    | C               | Unknown                 |                      |                 | Not Reported |                |
|                                                                         | Euthyral                              |                    |                    | C               | Unknown                 | 0.75 Df              |                 | Not Reported |                |
|                                                                         | Mianserine                            |                    |                    | C               | Unknown                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Jun-2016                                                             | 12468676                              | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000085290       |                      |                 | Male         | FRA            |
| <u>Preferred Term</u>                                                   | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Foetal Heart Rate<br>Disorder                                           | Escitalopram                          |                    |                    | S               | Transplacental          | 10 Mg                |                 | Forest       |                |
|                                                                         | Leponex                               |                    |                    | S               | Transplacental          | 250 Mg               |                 | Not Reported |                |
|                                                                         | Seresta                               |                    |                    | S               | Transplacental          | 10 Mg                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Jun-2016                                                             | 12468756                              | EXPEDITED (15-DAY) |                    | HO, LT          | FR-DSJP-DSE-2016-119929 |                      |                 | Unknown      | FRA            |
| <u>Preferred Term</u>                                                   | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Ischaemic Stroke                                                        | Alteis 20 Mg                          |                    |                    | S               | Oral                    | 20 Mg, Qd            |                 | Daiichi      |                |
|                                                                         | Raloxifene Biogaran                   |                    |                    | S               | Oral                    | 60 Mg, Qd            |                 | Not Reported |                |
|                                                                         | Candesartan Biogaran (Non-Az Product) |                    |                    | S               | Oral                    | 4 Mg, Qd             |                 | Not Reported |                |
|                                                                         | Escitalopram Oxalate                  |                    |                    | S               | Oral                    | 20 Mg, Qd            |                 | Not Reported |                |
|                                                                         | Bromazepam Biogaran                   |                    |                    | S               | Oral                    | 6 Mg, Unk            |                 | Not Reported |                |
|                                                                         | Lamaline /01708901/                   |                    |                    | S               | Oral                    | 3 Df, Qd As Needed   |                 | Not Reported |                |

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|                     |   |      |            |              |
|---------------------|---|------|------------|--------------|
| Sulfarlem S 25 Mg   | S | Oral | 25 Mg, Unk | Not Reported |
| Omeprazole Biogaran | S | Oral | 20 Mg, Unk | Not Reported |
| Urbanyl             | S | Oral | 10 Mg, Unk | Not Reported |
| Nebivolol Biogaran  | C | Oral | 5 Mg, Unk  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 15-Jun-2016              | 12468860      | EXPEDITED (15-DAY) |                    | DS              | NL-MYLANLABS-2016M1024023 |                      |            | Unknown    | NLD            |

| <u>Preferred Term</u>                                             | <u>Product</u>                                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                             | <u>Duration</u> | <u>Mfr</u> |
|-------------------------------------------------------------------|------------------------------------------------|--------------|------------|-------------|--------------|------------------------------------------------|-----------------|------------|
| Hypersensitivity; Therapeutic Response Unexpected; Tooth Disorder | Escitalopram Mylan 10 Mg Filmomhulde Tabletten |              |            | S           | Oral         | 10 Mg, Qd (1 Keer Per Dag 1 Stuk(S))           |                 | Mylan      |
|                                                                   | Cipramil /00582602/                            |              |            | S           | Oral         | Unk (1 Keer Per Dag 1 Stuk(S))                 |                 | Mylan      |
|                                                                   | Resure                                         |              |            | C           |              | Unk                                            |                 | Mylan      |
|                                                                   | Omeprazol /00661201/                           |              |            | C           | Oral         | Extra Info: Alleen Als Ik Bv Antibiotica Krijg |                 | Mylan      |
|                                                                   | Ascorbinezuur                                  |              |            | C           | Oral         | Extra Info: Af En Toe Bij (Hoofd)Pijn          |                 | Mylan      |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Jun-2016              | 12471723      | DIRECT           | Y                  | HO              |                      |                      | 35 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Chest Pain; Condition Aggravated; Drug Interaction; Dyspnoea; Electrocardiogram Qt Prolonged | Flecainidide   |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                              | Lexapro        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                              | Coreg          |              |            | C           |              |                    |                 | Not Reported |
|                                                                                              | Zyrtec         |              |            | C           |              |                    |                 | Not Reported |
|                                                                                              | Coenzyme Q10   |              |            | C           |              |                    |                 | Not Reported |
|                                                                                              | Toviaz         |              |            | C           |              |                    |                 | Not Reported |
|                                                                                              | Tambicor       |              |            | C           |              |                    |                 | Not Reported |
|                                                                                              | Folvite        |              |            | C           |              |                    |                 | Not Reported |
|                                                                                              | Novolog        |              |            | C           |              |                    |                 | Not Reported |
|                                                                                              | Lantus         |              |            | C           |              |                    |                 | Not Reported |
|                                                                                              | Calciu         |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>   | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------|------------------------|--------------------|--------------------|-----------------|------------------------------------------------|---------------------------|-----------------|--------------|----------------|
| 16-Jun-2016                | 12077720               | EXPEDITED (15-DAY) |                    | OT              | PHHY2016IT016600                               |                           | 42 YR           | Female       | ITA            |
| <u>Preferred Term</u>      | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |                |
| Aortic Stenosis;           | Tasigna                |                    |                    | S               | Oral                                           | 400 Mg, Qd                |                 | Novartis     |                |
| Concomitant Disease        | Cipralext/Escitalopram |                    |                    | S               | Oral                                           | 1 Df, Qd                  |                 | Not Reported |                |
| Aggravated; Maternal       | Carbolithium           |                    |                    | S               | Oral                                           | 750 Mg, Qd                |                 | Not Reported |                |
| Exposure During            | Tavor (Lorazepam)      |                    |                    | S               | Oral                                           | 1 Df, Qd                  |                 | Not Reported |                |
| Pregnancy;                 | Tirosint               |                    |                    | S               | Oral                                           | 150 Ug, Qd                |                 | Not Reported |                |
| Thrombophlebitis           |                        |                    |                    |                 |                                                |                           |                 |              |                |
| Superficial                |                        |                    |                    |                 |                                                |                           |                 |              |                |
| <u>FDA Received Date</u>   | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Jun-2016                | 12077731               | EXPEDITED (15-DAY) |                    | OT              | PHHY2016IT016208                               |                           |                 | Unknown      | ITA            |
| <u>Preferred Term</u>      | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |                |
| Aorta Hypoplasia; Foetal   | Tasigna                |                    |                    | S               | Transplacental                                 | Mother Dose:400 Mg, Qd    |                 | Novartis     |                |
| Exposure During            | Cipralext/Escitalopram |                    |                    | S               | Transplacental                                 | Mother Dose:1 Df, Qd      |                 | Not Reported |                |
| Pregnancy; Foetal          |                        |                    |                    |                 |                                                | (One Posologic Unit) For  |                 |              |                |
| Malformation; Mitral Valve | Carbolithium           |                    |                    | S               | Transplacental                                 | Mother Dose:750 Mg, Qd    |                 | Not Reported |                |
| Atresia; Univentricular    |                        |                    |                    |                 |                                                | (For 11 Years)            |                 |              |                |
| Heart                      | Tavor//Lorazepam       |                    |                    | S               | Transplacental                                 | Mother Dose:1 Df, Qd      |                 | Not Reported |                |
|                            |                        |                    |                    |                 |                                                | (One Posologic Unit) (For |                 |              |                |
|                            | Tirosint               |                    |                    | S               | Transplacental                                 | Mother Dose:150 Ug, Qd    |                 | Not Reported |                |
|                            |                        |                    |                    |                 |                                                | (For 17 Years)            |                 |              |                |
| <u>FDA Received Date</u>   | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Jun-2016                | 12470397               | EXPEDITED (15-DAY) |                    | DE, HO          | US-STRIDES ARCOLAB<br>LIMITED-<br>2016SP006874 |                           |                 | Unknown      | USA            |
| <u>Preferred Term</u>      | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |                |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                  |                         |   |      |     |              |
|--------------------------------------------------|-------------------------|---|------|-----|--------------|
| Completed Suicide;<br>Toxicity To Various Agents | Meloxicam               | S | Oral | Unk | Strides      |
|                                                  | Buspirone Hydrochloride | S |      | Unk | Strides      |
|                                                  | Benzonatate             | S | Oral | Unk | Unknown      |
|                                                  | Escitalopram            | S | Oral | Unk | Not Reported |
|                                                  | Topiramate              | S | Oral | Unk | Not Reported |
|                                                  | Sumatriptan             | S | Oral | Unk | Not Reported |
|                                                  | Chlorphenamine          | S | Oral | Unk | Not Reported |
|                                                  | Dextromethorphan        | S | Oral | Unk | Not Reported |
|                                                  | Cyclobenzaprine         | S | Oral | Unk | Not Reported |
|                                                  | Olanzapine              | S | Oral | Unk | Not Reported |
|                                                  | Trazodone               | S | Oral | Unk | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------|----------------------|------------|------------|----------------|
| 16-Jun-2016              | 12472861      | NON-EXPEDITED    |                    |                 | US-JAZZ-2015-US-019723 |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                                     | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Feeling Abnormal; Loss Of<br>Personal Independence In<br>Daily Activities | Xyrem                  |              |            | S           | Oral         | 3 G, Bid           |                 | Jazz         |
|                                                                           | Xyrem                  |              |            | S           | Oral         | 4.5 G, Bid         |                 | Jazz         |
|                                                                           | Lexapro                |              |            | S           |              | Unk                |                 | Not Reported |
|                                                                           | Adderall               |              |            | C           |              | Unk                |                 | Not Reported |
|                                                                           | Amoxicillin Trihydrate |              |            | C           |              | Unk                |                 | Not Reported |
|                                                                           | Amphetamine Salts      |              |            | C           |              | Unk                |                 | Not Reported |
|                                                                           | Flonase Allergy Rlf    |              |            | C           |              | Unk                |                 | Not Reported |
|                                                                           | Imitrex                |              |            | C           |              | Unk                |                 | Not Reported |
|                                                                           | Lamictal               |              |            | C           |              | Unk                |                 | Not Reported |
|                                                                           | Methotrexate           |              |            | C           |              | Unk                |                 | Not Reported |
|                                                                           | Mucinex Allergy        |              |            | C           |              | Unk                |                 | Not Reported |
|                                                                           | Naltrexone Hcl         |              |            | C           |              | Unk                |                 | Not Reported |
|                                                                           | Plaquenil              |              |            | C           |              | Unk                |                 | Not Reported |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                    |   |     |              |
|--------------------|---|-----|--------------|
| Proair Hfa         | C | Unk | Not Reported |
| Qvar               | C | Unk | Not Reported |
| Temazepam          | C | Unk | Not Reported |
| Trazodone          | C | Unk | Not Reported |
| Viibryd            | C | Unk | Not Reported |
| Xanax              | C | Unk | Not Reported |
| Xyzal              | C | Unk | Not Reported |
| Zofran Odt         | C | Unk | Not Reported |
| Dexedrine Spansule | C | Unk | Not Reported |
| Horizant Er        | C | Unk | Not Reported |
| Edluar             | C | Unk | Not Reported |
| Advil              | C | Unk | Not Reported |
| Aleve              | C | Unk | Not Reported |
| Flonase            | C | Unk | Not Reported |
| Folic Acid         | C | Unk | Not Reported |
| Vitamin B12        | C | Unk | Not Reported |
| Vitamin D Nos      | C | Unk | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 16-Jun-2016              | 12473898      | EXPEDITED (15-DAY) |                    | HO              | FR-009507513-1606FRA007732 |                      | 83 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u>                       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|--------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hyponatraemia         | Olmesartan Medoxomil                 |              |            | S           | Oral         | 40 Mg, Qd          |                 | Not Reported |
|                       | Aricept                              |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                       | Nebivolol Hydrochloride              |              |            | C           |              |                    |                 | Not Reported |
|                       | Levothyrox                           |              |            | C           |              |                    |                 | Not Reported |
|                       | Aspegic [Acetylsalicylate Lysine]    |              |            | C           |              |                    |                 | Not Reported |
|                       | Alepsal (Caffeine (+) Phenobarbital) |              |            | C           |              |                    |                 | Not Reported |
|                       | Nerisone                             |              |            | C           |              | Unk                |                 | Not Reported |
|                       | Desloratadine                        |              |            | S           | Oral         | 5 Mg, Qd           |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|              |   |      |           |              |
|--------------|---|------|-----------|--------------|
| Pantoprazole | S | Oral | 20 Mg, Qd | Not Reported |
| Escitalopram | S | Oral | 10 Mg, Qd | Not Reported |
| Furosemide   | S | Oral | 40 Mg, Qd | Merck        |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 17-Jun-2016              | 12256544      | EXPEDITED (15-DAY) |                    | HO, OT          | JP-PFIZER INC-2016203813 |                      | 48 YR      | Male       | JPN            |

| <u>Preferred Term</u>                                                                                                                                       | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Bipolar Disorder; Blood Glucose Increased; Blood Triglycerides Increased; Insomnia; Low Density Lipoprotein Increased; Mania; Somnolence; Suicidal Ideation | Effexor                |              |            | S           | Oral         | 37.5 Mg, 1x/Day    |                 | Pfizer       |
|                                                                                                                                                             | Effexor                |              |            | S           | Oral         | 75 Mg, 1x/Day      |                 | Pfizer       |
|                                                                                                                                                             | Effexor                |              |            | S           | Oral         | 112.5 Mg, 1x/Day   |                 | Pfizer       |
|                                                                                                                                                             | Effexor                |              |            | S           | Oral         | 150 Mg, 1x/Day     |                 | Pfizer       |
|                                                                                                                                                             | Effexor                |              |            | S           | Oral         | 112.5 Mg, 2x/Day   |                 | Pfizer       |
|                                                                                                                                                             | Lexapro                |              |            | S           | Oral         | 10 Mg, 1x/Day      |                 | Not Reported |
|                                                                                                                                                             | Seniran                |              |            | C           | Oral         | 2 Mg, 3x/Day       |                 | Not Reported |
|                                                                                                                                                             | Vegetamin B            |              |            | C           | Oral         | 1 Df, 1x/Day       |                 | Not Reported |
|                                                                                                                                                             | Sorentmin (Brotizolam) |              |            | C           | Oral         | 0.25 Mg, 1x/Day    |                 | Not Reported |
|                                                                                                                                                             | Flunitrazepam          |              |            | C           | Oral         | 4 Mg, 1x/Day       |                 | Not Reported |
|                                                                                                                                                             | Quetiapine             |              |            | C           | Oral         | 100 Mg, 1x/Day     |                 | Not Reported |
|                                                                                                                                                             | Cystanin               |              |            | C           | Oral         | 100 Mg, 3x/Day     |                 | Not Reported |
|                                                                                                                                                             | Alosenn /00476901/     |              |            | C           | Oral         | 0.5 G, 3x/Day      |                 | Not Reported |
|                                                                                                                                                             | Pantosin               |              |            | C           | Oral         | 1 G, 3x/Day        |                 | Not Reported |
|                                                                                                                                                             | Vemas                  |              |            | C           | Oral         | 2 Df, 3x/Day       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Jun-2016              | 12399251      | EXPEDITED (15-DAY) |                    | HO              | CN-FRI-1000084845    |                      | 16 YR      | Female     | CHN            |

| <u>Preferred Term</u>                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Amenorrhoea; Drug-Induced Liver Injury; | Escitalopram   |              |            | S           | Oral         | 10 Mg              |                 | Forest     |
|                                         | Escitalopram   |              |            | S           | Oral         |                    |                 | Forest     |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Product Use In  
Unapproved Indication;  
Product Use Issue

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------|----------------------|------------|------------|----------------|
| 17-Jun-2016              | 12465237      | EXPEDITED (15-DAY) |                    | HO              | FR-DSJP-DSE-2016-119943 |                      |            | Unknown    | FRA            |

| <u>Preferred Term</u> | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hyponatraemia         | Alteis 40 Mg            |              |            | S           | Oral         | 40 Mg, Qd          |                 | Daiichi      |
|                       | Aricept                 |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                       | Desloratadine           |              |            | S           | Oral         | 5 Mg, Qd           |                 | Not Reported |
|                       | Pantoprazole            |              |            | S           | Oral         | 20 Mg, Qd          |                 | Not Reported |
|                       | Escitalopram            |              |            | S           | Oral         | 10 Mg, Qd          |                 | Not Reported |
|                       | Furosemide              |              |            | S           | Oral         | 40 Mg, Qd          |                 | Not Reported |
|                       | Nebivolol Hydrochloride |              |            | C           | Oral         | Unk                |                 | Not Reported |
|                       | Levothyrox              |              |            | C           | Oral         | Unk                |                 | Not Reported |
|                       | Aspegic /00002703/      |              |            | C           |              | Unk                |                 | Not Reported |
|                       | Alepsal /01606601/      |              |            | C           | Oral         | Unk                |                 | Not Reported |
|                       | Nerisone                |              |            | C           | Topical      | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------------------------------|----------------------|------------|------------|----------------|
| 17-Jun-2016              | 12474608      | EXPEDITED (15-DAY) |                    | OT              | KR-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>BMS-2016-048797 |                      | 40 YR      | Female     | KOR            |

| <u>Preferred Term</u>                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>           |
|---------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------|
| Dyspnoea; Facial<br>Paralysis; Palpitations | Abilify        |              |            | S           | Unknown      | 2 Mg, Unk          |                 | Bristol Myers Squibb |
|                                             | Alprazolam     |              |            | S           | Unknown      | Unk                |                 | Not Reported         |
|                                             | Escitalopram   |              |            | S           | Unknown      | Unk                |                 | Not Reported         |
|                                             | Valproic Acid  |              |            | S           | Unknown      | Unk                |                 | Not Reported         |
|                                             | Zolpidem       |              |            | S           | Unknown      | Unk                |                 | Not Reported         |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 17-Jun-2016              | 12474715      | EXPEDITED (15-DAY) |                    | LT              | FR-ASTRAZENECA-2016SE65737 |                      | 71 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                                                          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Candida Infection;<br>Diarrhoea; Inappropriate<br>Antidiuretic Hormone<br>Secretion; Urticaria | Inexium        |              |            | S           | Oral         | 40.0mg Unknown     |                 | Astrazeneca  |
|                                                                                                | Seroplex       |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                | Xarelto        |              |            | C           |              | 20.0mg Unknown     |                 | Not Reported |
|                                                                                                | Co-Kenzen      |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                | Tahor          |              |            | C           |              | 40.0mg Unknown     |                 | Not Reported |
|                                                                                                | Diamicron      |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                | Stagid         |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                | Detensiel      |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                | Lyrica         |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                | Victoza        |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                | Allopurinol    |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                | Doliprane      |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                | Ixprim         |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                | Xatral         |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                | Seresta        |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                | Betagan        |              |            | C           | Ophthalmic   |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 17-Jun-2016              | 12475170      | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2016285810 |                      | 60 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Hypersensitivity | Xanax          |              |            | S           |              | Unk                |                 | Pfizer       |
|                       | Lexapro        |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Phenergan      |              |            | S           |              | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Jun-2016              | 12477134      | EXPEDITED (15-DAY) |                    | OT              | CN-FRI-1000085286    |                      |            | Female     | CHN            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                  |              |   |         |        |
|------------------|--------------|---|---------|--------|
| Abortion Induced | Escitalopram | S | Unknown | Forest |
|------------------|--------------|---|---------|--------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------|----------------------|------------|------------|----------------|
| 17-Jun-2016              | 12477890      | EXPEDITED (15-DAY) |                    | LT              | FR-LUNDBECK-DKLU2015242 |                      | 79 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u>                                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Ischaemic Stroke      | Urbanyl                                        |              |            | S           | Oral         |                    |                 | Lundbeck     |
|                       | Escitalopram                                   |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Candesartan                                    |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Alteis                                         |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Bromazepam                                     |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Lamaline<br>(Acetaminophen\Caffeine\Opium<br>) |              |            | S           | Oral         | Prn                |                 | Not Reported |
|                       | Raloxifene                                     |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Sulfarlem                                      |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Omeprazole                                     |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Nebivolol                                      |              |            | C           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Jun-2016              | 12436159      | EXPEDITED (15-DAY) |                    | DS, OT          | IT-TEVA-664792ACC    |                      | 61 YR      | Male       | ITA            |

| <u>Preferred Term</u>                                                                                                           | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------|------------|-------------|--------------|----------------------|-----------------|--------------|
| Anxiety; Dysgraphia;<br>Dyskinesia; Product Use<br>In Unapproved Indication;<br>Therapeutic Product Effect<br>Decreased; Tremor | Quetiapine Fumarate      |              |            | S           | Oral         |                      |                 | Teva         |
|                                                                                                                                 | Quetiapine Fumarate      |              |            | S           |              |                      |                 | Teva         |
|                                                                                                                                 | Sertraline Hydrochloride |              |            | S           |              | 50 Milligram Daily;  |                 | Not Reported |
|                                                                                                                                 | Sertraline Hydrochloride |              |            | S           |              | 200 Milligram Daily; |                 | Not Reported |
|                                                                                                                                 | Mirtazapine              |              |            | S           |              |                      |                 | Teva         |
|                                                                                                                                 | Mirtazapine              |              |            | S           |              |                      |                 | Teva         |
|                                                                                                                                 | Venlafaxine              |              |            | S           |              |                      |                 | Teva         |
|                                                                                                                                 | Venlafaxine              |              |            | S           |              |                      |                 | Teva         |
|                                                                                                                                 | Valproic Acid            |              |            | S           |              |                      |                 | Not Reported |
|                                                                                                                                 | Valproic Acid            |              |            | S           |              |                      |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                   |                                                                        |                    |                    |                 |                               |                            |                 |              |                |
|-----------------------------------|------------------------------------------------------------------------|--------------------|--------------------|-----------------|-------------------------------|----------------------------|-----------------|--------------|----------------|
|                                   | Escitalopram                                                           |                    |                    | S               |                               |                            |                 |              | Ivax           |
|                                   | Escitalopram                                                           |                    |                    | S               |                               |                            |                 |              | Ivax           |
| <u>FDA Received Date</u>          | <u>Case #</u>                                                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Jun-2016                       | 12479877                                                               | EXPEDITED (15-DAY) |                    | OT              | IT-CIPLA LTD.-<br>2016IT06662 |                            |                 | Unknown      | ITA            |
| <u>Preferred Term</u>             | <u>Product</u>                                                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>   |                |
| Sopor; Toxicity To Various Agents | Escitalopram                                                           |                    |                    | S               | Oral                          | 27 Df Total                |                 | Invagen      |                |
|                                   | Depakin "200 Mg Compresse Gastroresistenti"40 Compresse - (Sanofi S.P) |                    |                    | S               | Oral                          | 20 Df Total                |                 | Not Reported |                |
| <u>FDA Received Date</u>          | <u>Case #</u>                                                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Jun-2016                       | 12480322                                                               | EXPEDITED (15-DAY) |                    | OT              | IT-FRI-1000085373             |                            | 31 YR           | Female       | ITA            |
| <u>Preferred Term</u>             | <u>Product</u>                                                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>   |                |
| Sopor; Toxicity To Various Agents | Escitalopram                                                           |                    |                    | S               | Oral                          | Overdose: 27 Dosage Forms. |                 | Forest       |                |
|                                   | Depakin "200mg Compresse Gastroresistenti"                             |                    |                    | S               | Oral                          | 20 Dosage Forms.           |                 | Not Reported |                |
| <u>FDA Received Date</u>          | <u>Case #</u>                                                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Jun-2016                       | 11928376                                                               | EXPEDITED (15-DAY) |                    | HO, LT, OT      | JP-FRI-1000082094             |                            | 73 YR           | Female       | JPN            |
| <u>Preferred Term</u>             | <u>Product</u>                                                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>   |                |
| Autoimmune Haemolytic Anaemia     | Lexapro                                                                |                    |                    | S               | Oral                          | 10 Mg                      |                 | Forest       |                |
|                                   | Lexapro                                                                |                    |                    | S               | Oral                          |                            |                 | Forest       |                |
|                                   | Wypax                                                                  |                    |                    | C               | Oral                          | 3 Mg                       |                 | Not Reported |                |
|                                   | Aricept                                                                |                    |                    | C               | Oral                          |                            |                 | Not Reported |                |
|                                   | Norvasc                                                                |                    |                    | C               | Oral                          | 10 Mg                      |                 | Not Reported |                |
|                                   | Selectol                                                               |                    |                    | C               | Oral                          | 100 Mg                     |                 | Not Reported |                |
|                                   | Diovan                                                                 |                    |                    | C               | Oral                          | 20 Mg                      |                 | Not Reported |                |

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|         |   |      |         |              |
|---------|---|------|---------|--------------|
| Sermion | C | Oral | 15 Mg   | Not Reported |
| Nexium  | C | Oral | Unknown | Not Reported |
| Desyrel | C | Oral | 25 Mg   | Not Reported |
| Lexotan | C | Oral | 1 Mg    | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------|----------------------|------------|------------|----------------|
| 21-Jun-2016              | 12392962      | EXPEDITED (15-DAY) |                    | DS, OT          | CA-APOTEX-2016AP008468 |                      | 64 YR      | Female     | CAN            |

| <u>Preferred Term</u>                                                      | <u>Product</u>   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|----------------------------------------------------------------------------|------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Anxiety; Depression; Drug Ineffective; Fatigue; Product Substitution Issue | Apo-Escitalopram |              |            | S           | Oral         | 10 Mg, Qd          |                 | Apotex     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Jun-2016              | 12434723      | EXPEDITED (15-DAY) |                    | HO              | US-FRI-1000085083    |                      | 31 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|----------------------------|-----------------|--------------|
| Generalised Tonic-Clonic Seizure; Intentional Overdose; Loss Of Consciousness; Neuroleptic Malignant Syndrome | Escitalopram   |              |            | S           | Oral         | 20mg                       |                 | Forest       |
|                                                                                                               | Escitalopram   |              |            | S           |              |                            |                 | Forest       |
|                                                                                                               | Geodon         |              |            | S           | Oral         | 20mg                       |                 | Not Reported |
|                                                                                                               | Geodon         |              |            | S           | Oral         | 20mg Qam And 40mg Q Dinner |                 | Not Reported |
|                                                                                                               | Geodon         |              |            | S           |              | 420 Mg                     |                 | Not Reported |
|                                                                                                               | Lamotrigine    |              |            | S           | Oral         | 150mg                      |                 | Not Reported |
|                                                                                                               | Lamotrigine    |              |            | S           |              | 1050 Mg                    |                 | Not Reported |
|                                                                                                               | Alprazolam     |              |            | S           | Oral         | 1.5mg                      |                 | Not Reported |
|                                                                                                               | Zolpidem       |              |            | S           | Oral         | 10mg                       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                    | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------------------------|----------------------|------------|------------|----------------|
| 21-Jun-2016              | 12483269      | EXPEDITED (15-DAY) |                    | DE, HO          | US-STRIDES ARCOLAB LIMITED-2016SP006890 |                      |            | Unknown    | USA            |

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| <u>Preferred Term</u>                                                                   | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
|-----------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|------------------------------------------------|------------------------------|-----------------|--------------|----------------|
| Toxicity To Various Agents                                                              | Buspirone Hydrochloride |                    |                    | S               | Oral                                           | Unk                          |                 | Strides      |                |
|                                                                                         | Paracetamol             |                    |                    | S               | Oral                                           | Unk                          |                 | Not Reported |                |
|                                                                                         | Quetiapine              |                    |                    | S               | Oral                                           | Unk                          |                 | Not Reported |                |
|                                                                                         | Escitalopram            |                    |                    | S               | Oral                                           | Unk                          |                 | Not Reported |                |
|                                                                                         | Sertraline              |                    |                    | S               | Oral                                           | Unk                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Jun-2016                                                                             | 12483609                | EXPEDITED (15-DAY) |                    | OT              | IT-ACCORD-041588                               |                              | 31 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                                   | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Abuse; Sopor;<br>Toxicity To Various Agents                                        | Depakin                 |                    |                    | S               | Oral                                           | Strength: 200 Mg             |                 | Not Reported |                |
|                                                                                         | Escitalopram            |                    |                    | S               | Oral                                           |                              |                 | Accord       |                |
| <u>FDA Received Date</u>                                                                | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Jun-2016                                                                             | 12484033                | EXPEDITED (15-DAY) |                    | OT              | US-LUPIN<br>PHARMACEUTICALS<br>INC.-2016-02747 |                              | 32 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                   | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Breast Pain; Drug<br>Interaction; Galactorrhoea;<br>Libido Increased; Vision<br>Blurred | Escitalopram            |                    |                    | S               | Unknown                                        |                              |                 | Not Reported |                |
|                                                                                         | Escitalopram            |                    |                    | S               |                                                |                              |                 | Not Reported |                |
|                                                                                         | Venlafaxine             |                    |                    | S               | Unknown                                        | 75 Mg                        |                 | Not Reported |                |
|                                                                                         | Venlafaxine             |                    |                    | S               | Unknown                                        | 37.5 Mg                      |                 | Not Reported |                |
|                                                                                         | Omeprazole              |                    |                    | S               | Unknown                                        |                              |                 | Not Reported |                |
|                                                                                         | Paroxetine              |                    |                    | C               | Unknown                                        |                              |                 | Not Reported |                |
|                                                                                         | Paroxetine              |                    |                    | C               |                                                |                              |                 | Not Reported |                |
|                                                                                         | Buspirone               |                    |                    | C               | Unknown                                        |                              |                 | Not Reported |                |
|                                                                                         | Buspirone               |                    |                    | C               |                                                |                              |                 | Not Reported |                |
|                                                                                         | Sertraline              |                    |                    | C               | Unknown                                        |                              |                 | Not Reported |                |
| Sertraline                                                                              |                         |                    |                    | C               | Unknown                                        | Increased To Maximum<br>Dose |                 | Not Reported |                |



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|                               |   |         |              |
|-------------------------------|---|---------|--------------|
| Clonazepam                    | C | Unknown | Not Reported |
| Fexofenadine                  | C | Unknown | Not Reported |
| Pseudoephedrine Hydrochloride | C | Unknown | Not Reported |
| Fluticasone                   | C | Unknown | Not Reported |
| Albuterol                     | C | Unknown | Not Reported |
| Budesonide/Formoterol         | C | Unknown | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Jun-2016              | 12484410      | EXPEDITED (15-DAY) |                    | OT              | IT-TEVA-668084ACC    |                      | 31 YR      | Female     | ITA            |

| <u>Preferred Term</u>             | <u>Product</u>                   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------|----------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Sopor; Toxicity To Various Agents | Escitalopram                     |              |            | S           | Oral         | 27 Df Total        |                 | Ivax         |
|                                   | Depakin - 200 Mg Comprese        |              |            | S           | Oral         | 20 Df Total        |                 | Not Reported |
|                                   | Gastroresistenti - Sanofi S.P.A. |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 21-Jun-2016              | 12484788      | NON-EXPEDITED    |                    |                 | US-ACTAVIS-2015-15463 |                      |            | Female     | USA            |

| <u>Preferred Term</u>                | <u>Product</u>                                       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------|------------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abnormal Behaviour; Drug Ineffective | Bupropion Hydrochloride XI (Actavis Laboratories FI) |              |            | S           | Oral         | Unknown            |                 | Actavis      |
|                                      | Escitalopram                                         |              |            | S           | Unknown      | Unknown            |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Jun-2016              | 12484794      | EXPEDITED (15-DAY) |                    | DE              | US-NOVOPROD-496470   |                      |            | Male       | USA            |

| <u>Preferred Term</u>             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cerebrovascular Accident; Seizure | Levemir        |              |            | S           | Subcutaneous |                    |                 | Novo Nordisk |
|                                   | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

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### Detailed Report

| <a href="#">FDA Received Date</a>                                                                                                                       | <a href="#">Case #</a>     | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 21-Jun-2016                                                                                                                                             | 12485321                   | EXPEDITED (15-DAY)        |                             | HO                       | GB-FRI-1000084664             |                               |                          | Unknown             | GBR                     |
| <a href="#">Preferred Term</a>                                                                                                                          | <a href="#">Product</a>    | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Dyspnoea; Foetal Exposure During Pregnancy                                                                                                              | Escitalopram               |                           |                             | S                        | Transplacental                | 20 Mg Daily                   |                          | Forest              |                         |
| <a href="#">FDA Received Date</a>                                                                                                                       | <a href="#">Case #</a>     | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 21-Jun-2016                                                                                                                                             | 12486178                   | EXPEDITED (15-DAY)        |                             | HO                       | JP-FRI-1000082013             |                               | 83 YR                    | Female              | JPN                     |
| <a href="#">Preferred Term</a>                                                                                                                          | <a href="#">Product</a>    | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Hyponatraemia; Polydipsia                                                                                                                               | Lexapro                    |                           |                             | S                        | Oral                          | 10 Mg                         |                          | Forest              |                         |
|                                                                                                                                                         | Bisoprolol                 |                           |                             | C                        | Oral                          | 2.5 Mg                        |                          | Not Reported        |                         |
|                                                                                                                                                         | Inhibace                   |                           |                             | C                        | Oral                          | 0.25 Mg                       |                          | Not Reported        |                         |
|                                                                                                                                                         | Livalo                     |                           |                             | C                        | Oral                          | 2 Mg                          |                          | Not Reported        |                         |
|                                                                                                                                                         | Uritos                     |                           |                             | C                        | Oral                          | 0.2 Mg                        |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                                                       | <a href="#">Case #</a>     | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 21-Jun-2016                                                                                                                                             | 12486506                   | EXPEDITED (15-DAY)        |                             | HO, LT                   | FR-FRI-1000085478             |                               | 52 YR                    | Male                | FRA                     |
| <a href="#">Preferred Term</a>                                                                                                                          | <a href="#">Product</a>    | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Cardiac Arrest; Cardiovascular Insufficiency; Drug Interaction; Electrocardiogram Qt Interval; Product Use In Unapproved Indication; Torsade De Pointes | Escitalopram               |                           |                             | S                        | Oral                          | 10 Mg                         |                          | Forest              |                         |
|                                                                                                                                                         | Clopixol Comprimés Enrobés |                           |                             | S                        | Oral                          |                               |                          | Not Reported        |                         |
|                                                                                                                                                         | Solian                     |                           |                             | S                        | Oral                          | 66.6667 Mg                    |                          | Not Reported        |                         |
|                                                                                                                                                         | Theralene                  |                           |                             | S                        | Unknown                       | 100 Mg                        |                          | Not Reported        |                         |
|                                                                                                                                                         | Parkinane                  |                           |                             | C                        | Unknown                       |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                                                       | <a href="#">Case #</a>     | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 22-Jun-2016                                                                                                                                             | 12213939                   | EXPEDITED (15-DAY)        |                             | HO, LT, OT               | ES-WATSON-2016-               |                               | 84 YR                    | Female              | ESP                     |

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| <u>Preferred Term</u>                                    | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                             | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------|------------------------|--------------|------------|-------------|------------------------------------------|--------------------|-----------------|--------------|
| Electrocardiogram Qt<br>Prolonged; Torsade De<br>Pointes | Escitalopram (Unknown) |              |            | S           | Unknown                                  | Unk                |                 | Not Reported |
|                                                          | Levofloxacin (Unknown) |              |            | S           | Unknown                                  | Unk                |                 | Watson       |
|                                                          | Solifenacin (Unknown)  |              |            | S           | Unknown                                  | Unk                |                 | Not Reported |
|                                                          | Digoxin (Unknown)      |              |            | S           | Unknown                                  | Unk                |                 | Not Reported |
|                                                          | Amiodarone /00133102/  |              |            | S           | Intravenous (not<br>otherwise specified) | Unk                |                 | Not Reported |
|                                                          | Candesartan            |              |            | C           | Unknown                                  | Unk                |                 | Not Reported |
|                                                          | Furosemide             |              |            | C           | Unknown                                  | Unk                |                 | Not Reported |
|                                                          | Acenocoumarol          |              |            | C           | Unknown                                  | Unk                |                 | Not Reported |
|                                                          | Simvastatin            |              |            | C           | Unknown                                  | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Jun-2016              | 12214362      | EXPEDITED (15-DAY) |                    | HO, LT, OT      | ES-TEVA-647341ISR    |                      | 84 YR      | Female     | ESP            |

| <u>Preferred Term</u>                                                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                             | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|------------------------------------------|--------------------|-----------------|--------------|
| Electrocardiogram Qt<br>Prolonged; Hypokalaemia;<br>Hypomagnesaemia;<br>Torsade De Pointes | Levofloxacin   |              |            | S           |                                          |                    |                 | Teva         |
|                                                                                            | Escitalopram   |              |            | S           |                                          |                    |                 | Ivax         |
|                                                                                            | Sulpiride      |              |            | S           |                                          |                    |                 | Not Reported |
|                                                                                            | Solifenacin    |              |            | S           |                                          |                    |                 | Not Reported |
|                                                                                            | Amiodarone     |              |            | S           | Intravenous (not<br>otherwise specified) |                    |                 | Not Reported |
|                                                                                            | Digoxin        |              |            | S           |                                          |                    |                 | Not Reported |
|                                                                                            | Candesartan    |              |            | C           |                                          |                    |                 | Not Reported |
|                                                                                            | Furosemide     |              |            | C           |                                          |                    |                 | Not Reported |
|                                                                                            | Acenocoumarol  |              |            | C           |                                          |                    |                 | Not Reported |
|                                                                                            | Simvastatin    |              |            | C           |                                          |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

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| <u>FDA Received Date</u>                      | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------|----------------------------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|-----------------|--------------|----------------|
| 22-Jun-2016                                   | 12487949                         | EXPEDITED (15-DAY) |                    | OT              | IT-AUROBINDO-AUR-APL-2016-07792 |                      | 31 YR           | Female       | ITA            |
| <u>Preferred Term</u>                         | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Abuse; Sopor; Toxicity To Various Agents | Escitalopram Film-Coated Tablets |                    |                    | S               | Oral                            | 27 Df, Unk           |                 | Aurobindo    |                |
|                                               | Depakin                          |                    |                    | S               | Oral                            | 20 Df, Total         |                 | Not Reported |                |

| <u>FDA Received Date</u>  | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------|-----------------------|--------------------|--------------------|-----------------|---------------------------------------------|----------------------|-----------------|--------------|----------------|
| 22-Jun-2016               | 12488914              | EXPEDITED (15-DAY) |                    | HO              | US-NOVEN PHARMACEUTICALS, INC.-US2016001543 |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>     | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Gait Disturbance | 485 (Methylphenidate) |                    |                    | S               | Unknown                                     | Unknown              |                 | Noven        |                |
|                           | Sertraline            |                    |                    | S               | Unknown                                     | Unk, Unknown         |                 | Not Reported |                |
|                           | Escitalopram          |                    |                    | S               | Unknown                                     | Unk, Unknown         |                 | Not Reported |                |
|                           | Venlafaxine           |                    |                    | S               | Unknown                                     | Unk, Unknown         |                 | Not Reported |                |
|                           | Mirtazapine           |                    |                    | S               | Unknown                                     | Unk, Unknown         |                 | Not Reported |                |
|                           | Bupropion             |                    |                    | S               | Unknown                                     | Unk, Unknown         |                 | Not Reported |                |
|                           | Trazodone Hcl         |                    |                    | S               | Unknown                                     | Unk, Unknown         |                 | Not Reported |                |
|                           | Lamotrigine           |                    |                    | S               | Unknown                                     | Unk, Unknown         |                 | Not Reported |                |
|                           | Lorazepam             |                    |                    | S               | Unknown                                     | Unk, Unknown         |                 | Not Reported |                |
|                           | Clonazepam            |                    |                    | S               | Unknown                                     | Unk, Unknown         |                 | Not Reported |                |
|                           | Donepezil             |                    |                    | S               | Unknown                                     | Unk, Unknown         |                 | Not Reported |                |
|                           | Memantine             |                    |                    | S               | Unknown                                     | Unk, Unknown         |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 22-Jun-2016              | 12490002       | EXPEDITED (15-DAY) |                    | CA              | DE-TEVA-668672GER    |                      | 1 DAY           | Male       | DEU            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                 |              |   |                |                                           |              |
|---------------------------------------------------------------------------------|--------------|---|----------------|-------------------------------------------|--------------|
| Cleft Lip And Palate;<br>Foetal Exposure During<br>Pregnancy; Premature<br>Baby | Escitalopram | S | Transplacental | 10 Milligram Daily; From 0-6 And 23-30+6. | Ivax         |
|                                                                                 | L-Thyrox     | C | Transplacental | 50 Microgram Daily;                       | Not Reported |
|                                                                                 | Folsäure     | C | Transplacental |                                           | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Jun-2016              | 12490206      | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000085534    |                      | 65 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Agitation; Anxiety;<br>Homicide; Impulsive<br>Behaviour; Irritability | Escitalopram   |              |            | S           | Oral         | 20 Mg              |                 | Forest       |
|                                                                       | Escitalopram   |              |            | S           |              |                    |                 | Forest       |
|                                                                       | Amlor          |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                       | Atacand        |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                       | Bisoprolol     |              |            | C           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Jun-2016              | 12490207      | EXPEDITED (15-DAY) |                    | LT              | FR-FRI-1000085532    |                      | 80 YR      | Female     | FRA            |

| <u>Preferred Term</u>                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------|----------------|--------------|------------|-------------|--------------|------------------------|-----------------|--------------|
| Cerebral Haemorrhage;<br>Drug Interaction | Escitalopram   |              |            | S           | Oral         | 10 Mg                  |                 | Forest       |
|                                           | Lovenox        |              |            | S           | Subcutaneous | 4000 Ui Anti-Xa/0,4 MI |                 | Not Reported |
|                                           | Lamictal       |              |            | C           |              | 300 Mg                 |                 | Not Reported |
|                                           | Lamictal       |              |            | C           |              |                        |                 | Not Reported |
|                                           | Omeprazole     |              |            | C           |              | 20 Mg                  |                 | Not Reported |
|                                           | Xatral Lp      |              |            | C           |              | 10 Mg                  |                 | Not Reported |
|                                           | Sectral        |              |            | C           |              | 200 Mg                 |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------|----------------------|------------|------------|----------------|
| 22-Jun-2016              | 12490557      | NON-EXPEDITED    |                    |                 | US-JAZZ-2015-US-020674 |                      | 55 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                           |                     |   |      |                  |              |
|---------------------------|---------------------|---|------|------------------|--------------|
| Anxiety; Feeling          | Xyrem               | S | Oral | 2.25 G, Bid      | Jazz         |
| Abnormal; Heart Rate      | Xyrem               | S | Oral | Dose Adjustments | Jazz         |
| Increased;                | Xyrem               | S | Oral | 3 G, Bid         | Jazz         |
| Hypersensitivity;         | Chantix             | S |      | Unk              | Not Reported |
| Peripheral Swelling;      | Chantix             | S |      | Unk              | Not Reported |
| Serum Serotonin           | Lexapro             | S |      |                  | Not Reported |
| Increased; Somnolence;    | Atenolol            | S |      |                  | Not Reported |
| Unevaluable Event;        | Zolpidem Tartrate   | C |      | Unk              | Not Reported |
| Vertigo; Vomiting; Weight | Calcium + Vitamin D | C |      | Unk              | Not Reported |
| Decreased                 | Clonazepam          | C |      | Unk              | Not Reported |
|                           | Proair Hfa          | C |      | Unk              | Not Reported |
|                           | Veramyst            | C |      | Unk              | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Jun-2016              | 12492057      | DIRECT           |                    | HO              |                      |                      | 74 YR      | Female     | USA            |

| <u>Preferred Term</u>      | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Influenza; Middle          | Escitalopram 10mg Tablet |              |            | S           | Oral         |                    |                 | Accord       |
| Insomnia; Musculoskeletal  | Accord                   |              |            |             |              |                    |                 |              |
| Pain; Neck Pain; Pain In   | Combivent                |              |            | C           |              |                    |                 | Not Reported |
| Extremity; Pain In Jaw;    | Qvar                     |              |            | C           |              |                    |                 | Not Reported |
| Toothache; Vasodilatation; | Hydrocide                |              |            | C           |              |                    |                 | Not Reported |
| Weight Decreased           | Previd                   |              |            | C           |              |                    |                 | Not Reported |
|                            | Milk Thistle             |              |            | C           |              |                    |                 | Not Reported |
|                            | Vit D3                   |              |            | C           |              |                    |                 | Not Reported |
|                            | Vit A&D Ointment         |              |            | C           |              |                    |                 | Not Reported |
|                            | Magnesium                |              |            | C           |              |                    |                 | Not Reported |
|                            | C                        |              |            | C           |              |                    |                 | Not Reported |
|                            | B6                       |              |            | C           |              |                    |                 | Not Reported |
|                            | Blink Gel Eye Drops      |              |            | C           |              |                    |                 | Not Reported |
|                            | Gas X                    |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Jun-2016              | 11552918      | EXPEDITED (15-DAY) |                    | HO, OT          | PHHY2015CA113466     |                      | 182 DAY    | Female     | CAN            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                                    | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                      | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |                |
|------------------------------------------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|---------------------------------------------------|----------------------------------------|-----------------|--------------|----------------|
| Exposure Via Breast Milk; Seizure                                                        | Bupropion                     |                    |                    | S               | Transmammary                                      |                                        |                 | Novartis     |                |
|                                                                                          | Escitalopram                  |                    |                    | S               | Transmammary                                      |                                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                 | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                              | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Jun-2016                                                                              | 11669861                      | EXPEDITED (15-DAY) |                    | DE              | CA-FRI-1000080408                                 |                                        | 41 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                                                    | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                      | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Arrhythmia; Death                                                                        | Escitalopram                  |                    |                    | S               | Oral                                              | 20 Mg                                  |                 | Forest       |                |
|                                                                                          | Quetiapine                    |                    |                    | S               | Unknown                                           |                                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                 | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                              | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Jun-2016                                                                              | 11669862                      | EXPEDITED (15-DAY) |                    | OT              | CA-FRI-1000080406                                 |                                        | 9 YR            | Male         | CAN            |
| <u>Preferred Term</u>                                                                    | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                      | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Anaemia; Gastrointestinal Haemorrhage; Haematemesis; Nausea; Product Use Issue; Vomiting | Escitalopram                  |                    |                    | S               | Unknown                                           | Daily Dose Not Reported.               |                 | Forest       |                |
|                                                                                          | Methylphenidate Hydrochloride |                    |                    | S               | Unknown                                           | Daily Dose Not Reported.               |                 | Not Reported |                |
|                                                                                          | Risperidone                   |                    |                    | S               | Unknown                                           | Daily Dose Not Reported.               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                 | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                              | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Jun-2016                                                                              | 12491100                      | EXPEDITED (15-DAY) |                    | CA, HO, OT      | DE-MACLEODS PHARMACEUTICALS US LTD- MAC2016002832 |                                        |                 | Unknown      | DEU            |
| <u>Preferred Term</u>                                                                    | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                      | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Cleft Lip And Palate; Foetal Exposure During Pregnancy; Premature Baby                   | Escitalopram                  |                    |                    | S               | Transplacental                                    | 10 Mg, Qd (From 0-6 And 23-30+6 Weeek) |                 | Macleods     |                |
|                                                                                          | L-Thyroxine Sodium            |                    |                    | C               | Transplacental                                    | 50 Mg, Qd (30.6-30.6 Gestational Week) |                 | Not Reported |                |
|                                                                                          | Folsäure                      |                    |                    | C               | Transplacental                                    | Unk (0. - 30.6. Gestational Week)      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                 | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|--------------------|--------------------|-----------------|------------------------------------------|----------------------|-----------------|--------------|----------------|
| 23-Jun-2016                                                                                                                                                                                                                                                                              | 12491915              | EXPEDITED (15-DAY) |                    | HO, LT, OT      | ES-CIPLA LTD.-<br>2016ES07759            |                      |                 | Unknown      | ESP            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                    | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Electrocardiogram Qt Prolonged;<br>Haemodynamic Instability;<br>Hypokalaemia;<br>Hypomagnesaemia;<br>Torsade De Pointes                                                                                                                                                                  | Levofloxacin          |                    |                    | S               | Unknown                                  | Unk                  |                 | Cipla        |                |
|                                                                                                                                                                                                                                                                                          | Escitalopram          |                    |                    | S               |                                          |                      |                 | Invagen      |                |
|                                                                                                                                                                                                                                                                                          | Sulpiride             |                    |                    | S               | Intravenous (not<br>otherwise specified) |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                          | Amiodarone            |                    |                    | S               |                                          |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                          | Digoxin               |                    |                    | S               |                                          |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                          | Solifenacin           |                    |                    | S               |                                          |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                          | Acenocoumarol         |                    |                    | C               |                                          |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                          | Simvastatin           |                    |                    | C               |                                          |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                          | Furosemide            |                    |                    | C               |                                          |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                          | Candesartan           |                    |                    | C               |                                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                 | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Jun-2016                                                                                                                                                                                                                                                                              | 12493339              | EXPEDITED (15-DAY) |                    | HO, LT, OT      | ES-PFIZER INC-<br>2016307403             |                      | 84 YR           | Female       | ESP            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                    | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrial Fibrillation; Bundle<br>Branch Block Left;<br>Contraindicated Product<br>Administered;<br>Electrocardiogram Qrs<br>Complex Prolonged;<br>Electrocardiogram Qt<br>Prolonged; Hypokalaemia;<br>Hypomagnesaemia;<br>Tachycardia; Torsade De<br>Pointes; Ventricular<br>Extrasystoles | Amiodarone Hcl        |                    |                    | S               | Unknown                                  | Unk                  |                 | Pfizer       |                |
|                                                                                                                                                                                                                                                                                          | Levofloxacin          |                    |                    | S               |                                          |                      |                 | Pfizer       |                |
|                                                                                                                                                                                                                                                                                          | Amiodarone Hcl        |                    |                    | S               | Intravenous (not<br>otherwise specified) |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                          | Escitalopram Oxalate  |                    |                    | S               |                                          |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                          | Digoxin               |                    |                    | S               | Unknown                                  | Unk                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                          | Sulpiride             |                    |                    | S               | Unknown                                  | Unk                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                          | Solifenacin Succinate |                    |                    | S               | Unknown                                  | Unk                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                          | Candesartan           |                    |                    | C               |                                          | Unk                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                          | Furosemide            |                    |                    | C               |                                          | Unk                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                          | Acenocoumarol         |                    |                    | C               |                                          | Unk                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                          | Simvastatin           |                    |                    | C               |                                          | Unk                  |                 | Not Reported |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                   |                    |                    |                    |                 |                                                    |                                                          |                 |              |                |
|---------------------------------------------------------------------------------------------------|--------------------|--------------------|--------------------|-----------------|----------------------------------------------------|----------------------------------------------------------|-----------------|--------------|----------------|
| Magnesium Sulfate                                                                                 |                    |                    | C                  |                 | Unk                                                |                                                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                          | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                               | <u>503B Facility</u>                                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Jun-2016                                                                                       | 12493558           | EXPEDITED (15-DAY) |                    | CA              | DE-MYLANLABS-2016M1025223                          |                                                          |                 | Unknown      | DEU            |
| <u>Preferred Term</u>                                                                             | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                       | <u>Dosage Text</u>                                       | <u>Duration</u> | <u>Mfr</u>   |                |
| Cleft Lip And Palate;<br>Foetal Exposure During<br>Pregnancy; Premature<br>Baby                   | Escitalopram Mylan |                    |                    | S               | Transplacental                                     | 10 Mg, Qd (10 [Mg/D ]/<br>From 0-6 And 23-30+6.)         |                 | Mylan        |                |
|                                                                                                   | L-Thyrox           |                    |                    | C               | Transplacental                                     | 50 Mg, Qd (50 [Mg/D ]/<br>Since When And Until<br>When?) |                 | Mylan        |                |
|                                                                                                   | Folsaeure          |                    |                    | C               | Transplacental                                     |                                                          |                 | Mylan        |                |
| <u>FDA Received Date</u>                                                                          | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                               | <u>503B Facility</u>                                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Jun-2016                                                                                       | 12494003           | EXPEDITED (15-DAY) |                    | HO              | FR-JNJFOC-20160616374                              |                                                          | 71 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                             | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                       | <u>Dosage Text</u>                                       | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrial Fibrillation; Coma;<br>Lung Infection;<br>Respiratory Depression;<br>Sensorimotor Disorder | Topalgic (France)  |                    |                    | S               | Oral                                               |                                                          |                 | Not Reported |                |
|                                                                                                   | Seroplex           |                    |                    | S               | Oral                                               |                                                          |                 | Not Reported |                |
|                                                                                                   | Lexomil            |                    |                    | S               | Oral                                               |                                                          |                 | Not Reported |                |
|                                                                                                   | Xarelto            |                    |                    | C               | Unknown                                            |                                                          |                 | Not Reported |                |
|                                                                                                   | Bisoprolol         |                    |                    | C               | Unknown                                            |                                                          |                 | Not Reported |                |
|                                                                                                   | Esidrex            |                    |                    | C               | Unknown                                            |                                                          |                 | Not Reported |                |
|                                                                                                   | Losartan           |                    |                    | C               | Unknown                                            |                                                          |                 | Not Reported |                |
|                                                                                                   | Movicol            |                    |                    | C               | Unknown                                            |                                                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                          | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                               | <u>503B Facility</u>                                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Jun-2016                                                                                       | 12494086           | NON-EXPEDITED      |                    |                 | US-PRINSTON<br>PHARMACEUTICAL<br>INC.-2016PRN00078 |                                                          |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                             | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                       | <u>Dosage Text</u>                                       | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                  |              |   |     |                         |
|------------------|--------------|---|-----|-------------------------|
| Hypersensitivity | Escitalopram | S | Unk | Prinston Pharmaceutical |
|------------------|--------------|---|-----|-------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------------------------------------|----------------------|------------|------------|----------------|
| 24-Jun-2016              | 12220589      | EXPEDITED (15-DAY) |                    | HO, LT, OT      | ES-SUN<br>PHARMACEUTICAL<br>INDUSTRIES LTD-<br>2016RR-113916 |                      | 84 YR      | Female     | ESP            |

| <u>Preferred Term</u>                                                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                             | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|------------------------------------------|--------------------|-----------------|--------------|
| Electrocardiogram Qt<br>Prolonged; Hypokalaemia;<br>Hypomagnesaemia;<br>Torsade De Pointes | Sulpiride      |              |            | S           | Unknown                                  |                    |                 | Not Reported |
|                                                                                            | Escitalopram   |              |            | S           | Unknown                                  |                    |                 | Not Reported |
|                                                                                            | Levofloxacin   |              |            | S           | Unknown                                  |                    |                 | Ranbaxy      |
|                                                                                            | Solifenacin    |              |            | S           | Unknown                                  |                    |                 | Not Reported |
|                                                                                            | Amiodarone     |              |            | S           | Intravenous (not<br>otherwise specified) |                    |                 | Not Reported |
|                                                                                            | Digoxin        |              |            | S           | Unknown                                  |                    |                 | Sun          |
|                                                                                            | Candesartan    |              |            | C           | Unknown                                  |                    |                 | Not Reported |
|                                                                                            | Furosemide     |              |            | C           | Unknown                                  |                    |                 | Not Reported |
|                                                                                            | Acenocoumarol  |              |            | C           | Unknown                                  |                    |                 | Not Reported |
|                                                                                            | Simvastatin    |              |            | C           | Unknown                                  |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|------------|------------|----------------|
| 24-Jun-2016              | 12495464      | EXPEDITED (15-DAY) |                    | OT              | US-009507513-<br>1606USA008092 |                      |            | Male       | USA            |

| <u>Preferred Term</u>    | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|-------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Conjunctival Haemorrhage | Cozaar                        |              |            | S           | Oral         | 100 Mg, Qd         |                 | Merck        |
|                          | Hydrochlorothiazide           |              |            | S           | Oral         | 25 Mg, Qd          |                 | Not Reported |
|                          | Eliquis                       |              |            | S           |              | 5 Mg, Bid          |                 | Not Reported |
|                          | Lipitor                       |              |            | S           |              | 20 Mg, Qd          |                 | Not Reported |
|                          | Lexapro                       |              |            | S           |              | 10 Mg, Qd          |                 | Not Reported |
|                          | Acetylcarnitine Hydrochloride |              |            | C           |              | Unk                |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                  | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------|-------------------------------------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|-----------------|--------------|----------------|
| 24-Jun-2016                                                                               | 12495689                                  | EXPEDITED (15-DAY) |                    | OT              | DE-CIPLA LTD.-<br>2016DE08041 |                      |                 | Unknown      | DEU            |
| <u>Preferred Term</u>                                                                     | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Overdose;<br>Somnolence; Tachycardia                                          | Escitalopram                              |                    |                    | S               | Oral                          | Unk                  |                 | Invagen      |                |
|                                                                                           | Quetiapine                                |                    |                    | S               | Oral                          | Unk                  |                 | Cipla        |                |
| <u>FDA Received Date</u>                                                                  | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Jun-2016                                                                               | 12497302                                  | EXPEDITED (15-DAY) |                    | DE              | JP-PFIZER INC-<br>2016312225  |                      | 30 YR           | Female       | JPN            |
| <u>Preferred Term</u>                                                                     | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alcohol Use; Circulatory<br>Collapse; Completed<br>Suicide; Overdose;<br>Pulmonary Oedema | Alprazolam                                |                    |                    | S               | Oral                          | Unk                  |                 | Pfizer       |                |
|                                                                                           | Levomepromazine                           |                    |                    | S               |                               | Unk                  |                 | Not Reported |                |
|                                                                                           | Mirtazapine                               |                    |                    | S               |                               | Unk                  |                 | Not Reported |                |
|                                                                                           | Duloxetine Hydrochloride<br>W/Mecobalamin |                    |                    | S               |                               | Unk                  |                 | Not Reported |                |
|                                                                                           | Escitalopram Oxalate<br>W/Etizolam        |                    |                    | S               |                               | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                  | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Jun-2016                                                                               | 12499536                                  | DIRECT             | Y                  | OT              |                               |                      | 25 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                     | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective; Product<br>Substitution Issue                                           | Escitalopram 20 Mg                        |                    |                    | S               | Oral                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                  | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Jun-2016                                                                               | 12484260                                  | EXPEDITED (15-DAY) |                    | DS              | GXKR2016DE002799              |                      | 88 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                                                     | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Cognitive<br>Disorder; Decreased                                                | Ramipril                                  |                    |                    | S               | Oral                          | 5 Mg, Bid            |                 | Novartis     |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                          |                       |   |      |                     |              |
|----------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|---|------|---------------------|--------------|
| Appetite; General Physical Health Deterioration; Hypotension; Impaired Self-Care; Mobility Decreased; Somnolence; Urinary Incontinence; Weight Decreased | Candesartan Cilexetil | S | Oral | 16 Mg, Qd           | Not Reported |
|                                                                                                                                                          | Isosorbide Dinitrate  | S | Oral | 20 Mg, Bid          | Not Reported |
|                                                                                                                                                          | Metoprolol            | S | Oral | 47.5 Mg, Bid        | Not Reported |
|                                                                                                                                                          | Furosemide            | S | Oral | 40 Mg, Bid          | Not Reported |
|                                                                                                                                                          | Hydrochlorothiazide   | S | Oral | 25 Mg, Qd           | Not Reported |
|                                                                                                                                                          | Moxonidine            | S | Oral | 0.4 Mg, Qd          | Not Reported |
|                                                                                                                                                          | Metformin             | S | Oral | 850 Mg, Bid         | Not Reported |
|                                                                                                                                                          | Glimepiride           | S | Oral | 1 Mg, Qd            | Not Reported |
|                                                                                                                                                          | Allopurinol           | S | Oral | 300 Mg, Qd          | Not Reported |
|                                                                                                                                                          | Escitalopram          | S | Oral | 20 Mg, Qd           | Not Reported |
|                                                                                                                                                          | Pantoprazol           | S | Oral | 40 Mg, Qd           | Not Reported |
|                                                                                                                                                          | Tilidine+Naloxone     | S | Oral | 1 Df, Tid           | Not Reported |
|                                                                                                                                                          | Trospium              | S | Oral | 15 Mg, Qd           | Not Reported |
|                                                                                                                                                          | Digitoxin             | S |      | 0.07 Mg, Once Daily | Not Reported |
|                                                                                                                                                          | Insulin               | S |      | 26-0-16             | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Jun-2016              | 12503494      | DIRECT           |                    |                 |                      |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Ineffective; Feeling Abnormal; Feeling Jittery; Nervousness | Lexapro        |              |            | S           |              |                    |                 | Not Reported |
|                                                                  | Prozac         |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Jun-2016              | 11665135      | EXPEDITED (15-DAY) |                    | OT              | CA-FRI-1000080431    |                      | 17 YR      | Female     | CAN            |

| <u>Preferred Term</u>                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Joint Noise; Pain In Jaw; Product Use Issue | Celexa         |              |            | S           | Oral         |                    |                 | Forest       |
|                                             | Escitalopram   |              |            | S           | Oral         |                    |                 | Forest       |
|                                             | Abilify        |              |            | S           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>   | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
|----------------------------|-----------------------|--------------------|--------------------|-----------------|-----------------------------------------------------------|----------------------|-----------------|------------------|----------------|
| 28-Jun-2016                | 12504120              | EXPEDITED (15-DAY) |                    | DE, OT          | JP-<br>ELI_LILLY_AND_COMP<br>ANY-JP201606009024           |                      | 25 YR           | Female           | JPN            |
| <u>Preferred Term</u>      | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |
| Alcohol Interaction;       | Cymbalta              |                    |                    | S               | Oral                                                      |                      |                 | Eli Lilly And Co |                |
| Circulatory Collapse;      | Alprazolam            |                    |                    | S               | Oral                                                      |                      |                 | Not Reported     |                |
| Completed Suicide;         | Levomepromazine       |                    |                    | S               | Oral                                                      |                      |                 | Not Reported     |                |
| Depressed Level Of         | Escitalopram          |                    |                    | S               | Oral                                                      |                      |                 | Not Reported     |                |
| Consciousness;             | Mirtazapine           |                    |                    | S               | Oral                                                      |                      |                 | Not Reported     |                |
| Pulmonary Oedema           |                       |                    |                    |                 |                                                           |                      |                 |                  |                |
| <u>FDA Received Date</u>   | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 28-Jun-2016                | 12504346              | EXPEDITED (15-DAY) |                    | DS              | DE-VALIDUS<br>PHARMACEUTICALS<br>LLC-DE-<br>2016VAL002174 |                      | 88 YR           | Female           | DEU            |
| <u>Preferred Term</u>      | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |
| Asthenia; Cognitive        | Metoprolol Tartrate   |                    |                    | S               | Oral                                                      | 47.5 Mg, Bid         |                 | Validus          |                |
| Disorder; Decreased        | Furosemide            |                    |                    | S               | Oral                                                      | 40 Mg, Bid           |                 | Validus          |                |
| Appetite; General Physical | Ramipril              |                    |                    | S               | Oral                                                      | 5 Mg, Bid            |                 | Not Reported     |                |
| Health Deterioration;      | Candesartan Cilexetil |                    |                    | S               | Oral                                                      | 16 Mg, Qd            |                 | Not Reported     |                |
| Hypotension; Impaired      | Isosorbide Dinitrate  |                    |                    | S               |                                                           | 20 Mg, Bid           |                 | Not Reported     |                |
| Self-Care; Mobility        | Hydrochlorothiazide   |                    |                    | S               | Oral                                                      | 25 Mg, Qd            |                 | Not Reported     |                |
| Decreased; Somnolence;     | Moxonidine            |                    |                    | S               | Oral                                                      | 0.4 Mg, Qd           |                 | Not Reported     |                |
| Urinary Incontinence;      | Metformin             |                    |                    | S               | Oral                                                      | 850 Mg, Bid          |                 | Not Reported     |                |
| Weight Decreased           | Glimepiride           |                    |                    | S               | Oral                                                      | 1 Mg, Qd             |                 | Not Reported     |                |
|                            | Allopurinol           |                    |                    | S               | Oral                                                      | 300 Mg, Qd           |                 | Not Reported     |                |
|                            | Escitalopram          |                    |                    | S               | Oral                                                      | 20 Mg, Qd            |                 | Not Reported     |                |
|                            | Pantoprazole          |                    |                    | S               | Oral                                                      | 40 Mg, Qd            |                 | Not Reported     |                |
|                            | Naloxone W/Tilidine   |                    |                    | S               | Oral                                                      | 1 Df, Tid (4/50mg)   |                 | Not Reported     |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|           |   |      |                   |              |
|-----------|---|------|-------------------|--------------|
| Trospium  | S | Oral | 15 Mg, Qd         | Not Reported |
| Digitoxin | S |      | 0.07 Mg, Qd       | Not Reported |
| Insulin   | S |      | 30/70 Iu, 26-0-16 | Not Reported |

| <u>FDA Received Date</u>                                                        | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 28-Jun-2016                                                                     | 12504436       | EXPEDITED (15-DAY) | CA                 |                 | DE-FRI-1000085671    |                      | < 1 DAY         | Male         | DEU            |
| <u>Preferred Term</u>                                                           | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cleft Lip And Palate;<br>Foetal Exposure During<br>Pregnancy; Premature<br>Baby | Escitalopram   |                    |                    | S               | Transplacental       | 10 Mg                |                 | Forest       |                |
|                                                                                 | L-Thyrox       |                    |                    | C               | Transplacental       | 50 Mcg               |                 | Not Reported |                |
|                                                                                 | Folsaeure      |                    |                    | C               | Transplacental       |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|--------------------------------------------|----------------------|-----------------|-----------------|----------------|
| 28-Jun-2016                                                                                                              | 12505181       | EXPEDITED (15-DAY) | HO, OT             |                 | FR-<br>GLAXOSMITHKLINE-<br>FR2016GSK090584 |                      | 87 YR           | Female          | FRA            |
| <u>Preferred Term</u>                                                                                                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Intentional Product Use<br>Issue; Pyrexia; Rash<br>Erythematous; Rash<br>Pruritic; Rash Pustular;<br>Toxic Skin Eruption | Lamisil        |                    |                    | S               | Topical                                    | Unk                  |                 | Glaxosmithkline |                |
|                                                                                                                          | Lamisil        |                    |                    | S               | Oral                                       | Unk                  |                 | Glaxosmithkline |                |
|                                                                                                                          | Seroplex       |                    |                    | S               | Oral                                       | Unk                  |                 | Not Reported    |                |
|                                                                                                                          | Tiapridal      |                    |                    | S               | Oral                                       | Unk                  |                 | Not Reported    |                |
|                                                                                                                          | Econazole      |                    |                    | C               |                                            | Unk                  |                 | Not Reported    |                |

| <u>FDA Received Date</u>                                                               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 28-Jun-2016                                                                            | 12505544       | EXPEDITED (15-DAY) | HO                 |                 | PHHY2016FR086751     |                      | 86 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Pyrexia; Rash<br>Erythematous; Rash<br>Pruritic; Rash Pustular;<br>Toxic Skin Eruption | Lamisil        |                    |                    | S               | Oral                 | Unk                  |                 | Novartis     |                |
|                                                                                        | Lamisil        |                    |                    | S               | Topical              | 1 %, Unk             |                 | Not Reported |                |
|                                                                                        | Seroplex       |                    |                    | S               | Unknown              | 0.5 MI, Qd           |                 | Not Reported |                |

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|                                                                                |                   |                    |                    |                 |                      |                                       |                 |              |                |
|--------------------------------------------------------------------------------|-------------------|--------------------|--------------------|-----------------|----------------------|---------------------------------------|-----------------|--------------|----------------|
| Tiapridal                                                                      |                   |                    | S                  | Unknown         | 10 Drops Daily       | Not Reported                          |                 |              |                |
| <u>FDA Received Date</u>                                                       | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Jun-2016                                                                    | 12506126          | EXPEDITED (15-DAY) | HO                 |                 | FR-FRI-1000085622    |                                       | 71 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                          | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Coma; Sensorimotor Disorder                                                    | Escitalopram      |                    |                    | S               | Unknown              | 15 Mg                                 |                 | Forest       |                |
|                                                                                | Lexomil Roche     |                    |                    | S               | Oral                 |                                       |                 | Not Reported |                |
|                                                                                | Topalgic (France) |                    |                    | S               | Oral                 |                                       |                 | Not Reported |                |
|                                                                                | Xarelto           |                    |                    | C               | Unknown              | 20 Mg                                 |                 | Not Reported |                |
|                                                                                | Bisoprolol        |                    |                    | C               | Unknown              | 10 Mg                                 |                 | Not Reported |                |
|                                                                                | Esidrex           |                    |                    | C               | Unknown              | 12.5 Mg                               |                 | Not Reported |                |
|                                                                                | Losartan          |                    |                    | C               | Unknown              | 25 Mg                                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                       | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Jun-2016                                                                    | 12480321          | EXPEDITED (15-DAY) | HO                 |                 | FR-FRI-1000085405    |                                       | 58 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                          | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Bradypnoea; Hypercapnia; Prescribed Overdose; Respiratory Acidosis; Somnolence | Escitalopram      |                    |                    | S               | Oral                 | Overdose: Escitalopram<br>30 Mg Daily |                 | Forest       |                |
|                                                                                | Skenan            |                    |                    | S               | Oral                 |                                       |                 | Not Reported |                |
|                                                                                | Actiskenan        |                    |                    | S               | Oral                 |                                       |                 | Not Reported |                |
|                                                                                | Domperidone Arrow |                    |                    | S               | Oral                 | 6.6667 Mg                             |                 | Not Reported |                |
|                                                                                | Stilnox           |                    |                    | S               | Oral                 | 10 Mg                                 |                 | Not Reported |                |
|                                                                                | Lysanxia          |                    |                    | S               | Oral                 | 3.3333 Mg                             |                 | Not Reported |                |
|                                                                                | Novorapid         |                    |                    | C               |                      |                                       |                 | Not Reported |                |
|                                                                                | Lantus            |                    |                    | C               |                      |                                       |                 | Not Reported |                |
|                                                                                | Lovenox           |                    |                    | C               |                      |                                       |                 | Not Reported |                |
|                                                                                | Macrogols         |                    |                    | C               |                      |                                       |                 | Not Reported |                |
|                                                                                | Eupantol          |                    |                    | C               |                      |                                       |                 | Not Reported |                |
|                                                                                | Adrovan           |                    |                    | C               |                      |                                       |                 | Not Reported |                |
|                                                                                | Amoxicillin       |                    |                    | C               |                      |                                       |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| Vitamin D3                                                                             |                    |                    | C                  |                 |                                    | Not Reported                |                 |                 |                |
|----------------------------------------------------------------------------------------|--------------------|--------------------|--------------------|-----------------|------------------------------------|-----------------------------|-----------------|-----------------|----------------|
| <u>FDA Received Date</u>                                                               | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 29-Jun-2016                                                                            | 12507679           | EXPEDITED (15-DAY) |                    | CA, OT          | DE-AUROBINDO-AUR-APL-2016-08107    |                             | 1 DAY           | Male            | DEU            |
| <u>Preferred Term</u>                                                                  | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                       | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>      |                |
| Cleft Lip And Palate;<br>Foetal Exposure During<br>Pregnancy; Premature<br>Baby        | Escitalopram 10 Mg |                    |                    | S               | Transplacental                     | 10 Mg, Daily                |                 | Aurobindo       |                |
|                                                                                        | L-Thyrox           |                    |                    | C               | Transplacental                     | 50 Mcg, Daily               |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                               | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 29-Jun-2016                                                                            | 12508924           | EXPEDITED (15-DAY) |                    | OT              | IT-MYLANLABS-2016M1026869          |                             |                 | Unknown         | ITA            |
| <u>Preferred Term</u>                                                                  | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                       | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>      |                |
| Pemphigoid                                                                             | Escitalopram       |                    |                    | S               | Unknown                            | 10 Mg/Day                   |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                               | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 30-Jun-2016                                                                            | 12518628           | EXPEDITED (15-DAY) |                    | HO, OT          | FR-GLAXOSMITHKLINE-FR2016GSK092261 |                             | 87 YR           | Female          | FRA            |
| <u>Preferred Term</u>                                                                  | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                       | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>      |                |
| Pyrexia; Rash<br>Erythematous; Rash<br>Pruritic; Rash Pustular;<br>Toxic Skin Eruption | Lamisil            |                    |                    | S               | Oral                               | Unk                         |                 | Glaxosmithkline |                |
|                                                                                        | Lamisil            |                    |                    | S               | Topical                            | 1 %, Unk                    |                 | Glaxosmithkline |                |
|                                                                                        | Seroplex           |                    |                    | S               |                                    | 0.5 MI, Qd                  |                 | Glaxosmithkline |                |
|                                                                                        | Tiapridal          |                    |                    | S               |                                    | 10 Df, Unk (10 Drops Daily) |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                               | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 30-Jun-2016                                                                            | 12521218           | DIRECT             |                    | OT              |                                    |                             | 53 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                                  | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                       | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>      |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                           |                          |   |      |              |
|---------------------------|--------------------------|---|------|--------------|
| Balance Disorder; Vertigo | Escitalopram Tablet 20mg | S | Oral | Not Reported |
|---------------------------|--------------------------|---|------|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Jul-2016              | 12521778      | EXPEDITED (15-DAY) |                    | DS              | DE-SA-2016SA120271   |                      | 88 YR      | Female     | DEU            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                         | <u>Product</u>                            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                      | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|--------------|------------|-------------|-----------------------------------|--------------------|-----------------|--------------|
| Asthenia; Blood Sodium Decreased; Cognitive Disorder; Decreased Appetite; Dysstasia; Gait Inability; General Physical Health Deterioration; Haemoglobin Decreased; Hypotension; Impaired Self-Care; Multiple Drug Therapy; Somnolence; Urinary Incontinence; Weight Decreased | Furosemide                                |              |            | S           | Oral                              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                               | Metoprolol Tartrate                       |              |            | S           | Oral                              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                               | Ramipril                                  |              |            | S           | Oral                              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                               | Candesartan Cilexetil                     |              |            | S           | Oral                              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                               | Isosorbide Dinitrate                      |              |            | S           | Unknown                           |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                               | Hydrochlorothiazide                       |              |            | S           | Oral                              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                               | Metformin                                 |              |            | S           | Oral                              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                               | Glimepiride                               |              |            | S           | Oral                              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                               | Allopurinol                               |              |            | S           | Oral                              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                               | Escitalopram                              |              |            | S           | Oral                              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                               | Pantoprazole                              |              |            | S           | Oral                              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                               | Naloxone Hydrochloride/Tilidine Phosphate |              |            | S           | Oral                              | 4/50 Mg            |                 | Not Reported |
|                                                                                                                                                                                                                                                                               | Trospium                                  |              |            | S           | Oral                              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                               | Digitoxin                                 |              |            | S           | Unknown                           |                    |                 | Not Reported |
| Insulin                                                                                                                                                                                                                                                                       |                                           |              | S          | Unknown     | 30/70 lu; At A Dose Of 26-0-16 lu |                    | Not Reported    |              |
| Moxonidine                                                                                                                                                                                                                                                                    |                                           |              | S          | Oral        |                                   |                    | Not Reported    |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Jul-2016              | 12522767      | NON-EXPEDITED    |                    | HO, LT          | ZA-FRI-1000084412    |                      | 83 YR      | Female     | ZAF            |

| <u>Preferred Term</u>                        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|----------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Delusion; Dyskinesia; Hallucination, Visual; | Escitalopram   |              |            | S           | Oral         | 10 Mg              |                 | Forest     |
|                                              | Escitalopram   |              |            | S           |              |                    |                 | Forest     |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                          |                        |   |             |                              |              |
|--------------------------|------------------------|---|-------------|------------------------------|--------------|
| Hyperhidrosis;           | Rasagiline             | S | Oral        | 1 Mg                         | Not Reported |
| Hyperkalaemia;           | Paracetamol W/Tramadol | S | Oral        | 18.75 Mg                     | Not Reported |
| Hypertension; Psychotic  | Hydrochloride          | S | Transdermal | 12.5 Microgram Per Hour      | Not Reported |
| Disorder; Pyrexia; Renal | Fentanyl               | S | Oral        | 500 Mg                       | Not Reported |
| Failure; Rhabdomyolysis; | Stalevo                | S | Oral        | 100 Mg                       | Not Reported |
| Tachycardia              | Celecoxib              | C | Oral        | Nocte Day                    | Not Reported |
|                          | Zopiclone              | C | Oral        | 50/200 Mg Od For Years       | Not Reported |
|                          | Sinemet                | C | Oral        | Nocte Day                    | Not Reported |
|                          | Ergocalciferol         | C | Oral        | Monday, Wednesday And Friday | Not Reported |
|                          | Ocuvite Lutein         | C | Unknown     |                              | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Jul-2016              | 12522771      | EXPEDITED (15-DAY) | CA, HO             |                 | NL-FRI-1000085834    |                      | < 1 DAY    | Female     | NLD            |

| <u>Preferred Term</u>   | <u>Product</u>             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------|----------------------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Choanal Atresia; Foetal | Escitalopram               |              |            | S           | Transplacental |                    |                 | Forest       |
| Exposure During         | Omeprazol Capsule Msr 40mg |              |            | C           | Transplacental | 40 Mg              |                 | Not Reported |
| Pregnancy               | Folic Acid                 |              |            | C           | Transplacental |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Jul-2016              | 12522772      | EXPEDITED (15-DAY) | OT                 |                 | GB-FRI-1000085740    |                      | 20 YR      | Male       | GBR            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Narcolepsy            | Escitalopram   |              |            | S           | Oral         | 10 Mg              |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 04-Jul-2016              | 12525417      | EXPEDITED (15-DAY) | DS                 |                 | DE-BAUSCH-BL-2016-015760 |                      | 88 YR      | Female     | DEU            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                          |                                           |   |         |              |
|----------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|---|---------|--------------|
| Asthenia; Decreased Appetite; General Physical Health Deterioration; Hypotension; Mobility Decreased; Somnolence; Urinary Incontinence; Weight Decreased | Isosorbide Dinitrate                      | S | Unknown | Not Reported |
|                                                                                                                                                          | Metformin                                 | S | Oral    | Santarus     |
|                                                                                                                                                          | Ramipril                                  | S | Oral    | Not Reported |
|                                                                                                                                                          | Ramipril                                  | S | Oral    | Not Reported |
|                                                                                                                                                          | Allopurinol                               | S | Oral    | Not Reported |
|                                                                                                                                                          | Pantoprazole                              | S | Oral    | Not Reported |
|                                                                                                                                                          | Furosemide                                | S | Oral    | Not Reported |
|                                                                                                                                                          | Furosemide                                | S | Oral    | Not Reported |
|                                                                                                                                                          | Metoprolol Tartrate                       | S | Oral    | Not Reported |
|                                                                                                                                                          | Metoprolol Tartrate                       | S | Oral    | Not Reported |
|                                                                                                                                                          | Candesartan Cilexetil                     | S | Oral    | Not Reported |
|                                                                                                                                                          | Hydrochlorothiazide                       | S | Oral    | Not Reported |
|                                                                                                                                                          | Glimepiride                               | S | Oral    | Not Reported |
|                                                                                                                                                          | Escitalopram                              | S | Oral    | Not Reported |
|                                                                                                                                                          | Naloxone Hydrochloride/Tilidine Phosphate | S | Oral    | Not Reported |
|                                                                                                                                                          | Trospium                                  | S | Oral    | Not Reported |
|                                                                                                                                                          | Digitoxin                                 | S | Unknown | Not Reported |
|                                                                                                                                                          | Insulin                                   | S | Unknown | Not Reported |
|                                                                                                                                                          | Moxonidine                                | S | Oral    | Not Reported |

| <u>FDA Received Date</u>                                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| 04-Jul-2016                                                                         | 12525438       | EXPEDITED (15-DAY) |                    | DE              | CA-ASTRAZENECA-2016SE71737 |                      | 49 YR           | Male         | CAN            |
| <u>Preferred Term</u>                                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Drug Ineffective; Feelings Of Worthlessness; Insomnia; Suicidal Ideation | Seroquel       |                    |                    | S               | Oral                       |                      |                 | Zeneca       |                |
|                                                                                     | Seroquel       |                    |                    | S               | Oral                       |                      |                 | Zeneca       |                |
|                                                                                     | Seroquel       |                    |                    | S               | Oral                       |                      |                 | Zeneca       |                |
|                                                                                     | Seroquel       |                    |                    | S               | Oral                       |                      |                 | Zeneca       |                |
|                                                                                     | Ciprallex      |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |             |   |      |  |  |  |  |  |              |
|--|-------------|---|------|--|--|--|--|--|--------------|
|  | Cipralex    | S | Oral |  |  |  |  |  | Not Reported |
|  | Trazodone   | C | Oral |  |  |  |  |  | Not Reported |
|  | Vitamin B12 | C |      |  |  |  |  |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Jul-2016              | 9695780       | NON-EXPEDITED    |                    | DS, OT          | JP-FRI-1000051453    |                      | 29 YR      | Male       | JPN            |

| <u>Preferred Term</u>                               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Depressed Level Of Consciousness;                   | Lexapro        |              |            | S           | Oral         |                    |                 | Forest       |
| Hyperhidrosis; Intentional Overdose; Off Label Use; | Lexapro        |              |            | S           | Oral         |                    |                 | Forest       |
| Pyrexia; Rhabdomyolysis;                            | Meilax         |              |            | C           | Oral         |                    |                 | Not Reported |
| Suicide Attempt; Tachycardia                        | Allegra        |              |            | C           | Oral         | 60 G               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Jul-2016              | 12511133      | EXPEDITED (15-DAY) |                    | DE              | AU-FRI-1000085661    |                      |            | Female     | AUS            |

| <u>Preferred Term</u>                                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|----------------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|------------|
| Foetal Exposure During Pregnancy; Pulmonary Hypertension | Escitalopram   |              |            | S           | Transplacental |                    |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 05-Jul-2016              | 12526419      | EXPEDITED (15-DAY) |                    |                 | IT-HETERO LABS LTD-1054612 |                      | 78 YR      | Female     | ITA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Pemphigoid            | Escitalopram   |              |            | S           | Unknown      |                    |                 | Hetero       |
|                       | Betamethasone  |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------------------------|----------------------|------------|------------|----------------|
| 05-Jul-2016              | 12529266      | EXPEDITED (15-DAY) |                    | HO              | ES-B.I. PHARMACEUTICALS, INC./RIDGEFIELD-2016- |                      | 81 YR      | Female     | ESP            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

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| <u>Preferred Term</u>                                                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>           |
|----------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------|
| Drug Interaction;<br>Inappropriate Antidiuretic<br>Hormone Secretion | Micardisplus   |              |            | S           | Oral         | 80 Mg              |                 | Boehringer Ingelheim |
|                                                                      | Escitalopram   |              |            | S           | Oral         | 15 Mg              |                 | Not Reported         |
|                                                                      | Sertraline     |              |            | S           | Oral         | 50 Mg              |                 | Not Reported         |
|                                                                      | Carduran Neo   |              |            | C           | Unknown      | 4 Mg               |                 | Not Reported         |
|                                                                      | Sumial         |              |            | C           | Unknown      | 60 Mg              |                 | Not Reported         |
|                                                                      | Atorvastatin   |              |            | C           | Unknown      | 20 Mg              |                 | Not Reported         |
|                                                                      | Diazepam       |              |            | C           | Unknown      | 10 Mg              |                 | Not Reported         |
|                                                                      | Sinemet Plus   |              |            | C           | Unknown      |                    |                 | Not Reported         |
|                                                                      | Azilect        |              |            | C           | Unknown      | 1 Mg               |                 | Not Reported         |
|                                                                      | Exelon         |              |            | C           | Unknown      | 9.5 Mg             |                 | Not Reported         |
|                                                                      | Clopidogrel    |              |            | C           | Unknown      | 75 Mg              |                 | Not Reported         |
|                                                                      | Quetiapine     |              |            | C           | Unknown      | 25 Mg              |                 | Not Reported         |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------------------------------------|----------------------|------------|------------|----------------|
| 06-Jul-2016              | 12529690      | EXPEDITED (15-DAY) |                    |                 | US-MACLEODS<br>PHARMACEUTICALS<br>US LTD-<br>MAC2016002693 |                      |            | Unknown    | USA            |

| <u>Preferred Term</u> | <u>Product</u>                      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|-------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Hypersensitivity      | Escitalopram Oxalate 10mg<br>Tablet |              |            | S           | Oral         | 10 Mg              |                 | Macleods   |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Jul-2016              | 12530856      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000085794    |                      | 87 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u>             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Pyrexia; Rash         | Escitalopram Oral Solution |              |            | S           | Oral         | 0.5 MI             |                 | Forest     |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                          |           |   |         |        |              |
|--------------------------|-----------|---|---------|--------|--------------|
| Erythematous; Rash       | Lamisil   | S | Oral    |        | Not Reported |
| Pruritic; Rash Pustular; | Lamisil   | S | Topical |        | Not Reported |
| Toxic Skin Eruption      | Tiapridal | S | Oral    | 10 Gtt | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------------------------------|----------------------|------------|------------|----------------|
| 06-Jul-2016              | 12530874      | EXPEDITED (15-DAY) |                    | HO, LT, OT      | FR-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>BMS-2016-054412 |                      | 53 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>           |
|---------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------|
| Coma; Electrocardiogram<br>Qt Prolonged; Hypotonia;<br>Miosis | Abilify        |              |            | S           | Oral         | 5 Mg, Qd           |                 | Bristol Myers Squibb |
|                                                               | Zopiclone      |              |            | S           | Oral         | 210 Mg, Qd         |                 | Not Reported         |
|                                                               | Zyprexa        |              |            | S           | Oral         | 1 Df, Unk          |                 | Not Reported         |
|                                                               | Lysanxia       |              |            | S           | Oral         | 1440 Mg, Unk       |                 | Not Reported         |
|                                                               | Seroplex       |              |            | S           | Oral         | 140 Mg, Unk        |                 | Not Reported         |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Jul-2016              | 12532241      | EXPEDITED (15-DAY) |                    | DE              | JP-FRI-1000085843    |                      |            | Female     | JPN            |

| <u>Preferred Term</u>          | <u>Product</u>                      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------|-------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide;<br>Overdose | Escitalopram                        |              |            | S           | Oral         |                    |                 | Forest       |
|                                | Levomepromazine                     |              |            | S           | Oral         |                    |                 | Not Reported |
|                                | Mirtazapine                         |              |            | C           | Oral         |                    |                 | Not Reported |
|                                | Duloxetine Hydrochloride            |              |            | C           | Oral         |                    |                 | Not Reported |
|                                | Alprazolam                          |              |            | C           | Oral         |                    |                 | Not Reported |
|                                | Risperidone                         |              |            | C           | Oral         |                    |                 | Not Reported |
|                                | Paroxetine Hydrochloride<br>Hydrate |              |            | C           | Oral         |                    |                 | Not Reported |
|                                | Flunitrazepam                       |              |            | C           | Oral         |                    |                 | Not Reported |
|                                | Quazepam                            |              |            | C           | Oral         |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|------------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 07-Jul-2016                                                                                | 11389271       | EXPEDITED (15-DAY) |                    | OT              | TR-FRI-1000079024                                    |                      | 18 YR           | Female       | TUR            |
| <u>Preferred Term</u>                                                                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Pupils Unequal                                                                             | Escitalopram   |                    |                    | S               | Unknown                                              | 5 Mg                 |                 | Forest       |                |
|                                                                                            | Escitalopram   |                    |                    | S               | Unknown                                              | 10 Mg                |                 | Forest       |                |
|                                                                                            | Escitalopram   |                    |                    | S               | Unknown                                              | 5 Mg                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Jul-2016                                                                                | 12488693       | EXPEDITED (15-DAY) |                    | HO, LT, OT      | ES-CONCORDIA<br>PHARMACEUTICALS<br>INC.-E2B_00007764 |                      | 84 YR           | Female       | ESP            |
| <u>Preferred Term</u>                                                                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Electrocardiogram Qt<br>Prolonged; Hypokalaemia;<br>Hypomagnesaemia;<br>Torsade De Pointes | Digoxin        |                    |                    | S               |                                                      |                      |                 | Concordia    |                |
|                                                                                            | Sulpiride      |                    |                    | S               |                                                      |                      |                 | Not Reported |                |
|                                                                                            | Escitalopram   |                    |                    | S               |                                                      |                      |                 | Not Reported |                |
|                                                                                            | Levofloxacin   |                    |                    | S               |                                                      |                      |                 | Not Reported |                |
|                                                                                            | Solifenacin    |                    |                    | S               |                                                      |                      |                 | Not Reported |                |
|                                                                                            | Amiodarone     |                    |                    | S               | Intravenous (not<br>otherwise specified)             |                      |                 | Not Reported |                |
|                                                                                            | Candesartan    |                    |                    | C               |                                                      |                      |                 | Not Reported |                |
|                                                                                            | Furosemide     |                    |                    | C               |                                                      |                      |                 | Not Reported |                |
|                                                                                            | Acenocoumarol  |                    |                    | C               |                                                      |                      |                 | Not Reported |                |
|                                                                                            | Simvastatin    |                    |                    | C               |                                                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Jul-2016                                                                                | 12535028       | EXPEDITED (15-DAY) |                    | OT              | US-CIPLA LTD.-<br>2016US08328                        |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Laboratory Test Abnormal                                                                   | Escitalopram   |                    |                    | S               | Oral                                                 | 10 Mg, Qd            |                 | Invagen      |                |
| <u>FDA Received Date</u>                                                                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Jul-2016                                                                                | 12537869       | EXPEDITED (15-DAY) |                    | OT              | SE-FRI-1000085896                                    |                      | 37 YR           | Female       | SWE            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Bradyphrenia;<br>Derealisation; Dizziness;<br>Fatigue; Headache;<br>Muscle Twitching;<br>Nausea; Vision Blurred | Escitalopram   |              |            | S           | Unknown      |                    |                 | Forest       |
|                                                                                                                 | Escitalopram   |              |            | S           |              |                    |                 | Forest       |
|                                                                                                                 | Escitalopram   |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                 | Escitalopram   |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                 | Yaz            |              |            | C           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 07-Jul-2016              | 12537957      | EXPEDITED (15-DAY) |                    | CA, OT          | DE-MYLANLABS-2016M1027346 |                      |            | Unknown    | DEU            |

| <u>Preferred Term</u>                                                                                                                             | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u>                                                                                    | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|--------------|------------|-------------|----------------|-------------------------------------------------------------------------------------------------------|-----------------|--------------|
| Bradycardia Neonatal;<br>Congenital<br>Hydronephrosis; Foetal<br>Exposure During<br>Pregnancy; Kidney<br>Duplex; Respiratory<br>Disorder Neonatal | Escitalopram          |              |            | S           | Transplacental | 10 [Mg/D ]/ Intermittently<br>7.5 Mg/D For A Short Time<br>Period.                                    |                 | Not Reported |
|                                                                                                                                                   | Decortin-H /00016201/ |              |            | S           | Transplacental | 5.5 [Mg/D ]/ Minimum<br>Dosage 5 Mg/D                                                                 |                 | Mylan        |
|                                                                                                                                                   | L-Thyroxin            |              |            | C           | Transplacental | 75 [Mg/D ]                                                                                            |                 | Mylan        |
|                                                                                                                                                   | Dekristol             |              |            | C           | Transplacental | 1000 [Ie/D ]/ Probably<br>Taken Longer. Reduction<br>To 500 Ie/D, Stopped<br>During The 1st Trimester |                 | Mylan        |
|                                                                                                                                                   | Cytotec               |              |            | C           | Transplacental |                                                                                                       |                 | Mylan        |
|                                                                                                                                                   | Femibion 1            |              |            | C           | Transplacental | 0.8 [Mg/D ]                                                                                           |                 | Mylan        |
|                                                                                                                                                   | Ampicillin            |              |            | C           | Transplacental | Unk                                                                                                   |                 | Mylan        |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Jul-2016              | 12538046      | EXPEDITED (15-DAY) |                    | OT              | ZA-FRI-1000085886    |                      |            | Female     | ZAF            |

| <u>Preferred Term</u>                            | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Neutropenia; White Blood<br>Cell Count Decreased | Escitalopram              |              |            | S           | Unknown      |                    |                 | Forest       |
|                                                  | Tetralysal [Tetracycline] |              |            | C           | Unknown      |                    |                 | Not Reported |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Jul-2016              | 12538221      | EXPEDITED (15-DAY) |                    | HO              | NL-FRI-1000085837    |                      |            | Female     | NLD            |

| <u>Preferred Term</u>                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Electrocardiogram Abnormal; Poisoning | Escitalopram   |              |            | S           | Unknown      |                    |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 08-Jul-2016              | 11021240      | EXPEDITED (15-DAY) |                    | OT              | US-009507513-1504USA005235 |                      |            | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Arthralgia;                                                                                                                                                                                                                                                                                                 | Propecia       |              |            | S           | Oral         | 1 Mg, Qd           |                 | Merck        |
| Asthenia; Attention Deficit/Hyperactivity Disorder; Back Pain;                                                                                                                                                                                                                                                       | Metoprolol     |              |            | S           | Unknown      | Unk, Unknown       |                 | Not Reported |
| Blood Testosterone Decreased; Cardiac Arrest; Colon Adenoma;                                                                                                                                                                                                                                                         | Lexapro        |              |            | S           | Oral         | 10 Mg, Qd          |                 | Not Reported |
| Cough; Cough; Depressed Level Of Consciousness; Depression; Dizziness;                                                                                                                                                                                                                                               | Lexapro        |              |            | S           | Oral         | 20 Mg, Qd          |                 | Not Reported |
| Dysphonia; Erectile Dysfunction; Fall; Fall; Fatigue; Fatigue;                                                                                                                                                                                                                                                       | Wellbutrin     |              |            | S           | Unknown      | Unk, Unknown       |                 | Not Reported |
| Gastrooesophageal Reflux Disease; Hypersensitivity; Hypogonadism Male; Hypotension; Joint Dislocation; Libido Decreased; Ligament Rupture; Lipids Increased; Malaise; Meningioma; Meniscus Injury; Musculoskeletal Chest Pain; Neck Pain; Nocturia; Orgasm Abnormal; Osteoarthritis; Plantar Fasciitis; Pollakiuria; |                |              |            |             |              |                    |                 |              |

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Psychosexual Disorder;  
Rib Fracture; Rotator Cuff  
Syndrome; Rotator Cuff  
Syndrome; Skin Abrasion;  
Sperm Concentration  
Decreased; Stress At  
Work; Tendonitis;  
Tendonitis; Ventricular  
Extrasystoles; Ventricular  
Fibrillation; Viral  
Myocarditis; Weight  
Increased

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                 | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------------------------------|----------------------|------------|------------|----------------|
| 08-Jul-2016              | 12538711      | EXPEDITED (15-DAY) |                    | HO, OT          | CA-SCIEGEN<br>PHARMACEUTICALS<br>INC-2016SCILIT00291 |                      | 182 DAY    | Female     | CAN            |

| <u>Preferred Term</u>                                            | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Maternal Exposure During<br>Breast Feeding; Seizure;<br>Vomiting | Bupropion Hydrochloride |              |            | S           | Transmammary | Unk                |                 | Sciegen      |
|                                                                  | Escitalopram            |              |            | S           | Transmammary | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|------------|------------|----------------|
| 08-Jul-2016              | 12539799      | EXPEDITED (15-DAY) |                    | HO, OT          | ES-CIPLA LTD.-<br>2016ES08290 |                      |            | Unknown    | ESP            |

| <u>Preferred Term</u>                                                                                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Biliary Colic; Cardio-<br>Respiratory Arrest; Drug<br>Interaction; Hypokalaemia;<br>Hypomagnesaemia;<br>Torsade De Pointes | Escitalopram   |              |            | S           | Unknown      | Unk                |                 | Invagen      |
|                                                                                                                            | Losartan       |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                                                                                                                            | Simvastatin    |              |            | S           | Unknown      | Unk                |                 | Cipla        |
|                                                                                                                            | Amiodarone     |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                                                                                                                            | Metformin      |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                                                                                                                            | Iron Sulfate   |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                                                                                                                            | Betahistine    |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                                                                                                                            | Bisoprolol     |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                                                                                                                            | Acenocoumarol  |              |            | S           | Unknown      | Unk                |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                 | Metoclopramide             |                    | S                  | Unknown         | Unk                        |                                                                                        |                 | Not Reported |                |
|---------------------------------------------------------------------------------------------------------------------------------|----------------------------|--------------------|--------------------|-----------------|----------------------------|----------------------------------------------------------------------------------------|-----------------|--------------|----------------|
|                                                                                                                                 | Metoclopramide             |                    | S                  |                 |                            |                                                                                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                        | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                                                                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Jul-2016                                                                                                                     | 12541535                   | EXPEDITED (15-DAY) |                    | CA, OT          | DE-TEVA-672270GER          |                                                                                        | 1 DAY           | Female       | DEU            |
| <u>Preferred Term</u>                                                                                                           | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                                                                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Bradycardia Neonatal; Congenital Hydronephrosis; Foetal Exposure During Pregnancy; Kidney Duplex; Respiratory Disorder Neonatal | Escitalopram               |                    |                    | S               | Transplacental             | 10mg/Day; Intermittently 7.5 Mg/D For A Short Time Period; 0. - 36.2. Gestational Week |                 | Ivax         |                |
|                                                                                                                                 | Decortin-H                 |                    |                    | S               | Transplacental             | 5.5mg/Day; Minimum Dosage 5 Mg/D; 0. - 36.2. Gestational Week                          |                 | Not Reported |                |
|                                                                                                                                 | L-Thyroxin                 |                    |                    | C               | Transplacental             | 75 Microgram Daily; 0. - 36.2. Gestational Week                                        |                 | Not Reported |                |
|                                                                                                                                 | Dekristol                  |                    |                    | C               | Transplacental             |                                                                                        |                 | Not Reported |                |
|                                                                                                                                 | Cytotec                    |                    |                    | C               | Transplacental             | 36.2. - 36.2. Gestational Week                                                         |                 | Not Reported |                |
|                                                                                                                                 | Femibion Schwangerschaft 1 |                    |                    | C               | Transplacental             | .8 Milligram Daily;                                                                    |                 | Not Reported |                |
|                                                                                                                                 | Ampicillin                 |                    |                    | C               | Transplacental             | 36.2. - 36.2. Gestational Week                                                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                        | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                                                                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Jul-2016                                                                                                                     | 12298439                   | NON-EXPEDITED      |                    |                 | US-009507513-1604USA004800 |                                                                                        |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                                                                           | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                                                                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction                                                                                                                | Zetia                      |                    |                    | S               | Oral                       | Unk                                                                                    |                 | Merck        |                |
|                                                                                                                                 | Lexapro                    |                    |                    | S               |                            | Unk                                                                                    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                        | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                                                                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Jul-2016                                                                                                                     | 12543832                   | NON-EXPEDITED      |                    | OT              | US-JAZZ-JPI-P-022332       |                                                                                        | 33 YR           | Female       | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <a href="#">Preferred Term</a>                                                                                                                | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                          | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
|-----------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|------------------------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Acne; Anxiety; Arthralgia;<br>Cataplexy; Dysphagia;<br>Muscle Contractions<br>Involuntary; Muscle<br>Discomfort;<br>Musculoskeletal Stiffness | Xyrem                   |                           |                             | S                        | Oral                                           | 2.25 G, Bid                   |                          | Jazz                |                         |
|                                                                                                                                               | Xyrem                   |                           |                             | S                        | Oral                                           | Dose Adjustments              |                          | Jazz                |                         |
|                                                                                                                                               | Xyrem                   |                           |                             | S                        | Oral                                           | 4.5 G, Bid                    |                          | Jazz                |                         |
|                                                                                                                                               | Lexapro                 |                           |                             | S                        |                                                |                               |                          | Not Reported        |                         |
|                                                                                                                                               | Nuvigil                 |                           |                             | S                        |                                                |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                                             | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>                  | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 11-Jul-2016                                                                                                                                   | 12544289                | EXPEDITED (15-DAY)        |                             | HO                       | IT-LUPIN<br>PHARMACEUTICALS<br>INC.-2016-03033 |                               | 78 YR                    | Female              | ITA                     |
| <a href="#">Preferred Term</a>                                                                                                                | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                          | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Pemphigoid                                                                                                                                    | Escitalopram            |                           |                             | S                        | Unknown                                        |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                                             | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>                  | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 11-Jul-2016                                                                                                                                   | 12544574                | EXPEDITED (15-DAY)        |                             | OT                       | DE-AUROBINDO-AUR-<br>APL-2016-09014            |                               | 39 YR                    | Female              | DEU                     |
| <a href="#">Preferred Term</a>                                                                                                                | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                          | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Amniotic Fluid Volume<br>Increased; Exposure<br>During Pregnancy;<br>Premature Rupture Of<br>Membranes                                        | Escitalopram 10 Mg      |                           |                             | S                        | Oral                                           | 10 Mg, Daily                  |                          | Aurobindo           |                         |
|                                                                                                                                               | Decortin-H /00016201/   |                           |                             | S                        | Oral                                           | 5.5 Mg, Daily                 |                          | Not Reported        |                         |
|                                                                                                                                               | L-Thyroxin              |                           |                             | C                        | Oral                                           | 75 Mcg, Daily                 |                          | Not Reported        |                         |
|                                                                                                                                               | Dekristol               |                           |                             | C                        | Oral                                           | Unk                           |                          | Not Reported        |                         |
|                                                                                                                                               | Cytotec                 |                           |                             | C                        | Unknown                                        | Unk                           |                          | Not Reported        |                         |
|                                                                                                                                               | Ampicillin              |                           |                             | C                        | Unknown                                        | Unk                           |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                                             | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>                  | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 11-Jul-2016                                                                                                                                   | 12544656                | EXPEDITED (15-DAY)        |                             | CA, OT                   | DE-AUROBINDO-AUR-<br>APL-2016-08582            |                               | 1 DAY                    | Female              | DEU                     |
| <a href="#">Preferred Term</a>                                                                                                                | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                          | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Bradycardia Neonatal;<br>Congenital<br>Hydronephrosis;                                                                                        | Escitalopram 10 Mg      |                           |                             | S                        | Transplacental                                 | 10 Mg, Daily                  |                          | Aurobindo           |                         |
|                                                                                                                                               | Decortin-H /00016201/   |                           |                             | S                        | Transplacental                                 | 5.5 Mg, Daily                 |                          | Not Reported        |                         |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                      |            |   |                |                |              |
|----------------------|------------|---|----------------|----------------|--------------|
| Hypotonia Neonatal;  | L-Thyroxin | C | Transplacental | 75 Mcg, Daily  | Not Reported |
| Kidney Duplex;       | Dekristol  | C | Transplacental | 1000 Iu, Daily | Not Reported |
| Respiratory Disorder | Cytotec    | C | Transplacental | Unk            | Not Reported |
| Neonatal             | Ampicillin | C | Transplacental | Unk            | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Jul-2016              | 12546801      | EXPEDITED (15-DAY) |                    | DE              | FR-SA-2016SA124957   |                      | 66 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                    | <u>Product</u>                                       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------|------------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardio-Respiratory Arrest;<br>Completed Suicide;<br>Intentional Overdose | Stilnox                                              |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                          | Escitalopram                                         |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                          | Propafenone Hydrochloride                            |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                          | Stagid                                               |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                          | Diamicron                                            |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                          | Noctamide                                            |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                          | Lexomil                                              |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                          | Spasfon (Phloroglucinol,<br>Trimethylphloroglucinol) |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                          | Dafalgan                                             |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                          | Meteoxane                                            |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                          | Fortum                                               |              |            | C           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Jul-2016              | 12547164      | EXPEDITED (15-DAY) |                    | CA, OT          | DE-FRI-1000085908    |                      | < 1 DAY    | Female     | DEU            |

| <u>Preferred Term</u>                                                                                                        | <u>Product</u>                       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Bradycardia Neonatal;<br>Congenital<br>Hydronephrosis; Foetal<br>Exposure During<br>Pregnancy; Kidney<br>Duplex; Respiratory | Escitalopram                         |              |            | S           | Transplacental | 10 Mg              |                 | Forest       |
|                                                                                                                              | Decortin-H / Prednisolone            |              |            | S           | Transplacental | 5.5 Mg             |                 | Not Reported |
|                                                                                                                              | Decortin-H / Prednisolone            |              |            | S           | Transplacental |                    |                 | Not Reported |
|                                                                                                                              | L-Thyroxin / Levothyroxine<br>Sodium |              |            | C           | Transplacental | 75 Mg              |                 | Not Reported |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                   |                                         |   |                |         |              |
|-------------------|-----------------------------------------|---|----------------|---------|--------------|
| Disorder Neonatal | Dekristol / Colecalciferol              | C | Transplacental | 1000 lu | Not Reported |
|                   | Dekristol / Colecalciferol              | C | Transplacental |         | Not Reported |
|                   | Cytotec / Misoprostol                   | C | Transplacental |         | Not Reported |
|                   | Femibion Schwangerschaft 1 / Folic Acid | C | Transplacental | 0.8 Mg  | Not Reported |
|                   | Ampicillin / Ampicillin                 | C | Transplacental |         | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Jul-2016              | 12547176      | EXPEDITED (15-DAY) |                    | HO              | CH-FRI-1000085894    |                      | 25 YR      | Female     | CHE            |

| <u>Preferred Term</u>        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Supraventricular Tachycardia | Escitalopram   |              |            | S           | Oral         |                    |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Jul-2016              | 11705407      | EXPEDITED (15-DAY) |                    | HO              | PHHY2015GB140223     |                      | 121 DAY    | Female     | GBR            |

| <u>Preferred Term</u>                                                                | <u>Product</u>               | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------|------------------------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Sepsis Neonatal | Omeprazole                   |              |            | S           | Transplacental |                    |                 | Novartis     |
|                                                                                      | Omeprazole                   |              |            | S           | Transplacental |                    |                 | Novartis     |
|                                                                                      | Omeprazole                   |              |            | S           | Transplacental |                    |                 | Novartis     |
|                                                                                      | Azathioprine                 |              |            | S           | Transplacental |                    |                 | Not Reported |
|                                                                                      | Co-Dydramol                  |              |            | S           | Transplacental | Strength: 10/500   |                 | Not Reported |
|                                                                                      | Escitalopram                 |              |            | S           | Transplacental |                    |                 | Not Reported |
|                                                                                      | Oramorph                     |              |            | S           | Transplacental | 15 Mg, Unk         |                 | Not Reported |
|                                                                                      | Oramorph                     |              |            | S           | Unknown        | Unk                |                 | Not Reported |
|                                                                                      | Tapentadol                   |              |            | S           | Transplacental | 100 Mg             |                 | Not Reported |
|                                                                                      | Daktarin//Miconazole Nitrate |              |            | C           | Unknown        |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 12-Jul-2016              | 12549982      | EXPEDITED (15-DAY) |                    | HO              | IT-MYLANLABS-2016M1028499 |                      |            | Unknown    | ITA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                                                          | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|----------------------------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Anxiety; Drug Abuse                                                                                            | Escitalopram              |                    |                    | S               | Oral                 | 300 Mg, Total        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                       | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Jul-2016                                                                                                    | 12550266                  | EXPEDITED (15-DAY) |                    | HO, LT          | FR-FRI-1000086042    |                      | 43 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                          | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depressed Level Of Consciousness; Hypoglycaemia; Hypokalaemia; Intentional Overdose; Miosis; Sinus Bradycardia | Escitalopram              |                    |                    | S               | Oral                 | 14 Tablets At Once   |                 | Forest       |                |
|                                                                                                                | Corgard                   |                    |                    | S               | Oral                 | 28 Tablets At Once   |                 | Not Reported |                |
|                                                                                                                | Alprazolam                |                    |                    | S               | Oral                 | 30 Tablets At Once   |                 | Not Reported |                |
|                                                                                                                | Levothyrox                |                    |                    | S               | Oral                 | 30 Tablets At Once   |                 | Not Reported |                |
|                                                                                                                | Esomeprazole              |                    |                    | S               | Oral                 | 4 Tablets At Once    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                       | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Jul-2016                                                                                                    | 12550272                  | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000086012    |                      | 89 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                          | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Iron Deficiency Anaemia                                                                                        | Escitalopram              |                    |                    | S               | Oral                 | 20 Mg                |                 | Forest       |                |
|                                                                                                                | Kardegic                  |                    |                    | S               | Oral                 | 75 Mg                |                 | Not Reported |                |
|                                                                                                                | Clopidogrel               |                    |                    | S               | Oral                 | 1 Df                 |                 | Not Reported |                |
|                                                                                                                | Ebixa Film-Coated Tablets |                    |                    | C               | Unknown              |                      |                 | Not Reported |                |
|                                                                                                                | Levothyrox                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                | Eupantol                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                | Lasilix                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                | Diffu K                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                       | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Jul-2016                                                                                                    | 12550406                  | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000085949    |                      | 69 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                          | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Muscle Haemorrhage                                                                                             | Escitalopram              |                    |                    | S               | Unknown              |                      |                 | Forest       |                |

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|                        |   |         |       |              |
|------------------------|---|---------|-------|--------------|
| Coumadine              | S | Oral    | 4 Mg  | Not Reported |
| Kardegic               | S | Oral    | 75 Mg | Not Reported |
| Bisoprolol             | C | Unknown |       | Not Reported |
| Stilnox                | C | Unknown |       | Not Reported |
| Oxycontin Lp           | C | Unknown |       | Not Reported |
| Oxynormoro             | C | Unknown |       | Not Reported |
| Inexium                | C | Unknown |       | Not Reported |
| Triatec (Ramipril)     | C | Unknown |       | Not Reported |
| Tahor                  | C | Unknown |       | Not Reported |
| Hydrocortisone Roussel | C | Unknown |       | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Jul-2016              | 12550608      | EXPEDITED (15-DAY) |                    | HO              | IT-FRI-1000086090    |                      | 40 YR      | Male       | ITA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Anxiety; Drug Abuse   | Escitalopram   |              |            | S           | Oral         |                    |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Jul-2016              | 12521680      | EXPEDITED (15-DAY) |                    | HO, OT          | US-TEVA-673427USA    |                      | 45 YR      | Female     | USA            |

| <u>Preferred Term</u>                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Reversible Cerebral Vasoconstriction Syndrome | Escitalopram   |              |            | S           |              |                    |                 | Ivax         |
|                                               | Estrogen Nos   |              |            | S           |              |                    |                 | Not Reported |
|                                               | Trazodone      |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 13-Jul-2016              | 12526479      | EXPEDITED (15-DAY) |                    | HO, OT          | US-CIPLA LTD.-2016US08452 |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------|----------------|--------------|------------|-------------|--------------|----------------------|-----------------|--------------|
| Reversible Cerebral Vasoconstriction Syndrome | Escitalopram   |              |            | S           | Unknown      | Unk                  |                 | Invagen      |
|                                               | Estrogen Nos   |              |            | S           | Unknown      | Unk, Supplementation |                 | Not Reported |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                   |                      |                    |                    |                 |                            |                      |                 |              |                |  |
|-------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|--|
| Trazodone                                                         |                      |                    | C                  |                 | Unknown                    |                      | Unk             |              | Not Reported   |  |
| <u>FDA Received Date</u>                                          | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |  |
| 13-Jul-2016                                                       | 12552745             | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000086062          |                      | 55 YR           | Female       | FRA            |  |
| <u>Preferred Term</u>                                             | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |  |
| Drug-Induced Liver Injury                                         | Escitalopram         |                    |                    | S               | Unknown                    | 10 Mg                |                 | Forest       |                |  |
|                                                                   | Chlorpromazine       |                    |                    | C               | Unknown                    |                      |                 | Not Reported |                |  |
| <u>FDA Received Date</u>                                          | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |  |
| 13-Jul-2016                                                       | 12553050             | EXPEDITED (15-DAY) |                    | OT              | ES-JNJFOC-20160706142      |                      | 49 YR           | Female       | ESP            |  |
| <u>Preferred Term</u>                                             | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |  |
| Hyponatraemia;<br>Inappropriate Antidiuretic<br>Hormone Secretion | Xeplion              |                    |                    | S               | Intramuscular              |                      |                 | Not Reported |                |  |
|                                                                   | Escitalopram Oxalate |                    |                    | S               | Oral                       | 28 Tablets           |                 | Not Reported |                |  |
|                                                                   | Trileptal            |                    |                    | S               | Oral                       | 50 Tablets           |                 | Not Reported |                |  |
| <u>FDA Received Date</u>                                          | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |  |
| 13-Jul-2016                                                       | 12553769             | EXPEDITED (15-DAY) |                    | OT              | US-JNJFOC-20160704609      |                      |                 | Male         | USA            |  |
| <u>Preferred Term</u>                                             | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |  |
| Cardiac Failure<br>Congestive; Pneumonia;<br>Serotonin Syndrome   | Ultram               |                    |                    | S               | Oral                       | As Necessary         |                 | Not Reported |                |  |
|                                                                   | Viibryd              |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |  |
|                                                                   | Lexapro              |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |  |
| <u>FDA Received Date</u>                                          | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |  |
| 14-Jul-2016                                                       | 11038727             | EXPEDITED (15-DAY) |                    | HO, OT          | US-009507513-1504USA013052 |                      |                 | Male         | USA            |  |
| <u>Preferred Term</u>                                             | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |  |
| Brain Injury; Depression;<br>Depression; Ejaculation              | Propecia             |                    |                    | S               | Oral                       | 1 Mg, Qd             |                 | Merck        |                |  |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                                                                                                                                                                                                                     |         |   |      |           |              |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|---|------|-----------|--------------|
| Disorder; Endocrine Disorder; Erectile Dysfunction; Essential Hypertension; Gastroesophageal Reflux Disease; Generalised Anxiety Disorder; Haemorrhoidal Haemorrhage; Hand Fracture; Hormone Level Abnormal; Insomnia; Loss Of Libido; Nocturia; Organic Erectile Dysfunction; Painful Ejaculation; Penile Size Reduced; Penis Injury; Sexual Dysfunction; Skin Lesion; Sunburn; Testicular Atrophy | Lexapro | S | Oral | 10 Mg, Qd | Not Reported |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|---|------|-----------|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 14-Jul-2016              | 12556099      | EXPEDITED (15-DAY) |                    | OT              | AU-MYLANLABS-2016M1028896 |                      |            | Unknown    | AUS            |

| <u>Preferred Term</u>                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Accident; Drug Interaction; Somnambulism | Zolpidem       |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                          | Escitalopram   |              |            | S           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 14-Jul-2016              | 12556345      | EXPEDITED (15-DAY) |                    | HO              | FR-PFIZER INC-2016335220 |                      | 90 YR      | Male       | FRA            |

| <u>Preferred Term</u>                              | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Confusional State; Drug Interaction; Hyponatraemia | Xanax                    |              |            | S           | Oral         | 0.5 Mg, 2x/Day     |                 | Pfizer       |
|                                                    | Indapamide W/Perindopril |              |            | S           | Oral         | 0.5 Df, 1x/Day     |                 | Not Reported |
|                                                    | Zopiclone                |              |            | S           | Oral         | 3.75 Mg, 1x/Day    |                 | Not Reported |
|                                                    | Seroplex                 |              |            | S           | Oral         | 5 Mg, 1x/Day       |                 | Not Reported |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                      | Clopidogrel                     | C                  | Oral               | 75 Mg, 1x/Day   | Not Reported                             |                      |                 |                      |                |
|--------------------------------------------------------------------------------------|---------------------------------|--------------------|--------------------|-----------------|------------------------------------------|----------------------|-----------------|----------------------|----------------|
|                                                                                      | Nebivolol                       | C                  | Oral               | 5 Mg, 1x/Day    | Not Reported                             |                      |                 |                      |                |
|                                                                                      | Movicol                         | C                  |                    | 20 Mg, 1x/Day   | Not Reported                             |                      |                 |                      |                |
| <u>FDA Received Date</u>                                                             | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 14-Jul-2016                                                                          | 12557791                        | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000084831                        |                      |                 | Female               | FRA            |
| <u>Preferred Term</u>                                                                | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Abortion Induced                                                                     | Escitalopram                    |                    |                    | S               | Oral                                     | 10 Mg                |                 | Forest               |                |
|                                                                                      | Escitalopram                    |                    |                    | S               | Oral                                     | 15 Mg                |                 | Forest               |                |
| <u>FDA Received Date</u>                                                             | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 14-Jul-2016                                                                          | 12560260                        | DIRECT             |                    | DS              |                                          |                      | 23 YR           | Male                 | USA            |
| <u>Preferred Term</u>                                                                | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Hypoaesthesia; Pain; Rash                                                            | Escitalopram/Lexapro 10mg, 10mg |                    |                    | S               | Oral                                     |                      |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                             | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 15-Jul-2016                                                                          | 10332632                        | EXPEDITED (15-DAY) |                    | HO, LT, OT      | TR-BRISTOL-MYERS SQUIBB COMPANY-21204250 |                      | 31 YR           | Female               | TUR            |
| <u>Preferred Term</u>                                                                | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Anal Incontinence; Drug Interaction; Overdose; Suicide Attempt; Urinary Incontinence | Aripiprazole                    |                    |                    | S               | Oral                                     | 14 Tabs              |                 | Bristol Myers Squibb |                |
|                                                                                      | Escitalopram                    |                    |                    | S               | Oral                                     | 20 Tabs              |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                             | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 15-Jul-2016                                                                          | 12550607                        | EXPEDITED (15-DAY) |                    | HO              | DK-FRI-1000085955                        |                      |                 | Female               | DNK            |
| <u>Preferred Term</u>                                                                | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |

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|                                                                                                   |              |   |         |              |
|---------------------------------------------------------------------------------------------------|--------------|---|---------|--------------|
| Aggression; Confusional State; Drug Ineffective; Feeling Abnormal; Limb Discomfort; Muscle Spasms | Escitalopram | S | Unknown | Forest       |
|                                                                                                   | Brintellix   | S | Unknown | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                               | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------------------------------|----------------------|------------|------------|----------------|
| 15-Jul-2016              | 12562625      | EXPEDITED (15-DAY) |                    | OT              | IT-PRINSTON<br>PHARMACEUTICAL<br>INC.-2016PRN00173 |                      | 78 YR      | Female     | ITA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                 |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------------|
| Pemphigoid            | Escitalopram   |              |            | S           | Unknown      | 10 Mg, 1x/Day      |                 | Prinston<br>Pharmaceutical |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Jul-2016              | 12563336      | EXPEDITED (15-DAY) |                    | OT              | PHHY2016AU096166     |                      | 34 YR      | Male       | AUS            |

| <u>Preferred Term</u>                        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction;                            | Zolpidem       |              |            | S           | Unknown      |                    |                 | Novartis     |
| Hallucination; Sleep-Related Eating Disorder | Escitalopram   |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                              | Oxycodone      |              |            | C           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>              | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------------------|----------------------|------------|------------|----------------|
| 16-Jul-2016              | 12562212      | EXPEDITED (15-DAY) |                    | HO, OT          | AU-ACTAVIS PTY LTD-<br>2016-15379 |                      | 66 YR      | Male       | AUS            |

| <u>Preferred Term</u>                                                                             | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>     |
|---------------------------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------|
| Electrocardiogram Qt Prolonged; Hypokalaemia; Hypomagnesaemia; Orthostatic Hypotension; Poisoning | Escitalopram (Unknown)  |              |            | S           | Unknown      | 10 Mg, Daily       |                 | Not Reported   |
|                                                                                                   | Perindopril (Unknown)   |              |            | S           | Unknown      | Unk                |                 | Not Reported   |
|                                                                                                   | Atenolol (Unknown)      |              |            | S           | Unknown      | Unk                |                 | Watson         |
|                                                                                                   | Rosuvastatin (Unknown)  |              |            | S           | Unknown      | Unk                |                 | Watson         |
|                                                                                                   | Pantoprazole (Unknown)  |              |            | S           | Unknown      | Unk                |                 | Actavis Totowa |
|                                                                                                   | Lercanidipine (Unknown) |              |            | S           | Unknown      | Unk                |                 | Not Reported   |

# FDA Adverse Event Reporting System

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### Detailed Report

| <u>FDA Received Date</u>                                                                                            | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------|-----------------------------------------|--------------------|--------------------|-----------------|------------------------------------------------------------|----------------------|-----------------|----------------------|----------------|
| 16-Jul-2016                                                                                                         | 12563716                                | EXPEDITED (15-DAY) |                    | CA, OT          | DE-HETERO LABS<br>LTD-1055129                              |                      | 1 DAY           | Female               | DEU            |
| <u>Preferred Term</u>                                                                                               | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Bradycardia Neonatal;<br>Congenital                                                                                 | Escitalopram                            |                    |                    | S               | Transplacental                                             |                      |                 | Hetero               |                |
| Hydronephrosis; Exposure<br>During Pregnancy; Kidney<br>Duplex; Premature Baby;<br>Respiratory Disorder<br>Neonatal | Decortin-H                              |                    |                    | S               | Transplacental                                             |                      |                 | Not Reported         |                |
|                                                                                                                     | L-Thyroxin                              |                    |                    | C               | Transplacental                                             |                      |                 | Not Reported         |                |
|                                                                                                                     | Dekristol                               |                    |                    | C               |                                                            |                      |                 | Not Reported         |                |
|                                                                                                                     | Cytotec                                 |                    |                    | C               |                                                            |                      |                 | Not Reported         |                |
|                                                                                                                     | Femibion [Minerals Nos;Vitamins<br>Nos] |                    |                    | C               |                                                            |                      |                 | Not Reported         |                |
|                                                                                                                     | Ampicillin Sodium                       |                    |                    | C               |                                                            |                      |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                                                            | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 16-Jul-2016                                                                                                         | 12563795                                | EXPEDITED (15-DAY) |                    | HO, OT          | AU-MACLEODS<br>PHARMACEUTICALS<br>US LTD-<br>MAC2016002905 |                      |                 | Unknown              | AUS            |
| <u>Preferred Term</u>                                                                                               | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Electrocardiogram Qt<br>Prolonged; Hypokalaemia;<br>Hypomagnesaemia;<br>Orthostatic Hypotension;<br>Poisoning       | Escitalopram Oxalate                    |                    |                    | S               | Unknown                                                    | 10 Mg, Qd            |                 | Macleods             |                |
|                                                                                                                     | Pantoprazole                            |                    |                    | S               | Unknown                                                    | Unk                  |                 | Macleods             |                |
|                                                                                                                     | Rosuvastatin                            |                    |                    | S               | Unknown                                                    | Unk                  |                 | Not Reported         |                |
|                                                                                                                     | Atenolol                                |                    |                    | S               | Unknown                                                    | Unk                  |                 | Not Reported         |                |
|                                                                                                                     | Lercanidipine                           |                    |                    | S               | Unknown                                                    | Unk                  |                 | Not Reported         |                |
|                                                                                                                     | Perindopril                             |                    |                    | S               | Unknown                                                    | Unk                  |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                                                            | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 18-Jul-2016                                                                                                         | 11841133                                | EXPEDITED (15-DAY) |                    | DE, OT          | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>BMS-2015-087890     |                      | 16 YR           | Male                 | USA            |
| <u>Preferred Term</u>                                                                                               | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Completed Suicide;<br>Intentional Overdose                                                                          | Paracetamol                             |                    |                    | S               | Unknown                                                    |                      |                 | Bristol Myers Squibb |                |

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|                 |   |         |                      |
|-----------------|---|---------|----------------------|
| Hydrocodone     | S | Unknown | Bristol Myers Squibb |
| Aripiprazole    | S | Unknown | Bristol Myers Squibb |
| Escitalopram    | S | Unknown | Not Reported         |
| Cyclobenzaprine | S | Unknown | Not Reported         |
| Morphine        | S | Unknown | Not Reported         |

| <u>FDA Received Date</u>                      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 18-Jul-2016                                   | 12520705       | EXPEDITED (15-DAY) |                    | HO              | US-WEST-WARD<br>PHARMACEUTICALS<br>CORP.-US-H14001-16-01 |                      | 45 YR           | Female       | USA            |
| <u>Preferred Term</u>                         | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Reversible Cerebral Vasoconstriction Syndrome | Escitalopram   |                    |                    | S               | Unknown                                                  |                      |                 | Hikma        |                |
|                                               | Estrogen Nos   |                    |                    | S               | Unknown                                                  |                      |                 | Not Reported |                |
|                                               | Trazodone      |                    |                    | C               | Unknown                                                  |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                          | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|-------------------------|----------------------|-----------------|--------------|----------------|
| 18-Jul-2016                                                                                       | 12546509       | EXPEDITED (15-DAY) |                    | HO              | DK-TAKEDA-2016TUS011790 |                      | 73 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                             | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Confusional State; Drug Ineffective; Feeling Abnormal; Limb Discomfort; Muscle Spasms | Brintellix     |                    |                    | S               | Unknown                 | 5 Mg, Unk            |                 | Takeda       |                |
|                                                                                                   | Escitalopram   |                    |                    | S               | Unknown                 | Unk                  |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|-------------------------|----------------------|-----------------|--------------|----------------|
| 18-Jul-2016              | 12554768       | EXPEDITED (15-DAY) |                    |                 | CA-TAKEDA-2016TUS012216 |                      | 37 YR           | Female       | CAN            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Adverse Event            | Trintellix     |                    |                    | S               | Oral                    | 10 Mg, Qd            |                 | Takeda       |                |
|                          | Cipralext      |                    |                    | S               | Unknown                 | Unk                  |                 | Not Reported |                |

# FDA Adverse Event Reporting System

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### Detailed Report

| <u>FDA Received Date</u>                 | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------|--------------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|-----------------|--------------|----------------|
| 18-Jul-2016                              | 12564976           | EXPEDITED (15-DAY) |                    | HO              | IT-ACCORD-042357                |                      | 40 YR           | Male         | ITA            |
| <u>Preferred Term</u>                    | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Drug Abuse                      | Escitalopram       |                    |                    | S               | Oral                            |                      |                 | Accord       |                |
| <u>FDA Received Date</u>                 | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Jul-2016                              | 12565022           | EXPEDITED (15-DAY) |                    | OT              | IT-AUROBINDO-AUR-APL-2016-09314 |                      | 78 YR           | Female       | ITA            |
| <u>Preferred Term</u>                    | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Pemphigoid                               | Escitalopram 10 Mg |                    |                    | S               | Unknown                         | 10 Mg, Unk           |                 | Aurobindo    |                |
| <u>FDA Received Date</u>                 | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Jul-2016                              | 12565399           | EXPEDITED (15-DAY) |                    | OT              | PHHY2016AU096174                |                      | 35 YR           | Male         | AUS            |
| <u>Preferred Term</u>                    | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Accident; Drug Interaction; Somnambulism | Zolpidem           |                    |                    | S               | Unknown                         |                      |                 | Novartis     |                |
|                                          | Escitalopram       |                    |                    | S               | Unknown                         |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                 | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Jul-2016                              | 12567220           | EXPEDITED (15-DAY) |                    | OT              | SE-TEVA-675678ISR               |                      | 52 YR           | Female       | SWE            |
| <u>Preferred Term</u>                    | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypoaesthesia Oral; Pharyngeal Oedema    | Escitalopram       |                    |                    | S               | Oral                            |                      |                 | Ivax         |                |
| <u>FDA Received Date</u>                 | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Jul-2016                              | 12567222           | EXPEDITED (15-DAY) |                    | OT              | SE-TEVA-675733ISR               |                      | 77 YR           | Female       | SWE            |
| <u>Preferred Term</u>                    | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|                                          |                    |                    |                    |                 |                                 |                      |                 |              |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                              |                    |                    |                    |                 |                      |                        |                 |              |                |
|------------------------------|--------------------|--------------------|--------------------|-----------------|----------------------|------------------------|-----------------|--------------|----------------|
| Hypoacusis                   |                    | Escitalopram       |                    | S               | Oral                 |                        | Ivax            |              |                |
| <u>FDA Received Date</u>     | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Jul-2016                  | 12570116           | DIRECT             |                    | HO              |                      |                        | 67 YR           | Female       | USA            |
| <u>Preferred Term</u>        | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Calcium Decreased;     | Omeprazole, 20 Mg  |                    |                    | S               | Oral                 | 90 Capsule(S) In The   |                 | Not Reported |                |
| Blood Potassium              |                    |                    |                    |                 |                      | Morning Taken By Mouth |                 |              |                |
| Decreased; Contusion;        | Escitalopram, 10mg |                    |                    | S               | Oral                 | 90 Tablet(S) In The    |                 | Not Reported |                |
| Foot Fracture; Impaired      |                    |                    |                    |                 |                      | Morning Taken By Mouth |                 |              |                |
| Driving Ability; Lip Injury; | Lexapro            |                    |                    | C               |                      |                        |                 | Not Reported |                |
| Road Traffic Accident;       | Omeprazole         |                    |                    | C               |                      |                        |                 | Not Reported |                |
| Seizure; Skin Laceration     | Vitamin C          |                    |                    | C               |                      |                        |                 | Not Reported |                |
|                              | D3                 |                    |                    | C               |                      |                        |                 | Not Reported |                |
|                              | Bcompex            |                    |                    | C               |                      |                        |                 | Not Reported |                |
|                              | Calcium            |                    |                    | C               |                      |                        |                 | Not Reported |                |
| <u>FDA Received Date</u>     | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Jul-2016                  | 12336751           | EXPEDITED (15-DAY) |                    | OT              | CA-FRI-1000084380    |                        |                 | Female       | CAN            |
| <u>Preferred Term</u>        | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Contusion; Diarrhoea;        | Escitalopram       |                    |                    | S               |                      | 20 Mg                  |                 | Forest       |                |
| Haematochezia;               | Flurazepam         |                    |                    | C               |                      | 7.5 Mg                 |                 | Not Reported |                |
| Haematochezia                | Omega 3            |                    |                    | C               |                      |                        |                 | Not Reported |                |
|                              | Vitamin C          |                    |                    | C               |                      | 250 Mg                 |                 | Not Reported |                |
| <u>FDA Received Date</u>     | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Jul-2016                  | 12520109           | EXPEDITED (15-DAY) |                    | HO, OT          | US-FRI-1000085735    |                        | 45 YR           | Female       | USA            |
| <u>Preferred Term</u>        | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Reversible Cerebral          | Escitalopram       |                    |                    | S               | Unknown              |                        |                 | Forest       |                |
| Vasoconstriction             | Estrogens          |                    |                    | S               | Unknown              |                        |                 | Not Reported |                |
| Syndrome                     | Trazodone          |                    |                    | C               | Unknown              |                        |                 | Not Reported |                |



# FDA Adverse Event Reporting System

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| <u>FDA Received Date</u>                   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------------------------------|----------------------|-----------------|--------------|----------------|
| 19-Jul-2016                                | 12546261             | EXPEDITED (15-DAY) |                    | OT              | IT-TEVA-674867ISR                            |                      | 78 YR           | Female       | ITA            |
| <u>Preferred Term</u>                      | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Pemphigoid                                 | Escitalopram         |                    |                    | S               |                                              | 10 Milligram Daily;  |                 | Ivax         |                |
| <u>FDA Received Date</u>                   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Jul-2016                                | 12568499             | EXPEDITED (15-DAY) |                    | OT              | IT-JUBILANT<br>GENERICIS LIMITED-<br>1055224 |                      | 78 YR           | Female       | ITA            |
| <u>Preferred Term</u>                      | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Pemphigoid                                 | Escitalopram Oxalate |                    |                    | S               |                                              |                      |                 | Jubilant     |                |
| <u>FDA Received Date</u>                   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Jul-2016                                | 12569923             | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000086190                            |                      |                 | Female       | FRA            |
| <u>Preferred Term</u>                      | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Neutropenia                                | Escitalopram         |                    |                    | S               | Oral                                         |                      |                 | Forest       |                |
|                                            | Inexium              |                    |                    | S               | Unknown                                      |                      |                 | Not Reported |                |
|                                            | Lysanxia             |                    |                    | S               | Unknown                                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Jul-2016                                | 12571397             | EXPEDITED (15-DAY) |                    | OT              | IT-MYLANLABS-<br>2016M1029817                |                      |                 | Unknown      | ITA            |
| <u>Preferred Term</u>                      | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Abuse; Intentional<br>Overdose; Sopor | Mirtazapine          |                    |                    | S               | Oral                                         | 20 Df, Total         |                 | Not Reported |                |
|                                            | Sertraline           |                    |                    | S               | Oral                                         | 25 Df, Total         |                 | Not Reported |                |
|                                            | Escitalopram         |                    |                    | S               | Oral                                         | 10 Gtt, Total        |                 | Not Reported |                |
|                                            | Samyr /00882301/     |                    |                    | S               | Oral                                         | 1 Df, Total          |                 | Mylan        |                |
|                                            | Zolpidem             |                    |                    | S               | Oral                                         | 20 Df, Total         |                 | Mylan        |                |

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| <u>FDA Received Date</u>                                                                                                                       | <u>Case #</u>                                                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>        | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|--------------------|--------------------|-----------------|-----------------------------|----------------------|-----------------|--------------|----------------|
| 19-Jul-2016                                                                                                                                    | 12573225                                                                    | DIRECT             |                    | OT              |                             |                      | 41 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                          | <u>Product</u>                                                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Diarrhoea; Nausea;<br>Product Measured<br>Potency Issue; Product<br>Size Issue                                                                 | Escitalopram                                                                |                    |                    | S               | Oral                        |                      |                 | Aurobindo    |                |
| <u>FDA Received Date</u>                                                                                                                       | <u>Case #</u>                                                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>        | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Jul-2016                                                                                                                                    | 12549764                                                                    | EXPEDITED (15-DAY) |                    | DE, HO          | AR-BAXTER-<br>2016BAX035857 |                      | 80 YR           | Male         | ARG            |
| <u>Preferred Term</u>                                                                                                                          | <u>Product</u>                                                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anal Incontinence; Death;<br>Decreased Appetite;<br>Diarrhoea; Fall; Gait<br>Disturbance; Hypotension;<br>Peritonitis; Urinary<br>Incontinence | Dianeal Pd2 / Solución Para<br>Diálisis Peritoneal, Dextrosa,<br>Cloruro De |                    |                    | S               | Intraperitoneal             |                      |                 | Baxter       |                |
|                                                                                                                                                | Dianeal Pd2 / Solución Para<br>Diálisis Peritoneal, Dextrosa,<br>Cloruro De |                    |                    | S               |                             |                      |                 | Baxter       |                |
|                                                                                                                                                | Escitalopram                                                                |                    |                    | S               | Oral                        |                      |                 | Not Reported |                |
|                                                                                                                                                | Amiodarone                                                                  |                    |                    | S               | Oral                        |                      |                 | Not Reported |                |
|                                                                                                                                                | Folic Acid                                                                  |                    |                    | C               | Oral                        |                      |                 | Not Reported |                |
|                                                                                                                                                | B Complex                                                                   |                    |                    | C               | Oral                        |                      |                 | Not Reported |                |
|                                                                                                                                                | Rosuvastatin                                                                |                    |                    | C               | Oral                        |                      |                 | Not Reported |                |
|                                                                                                                                                | Trimebutine                                                                 |                    |                    | C               | Oral                        |                      |                 | Not Reported |                |
|                                                                                                                                                | Simethicone                                                                 |                    |                    | C               | Oral                        |                      |                 | Not Reported |                |
|                                                                                                                                                | Amiodarone                                                                  |                    |                    | C               | Oral                        |                      |                 | Not Reported |                |
|                                                                                                                                                | Aspirin                                                                     |                    |                    | C               | Oral                        |                      |                 | Not Reported |                |
|                                                                                                                                                | Escitalopram                                                                |                    |                    | C               | Oral                        |                      |                 | Not Reported |                |
|                                                                                                                                                | Leuprolide                                                                  |                    |                    | C               | Unknown                     |                      |                 | Not Reported |                |
|                                                                                                                                                | Ranitidine                                                                  |                    |                    | C               | Oral                        |                      |                 | Not Reported |                |
|                                                                                                                                                | Erythropoietin                                                              |                    |                    | C               | Subcutaneous                |                      |                 | Not Reported |                |

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Red Blood Cells

C

Unknown

Not Reported

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------------------------------------|----------------------|------------|------------|----------------|
| 20-Jul-2016              | 12572879      | EXPEDITED (15-DAY) |                    | HO, OT          | US-MACLEODS<br>PHARMACEUTICALS<br>US LTD-<br>MAC2016002908 |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>                                                     | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Autoimmune Hepatitis;<br>Liver Function Test<br>Increased; Ocular Icterus | Escitalopram Oxalate |              |            | S           | Unknown      | Unk                |                 | Macleods     |
|                                                                           | Escitalopram Oxalate |              |            | S           | Unknown      | Unk                |                 | Macleods     |
|                                                                           | Zolpidem             |              |            | C           | Unknown      | Unk                |                 | Not Reported |
|                                                                           | Lorazepam            |              |            | C           | Unknown      | Unk                |                 | Not Reported |
|                                                                           | Fexofenadine         |              |            | C           | Unknown      | Unk                |                 | Not Reported |
|                                                                           | Diazepam             |              |            | C           | Unknown      | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------|----------------------|------------|------------|----------------|
| 20-Jul-2016              | 12573058      | EXPEDITED (15-DAY) |                    | HO              | IT-AUROBINDO-AUR-<br>APL-2016-09017 |                      | 40 YR      | Male       | ITA            |

| <u>Preferred Term</u> | <u>Product</u>                      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|-------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Anxiety; Drug Abuse   | Escitalopram Film-Coated<br>Tablets |              |            | S           | Oral         | 300 Mg, Total      |                 | Aurobindo  |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Jul-2016              | 12577815      | DIRECT           | Y                  | OT              |                      |                      | 15 YR      | Female     | USA            |

| <u>Preferred Term</u>                                         | <u>Product</u>                          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------|-----------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Behaviour<br>Disorder; Product<br>Substitution Issue | Escitalopram, 10mg Accord<br>Healthcare |              |            | S           | Oral         |                    |                 | Accord       |
|                                                               | Risperidone                             |              |            | C           |              |                    |                 | Not Reported |
|                                                               | Dexmethylphenidate                      |              |            | C           |              |                    |                 | Not Reported |
|                                                               | Methylphenidate                         |              |            | C           |              |                    |                 | Not Reported |

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| <u>FDA Received Date</u>                                                                | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u>                          | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|-----------------------------------------------------------------------------------------|------------------------------|--------------------|--------------------|-----------------|--------------------------------------------------------|-----------------------------------------------|-----------------|----------------------|----------------|
| 20-Jul-2016                                                                             | 12578070                     | DIRECT             |                    |                 |                                                        |                                               | 53 YR           | Male                 | USA            |
| <u>Preferred Term</u>                                                                   | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                           | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u>           |                |
| Anxiety; Fatigue;<br>Hallucination, Auditory;<br>Nervousness; Restless<br>Legs Syndrome | Escitalopram Tab 20mg, 20 Mg |                    |                    | S               | Oral                                                   | 30 Tablet(S) In The<br>Morning Taken By Mouth | 6 WEEK          | Camber               |                |
|                                                                                         | Norvir                       |                    |                    | C               |                                                        |                                               |                 | Not Reported         |                |
|                                                                                         | Truvada                      |                    |                    | C               |                                                        |                                               |                 | Not Reported         |                |
|                                                                                         | Prezista                     |                    |                    | C               |                                                        |                                               |                 | Not Reported         |                |
|                                                                                         | Wellbutrin Sr                |                    |                    | C               |                                                        |                                               |                 | Not Reported         |                |
|                                                                                         | Escitalopram                 |                    |                    | C               |                                                        |                                               |                 | Not Reported         |                |
|                                                                                         | Cpap                         |                    |                    | C               |                                                        |                                               |                 | Not Reported         |                |
|                                                                                         | Multi-Vitamin                |                    |                    | C               |                                                        |                                               |                 | Not Reported         |                |
|                                                                                         | Pre-Biotic                   |                    |                    | C               |                                                        |                                               |                 | Not Reported         |                |
|                                                                                         | Pro-Biotic                   |                    |                    | C               |                                                        |                                               |                 | Not Reported         |                |
|                                                                                         | Melatonin                    |                    |                    | C               |                                                        |                                               |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                                | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u>                          | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 21-Jul-2016                                                                             | 12017039                     | NON-EXPEDITED      |                    |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>BMS-2016-009165 |                                               |                 | Unknown              | USA            |
| <u>Preferred Term</u>                                                                   | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                           | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u>           |                |
| Off Label Use                                                                           | Abilify                      |                    |                    | S               | Unknown                                                |                                               |                 | Bristol Myers Squibb |                |
|                                                                                         | Escitalopram                 |                    |                    | S               | Unknown                                                |                                               |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                                | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u>                          | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 21-Jul-2016                                                                             | 12184833                     | EXPEDITED (15-DAY) |                    | HO              | IT-FRI-1000083124                                      |                                               | 78 YR           | Female               | ITA            |
| <u>Preferred Term</u>                                                                   | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                           | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u>           |                |
| Pemphigoid                                                                              | Escitalopram                 |                    |                    | S               | Unknown                                                | 10 Mg                                         |                 | Forest               |                |
| <u>FDA Received Date</u>                                                                | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u>                          | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 21-Jul-2016                                                                             | 12379063                     | EXPEDITED (15-DAY) |                    | OT              | CA-FRI-1000084615                                      |                                               |                 | Female               | CAN            |

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| <u>Preferred Term</u>                                                                             | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------------------------------------------------------|------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Hot Flush; Seizure                                                                                | Escitalopram     |                    |                    | S               |                      |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                          | <u>Case #</u>    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Jul-2016                                                                                       | 12568944         | EXPEDITED (15-DAY) |                    | HO              | DK-ACCORD-042319     |                      | 73 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                             | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Confusional State; Drug Ineffective; Feeling Abnormal; Limb Discomfort; Muscle Spasms | Escitalopram     |                    |                    | S               |                      |                      |                 | Accord       |                |
|                                                                                                   | Brintellix       |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                          | <u>Case #</u>    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Jul-2016                                                                                       | 12579600         | EXPEDITED (15-DAY) |                    | HO              | JP-FRI-1000082182    |                      | 32 YR           | Female       | JPN            |
| <u>Preferred Term</u>                                                                             | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Off Label Use; Pregnancy; Premature Labour                                                        | Lexapro          |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                                                                                   | Lexapro          |                    |                    | S               |                      |                      |                 | Forest       |                |
|                                                                                                   | Depas (Etizolam) |                    |                    | S               | Oral                 | 4.5 Mg               |                 | Not Reported |                |
|                                                                                                   | Magmitt          |                    |                    | C               |                      | 1500 Mg              |                 | Not Reported |                |
|                                                                                                   | Famotidine       |                    |                    | C               | Oral                 | 20 Mg                |                 | Not Reported |                |
|                                                                                                   | Ritodrine        |                    |                    | C               | Intravenous drip     |                      |                 | Not Reported |                |
|                                                                                                   | Racol            |                    |                    | C               | Unknown              |                      |                 | Not Reported |                |
|                                                                                                   | Medicon          |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                          | <u>Case #</u>    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Jul-2016                                                                                       | 12579608         | EXPEDITED (15-DAY) |                    | DE              | FR-FRI-1000086164    |                      | 66 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                             | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Completed Suicide; Intentional                                                    | Escitalopram     |                    |                    | S               | Oral                 |                      |                 | Forest       |                |
|                                                                                                   | Stilnox          |                    |                    | S               | Unknown              |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|          |                                                   |   |         |              |
|----------|---------------------------------------------------|---|---------|--------------|
| Overdose | Propafenone Hydrochloride                         | S | Unknown | Not Reported |
|          | Stagid                                            | S | Oral    | Not Reported |
|          | Diamicron                                         | S | Oral    | Not Reported |
|          | Noctamide                                         | S | Oral    | Not Reported |
|          | Lexomil                                           | S | Oral    | Not Reported |
|          | Spasfon (Phloroglucinol, Trimethylphloroglucinol) | C | Unknown | Not Reported |
|          | Dafalgan                                          | C | Unknown | Not Reported |
|          | Meteoxane                                         | C | Unknown | Not Reported |
|          | Fortum                                            | C | Unknown | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Jul-2016              | 12579617      | EXPEDITED (15-DAY) |                    | OT              | JP-FRI-1000086249    |                      | 56 YR      | Male       | JPN            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Eructation            | Lexapro        |              |            | S           | Oral         |                    |                 | Forest       |
|                       | Reflex         |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Peroric        |              |            | C           | Oral         | 9 Df               |                 | Not Reported |
|                       | Famotidine     |              |            | C           | Unknown      |                    |                 | Not Reported |
|                       | Lyrica         |              |            | C           | Oral         | 4 Df               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Jul-2016              | 12580160      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000086240    |                      | 81 YR      | Male       | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cerebral Haematoma    | Escitalopram   |              |            | S           | Oral         | 1 Df               |                 | Forest       |
|                       | Xarelto        |              |            | S           | Oral         | 20 Mg              |                 | Not Reported |
|                       | Kardegic       |              |            | S           | Oral         | 75 Mg              |                 | Not Reported |
|                       | Lasilix        |              |            | S           | Oral         | 40 Mg              |                 | Not Reported |
|                       | Spiriva        |              |            | C           | Unknown      |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|            |   |         |              |
|------------|---|---------|--------------|
| Cordarone  | C | Unknown | Not Reported |
| Bisoprolol | C | Unknown | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 21-Jul-2016              | 12580283      | EXPEDITED (15-DAY) |                    | HO, LT          | CA-ASTRAZENECA-2016SE78065 |                      | 39 YR      | Male       | CAN            |

| <u>Preferred Term</u>                                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Overdose; Potentiating Drug Interaction; Serotonin Syndrome | Quetiapine     |              |            | S           | Oral         |                    |                 | Zeneca       |
|                                                             | Bupropion      |              |            | S           |              |                    |                 | Not Reported |
|                                                             | Escitalopram   |              |            | S           |              |                    |                 | Not Reported |
|                                                             | Olanzapine     |              |            | S           |              |                    |                 | Not Reported |
|                                                             | Primidone      |              |            | S           |              |                    |                 | Not Reported |
|                                                             | Phenytoin      |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Jul-2016              | 12580822      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000086239    |                      | 81 YR      | Male       | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Haematuria            | Escitalopram   |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                       | Xarelto        |              |            | S           | Oral         | 20 Mg              |                 | Not Reported |
|                       | Kardegic       |              |            | S           | Oral         | 1 Dosage Forms     |                 | Not Reported |
|                       | Cardensiel     |              |            | C           | Unknown      |                    |                 | Not Reported |
|                       | Lasilix        |              |            | C           | Unknown      |                    |                 | Not Reported |
|                       | Atacand        |              |            | C           | Unknown      |                    |                 | Not Reported |
|                       | Inexium        |              |            | C           | Unknown      |                    |                 | Not Reported |
|                       | Spiriva        |              |            | C           | Unknown      |                    |                 | Not Reported |
|                       | Crestor        |              |            | C           | Unknown      |                    |                 | Not Reported |
|                       | Cordarone      |              |            | C           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Jul-2016              | 12581177      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000086241    |                      | 78 YR      | Female     | FRA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                                                 | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------------------------------------------------------------------------|---------------------|--------------------|--------------------|-----------------|------------------------------------------|----------------------|-----------------|--------------|----------------|
| Cerebral Haematoma;<br>Hemianopia; Hemiparesis                                                        | Escitalopram        |                    |                    | S               | Oral                                     | 5 Mg                 |                 | Forest       |                |
|                                                                                                       | Kardegic            |                    |                    | S               | Oral                                     | 160 Mg               |                 | Not Reported |                |
|                                                                                                       | Tahor               |                    |                    | C               | Oral                                     | 40 Mg                |                 | Not Reported |                |
|                                                                                                       | Temerit             |                    |                    | C               | Oral                                     | 2.5 Mg               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                              | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Jul-2016                                                                                           | 12582280            | DIRECT             |                    |                 |                                          |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                 | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Arterial Occlusive<br>Disease; Drug Resistance;<br>Palpitations; Sleep Terror                         | Escitalopram 20 Mg  |                    |                    | S               |                                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                              | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Jul-2016                                                                                           | 12424587            | EXPEDITED (15-DAY) |                    | HO              | FR-PFIZER INC-<br>2016277695             |                      | 77 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                 | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Acute Kidney Injury;<br>Dehydration; Diarrhoea;<br>Fatigue; Hyponatraemia;<br>Renal Failure; Vomiting | Paclitaxel Hospira  |                    |                    | S               | Intravenous (not<br>otherwise specified) | 60 Mg/M2, Cyclic     |                 | Pfizer       |                |
|                                                                                                       | Hydrochlorothiazide |                    |                    | S               | Oral                                     | 1 Df, 1x/Day         |                 | Not Reported |                |
|                                                                                                       | Telmisartan         |                    |                    | S               | Oral                                     | 1 Df, 1x/Day         |                 | Not Reported |                |
|                                                                                                       | Heptamyl            |                    |                    | S               | Oral                                     | 187.8 Mg, 3x/Day     |                 | Not Reported |                |
|                                                                                                       | Escitalopram        |                    |                    | S               | Oral                                     | 5 Mg, 1x/Day         |                 | Not Reported |                |
|                                                                                                       | Zopiclone           |                    |                    | C               |                                          | Unk                  |                 | Not Reported |                |
|                                                                                                       | Paracetamol         |                    |                    | C               |                                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                              | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Jul-2016                                                                                           | 12535474            | EXPEDITED (15-DAY) |                    | HO, OT          | US-ACCORD-042141                         |                      | 45 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                 | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| Reversible Cerebral Vasoconstriction Syndrome                           | Escitalopram       |                    | S                  |                 |                                 |                      |                 |              | Accord         |
|-------------------------------------------------------------------------|--------------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|-----------------|--------------|----------------|
|                                                                         | Estrogen Nos       |                    | S                  |                 |                                 |                      |                 |              | Not Reported   |
|                                                                         | Trazodone          |                    | C                  |                 |                                 |                      |                 |              | Not Reported   |
| <u>FDA Received Date</u>                                                | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Jul-2016                                                             | 12549093           | EXPEDITED (15-DAY) |                    | HO, OT          | US-AUROBINDO-AUR-APL-2016-08931 |                      | 45 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                   | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Reversible Cerebral Vasoconstriction Syndrome                           | Escitalopram       |                    |                    | S               | Unknown                         | Unk                  |                 | Aurobindo    |                |
|                                                                         | Estrogen Nos       |                    |                    | S               | Unknown                         |                      |                 | Not Reported |                |
|                                                                         | Trazodone          |                    |                    | C               | Unknown                         |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Jul-2016                                                             | 12583109           | EXPEDITED (15-DAY) |                    | OT              | AU-APOTEX-2016AP009798          |                      | 35 YR           | Male         | AUS            |
| <u>Preferred Term</u>                                                   | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Accident; Drug Interaction; Sleep-Related Eating Disorder; Somnambulism | Chemmart Zolpidem  |                    |                    | S               | Unknown                         |                      |                 | Apotex       |                |
|                                                                         | Escitalopram       |                    |                    | S               | Unknown                         |                      |                 | Apotex       |                |
| <u>FDA Received Date</u>                                                | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Jul-2016                                                             | 12586233           | DIRECT             | Y                  | OT              |                                 |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                   | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dyspnoea; Nausea; Swelling                                              | Escitalopram, 10mg |                    |                    | S               | Oral                            |                      |                 | Not Reported |                |
|                                                                         | Escitalopram       |                    |                    | C               |                                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Jul-2016                                                             | 12585103           | EXPEDITED (15-DAY) |                    | HO              | US-ACCORD-042599                |                      | 67 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                   | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Autoimmune Hepatitis                                                    | Escitalopram       |                    |                    | S               |                                 | In May-2015, Her     |                 | Accord       |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Diazepam  
Lorazepam  
Zolpidem  
Fexofenadine/Hydrochloride

C  
C  
C  
C

Psychiatrist Restarted  
Antidepressant Treatment  
With Escitalopram 10 Mg  
For 5 Days

Not Reported  
Not Reported  
Not Reported  
Not Reported

| <u>FDA Received Date</u>                | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------|--------------------------|--------------------|--------------------|-----------------|----------------------------|-------------------------------------|-----------------|--------------|----------------|
| 25-Jul-2016                             | 12572182                 | EXPEDITED (15-DAY) |                    | OT              | IT-PFIZER INC-2016347528   |                                     | 25 YR           | Female       | ITA            |
| <u>Preferred Term</u>                   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Abuse; Overdose; Somnolence; Sopor | Sertraline Hcl           |                    |                    | S               | Oral                       | 25 Df, Total                        |                 | Pfizer       |                |
|                                         | Samyr /00882301/         |                    |                    | S               | Oral                       | 1 Df, Total                         |                 | Not Reported |                |
|                                         | Zolpidem                 |                    |                    | S               | Oral                       | 20 Df, Total                        |                 | Not Reported |                |
|                                         | Mirtazapine              |                    |                    | S               | Oral                       | 20 Df, Total                        |                 | Not Reported |                |
|                                         | Escitalopram             |                    |                    | S               | Oral                       | 10 Drops, Total                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Jul-2016                             | 12581809                 | EXPEDITED (15-DAY) |                    | OT              | IT-009507513-1607ITA008429 |                                     | 25 YR           | Female       | ITA            |
| <u>Preferred Term</u>                   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Abuse; Sopor                       | Mirtazapine              |                    |                    | S               | Oral                       | Total: 20 Dose Unit                 |                 | Merck        |                |
|                                         | Samyr                    |                    |                    | S               | Oral                       | 400 Mg, Total: 1 Dose Unit          |                 | Not Reported |                |
|                                         | Zolpidem                 |                    |                    | S               | Oral                       | Total: 20 Dose Units                |                 | Not Reported |                |
|                                         | Sertraline Hydrochloride |                    |                    | S               | Oral                       | Total: 25 Dose Units                |                 | Not Reported |                |
|                                         | Escitalopram             |                    |                    | S               | Oral                       | Total: 10 Drops, Formulation: Drops |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>            | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------|--------------------|--------------------|--------------------|-----------------|-------------------------|-------------------------------|-----------------|--------------|----------------|
| 25-Jul-2016                         | 12585906           | NON-EXPEDITED      |                    | OT              | US-TAKEDA-2016TUS012732 |                               |                 | Female       | USA            |
| <u>Preferred Term</u>               | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Nausea; Serotonin Syndrome          | Trintellix         |                    |                    | S               | Oral                    | 5 Mg, Qd                      |                 | Takeda       |                |
|                                     | Lexapro            |                    |                    | S               | Oral                    | 10 Mg, Unk                    |                 | Not Reported |                |
| <u>FDA Received Date</u>            | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Jul-2016                         | 12585936           | EXPEDITED (15-DAY) |                    | OT              | IT-ACCORD-042650        |                               | 25 YR           | Female       | ITA            |
| <u>Preferred Term</u>               | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Abuse; Sopor                   | Escitalopram       |                    |                    | S               | Oral                    |                               |                 | Accord       |                |
|                                     | Sertraline         |                    |                    | S               | Oral                    |                               |                 | Accord       |                |
|                                     | Samyr Bgp Products |                    |                    | S               | Oral                    | Strength: 400 Mg              |                 | Not Reported |                |
|                                     | Zolpidem           |                    |                    | S               | Oral                    |                               |                 | Not Reported |                |
|                                     | Mirtazapine        |                    |                    | S               | Oral                    |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>            | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Jul-2016                         | 12585953           | EXPEDITED (15-DAY) |                    | OT              | SA-ACCORD-042607        |                               | 28 YR           | Female       | SAU            |
| <u>Preferred Term</u>               | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Alopecia; Gastrointestinal Disorder | Escitalopram       |                    |                    | S               |                         | Escitalopram Up To 10 Mg/ Day |                 | Accord       |                |
| <u>FDA Received Date</u>            | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Jul-2016                         | 12586258           | NON-EXPEDITED      |                    |                 | US-JAZZ-2016-US-002302  |                               |                 | Female       | USA            |
| <u>Preferred Term</u>               | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Feeling Abnormal        | Xyrem              |                    |                    | S               | Oral                    | 2.25 G, Bid                   |                 | Jazz         |                |
|                                     | Xyrem              |                    |                    | S               | Oral                    | Dose Adjustments              |                 | Jazz         |                |

**FDA Adverse Event Reporting System  
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|                     |   |             |              |
|---------------------|---|-------------|--------------|
| Xyrem               | S | 3.75 G, Bid | Jazz         |
| Wellbutrin          | S |             | Not Reported |
| Lexapro             | S |             | Not Reported |
| Ramipril            | C | Unk         | Not Reported |
| Synthroid           | C | Unk         | Not Reported |
| Citracal + D        | C | Unk         | Not Reported |
| Multivitamins       | C | Unk         | Not Reported |
| Vitamin C           | C | Unk         | Not Reported |
| Allegra Allergy     | C | Unk         | Not Reported |
| Delsym              | C | Unk         | Not Reported |
| Claritin            | C | Unk         | Not Reported |
| Cod Liver Oil       | C | Unk         | Not Reported |
| Mucinex Dm          | C | 1200-60 Mg  | Not Reported |
| Losartan Potassium  | C | Unk         | Not Reported |
| Vitamin B-12        | C | Unk         | Not Reported |
| Bupropion Hcl       | C | Unk         | Not Reported |
| Potassium Cl        | C | Unk         | Not Reported |
| Escitalopram        | C | Unk         | Not Reported |
| Nuvigil             | C | Unk         | Not Reported |
| Spironolactone      | C | Unk         | Not Reported |
| Vitamin D3          | C | Unk         | Not Reported |
| Amlodipine Besylate | C | Unk         | Not Reported |
| Fenofibrate         | C | Unk         | Not Reported |
| Hydroxychloroquine  | C | Unk         | Not Reported |
| Welchol             | C | Unk         | Not Reported |
| Hydrocortisone      | C | 10 Mg, Unk  | Not Reported |
| Hydrocortisone      | C | 5 Mg, Unk   | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 25-Jul-2016              | 12586528      | NON-EXPEDITED    |                    |                 | US-PFIZER INC-<br>2016322725 |                      | 65 YR      | Female     | USA            |

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| <u>Preferred Term</u>                                                                                                   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                     | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|-------------------------------------------------|--------------------------------------------------------|-----------------|--------------|----------------|
| Disease Progression;<br>Fibromyalgia                                                                                    | Menest         |                    |                    | S               |                                                 | 0.3 Mg                                                 |                 | Pfizer       |                |
|                                                                                                                         | Menest         |                    |                    | S               |                                                 |                                                        |                 | Pfizer       |                |
|                                                                                                                         | Menest         |                    |                    | S               |                                                 |                                                        |                 | Pfizer       |                |
|                                                                                                                         | Oxycodone      |                    |                    | S               |                                                 | 5-325 Tab Half In The Morning, Half At Night As Needed |                 | Not Reported |                |
|                                                                                                                         | Escitalopram   |                    |                    | S               |                                                 | 30mg A Day                                             |                 | Not Reported |                |
|                                                                                                                         | Xanax          |                    |                    | C               |                                                 | Unk                                                    |                 | Not Reported |                |
|                                                                                                                         | Alprazolam     |                    |                    | C               | Oral                                            | 0.25 Mg, 2x/Day                                        |                 | Not Reported |                |
|                                                                                                                         | Naproxen       |                    |                    | C               | Oral                                            | 500 Mg, 2x/Day                                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Jul-2016                                                                                                             | 12589337       | EXPEDITED (15-DAY) |                    | HO, OT          | AU-MYLANLABS-2016M1030517                       |                                                        |                 | Unknown      | AUS            |
| <u>Preferred Term</u>                                                                                                   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Electrocardiogram Qt Prolonged; Heart Rate Increased; Hypokalaemia; Hypomagnesaemia; Orthostatic Hypotension; Poisoning | Lercanidipine  |                    |                    | S               |                                                 | Unk                                                    |                 | Not Reported |                |
|                                                                                                                         | Rosuvastatin   |                    |                    | S               |                                                 | Unk                                                    |                 | Not Reported |                |
|                                                                                                                         | Perindopril    |                    |                    | S               |                                                 | Unk                                                    |                 | Not Reported |                |
|                                                                                                                         | Escitalopram   |                    |                    | S               |                                                 | 10 Mg, Qd                                              |                 | Not Reported |                |
|                                                                                                                         | Pantoprazole   |                    |                    | S               |                                                 | Unk                                                    |                 | Not Reported |                |
|                                                                                                                         | Atenolol       |                    |                    | S               |                                                 | Unk                                                    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Jul-2016                                                                                                             | 12590266       | EXPEDITED (15-DAY) |                    | HO              | FR-VALIDUS PHARMACEUTICALS LLC-FR-2016VAL002302 |                                                        | 81 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                                   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Cerebral Haematoma                                                                                                      | Furosemide     |                    |                    | S               | Oral                                            | 1 Df, Qd                                               |                 | Validus      |                |
|                                                                                                                         | Kardegic       |                    |                    | S               | Oral                                            | 1 Df, Qd                                               |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|            |   |      |          |              |
|------------|---|------|----------|--------------|
| Xarelto    | S | Oral | 1 Df, Qd | Not Reported |
| Seroplex   | S | Oral | 1 Df, Qd | Not Reported |
| Spiriva    | C |      | Unk      | Not Reported |
| Cordarone  | C |      | Unk      | Not Reported |
| Bisoprolol | C |      | Unk      | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------------------------|----------------------|------------|------------|----------------|
| 25-Jul-2016              | 12590603      | NON-EXPEDITED    |                    | HO              | ES-LUPIN<br>PHARMACEUTICALS<br>INC.-2016-01164 |                      | 84 YR      | Female     | ESP            |

| <u>Preferred Term</u>                              | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                          | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------|-------------------|--------------|------------|-------------|---------------------------------------|--------------------|-----------------|--------------|
| Electrocardiogram Qt Prolonged; Torsade De Pointes | Amiodarone        |              |            | S           | Intravenous (not otherwise specified) |                    |                 | Not Reported |
|                                                    | Sulpiride         |              |            | S           | Unknown                               |                    |                 | Not Reported |
|                                                    | Escitalopram      |              |            | S           | Unknown                               |                    |                 | Not Reported |
|                                                    | Levofloxacin      |              |            | S           | Unknown                               |                    |                 | Not Reported |
|                                                    | Solifenacin       |              |            | S           | Unknown                               |                    |                 | Not Reported |
|                                                    | Acenocoumarol     |              |            | C           | Unknown                               |                    |                 | Not Reported |
|                                                    | Furosemide        |              |            | C           | Unknown                               |                    |                 | Not Reported |
|                                                    | Candesartan       |              |            | C           | Unknown                               |                    |                 | Not Reported |
|                                                    | Digoxin           |              |            | C           | Unknown                               |                    |                 | Not Reported |
|                                                    | Simvastatin       |              |            | C           | Unknown                               |                    |                 | Not Reported |
|                                                    | Magnesium Sulfate |              |            | C           | Intravenous (not otherwise specified) |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 26-Jul-2016              | 10576664      | EXPEDITED (15-DAY) |                    | OT              | CH-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>21581913 |                      | 28 YR      | Female     | CHE            |

| <u>Preferred Term</u>                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>           |
|---------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------|
| Caesarean Section; Maternal Exposure During | Abilify        |              |            | S           | Oral         | 10 Mg, Qd          |                 | Bristol Myers Squibb |
|                                             | Abilify        |              |            | S           |              |                    |                 | Bristol Myers Squibb |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                     |                     |   |         |           |              |
|-----------------------------------------------------------------------------------------------------|---------------------|---|---------|-----------|--------------|
| Pregnancy; Metrorrhagia;<br>Off Label Use; Premature<br>Delivery; Premature<br>Rupture Of Membranes | Latuda              | S | Unknown | 40 Mg, Qd | Not Reported |
|                                                                                                     | Latuda              | S |         |           | Not Reported |
|                                                                                                     | Cipralext           | S | Oral    | 20 Mg, Qd | Not Reported |
|                                                                                                     | Cipralext           | S |         |           | Not Reported |
|                                                                                                     | Seropram /00582602/ | S | Unknown | 20 Mg, Qd | Not Reported |
|                                                                                                     | Seropram /00582602/ | S |         |           | Not Reported |
|                                                                                                     | Edronax             | S | Oral    | 4 Mg, Qd  | Not Reported |
|                                                                                                     | Edronax             | S |         |           | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>              | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------------------|----------------------|------------|------------|----------------|
| 26-Jul-2016              | 12089311      | EXPEDITED (15-DAY) |                    | OT              | AU-ACTAVIS PTY LTD-<br>2016-03199 |                      | 70 YR      | Female     | AUS            |

| <u>Preferred Term</u>                                                                  | <u>Product</u>                       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------|--------------------------------------|--------------|------------|-------------|--------------|-----------------------------|-----------------|--------------|
| Drug Interaction;<br>Hyponatraemia;<br>Inappropriate Antidiuretic<br>Hormone Secretion | Escitalopram (Unknown)               |              |            | S           | Unknown      | 30 Mg, Daily                |                 | Not Reported |
|                                                                                        | Bupropion Hydrochloride<br>(Unknown) |              |            | S           | Oral         | 75 Mg Po Mane               |                 | Actavis      |
|                                                                                        | Dothiepin /00160401/                 |              |            | S           | Unknown      | Increased To 225 Mg, Unk    |                 | Not Reported |
|                                                                                        | Dothiepin /00160401/                 |              |            | S           | Unknown      | Decreased To 175 Mg,<br>Unk |                 | Not Reported |
|                                                                                        | Ramipril (Unknown)                   |              |            | S           | Unknown      | Unk                         |                 | Watson       |
|                                                                                        | Norfloxacin                          |              |            | C           | Unknown      | 400 Mg, Bid                 |                 | Not Reported |
|                                                                                        | Quetiapine                           |              |            | C           | Unknown      | 400 Mg, Qhs                 |                 | Not Reported |
|                                                                                        | Lamotrigine                          |              |            | C           | Unknown      | 75 Mg, Bid                  |                 | Not Reported |
|                                                                                        | Oestradiol /00045401/                |              |            | C           | Unknown      | Unk                         |                 | Not Reported |
|                                                                                        | Glipizide                            |              |            | C           | Unknown      | Unk                         |                 | Not Reported |
|                                                                                        | Metformin                            |              |            | C           | Unknown      | Unk                         |                 | Not Reported |
|                                                                                        | Lantus                               |              |            | C           | Unknown      | Unk                         |                 | Not Reported |
|                                                                                        | Atorvastatin                         |              |            | C           | Unknown      | Unk                         |                 | Not Reported |
|                                                                                        | Acetylsalicylic Acid                 |              |            | C           | Unknown      | Unk                         |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 26-Jul-2016              | 12380456      | NON-EXPEDITED    |                    |                 | US-PFIZER INC-<br>2016247753 |                      |            | Female     | USA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                           | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
|-----------------------------------------------------------------|----------------------------|--------------------|--------------------|-----------------|--------------------------|------------------------|-----------------|--------------|----------------|
| Drug Hypersensitivity                                           | Benzylpenicillin Potassium |                    |                    | S               |                          |                        |                 | Pfizer       |                |
|                                                                 | Levofloxacin               |                    |                    | S               |                          | Unk                    |                 | Not Reported |                |
|                                                                 | Lexapro                    |                    |                    | S               |                          | Unk                    |                 | Not Reported |                |
|                                                                 | Prednisone                 |                    |                    | S               |                          |                        |                 | Not Reported |                |
|                                                                 | Influenza                  |                    |                    | S               |                          |                        |                 | Not Reported |                |
|                                                                 | Baclofen                   |                    |                    | S               |                          |                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                        | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Jul-2016                                                     | 12535473                   | EXPEDITED (15-DAY) |                    | DE              | PHHY2016TR092498         |                        | 81 YR           | Male         | TUR            |
| <u>Preferred Term</u>                                           | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Lung Infection; Product Use In Unapproved Indication | Rivastigmine               |                    |                    | S               | Transdermal              | 5-10 Cm2/Day           |                 | Not Reported |                |
|                                                                 | Quetiapine                 |                    |                    | S               | Unknown                  | 150 Mg (50-150 Mg), Qd |                 | Novartis     |                |
|                                                                 | Escitalopram               |                    |                    | S               | Oral                     | 15 Mg (10-15 Mg), Qd   |                 | Not Reported |                |
|                                                                 | Melatonin                  |                    |                    | S               | Unknown                  | 3 Mg, Qd               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                        | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Jul-2016                                                     | 12589106                   | EXPEDITED (15-DAY) |                    | OT              | PHHY2016IT098237         |                        | 25 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                           | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Abuse; Sopor                                               | Sertraline                 |                    |                    | S               | Oral                     | 25 Df, Once/Single     |                 | Novartis     |                |
|                                                                 | Zolpidem                   |                    |                    | S               | Oral                     | 20 Df, Once/Single     |                 | Not Reported |                |
|                                                                 | Mirtazapina                |                    |                    | S               | Oral                     | 20 Df, Once/Single     |                 | Not Reported |                |
|                                                                 | Escitalopram               |                    |                    | S               | Oral                     | 10 Gtt, Once/Single    |                 | Not Reported |                |
|                                                                 | Samyr (Ademetionine)       |                    |                    | S               | Oral                     | 400 Mg, Once/Single    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                        | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Jul-2016                                                     | 12593793                   | EXPEDITED (15-DAY) |                    | HO              | FR-PFIZER INC-2016349243 |                        | 84 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                           | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |



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|                                 |             |   |      |               |              |
|---------------------------------|-------------|---|------|---------------|--------------|
| Fall; Hyponatraemia;<br>Vertigo | Zithromax   | S | Oral | 1 Df, 3x/Week | Pfizer       |
|                                 | Seroplex    | S | Oral | 5 Mg, 1x/Day  | Not Reported |
|                                 | Tenstaten   | S | Oral | 50 Mg, 1x/Day | Not Reported |
|                                 | Kardegic    | C |      | Unk           | Not Reported |
|                                 | Temerit     | C |      | Unk           | Not Reported |
|                                 | Fenofibrate | C |      | Unk           | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Jul-2016              | 12597130      | EXPEDITED (15-DAY) |                    | OT              | IT-FRI-1000086349    |                      | 25 YR      | Female     | ITA            |

| <u>Preferred Term</u> | <u>Product</u>                         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Abuse; Sopor     | Escitalopram Oral Solution             |              |            | S           | Oral         |                    |                 | Forest       |
|                       | Sertraline                             |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Mirtazapine                            |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Mirtazapine                            |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Zolpidem                               |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Samyr 400mg Compresse Gastroresistenti |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------------------|----------------------|------------|------------|----------------|
| 26-Jul-2016              | 12598115      | EXPEDITED (15-DAY) |                    | HO, LT, OT      | CA-ELI_LILLY_AND_COMP<br>ANY-CA201607010050 |                      | 39 YR      | Unknown    | CAN            |

| <u>Preferred Term</u>                                                                                                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Alcohol Withdrawal Syndrome; Arrhythmia; Drug Interaction; Hyperthermia; Major Depression; Overdose; Pneumonia; Sepsis; Serotonin Syndrome | Olanzapine     |              |            | S           | Unknown      | Unk, Unknown       |                 | Unknown      |
|                                                                                                                                            | Olanzapine     |              |            | S           | Unknown      | Unk, Unknown       |                 | Unknown      |
|                                                                                                                                            | Primidone      |              |            | S           | Unknown      | Unk, Unknown       |                 | Not Reported |
|                                                                                                                                            | Primidone      |              |            | S           | Unknown      | Unk, Unknown       |                 | Not Reported |
|                                                                                                                                            | Quetiapine     |              |            | S           | Unknown      | Unk, Unknown       |                 | Not Reported |
|                                                                                                                                            | Quetiapine     |              |            | S           | Unknown      | Unk, Unknown       |                 | Not Reported |
|                                                                                                                                            | Bupropion      |              |            | S           | Unknown      | Unk, Unknown       |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|              |   |         |              |              |
|--------------|---|---------|--------------|--------------|
| Citalopram   | S | Unknown | Unk, Unknown | Not Reported |
| Citalopram   | S | Unknown | Unk, Unknown | Not Reported |
| Phenytoin    | S | Unknown | Unk, Unknown | Not Reported |
| Phenytoin    | S | Unknown | Unk, Unknown | Not Reported |
| Escitalopram | S | Unknown | Unk, Unknown | Not Reported |
| Escitalopram | S | Unknown | Unk, Unknown | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|-----------------------|--------------------|--------------------|-----------------|------------------------|----------------------|-----------------|--------------|----------------|
| 26-Jul-2016              | 12598339              | EXPEDITED (15-DAY) | OT                 |                 | IT-APOTEX-2016AP009909 |                      | 25 YR           | Female       | ITA            |
| <u>Preferred Term</u>    | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Abuse; Sopor        | Zolpidem Doc Generici |                    |                    | S               | Oral                   | 20 Df, Total         |                 | Apotex       |                |
|                          | Sertraline            |                    |                    | S               | Oral                   | 25 Df, Total         |                 | Apotex       |                |
|                          | Mirtazapine           |                    |                    | S               | Oral                   | 20 Df, Total         |                 | Not Reported |                |
|                          | Escitalopram          |                    |                    | S               | Oral                   | 10 Gtt, Total        |                 | Not Reported |                |
|                          | Samyr /00882301/      |                    |                    | S               | Oral                   | 1 Df, Total          |                 | Not Reported |                |

| <u>FDA Received Date</u>                              | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 26-Jul-2016                                           | 12598443                    | EXPEDITED (15-DAY) | HO                 |                 | US-ALLERGAN-1663708US |                      | 58 YR           | Female       | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Limb Discomfort; Liver Disorder; Pruritus Generalised | Norco 5/325                 |                    |                    | S               | Oral                  |                      |                 | Allergan     |                |
|                                                       | Humira                      |                    |                    | S               | Subcutaneous          | 40mg/0.8ml           |                 | Not Reported |                |
|                                                       | Advair                      |                    |                    | S               |                       |                      |                 | Not Reported |                |
|                                                       | Albuterol                   |                    |                    | S               |                       |                      |                 | Not Reported |                |
|                                                       | Cyclobenzaprine             |                    |                    | S               |                       |                      |                 | Not Reported |                |
|                                                       | Amoxicillin Clavulanic Acid |                    |                    | S               |                       |                      |                 | Not Reported |                |
|                                                       | Escitalopram                |                    |                    | S               |                       |                      |                 | Not Reported |                |
|                                                       | Hydrochlorothiazide         |                    |                    | S               |                       |                      |                 | Not Reported |                |
|                                                       | Lisinopril                  |                    |                    | S               |                       |                      |                 | Not Reported |                |
|                                                       | Lovastatin                  |                    |                    | S               |                       |                      |                 | Not Reported |                |
|                                                       | Losartan Potassium          |                    |                    | S               |                       |                      |                 | Not Reported |                |
|                                                       | Meclizine                   |                    |                    | S               |                       |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                     |   |              |
|---------------------|---|--------------|
| Methotrexate        | S | Not Reported |
| Pantoprazole Sodium | S | Not Reported |
| Prednisone          | S | Not Reported |
| Tramadol            | S | Not Reported |
| Ranitidine          | S | Not Reported |
| Ventolin            | S | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 27-Jul-2016              | 12231895      | EXPEDITED (15-DAY) |                    | HO, LT, OT      | ES-ASTELLAS-2016US011929 |                      | 84 YR      | Female     | ESP            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                     | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                          | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|---------------------------------------|------------------------|-----------------|--------------|
| Atrial Fibrillation; Bundle Branch Block Left; Cardiac Disorder; Contraindicated Product Administered; Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Hypokalaemia; Hypomagnesaemia; Tachycardia; Torsade De Pointes; Ventricular Extrasystoles | Solifenacin             |              |            | S           | Unknown                               | Unk, Unknown Freq.     |                 | Astellas     |
|                                                                                                                                                                                                                                                                           | Escitalopram /01588502/ |              |            | S           | Unknown                               | Unk, Unknown Freq.     |                 | Not Reported |
|                                                                                                                                                                                                                                                                           | Sulpiride Gd Ulcer      |              |            | S           | Unknown                               | Unk, Unknown Freq.     |                 | Not Reported |
|                                                                                                                                                                                                                                                                           | Levofloxacin            |              |            | S           | Unknown                               | Unk, Unknown Freq.     |                 | Not Reported |
|                                                                                                                                                                                                                                                                           | Amiodarone              |              |            | S           | Intravenous (not otherwise specified) | Unk, Unknown Freq.     |                 | Not Reported |
|                                                                                                                                                                                                                                                                           | Digoxin                 |              |            | S           | Unknown                               | Unk, Unknown Freq.     |                 | Not Reported |
|                                                                                                                                                                                                                                                                           | Candesartan             |              |            | C           | Unknown                               | Unk Unk, Unknown Freq. |                 | Not Reported |
|                                                                                                                                                                                                                                                                           | Furosemide              |              |            | C           | Unknown                               | Unk Unk, Unknown Freq. |                 | Not Reported |
|                                                                                                                                                                                                                                                                           | Acenocoumarol           |              |            | C           | Unknown                               | Unk Unk, Unknown Freq. |                 | Not Reported |
|                                                                                                                                                                                                                                                                           | Simvastatin             |              |            | C           | Unknown                               | Unk Unk, Unknown Freq. |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Jul-2016              | 12450253      | EXPEDITED (15-DAY) |                    | OT              | US-ACCORD-041125     |                      | 74 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                  | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|--------------|------------|-------------|--------------|---------------------------|-----------------|--------------|
| Alopecia; Arthralgia; Arthritis; Carpal Tunnel Syndrome; Constipation; Dyspnoea; Grandiosity; Headache; Hyperhidrosis; Hypertension; Influenza Like Illness; Insomnia; | Escitalopram        |              |            | S           | Oral         |                           |                 | Accord       |
|                                                                                                                                                                        | Armor Thyroid       |              |            | C           |              |                           |                 | Not Reported |
|                                                                                                                                                                        | Combivent           |              |            | C           |              | Combivent Inhaler 2 Puffs |                 | Not Reported |
|                                                                                                                                                                        | Klor-Con            |              |            | C           |              |                           |                 | Not Reported |
|                                                                                                                                                                        | Hydrochlorothiazide |              |            | C           |              |                           |                 | Not Reported |
|                                                                                                                                                                        | Prevacid Solo       |              |            | C           | Sublingual   |                           |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                           |                      |   |              |
|-------------------------------------------|----------------------|---|--------------|
| Myalgia; Nausea; Neck Pain; Paraesthesia; | Lasix                | C | Not Reported |
| Peripheral Swelling;                      | Lidoderm             | C | Not Reported |
| Sinusitis; Skin Odour                     | Prednisone           | C | Not Reported |
| Abnormal; Tachyphrenia;                   | Acetylsalicylic Acid | C | Not Reported |
| Toothache; Vascular Pain;                 | Colecalciferol       | C | Not Reported |
| Weight Decreased;                         | Retinol              | C | Not Reported |
| Yawning                                   | Pyridoxine           | C | Not Reported |
|                                           | Biotin               | C | Not Reported |
|                                           | Magnesium Hydroxide  | C | Not Reported |
|                                           | Milk Thistle         | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Jul-2016              | 12540725      | EXPEDITED (15-DAY) |                    | HO              | US-FRI-1000085879    |                      | 68 YR      | Female     | USA            |

| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug-Induced Liver Injury | Escitalopram   |              |            | S           | Unknown      |                    |                 | Forest       |
|                           | Escitalopram   |              |            | S           | Unknown      | 10 Mg              |                 | Forest       |
|                           | Diazepam       |              |            | C           | Unknown      |                    |                 | Not Reported |
|                           | Lorazepam      |              |            | C           | Unknown      |                    |                 | Not Reported |
|                           | Zolpidem       |              |            | C           | Unknown      |                    |                 | Not Reported |
|                           | Fexofenadine   |              |            | C           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------------|----------------------|------------|------------|----------------|
| 27-Jul-2016              | 12598612      | EXPEDITED (15-DAY) |                    | HO, OT          | FR-GLAXOSMITHKLINE-FR2016GSK106386 |                      | 61 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|-----------------------|-------------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Hepatitis; Jaundice   | Voltarene Lp      |              |            | S           | Oral         | 75 Mg, Unk         |                 | Glaxosmithkline |
|                       | Voltarene Lp      |              |            | S           | Oral         | 1 Df, Bid          |                 | Glaxosmithkline |
|                       | Sipralexa         |              |            | S           |              | 1 Df, Qd           |                 | Glaxosmithkline |
|                       | Seresta           |              |            | S           |              | 0.5 Df, Unk        |                 | Glaxosmithkline |
|                       | Naprosyne         |              |            | S           | Oral         | Unk                |                 | Glaxosmithkline |
|                       | Altim//Cortivazol |              |            | S           |              |                    |                 | Not Reported    |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                             | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 27-Jul-2016                                          | 12600187                 | EXPEDITED (15-DAY) |                    | OT              | IT-EISAI MEDICAL<br>RESEARCH-EC-2016-<br>018837 |                      | 45 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Overdose;<br>Intentional Self-Injury     | Pariet                   |                    |                    | S               | Oral                                            | Unknown              |                 | Not Reported |                |
|                                                      | Levosulpiride            |                    |                    | S               | Oral                                            | Unknown              |                 | Not Reported |                |
|                                                      | En                       |                    |                    | S               | Oral                                            | Unknown              |                 | Not Reported |                |
|                                                      | Entact                   |                    |                    | S               | Oral                                            | Unknown              |                 | Not Reported |                |
| <u>FDA Received Date</u>                             | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Jul-2016                                          | 12600700                 | EXPEDITED (15-DAY) |                    | HO              | IT-FRI-1000086344                               |                      | 74 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Abuse; Sopor;<br>Toxicity To Various Agents     | Escitalopram             |                    |                    | S               | Oral                                            |                      |                 | Forest       |                |
|                                                      | Delorazepam              |                    |                    | S               | Oral                                            |                      |                 | Not Reported |                |
|                                                      | Coumadin                 |                    |                    | C               | Oral                                            |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                             | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Jul-2016                                          | 12600705                 | EXPEDITED (15-DAY) |                    | DS, HO          | CA-FRI-1000086485                               |                      | 30 YR           | Male         | CAN            |
| <u>Preferred Term</u>                                | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Dreams; Chills;<br>Hyperhidrosis; Nightmare | Escitalopram             |                    |                    | S               |                                                 |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                             | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Jul-2016                                          | 12601721                 | DIRECT             |                    | OT              |                                                 |                      | 66 YR           | Female       | USA            |
| <u>Preferred Term</u>                                | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Chronic Obstructive<br>Pulmonary Disease;            | Escitalopram, Blue Point |                    |                    | S               | Oral                                            |                      |                 | Not Reported |                |
|                                                      | Nebulizer                |                    |                    | C               |                                                 |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                           |                    |   |              |
|---------------------------|--------------------|---|--------------|
| Feeling Abnormal; Seizure | Inhaler            | C | Not Reported |
|                           | Risperdone         | C | Not Reported |
|                           | Lorazepam          | C | Not Reported |
|                           | Lexapro            | C | Not Reported |
|                           | Ranitidine         | C | Not Reported |
|                           | Vitamins One-A-Day | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Jul-2016              | 12599178      | EXPEDITED (15-DAY) |                    | OT              | IT-TEVA-679245ACC    |                      | 25 YR      | Female     | ITA            |

| <u>Preferred Term</u> | <u>Product</u>                            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Abuse; Sopor     | Zolpidem                                  |              |            | S           | Oral         | 20 Df Total        |                 | Teva         |
|                       | Mirtazapine                               |              |            | S           | Oral         | 20 Df Total        |                 | Not Reported |
|                       | Sertraline                                |              |            | S           | Oral         | 25 Df Total        |                 | Not Reported |
|                       | Escitalopram                              |              |            | S           | Oral         | 10 Gtt Total       |                 | Not Reported |
|                       | Samyr - 400 Mg Compresse Gastroresistenti |              |            | S           | Oral         | 1 Df Total         |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|------------|------------|----------------|
| 28-Jul-2016              | 12601626      | EXPEDITED (15-DAY) |                    | OT              | IT-AUROBINDO-AUR-APL-2016-09564 |                      | 25 YR      | Female     | ITA            |

| <u>Preferred Term</u> | <u>Product</u>   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|------------------|--------------|------------|-------------|--------------|---------------------|-----------------|--------------|
| Drug Abuse; Sopor     | Mirtazapine      |              |            | S           | Oral         | 20 Df, Total        |                 | Aurobindo    |
|                       | Sertraline       |              |            | S           | Oral         | 25 Df, Total        |                 | Aurobindo    |
|                       | Escitalopram     |              |            | S           | Oral         | 10 Gtt, Drops Total |                 | Aurobindo    |
|                       | Samyr /00882301/ |              |            | S           | Oral         | 1 Df, Total         |                 | Not Reported |
|                       | Zolpidem         |              |            | S           | Oral         | 20 Df, Total        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 28-Jul-2016              | 12601933      | EXPEDITED (15-DAY) |                    | OT              | RO-JNJFOC-20160721392 |                      | 20 YR      | Male       | ROM            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                      |               |   |         |                                      |              |
|--------------------------------------------------------------------------------------------------------------------------------------|---------------|---|---------|--------------------------------------|--------------|
| Anxiety; Erectile Dysfunction; Mental Impairment; Muscle Spasms; Off Label Use; Panic Disorder; Product Use In Unapproved Indication | Risperidone   | S | Unknown | 3 Weeks Ago From The Time Of Report. | Not Reported |
|                                                                                                                                      | Valproic Acid | S | Unknown | 3 Weeks Ago From The Time Of Report. | Not Reported |
|                                                                                                                                      | Cipralex      | S | Unknown | 3 Weeks Ago From The Time Of Report. | Not Reported |
|                                                                                                                                      | Neuromultivit | S | Unknown | 3 Weeks Ago From The Time Of Report. | Not Reported |

| <u>FDA Received Date</u>                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------|----------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 28-Jul-2016                                | 12602861       | EXPEDITED (15-DAY) |                    | HO              | FR-PFIZER INC-2016355784 |                      | 53 YR           | Male         | FRA            |
| <u>Preferred Term</u>                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Coma; Overdose; Toxicity To Various Agents | Xanax          |                    |                    | S               | Oral                     | 15 Mg, Single        |                 | Pfizer       |                |
|                                            | Seroplex       |                    |                    | S               | Oral                     | 20 Mg, Single        |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|-----------------------|-----------------|--------------|----------------|
| 28-Jul-2016              | 12603297               | EXPEDITED (15-DAY) |                    | OT              | IT-WATSON-2016-15833 |                       | 25 YR           | Female       | ITA            |
| <u>Preferred Term</u>    | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Abuse; Sopor        | Zolpidem (Unknown)     |                    |                    | S               | Oral                 | 20 Df, Total          |                 | Watson       |                |
|                          | Mirtazapine (Unknown)  |                    |                    | S               | Oral                 | 20 Df, Total          |                 | Actavis      |                |
|                          | Sertraline (Unknown)   |                    |                    | S               | Oral                 | 25 Df, Total          |                 | Watson       |                |
|                          | Escitalopram (Unknown) |                    |                    | S               | Oral                 | 10 Gtt Drop(S), Total |                 | Not Reported |                |
|                          | Samyr /00882301/       |                    |                    | S               | Oral                 | 1 Df, Total           |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 28-Jul-2016              | 12604738       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000086499    |                      | 61 YR           | Female     | FRA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Hepatitis; Jaundice      | Escitalopram   |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest     |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                   |   |                 |                         |              |
|-------------------|---|-----------------|-------------------------|--------------|
| Voltaren Lp       | S | Oral            | 150 Mg                  | Not Reported |
| Seresta           | S | Oral            | 25 Mg                   | Not Reported |
| Altim//Cortivazol | S | Intra-articular | Daily Dose Not Reported | Not Reported |
| Naprosyne         | S | Oral            | Daily Dose Not Reported | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Jul-2016              | 12604781      | EXPEDITED (15-DAY) | HO                 |                 | FR-FRI-1000086500    |                      | 94 YR      | Female     | FRA            |

| <u>Preferred Term</u>                          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------|----------------|--------------|------------|-------------|--------------|-------------------------|-----------------|--------------|
| Aggression; Agitation;<br>Persecutory Delusion | Escitalopram   |              |            | S           | Oral         |                         |                 | Forest       |
|                                                | Kardegic       |              |            | C           | Unknown      | Daily Dose Not Reported |                 | Not Reported |
|                                                | Ramipril       |              |            | C           | Unknown      | Daily Dose Not Reported |                 | Not Reported |
|                                                | Nebivolol      |              |            | C           | Unknown      | Daily Dose Not Reported |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------|----------------------|------------|------------|----------------|
| 29-Jul-2016              | 9786252       | EXPEDITED (15-DAY) | OT                 |                 | US-FRI-S03-USA-03330-01 |                      | 76 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abdominal Distension;<br>Abdominal Pain; Back<br>Pain; Balance Disorder;<br>Blindness Unilateral;<br>Chills; Corneal Oedema;<br>Corneal Opacity;<br>Diarrhoea; Diplopia;<br>Drooling; Dyskinesia;<br>Ecchymosis; Fall;<br>Flatulence;<br>Gastrooesophageal Reflux<br>Disease; Hallucination,<br>Visual; Headache;<br>Hyperhidrosis;<br>Hypoaesthesia Oral; Joint<br>Swelling; Nausea;<br>Neuralgia; Nightmare; Off | Lexapro        |              |            | S           | Oral         | 10mg               |                 | Forest       |
|                                                                                                                                                                                                                                                                                                                                                                                                                    | Lexapro        |              |            | S           |              |                    |                 | Forest       |
|                                                                                                                                                                                                                                                                                                                                                                                                                    | Inderal        |              |            | C           |              | 60mg               |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                    | Premarin       |              |            | C           |              | 0.3mg              |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                    | Valium         |              |            | C           |              | 5mg                |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                    | Tylenol        |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                    |                |              |            |             |              |                    |                 |              |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Label Use;  
Ophthalmoplegia; Pain In  
Extremity; Palpitations;  
Paraesthesia; Pruritus  
Generalised; Restless  
Legs Syndrome; Retinal  
Aneurysm; Skin Lesion;  
Visual Impairment;  
Vitreous Floaters

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Jul-2016              | 12579615      | EXPEDITED (15-DAY) |                    | OT              | US-FRI-1000086160    |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                              | <u>Product</u>                          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>      | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                                             |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|--------------|------------|------------------|--------------|--------------------|-----------------|--------------------------------------------------------|
| Blindness Unilateral;<br>Chills; Decubitus Ulcer;<br>Diplopia; Dyskinesia;<br>Headache; Pain In<br>Extremity; Palpitations;<br>Retinal Aneurysm; Vision<br>Blurred | Lexapro<br>Inderal<br>Valium<br>Tylenol |              |            | S<br>C<br>C<br>C | Oral         | 10mg               |                 | Forest<br>Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------------------------------------|----------------------|------------|------------|----------------|
| 29-Jul-2016              | 12605774      | EXPEDITED (15-DAY) |                    | OT              | AU-SUN<br>PHARMACEUTICAL<br>INDUSTRIES LTD-<br>2016RR-121003 |                      | 34 YR      | Male       | AUS            |

| <u>Preferred Term</u>                                                  | <u>Product</u>                        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                  | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                 |
|------------------------------------------------------------------------|---------------------------------------|--------------|------------|-------------|-------------------------------|--------------------|-----------------|----------------------------|
| Abnormal Dreams; Drug<br>Interaction; Sleep-Related<br>Eating Disorder | Zolpidem<br>Escitalopram<br>Oxycodone |              |            | S<br>S<br>S | Unknown<br>Unknown<br>Unknown | Unk<br>Unk<br>Unk  |                 | Sun<br>Not Reported<br>Sun |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------------------------------------|----------------------|------------|------------|----------------|
| 29-Jul-2016              | 12605863      | EXPEDITED (15-DAY) |                    | OT              | AU-SUN<br>PHARMACEUTICAL<br>INDUSTRIES LTD-<br>2016RR-121048 |                      | 35 YR      | Male       | AUS            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                      | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|----------------------------------------------------------------------------|--------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
| Accident; Drug Interaction; Sleep-Related Eating Disorder; Somnambulism    | Zolpidem           |                    |                    | S               | Unknown                   | Unk                  |                 | Sun          |                |
|                                                                            | Escitalopram       |                    |                    | S               | Unknown                   | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                   | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Jul-2016                                                                | 12606368           | EXPEDITED (15-DAY) |                    | OT              | HR-CIPLA LTD.-2016HR09985 |                      |                 | Unknown      | HRV            |
| <u>Preferred Term</u>                                                      | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Overdose; No Adverse Event; Suicide Attempt                    | Escitalopram       |                    |                    | S               | Oral                      | 140 Mg, Unk          |                 | Invagen      |                |
| <u>FDA Received Date</u>                                                   | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Jul-2016                                                                | 12608565           | EXPEDITED (15-DAY) |                    | HO, OT          | CA-BAUSCH-BL-2016-018256  |                      | 39 YR           | Male         | CAN            |
| <u>Preferred Term</u>                                                      | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Overdose; Serotonin Syndrome; Toxicity To Various Agents | Bupropion          |                    |                    | S               | Unknown                   |                      |                 | Not Reported |                |
|                                                                            | Primidone          |                    |                    | S               | Unknown                   |                      |                 | Not Reported |                |
|                                                                            | Olanzapine         |                    |                    | S               | Unknown                   |                      |                 | Not Reported |                |
|                                                                            | Escitalopram       |                    |                    | S               | Unknown                   |                      |                 | Not Reported |                |
|                                                                            | Quetiapine         |                    |                    | S               | Unknown                   |                      |                 | Not Reported |                |
|                                                                            | Phenytoin          |                    |                    | S               | Unknown                   |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                   | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Jul-2016                                                                | 12609579           | DIRECT             | Y                  | OT              |                           |                      | 26 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                      | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Hypersomnia; Increased Appetite; Product Substitution Issue    | Escitalopram 10 Mg | Unknown            |                    | S               | Oral                      |                      |                 | Unknown      |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                       | <u>Case #</u>                               | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------|---------------------------------------------|------------------|--------------------|-----------------|----------------------|------------------------------------------------|-----------------|--------------|----------------|
| 29-Jul-2016                                                    | 12609617                                    | DIRECT           |                    | HO              |                      |                                                | 67 YR           | Female       | USA            |
| <u>Preferred Term</u>                                          | <u>Product</u>                              | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                             | <u>Duration</u> | <u>Mfr</u>   |                |
| Impaired Driving Ability;<br>Road Traffic Accident;<br>Seizure | Escitalopram 10 Mg, 10 Mg<br>Lupin Pharmacy |                  |                    | S               | Oral                 | 90 Tablet(S) In The<br>Morning Taken By Mouth  |                 | Lupin        |                |
|                                                                | Omeprazole, 20 Mg Zydus                     |                  |                    | S               | Oral                 | 90 Capsule(S) In The<br>Morning Taken By Mouth |                 | Zydus Pharm  |                |
|                                                                | Multi Vitamin                               |                  |                    | C               |                      |                                                |                 | Not Reported |                |
|                                                                | Vitamin D Nos                               |                  |                    | C               |                      |                                                |                 | Not Reported |                |
|                                                                | Vitamin B3                                  |                  |                    | C               |                      |                                                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>                               | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Jul-2016                                                    | 12610410                                    | DIRECT           |                    | OT              |                      |                                                | 66 YR           | Female       | USA            |
| <u>Preferred Term</u>                                          | <u>Product</u>                              | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                             | <u>Duration</u> | <u>Mfr</u>   |                |
| Dry Eye; Eye Pain;<br>Vitreous Floaters                        | Escitalopram 10mg                           |                  |                    | S               | Oral                 | 10 Mg 90 Tablets Once A<br>Day Taken By Mouth  |                 | Not Reported |                |
|                                                                | Bisoprol/Hctz                               |                  |                    | C               |                      |                                                |                 | Not Reported |                |
|                                                                | Hydrochlorothiazide                         |                  |                    | C               |                      |                                                |                 | Not Reported |                |
|                                                                | Nabumetone                                  |                  |                    | C               |                      |                                                |                 | Not Reported |                |
|                                                                | Progesterone                                |                  |                    | C               |                      |                                                |                 | Not Reported |                |
|                                                                | Estradiol                                   |                  |                    | C               |                      |                                                |                 | Not Reported |                |
|                                                                | Zantac                                      |                  |                    | C               |                      |                                                |                 | Not Reported |                |
|                                                                | Testosterone Cream 2%                       |                  |                    | C               |                      |                                                |                 | Not Reported |                |
|                                                                | Melatonin                                   |                  |                    | C               |                      |                                                |                 | Not Reported |                |
|                                                                | Vit D3                                      |                  |                    | C               |                      |                                                |                 | Not Reported |                |
|                                                                | Multi Vitamin                               |                  |                    | C               |                      |                                                |                 | Not Reported |                |
|                                                                | B-12                                        |                  |                    | C               |                      |                                                |                 | Not Reported |                |
|                                                                | Proomega                                    |                  |                    | C               |                      |                                                |                 | Not Reported |                |
|                                                                | Efa                                         |                  |                    | C               |                      |                                                |                 | Not Reported |                |
|                                                                | Epa                                         |                  |                    | C               |                      |                                                |                 | Not Reported |                |
|                                                                | Dha                                         |                  |                    | C               |                      |                                                |                 | Not Reported |                |
|                                                                | Probiotic                                   |                  |                    | C               |                      |                                                |                 | Not Reported |                |
|                                                                | Cranberry                                   |                  |                    | C               |                      |                                                |                 | Not Reported |                |
|                                                                | Coq10                                       |                  |                    | C               |                      |                                                |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|              |   |              |
|--------------|---|--------------|
| Calcium      | C | Not Reported |
| Milk Thistle | C | Not Reported |
| Slo-Niacin   | C | Not Reported |
| Aspirin      | C | Not Reported |
| Dhea         | C | Not Reported |
| Lutein       | C | Not Reported |
| Selenium     | C | Not Reported |
| Folic Acid   | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 01-Aug-2016              | 12083021      | NON-EXPEDITED    |                    |                 | US-PFIZER INC-<br>2016078048 |                      | 58 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|--------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Hypersensitivity | Effexor            |              |            | S           |              | Unk                |                 | Pfizer       |
|                       | Promethazine Hcl   |              |            | S           |              | Unk                |                 | Unknown      |
|                       | Cortisone          |              |            | S           |              | Unk                |                 | Pfizer       |
|                       | Enbrel             |              |            | S           |              | Unk                |                 | Pfizer       |
|                       | Methotrexate       |              |            | S           |              | Unk                |                 | Pfizer       |
|                       | Amoxicillin        |              |            | S           |              | Unk                |                 | Pfizer       |
|                       | Codeine            |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Prednisone         |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Leucovorin Calcium |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Biaxin             |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Aciphex            |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Carafate           |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Ambien             |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Actemra            |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Bactrim            |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Humira             |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Hctz               |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Leflunomide        |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Lexapro            |              |            | S           |              | Unk                |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|            |   |     |              |
|------------|---|-----|--------------|
| Mobic      | S | Unk | Not Reported |
| Buspar     | S | Unk | Not Reported |
| Orencia    | S | Unk | Not Reported |
| Paxil      | S | Unk | Not Reported |
| Prilosec   | S | Unk | Not Reported |
| Wellbutrin | S | Unk | Not Reported |
| Keflex     | S | Unk | Not Reported |
| Amitiza    | S | Unk | Not Reported |
| Align      | S | Unk | Not Reported |

| <u>FDA Received Date</u>                                                      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 01-Aug-2016                                                                   | 12591776       | EXPEDITED (15-DAY) |                    | OT              | AU-LUPIN<br>PHARMACEUTICALS<br>INC.-2016-03261 |                      | 35 YR           | Male         | AUS            |
| <u>Preferred Term</u>                                                         | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Accident; Drug Interaction;<br>Sleep-Related Eating<br>Disorder; Somnambulism | Zolpidem       |                    |                    | S               | Unknown                                        |                      |                 | Not Reported |                |
|                                                                               | Escitalopram   |                    |                    | S               | Unknown                                        |                      |                 | Not Reported |                |
|                                                                               | Zolpidem       |                    |                    | S               | Unknown                                        |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|-----------------|--------------|----------------|
| 01-Aug-2016              | 12609272       | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-<br>2016M1030836 |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Autoimmune Hepatitis     | Escitalopram   |                    |                    | S               | Unknown                       |                      |                 | Not Reported |                |
|                          | Diazepam       |                    |                    | C               | Unknown                       |                      |                 | Mylan        |                |
|                          | Lorazepam      |                    |                    | C               | Unknown                       |                      |                 | Mylan        |                |
|                          | Zolpidem       |                    |                    | C               | Unknown                       |                      |                 | Mylan        |                |
|                          | Fexofenadine   |                    |                    | C               | Unknown                       |                      |                 | Mylan        |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                            | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|-------------------------------------------------------------------------------------|--------------------------------------|--------------------|--------------------|-----------------|------------------------------------------------|----------------------|-----------------|----------------------|----------------|
| 01-Aug-2016                                                                         | 12609938                             | EXPEDITED (15-DAY) |                    | HO, LT          | CA-LUPIN<br>PHARMACEUTICALS<br>INC.-2016-03331 |                      | 39 YR           | Male                 | CAN            |
| <u>Preferred Term</u>                                                               | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Overdose; Serotonin<br>Syndrome                                                     | Bupropion                            |                    |                    | S               | Unknown                                        |                      |                 | Not Reported         |                |
|                                                                                     | Escitalopram                         |                    |                    | S               | Unknown                                        |                      |                 | Not Reported         |                |
|                                                                                     | Olanzapine                           |                    |                    | S               | Unknown                                        |                      |                 | Not Reported         |                |
|                                                                                     | Phenytoin                            |                    |                    | S               | Unknown                                        |                      |                 | Not Reported         |                |
|                                                                                     | Primidone                            |                    |                    | S               | Unknown                                        |                      |                 | Not Reported         |                |
|                                                                                     | Quetiapine                           |                    |                    | S               | Unknown                                        |                      |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                            | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 01-Aug-2016                                                                         | 12610580                             | EXPEDITED (15-DAY) |                    | HO, OT          | CA-ACTAVIS-2016-<br>16766                      |                      | 39 YR           | Male                 | CAN            |
| <u>Preferred Term</u>                                                               | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Drug Interaction;<br>Overdose; Serotonin<br>Syndrome; Toxicity To<br>Various Agents | Bupropion Hydrochloride<br>(Unknown) |                    |                    | S               | Unknown                                        | Unk                  |                 | Actavis              |                |
|                                                                                     | Escitalopram (Unknown)               |                    |                    | S               | Unknown                                        | Unk                  |                 | Not Reported         |                |
|                                                                                     | Olanzapine (Unknown)                 |                    |                    | S               | Unknown                                        | Unk                  |                 | Not Reported         |                |
|                                                                                     | Phenytoin (Amalco)                   |                    |                    | S               | Unknown                                        | Unk                  |                 | Actavis Mid Atlantic |                |
|                                                                                     | Primidone (Watson<br>Laboratories)   |                    |                    | S               | Unknown                                        | Unk                  |                 | Watson               |                |
|                                                                                     | Quetiapine (Unknown)                 |                    |                    | S               | Unknown                                        | Unk                  |                 | Actavis              |                |
| <u>FDA Received Date</u>                                                            | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 01-Aug-2016                                                                         | 12611266                             | EXPEDITED (15-DAY) |                    | HO, OT          | CN-FRI-1000086531                              |                      | 15 YR           | Female               | CHN            |
| <u>Preferred Term</u>                                                               | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Product Use Issue;<br>Systemic Lupus<br>Erythematosus; Tic                          | Lexapro                              |                    |                    | S               | Oral                                           |                      |                 | Forest               |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                     | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|--------------------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 01-Aug-2016                                                                                  | 12614442                 | DIRECT             | Y                  |                 |                                                              |                      | 152 DAY         | Male         |                |
| <u>Preferred Term</u>                                                                        | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Feeling Abnormal; Product Substitution Issue                                                 | Escitalopram, 20mg Cipla |                    |                    | S               | Oral                                                         |                      |                 | Cipla        |                |
| <u>FDA Received Date</u>                                                                     | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Aug-2016                                                                                  | 12456801                 | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000085207                                            |                      | 77 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                        | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Acute Kidney Injury; Dehydration; Diarrhoea; Fatigue; Hyponatraemia; Renal Failure; Vomiting | Escitalopram             |                    |                    | S               | Oral                                                         | 5 Mg                 |                 | Forest       |                |
|                                                                                              | Paclitaxel Hospira       |                    |                    | S               | Intravenous (not otherwise specified)                        | 60 Mg/M2             |                 | Not Reported |                |
|                                                                                              | Hydrochlorothiazide      |                    |                    | S               | Oral                                                         | 1 Df                 |                 | Not Reported |                |
|                                                                                              | Telmisartan              |                    |                    | S               | Oral                                                         | 1 Df                 |                 | Not Reported |                |
|                                                                                              | Hept A Myl               |                    |                    | S               | Oral                                                         | 3 Df                 |                 | Not Reported |                |
|                                                                                              | Zopiclone                |                    |                    | C               |                                                              |                      |                 | Not Reported |                |
|                                                                                              | Paracetamol              |                    |                    | C               |                                                              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                     | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Aug-2016                                                                                  | 12605571                 | EXPEDITED (15-DAY) |                    | OT              | IT-SUN<br>PHARMACEUTICAL<br>INDUSTRIES LTD-<br>2016RR-121005 |                      | 25 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                                        | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Abuse; Sopor                                                                            | Zolpidem                 |                    |                    | S               | Oral                                                         | 20 Df Total          |                 | Sun          |                |
|                                                                                              | Mirtazapine              |                    |                    | S               | Oral                                                         | 20 Df Total          |                 | Sun          |                |
|                                                                                              | Sertraline               |                    |                    | S               | Oral                                                         | 25 Df Total          |                 | Sun          |                |
|                                                                                              | Escitalopram             |                    |                    | S               | Oral                                                         | 10 Gtt Total         |                 | Not Reported |                |
|                                                                                              | Samyr 400 Mg             |                    |                    | S               | Oral                                                         | 1 Df Total           |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                               | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                        | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|-------------------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 02-Aug-2016                                                                                            | 12612893                      | EXPEDITED (15-DAY) |                    | HO, OT          | CA-ALEMBIC<br>PHARMACUETICALS<br>LIMITED-<br>2016SCAL000621 |                      |                 | Unknown      | CAN            |
| <u>Preferred Term</u>                                                                                  | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;<br>Overdose; Serotonin<br>Syndrome; Toxicity To<br>Various Agents                    | Quetiapine Fumarate           |                    |                    | S               |                                                             | Unk                  |                 | Alembic      |                |
|                                                                                                        | Olanzapine                    |                    |                    | S               |                                                             | Unk                  |                 | Not Reported |                |
|                                                                                                        | Escitalopram                  |                    |                    | S               |                                                             | Unk                  |                 | Not Reported |                |
|                                                                                                        | Phenytoin                     |                    |                    | S               |                                                             | Unk                  |                 | Not Reported |                |
|                                                                                                        | Primidone                     |                    |                    | S               |                                                             | Unk                  |                 | Not Reported |                |
|                                                                                                        | Bupropion                     |                    |                    | S               |                                                             | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                               | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                        | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Aug-2016                                                                                            | 12613166                      | EXPEDITED (15-DAY) |                    | HO, OT          | CA-PAR<br>PHARMACEUTICAL<br>COMPANIES-<br>2016SCPR015669    |                      |                 | Unknown      | CAN            |
| <u>Preferred Term</u>                                                                                  | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective For<br>Unapproved Indication;<br>Drug Interaction;<br>Overdose; Serotonin<br>Syndrome | Bupropion Hcl XI              |                    |                    | S               | Unknown                                                     | Unk, Unknown         |                 | Par          |                |
|                                                                                                        | Olanzapine                    |                    |                    | S               | Unknown                                                     | Unk, Unknown         |                 | Par          |                |
|                                                                                                        | Cyproheptadine                |                    |                    | S               | Unknown                                                     | Unk, Unknown         |                 | Par          |                |
|                                                                                                        | Clonidine                     |                    |                    | S               | Unknown                                                     | Unk Unk, Unknown     |                 | Par          |                |
|                                                                                                        | Dexmedetomidine Hydrochloride |                    |                    | S               | Unknown                                                     | Unk Unk, Unknown     |                 | Par          |                |
|                                                                                                        | Escitalopram                  |                    |                    | S               | Unknown                                                     | Unk, Unknown         |                 | Not Reported |                |
|                                                                                                        | Phenytoin                     |                    |                    | S               | Unknown                                                     | Unk, Unknown         |                 | Not Reported |                |
|                                                                                                        | Primidone                     |                    |                    | S               | Unknown                                                     | Unk, Unknown         |                 | Not Reported |                |
|                                                                                                        | Quetiapine                    |                    |                    | S               | Unknown                                                     | Unk, Unknown         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                               | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                        | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Aug-2016                                                                                            | 12613451                      | EXPEDITED (15-DAY) |                    | HO, LT, OT      | CA-MACLEODS<br>PHARMACEUTICALS                              |                      |                 | Unknown      | CAN            |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

US LTD-  
MAC2016002958

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                   | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Agitation; Arrhythmia;<br>Communication Disorder;<br>Condition Aggravated;<br>Confusional State;<br>Delirium; Drug Interaction;<br>Hyperhidrosis;<br>Hyperreflexia;<br>Hyperthermia; Mental<br>Status Changes; Muscle<br>Rigidity; Myoclonus;<br>Overdose; Serotonin<br>Syndrome; Toxicity To<br>Various Agents; Tremor | Escitalopram Oxalate |              |            | S           | Unknown      | Unk                |                 | Macleods     |
|                                                                                                                                                                                                                                                                                                                         | Olanzapine           |              |            | S           | Unknown      | Unk                |                 | Macleods     |
|                                                                                                                                                                                                                                                                                                                         | Quetiapine           |              |            | S           | Unknown      | Unk                |                 | Macleods     |
|                                                                                                                                                                                                                                                                                                                         | Phenytoin            |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                         | Primidone            |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                         | Bupropion            |              |            | S           | Unknown      | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Aug-2016              | 12614114      | EXPEDITED (15-DAY) |                    | OT              | SK-FRI-1000086553    |                      | 74 YR      | Unknown    | SVK            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Skin Haemorrhage      | Escitalopram   |              |            | S           | Unknown      |                    |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Aug-2016              | 12614118      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000086580    |                      | 53 YR      | Male       | FRA            |

| <u>Preferred Term</u>               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------------|-----------------|--------------|
| Coma; Toxicity To Various<br>Agents | Escitalopram   |              |            | S           | Oral         |                          |                 | Forest       |
|                                     | Xanax          |              |            | S           | Oral         | 30 Tablets Taken At Once |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Aug-2016              | 12616703      | EXPEDITED (15-DAY) |                    | OT              | DE-FRI-1000086532    |                      | 43 YR      | Female     | DEU            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Aggression; Bruxism;<br>Derealisation; Dizziness;<br>Feeling Of Despair;<br>Insomnia; Muscle<br>Twitching; Nausea; Panic<br>Reaction; Withdrawal<br>Syndrome | Escitalopram   |              |            | S           | Oral         |                    |                 | Forest       |
|                                                                                                                                                              | Escitalopram   |              |            | S           | Oral         |                    |                 | Forest       |
|                                                                                                                                                              | Elontril       |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                                              | Zopiclin       |              |            | C           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Aug-2016              | 12617186      | EXPEDITED (15-DAY) |                    | OT              | FR-ZYDUS-011751      |                      | 55 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                                                                                                                                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Alanine Aminotransferase<br>Increased; Drug<br>Interaction; Drug-Induced<br>Liver Injury; Eosinophilia;<br>Hepatocellular Injury;<br>Influenza Like Illness;<br>Liver Function Test<br>Abnormal | Escitalopram   |              |            | S           | Unknown      |                    |                 | Zydus Pharm  |
|                                                                                                                                                                                                 | Chlorpromazine |              |            | S           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Aug-2016              | 12617219      | EXPEDITED (15-DAY) |                    | OT              | FR-ROCHE-1807062     |                      | 15 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hepatitis             | Rivotril       |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Theralene      |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Adepal         |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Noctamide      |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Risperdal      |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Seresta        |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Seroplex       |              |            | S           | Oral         |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>    | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|-----------------------------|-----------------|--------------------|--------------------|-----------------|--------------------------------------------------|----------------------|-----------------|-----------------|----------------|
| 03-Aug-2016                 | 12618451        | EXPEDITED (15-DAY) |                    | HO, OT          | CA-GLAXOSMITHKLINE-CA2016GSK109401               |                      | 39 YR           | Male            | CAN            |
| <u>Preferred Term</u>       | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                     | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Agitation; Arrhythmia;      | Bupropion       |                    |                    | S               |                                                  |                      |                 | Glaxosmithkline |                |
| Clonus; Cognitive           | Escitalopram    |                    |                    | S               |                                                  |                      |                 | Glaxosmithkline |                |
| Disorder; Condition         | Olanzapine      |                    |                    | S               |                                                  |                      |                 | Glaxosmithkline |                |
| Aggravated; Confusional     | Phenytoin       |                    |                    | S               |                                                  |                      |                 | Glaxosmithkline |                |
| State; Delirium; Device     | Quetiapine      |                    |                    | S               |                                                  |                      |                 | Glaxosmithkline |                |
| Related Sepsis; Drug        | Primidone       |                    |                    | S               |                                                  |                      |                 | Glaxosmithkline |                |
| Interaction; Hyperhidrosis; |                 |                    |                    |                 |                                                  |                      |                 | Not Reported    |                |
| Hyperreflexia;              |                 |                    |                    |                 |                                                  |                      |                 |                 |                |
| Hyperthermia; Incoherent;   |                 |                    |                    |                 |                                                  |                      |                 |                 |                |
| Muscle Rigidity;            |                 |                    |                    |                 |                                                  |                      |                 |                 |                |
| Myoclonus; Overdose;        |                 |                    |                    |                 |                                                  |                      |                 |                 |                |
| Pneumonia; Serotonin        |                 |                    |                    |                 |                                                  |                      |                 |                 |                |
| Syndrome; Tachycardia;      |                 |                    |                    |                 |                                                  |                      |                 |                 |                |
| Toxicity To Various         |                 |                    |                    |                 |                                                  |                      |                 |                 |                |
| Agents; Tremor              |                 |                    |                    |                 |                                                  |                      |                 |                 |                |
| <u>FDA Received Date</u>    | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 03-Aug-2016                 | 12619452        | EXPEDITED (15-DAY) |                    | HO              | CA-UNICHEM LABORATORIES LIMITED-UCM201608-000167 |                      | 39 YR           | Male            | CAN            |
| <u>Preferred Term</u>       | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                     | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Arrhythmia; Intentional     | Quetiapine      |                    |                    | S               |                                                  |                      |                 | Unichem         |                |
| Overdose; Potentiating      | Bupropion       |                    |                    | S               |                                                  |                      |                 | Not Reported    |                |
| Drug Interaction;           | Escitalopram    |                    |                    | S               |                                                  |                      |                 | Not Reported    |                |
| Serotonin Syndrome;         | Olanzapine      |                    |                    | S               |                                                  |                      |                 | Not Reported    |                |
| Toxicity To Various Agents  | Phenytoin       |                    |                    | S               |                                                  |                      |                 | Not Reported    |                |
|                             | Primidone       |                    |                    | S               |                                                  |                      |                 | Not Reported    |                |
|                             | Dexmedetomidine |                    |                    | C               |                                                  |                      |                 | Not Reported    |                |
|                             | Clonidine       |                    |                    | C               |                                                  |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>    | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 03-Aug-2016                 | 12619812        | EXPEDITED (15-DAY) |                    | HO              | CH-FRI-1000086637                                |                      | 61 YR           | Female          | CHE            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                          | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Duodenal Ulcer;<br>Haematemesis                                                                                                                | Escitalopram Oral Solution            |                    |                    | S               | Oral                 |                      |                 | Forest       |                |
|                                                                                                                                                | Marcourmar/Phenprocoumon              |                    |                    | S               | Oral                 | 3 Mg                 |                 | Not Reported |                |
|                                                                                                                                                | Bilol/Bisoprolol Fumarate             |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                                                | Bioflorin/Enterococcus Faecalis       |                    |                    | C               | Unknown              |                      |                 | Not Reported |                |
|                                                                                                                                                | Amlodipin Actavis/Amlodipine Besilate |                    |                    | C               | Unknown              |                      |                 | Not Reported |                |
|                                                                                                                                                | Imodium Akut/Loperamide Hydrochlorid  |                    |                    | C               | Unknown              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                       | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Aug-2016                                                                                                                                    | 12619818                              | EXPEDITED (15-DAY) |                    | HO              | IL-FRI-1000086581    |                      | 79 YR           | Female       | ISR            |
| <u>Preferred Term</u>                                                                                                                          | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| General Physical Health<br>Deterioration; Hepatic<br>Function Abnormal                                                                         | Escitalopram                          |                    |                    | S               | Unknown              |                      |                 | Forest       |                |
|                                                                                                                                                | Eliquis 5mg (Apixaban)                |                    |                    | S               |                      | 10 Mg                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                       | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Aug-2016                                                                                                                                    | 12621200                              | DIRECT             | Y                  | OT              |                      |                      | 51 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                          | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective;<br>Dyspnoea; Feeling<br>Abnormal; Product<br>Formulation Issue;<br>Product Substitution Issue;<br>Toxicity To Various Agents | Escitalopram, 10 Mg                   |                    |                    | S               | Oral                 |                      |                 | Aurobindo    |                |
| <u>FDA Received Date</u>                                                                                                                       | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Aug-2016                                                                                                                                    | 12554652                              | EXPEDITED (15-DAY) |                    | OT              | CH-FRI-1000086040    |                      | 75 YR           | Female       | CHE            |
| <u>Preferred Term</u>                                                                                                                          | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

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|                          |                            |   |         |                              |              |
|--------------------------|----------------------------|---|---------|------------------------------|--------------|
| Cerebral Ischaemia;      | Escitalopram Oral Solution | S | Oral    | 5 Mg                         | Forest       |
| Extrapyramidal Disorder; | Surmontil                  | S | Oral    | 12 Mg                        | Not Reported |
| Tremor                   | Zolpidem                   | C | Unknown | 5 Mg Per Os/Each 1 - 2 Weeks | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>                            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|-----------------------|-------------------------------------------------|-----------------|--------------|----------------|
| 04-Aug-2016              | 12622936       | EXPEDITED (15-DAY) |                    | OT              | FR-JNJFOC-20160800910 |                                                 | 15 YR           | Female       | FRA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>                              | <u>Duration</u> | <u>Mfr</u>   |                |
| Hepatitis                | Risperdal      |                    |                    | S               | Oral                  |                                                 |                 | Not Reported |                |
|                          | Theralene      |                    |                    | S               | Oral                  |                                                 |                 | Not Reported |                |
|                          | Adepal         |                    |                    | S               | Oral                  | 1 During The Menstrual Cycle, For Contraception |                 | Not Reported |                |
|                          | Noctamide      |                    |                    | S               | Oral                  |                                                 |                 | Not Reported |                |
|                          | Seresta        |                    |                    | S               | Oral                  |                                                 |                 | Not Reported |                |
|                          | Rivotril       |                    |                    | S               | Oral                  |                                                 |                 | Not Reported |                |
|                          | Seroplex       |                    |                    | S               | Oral                  |                                                 |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 04-Aug-2016              | 12623494       | EXPEDITED (15-DAY) |                    | HO              | CN-FRI-1000086558    |                      | 45 YR           | Female       | CHN            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Liver Function Test      | Lexapro        |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
| Abnormal; Product Use In | Lexapro        |                    |                    | S               | Oral                 |                      |                 | Forest       |                |
| Unapproved Indication    | Risperdal      |                    |                    | S               | Oral                 | 4 Mg                 |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|---------------------------------------|----------------------|-----------------|------------|----------------|
| 04-Aug-2016              | 12623514       | EXPEDITED (15-DAY) |                    | OT              | IT-ECLAT PHARMACEUTICALS-2016ECL00019 |                      | 45 YR           | Female     | ITA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

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|                                                     |               |   |      |     |              |
|-----------------------------------------------------|---------------|---|------|-----|--------------|
| Intentional Product Misuse; Intentional Self-Injury | Pariet        | S | Oral | Unk | Eclat        |
|                                                     | Levosulpiride | S | Oral | Unk | Not Reported |
|                                                     | En            | S | Oral | Unk | Not Reported |
|                                                     | Entact        | S | Oral | Unk | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 05-Aug-2016              | 12627119       | EXPEDITED (15-DAY) |                    | OT              | FR-PFIZER INC-2016369507 |                      | 15 YR           | Female       | FRA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hepatitis                | Adepal         |                    |                    | S               | Oral                     | 1 Df, Daily          |                 | Pfizer       |                |
|                          | Theralene      |                    |                    | S               | Oral                     | 20 Mg, 1x/Day        |                 | Not Reported |                |
|                          | Noctamide      |                    |                    | S               | Oral                     | 1 Mg, 1x/Day         |                 | Not Reported |                |
|                          | Risperdal      |                    |                    | S               | Oral                     | 4 Mg, 1x/Day         |                 | Not Reported |                |
|                          | Seresta        |                    |                    | S               | Oral                     | 50 Mg, 1x/Day        |                 | Not Reported |                |
|                          | Rivotril       |                    |                    | S               | Oral                     | Unk                  |                 | Not Reported |                |
|                          | Seroplex       |                    |                    | S               | Oral                     | Unk                  |                 | Not Reported |                |

| <u>FDA Received Date</u>    | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------|-----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 05-Aug-2016                 | 12627212              | EXPEDITED (15-DAY) |                    | HO              | FR-SA-2016SA139032   |                      | 81 YR           | Male         | FRA            |
| <u>Preferred Term</u>       | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anaemia; Epistaxis; Melaena | Kardegic              |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                             | Kardegic              |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                             | Clopidogrel Bisulfate |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                             | Seroplex              |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                             | Bisoprolol            |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                             | Amlodipine            |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                             | Furosemide            |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                             | Simvastatin           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                             | Lansoprazole          |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                             | Xatral Lp             |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                             | Doliprane             |                    |                    | C               |                      |                      |                 | Not Reported |                |

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|                                |                       |                    |                    |                 |                      |                      |                 |              |                |
|--------------------------------|-----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Methotrexate                   |                       |                    | C                  |                 |                      | Not Reported         |                 |              |                |
| <u>FDA Received Date</u>       | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Aug-2016                    | 12627214              | EXPEDITED (15-DAY) |                    | HO              | FR-SA-2016SA139036   |                      | 81 YR           | Male         | FRA            |
| <u>Preferred Term</u>          | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anaemia; Epistaxis;<br>Melaena | Kardegic              |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                | Kardegic              |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                | Clopidogrel Bisulfate |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                | Seroplex              |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                | Bisoprolol            |                    |                    | C               | Unknown              |                      |                 | Not Reported |                |
|                                | Amlodipine            |                    |                    | C               | Unknown              |                      |                 | Not Reported |                |
|                                | Furosemide            |                    |                    | C               | Unknown              |                      |                 | Not Reported |                |
|                                | Simvastatin           |                    |                    | C               | Unknown              |                      |                 | Not Reported |                |
|                                | Lansoprazole          |                    |                    | C               | Unknown              |                      |                 | Not Reported |                |
|                                | Xatral Lp             |                    |                    | C               | Unknown              |                      |                 | Not Reported |                |
|                                | Doliprane             |                    |                    | C               | Unknown              |                      |                 | Not Reported |                |
|                                | Methotrexate          |                    |                    | C               | Unknown              |                      |                 | Not Reported |                |
|                                | Methotrexate          |                    |                    | C               | Unknown              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>       | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Aug-2016                    | 12628642              | DIRECT             |                    | HO              |                      |                      | 40 YR           | Female       | USA            |
| <u>Preferred Term</u>          | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Arthropathy; Asthenia          | Escitalopram, 10 Mg   |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                | Caffeine              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                | Gabapentin            |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                | Pyridostigmine        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                | Ranitidine            |                    |                    | C               |                      |                      |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                                          | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------|-----------------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
| 05-Aug-2016                                                                                       | 12628933                          | DIRECT             | Y                  | OT              |                           |                      | 56 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                             | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Condition Aggravated; Depression; Drug Ineffective; Insomnia; Product Substitution Issue | Escitalopram, 20mg Cipla          |                    |                    | S               | Oral                      |                      |                 | Cipla        |                |
| <u>FDA Received Date</u>                                                                          | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Aug-2016                                                                                       | 12628451                          | EXPEDITED (15-DAY) |                    | CA, OT          | US-CIPLA LTD.-2016US16994 |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                                             | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Foetal Exposure During Pregnancy; Talipes                                                         | Escitalopram                      |                    |                    | S               | Transplacental            | Unk                  |                 | Invagen      |                |
| <u>FDA Received Date</u>                                                                          | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Aug-2016                                                                                       | 12628509                          | EXPEDITED (15-DAY) |                    | CA, OT          | US-CIPLA LTD.-2016US16993 |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                                             | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Foetal Exposure During Pregnancy; Talipes                                                         | Escitalopram                      |                    |                    | S               | Transplacental            | Unk                  |                 | Invagen      |                |
| <u>FDA Received Date</u>                                                                          | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Aug-2016                                                                                       | 12628746                          | EXPEDITED (15-DAY) |                    | HO, OT          | CA-ACCORD-042925          |                      | 39 YR           | Male         | CAN            |
| <u>Preferred Term</u>                                                                             | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Overdose; Serotonin Syndrome                                                    | Escitalopram                      |                    |                    | S               |                           |                      |                 | Accord       |                |
|                                                                                                   | Quetiapine                        |                    |                    | S               |                           |                      |                 | Accord       |                |
|                                                                                                   | Bupropion/Bupropion Hydrochloride |                    |                    | S               |                           |                      |                 | Not Reported |                |
|                                                                                                   | Olanzapine                        |                    |                    | S               |                           |                      |                 | Not Reported |                |
|                                                                                                   | Phenytoin                         |                    |                    | S               |                           |                      |                 | Not Reported |                |
|                                                                                                   | Primidone                         |                    |                    | S               |                           |                      |                 | Not Reported |                |



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| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 08-Aug-2016                       | 12629618                | EXPEDITED (15-DAY)        |                             | HO                       | FR-FRI-1000086672             |                               | 92 YR                    | Female              | FRA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Subdural Haematoma                | Escitalopram            |                           |                             | S                        | Oral                          | 5 Mg                          |                          | Forest              |                         |
|                                   | Previscan (Fluindione)  |                           |                             | S                        | Oral                          | 10 Mg                         |                          | Not Reported        |                         |
|                                   | Cardensiel              |                           |                             | C                        | Unknown                       | 1.25 Mg                       |                          | Not Reported        |                         |
|                                   | Lasilix                 |                           |                             | C                        | Unknown                       | 80 Mg                         |                          | Not Reported        |                         |
|                                   | Lasilix                 |                           |                             | C                        | Unknown                       | 40 Mg                         |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 08-Aug-2016                       | 12629826                | EXPEDITED (15-DAY)        |                             | LT                       | FR-FRI-1000086697             |                               | 68 YR                    | Female              | FRA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Haemorrhagic Stroke               | Escitalopram            |                           |                             | S                        | Oral                          |                               |                          | Forest              |                         |
|                                   | Eliquis                 |                           |                             | S                        | Oral                          | 10 Mg                         |                          | Not Reported        |                         |
|                                   | Crestor                 |                           |                             | C                        | Unknown                       |                               |                          | Not Reported        |                         |
|                                   | Beta-2 Mimetic          |                           |                             | C                        | Unknown                       |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 08-Aug-2016                       | 12635272                | NON-EXPEDITED             |                             | OT                       | US-FRI-1000086747             |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Ineffective; Seizure         | Lexapro                 |                           |                             | S                        |                               |                               |                          | Forest              |                         |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 08-Aug-2016                       | 12635274                | EXPEDITED (15-DAY)        |                             | HO                       | FR-FRI-1000086694             |                               |                          | Male                | FRA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Anaemia; Drug Interaction;        | Escitalopram            |                           |                             | S                        | Oral                          | 10 Mg                         |                          | Forest              |                         |

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|                    |                  |   |      |         |              |
|--------------------|------------------|---|------|---------|--------------|
| Epistaxis; Melaena | Kardegic         | S | Oral | 75 Mg   | Not Reported |
|                    | Clopidogrel Base | S | Oral | 75 Mg   | Not Reported |
|                    | Bisoprolol       | C |      | 1 Df    | Not Reported |
|                    | Amlodipine       | C |      | 1 Df    | Not Reported |
|                    | Furosemide       | C |      | 1 Df    | Not Reported |
|                    | Simvastatin      | C |      | 1 Df    | Not Reported |
|                    | Lansoprazole     | C |      | 1 Df    | Not Reported |
|                    | Xatral Lp        | C |      | 1 Df    | Not Reported |
|                    | Doliprane        | C |      |         | Not Reported |
|                    | Methotrexate     | C |      | 5.71 Mg | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Aug-2016              | 12473368      | EXPEDITED (15-DAY) |                    | DS              | IT-FRI-1000085347    |                      | 48 YR      | Male       | ITA            |

| <u>Preferred Term</u>                                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Drug Ineffective;<br>Dysgraphia; Dyskinesia;<br>Tremor | Escitalopram   |              |            | S           | Unknown      |                    |                 | Forest       |
|                                                                 | Quetiapine     |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                 | Venlafaxine    |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                 | Valproic Acid  |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                 | Sertraline     |              |            | S           | Unknown      | 50 Mg              |                 | Not Reported |
|                                                                 | Sertraline     |              |            | S           | Unknown      | 200 Mg             |                 | Not Reported |
|                                                                 | Sertraline     |              |            | S           | Unknown      | 50 Mg              |                 | Not Reported |
|                                                                 | Mirtazapine    |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                 | Mirtazapine    |              |            | S           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------|----------------------|------------|------------|----------------|
| 09-Aug-2016              | 12612603      | EXPEDITED (15-DAY) |                    | OT              | US-JAZZ-2016-US-013950 |                      |            | Female     | USA            |

| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Depression; Exostosis; | Xyrem          |              |            | S           | Oral         | 2.25 G, Bid        |                 | Jazz       |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                           |                           |   |      |                  |              |
|---------------------------|---------------------------|---|------|------------------|--------------|
| Fatigue; Weight Increased | Xyrem                     | S | Oral | Dose Adjustments | Jazz         |
|                           | Xyrem                     | S | Oral | 4.5 G, Bid       | Jazz         |
|                           | Lexapro                   | S |      |                  | Not Reported |
|                           | Nuvigil                   | C |      | Unk              | Not Reported |
|                           | Hydrocodone/Acetaminophen | C |      | Unk              | Not Reported |
|                           | Levothyroxine             | C |      | Unk              | Not Reported |
|                           | Phentermine               | C |      | Unk              | Not Reported |
|                           | Advil                     | C |      | Unk              | Not Reported |
|                           | Escitalopram              | C |      | Unk              | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 09-Aug-2016              | 12629800      | EXPEDITED (15-DAY) |                    | OT              | FR-PFIZER INC-2016371590 |                      | 33 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                                             | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                          | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|---------------------------------------|---------------------------------|-----------------|--------------|
| Cough; Nausea; Nervous System Disorder; Respiratory Distress; Vertigo; Wrong Product Administered | Lyrica               |              |            | S           | Oral                                  | 50 Mg, Unk                      |                 | Pfizer       |
|                                                                                                   | Laroxyl              |              |            | S           | Oral                                  | 50 Drops                        |                 | Not Reported |
|                                                                                                   | Imurel               |              |            | S           | Oral                                  | Unk                             |                 | Not Reported |
|                                                                                                   | Lansoprazole Mylan   |              |            | S           | Oral                                  | 15 Mg, Unk                      |                 | Not Reported |
|                                                                                                   | Calcidose Vitamine D |              |            | S           | Oral                                  | Unk                             |                 | Not Reported |
|                                                                                                   | Escitalopram Arrow   |              |            | S           | Oral                                  | 10 Mg, Unk                      |                 | Not Reported |
|                                                                                                   | Mytelase             |              |            | S           | Oral                                  | Unk                             |                 | Not Reported |
|                                                                                                   | Clairyg              |              |            | C           | Intravenous (not otherwise specified) | 0.4 G/Kg, Daily                 |                 | Not Reported |
|                                                                                                   | Lovenox              |              |            | C           | Subcutaneous                          | 0.4 MI, 1x/Day (In The Evening) |                 | Not Reported |
|                                                                                                   | Magnevie B6          |              |            | C           |                                       | 2 Tablets, 3x/Day               |                 | Not Reported |
|                                                                                                   | Folic Acid           |              |            | C           |                                       | 5 Mg, Daily                     |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------------------|----------------------|------------|------------|----------------|
| 09-Aug-2016              | 12634222      | EXPEDITED (15-DAY) |                    | HO              | CA-IMPAX LABORATORIES, INC-2016-IPXL-00838 |                      | 39 YR      | Male       | CAN            |

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| <a href="#">Preferred Term</a>                       | <a href="#">Product</a>    | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
|------------------------------------------------------|----------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Arrhythmia; Intentional Overdose; Serotonin Syndrome | Bupropion Hydrochloride Sr |                           |                             | S                        | Unknown                       | Unk                           |                          | Impax               |                         |
|                                                      | Phenytoin Chewable         |                           |                             | S                        | Unknown                       | Unk                           |                          | Corepharma          |                         |
|                                                      | Escitalopram               |                           |                             | S                        | Unknown                       | Unk                           |                          | Not Reported        |                         |
|                                                      | Olanzapine                 |                           |                             | S                        | Unknown                       | Unk                           |                          | Not Reported        |                         |
|                                                      | Primidone                  |                           |                             | S                        | Unknown                       | Unk                           |                          | Not Reported        |                         |
|                                                      | Quetiapine                 |                           |                             | S                        | Unknown                       | Unk                           |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                    | <a href="#">Case #</a>     | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 09-Aug-2016                                          | 12636093                   | EXPEDITED (15-DAY)        |                             | CA, OT                   | US-CIPLA LTD.-<br>2016US16987 |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>                       | <a href="#">Product</a>    | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Foetal Exposure During Pregnancy; Talipes            | Escitalopram               |                           |                             | S                        | Transplacental                | Unk                           |                          | Invagen             |                         |
| <a href="#">FDA Received Date</a>                    | <a href="#">Case #</a>     | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 09-Aug-2016                                          | 12636109                   | EXPEDITED (15-DAY)        |                             | CA, OT                   | US-CIPLA LTD.-<br>2016US16980 |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>                       | <a href="#">Product</a>    | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Congenital Anomaly; Foetal Exposure During Pregnancy | Escitalopram               |                           |                             | S                        | Transplacental                | Unk                           |                          | Invagen             |                         |
| <a href="#">FDA Received Date</a>                    | <a href="#">Case #</a>     | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 09-Aug-2016                                          | 12636111                   | EXPEDITED (15-DAY)        |                             | CA, OT                   | US-CIPLA LTD.-<br>2016US16989 |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>                       | <a href="#">Product</a>    | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Foetal Exposure During Pregnancy; Talipes            | Escitalopram               |                           |                             | S                        | Transplacental                | Unk                           |                          | Invagen             |                         |
| <a href="#">FDA Received Date</a>                    | <a href="#">Case #</a>     | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 09-Aug-2016                                          | 12636119                   | EXPEDITED (15-DAY)        |                             | CA, OT                   | US-CIPLA LTD.-<br>2016US16999 |                               |                          | Unknown             | USA                     |

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| <u>Preferred Term</u>                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
|-------------------------------------------|----------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|-----------------|------------|----------------|
| Foetal Exposure During Pregnancy; Talipes | Escitalopram   |                    |                    | S               | Transplacental                | Unk                  |                 | Invagen    |                |
| <u>FDA Received Date</u>                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 09-Aug-2016                               | 12636120       | EXPEDITED (15-DAY) |                    | CA, OT          | US-CIPLA LTD.-<br>2016US16995 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Foetal Exposure During Pregnancy; Talipes | Escitalopram   |                    |                    | S               | Transplacental                | Unk                  |                 | Invagen    |                |
| <u>FDA Received Date</u>                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 09-Aug-2016                               | 12636125       | EXPEDITED (15-DAY) |                    | CA, OT          | US-CIPLA LTD.-<br>2016US16998 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Foetal Exposure During Pregnancy; Talipes | Escitalopram   |                    |                    | S               | Transplacental                | Unk                  |                 | Invagen    |                |
| <u>FDA Received Date</u>                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 09-Aug-2016                               | 12636129       | EXPEDITED (15-DAY) |                    | CA, OT          | US-CIPLA LTD.-<br>2016US16996 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Foetal Exposure During Pregnancy; Talipes | Escitalopram   |                    |                    | S               | Transplacental                | Unk                  |                 | Invagen    |                |
| <u>FDA Received Date</u>                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 09-Aug-2016                               | 12636131       | EXPEDITED (15-DAY) |                    | CA, OT          | US-CIPLA LTD.-<br>2016US16992 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Foetal Exposure During Pregnancy; Talipes | Escitalopram   |                    |                    | S               | Transplacental                |                      |                 | Invagen    |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|---------------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 09-Aug-2016                                                  | 12636718       | EXPEDITED (15-DAY) |                    | HO              | US-TARO<br>PHARMACEUTICALS<br>USA.,INC-<br>2016SUN00387 |                      | 68 YR           | Female       | USA            |
| <u>Preferred Term</u>                                        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                            | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Autoimmune Hepatitis;<br>Drug-Induced Liver Injury           | Escitalopram   |                    |                    | S               | Unknown                                                 | 10 Mg, Daily         |                 | Taro         |                |
|                                                              | Diazepam       |                    |                    | C               |                                                         |                      |                 | Not Reported |                |
|                                                              | Lorazepam      |                    |                    | C               |                                                         |                      |                 | Not Reported |                |
|                                                              | Zolpidem       |                    |                    | C               |                                                         |                      |                 | Not Reported |                |
|                                                              | Fexofenadine   |                    |                    | C               |                                                         |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Aug-2016                                                  | 12637031       | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000086761                                       |                      | 18 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                            | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Erythema Nodosum                                             | Escitalopram   |                    |                    | S               | Oral                                                    | 1 Df                 |                 | Forest       |                |
|                                                              | Stresam        |                    |                    | S               | Oral                                                    | 1 Df                 |                 | Not Reported |                |
|                                                              | Leeloo         |                    |                    | S               | Oral                                                    | 0.1 Mg/0.02 Mg       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Aug-2016                                                  | 12638798       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000086763                                       |                      | 69 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                            | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State;<br>Delusion; Hyponatraemia;<br>Somnolence | Escitalopram   |                    |                    | S               | Oral                                                    | 5 Mg                 |                 | Forest       |                |
|                                                              | Risperidone    |                    |                    | S               | Oral                                                    |                      |                 | Not Reported |                |
|                                                              | Risperidone    |                    |                    | S               | Oral                                                    |                      |                 | Not Reported |                |
|                                                              | Alprazolam     |                    |                    | S               | Oral                                                    |                      |                 | Not Reported |                |
|                                                              | Alprazolam     |                    |                    | S               | Oral                                                    |                      |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                                    | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                    | <u>503B Facility</u>                                            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------|-----------------------|--------------------|--------------------|-----------------|-----------------------------------------|-----------------------------------------------------------------|-----------------|--------------|----------------|
| 10-Aug-2016                                                                                 | 9687412               | EXPEDITED (15-DAY) |                    | DE, HO          | US-RANBAXY-2013US-75060                 |                                                                 | 29 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                       | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                            | <u>Dosage Text</u>                                              | <u>Duration</u> | <u>Mfr</u>   |                |
| Brain Injury; Cardiac Arrest; Circulatory Collapse; Overdose; Pulseless Electrical Activity | Ibuprofen             |                    | Y                  | S               | Unknown                                 | Unk                                                             |                 | Ranbaxy      |                |
|                                                                                             | Escitalopram          |                    |                    | S               | Unknown                                 | Unk                                                             |                 | Not Reported |                |
|                                                                                             | Quetiapine            |                    |                    | S               | Unknown                                 | Unk                                                             |                 | Sun          |                |
|                                                                                             | Bupropion             |                    |                    | S               | Unknown                                 | Unk                                                             |                 | Not Reported |                |
|                                                                                             | Desvenlafaxine        |                    |                    | S               | Unknown                                 | Unk                                                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                    | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                    | <u>503B Facility</u>                                            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Aug-2016                                                                                 | 12640082              | EXPEDITED (15-DAY) |                    | OT              | US-FRI-1000086664                       |                                                                 | 34 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                       | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                            | <u>Dosage Text</u>                                              | <u>Duration</u> | <u>Mfr</u>   |                |
| Generalised Tonic-Clonic Seizure                                                            | Lexapro               |                    |                    | S               | Oral                                    |                                                                 |                 | Forest       |                |
|                                                                                             | Humira                |                    |                    | S               | Subcutaneous                            | 40mg/0.8ml                                                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                    | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                    | <u>503B Facility</u>                                            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Aug-2016                                                                                 | 12640730              | EXPEDITED (15-DAY) |                    | OT              | FR-TEVA-681668ISR                       |                                                                 | 18 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                       | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                            | <u>Dosage Text</u>                                              | <u>Duration</u> | <u>Mfr</u>   |                |
| Erythema Nodosum                                                                            | Leeloo 0,1 Mg/0,02 Mg |                    |                    | S               | Oral                                    | 1 Dosage Form= 0.02 Mg Ethinylestradiol + 0.1 Mg Levonorgestrel |                 | Duramed      |                |
|                                                                                             | Stresam               |                    |                    | S               | Oral                                    | 1 Dosage Forms Daily;                                           |                 | Not Reported |                |
|                                                                                             | Seroplex              |                    |                    | S               | Oral                                    | 1 Dosage Forms Daily;                                           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                    | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                    | <u>503B Facility</u>                                            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Aug-2016                                                                                 | 12641024              | EXPEDITED (15-DAY) |                    | HO, OT          | CA-ALKEM LABORATORIES LIMITED-CA-ALKEM- |                                                                 | 39 YR           | Male         | CAN            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

2016-00110

| <u>Preferred Term</u>                                                               | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction;<br>Overdose; Serotonin<br>Syndrome; Toxicity To<br>Various Agents | Quetiapine Fumarate |              |            | S           |              | Unknown            |                 | Alkem        |
|                                                                                     | Olanzapine          |              |            | S           |              | Unknown            |                 | Alkem        |
|                                                                                     | Bupropion           |              |            | S           |              | Unknown            |                 | Not Reported |
|                                                                                     | Escitalopram        |              |            | S           |              | Unknown            |                 | Not Reported |
|                                                                                     | Phenytoin           |              |            | S           |              | Unknown            |                 | Not Reported |
|                                                                                     | Primidone           |              |            | S           |              | Unknown            |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 10-Aug-2016              | 12641689      | NON-EXPEDITED    |                    |                 | US-<br>ELI_LILLY_AND_COMP<br>ANY-US201608005099 |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                                                        | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>       |
|----------------------------------------------------------------------------------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------------|
| Drug Interaction; Nausea;<br>Respiratory Tract<br>Congestion; Throat<br>Irritation; Vomiting | Zyprexa             |              |            | S           | Unknown      | Unk, Unknown       |                 | Eli Lilly And Co |
|                                                                                              | Humira              |              |            | S           | Subcutaneous | 2 In 1 Once        |                 | Not Reported     |
|                                                                                              | Trintellix          |              |            | S           | Unknown      | Unk Unk, Unknown   |                 | Not Reported     |
|                                                                                              | Lexapro             |              |            | S           | Unknown      | Unk, Unknown       |                 | Not Reported     |
|                                                                                              | Lamictal            |              |            | S           | Unknown      | Unk, Unknown       |                 | Not Reported     |
|                                                                                              | Ativan              |              |            | C           | Unknown      | Unk, Unknown       |                 | Not Reported     |
|                                                                                              | Prilosec /00661201/ |              |            | C           | Unknown      | Unk, Unknown       |                 | Not Reported     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Aug-2016              | 12642456      | EXPEDITED (15-DAY) |                    | DE, HO          | FR-PFM-FR-2016-2359  |                      | 58 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                             | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                 |
|-------------------------------------------------------|----------------|--------------|------------|-------------|------------------------------------------|--------------------|-----------------|----------------------------|
| Cerebrovascular Accident;<br>Death; Prinzmetal Angina | Navelbine      |              |            | S           | Intravenous (not<br>otherwise specified) | Unk                |                 | Pierre Fabre<br>Medicament |



## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|              |   |                                       |     |              |
|--------------|---|---------------------------------------|-----|--------------|
| Carboplatine | S | Intravenous (not otherwise specified) | Unk | Not Reported |
| Amlodipine   | S | Oral                                  | Unk | Not Reported |
| Bi-Tildiem   | S | Oral                                  | Unk | Not Reported |
| Cortancyl    | S | Oral                                  | Unk | Not Reported |
| Eupantol     | S | Oral                                  |     | Not Reported |
| Hydroxyzine  | S | Oral                                  | Unk | Not Reported |
| Zophren      | S | Oral                                  | Unk | Not Reported |
| Oxycodone    | S | Oral                                  |     | Not Reported |
| Seroplex     | S | Oral                                  |     | Not Reported |
| Colchicine   | C | Unknown                               |     | Not Reported |
| Natispray    | C | Unknown                               |     | Not Reported |
| Morphine     | C | Unknown                               |     | Not Reported |
| Inexium      | C | Unknown                               |     | Not Reported |

| <u>FDA Received Date</u>                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 11-Aug-2016                                | 12504427       | EXPEDITED (15-DAY) |                    | OT              | JP-FRI-1000085659    |                      | 45 YR           | Male       | JPN            |
| <u>Preferred Term</u>                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Generalised Erythema;<br>Pain In Extremity | Lexapro        |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest     |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 11-Aug-2016              | 12622013       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000086555    |                      | 45 YR           | Female       | FRA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Overdose;    | Escitalopram   |                    |                    | S               | Oral                 |                      |                 | Forest       |                |
| Multiple Fractures;      | Lysanxia       |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
| Pneumothorax Traumatic;  | Levothyrox     |                    |                    | C               | Unknown              | 125 Mcg              |                 | Not Reported |                |
| Road Traffic Accident;   | Inexium        |                    |                    | C               | Unknown              | 40 Mg                |                 | Not Reported |                |
| Subcutaneous Emphysema   |                |                    |                    |                 |                      |                      |                 |              |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                  | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                              | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|---------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 11-Aug-2016                               | 12644638                    | EXPEDITED (15-DAY) |                    | HO, OT          | DE-IMPAX<br>LABORATORIES, INC-<br>2016-IPXL-00847 |                      | 76 YR           | Male         | DEU            |
| <u>Preferred Term</u>                     | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                      | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Mania                                     | Galantamine Hydrobromide Er |                    |                    | S               | Unknown                                           | 8 Mg, Unk            |                 | Impax        |                |
|                                           | Galantamine Hydrobromide Er |                    |                    | S               | Unknown                                           | 16 Mg, Unk           |                 | Impax        |                |
|                                           | Escitalopram                |                    |                    | S               | Unknown                                           | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                  | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                              | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Aug-2016                               | 12648767                    | NON-EXPEDITED      |                    |                 | US-PFIZER INC-<br>2016379981                      |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                     | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                      | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity                     | Flagyl                      |                    |                    | S               |                                                   | Unk                  |                 | Pfizer       |                |
|                                           | Zoloft                      |                    |                    | S               |                                                   | Unk                  |                 | Pfizer       |                |
|                                           | Citalopram                  |                    |                    | S               |                                                   | Unk                  |                 | Not Reported |                |
|                                           | Lexapro                     |                    |                    | S               |                                                   | Unk                  |                 | Not Reported |                |
|                                           | Oxybutynin                  |                    |                    | S               |                                                   | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                  | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                              | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Aug-2016                               | 12648971                    | EXPEDITED (15-DAY) |                    | HO              | CH-BAYER-2016-<br>149753                          |                      | 82 YR           | Male         | CHE            |
| <u>Preferred Term</u>                     | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                      | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Diarrhoea; Pyrexia;<br>Serotonin Syndrome | Ciprofloxacin               |                    |                    | S               | Oral                                              | Unk, Every Week      |                 | Bayer        |                |
|                                           | Cipraxel                    |                    |                    | S               | Oral                                              | 20 Mg, Qd            |                 | Not Reported |                |
|                                           | Duodart                     |                    |                    | C               | Oral                                              | 1 Df, Qd             |                 | Not Reported |                |
|                                           | Enalapril                   |                    |                    | C               | Oral                                              | 20 Mg, Qd            |                 | Not Reported |                |
| <u>FDA Received Date</u>                  | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                              | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Aug-2016                               | 12649338                    | EXPEDITED (15-DAY) |                    | OT              | FR-MYLANLABS-<br>2016M1032982                     |                      |                 | Unknown      | FRA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                       | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                          | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|---------------------------------------|--------------------|-----------------|------------|
| Maternal Exposure During Pregnancy; Medication Error; Nausea; Respiratory Distress; Vertigo | Mylan-Lansoprazole   |              |            | S           | Oral                                  | 15 Mg, Unk         |                 | Mylan      |
|                                                                                             | Laroxyl              |              |            | S           | Oral                                  | 50 Gtt, Unk        |                 | Mylan      |
|                                                                                             | Lyrica               |              |            | S           | Oral                                  | 50 Mg, Unk         |                 | Mylan      |
|                                                                                             | Imurel /00001501/    |              |            | S           | Oral                                  | Unk                |                 | Mylan      |
|                                                                                             | Calcidose /07357001/ |              |            | S           | Oral                                  | Unk                |                 | Mylan      |
|                                                                                             | Escitalopram Arrow   |              |            | S           | Oral                                  | 10 Mg, Unk         |                 | Mylan      |
|                                                                                             | Mytelase             |              |            | S           | Oral                                  | Unk                |                 | Mylan      |
|                                                                                             | Vitamin D3           |              |            | S           | Oral                                  | Unk                |                 | Mylan      |
|                                                                                             | Clairyg              |              |            | C           | Intravenous (not otherwise specified) | Unk Unk, Qd        |                 | Mylan      |
|                                                                                             | Lovenox              |              |            | C           | Subcutaneous                          | 0.4 MI, Qd         |                 | Mylan      |
|                                                                                             | Magnevie B6          |              |            | C           |                                       | 2 Df, Tid          |                 | Mylan      |
|                                                                                             | Folic Acid           |              |            | C           |                                       | 5 Mg, Qd           |                 | Mylan      |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Aug-2016              | 12448146      | EXPEDITED (15-DAY) |                    | HO, OT          | US-TEVA-664092USA    |                      | 31 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------------------|-----------------|--------------|
| Fatigue; Generalised Tonic-Clonic Seizure; Loss Of Consciousness; Muscle Twitching; Neuroleptic Malignant Syndrome; Overdose | Lamotrigine    |              |            | S           | Oral         | 150 Milligram Daily;           |                 | Teva         |
|                                                                                                                              | Geodon         |              |            | S           | Oral         |                                |                 | Not Reported |
|                                                                                                                              | Lexapro        |              |            | S           | Oral         | 20 Milligram Daily;            |                 | Not Reported |
|                                                                                                                              | Lexapro        |              |            | S           |              |                                |                 | Not Reported |
|                                                                                                                              | Alprazolam     |              |            | S           | Oral         | 1.5 Milligram Daily; As Needed |                 | Not Reported |
|                                                                                                                              | Zolpidem       |              |            | S           | Oral         | 10 Milligram Daily;            |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Aug-2016              | 12650435      | EXPEDITED (15-DAY) |                    | OT              | FR-ROCHE-1810975     |                      | 46 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                  |                  |   |                                       |              |
|------------------|------------------|---|---------------------------------------|--------------|
| Thrombocytopenia | Rivotril         | S | Intravenous (not otherwise specified) | Not Reported |
|                  | Valium           | S | Oral                                  | Not Reported |
|                  | Xeroquel         | S | Oral                                  | Not Reported |
|                  | Xeroquel         | S | Oral                                  | Not Reported |
|                  | Loxapac          | S | Intravenous (not otherwise specified) | Not Reported |
|                  | Seroplex         | S | Oral                                  | Not Reported |
|                  | Lepticur         | S | Oral                                  | Not Reported |
|                  | Seresta          | S | Oral                                  | Not Reported |
|                  | Aotal            | S | Oral                                  | Not Reported |
|                  | Temesta (France) | C |                                       | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------|----------------------|------------|------------|----------------|
| 15-Aug-2016              | 12651151      | NON-EXPEDITED    |                    | OT              | US-JAZZ-2016-US-005360 |                      | 40 YR      | Female     | USA            |

| <u>Preferred Term</u>                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Depression; Paraesthesia; Somnolence | Xyrem          |              |            | S           | Oral         | 2.25 G, Bid        |                 | Jazz         |
|                                      | Xyrem          |              |            | S           | Oral         | Dose Adjustments   |                 | Jazz         |
|                                      | Xyrem          |              |            | S           | Oral         | 4.5 G, Bid         |                 | Jazz         |
|                                      | Lexapro        |              |            | S           |              |                    |                 | Not Reported |
|                                      | Zoloft         |              |            | S           |              |                    |                 | Not Reported |
|                                      | Neurontin      |              |            | C           |              | Unk                |                 | Not Reported |
|                                      | Nordette-28    |              |            | C           |              | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Aug-2016              | 12654153      | DIRECT           |                    | DS              |                      |                      | 47 YR      | Female     | USA            |

| <u>Preferred Term</u>                                     | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Aphasia; Asthenia; Balance Disorder; Dizziness; Ear Pain; | Escitalopram, 10 Mg |              |            | S           | Oral         |                    |                 | Forest       |
|                                                           | Estrogens           |              |            | C           |              |                    |                 | Not Reported |
|                                                           | Fish Oil            |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                                                                               |                                 |        |                              |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|--------|------------------------------|
| Fatigue; Feeling Abnormal; Gait Disturbance; Headache; Hypoaesthesia; Impaired Work Ability; Memory Impairment; Nerve Injury; Paraesthesia; Paraesthesia; Paraesthesia; Paraesthesia Oral; Paraesthesia Oral; Pharyngeal Paraesthesia; Tremor; Vision Blurred | Women'S Multi-Vitamin Magnesium | C<br>C | Not Reported<br>Not Reported |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|--------|------------------------------|

| <u>FDA Received Date</u>                 | <u>Case #</u>          | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------|------------------------|------------------|--------------------|-----------------|----------------------|----------------------------|-----------------|--------------|----------------|
| 15-Aug-2016                              | 12654688               | DIRECT           |                    | LT              |                      |                            | 35 YR           | Female       | USA            |
| <u>Preferred Term</u>                    | <u>Product</u>         | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Drug Interaction; Menorrhagia | Lexapro (Escitalopram) |                  |                    | S               | Oral                 | 1 Pill Once A Day By Mouth |                 | Costco       |                |
|                                          | Metoprolol             |                  |                    | C               |                      |                            |                 | Not Reported |                |
|                                          | Hectorol               |                  |                    | C               |                      |                            |                 | Not Reported |                |
|                                          | Epogen                 |                  |                    | C               |                      |                            |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                                                                                             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 16-Aug-2016                                                                                                                                                                                                          | 12629921       | EXPEDITED (15-DAY) |                    | OT              | DE-FRI-1000086680    |                      | 42 YR           | Female     | DEU            |
| <u>Preferred Term</u>                                                                                                                                                                                                | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Dizziness; Dysuria; Increased Appetite; Malaise; Micturition Disorder; Micturition Urgency; Muscular Weakness; Nausea; Paraesthesia; Product Use In Unapproved Indication; Pruritus; Sexual Dysfunction; Somnolence; | Escitalopram   |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest     |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Tremor; Urinary Retention;  
Urticaria; Weight  
Increased

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Aug-2016              | 12654020      | EXPEDITED (15-DAY) |                    | OT              | US-ACCORD-043050     |                      | 22 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                           | <u>Duration</u> | <u>Mfr</u> |
|---------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------------------------------------------------|-----------------|------------|
| Drug Ineffective;<br>Headache; Somnolence;<br>Violence-Related<br>Symptom | Escitalopram   |              |            | S           |              | Started At 10 Mg, 20 Mg<br>Pill To Reach Prescribed<br>Doses |                 | Accord     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Aug-2016              | 12654445      | EXPEDITED (15-DAY) |                    | OT              | GB-FRI-1000086835    |                      |            | Female     | GBR            |

| <u>Preferred Term</u>            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|----------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Colitis Ulcerative;<br>Diarrhoea | Escitalopram   |              |            | S           | Oral         | 5 Mg Daily         |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>        | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-----------------------------|----------------------|------------|------------|----------------|
| 16-Aug-2016              | 12656508      | NON-EXPEDITED    |                    |                 | US-TAKEDA-<br>2016TUS013973 |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                                   | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Nausea; Respiratory Tract<br>Congestion; Throat<br>Irritation; Vomiting | Trintellix          |              |            | S           | Unknown      | Unk                |                 | Takeda       |
|                                                                         | Humira              |              |            | S           | Subcutaneous | Unk Unk, Qd        |                 | Not Reported |
|                                                                         | Lexapro             |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                                                                         | Lamictal            |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                                                                         | Zyprexa             |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                                                                         | Ativan              |              |            | C           |              | Unk                |                 | Not Reported |
|                                                                         | Prilosec /00661201/ |              |            | C           |              | Unk                |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                      | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------|----------------------------------|--------------------|--------------------|-----------------|------------------------------------------|----------------------------------|-----------------|--------------|----------------|
| 16-Aug-2016                                                                                                   | 12657164                         | EXPEDITED (15-DAY) |                    | HO, OT          | FR-ASTRAZENECA-2016SE87089               |                                  | 47 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                         | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Bipolar Disorder;<br>Thrombocytopenia                                                                         | Xeroquel                         |                    |                    | S               | Oral                                     | 1.0df Once/Single Administration |                 | Astrazeneca  |                |
|                                                                                                               | Xeroquel                         |                    |                    | S               | Oral                                     | Once/Single Administration       |                 | Astrazeneca  |                |
|                                                                                                               | Rivotril                         |                    |                    | S               | Intravenous (not otherwise specified)    | 1.0df Once/Single Administration |                 | Not Reported |                |
|                                                                                                               | Valium                           |                    |                    | S               | Oral                                     |                                  |                 | Not Reported |                |
|                                                                                                               | Loxapac                          |                    |                    | S               | Intravenous (not otherwise specified)    | 2.0df Once/Single Administration |                 | Not Reported |                |
|                                                                                                               | Seroplex                         |                    |                    | S               | Oral                                     |                                  |                 | Not Reported |                |
|                                                                                                               | Lepticur                         |                    |                    | S               | Oral                                     |                                  |                 | Not Reported |                |
|                                                                                                               | Seresta                          |                    |                    | S               | Oral                                     |                                  |                 | Not Reported |                |
|                                                                                                               | Aotal                            |                    |                    | S               | Oral                                     |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                      | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Aug-2016                                                                                                   | 12474968                         | EXPEDITED (15-DAY) |                    | HO, OT          | AU-ACCORD-041674                         |                                  | 66 YR           | Male         | AUS            |
| <u>Preferred Term</u>                                                                                         | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Electrocardiogram Qt<br>Prolonged; Hypokalaemia;<br>Hypomagnesaemia;<br>Orthostatic Hypotension;<br>Poisoning | Escitalopram                     |                    |                    | S               |                                          |                                  |                 | Accord       |                |
|                                                                                                               | Perindopril/Perindopril Erbumine |                    |                    | S               |                                          |                                  |                 | Not Reported |                |
|                                                                                                               | Atenolol/Atenolol Hydrochloride  |                    |                    | S               |                                          |                                  |                 | Not Reported |                |
|                                                                                                               | Rosuvastatin/Rosuvastatin        |                    |                    | S               |                                          |                                  |                 | Not Reported |                |
|                                                                                                               | Calcium                          |                    |                    |                 |                                          |                                  |                 |              |                |
|                                                                                                               | Lercanidipine                    |                    |                    | S               |                                          |                                  |                 | Not Reported |                |
|                                                                                                               | Pantoprazole                     |                    |                    | S               |                                          |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                      | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Aug-2016                                                                                                   | 12658186                         | EXPEDITED (15-DAY) |                    | OT              | US-LUPIN PHARMACEUTICALS INC.-2016-03496 |                                  |                 | Female       | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                                                                                             | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------------|----------------|
| Coeliac Disease; Malaise                                                                                                                                                                                                          | Escitalopram Oxalate                 |                    |                    | S               | Unknown              |                      |                 | Not Reported     |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                          | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 17-Aug-2016                                                                                                                                                                                                                       | 12660266                             | NON-EXPEDITED      |                    |                 | US-FRI-1000078695    |                      | 77 YR           | Female           | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                             | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |
| Drug Ineffective                                                                                                                                                                                                                  | Celexa<br>Lexapro                    |                    |                    | S<br>S          |                      |                      |                 | Forest<br>Forest |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                          | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 18-Aug-2016                                                                                                                                                                                                                       | 10742763                             | EXPEDITED (15-DAY) |                    | OT              | CA-FRI-1000073858    |                      | 33 YR           | Female           | CAN            |
| <u>Preferred Term</u>                                                                                                                                                                                                             | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |
| Acute Hepatitis C; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Blood Bilirubin Increased; Gamma-Glutamyltransferase Increased; Lymphocyte Morphology Abnormal | Escitalopram                         |                    |                    | S               | Oral                 |                      |                 | Forest           |                |
|                                                                                                                                                                                                                                   | Buprenorphine Hydrochloride/Naloxone |                    |                    | S               | Sublingual           | 8 Mg                 |                 | Not Reported     |                |
|                                                                                                                                                                                                                                   | Buprenorphine Hydrochloride/Naloxone |                    |                    | S               | Sublingual           | 12 Mg                |                 | Not Reported     |                |
|                                                                                                                                                                                                                                   | Diazepam                             |                    |                    | S               | Oral                 |                      |                 | Not Reported     |                |
|                                                                                                                                                                                                                                   | Oxazepam                             |                    |                    | S               | Sublingual           |                      |                 | Not Reported     |                |
|                                                                                                                                                                                                                                   |                                      |                    |                    |                 |                      |                      |                 |                  |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                          | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 18-Aug-2016                                                                                                                                                                                                                       | 12405467                             | EXPEDITED (15-DAY) |                    | HO              | JP-FRI-1000084906    |                      | 60 YR           | Female           | JPN            |
| <u>Preferred Term</u>                                                                                                                                                                                                             | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |
| Hypotension; Loss Of Consciousness                                                                                                                                                                                                | Escitalopram                         |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest           |                |
|                                                                                                                                                                                                                                   | Escitalopram                         |                    |                    | S               | Oral                 |                      |                 | Forest           |                |
|                                                                                                                                                                                                                                   | Ecard                                |                    |                    | S               | Oral                 |                      |                 | Not Reported     |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                   |   |      |              |
|-------------------|---|------|--------------|
| Atorvastatin      | C | Oral | Not Reported |
| Myslee            | C | Oral | Not Reported |
| Depas (Etizolam)  | C | Oral | Not Reported |
| Rize              | C | Oral | Not Reported |
| Zolpidem Tartrate | C | Oral | Not Reported |
| Lexotan           | C | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Aug-2016              | 12505288      | EXPEDITED (15-DAY) |                    | OT              | JP-FRI-1000085688    |                      | 50 YR      | Female     | JPN            |

| <u>Preferred Term</u>                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Electrocardiogram Qt Prolonged; Sinus Bradycardia | Escitalopram   |              |            | S           | Oral         |                    |                 | Forest       |
|                                                   | Escitalopram   |              |            | S           | Oral         | 20 Mg              |                 | Forest       |
|                                                   | Escitalopram   |              |            | S           | Oral         | 10 Mg              |                 | Not Reported |
|                                                   | Escitalopram   |              |            | S           | Oral         | 5 Mg               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-------------------------|----------------------|------------|------------|----------------|
| 18-Aug-2016              | 12662945      | NON-EXPEDITED    |                    |                 | US-TAKEDA-2016TUS014280 |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Ineffective; Libido Decreased | Brintellix     |              |            | S           | Unknown      | Unk                |                 | Takeda       |
|                                    | Lexapro        |              |            | S           | Unknown      | 20 Mg, Unk         |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Aug-2016              | 12665672      | NON-EXPEDITED    |                    |                 | US-FRI-1000085631    |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Drug Hypersensitivity | Celexa         |              |            | S           |              |                    |                 | Forest     |
|                       | Lexapro        |              |            | S           |              |                    |                 | Forest     |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Aug-2016              | 12666033      | NON-EXPEDITED    |                    |                 | US-JAZZ-JPI-P-006566 |                      | 29 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                 | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>             | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------------------|--------------------|-----------------|--------------|
| Amnesia; Blood Pressure Increased; Depression; Insomnia; Somnolence; Weight Increased | Xyrem                |              |            | S           | Oral                     | 2.5 G, Bid         |                 | Jazz         |
|                                                                                       | Xyrem                |              |            | S           | Oral                     | 3.5 G, Qd          |                 | Jazz         |
|                                                                                       | Xyrem                |              |            | S           | Oral                     | 3 G, Qd            |                 | Jazz         |
|                                                                                       | Xyrem                |              |            | S           | Oral                     | 4 G, Bid           |                 | Jazz         |
|                                                                                       | Aripiprazole         |              |            | S           | Oral                     | Unk                |                 | Not Reported |
|                                                                                       | Escitalopram Oxalate |              |            | S           | Oral                     | Unk                |                 | Not Reported |
|                                                                                       | Ciclesonide          |              |            | C           | Respiratory (inhalation) |                    |                 | Not Reported |
|                                                                                       | Dextroamphetamine    |              |            | C           |                          |                    |                 | Not Reported |
|                                                                                       | Dextroamphetamine    |              |            | C           |                          |                    |                 | Not Reported |
|                                                                                       | Pramipexole          |              |            | C           |                          |                    |                 | Not Reported |
|                                                                                       | Pramipexole          |              |            | C           |                          |                    |                 | Not Reported |
|                                                                                       | Citalopram           |              |            | C           |                          |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Aug-2016              | 12666409      | EXPEDITED (15-DAY) |                    | OT              | ZA-FRI-1000086853    |                      | 3 YR       | Male       | ZAF            |

| <u>Preferred Term</u>                                                                                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|------------|
| Autism Spectrum Disorder; Facial Paralysis; Foetal Exposure During Pregnancy; Muscle Contractions Involuntary | Escitalopram   |              |            | S           | Transplacental |                    |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Aug-2016              | 12666410      | EXPEDITED (15-DAY) |                    | DS, HO, LT      | SE-FRI-1000086893    |                      | 41 YR      | Male       | SWE            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                         |              |   |         |                                         |              |
|-------------------------|--------------|---|---------|-----------------------------------------|--------------|
| Epilepsy; Muscle Spasms | Escitalopram | S | Unknown | High Dose Which Was Decreased Last Year | Forest       |
|                         | Perphenazine | C | Unknown |                                         | Not Reported |
|                         | Haldol       | C | Unknown |                                         | Not Reported |
|                         | Abilify      | C | Unknown |                                         | Not Reported |
|                         | Stesolid     | C | Unknown |                                         | Not Reported |
|                         | Risperdal    | C | Unknown |                                         | Not Reported |
|                         | Voxra        | C | Unknown |                                         | Not Reported |
|                         | Sobril       | C | Unknown |                                         | Not Reported |
|                         | Nozinan      | C | Unknown |                                         | Not Reported |
|                         | Zyprexa      | C | Unknown |                                         | Not Reported |
|                         | Atarax       | C | Unknown |                                         | Not Reported |
|                         | Xanor        | C | Unknown |                                         | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Aug-2016              | 12666412      | EXPEDITED (15-DAY) |                    | HO              | KR-FRI-1000086892    |                      | 33 YR      | Male       | KOR            |

| <u>Preferred Term</u>                                                  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Depressed Level Of Consciousness; Product Use In Unapproved Indication | Escitalopram   |              |            | S           | Oral         | 2.5 Mg             |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Aug-2016              | 12667262      | DIRECT           |                    | DS              |                      |                      | 56 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                 | <u>Product</u>                                                    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------|-------------------------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Depression; Disease Recurrence; Drug Ineffective; Product Substitution Issue | Escitalopram Oxalate Oral Sol'n, 5 Mg Camber Pharmaceuticals, Inc |              |            | S           | Oral         | 2 Teaspoon         |                 | Camber       |
|                                                                                       | Centrum Silver Multivitamin                                       |              |            | C           |              |                    |                 | Not Reported |
|                                                                                       | Fish Oil                                                          |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|------------|------------|----------------|
| 19-Aug-2016              | 12666498      | EXPEDITED (15-DAY) |                    | OT              | US-CIPLA LTD.-<br>2016US08309 |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>                                                                              | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------|-------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Breast Pain; Condition Aggravated; Drug Ineffective; Galactorrhoea; Hypersexuality; Vision Blurred | Escitalopram                  |              |            | S           | Unknown      | Unk                |                 | Invagen      |
|                                                                                                    | Escitalopram                  |              |            | S           |              |                    |                 | Invagen      |
|                                                                                                    | Sertraline                    |              |            | S           | Unknown      | Unk                |                 | Invagen      |
|                                                                                                    | Sertraline                    |              |            | S           |              |                    |                 | Invagen      |
|                                                                                                    | Venlafaxine                   |              |            | S           | Unknown      | 75 Mg, Qd          |                 | Cipla        |
|                                                                                                    | Venlafaxine                   |              |            | S           | Unknown      | 37.5 Mg, Qd        |                 | Cipla        |
|                                                                                                    | Buspirone                     |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                                                                                                    | Buspirone                     |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                    | Paroxetine                    |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                                                                                                    | Paroxetine                    |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                    | Clonazepam                    |              |            | C           | Unknown      | 0.25 Mg, Prn       |                 | Not Reported |
|                                                                                                    | Fexofenadine                  |              |            | C           | Unknown      | Unk                |                 | Not Reported |
|                                                                                                    | Pseudoephedrine Hydrochloride |              |            | C           | Unknown      | Unk                |                 | Not Reported |
|                                                                                                    | Fluticasone                   |              |            | C           | Unknown      | Unk                |                 | Not Reported |
|                                                                                                    | Albuterol                     |              |            | C           | Unknown      | Unk                |                 | Not Reported |
|                                                                                                    | Budesonide/Formoterol         |              |            | C           | Unknown      | Unk                |                 | Not Reported |
|                                                                                                    | Omeprazole                    |              |            | C           | Unknown      | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>        | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-----------------------------|----------------------|------------|------------|----------------|
| 19-Aug-2016              | 12666719      | NON-EXPEDITED    |                    |                 | US-TAKEDA-<br>2016TUS014194 |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>                            | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------|-------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Dizziness; Headache; Off Label Use; Paraesthesia | Brintellix        |              |            | S           | Unknown      | 10 Mg, Unk         |                 | Takeda       |
|                                                  | Elicea /01588501/ |              |            | S           | Unknown      | 2.5 Mg, Unk        |                 | Not Reported |
|                                                  | Elicea /01588501/ |              |            | S           | Unknown      | 5 Mg, Unk          |                 | Not Reported |
|                                                  | Elicea /01588501/ |              |            | S           | Unknown      | 7.5 Mg, Unk        |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Elicea /01588501/

S

Unknown

10 Mg, Unk

Not Reported

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-------------------------|----------------------|------------|------------|----------------|
| 19-Aug-2016              | 12667569      | NON-EXPEDITED    |                    |                 | US-TAKEDA-2016TUS014274 |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>                                                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Dizziness; Dysstasia; Feeling Abnormal; Speech Disorder; Tremor | Brintellix     |              |            | S           | Unknown      | 5 Mg, Unk          |                 | Takeda       |
|                                                                          | Brintellix     |              |            | S           | Unknown      | 10 Mg, Unk         |                 | Takeda       |
|                                                                          | Brintellix     |              |            | S           | Unknown      | 20 Mg, Unk         |                 | Takeda       |
|                                                                          | Lexapro        |              |            | S           | Unknown      | 20 Mg, Unk         |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Aug-2016              | 12669861      | EXPEDITED (15-DAY) |                    | HO, LT          | ZA-FRI-1000015964    |                      | 83 YR      | Female     | ZAF            |

| <u>Preferred Term</u>                                                                                                           | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------|-----------------------------|--------------|------------|-------------|--------------|---------------------------------|-----------------|--------------|
| Dyskinesia; Hyperhidrosis; Hyperkalaemia; Hypertension; Psychotic Disorder; Pyrexia; Renal Failure; Rhabdomyolysis; Tachycardia | Escitalopram                |              |            | S           | Oral         | 10 Mg                           |                 | Forest       |
|                                                                                                                                 | Escitalopram                |              |            | S           |              |                                 |                 | Forest       |
|                                                                                                                                 | Rasagiline                  |              |            | S           | Oral         |                                 |                 | Not Reported |
|                                                                                                                                 | Tramacet                    |              |            | S           | Oral         | 300 Mg                          |                 | Not Reported |
|                                                                                                                                 | Duragesic                   |              |            | S           | Other        | 4.1667 Mcg                      |                 | Not Reported |
|                                                                                                                                 | Stalevo                     |              |            | S           | Oral         | 500 Mg                          |                 | Not Reported |
|                                                                                                                                 | Celebrex                    |              |            | C           | Oral         | 100 Mg                          |                 | Not Reported |
|                                                                                                                                 | Immovane                    |              |            | C           | Oral         | 7.5 Mg                          |                 | Not Reported |
|                                                                                                                                 | Sinemet Cr                  |              |            | C           | Oral         | 50/200 Mg A Day                 |                 | Not Reported |
|                                                                                                                                 | Calciferol [Ergocalciferol] |              |            | C           |              | 50,000 Iu/Mg Every Mon/Wed/Fri. |                 | Not Reported |
|                                                                                                                                 | Ocuvite Lutein              |              |            | C           |              |                                 |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Aug-2016              | 12671153      | DIRECT           |                    | HO, LT, OT      |                      |                      | 24 YR      | Female     | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                             | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|-------------------------------------|----------------------|-----------------|--------------|----------------|
| Suicide Attempt                                                                                                                                                   | Lexapro, 20 Mg       |                    |                    | S               | Oral                                | At Bedtime           |                 | Not Reported |                |
|                                                                                                                                                                   | Multiple Vitamins    |                    |                    | C               |                                     |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                          | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Aug-2016                                                                                                                                                       | 12671512             | EXPEDITED (15-DAY) |                    | OT              | FR-AUROBINDO-AUR-<br>APL-2016-10372 |                      | 33 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                                             | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Nausea; Respiratory<br>Distress; Vertigo; Wrong<br>Patient Received Product                                                                                       | Escitalopram Arrow   |                    |                    | S               | Oral                                | 10 Mg, Unk           |                 | Aurobindo    |                |
|                                                                                                                                                                   | Laroxyl              |                    |                    | S               | Oral                                | 50 Drops             |                 | Not Reported |                |
|                                                                                                                                                                   | Imurel /00001501/    |                    |                    | S               | Unknown                             | Unk                  |                 | Not Reported |                |
|                                                                                                                                                                   | Lansoprazole Mylan   |                    |                    | S               | Oral                                | 15 Mg, Unk           |                 | Not Reported |                |
|                                                                                                                                                                   | Calcidose Vitamine D |                    |                    | S               | Oral                                | Unk                  |                 | Not Reported |                |
|                                                                                                                                                                   | Mytelase             |                    |                    | S               | Oral                                | Unk                  |                 | Not Reported |                |
|                                                                                                                                                                   | Lyrica               |                    |                    | S               | Oral                                | 50 Mg, Unk           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                          | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Aug-2016                                                                                                                                                       | 12672075             | EXPEDITED (15-DAY) |                    | DE, HO, LT      | CH-JNJFOC-<br>20160813272           |                      | 60 YR           | Male         | CHE            |
| <u>Preferred Term</u>                                                                                                                                             | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Drug<br>Interaction; Drug Level<br>Increased; Inhibitory Drug<br>Interaction; Sinus Node<br>Dysfunction; Upper<br>Gastrointestinal<br>Haemorrhage | Imbruvica            |                    |                    | S               | Oral                                |                      |                 | Not Reported |                |
|                                                                                                                                                                   | Amiodarone           |                    |                    | S               | Oral                                |                      |                 | Not Reported |                |
|                                                                                                                                                                   | Xarelto              |                    |                    | S               | Oral                                |                      |                 | Not Reported |                |
|                                                                                                                                                                   | Cipraxel             |                    |                    | S               | Oral                                |                      |                 | Not Reported |                |
|                                                                                                                                                                   | Nebivolol            |                    |                    | C               | Oral                                |                      |                 | Not Reported |                |
|                                                                                                                                                                   | Ramipril             |                    |                    | C               | Oral                                |                      |                 | Not Reported |                |
|                                                                                                                                                                   | Eplerenone           |                    |                    | C               | Oral                                |                      |                 | Not Reported |                |
|                                                                                                                                                                   | Atorvastatin         |                    |                    | C               | Oral                                |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                         | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|----------------------|----------------|
| 22-Aug-2016                                                                                                                      | 12673653                | EXPEDITED (15-DAY) |                    | HO, OT          | AU-TEVA-2016-15379                              |                      | 66 YR           | Male                 | AUS            |
| <u>Preferred Term</u>                                                                                                            | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Electrocardiogram Qt Prolonged; Hypokalaemia; Hypomagnesaemia; Orthostatic Hypotension; Poisoning                                | Escitalopram (Unknown)  |                    |                    | S               | Unknown                                         | 10 Milligram Daily;  |                 | Ivax                 |                |
|                                                                                                                                  | Atenolol                |                    |                    | S               | Unknown                                         |                      |                 | Not Reported         |                |
|                                                                                                                                  | Rosuvastatin            |                    |                    | S               | Unknown                                         |                      |                 | Not Reported         |                |
|                                                                                                                                  | Pantoprazole (Unknown)  |                    |                    | S               | Unknown                                         |                      |                 | Teva                 |                |
|                                                                                                                                  | Perindopril (Unknown)   |                    |                    | S               | Unknown                                         |                      |                 | Not Reported         |                |
|                                                                                                                                  | Lercanidipine (Unknown) |                    |                    | S               | Unknown                                         |                      |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                                                                         | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 23-Aug-2016                                                                                                                      | 10892989                | EXPEDITED (15-DAY) |                    | CA, OT          | FR-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-013971 |                      | 238 DAY         | Unknown              | FRA            |
| <u>Preferred Term</u>                                                                                                            | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Congenital Aortic Anomaly; Foetal Exposure During Pregnancy; Premature Baby; Pulmonary Valve Stenosis; Ventricular Septal Defect | Abilify                 |                    |                    | S               | Transplacental                                  | Unk Unk, Qd          |                 | Bristol Myers Squibb |                |
|                                                                                                                                  | Dihydroergotamine       |                    |                    | S               | Transplacental                                  |                      |                 | Not Reported         |                |
|                                                                                                                                  | Escitalopram            |                    |                    | S               | Transplacental                                  | Unk                  |                 | Not Reported         |                |
|                                                                                                                                  | Oxazepam                |                    |                    | S               | Transplacental                                  | Unk                  |                 | Not Reported         |                |
|                                                                                                                                  | Pipamperone             |                    |                    | S               | Transplacental                                  | Unk                  |                 | Not Reported         |                |
|                                                                                                                                  | Loprazolam              |                    |                    | S               | Transplacental                                  | Unk                  |                 | Not Reported         |                |
|                                                                                                                                  | Dipotassium Clorazepate |                    |                    | S               | Transplacental                                  | Unk                  |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                                                                         | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 23-Aug-2016                                                                                                                      | 11968404                | EXPEDITED (15-DAY) |                    | OT              | CH-BRISTOL-MYERS SQUIBB COMPANY-17035734        |                      |                 | Female               | CHE            |
| <u>Preferred Term</u>                                                                                                            | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Breech Presentation; Foetal Exposure During                                                                                      | Abilify                 |                    |                    | S               | Transplacental                                  | 15 Mg, Qd            |                 | Bristol Myers Squibb |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                  |                         |                    |                    |                 |                                                            |                      |                 |            |                      |
|----------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|------------------------------------------------------------|----------------------|-----------------|------------|----------------------|
| Pregnancy                                                                        | Ciprallex               |                    |                    | S               | Transplacental                                             | 20 Mg, Qd            |                 |            | Not Reported         |
|                                                                                  | Temesta (Lorazepam)     |                    |                    | S               | Transplacental                                             | Unk                  |                 |            | Not Reported         |
| <u>FDA Received Date</u>                                                         | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u>       |
| 23-Aug-2016                                                                      | 12046834                | EXPEDITED (15-DAY) |                    | OT              | CH-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>BMS-2012-000050     |                      | 28 YR           | Female     | CHE                  |
| <u>Preferred Term</u>                                                            | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                      |
| Caesarean Section; Live Birth; Maternal Exposure During Pregnancy; Off Label Use | Abilify                 |                    |                    | S               | Oral                                                       | 15 Mg, Qd            |                 |            | Bristol Myers Squibb |
|                                                                                  | Ciprallex               |                    |                    | S               | Oral                                                       | 20 Mg, Qd            |                 |            | Not Reported         |
|                                                                                  | Temesta (Lorazepam)     |                    |                    | S               | Oral                                                       | Unk                  |                 |            | Not Reported         |
| <u>FDA Received Date</u>                                                         | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u>       |
| 23-Aug-2016                                                                      | 12675086                | EXPEDITED (15-DAY) |                    | OT              | GB-MACLEODS<br>PHARMACEUTICALS<br>US LTD-<br>MAC2016003009 |                      |                 | Unknown    | GBR                  |
| <u>Preferred Term</u>                                                            | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                      |
| Colitis Ulcerative; Diarrhoea                                                    | Escitalopram 5mg Tablet |                    |                    | S               | Oral                                                       | 5 Mg, Qd (Daily)     |                 |            | Macleods             |
| <u>FDA Received Date</u>                                                         | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u>       |
| 23-Aug-2016                                                                      | 12675771                | NON-EXPEDITED      |                    | OT              | US-JAZZ-2016-US-<br>006684                                 |                      | 34 YR           | Female     | USA                  |
| <u>Preferred Term</u>                                                            | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                      |
| Hypertension                                                                     | Xyrem                   |                    |                    | S               | Oral                                                       | 2.25 G, Bid          |                 |            | Jazz                 |
|                                                                                  | Xyrem                   |                    |                    | S               | Oral                                                       | Dose Adjustments     |                 |            | Jazz                 |
|                                                                                  | Xyrem                   |                    |                    | S               | Oral                                                       | 4.5 G, Bid           |                 |            | Jazz                 |
|                                                                                  | Plaquenil               |                    |                    | C               |                                                            | Unk                  |                 |            | Not Reported         |
|                                                                                  | Mirtazapine             |                    |                    | C               |                                                            | Unk                  |                 |            | Not Reported         |
|                                                                                  | Quasense                |                    |                    | C               |                                                            | Unk                  |                 |            | Not Reported         |
|                                                                                  | Xanax                   |                    |                    | C               |                                                            | Unk                  |                 |            | Not Reported         |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                         |   |                |              |
|-------------------------|---|----------------|--------------|
| Probiotic               | C | Unk            | Not Reported |
| Olux                    | C | Unk            | Not Reported |
| Desonide                | C | Unk            | Not Reported |
| Cyclobenzaprine         | C | Unk            | Not Reported |
| Synthroid               | C | Unk            | Not Reported |
| Ambien                  | C | Unk            | Not Reported |
| Ferrous Gluconate       | C |                | Not Reported |
| Lexapro                 | S |                | Not Reported |
| Mirapex                 | C | Unk            | Not Reported |
| Multivitamins Plus Iron | C | Unk            | Not Reported |
| Nuvigil                 | C |                | Not Reported |
| Relpax                  | C |                | Not Reported |
| Seasonique              | C | 0.15-0.03-0.01 | Not Reported |
| Valpax                  | C |                | Not Reported |
| Iron                    | C |                | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Aug-2016              | 12676448      | EXPEDITED (15-DAY) |                    | OT              | IE-TEVA-684431ACC    |                      |            | Female     | IRL            |

| <u>Preferred Term</u>                                                                                                | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------|-------------------|--------------|------------|-------------|--------------|-----------------------------|-----------------|--------------|
| Epistaxis; Feeling Abnormal; Headache; Lethargy; Slow Speech; Somnolence; Speech Disorder; Thinking Abnormal; Thirst | Escitalopram Teva |              |            | S           | Oral         |                             |                 | Ivax         |
|                                                                                                                      | Eltroxin          |              |            | C           |              | 50mg Mon-Fri, 100mg Sat-Sun |                 | Not Reported |
|                                                                                                                      | Eltroxin          |              |            | C           |              | 50mg Mon-Fri, 100mg Sat-Sun |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------------|----------------------|------------|------------|----------------|
| 23-Aug-2016              | 12676480      | NON-EXPEDITED    |                    |                 | US-GLAXOSMITHKLINE-US2016GSK115859 |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                          | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|----------------------------------------------------------------|-------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Drug Interaction; Nausea; Respiratory Tract Congestion; Throat | Lamictal                      |              |            | S           |              | Unk Unk, U         |                 | Glaxosmithkline |
|                                                                | Humira Solution For Injection |              |            | S           | Subcutaneous | 2 In 1 Once        |                 | Not Reported    |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                      |            |   |            |              |
|----------------------|------------|---|------------|--------------|
| Irritation; Vomiting | Trintellix | S | Unk Unk, U | Not Reported |
|                      | Lexapro    | S | Unk Unk, U | Not Reported |
|                      | Zyprexa    | S | Unk Unk, U | Not Reported |
|                      | Ativan     | C | Unk Unk, U | Not Reported |
|                      | Prilosec   | C | Unk Unk, U | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-------------------------|----------------------|------------|------------|----------------|
| 23-Aug-2016              | 12677222      | NON-EXPEDITED    |                    |                 | US-TAKEDA-2016TUS014301 |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>                                                                  | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------|-------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anger; Nausea; Vomiting; Withdrawal Syndrome; Wrong Technique In Product Usage Process | Trintellix        |              |            | S           | Unknown      | 5 Mg, Unk          |                 | Takeda       |
|                                                                                        | Trintellix        |              |            | S           | Unknown      | 20 Mg, Unk         |                 | Takeda       |
|                                                                                        | Trintellix        |              |            | S           | Unknown      | 5 Mg, Unk          |                 | Takeda       |
|                                                                                        | Trintellix        |              |            | S           | Unknown      | 2 Mg, Unk          |                 | Takeda       |
|                                                                                        | Celexa /00582602/ |              |            | S           | Unknown      | 5 Mg, Unk          |                 | Not Reported |
|                                                                                        | Lexapro           |              |            | S           | Unknown      | 5 Mg, Unk          |                 | Not Reported |
|                                                                                        | Lexapro           |              |            | S           | Unknown      | 7 Mg, Unk          |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Aug-2016              | 12679239      | DIRECT           |                    |                 |                      |                      | 49 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                      | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|------------------------------------------------------------------------------------------------------------|-------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Product Dose Omission; Product Formulation Issue; Product Substitution Issue; Somnolence; Weight Increased | Escitalopram 10 Mg Tab, 10 Mg |              |            | S           | Oral         |                    |                 | Accord     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Aug-2016              | 12679489      | DIRECT           | Y                  | RI              |                      |                      | 33 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Suicidal Ideation; Thinking Abnormal      Escitalopram      S      Oral      Not Reported

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 24-Aug-2016              | 11876537      | EXPEDITED (15-DAY) |                    | OT              | RO-JNJFOC-20151219642 |                      | 71 YR      | Female     | ROM            |

| <u>Preferred Term</u>                                                                                                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cognitive Disorder; Drug Ineffective For Unapproved Indication; Extrapyramidal Disorder; Hallucination; Off Label Use | Risperdal      |              |            | S           | Unknown      | For 2 Weeks        |                 | Not Reported |
|                                                                                                                       | Risperdal      |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                                       | Risperdal      |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                                       | Risperdal      |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                                       | Risperdal      |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                                       | Risperdal      |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                                       | Risperdal      |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                                       | Risperdal      |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                                       | Risperdal      |              |            | S           | Unknown      | For 2 Weeks        |                 | Not Reported |
|                                                                                                                       | Escitalopram   |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                                       | Lorazepam      |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                                       | Diosminum      |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                                                                       | Betahistinum   |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                                                                       | Ginkgo Biloba  |              |            | C           | Unknown      |                    |                 | Not Reported |
| Acidum Valproicum                                                                                                     |                |              | C          | Unknown     |              |                    | Not Reported    |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 24-Aug-2016              | 12678995      | EXPEDITED (15-DAY) |                    | OT              | US-CIPLA LTD.-2016US17472 |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Angle Closure Glaucoma; Choroidal Effusion | Escitalopram   |              |            | S           | Unknown      | Unk                |                 | Invagen    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Aug-2016              | 12679935      | NON-EXPEDITED    |                    | HO, OT          | US-FRI-1000080356    |                      | 51 YR      | Male       | USA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                                                              | <u>Product</u>                 | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|--------------------------------------------------------------------------------------------------------------------|--------------------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Extrapyramidal Disorder;<br>Rhabdomyolysis                                                                         | Lexapro                        |                  |                    | S               |                      | 15mg                 |                 | Forest       |                |
|                                                                                                                    | Mirtazapine                    |                  |                    | S               |                      | 15mg                 |                 | Not Reported |                |
|                                                                                                                    | Lipitor                        |                  |                    | C               |                      | 10mg                 |                 | Not Reported |                |
|                                                                                                                    | Seroquel                       |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                    | Depakote                       |                  |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                           | <u>Case #</u>                  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Aug-2016                                                                                                        | 12680017                       | NON-EXPEDITED    |                    | HO              | US-FRI-1000080537    |                      | 13 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                              | <u>Product</u>                 | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depressed Mood; Suicidal<br>Ideation                                                                               | Lexapro                        |                  |                    | S               |                      |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                           | <u>Case #</u>                  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Aug-2016                                                                                                        | 12680019                       | NON-EXPEDITED    |                    | OT              | US-FRI-1000080427    |                      | 89 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                              | <u>Product</u>                 | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Depression;<br>Drug Ineffective; Fatigue;<br>Gait Disturbance;<br>Headache; Suicidal<br>Ideation; Tremor | Lexapro                        |                  |                    | S               | Oral                 |                      |                 | Forest       |                |
|                                                                                                                    | Lexapro                        |                  |                    | S               | Oral                 |                      |                 | Forest       |                |
|                                                                                                                    | Xanax                          |                  |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                           | <u>Case #</u>                  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Aug-2016                                                                                                        | 12680020                       | NON-EXPEDITED    |                    | HO              | US-FRI-1000080810    |                      | 66 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                              | <u>Product</u>                 | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyponatraemia                                                                                                      | Lexapro                        |                  |                    | S               |                      |                      |                 | Forest       |                |
|                                                                                                                    | Blinded Ruxolitinib Or Placebo |                  |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                    | Capecitabine                   |                  |                    | S               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 24-Aug-2016              | 12680096       | NON-EXPEDITED    |                    | OT              | US-FRI-1000086227    |                      | 26 YR           | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Suicidal Ideation        | Lexapro        |                  |                    | S               | Oral                 | 0.5mg                |                 | Forest       | Not Reported   |
|                          | Rexulti        |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                          | Xanax          |                  |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                    | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 24-Aug-2016                                                                                 | 12680102       | NON-EXPEDITED    |                    | OT              | US-FRI-1000083654    |                      | 43 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                       | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Intentional Self-Injury; Morbid Thoughts; Suicidal Behaviour; Unevaluable Event | Lexapro        |                  |                    | S               |                      |                      |                 | Forest       | Not Reported   |
|                                                                                             | Rexulti        |                  |                    | S               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                  | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|-----------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 24-Aug-2016                                               | 12680103       | NON-EXPEDITED    |                    | OT              | US-FRI-1000083578    |                      |                 | Female     | USA            |
| <u>Preferred Term</u>                                     | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Depression; Intentional Product Misuse; Suicidal Ideation | Lexapro        |                  |                    | S               |                      | 20mg                 |                 | Forest     |                |
|                                                           | Lexapro        |                  |                    | S               |                      | 40mg                 |                 | Forest     |                |

| <u>FDA Received Date</u>                                                  | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 24-Aug-2016                                                               | 12680105       | NON-EXPEDITED    |                    | HO              | US-FRI-1000085455    |                      | 13 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                     | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain Upper; Arthralgia; Depressed Mood; Headache; Off Label Use | Lexapro        |                  |                    | S               |                      | 10mg                 |                 | Forest       | Not Reported   |
|                                                                           | Flonase        |                  |                    | C               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 24-Aug-2016                                                          | 12680120       | EXPEDITED (15-DAY) |                    | OT              | US-FRI-1000086504    |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Nausea; Serotonin Syndrome                                           | Escitalopram   |                    |                    | S               | Oral                 | 10 Mg, Unk           |                 | Forest       |                |
|                                                                      | Trintellix     |                    |                    | S               | Oral                 | 5 Mg, Qd             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Aug-2016                                                          | 12680190       | NON-EXPEDITED      |                    | HO              | US-FRI-1000084522    |                      | 15 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Intentional Overdose; Suicidal Ideation; Suicide Attempt | Lexapro        |                    |                    | S               | Oral                 |                      |                 | Forest       |                |
|                                                                      | Lexapro        |                    |                    | S               | Oral                 | 50 Mg                |                 | Forest       |                |
|                                                                      | Lexapro        |                    |                    | S               |                      | 20 Mg                |                 | Not Reported |                |
|                                                                      | Sertraline     |                    |                    | S               | Oral                 | 100mg                |                 | Not Reported |                |
|                                                                      | Seroquel       |                    |                    | C               |                      | 150mg                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Aug-2016                                                          | 12680434       | NON-EXPEDITED      |                    |                 | US-FRI-1000079160    |                      | 27 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Constipation; Malaise; Mydriasis; Nausea                             | Lexapro        |                    |                    | S               | Oral                 | 5mg                  |                 | Forest       |                |
| <u>FDA Received Date</u>                                             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Aug-2016                                                          | 12680436       | NON-EXPEDITED      |                    |                 | US-FRI-1000079170    |                      |                 | Male         | USA            |
| <u>Preferred Term</u>                                                | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective                                                     | Lexapro        |                    |                    | S               | Oral                 |                      |                 | Forest       |                |
|                                                                      | Lexapro        |                    |                    | S               |                      |                      |                 | Forest       |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| Mirtazapine                |                                 |                  | C                  |                 |                                       |                                                       | Not Reported    |            |                |
|----------------------------|---------------------------------|------------------|--------------------|-----------------|---------------------------------------|-------------------------------------------------------|-----------------|------------|----------------|
| <u>FDA Received Date</u>   | <u>Case #</u>                   | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>                                  | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 24-Aug-2016                | 12680437                        | NON-EXPEDITED    |                    |                 | US-FRI-1000079180                     |                                                       |                 | Male       | USA            |
| <u>Preferred Term</u>      | <u>Product</u>                  | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>                                    | <u>Duration</u> | <u>Mfr</u> |                |
| Intentional Product Misuse | Lexapro                         |                  |                    | S               | Oral                                  |                                                       |                 |            | Forest         |
| <u>FDA Received Date</u>   | <u>Case #</u>                   | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>                                  | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 24-Aug-2016                | 12680438                        | NON-EXPEDITED    |                    | HO              | US-FRI-1000077975                     |                                                       | 71 YR           | Female     | USA            |
| <u>Preferred Term</u>      | <u>Product</u>                  | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>                                    | <u>Duration</u> | <u>Mfr</u> |                |
| Hyponatraemia              | Lexapro                         |                  |                    | S               | Oral                                  |                                                       |                 |            | Forest         |
|                            | Ipatasertib                     |                  |                    | S               | Oral                                  | Once A Day, 3 Weeks On, 1 Week Off                    |                 |            | Not Reported   |
|                            | Paclitaxel                      |                  |                    | S               | Intravenous (not otherwise specified) | 80 Mg/M2,Days 1, 8, And 15 Of 28 Day Cycle            |                 |            | Not Reported   |
|                            | Baclofen                        |                  |                    | C               | Oral                                  |                                                       |                 |            | Not Reported   |
|                            | Sinemet                         |                  |                    | C               | Oral                                  |                                                       |                 |            | Not Reported   |
|                            | Cymbalta                        |                  |                    | C               | Oral                                  |                                                       |                 |            | Not Reported   |
|                            | Ergocalciferol                  |                  |                    | C               | Oral                                  |                                                       |                 |            | Not Reported   |
|                            | Oxcarbazepine                   |                  |                    | C               | Oral                                  | Oxtellar Xr (Oxcarbazepine Extended-Release) (900 Mg) |                 |            | Not Reported   |
|                            | Oxycodone Hcl                   |                  |                    | C               | Oral                                  |                                                       |                 |            | Not Reported   |
|                            | Famotidine                      |                  |                    | C               | Oral                                  |                                                       |                 |            | Not Reported   |
|                            | Simvastatin                     |                  |                    | C               | Oral                                  |                                                       |                 |            | Not Reported   |
|                            | Synthroid(Levothyroxine Sodium) |                  |                    | C               | Oral                                  |                                                       |                 |            | Not Reported   |
|                            | Torsemide                       |                  |                    | C               | Oral                                  |                                                       |                 |            | Not Reported   |
|                            | Triamterene                     |                  |                    | C               | Oral                                  |                                                       |                 |            | Not Reported   |
|                            | Xanax                           |                  |                    | C               | Oral                                  |                                                       |                 |            | Not Reported   |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                          |                       |                  |                    |                 |                      |                      |                    |                 |                        |  |
|--------------------------|-----------------------|------------------|--------------------|-----------------|----------------------|----------------------|--------------------|-----------------|------------------------|--|
| Potassium Chloride       |                       |                  | C                  |                 | Oral                 |                      | Other              |                 | Not Reported           |  |
| <u>FDA Received Date</u> | <u>Case #</u>         | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u>         |  |
| 24-Aug-2016              | 12680479              | NON-EXPEDITED    |                    |                 | US-FRI-1000079202    |                      |                    | Female          | USA                    |  |
| <u>Preferred Term</u>    | <u>Product</u>        |                  | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>          | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>             |  |
| Dizziness; Insomnia      | Lexapro               |                  |                    |                 | S                    |                      |                    |                 | Forest                 |  |
| <u>FDA Received Date</u> | <u>Case #</u>         | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u>         |  |
| 24-Aug-2016              | 12680480              | NON-EXPEDITED    |                    |                 | US-FRI-1000079388    |                      |                    | Female          | USA                    |  |
| <u>Preferred Term</u>    | <u>Product</u>        |                  | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>          | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>             |  |
| Drug Ineffective         | Lexapro<br>Wellbutrin |                  |                    |                 | S<br>C               |                      |                    |                 | Forest<br>Not Reported |  |
| <u>FDA Received Date</u> | <u>Case #</u>         | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u>         |  |
| 24-Aug-2016              | 12680504              | NON-EXPEDITED    |                    |                 | US-FRI-1000079503    |                      |                    | Female          | USA                    |  |
| <u>Preferred Term</u>    | <u>Product</u>        |                  | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>          | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>             |  |
| Drug Ineffective         | Lexapro               |                  |                    |                 | S                    |                      |                    |                 | Forest                 |  |
| <u>FDA Received Date</u> | <u>Case #</u>         | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u>         |  |
| 24-Aug-2016              | 12680578              | NON-EXPEDITED    |                    |                 | US-FRI-1000079524    |                      |                    | Male            | USA                    |  |
| <u>Preferred Term</u>    | <u>Product</u>        |                  | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>          | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>             |  |
| Drug Ineffective         | Lexapro               |                  |                    |                 | S                    |                      |                    |                 | Forest                 |  |
| <u>FDA Received Date</u> | <u>Case #</u>         | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u>         |  |
| 24-Aug-2016              | 12680583              | NON-EXPEDITED    |                    |                 | US-FRI-1000079504    |                      |                    | Female          | USA                    |  |
| <u>Preferred Term</u>    | <u>Product</u>        |                  | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>          | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>             |  |
| Drug Ineffective         | Lexapro               |                  |                    |                 | S                    |                      |                    |                 | Forest                 |  |



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| <u>FDA Received Date</u>  | <u>Case #</u>                                      | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u>       | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                                       | <u>Country</u> |
|---------------------------|----------------------------------------------------|------------------|--------------------|-----------------------|----------------------|----------------------|-----------------|------------------------------------------------------------------|----------------|
| 24-Aug-2016               | 12680649                                           | NON-EXPEDITED    |                    |                       | US-FRI-1000080063    |                      |                 | Female                                                           | USA            |
| <u>Preferred Term</u>     | <u>Product</u>                                     | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>           | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                                       |                |
| Exposure During Pregnancy | Lexapro                                            |                  |                    | S                     |                      |                      |                 | Forest                                                           |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                                      | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u>       | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                                       | <u>Country</u> |
| 24-Aug-2016               | 12680650                                           | NON-EXPEDITED    |                    |                       | US-FRI-1000080057    |                      |                 | Female                                                           | USA            |
| <u>Preferred Term</u>     | <u>Product</u>                                     | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>           | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                                       |                |
| Irritability; Somnolence  | Lexapro                                            |                  |                    | S                     |                      | 30mg                 |                 | Forest                                                           |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                                      | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u>       | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                                       | <u>Country</u> |
| 24-Aug-2016               | 12680700                                           | NON-EXPEDITED    |                    |                       | US-FRI-1000080085    |                      |                 | Female                                                           | USA            |
| <u>Preferred Term</u>     | <u>Product</u>                                     | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>           | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                                       |                |
| Somnolence                | Lexapro<br>Xyrem                                   |                  |                    | S<br>S                |                      |                      |                 | Forest<br>Not Reported                                           |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                                      | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u>       | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                                       | <u>Country</u> |
| 24-Aug-2016               | 12680701                                           | NON-EXPEDITED    |                    |                       | US-FRI-1000080017    |                      |                 | Female                                                           | USA            |
| <u>Preferred Term</u>     | <u>Product</u>                                     | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>           | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                                       |                |
| Myalgia; Off Label Use    | Lexapro<br>Lexapro<br>Abilify<br>Abilify<br>Ativan |                  |                    | S<br>S<br>S<br>S<br>S |                      |                      |                 | Forest<br>Forest<br>Not Reported<br>Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                                      | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u>       | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                                       | <u>Country</u> |
| 24-Aug-2016               | 12680713                                           | NON-EXPEDITED    |                    |                       | US-FRI-1000079437    |                      |                 | Female                                                           | USA            |

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| <u>Preferred Term</u>          | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|--------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Dizziness; Malaise             | Escitalopram   |                  |                    | S               | Oral                 | 20mg                 |                 | Forest       |                |
| <u>FDA Received Date</u>       | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Aug-2016                    | 12680714       | NON-EXPEDITED    |                    |                 |                      | US-FRI-1000080234    | 55 YR           | Female       | USA            |
| <u>Preferred Term</u>          | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alopecia                       | Lexapro        |                  |                    | S               | Oral                 | 15mg                 |                 | Forest       |                |
|                                | Lexapro        |                  |                    | S               |                      |                      |                 | Forest       |                |
|                                | Tamoxifen      |                  |                    | C               | Oral                 |                      |                 | Not Reported |                |
|                                | Singulair      |                  |                    | C               | Oral                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>       | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Aug-2016                    | 12681029       | NON-EXPEDITED    |                    |                 |                      | US-FRI-1000081218    | 65 YR           | Female       | USA            |
| <u>Preferred Term</u>          | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Overdose           | Lexapro        |                  |                    | S               |                      |                      |                 | Forest       |                |
| <u>FDA Received Date</u>       | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Aug-2016                    | 12681032       | NON-EXPEDITED    |                    |                 |                      | US-FRI-1000080287    |                 | Female       | USA            |
| <u>Preferred Term</u>          | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Nausea              | Lexapro        |                  |                    | S               |                      |                      |                 | Forest       |                |
| <u>FDA Received Date</u>       | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Aug-2016                    | 12681033       | NON-EXPEDITED    |                    |                 |                      | US-FRI-1000080398    |                 | Female       | USA            |
| <u>Preferred Term</u>          | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Rash Generalised;<br>Urticaria | Lexapro        |                  |                    | S               |                      | 10mg                 |                 | Forest       |                |

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| <u>FDA Received Date</u>                                                                          | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 24-Aug-2016                                                                                       | 12681034       | NON-EXPEDITED    |                    |                 | US-FRI-1000080331    |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                             | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain Upper; Diarrhoea                                                                   | Lexapro        |                  |                    | S               | Oral                 |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                          | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Aug-2016                                                                                       | 12681035       | NON-EXPEDITED    |                    |                 | US-FRI-1000080205    |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                             | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Exposure During Pregnancy                                                                         | Lexapro        |                  |                    | S               |                      |                      |                 | Forest       |                |
|                                                                                                   | Lexapro        |                  |                    | S               |                      |                      |                 | Forest       |                |
|                                                                                                   | Lexapro        |                  |                    | S               |                      |                      |                 | Forest       |                |
|                                                                                                   | Zoloft         |                  |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                          | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Aug-2016                                                                                       | 12681036       | NON-EXPEDITED    |                    |                 | US-FRI-1000080253    |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                             | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alopecia                                                                                          | Lexapro        |                  |                    | S               |                      |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                          | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Aug-2016                                                                                       | 12681037       | NON-EXPEDITED    |                    |                 | US-FRI-1000080480    |                      | 34 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                             | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Disturbance In Attention; Drug Ineffective; Headache; Malaise; Off Label Use; Withdrawal Syndrome | Lexapro        |                  |                    | S               | Oral                 | 20mg                 |                 | Forest       |                |
|                                                                                                   | Levothyroxine  |                  |                    | C               |                      |                      |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                                                                                           | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|-------------------------|----------------------|-----------------|--------------|----------------|
| 24-Aug-2016                                                                                                                                        | 12681081       | NON-EXPEDITED    |                    |                 | US-TAKEDA-2016TUS014356 |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                                                                                              | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Cognitive Disorder; Drug Ineffective; Drug Tolerance; Emotional Poverty; Gait Disturbance; Lethargy; Limb Discomfort; Withdrawal Syndrome | Trintellix     |                  |                    | S               | Unknown                 | 10 Mg, Unk           |                 | Takeda       |                |
|                                                                                                                                                    | Trintellix     |                  |                    | S               | Unknown                 | 20 Mg, Unk           |                 | Takeda       |                |
|                                                                                                                                                    | Zoloft         |                  |                    | S               | Unknown                 | Unk                  |                 | Not Reported |                |
|                                                                                                                                                    | Lexapro        |                  |                    | S               | Unknown                 | Unk                  |                 | Not Reported |                |
|                                                                                                                                                    | Ativan         |                  |                    | C               | Unknown                 | Unk                  |                 | Not Reported |                |
|                                                                                                                                                    | Valium         |                  |                    | C               | Unknown                 | Unk                  |                 | Not Reported |                |

| <u>FDA Received Date</u>                                  | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 24-Aug-2016                                               | 12681108       | NON-EXPEDITED    |                    |                 | US-FRI-1000081735    |                      | 53 YR           | Female       | USA            |
| <u>Preferred Term</u>                                     | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Akathisia; Alopecia; Restless Legs Syndrome; Restlessness | Lexapro        |                  |                    | S               | Oral                 | 20mg                 |                 | Forest       |                |
|                                                           | Lexapro        |                  |                    | S               |                      |                      |                 | Forest       |                |
|                                                           | Lexapro        |                  |                    | S               |                      |                      |                 | Forest       |                |
|                                                           | Zoloft         |                  |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                               | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 24-Aug-2016                                            | 12681109       | NON-EXPEDITED    |                    |                 | US-FRI-1000081656    |                      |                 | Male       | USA            |
| <u>Preferred Term</u>                                  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Anxiety; Headache; Paraesthesia; Product Dose Omission | Lexapro        |                  |                    | S               |                      |                      |                 | Forest     |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 24-Aug-2016              | 12681138       | NON-EXPEDITED    |                    |                 | US-FRI-1000081772    |                      |                 | Female     | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

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|                                                                  |                |                  |                    |                 |                      |                      |                    |                 |                |
|------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|--------------------|-----------------|----------------|
| Insomnia                                                         | Lexapro        |                  |                    | S               |                      |                      |                    |                 | Forest         |
|                                                                  | Lexapro        |                  |                    | S               |                      |                      |                    |                 | Forest         |
| <u>FDA Received Date</u>                                         | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |
| 24-Aug-2016                                                      | 12681139       | NON-EXPEDITED    |                    |                 | US-FRI-1000081757    |                      | 20 YR              | Female          | USA            |
| <u>Preferred Term</u>                                            | <u>Product</u> |                  | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>          | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>     |
| Panic Attack                                                     | Lexapro        |                  |                    | S               |                      |                      |                    |                 | Forest         |
|                                                                  | Pristiq        |                  |                    | S               |                      | Oral                 |                    |                 | Not Reported   |
| <u>FDA Received Date</u>                                         | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |
| 24-Aug-2016                                                      | 12681140       | NON-EXPEDITED    |                    |                 | US-FRI-1000081811    |                      |                    | Female          | USA            |
| <u>Preferred Term</u>                                            | <u>Product</u> |                  | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>          | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>     |
| Anxiety; Asthenia;<br>Decreased Appetite;<br>Feeling Hot; Nausea | Lexapro        |                  |                    | S               |                      |                      |                    |                 | Forest         |
| <u>FDA Received Date</u>                                         | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |
| 24-Aug-2016                                                      | 12681151       | NON-EXPEDITED    |                    |                 | US-FRI-1000082021    |                      |                    | Female          | USA            |
| <u>Preferred Term</u>                                            | <u>Product</u> |                  | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>          | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>     |
| Drug Ineffective                                                 | Lexapro        |                  |                    | S               |                      | Oral                 | 20mg               |                 | Forest         |
| <u>FDA Received Date</u>                                         | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |
| 24-Aug-2016                                                      | 12681157       | NON-EXPEDITED    |                    |                 | US-FRI-1000082154    |                      |                    | Female          | USA            |
| <u>Preferred Term</u>                                            | <u>Product</u> |                  | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>          | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>     |
| Blood Glucose Decreased;<br>Dizziness; Nausea                    | Lexapro        |                  |                    | S               |                      |                      |                    |                 | Forest         |
| <u>FDA Received Date</u>                                         | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |
| 24-Aug-2016                                                      | 12681165       | NON-EXPEDITED    |                    |                 | US-FRI-1000082002    |                      |                    | Female          | USA            |

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| <u>Preferred Term</u>                                  | <u>Product</u>   | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>             |                |
|--------------------------------------------------------|------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------------------|----------------|
| Anorgasmia; Libido Decreased                           | Lexapro          |                  |                    | S               |                      | 10mg                 |                 | Forest                 |                |
| <u>FDA Received Date</u>                               | <u>Case #</u>    | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>             | <u>Country</u> |
| 24-Aug-2016                                            | 12681447         | NON-EXPEDITED    |                    |                 | US-FRI-1000080020    |                      |                 | Female                 | USA            |
| <u>Preferred Term</u>                                  | <u>Product</u>   | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>             |                |
| Drug Ineffective; Paranoia                             | Lexapro<br>Xyrem |                  |                    | S<br>C          |                      |                      |                 | Forest<br>Not Reported |                |
| <u>FDA Received Date</u>                               | <u>Case #</u>    | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>             | <u>Country</u> |
| 24-Aug-2016                                            | 12681448         | NON-EXPEDITED    |                    |                 | US-FRI-1000080095    |                      |                 | Female                 | USA            |
| <u>Preferred Term</u>                                  | <u>Product</u>   | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>             |                |
| Exposure During Pregnancy                              | Lexapro          |                  |                    | S               |                      |                      |                 | Forest                 |                |
| <u>FDA Received Date</u>                               | <u>Case #</u>    | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>             | <u>Country</u> |
| 24-Aug-2016                                            | 12681449         | NON-EXPEDITED    |                    |                 | US-FRI-1000081858    |                      |                 | Male                   | USA            |
| <u>Preferred Term</u>                                  | <u>Product</u>   | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>             |                |
| Abnormal Dreams; Intentional Product Misuse; Nightmare | Lexapro          |                  |                    | S               |                      |                      |                 | Forest                 |                |
|                                                        | Lexapro          |                  |                    | S               |                      |                      |                 | Forest                 |                |
|                                                        | Lexapro          |                  |                    | S               |                      |                      |                 | Forest                 |                |
|                                                        | Lexapro          |                  |                    | S               |                      |                      |                 | Forest                 |                |
|                                                        | Levothyroxine    |                  |                    | C               |                      | 50mcg                |                 | Not Reported           |                |
|                                                        | Finasteride      |                  |                    | C               |                      | 5mg                  |                 | Not Reported           |                |
|                                                        | Prilosec         |                  |                    | C               |                      |                      |                 | Not Reported           |                |
|                                                        | Flomax           |                  |                    | C               |                      | 0.8mg                |                 | Not Reported           |                |
| <u>FDA Received Date</u>                               | <u>Case #</u>    | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>             | <u>Country</u> |
| 24-Aug-2016                                            | 12681450         | NON-EXPEDITED    |                    |                 | US-FRI-1000079414    |                      |                 | Male                   | USA            |

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| <u>Preferred Term</u>                                                   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Constipation; Dizziness;<br>Dry Mouth; Nausea;<br>Product Dose Omission | Lexapro        |                  |                    | S               |                      |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Aug-2016                                                             | 12681451       | NON-EXPEDITED    |                    |                 | US-FRI-1000082529    |                      |                 | Male         | USA            |
| <u>Preferred Term</u>                                                   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Nightmare                                                               | Lexapro        |                  |                    | S               |                      | 15mg                 |                 | Forest       |                |
|                                                                         | Lexapro        |                  |                    | S               |                      | 20mg                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Aug-2016                                                             | 12681452       | NON-EXPEDITED    |                    |                 | US-FRI-1000080387    |                      |                 | Male         | USA            |
| <u>Preferred Term</u>                                                   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Fatigue                                                                 | Lexapro        |                  |                    | S               |                      |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Aug-2016                                                             | 12681453       | NON-EXPEDITED    |                    |                 | US-FRI-1000080706    |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness                                                               | Lexapro        |                  |                    | S               |                      |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Aug-2016                                                             | 12681454       | NON-EXPEDITED    |                    |                 | US-FRI-1000079982    |                      |                 | Male         | USA            |
| <u>Preferred Term</u>                                                   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain; Agitation;                                              | Lexapro        |                  |                    | S               |                      |                      |                 | Forest       |                |
| Depression;                                                             | Lexapro        |                  |                    | S               |                      |                      |                 | Not Reported |                |
| Hyperhidrosis; Insomnia                                                 | Lexapro        |                  |                    | S               |                      |                      |                 | Not Reported |                |

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| <a href="#">FDA Received Date</a>               | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 24-Aug-2016                                     | 12681455                | NON-EXPEDITED             |                             |                          | US-FRI-1000080879             |                               | 36 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>                  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Erectile Dysfunction                            | Lexapro                 |                           |                             | S                        | Oral                          | 20mg                          |                          | Forest              |                         |
|                                                 | Lexapro                 |                           |                             | S                        |                               |                               |                          | Forest              |                         |
| <a href="#">FDA Received Date</a>               | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 24-Aug-2016                                     | 12681456                | NON-EXPEDITED             |                             |                          | US-FRI-1000080267             |                               |                          | Male                | USA                     |
| <a href="#">Preferred Term</a>                  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Night Sweats                                    | Lexapro                 |                           |                             | S                        | Oral                          |                               |                          | Forest              |                         |
|                                                 | Lexapro                 |                           |                             | S                        | Oral                          |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>               | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 24-Aug-2016                                     | 12681457                | NON-EXPEDITED             |                             |                          | US-FRI-1000080462             |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>                  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Ineffective                                | Lexapro                 |                           |                             | S                        |                               |                               |                          | Forest              |                         |
| <a href="#">FDA Received Date</a>               | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 24-Aug-2016                                     | 12681458                | NON-EXPEDITED             |                             |                          | US-FRI-1000079567             |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>                  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Eye Pain; Eye Swelling; Insomnia; Swelling Face | Lexapro                 |                           |                             | S                        | Oral                          | 10mg                          |                          | Forest              |                         |
|                                                 | Coumadin                |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>               | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 24-Aug-2016                                     | 12681459                | NON-EXPEDITED             |                             |                          | US-FRI-1000079946             |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>                  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |



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|                                                                                        |                                                        |                  |                    |                       |                      |                      |                 |                                                                        |                |
|----------------------------------------------------------------------------------------|--------------------------------------------------------|------------------|--------------------|-----------------------|----------------------|----------------------|-----------------|------------------------------------------------------------------------|----------------|
| Drug Ineffective                                                                       |                                                        | Lexapro          |                    | S                     |                      | Forest               |                 |                                                                        |                |
| <u>FDA Received Date</u>                                                               | <u>Case #</u>                                          | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u>       | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                                             | <u>Country</u> |
| 24-Aug-2016                                                                            | 12681464                                               | NON-EXPEDITED    |                    |                       | US-FRI-1000080578    |                      | 29 YR           | Female                                                                 | USA            |
| <u>Preferred Term</u>                                                                  | <u>Product</u>                                         | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>           | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                                             |                |
| Abdominal Pain Upper;<br>Feeling Abnormal;<br>Intentional Product<br>Misuse; Pregnancy | Lexapro<br>Imuran<br>Cimzia<br>Vitamin B12<br>Entocort |                  |                    | S<br>C<br>C<br>C<br>C |                      |                      |                 | Forest<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                               | <u>Case #</u>                                          | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u>       | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                                             | <u>Country</u> |
| 24-Aug-2016                                                                            | 12681467                                               | NON-EXPEDITED    |                    |                       | US-FRI-1000082320    |                      |                 | Female                                                                 | USA            |
| <u>Preferred Term</u>                                                                  | <u>Product</u>                                         | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>           | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                                             |                |
| Feeling Abnormal;<br>Intentional Product Misuse                                        | Lexapro<br>Lexapro                                     |                  |                    | S<br>S                |                      |                      |                 | Forest<br>Not Reported                                                 |                |
| <u>FDA Received Date</u>                                                               | <u>Case #</u>                                          | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u>       | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                                             | <u>Country</u> |
| 24-Aug-2016                                                                            | 12681469                                               | NON-EXPEDITED    |                    |                       | US-FRI-1000082356    |                      |                 | Female                                                                 | USA            |
| <u>Preferred Term</u>                                                                  | <u>Product</u>                                         | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>           | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                                             |                |
| Drug Ineffective                                                                       | Lexapro                                                |                  |                    | S                     |                      |                      |                 | Forest                                                                 |                |
| <u>FDA Received Date</u>                                                               | <u>Case #</u>                                          | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u>       | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                                             | <u>Country</u> |
| 24-Aug-2016                                                                            | 12681470                                               | NON-EXPEDITED    |                    |                       | US-FRI-1000081358    |                      |                 | Female                                                                 | USA            |
| <u>Preferred Term</u>                                                                  | <u>Product</u>                                         | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>           | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                                             |                |
| Nightmare                                                                              | Lexapro                                                |                  |                    | S                     |                      |                      |                 | Forest                                                                 |                |
| <u>FDA Received Date</u>                                                               | <u>Case #</u>                                          | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u>       | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                                             | <u>Country</u> |
| 24-Aug-2016                                                                            | 12681479                                               | NON-EXPEDITED    |                    |                       | US-FRI-1000082078    |                      | 17 YR           | Female                                                                 | USA            |

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| <u>Preferred Term</u>                                 | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Alopecia                                              | Lexapro        |                  |                    | S               | Oral                 | 10mg                 |                 | Forest       |                |
|                                                       | Lexapro        |                  |                    | S               | Oral                 | 20mg                 |                 | Forest       |                |
|                                                       | Accutane       |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                                                       | Vyvanse        |                  |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Aug-2016                                           | 12681480       | NON-EXPEDITED    |                    |                 | US-FRI-1000081447    |                      | 88 YR           | Female       | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Tremor                                                | Lexapro        |                  |                    | S               |                      |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Aug-2016                                           | 12681732       | NON-EXPEDITED    |                    |                 | US-FRI-1000081190    |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Feeling Abnormal                                      | Escitalopram   |                  |                    | S               | Oral                 | 10mg                 |                 | Forest       |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Aug-2016                                           | 12681739       | NON-EXPEDITED    |                    |                 | US-FRI-1000081610    |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Feeling Abnormal; Muscle Spasms; Palpitations; Tremor | Lexapro        |                  |                    | S               | Oral                 | 10mg                 |                 | Forest       |                |
|                                                       | Lexapro        |                  |                    | S               | Oral                 | 20mg                 |                 | Forest       |                |
|                                                       | Trazodone      |                  |                    | C               | Oral                 | 100mg                |                 | Not Reported |                |
|                                                       | Trazodone      |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                       | Trazodone      |                  |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Aug-2016                                           | 12681741       | NON-EXPEDITED    |                    |                 | US-FRI-1000082970    |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

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|                                                            |         |   |      |      |        |
|------------------------------------------------------------|---------|---|------|------|--------|
| Drug Ineffective;                                          | Lexapro | S | Oral | 20mg | Forest |
| Paraesthesia; Product Quality Issue; Product Quality Issue | Lexapro | S |      |      | Forest |

| <u>FDA Received Date</u> | <u>Case #</u>                    | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 24-Aug-2016              | 12681742                         | NON-EXPEDITED    |                    |                 | US-FRI-1000082790    |                      | 31 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>                   | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Rash                     | Lexapro                          |                  |                    | S               | Oral                 | 10mg                 |                 | Forest       |                |
|                          | Birth Control Pill (Unspecified) |                  |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 24-Aug-2016              | 12681743       | NON-EXPEDITED    |                    |                 | US-FRI-1000083097    |                      | 57 YR           | Male       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Paraesthesia             | Lexapro        |                  |                    | S               | Oral                 |                      |                 | Forest     |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 24-Aug-2016              | 12681744       | NON-EXPEDITED    |                    |                 | US-FRI-1000082938    |                      |                 | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Headache; Somnolence     | Lexapro        |                  |                    | S               |                      | 5mg                  |                 | Forest       |                |
|                          | Lexapro        |                  |                    | S               |                      | 10mg                 |                 | Not Reported |                |
|                          | Lexapro        |                  |                    | S               |                      | 5mg                  |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 24-Aug-2016              | 12681745       | NON-EXPEDITED    |                    |                 | US-FRI-1000083013    |                      | 75 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Visual Impairment        | Lexapro        |                  |                    | S               | Oral                 | 5mg                  |                 | Forest       |                |
|                          | Nitrofurantoin |                  |                    | C               |                      |                      |                 | Not Reported |                |

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|                                 |                         |                  |                    |                 |                      |                      |                 |              |                |
|---------------------------------|-------------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Unspecified Statin              |                         |                  | C                  |                 |                      | Not Reported         |                 |              |                |
| <u>FDA Received Date</u>        | <u>Case #</u>           | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Aug-2016                     | 12681746                | NON-EXPEDITED    |                    |                 | US-FRI-1000082195    |                      | 35 YR           | Female       | USA            |
| <u>Preferred Term</u>           | <u>Product</u>          | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Off Label Use; Weight Increased | Lexapro                 |                  |                    | S               | Oral                 | 10mg                 |                 | Forest       |                |
|                                 | Lexapro                 |                  |                    | S               | Oral                 | 20mg                 |                 | Forest       |                |
|                                 | Lexapro                 |                  |                    | S               | Oral                 | 30mg                 |                 | Not Reported |                |
|                                 | Lexapro                 |                  |                    | S               | Oral                 | 40mg                 |                 | Not Reported |                |
|                                 | Lithium                 |                  |                    | C               | Oral                 |                      |                 | Not Reported |                |
|                                 | Unspecified Vitamins    |                  |                    | C               | Oral                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>        | <u>Case #</u>           | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Aug-2016                     | 12681748                | NON-EXPEDITED    |                    |                 | US-FRI-1000083195    |                      | 15 YR           | Male         | USA            |
| <u>Preferred Term</u>           | <u>Product</u>          | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Vision Blurred                  | Lexapro                 |                  |                    | S               | Oral                 | 20mg                 |                 | Forest       |                |
|                                 | Lexapro                 |                  |                    | S               | Oral                 | 10mg                 |                 | Forest       |                |
| <u>FDA Received Date</u>        | <u>Case #</u>           | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Aug-2016                     | 12681751                | NON-EXPEDITED    |                    |                 | US-FRI-1000082878    |                      |                 | Female       | USA            |
| <u>Preferred Term</u>           | <u>Product</u>          | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyponatraemia                   | Lexapro                 |                  |                    | S               | Oral                 | 5mg                  |                 | Forest       |                |
|                                 | Lunesta                 |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                 | Otc Allergy Medications |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                 | Nexium                  |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                 | Vitamins                |                  |                    | C               |                      |                      |                 | Not Reported |                |

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| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 24-Aug-2016                       | 12681752                | NON-EXPEDITED             |                             |                          | US-FRI-1000083363             |                               |                          | Male                | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Hypersomnia                       | Lexapro                 |                           |                             | S                        | Oral                          |                               |                          | Forest              |                         |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 24-Aug-2016                       | 12681753                | NON-EXPEDITED             |                             |                          | US-FRI-1000083383             |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Exposure During Pregnancy         | Lexapro                 |                           |                             | S                        |                               |                               |                          | Forest              |                         |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 24-Aug-2016                       | 12681754                | NON-EXPEDITED             |                             |                          | US-FRI-1000083442             |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Ineffective                  | Lexapro                 |                           |                             | S                        | Oral                          |                               |                          | Forest              |                         |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 24-Aug-2016                       | 12681760                | NON-EXPEDITED             |                             |                          | US-FRI-1000083046             |                               |                          | Male                | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Diplopia; Visual Impairment       | Lexapro                 |                           |                             | S                        |                               |                               |                          | Forest              |                         |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 24-Aug-2016                       | 12681761                | NON-EXPEDITED             |                             |                          | US-FRI-1000083152             |                               |                          | Male                | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Off Label Use; Pyrexia            | Lexapro                 |                           |                             | S                        |                               | 10mg                          |                          | Forest              |                         |

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|               |   |              |
|---------------|---|--------------|
| Lexapro       | S | Forest       |
| Atorvastatin  | C | Not Reported |
| Hydralazine   | C | Not Reported |
| Glipizide     | C | Not Reported |
| Levothyroxine | C | Not Reported |
| Clopidogrel   | C | Not Reported |
| Losartan      | C | Not Reported |
| Metoprolol    | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Aug-2016              | 12681763      | NON-EXPEDITED    |                    |                 | US-FRI-1000082614    |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Asthenia              | Lexapro        |              |            | S           |              |                    |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Aug-2016              | 12681764      | NON-EXPEDITED    |                    |                 | US-FRI-1000082966    |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Insomnia              | Lexapro        |              |            | S           |              |                    |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 24-Aug-2016              | 12681898      | EXPEDITED (15-DAY) |                    | OT              | GB-MYLANLABS-2016M1034545 |                      |            | Unknown    | GBR            |

| <u>Preferred Term</u>            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Colitis Ulcerative;<br>Diarrhoea | Escitalopram   |              |            | S           | Oral         | Unk (5 Mg Daily)   |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Aug-2016              | 12682316      | NON-EXPEDITED    |                    |                 | US-FRI-1000083457    |                      |            | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Rash                  | Lexapro        |              |            | S           |              |                    |                 | Forest     |

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| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 24-Aug-2016                       | 12682317                | NON-EXPEDITED             |                             |                          | US-FRI-1000083565             |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Ineffective                  | Lexapro                 |                           |                             | S                        |                               |                               |                          | Forest              |                         |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 24-Aug-2016                       | 12682318                | NON-EXPEDITED             |                             |                          | US-FRI-1000083049             |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Ineffective                  | Lexapro                 |                           |                             | S                        |                               |                               |                          | Forest              |                         |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 24-Aug-2016                       | 12682321                | NON-EXPEDITED             |                             |                          | US-FRI-1000083263             |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Ineffective                  | Lexapro                 |                           |                             | S                        |                               |                               |                          | Forest              |                         |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 24-Aug-2016                       | 12682329                | NON-EXPEDITED             |                             |                          | US-FRI-1000079266             |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Anxiety                           | Lexapro                 |                           |                             | S                        |                               |                               |                          | Forest              |                         |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 24-Aug-2016                       | 12682333                | NON-EXPEDITED             |                             |                          | US-FRI-1000083359             |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Ineffective                  | Lexapro                 |                           |                             | S                        | Oral                          | 1.5 Tablets Daily             |                          | Forest              |                         |
|                                   | Estradiol               |                           |                             | C                        | Oral                          | 1 Mg                          |                          | Not Reported        |                         |
|                                   | Metoprolol Succinate Er |                           |                             | C                        | Oral                          | 50 Mg                         |                          | Not Reported        |                         |

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|                     |   |      |                                        |              |
|---------------------|---|------|----------------------------------------|--------------|
| Amlodipine Besylate | C | Oral | 5 Mg                                   | Not Reported |
| Prednisone          | C | Oral | 30 Mg (3 Tablets Once Daily)           | Not Reported |
| Prednisone          | C | Oral | 20 Mg (2 Tablets Once Daily)           | Not Reported |
| Prednisone          | C | Oral | 10 Mg                                  | Not Reported |
| Prednisone          | C | Oral | 10mg Tablet, 1/2 Tablet Daily          | Not Reported |
| Tizanidine Hcl      | C | Oral | 12 Mg                                  | Not Reported |
| Pristiq             | C |      | 50 Mg                                  | Not Reported |
| Omeprazole          | C | Oral | 40 Mg                                  | Not Reported |
| Dapsone             | C | Oral | 100mg Tabletand 25mg Tablet Once Daily | Not Reported |
| Synthroid           | C | Oral | 50 Mcg                                 | Not Reported |
| Lisinopril          | C | Oral | 40 Mg                                  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>     | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
|--------------------------|-------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------------|----------------|
| 24-Aug-2016              | 12682334          | NON-EXPEDITED    |                    |                 | US-FRI-1000083106    |                      |                 | Female           | USA            |
| <u>Preferred Term</u>    | <u>Product</u>    | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |
| Drug Ineffective         | Lexapro<br>Celexa |                  |                    | S<br>S          |                      |                      |                 | Forest<br>Forest |                |

| <u>FDA Received Date</u> | <u>Case #</u>               | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                             | <u>Country</u> |
|--------------------------|-----------------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|----------------------------------------|----------------|
| 24-Aug-2016              | 12682335                    | NON-EXPEDITED    |                    |                 | US-FRI-1000082280    |                      |                 | Female                                 | USA            |
| <u>Preferred Term</u>    | <u>Product</u>              | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                             |                |
| Anxiety                  | Lexapro<br>Xyrem<br>Nuvigil |                  |                    | S<br>S<br>S     |                      |                      |                 | Forest<br>Not Reported<br>Not Reported |                |



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| <u>FDA Received Date</u>                                                                                   | <u>Case #</u>                                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>       | <u>Mfr Control #</u>                                                                   | <u>503B Facility</u>                                       | <u>Age</u>      | <u>Sex</u>                                                                           | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------|----------------------------------------------------------|--------------------|--------------------|-----------------------|----------------------------------------------------------------------------------------|------------------------------------------------------------|-----------------|--------------------------------------------------------------------------------------|----------------|
| 24-Aug-2016                                                                                                | 12682336                                                 | NON-EXPEDITED      |                    |                       | US-FRI-1000079348                                                                      |                                                            |                 | Female                                                                               | USA            |
| <u>Preferred Term</u>                                                                                      | <u>Product</u>                                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>           | <u>Route</u>                                                                           | <u>Dosage Text</u>                                         | <u>Duration</u> | <u>Mfr</u>                                                                           |                |
| Drug Ineffective                                                                                           | Lexapro                                                  |                    |                    | S                     |                                                                                        |                                                            |                 | Forest                                                                               |                |
| <u>FDA Received Date</u>                                                                                   | <u>Case #</u>                                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>       | <u>Mfr Control #</u>                                                                   | <u>503B Facility</u>                                       | <u>Age</u>      | <u>Sex</u>                                                                           | <u>Country</u> |
| 24-Aug-2016                                                                                                | 12682338                                                 | NON-EXPEDITED      |                    |                       | US-FRI-1000079406                                                                      |                                                            | 37 YR           | Female                                                                               | USA            |
| <u>Preferred Term</u>                                                                                      | <u>Product</u>                                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>           | <u>Route</u>                                                                           | <u>Dosage Text</u>                                         | <u>Duration</u> | <u>Mfr</u>                                                                           |                |
| Headache; Hyperhidrosis;<br>Menstrual Disorder;<br>Product Dose Omission                                   | Lexapro<br>Lactose                                       |                    |                    | S<br>C                | Oral                                                                                   | 10mg                                                       |                 | Forest<br>Not Reported                                                               |                |
| <u>FDA Received Date</u>                                                                                   | <u>Case #</u>                                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>       | <u>Mfr Control #</u>                                                                   | <u>503B Facility</u>                                       | <u>Age</u>      | <u>Sex</u>                                                                           | <u>Country</u> |
| 24-Aug-2016                                                                                                | 12682961                                                 | DIRECT             |                    |                       |                                                                                        |                                                            |                 | Female                                                                               | USA            |
| <u>Preferred Term</u>                                                                                      | <u>Product</u>                                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>           | <u>Route</u>                                                                           | <u>Dosage Text</u>                                         | <u>Duration</u> | <u>Mfr</u>                                                                           |                |
| Agitation; Anger;<br>Nervousness                                                                           | Prozac<br>Lexapro                                        |                    |                    | S<br>S                |                                                                                        |                                                            |                 | Not Reported<br>Not Reported                                                         |                |
| <u>FDA Received Date</u>                                                                                   | <u>Case #</u>                                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>       | <u>Mfr Control #</u>                                                                   | <u>503B Facility</u>                                       | <u>Age</u>      | <u>Sex</u>                                                                           | <u>Country</u> |
| 25-Aug-2016                                                                                                | 10619674                                                 | EXPEDITED (15-DAY) |                    | CA, OT                | FR-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>21634787                                        |                                                            | 3 DAY           | Male                                                                                 | FRA            |
| <u>Preferred Term</u>                                                                                      | <u>Product</u>                                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>           | <u>Route</u>                                                                           | <u>Dosage Text</u>                                         | <u>Duration</u> | <u>Mfr</u>                                                                           |                |
| Foetal Exposure During<br>Pregnancy; Patent Ductus<br>Arteriosus; Trisomy 21;<br>Ventricular Septal Defect | Abilify<br>Seroplex<br>Parkinane<br>Tenoretic<br>Tercian |                    |                    | S<br>S<br>S<br>S<br>S | Transplacental<br>Transplacental<br>Transplacental<br>Transplacental<br>Transplacental | 15 Mg, Qd<br>1 Df, Qd<br>1 Df, Unk<br>1 Df, Qd<br>1 Df, Qd |                 | Bristol Myers Squibb<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |                |

# FDA Adverse Event Reporting System

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| <u>FDA Received Date</u>                                              | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|-----------------------------------------------------------------------|-----------------------|--------------------|--------------------|-----------------|--------------------------------------------------------|----------------------|-----------------|----------------------|----------------|
| 25-Aug-2016                                                           | 11211478              | EXPEDITED (15-DAY) |                    | HO              | PHHY2015FR074700                                       |                      | 64 YR           | Female               | FRA            |
| <u>Preferred Term</u>                                                 | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Cardiac Failure                                                       | Exjade                |                    |                    | S               | Oral                                                   |                      |                 | Novartis             |                |
|                                                                       | Xagrid                |                    |                    | S               | Unknown                                                | 0.5 Mg, Unk          |                 | Not Reported         |                |
|                                                                       | Hydrea                |                    |                    | S               | Oral                                                   | 500 Mg, Unk          |                 | Not Reported         |                |
|                                                                       | Levothyrox            |                    |                    | S               | Oral                                                   |                      |                 | Not Reported         |                |
|                                                                       | Aspergic              |                    |                    | S               | Oral                                                   |                      |                 | Not Reported         |                |
|                                                                       | Seroplex              |                    |                    | S               | Oral                                                   | Unk                  |                 | Not Reported         |                |
|                                                                       | Nebilox               |                    |                    | S               | Oral                                                   | 5 Mg, Unk            |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                              | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 25-Aug-2016                                                           | 11229858              | EXPEDITED (15-DAY) |                    | HO, OT          | FR-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>BMS-2015-040936 |                      | 64 YR           | Female               | FRA            |
| <u>Preferred Term</u>                                                 | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Cardiac Failure; Off Label<br>Use; Pulmonary Arterial<br>Hypertension | Hydrea                |                    |                    | S               | Oral                                                   | 500 Mg, Unk          |                 | Bristol Myers Squibb |                |
|                                                                       | Xagrid                |                    |                    | S               | Oral                                                   | 0.5 Mg, Unk          |                 | Not Reported         |                |
|                                                                       | Exjade                |                    |                    | S               | Oral                                                   | Unk                  |                 | Not Reported         |                |
|                                                                       | Aspegic /00002703/    |                    |                    | S               | Oral                                                   | Unk                  |                 | Not Reported         |                |
|                                                                       | Seroplex              |                    |                    | S               | Oral                                                   | Unk                  |                 | Not Reported         |                |
|                                                                       | Levothyrox            |                    |                    | S               | Oral                                                   |                      |                 | Not Reported         |                |
|                                                                       | Nebilox               |                    |                    | S               | Oral                                                   | 5 Mg, Unk            |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                              | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 25-Aug-2016                                                           | 12528050              | EXPEDITED (15-DAY) |                    | DS              | DE-PFIZER INC-<br>2016329176                           |                      | 88 YR           | Female               | DEU            |
| <u>Preferred Term</u>                                                 | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Asthenia; Decreased                                                   | Candesartan Cilexetil |                    |                    | S               | Oral                                                   | 16 Mg, 1x/Day        |                 | Not Reported         |                |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                  |                      |   |         |                                                   |              |
|------------------------------------------------------------------------------------------------------------------|----------------------|---|---------|---------------------------------------------------|--------------|
| Appetite; General Physical Health Deterioration; Hypotension; Somnolence; Urinary Incontinence; Weight Decreased | Escitalopram Oxalate | S | Oral    | 20 Mg, 1x/Day                                     | Not Reported |
|                                                                                                                  | Escitalopram Oxalate | S |         | Unk (2 Weeks At Half-Dosage)                      | Not Reported |
|                                                                                                                  | Glimepiride          | S | Oral    | 1 Mg, 1x/Day                                      | Not Reported |
|                                                                                                                  | Metformin Hcl        | S | Oral    | 850 Mg, 2x/Day                                    | Pfizer       |
|                                                                                                                  | Ramipril             | S | Oral    | 5 Mg, 2x/Day                                      | Pfizer       |
|                                                                                                                  | Ramipril             | S |         | Unk (In 1/2 Dosage)                               | Pfizer       |
|                                                                                                                  | Allopurinol          | S | Oral    | 300 Mg, 1x/Day                                    | Not Reported |
|                                                                                                                  | Digitoxin            | S |         | 0.07 Mg, 1x/Day                                   | Not Reported |
|                                                                                                                  | Furosemide           | S | Oral    | 40 Mg, 2x/Day                                     | Not Reported |
|                                                                                                                  | Furosemide           | S |         | Unk (At Half Dosage)                              | Not Reported |
|                                                                                                                  | Hydrochlorothiazide  | S | Oral    | 25 Mg, 1x/Day                                     | Not Reported |
|                                                                                                                  | Insulin              | S | Unknown | 30/70 Iu, 26-0-16 (Continue But Adjust The Dose)  | Not Reported |
|                                                                                                                  | Isosorbide Dinitrate | S | Oral    | 20 Mg, 2x/Day (Taper The Drug Within A Week)      | Not Reported |
|                                                                                                                  | Metoprolol Tartrate  | S | Oral    | 47.5 Mg, 2x/Day                                   | Not Reported |
|                                                                                                                  | Metoprolol Tartrate  | S |         | Unk (At Half Dosage)                              | Not Reported |
|                                                                                                                  | Moxonidine           | S | Oral    | 0.4 Mg, 1x/Day (Taper Over One Week)              | Not Reported |
|                                                                                                                  | Tilidin              | S | Oral    | 1 Df, 3x/Day (50/4mg)                             | Not Reported |
|                                                                                                                  | Pantoprazole         | S | Oral    | 40 Mg, 1x/Day (2 Weeks At Half-Dosage, Then Stop) | Not Reported |
|                                                                                                                  | Trospium             | S | Oral    | 15 Mg, 1x/Day                                     | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|------------------------|----------------------|-----------------|------------|----------------|
| 25-Aug-2016              | 12617350       | EXPEDITED (15-DAY) |                    | OT              | US-APOTEX-2016AP010098 |                      | 68 YR           | Female     | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

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|                      |                      |   |         |     |              |
|----------------------|----------------------|---|---------|-----|--------------|
| Autoimmune Hepatitis | Escitalopram Oxalate | S | Unknown | Unk | Apotex       |
|                      | Diazepam             | C | Unknown | Unk | Not Reported |
|                      | Lorazepam            | C | Unknown | Unk | Not Reported |
|                      | Zolpidem             | C | Unknown | Unk | Not Reported |
|                      | Fexofenadine         | C | Unknown | Unk | Not Reported |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 25-Aug-2016                       | 12683826                | NON-EXPEDITED             |                             |                          | US-FRI-1000084095             |                               |                          | Male                | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Tinnitus                          | Lexapro                 |                           |                             | S                        |                               |                               |                          |                     | Forest                  |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 25-Aug-2016                       | 12683828                | NON-EXPEDITED             |                             |                          | US-FRI-1000084139             |                               |                          | Male                | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Rash                              | Lexapro                 |                           |                             | S                        |                               |                               |                          |                     | Forest                  |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 25-Aug-2016                       | 12683830                | NON-EXPEDITED             |                             |                          | US-FRI-1000084023             |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Ineffective; Insomnia        | Lexapro                 |                           |                             | S                        |                               |                               |                          |                     | Forest                  |
|                                   | Lexapro                 |                           |                             | S                        |                               |                               |                          |                     | Not Reported            |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 25-Aug-2016                       | 12683831                | NON-EXPEDITED             |                             |                          | US-FRI-1000085064             |                               |                          | Male                | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Libido Decreased                  | Lexapro                 |                           |                             | S                        | Oral                          | 40mg                          |                          |                     | Forest                  |
|                                   | Lexapro                 |                           |                             | S                        | Oral                          |                               |                          |                     | Forest                  |

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| <a href="#">FDA Received Date</a>                   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 25-Aug-2016                                         | 12683832                | NON-EXPEDITED             |                             |                          | US-FRI-1000083646             |                               | 73 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>                      | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Ineffective                                    | Lexapro                 |                           |                             | S                        |                               |                               |                          | Forest              |                         |
| <a href="#">FDA Received Date</a>                   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 25-Aug-2016                                         | 12683833                | NON-EXPEDITED             |                             |                          | US-FRI-1000083915             |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>                      | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Ineffective                                    | Lexapro                 |                           |                             | S                        |                               |                               |                          | Forest              |                         |
|                                                     | Lexapro                 |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 25-Aug-2016                                         | 12683834                | NON-EXPEDITED             |                             |                          | US-FRI-1000084007             |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>                      | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Malaise; Nausea                                     | Lexapro                 |                           |                             | S                        |                               |                               |                          | Forest              |                         |
| <a href="#">FDA Received Date</a>                   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 25-Aug-2016                                         | 12683846                | NON-EXPEDITED             |                             |                          | US-FRI-1000084315             |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>                      | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Hypersensitivity                               | Lexapro                 |                           |                             | S                        |                               |                               |                          | Forest              |                         |
| <a href="#">FDA Received Date</a>                   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 25-Aug-2016                                         | 12683847                | NON-EXPEDITED             |                             |                          | US-FRI-1000084573             |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>                      | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Condition Aggravated;<br>Intentional Product Misuse | Lexapro                 |                           |                             | S                        |                               | 20mg                          |                          | Forest              |                         |

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| <a href="#">FDA Received Date</a>                                   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|---------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 25-Aug-2016                                                         | 12684360                | NON-EXPEDITED             |                             |                          | US-FRI-1000085871             |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>                                      | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Ineffective                                                    | Lexapro                 |                           |                             | S                        |                               |                               |                          | Forest              |                         |
| <a href="#">FDA Received Date</a>                                   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 25-Aug-2016                                                         | 12684367                | NON-EXPEDITED             |                             |                          | US-FRI-1000084163             |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>                                      | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Malaise                                                             | Lexapro                 |                           |                             | S                        |                               | Full Dose                     |                          | Forest              |                         |
|                                                                     | Lexapro                 |                           |                             | S                        |                               | Half Dose                     |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 25-Aug-2016                                                         | 12684371                | NON-EXPEDITED             |                             |                          | US-FRI-1000086044             |                               | 47 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                      | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Blood Cholesterol Increased; Heart Rate Increased; Weight Increased | Lexapro                 |                           |                             | S                        |                               |                               |                          | Forest              |                         |
|                                                                     | Lexapro                 |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 25-Aug-2016                                                         | 12684382                | NON-EXPEDITED             |                             |                          | US-FRI-1000085766             |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>                                      | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Feeling Abnormal; Heart Rate Increased; Intentional Product Misuse  | Lexapro                 |                           |                             | S                        |                               | 1.25mg                        |                          | Forest              |                         |
| <a href="#">FDA Received Date</a>                                   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 25-Aug-2016                                                         | 12684383                | NON-EXPEDITED             |                             |                          | US-FRI-1000086018             |                               |                          | Female              | USA                     |

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| <u>Preferred Term</u>    | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|--------------------------|-------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Malaise                  | Lexapro                             |                    |                    | S               |                      |                      |                 | Forest       |                |
| <u>FDA Received Date</u> | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Aug-2016              | 12684384                            | NON-EXPEDITED      |                    |                 | US-FRI-1000085576    |                      | 46 YR           | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypomania                | Lexapro                             |                    |                    | S               |                      |                      |                 | Forest       |                |
|                          | Celexa                              |                    |                    | S               |                      |                      |                 | Forest       |                |
| <u>FDA Received Date</u> | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Aug-2016              | 12684516                            | NON-EXPEDITED      |                    |                 | US-FRI-1000086659    |                      |                 | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Weight Increased         | Lexapro                             |                    |                    | S               |                      |                      |                 | Forest       |                |
|                          | Rexulti                             |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Aug-2016              | 12684668                            | EXPEDITED (15-DAY) |                    | DS              | PHHY2016DK114561     |                      | 63 YR           | Male         | DNK            |
| <u>Preferred Term</u>    | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dysphemia                | Sertralin Hexal                     |                    |                    | S               | Oral                 | 50 Mg, Qd            |                 | Novartis     |                |
|                          | Escitalopram Stada                  |                    |                    | S               | Oral                 | 10 Mg, Qd            |                 | Not Reported |                |
|                          | Doltard                             |                    |                    | C               | Unknown              |                      |                 | Not Reported |                |
|                          | Hjertemagnyl///Acetylsalicylic Acid |                    |                    | C               | Unknown              |                      |                 | Not Reported |                |
|                          | Paracetamol Sandoz                  |                    |                    | C               | Unknown              |                      |                 | Not Reported |                |
|                          | Simvastatin                         |                    |                    | C               | Unknown              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Aug-2016              | 12684673                            | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000087005    |                      | 62 YR           | Male         | FRA            |

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| <u>Preferred Term</u>                                                                                                                                                    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Amnesia; Balance Disorder; Confusional State; Dysstasia; Time Perception Altered                                                                                         | Escitalopram   |                  |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                                                                                                                                                          | Lantus         |                  |                    | C               | Subcutaneous         |                      |                 | Not Reported |                |
|                                                                                                                                                                          | Novorapid      |                  |                    | C               | Unknown              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                 | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Aug-2016                                                                                                                                                              | 12684892       | NON-EXPEDITED    |                    |                 | US-FRI-1000079074    |                      | 84 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Blood Pressure Fluctuation; Confusional State; Contusion; Eye Swelling; Intentional Product Misuse; Ocular Icterus; Off Label Use; Pain In Extremity; Syncope | Lexapro        |                  |                    | S               | Oral                 | 15 Mg                |                 | Forest       |                |
|                                                                                                                                                                          | Lexapro        |                  |                    | S               |                      |                      |                 | Forest       |                |
|                                                                                                                                                                          | Klonopin       |                  |                    | C               | Oral                 | 4mg                  |                 | Not Reported |                |
|                                                                                                                                                                          | Aloe           |                  |                    | C               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                                                                          | Nexium         |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                          | Tums           |                  |                    | C               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                                                                          | Vitamin C      |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                          | Centrum Silver |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                          | Magnesium      |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                          | Vitamin B12    |                  |                    | C               |                      |                      |                 | Not Reported |                |
| Aspirin                                                                                                                                                                  |                |                  | C                  |                 |                      |                      | Not Reported    |              |                |
| <u>FDA Received Date</u>                                                                                                                                                 | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Aug-2016                                                                                                                                                              | 12684893       | NON-EXPEDITED    |                    |                 | US-FRI-1000086667    |                      | 69 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Pain In Extremity                                                                                                                                                        | Lexapro        |                  |                    | S               |                      |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                                                                 | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Aug-2016                                                                                                                                                              | 12685029       | NON-EXPEDITED    |                    |                 | US-FRI-1000080392    |                      | 89 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Rash Pruritic                                                                                                                                                            | Lexapro        |                  |                    | S               | Oral                 |                      |                 | Forest       |                |



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|                                                                  | Vitamins       |                  |                    | C               |                      |                      |                 |              | Not Reported   |
|------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
|                                                                  | Norvasc        |                  |                    | C               |                      |                      |                 |              | Not Reported   |
|                                                                  | Aspirin        |                  |                    | C               |                      |                      |                 |              | Not Reported   |
| <u>FDA Received Date</u>                                         | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Aug-2016                                                      | 12685031       | NON-EXPEDITED    |                    |                 | US-FRI-1000080466    |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                            | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity                                            | Lexapro        |                  |                    | S               |                      |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                         | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Aug-2016                                                      | 12685042       | NON-EXPEDITED    |                    |                 | US-FRI-1000079578    |                      |                 | Male         | USA            |
| <u>Preferred Term</u>                                            | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alcohol Abuse; Anxiety; Depression; Hypervigilance; Irritability | Escitalopram   |                  |                    | S               |                      |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                         | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Aug-2016                                                      | 12685043       | NON-EXPEDITED    |                    |                 | US-FRI-1000086662    |                      |                 | Male         | USA            |
| <u>Preferred Term</u>                                            | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Depression; Dizziness; Vertigo                          | Lexapro        |                  |                    | S               |                      |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                         | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Aug-2016                                                      | 12685044       | NON-EXPEDITED    |                    |                 | US-FRI-1000079662    |                      | 73 YR           | Male         | USA            |
| <u>Preferred Term</u>                                            | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Osteoporosis                                                     | Lexapro        |                  |                    | S               | Oral                 | 10mg                 |                 | Forest       |                |
|                                                                  | Atenolol       |                  |                    | C               | Oral                 | 50mg                 |                 | Not Reported |                |
|                                                                  | Atorvastatin   |                  |                    | C               | Oral                 | 10mg                 |                 | Not Reported |                |

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| <u>FDA Received Date</u>                      | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 25-Aug-2016                                   | 12685112       | NON-EXPEDITED    |                    |                 | US-FRI-1000086181    |                      | 50 YR           | Female       | USA            |
| <u>Preferred Term</u>                         | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alopecia                                      | Lexapro        |                  |                    | S               | Oral                 |                      |                 | Forest       |                |
|                                               | Lexapro        |                  |                    | S               |                      |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                      | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Aug-2016                                   | 12685550       | NON-EXPEDITED    |                    |                 | US-FRI-1000084405    |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                         | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Weight Increased                              | Lexapro        |                  |                    | S               |                      |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                      | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Aug-2016                                   | 12685555       | NON-EXPEDITED    |                    |                 | US-FRI-1000081866    |                      |                 | Male         | USA            |
| <u>Preferred Term</u>                         | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depressed Mood; Feeling Abnormal; Hypersomnia | Lexapro        |                  |                    | S               |                      |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                      | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Aug-2016                                   | 12685556       | NON-EXPEDITED    |                    |                 | US-FRI-1000085316    |                      | 51 YR           | Female       | USA            |
| <u>Preferred Term</u>                         | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Heart Rate Increased                          | Lexapro        |                  |                    | S               | Oral                 | 10mg                 |                 | Forest       |                |
|                                               | Lexapro        |                  |                    | S               | Oral                 | 5mg                  |                 | Forest       |                |
|                                               | Baclofen       |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                               | Ambien         |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                               | Ativan         |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                               | Xarelto        |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                               | Vit D          |                  |                    | C               |                      |                      |                 | Not Reported |                |

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| <a href="#">FDA Received Date</a>                                                                                       | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-------------------------------------------------------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 25-Aug-2016                                                                                                             | 12685557                | NON-EXPEDITED             |                             |                          | US-FRI-1000080882             |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                                                          | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Ineffective; Morbid Thoughts                                                                                       | Lexapro                 |                           |                             | S                        |                               |                               |                          | Forest              |                         |
| <a href="#">FDA Received Date</a>                                                                                       | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 25-Aug-2016                                                                                                             | 12685558                | NON-EXPEDITED             |                             |                          | US-FRI-1000081886             |                               | 56 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>                                                                                          | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Insomnia; Off Label Use                                                                                                 | Lexapro                 |                           |                             | S                        | Oral                          | 25mg                          |                          | Forest              |                         |
|                                                                                                                         | Multivitamin            |                           |                             | C                        | Oral                          |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                       | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 25-Aug-2016                                                                                                             | 12685572                | NON-EXPEDITED             |                             |                          | US-FRI-1000081998             |                               | 23 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                                                          | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Disturbance In Attention; Dizziness; Feeling Abnormal; Hypoaesthesia; Impaired Work Ability; Pruritus; Throat Tightness | Lexapro                 |                           |                             | S                        | Oral                          |                               |                          | Forest              |                         |
|                                                                                                                         | Xanax                   |                           |                             | C                        | Oral                          |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                       | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 25-Aug-2016                                                                                                             | 12685575                | NON-EXPEDITED             |                             |                          | US-FRI-1000082152             |                               |                          | Male                | USA                     |
| <a href="#">Preferred Term</a>                                                                                          | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Asthenia; Flushing; Frustration Tolerance Decreased; Heart Rate Increased; Helplessness; Hypertension; Irritability;    | Lexapro                 |                           |                             | S                        |                               | 10mg                          |                          | Forest              |                         |

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Stress

| <a href="#">FDA Received Date</a>          | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|--------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 25-Aug-2016                                | 12685581                | NON-EXPEDITED             |                             |                          | US-FRI-1000081444             |                               | 62 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>             | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Meibomian Gland Dysfunction; Nasal Dryness | Lexapro                 |                           |                             | S                        | Oral                          | 10mg                          |                          | Forest              |                         |
|                                            | Lexapro                 |                           |                             | S                        | Oral                          | 5mg                           |                          | Forest              |                         |
|                                            | Avapro                  |                           |                             | C                        | Oral                          | 300mg                         |                          | Not Reported        |                         |
|                                            | Tekturna                |                           |                             | C                        | Oral                          | 150mg                         |                          | Not Reported        |                         |
|                                            | Toprol                  |                           |                             | C                        | Oral                          |                               |                          | Not Reported        |                         |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 25-Aug-2016                       | 12685582                | NON-EXPEDITED             |                             |                          | US-FRI-1000080827             |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Glucose Tolerance Impaired        | Lexapro                 |                           |                             | S                        |                               |                               |                          | Forest              |                         |
|                                   | Spironolactone          |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |

| <a href="#">FDA Received Date</a>                              | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|----------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 25-Aug-2016                                                    | 12685905                | NON-EXPEDITED             |                             |                          | US-FRI-1000082441             |                               |                          | Male                | USA                     |
| <a href="#">Preferred Term</a>                                 | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Chest Discomfort; Drug Intolerance; Emotional Disorder; Tremor | Lexapro                 |                           |                             | S                        |                               |                               |                          | Forest              |                         |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 25-Aug-2016                       | 12685906                | NON-EXPEDITED             |                             |                          | US-FRI-1000082871             |                               | 29 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Ear Pain; Feeling Hot;            | Lexapro                 |                           |                             | S                        | Oral                          | 10mg                          |                          | Forest              |                         |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                 |           |   |      |  |                                                                  |              |
|-----------------------------------------------------------------|-----------|---|------|--|------------------------------------------------------------------|--------------|
| Neck Pain; Pain In Jaw;<br>Pigmentation Disorder;<br>Tenderness | Relion    | C |      |  | 100 Unit/MI (20 Units At<br>Breakfast And 12 Units At<br>Supper) | Not Reported |
|                                                                 | Relion    | C |      |  |                                                                  | Not Reported |
|                                                                 | Novolog   | C |      |  |                                                                  | Not Reported |
|                                                                 | Neurontin | C | Oral |  | 600mg                                                            | Not Reported |
|                                                                 | Zofran    | C | Oral |  | 24mg                                                             | Not Reported |
|                                                                 | Zofran    | C |      |  |                                                                  | Not Reported |
|                                                                 | Ultram    | C | Oral |  | 200mg                                                            | Not Reported |
|                                                                 | Albuterol | C |      |  | 90 Mcg/Act 1-2 Puffs Q4-<br>6h Wheezes And Sob                   | Not Reported |
|                                                                 | Albuterol | C |      |  |                                                                  | Not Reported |

| <u>FDA Received Date</u>                                                               | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 25-Aug-2016                                                                            | 12685932       | NON-EXPEDITED    |                    |                 | US-FRI-1000082576    |                      | 58 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bruxism; Joint Stiffness;<br>Muscle Spasms;<br>Musculoskeletal Stiffness;<br>Neck Pain | Lexapro        |                  |                    | S               | Oral                 | 10mg                 |                 | Forest       |                |
|                                                                                        | Vitamin D Nos  |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                        | Vitamin B12    |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                        | Prevacid       |                  |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 25-Aug-2016              | 12685933       | NON-EXPEDITED    |                    |                 | US-FRI-1000082612    |                      |                 | Female     | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Hypersensitivity    | Lexapro        |                  |                    | S               |                      |                      |                 | Forest     |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 25-Aug-2016              | 12685937       | NON-EXPEDITED    |                    |                 | US-FRI-1000082227    |                      | 74 YR           | Male       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Gynaecomastia            | Lexapro        |                  |                    | S               | Oral                 | 5mg                  |                 | Forest     |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                |   |      |        |              |
|----------------|---|------|--------|--------------|
| Lexapro        | S | Oral | 10mg   | Forest       |
| Lexapro        | S | Oral | 5mg    | Forest       |
| Finasteride    | S | Oral |        | Not Reported |
| Spironolactone | S | Oral | 25mg   | Not Reported |
| Vitamin D3     | C |      |        | Not Reported |
| Lisinopril     | C |      | 5mg    | Not Reported |
| Imdur          | C | Oral | 30mg   | Not Reported |
| Lasix          | C | Oral | 80mg   | Not Reported |
| Metoprolol     | C | Oral | 100mg  | Not Reported |
| Digoxin        | C | Oral | 125mcg | Not Reported |
| Loratadine     | C | Oral |        | Not Reported |
| Simvastatin    | C | Oral | 20mg   | Not Reported |
| Tamsulosin     | C | Oral | 0.4mg  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Aug-2016              | 12685940      | NON-EXPEDITED    |                    |                 | US-FRI-1000082336    |                      | 74 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                           | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------|-------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abdominal Discomfort;<br>Anxiety; Dizziness;<br>Flatulence; Nausea;<br>Nausea; Somnolence;<br>Thinking Abnormal | Lexapro           |              |            | S           | Oral         |                    |                 | Forest       |
|                                                                                                                 | Lipitor           |              |            | C           | Oral         | 40mg               |                 | Not Reported |
|                                                                                                                 | Asa               |              |            | C           | Oral         | 81mg               |                 | Not Reported |
|                                                                                                                 | Dymista           |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                 | Potassium Citrate |              |            | C           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Aug-2016              | 12685942      | NON-EXPEDITED    |                    |                 | US-FRI-1000082164    |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Drug Hypersensitivity | Lexapro        |              |            | S           |              |                    |                 | Forest     |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <a href="#">FDA Received Date</a>                                                            | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|----------------------------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 25-Aug-2016                                                                                  | 12686032                | NON-EXPEDITED             |                             |                          | US-FRI-1000082986             |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                               | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Affective Disorder;<br>Depressed Mood;<br>Irritability; Nausea; Social<br>Avoidant Behaviour | Lexapro                 |                           |                             | S                        |                               |                               |                          | Forest              |                         |
| <a href="#">FDA Received Date</a>                                                            | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 25-Aug-2016                                                                                  | 12686069                | NON-EXPEDITED             |                             |                          | US-FRI-1000082820             |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                               | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Adverse Drug Reaction                                                                        | Lexapro                 |                           |                             | S                        |                               |                               |                          | Forest              |                         |
| <a href="#">FDA Received Date</a>                                                            | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 25-Aug-2016                                                                                  | 12687568                | EXPEDITED (15-DAY)        |                             | DE                       | DE-FRI-1000087011             |                               | 32 YR                    | Male                | DEU                     |
| <a href="#">Preferred Term</a>                                                               | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Agitation; Asphyxia;<br>Completed Suicide                                                    | Escitalopram            |                           |                             | S                        | Oral                          |                               |                          | Forest              |                         |
| <a href="#">FDA Received Date</a>                                                            | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 25-Aug-2016                                                                                  | 12688907                | NON-EXPEDITED             |                             |                          | US-FRI-1000082916             |                               |                          | Male                | USA                     |
| <a href="#">Preferred Term</a>                                                               | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Adverse Event                                                                                | Lexapro                 |                           |                             | S                        |                               |                               |                          | Forest              |                         |
| <a href="#">FDA Received Date</a>                                                            | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 25-Aug-2016                                                                                  | 12688908                | NON-EXPEDITED             |                             |                          | US-FRI-1000086116             |                               | 39 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                               | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
|                                                                                              |                         |                           |                             |                          |                               |                               |                          |                     |                         |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                             |                |                  |                    |                 |                      |                      |                    |                 |                |
|---------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|--------------------|-----------------|----------------|
| Drug Ineffective                            | Lexapro        |                  | S                  | Oral            | 20mg                 |                      |                    | Forest          |                |
| <u>FDA Received Date</u>                    | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |
| 25-Aug-2016                                 | 12688909       | NON-EXPEDITED    |                    |                 | US-FRI-1000085273    |                      |                    | Female          | USA            |
| <u>Preferred Term</u>                       | <u>Product</u> |                  | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>          | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>     |
| Drug Ineffective                            | Lexapro        |                  | S                  |                 |                      |                      |                    |                 | Forest         |
| <u>FDA Received Date</u>                    | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |
| 25-Aug-2016                                 | 12688910       | NON-EXPEDITED    |                    |                 | US-FRI-1000084521    |                      |                    | Female          | USA            |
| <u>Preferred Term</u>                       | <u>Product</u> |                  | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>          | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>     |
| Feeling Abnormal                            | Lexapro        |                  | S                  |                 |                      |                      |                    |                 | Forest         |
| <u>FDA Received Date</u>                    | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |
| 25-Aug-2016                                 | 12688911       | NON-EXPEDITED    |                    |                 | US-FRI-1000086631    |                      |                    | Female          | USA            |
| <u>Preferred Term</u>                       | <u>Product</u> |                  | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>          | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>     |
| Diarrhoea                                   | Lexapro        |                  | S                  |                 |                      |                      |                    |                 | Forest         |
| <u>FDA Received Date</u>                    | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |
| 25-Aug-2016                                 | 12688912       | NON-EXPEDITED    |                    |                 | US-FRI-1000085082    |                      |                    | Male            | USA            |
| <u>Preferred Term</u>                       | <u>Product</u> |                  | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>          | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>     |
| Drug Ineffective                            | Lexapro        |                  | S                  |                 |                      | 10mg                 |                    |                 | Forest         |
| <u>FDA Received Date</u>                    | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |
| 25-Aug-2016                                 | 12688918       | NON-EXPEDITED    |                    |                 | US-FRI-1000085214    |                      |                    | Female          | USA            |
| <u>Preferred Term</u>                       | <u>Product</u> |                  | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>          | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>     |
| Drug Ineffective; Off Label Use; Withdrawal | Lexapro        |                  | S                  | Oral            | 20mg                 |                      |                    |                 | Forest         |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                    |                        |                  |                    |                 |                      |                      |                 |                              |                |
|----------------------------------------------------------------------------------------------------|------------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------------------------|----------------|
| Syndrome                                                                                           | Clonazepam<br>Lamictal |                  |                    | C<br>C          |                      |                      |                 | Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                           | <u>Case #</u>          | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 25-Aug-2016                                                                                        | 12688919               | NON-EXPEDITED    |                    |                 | US-FRI-1000082912    |                      |                 | Female                       | USA            |
| <u>Preferred Term</u>                                                                              | <u>Product</u>         | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Platelet Count Decreased                                                                           | Lexapro                |                  |                    | S               | Oral                 | 10mg                 |                 | Forest                       |                |
|                                                                                                    | Depakote               |                  |                    | S               | Oral                 | 1000 Mg              |                 | Not Reported                 |                |
|                                                                                                    | Depakote               |                  |                    | S               | Oral                 | 500 Mg               |                 | Not Reported                 |                |
|                                                                                                    | Depakote               |                  |                    | S               | Oral                 | 125 Mg               |                 | Not Reported                 |                |
|                                                                                                    | Levothyroxine          |                  |                    | C               | Oral                 | 50mg                 |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                                                                           | <u>Case #</u>          | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 25-Aug-2016                                                                                        | 12688920               | NON-EXPEDITED    |                    |                 | US-FRI-1000086045    |                      | 16 YR           | Female                       | USA            |
| <u>Preferred Term</u>                                                                              | <u>Product</u>         | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Alopecia                                                                                           | Lexapro                |                  |                    | S               |                      |                      |                 | Forest                       |                |
| <u>FDA Received Date</u>                                                                           | <u>Case #</u>          | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 25-Aug-2016                                                                                        | 12688921               | NON-EXPEDITED    |                    |                 | US-FRI-1000080988    |                      | 75 YR           | Female                       | USA            |
| <u>Preferred Term</u>                                                                              | <u>Product</u>         | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Abdominal Discomfort;<br>Anxiety; Decreased<br>Appetite; Dizziness; Dry<br>Mouth; Feeling Abnormal | Lexapro                |                  |                    | S               | Oral                 | 20mg                 |                 | Forest                       |                |
|                                                                                                    | Coumadin               |                  |                    | C               |                      |                      |                 | Not Reported                 |                |
|                                                                                                    | Temazepam              |                  |                    | C               |                      |                      |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                                                                           | <u>Case #</u>          | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 25-Aug-2016                                                                                        | 12688923               | NON-EXPEDITED    |                    |                 | US-FRI-1000080277    |                      |                 | Female                       | USA            |
| <u>Preferred Term</u>                                                                              | <u>Product</u>         | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                              |         |   |      |      |        |
|------------------------------------------------------------------------------|---------|---|------|------|--------|
| Hot Flush; Libido<br>Decreased; Paraesthesia<br>Oral; Withdrawal<br>Syndrome | Lexapro | S | Oral | 10mg | Forest |
|------------------------------------------------------------------------------|---------|---|------|------|--------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Aug-2016              | 12688924      | NON-EXPEDITED    |                    |                 | US-FRI-1000086653    |                      |            | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Anxiety; Paranoia     | Lexapro        |              |            | S           |              |                    |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Aug-2016              | 12688925      | NON-EXPEDITED    |                    |                 | US-FRI-1000079480    |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                                                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Agitation; Anxiety;<br>Dissociation; Fatigue;<br>Fatigue; Insomnia;<br>Nausea; Paraesthesia | Lexapro        |              |            | S           |              |                    |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Aug-2016              | 12688926      | NON-EXPEDITED    |                    |                 | US-FRI-1000086650    |                      |            | Male       | USA            |

| <u>Preferred Term</u>       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Blood Pressure<br>Decreased | Lexapro        |              |            | S           |              |                    |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Aug-2016              | 12688927      | NON-EXPEDITED    |                    |                 | US-FRI-1000080679    |                      | 72 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|----------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Auditory Disorder;                                                   | Lexapro        |              |            | S           | Oral         | 10mg               |                 | Forest     |
| Intentional Product<br>Misuse; Libido Decreased;<br>Libido Decreased | Lexapro        |              |            | S           | Oral         | 10mg               |                 | Forest     |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                         | Lexapro        |                  | S                  | Oral            |                      |                      |                 | Not Reported |                |
|-----------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
|                                         | Lexapro        |                  | S                  | Oral            |                      |                      |                 | Not Reported |                |
|                                         | Viagra         |                  | C                  | Oral            |                      |                      |                 | Not Reported |                |
|                                         | Xanax          |                  | C                  | Oral            | 2mg                  |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Aug-2016                             | 12688928       | NON-EXPEDITED    |                    |                 | US-FRI-1000085491    |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective; Tinnitus              | Lexapro        |                  |                    | S               |                      |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Aug-2016                             | 12688929       | NON-EXPEDITED    |                    |                 | US-FRI-1000085443    |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Increased Appetite;<br>Weight Increased | Lexapro        |                  |                    | S               |                      |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Aug-2016                             | 12688930       | NON-EXPEDITED    |                    |                 | US-FRI-1000081659    |                      | 31 YR           | Female       | USA            |
| <u>Preferred Term</u>                   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Pruritus                                | Lexapro        |                  |                    | S               |                      |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Aug-2016                             | 12688933       | NON-EXPEDITED    |                    |                 | US-FRI-1000079545    |                      | 66 YR           | Female       | USA            |
| <u>Preferred Term</u>                   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Potassium                         | Lexapro        |                  |                    | S               | Oral                 |                      |                 | Forest       |                |
| Increased; Cough;                       | Benazepril     |                  |                    | S               | Oral                 |                      |                 | Not Reported |                |
| Dyspnoea; Ear Pain;                     | Vitamins       |                  |                    | C               |                      |                      |                 | Not Reported |                |
| Haemoptysis; Headache;                  |                |                  |                    |                 |                      |                      |                 |              |                |
| Night Sweats; Pain;                     |                |                  |                    |                 |                      |                      |                 |              |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Weight Decreased

| <u>FDA Received Date</u>                                                    | <u>Case #</u>   | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------|-----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 25-Aug-2016                                                                 | 12688934        | NON-EXPEDITED    |                    |                 | US-FRI-1000080363    |                      | 13 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                       | <u>Product</u>  | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective; Food Craving; Weight Increased                            | Lexapro         |                  |                    | S               | Oral                 | 20mg                 |                 | Forest       |                |
|                                                                             | Melatonin       |                  |                    | C               | Oral                 | 10mg                 |                 | Not Reported |                |
|                                                                             | Folic Acid      |                  |                    | C               |                      | 15mg                 |                 | Not Reported |                |
|                                                                             | Pristiq         |                  |                    | C               | Oral                 | 50mg                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                    | <u>Case #</u>   | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Aug-2016                                                                 | 12688936        | NON-EXPEDITED    |                    |                 | US-FRI-1000080750    |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                       | <u>Product</u>  | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alopecia; Skin Disorder                                                     | Lexapro         |                  |                    | S               | Oral                 | 20mg                 |                 | Forest       |                |
|                                                                             | Lexapro         |                  |                    | S               |                      |                      |                 | Forest       |                |
|                                                                             | Xanax           |                  |                    | C               | Oral                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                    | <u>Case #</u>   | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Aug-2016                                                                 | 12688937        | NON-EXPEDITED    |                    |                 | US-FRI-1000085626    |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                       | <u>Product</u>  | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression                                                                  | Lexapro         |                  |                    | S               |                      | 20mg                 |                 | Forest       |                |
| <u>FDA Received Date</u>                                                    | <u>Case #</u>   | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Aug-2016                                                                 | 12688938        | NON-EXPEDITED    |                    |                 | US-FRI-1000082095    |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                       | <u>Product</u>  | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Disturbance In Attention; Impaired Driving Ability; Rash; Tremor; | Lexapro         |                  |                    | S               |                      |                      |                 | Forest       |                |
|                                                                             | Lyrica          |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                             | Anti-Depressant |                  |                    | S               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Unevaluable Event;  
Unevaluable Event;  
Unevaluable Event; Visual  
Impairment

| <a href="#">FDA Received Date</a>                    | <a href="#">Case #</a>     | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a>                    | <a href="#">Country</a> |
|------------------------------------------------------|----------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|----------------------------------------|-------------------------|
| 25-Aug-2016                                          | 12688939                   | NON-EXPEDITED             |                             |                          | US-FRI-1000085663             |                               |                          | Male                                   | USA                     |
| <a href="#">Preferred Term</a>                       | <a href="#">Product</a>    | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a>                    |                         |
| Drug Ineffective                                     | Lexapro                    |                           |                             | S                        |                               | 10mg                          |                          | Forest                                 |                         |
| <a href="#">FDA Received Date</a>                    | <a href="#">Case #</a>     | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a>                    | <a href="#">Country</a> |
| 25-Aug-2016                                          | 12688940                   | NON-EXPEDITED             |                             |                          | US-FRI-1000085699             |                               |                          | Female                                 | USA                     |
| <a href="#">Preferred Term</a>                       | <a href="#">Product</a>    | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a>                    |                         |
| Hyperhidrosis                                        | Lexapro                    |                           |                             | S                        |                               |                               |                          | Forest                                 |                         |
| <a href="#">FDA Received Date</a>                    | <a href="#">Case #</a>     | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a>                    | <a href="#">Country</a> |
| 25-Aug-2016                                          | 12688941                   | NON-EXPEDITED             |                             |                          | US-FRI-1000079817             |                               |                          | Female                                 | USA                     |
| <a href="#">Preferred Term</a>                       | <a href="#">Product</a>    | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a>                    |                         |
| Drug Ineffective;<br>Screaming; Unevaluable<br>Event | Lexapro<br>Prozac<br>Xanax |                           |                             | S<br>S<br>S              |                               |                               |                          | Forest<br>Not Reported<br>Not Reported |                         |
| <a href="#">FDA Received Date</a>                    | <a href="#">Case #</a>     | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a>                    | <a href="#">Country</a> |
| 25-Aug-2016                                          | 12688942                   | NON-EXPEDITED             |                             |                          | US-FRI-1000085560             |                               | 40 YR                    | Male                                   | USA                     |
| <a href="#">Preferred Term</a>                       | <a href="#">Product</a>    | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a>                    |                         |
| Anxiety; Panic Attack                                | Lexapro                    |                           |                             | S                        |                               |                               |                          | Forest                                 |                         |
| <a href="#">FDA Received Date</a>                    | <a href="#">Case #</a>     | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a>                    | <a href="#">Country</a> |
| 25-Aug-2016                                          | 12688943                   | NON-EXPEDITED             |                             |                          | US-FRI-1000079548             |                               | 50 YR                    | Female                                 | USA                     |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|----------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Dizziness; Swelling                                      | Lexapro        |                  |                    | S               | Oral                 | Either 10 Or 20mg    |                 | Forest       |                |
| <u>FDA Received Date</u>                                 | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Aug-2016                                              | 12688944       | NON-EXPEDITED    |                    |                 | US-FRI-1000086799    |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Heart Rate Increased                                     | Lexapro        |                  |                    | S               |                      |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                 | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Aug-2016                                              | 12688945       | NON-EXPEDITED    |                    |                 | US-FRI-1000081187    |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Drug Dose Titration Not Performed; Irritability | Lexapro        |                  |                    | S               |                      |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                 | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Aug-2016                                              | 12688946       | NON-EXPEDITED    |                    |                 | US-FRI-1000079481    |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity; Malaise; Nausea                   | Lexapro        |                  |                    | S               |                      |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                 | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Aug-2016                                              | 12688947       | NON-EXPEDITED    |                    |                 | US-FRI-1000080579    |                      | 32 YR           | Unknown      | USA            |
| <u>Preferred Term</u>                                    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Mental Disorder                                          | Lexapro        |                  |                    | S               |                      |                      |                 | Forest       |                |
|                                                          | Keppra         |                  |                    | S               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <a href="#">FDA Received Date</a>                                                                         | <a href="#">Case #</a>                   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a>              | <a href="#">Country</a> |
|-----------------------------------------------------------------------------------------------------------|------------------------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|----------------------------------|-------------------------|
| 25-Aug-2016                                                                                               | 12688948                                 | NON-EXPEDITED             |                             |                          | US-FRI-1000080335             |                               | 16 YR                    | Female                           | USA                     |
| <a href="#">Preferred Term</a>                                                                            | <a href="#">Product</a>                  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a>              |                         |
| Depression; Heart Rate Increased; Listless; Sleep Disorder                                                | Lexapro                                  |                           |                             | S                        | Oral                          | 7.5mg                         |                          | Forest                           |                         |
| <a href="#">FDA Received Date</a>                                                                         | <a href="#">Case #</a>                   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a>              | <a href="#">Country</a> |
| 25-Aug-2016                                                                                               | 12688959                                 | NON-EXPEDITED             |                             |                          | US-FRI-1000080422             |                               |                          | Female                           | USA                     |
| <a href="#">Preferred Term</a>                                                                            | <a href="#">Product</a>                  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a>              |                         |
| Feeling Abnormal; Motion Sickness; Nausea; Unevaluable Event                                              | Lexapro                                  |                           |                             | S                        |                               |                               |                          | Forest                           |                         |
| <a href="#">FDA Received Date</a>                                                                         | <a href="#">Case #</a>                   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a>              | <a href="#">Country</a> |
| 25-Aug-2016                                                                                               | 12688960                                 | NON-EXPEDITED             |                             |                          | US-FRI-1000080420             |                               | 51 YR                    | Female                           | USA                     |
| <a href="#">Preferred Term</a>                                                                            | <a href="#">Product</a>                  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a>              |                         |
| Disturbance In Attention; Dizziness; Dizziness; Fatigue; Feeling Abnormal; Paraesthesia; Weight Increased | Lexapro<br>Lexapro<br>Vitamins           |                           |                             | S<br>S<br>C              | Oral                          | 10mg                          |                          | Forest<br>Forest<br>Not Reported |                         |
| <a href="#">FDA Received Date</a>                                                                         | <a href="#">Case #</a>                   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a>              | <a href="#">Country</a> |
| 26-Aug-2016                                                                                               | 12500722                                 | EXPEDITED (15-DAY)        |                             | HO                       | IT-FRI-1000085538             |                               | 28 YR                    | Female                           | ITA                     |
| <a href="#">Preferred Term</a>                                                                            | <a href="#">Product</a>                  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a>              |                         |
| Dehydration; Hyperhidrosis; Hypotension; Product Use In Unapproved Indication;                            | Escitalopram<br>Escitalopram<br>Buscopan |                           |                             | S<br>S<br>C              | Oral<br>Oral<br>Oral          | 5 Mg<br>10 Mg                 |                          | Forest<br>Forest<br>Not Reported |                         |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                   |                                                   |   |      |                              |              |
|-------------------|---------------------------------------------------|---|------|------------------------------|--------------|
| Syncope; Vomiting | Prednisone                                        | C | Oral | 20 Mg                        | Not Reported |
|                   | Rivotril                                          | C | Oral | Unit Dose: 10-15 Drops (Prn) | Not Reported |
|                   | Fortimel Creme                                    | C | Oral | 2 Dfs                        | Not Reported |
|                   | Calcitriol                                        | C | Oral | .25 Mg                       | Not Reported |
|                   | Optalidon<br>[Butalbital;Caffeine;Propyphenazone] | C | Oral | 1 Df                         | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Aug-2016              | 12689083      | EXPEDITED (15-DAY) |                    | OT              | GB-ACCORD-043435     |                      |            | Female     | GBR            |

  

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Colitis Ulcerative    | Escitalopram   |              |            | S           | Oral         |                    |                 | Accord     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Aug-2016              | 12689928      | NON-EXPEDITED    |                    |                 | US-FRI-1000082302    |                      | 36 YR      | Female     | USA            |

  

| <u>Preferred Term</u>                                                                  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|----------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Burning Sensation; Dizziness; Erythema; Flushing; Nausea; Panic Reaction; Paraesthesia | Lexapro        |              |            | S           |              |                    |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Aug-2016              | 12689932      | NON-EXPEDITED    |                    |                 | US-FRI-1000079365    |                      |            | Male       | USA            |

  

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Unevaluable Event     | Lexapro        |              |            | S           |              |                    |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 26-Aug-2016              | 12689998      | EXPEDITED (15-DAY) |                    | HO              | FR-PFIZER INC-2016397146 |                      | 50 YR      | Female     | FRA            |



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| <u>Preferred Term</u>                               | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|-----------------------------------------------------|----------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Poisoning Deliberate;<br>Toxicity To Various Agents | Advil                |                  |                    | S               | Oral                 | 2 Df, Single         |                 | Pfizer       |                |
|                                                     | Escitalopram Oxalate |                  |                    | S               | Oral                 | 14 Df, Single        |                 | Not Reported |                |
|                                                     | Seresta              |                  |                    | S               | Oral                 | 26 Df, Single        |                 | Not Reported |                |
|                                                     | Tercian              |                  |                    | S               | Oral                 | 12 Df, Single        |                 | Not Reported |                |
| <u>FDA Received Date</u>                            | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Aug-2016                                         | 12690365             | NON-EXPEDITED    |                    |                 | US-FRI-1000084414    |                      |                 | Male         | USA            |
| <u>Preferred Term</u>                               | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dental Caries; Toothache                            | Lexapro              |                  |                    | S               |                      |                      |                 | Forest       |                |
|                                                     | Sertraline           |                  |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                            | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Aug-2016                                         | 12690366             | NON-EXPEDITED    |                    |                 | US-FRI-1000084730    |                      |                 | Female       | CAN            |
| <u>Preferred Term</u>                               | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypersensitivity                                    | Escitalopram         |                  |                    | S               |                      |                      |                 | Forest       |                |
|                                                     | Tysabri              |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                     | Fampyra              |                  |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                            | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Aug-2016                                         | 12690373             | NON-EXPEDITED    |                    |                 | US-FRI-1000084780    |                      |                 | Male         | USA            |
| <u>Preferred Term</u>                               | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Chest Discomfort;<br>Pruritus; Rash; Rash           | Lexapro              |                  |                    | S               |                      |                      |                 | Forest       |                |
|                                                     | Geodon               |                  |                    | S               |                      | 40                   |                 | Not Reported |                |
|                                                     | Geodon               |                  |                    | S               |                      | 60                   |                 | Not Reported |                |
| <u>FDA Received Date</u>                            | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Aug-2016                                         | 12690382             | NON-EXPEDITED    |                    |                 | US-FRI-1000083757    |                      |                 | Female       | USA            |

# FDA Adverse Event Reporting System

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| <u>Preferred Term</u>                                          | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|----------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Anger; Irritability                                            | Lexapro        |                  |                    | S               |                      |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Aug-2016                                                    | 12690384       | NON-EXPEDITED    |                    |                 | US-FRI-1000084109    |                      | 71 YR           | Male         | USA            |
| <u>Preferred Term</u>                                          | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dyskinesia; Dysphonia;<br>Ejaculation Delayed; Night<br>Sweats | Lexapro        |                  |                    | S               | Oral                 | 5mg                  |                 | Forest       |                |
|                                                                | Lexapro        |                  |                    | S               |                      |                      |                 | Forest       |                |
|                                                                | Vimpat         |                  |                    | C               | Oral                 | 25mg                 |                 | Not Reported |                |
|                                                                | Klonopin       |                  |                    | C               | Oral                 |                      |                 | Not Reported |                |
|                                                                | Ativan         |                  |                    | C               | Oral                 |                      |                 | Not Reported |                |
|                                                                | Aspirin        |                  |                    | C               | Oral                 | 81mg                 |                 | Not Reported |                |
|                                                                | Vitamin B      |                  |                    | C               | Oral                 |                      |                 | Not Reported |                |
|                                                                | Vitamin C      |                  |                    | C               | Oral                 |                      |                 | Not Reported |                |
|                                                                | Vitamin D3     |                  |                    | C               | Oral                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Aug-2016                                                    | 12690386       | NON-EXPEDITED    |                    |                 | US-FRI-1000084137    |                      |                 | Male         | USA            |
| <u>Preferred Term</u>                                          | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Depressed<br>Mood; Social Avoidant<br>Behaviour     | Lexapro        |                  |                    | S               |                      |                      |                 | Forest       |                |
|                                                                | Lexapro        |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                | Lexapro        |                  |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Aug-2016                                                    | 12690389       | NON-EXPEDITED    |                    |                 | US-FRI-1000084213    |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                          | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity                                          | Lexapro        |                  |                    | S               |                      |                      |                 | Forest       |                |

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| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 26-Aug-2016                | 12690393       | NON-EXPEDITED    |                    |                 | US-FRI-1000083683    |                      | 66 YR           | Female       | USA            |
| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain Upper;      | Lexapro        |                  |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
| Anxiety; Defaecation       | Lexapro        |                  |                    | S               | Oral                 | 7.5 Mg               |                 | Forest       |                |
| Urgency; Diarrhoea;        | Lexapro        |                  |                    | S               | Oral                 | 5 Mg                 |                 | Not Reported |                |
| Disturbance In Attention;  | Lexapro        |                  |                    | S               | Oral                 | 2.5 Mg               |                 | Not Reported |                |
| Gastrointestinal Sounds    | Lexapro        |                  |                    | S               | Oral                 | 5 Mg                 |                 | Not Reported |                |
| Abnormal; Intentional      | Lexapro        |                  |                    |                 |                      |                      |                 |              |                |
| Product Use Issue;         | Lexapro        |                  |                    |                 |                      |                      |                 |              |                |
| Irritability; Nausea;      |                |                  |                    |                 |                      |                      |                 |              |                |
| Restlessness; Sleep        |                |                  |                    |                 |                      |                      |                 |              |                |
| Disorder                   |                |                  |                    |                 |                      |                      |                 |              |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Aug-2016                | 12690394       | NON-EXPEDITED    |                    |                 | US-FRI-1000083703    |                      | 10 YR           | Female       | USA            |
| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain Upper;      | Lexapro        |                  |                    | S               | Oral                 | 2.5mg                |                 | Forest       |                |
| Arthralgia; Fatigue;       | Lexapro        |                  |                    | S               | Oral                 | 5mg                  |                 | Forest       |                |
| Headache; Intentional      | Lexapro        |                  |                    | S               | Oral                 | 7.5mg                |                 | Not Reported |                |
| Product Misuse; Nausea;    | Lexapro        |                  |                    | S               | Oral                 | 10mg                 |                 | Not Reported |                |
| Pain In Extremity;         | Lexapro        |                  |                    | S               | Oral                 | 7.5mg                |                 | Not Reported |                |
| Paraesthesia;              | Lexapro        |                  |                    | S               | Oral                 |                      |                 | Not Reported |                |
| Photosensitivity Reaction; | Tylenol        |                  |                    | C               |                      |                      |                 | Not Reported |                |
| Weight Increased           | Tylenol        |                  |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Aug-2016                | 12690395       | NON-EXPEDITED    |                    |                 | US-FRI-1000083738    |                      |                 | Female       | USA            |
| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity      | Lexapro        |                  |                    | S               |                      |                      |                 | Forest       |                |

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| <u>FDA Received Date</u>                                                 | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 26-Aug-2016                                                              | 12690397       | NON-EXPEDITED    |                    |                 | US-FRI-1000084343    |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cyanosis; Erythema;<br>Erythema; Flushing;<br>Intentional Product Misuse | Lexapro        |                  |                    | S               | Oral                 |                      |                 | Forest       |                |
|                                                                          | Topamax        |                  |                    | C               | Oral                 | 300mg                |                 | Not Reported |                |
|                                                                          | Klonopin       |                  |                    | C               | Oral                 | 0.01mg               |                 | Not Reported |                |
|                                                                          | Vitamins       |                  |                    | C               | Oral                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                 | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Aug-2016                                                              | 12690398       | NON-EXPEDITED    |                    |                 | US-FRI-1000084220    |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Chills; Hot Flush                                                        | Lexapro        |                  |                    | S               |                      |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                 | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Aug-2016                                                              | 12690404       | NON-EXPEDITED    |                    |                 | US-FRI-1000084799    |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Chest Pain; Drug<br>Hypersensitivity;<br>Headache                        | Lexapro        |                  |                    | S               |                      |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                 | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Aug-2016                                                              | 12690405       | NON-EXPEDITED    |                    |                 | US-FRI-1000084153    |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective; Feeling<br>Abnormal; Unevaluable<br>Event              | Lexapro        |                  |                    | S               | Oral                 | 10mg                 |                 | Forest       |                |
|                                                                          | Protonix       |                  |                    | C               | Oral                 | 40mg                 |                 | Not Reported |                |
|                                                                          | Gabapentin     |                  |                    | C               | Oral                 |                      |                 | Not Reported |                |

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|            |   |      |       |              |
|------------|---|------|-------|--------------|
| Tramadol   | C | Oral | 150mg | Not Reported |
| Oxycontin  | C | Oral |       | Not Reported |
| Xanax      | C | Oral |       | Not Reported |
| Tizanidine | C | Oral | 6mg   | Not Reported |
| Adipex     | C | Oral |       | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Aug-2016              | 12690411      | NON-EXPEDITED    |                    |                 | US-FRI-1000086537    |                      | 56 YR      | Male       | USA            |

| <u>Preferred Term</u>                                | <u>Product</u>   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------|------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Dizziness;<br>Headache; Insomnia;<br>Nausea | Lexapro          |              |            | S           | Oral         | 10mg               |                 | Forest       |
|                                                      | Lisinopril       |              |            | C           |              | 40mg Am            |                 | Not Reported |
|                                                      | Amlodipine       |              |            | C           |              | 2.5mg              |                 | Not Reported |
|                                                      | Fenofibrate      |              |            | C           |              | 48mg               |                 | Not Reported |
|                                                      | Humira           |              |            | C           |              | 30mg Q 2 Weeks     |                 | Not Reported |
|                                                      | Omega 3 Fish Oil |              |            | C           |              |                    |                 | Not Reported |
|                                                      | Probiotics       |              |            | C           |              |                    |                 | Not Reported |
|                                                      | Vit D            |              |            | C           |              | 2000 Iu            |                 | Not Reported |
|                                                      | Vit C            |              |            | C           |              | 1000 Mg            |                 | Not Reported |
|                                                      | Coq 10           |              |            | C           |              | 200mg              |                 | Not Reported |
|                                                      | Bayer Aspirin    |              |            | C           |              | 325mg              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Aug-2016              | 12690412      | NON-EXPEDITED    |                    |                 | US-FRI-1000082997    |                      | 23 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                             | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|------------------------------------------|--------------------|-----------------|--------------|
| Hypoacusis            | Lexapro        |              |            | S           | Oral                                     | 10mg               |                 | Forest       |
|                       | Lexapro        |              |            | S           |                                          |                    |                 | Forest       |
|                       | Remicade       |              |            | S           | Intravenous (not<br>otherwise specified) |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <a href="#">FDA Received Date</a>                                                        | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|------------------------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 26-Aug-2016                                                                              | 12690413                | NON-EXPEDITED             |                             |                          | US-FRI-1000083148             |                               | 81 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>                                                           | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Lacrimation Increased;<br>Product Dose Omission;<br>Vision Blurred; Visual<br>Impairment | Lexapro                 |                           |                             | S                        | Oral                          | 10mg                          |                          | Forest              |                         |

| <a href="#">FDA Received Date</a>                                                                                                | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a>          | <a href="#">Country</a> |
|----------------------------------------------------------------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|------------------------------|-------------------------|
| 26-Aug-2016                                                                                                                      | 12690414                | NON-EXPEDITED             |                             |                          | US-FRI-1000083087             |                               | 24 YR                    | Male                         | USA                     |
| <a href="#">Preferred Term</a>                                                                                                   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a>          |                         |
| Disturbance In Sexual<br>Arousal; Ejaculation<br>Failure; Erectile<br>Dysfunction; Erection<br>Increased; Prescribed<br>Overdose | Lexapro                 |                           |                             | S                        |                               | 40mg                          |                          | Forest                       |                         |
|                                                                                                                                  | Lamictal                |                           |                             | S                        | Oral                          | 400mg                         |                          | Not Reported                 |                         |
|                                                                                                                                  | Latuda                  |                           |                             | S                        | Oral                          | 120mg                         |                          | Not Reported                 |                         |
|                                                                                                                                  | Risperdal               |                           |                             | S                        | Oral                          | 0.5mg                         |                          | Not Reported                 |                         |
|                                                                                                                                  | Lithium                 |                           |                             | S                        | Oral                          | 30mg                          |                          | Not Reported                 |                         |
|                                                                                                                                  | Lithium<br>E-Cigs       |                           |                             | S<br>C                   |                               | 1 Pack A Day                  |                          | Not Reported<br>Not Reported |                         |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 26-Aug-2016                       | 12690415                | NON-EXPEDITED             |                             |                          | US-FRI-1000083260             |                               |                          | Male                | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Dyspepsia                         | Lexapro                 |                           |                             | S                        |                               |                               |                          | Forest              |                         |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 26-Aug-2016                       | 12690416                | NON-EXPEDITED             |                             |                          | US-FRI-1000083090             |                               |                          | Male                | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                         |                       |                    |                    |                 |                      |                      |                    |                 |                        |
|---------------------------------------------------------|-----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|--------------------|-----------------|------------------------|
| Pruritus                                                | Lexapro               |                    |                    | S               |                      |                      |                    |                 | Forest                 |
| <u>FDA Received Date</u>                                | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u>         |
| 26-Aug-2016                                             | 12690417              | NON-EXPEDITED      |                    |                 | US-FRI-1000083099    |                      |                    | Male            | USA                    |
| <u>Preferred Term</u>                                   | <u>Product</u>        |                    | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>          | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>             |
| Drug Hypersensitivity                                   | Lexapro               |                    |                    |                 | S                    |                      |                    |                 | Forest                 |
| <u>FDA Received Date</u>                                | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u>         |
| 26-Aug-2016                                             | 12690418              | NON-EXPEDITED      |                    |                 | US-FRI-1000083364    |                      |                    | Female          | USA                    |
| <u>Preferred Term</u>                                   | <u>Product</u>        |                    | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>          | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>             |
| Condition Aggravated;<br>Product Difficult To<br>Remove | Lexapro               |                    |                    |                 | S                    |                      |                    |                 | Forest                 |
| <u>FDA Received Date</u>                                | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u>         |
| 26-Aug-2016                                             | 12690419              | NON-EXPEDITED      |                    |                 | US-FRI-1000083144    |                      | 70 YR              | Female          | USA                    |
| <u>Preferred Term</u>                                   | <u>Product</u>        |                    | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>          | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>             |
| Crying                                                  | Lexapro<br>Nerve Pill |                    |                    |                 | S<br>C               |                      |                    |                 | Forest<br>Not Reported |
| <u>FDA Received Date</u>                                | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u>         |
| 26-Aug-2016                                             | 12690420              | NON-EXPEDITED      |                    |                 | US-FRI-1000083255    |                      |                    | Female          | USA                    |
| <u>Preferred Term</u>                                   | <u>Product</u>        |                    | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>          | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>             |
| Depression; Weight<br>Increased                         | Lexapro               |                    |                    |                 | S                    |                      |                    |                 | Forest                 |
| <u>FDA Received Date</u>                                | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u>         |
| 26-Aug-2016                                             | 12690790              | EXPEDITED (15-DAY) |                    | OT              | GB-TEVA-687245ACC    |                      |                    | Female          | GBR                    |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Colitis Ulcerative;<br>Diarrhoea                                        | Escitalopram   |                  |                    | S               | Oral                 | 5 Milligram Daily;   |                 | Ivax         |                |
| <u>FDA Received Date</u>                                                | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Aug-2016                                                             | 12690799       | NON-EXPEDITED    |                    |                 | US-FRI-1000085420    |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Unevaluable Event                                                       | Lexapro        |                  |                    | S               |                      |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Aug-2016                                                             | 12690800       | NON-EXPEDITED    |                    |                 | US-FRI-1000085475    |                      |                 | Male         | USA            |
| <u>Preferred Term</u>                                                   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Feeling Hot                                                             | Lexapro        |                  |                    | S               |                      |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Aug-2016                                                             | 12690801       | NON-EXPEDITED    |                    |                 | US-FRI-1000085423    |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Pain; Unevaluable Event                                                 | Lexapro        |                  |                    | S               |                      |                      |                 | Forest       |                |
|                                                                         | Lexapro        |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                         | Lexapro        |                  |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Aug-2016                                                             | 12690802       | NON-EXPEDITED    |                    |                 | US-FRI-1000085479    |                      | 15 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Disturbance In Attention;<br>Feeling Abnormal;                          | Lexapro        |                  |                    | S               |                      |                      |                 | Forest       |                |
|                                                                         | Lexapro        |                  |                    | S               |                      |                      |                 | Forest       |                |
| Memory Impairment; Off<br>Label Use; Therapeutic<br>Response Unexpected |                |                  |                    |                 |                      |                      |                 |              |                |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 26-Aug-2016                | 12690803       | NON-EXPEDITED    |                    |                 | US-FRI-1000086226    |                      |                 | Female       | USA            |
| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hallucination, Visual;     | Lexapro        |                  |                    | S               |                      |                      |                 | Forest       |                |
| Hyperhidrosis;             | Lexapro        |                  |                    | S               |                      |                      |                 | Not Reported |                |
| Hypnagogic Hallucination;  | Lexapro        |                  |                    | S               |                      |                      |                 | Not Reported |                |
| Migraine; Nausea; Vertigo; | Rexulti        |                  |                    | S               |                      |                      |                 | Not Reported |                |
| Withdrawal Syndrome        | Cymbalta       |                  |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Aug-2016                | 12690805       | NON-EXPEDITED    |                    |                 | US-FRI-1000086719    |                      |                 | Female       | USA            |
| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Female Orgasmic            | Lexapro        |                  |                    | S               |                      |                      |                 | Forest       |                |
| Disorder; Paraesthesia     | Lexapro        |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                            | Lexapro        |                  |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Aug-2016                | 12690808       | NON-EXPEDITED    |                    |                 | US-FRI-1000086630    |                      |                 | Female       | USA            |
| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Eye Pain; Headache;        | Lexapro        |                  |                    | S               |                      |                      |                 | Forest       |                |
| Photopsia; Visual          |                |                  |                    |                 |                      |                      |                 |              |                |
| Impairment                 |                |                  |                    |                 |                      |                      |                 |              |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Aug-2016                | 12690809       | NON-EXPEDITED    |                    |                 | US-FRI-1000086352    |                      |                 | Male         | USA            |
| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Behaviour Disorder;        | Lexapro        |                  |                    | S               |                      |                      |                 | Forest       |                |
| Condition Aggravated       |                |                  |                    |                 |                      |                      |                 |              |                |

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| <u>FDA Received Date</u>                                                   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 26-Aug-2016                                                                | 12690810       | NON-EXPEDITED    |                    |                 | US-FRI-1000086356    |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                      | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Breast Enlargement;<br>Breast Pain                                         | Lexapro        |                  |                    | S               | Oral                 | 10mg                 |                 | Forest       |                |
| <u>FDA Received Date</u>                                                   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Aug-2016                                                                | 12690811       | NON-EXPEDITED    |                    |                 | US-FRI-1000086821    |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                      | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Nausea; Respiratory Tract<br>Congestion; Throat<br>Irritation; Vomiting    | Lexapro        |                  |                    | S               | Subcutaneous         | 40mg/0.8ml           |                 | Forest       |                |
|                                                                            | Humira         |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                            | Trintellix     |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                            | Lamictal       |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                            | Zyprexa        |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                            | Ativan         |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                            | Prilosec       |                  |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Aug-2016                                                                | 12690814       | NON-EXPEDITED    |                    |                 | US-FRI-1000086564    |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                      | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Eye Irritation; Ocular<br>Hyperaemia; Vision<br>Blurred; Visual Impairment | Lexapro        |                  |                    | S               |                      |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Aug-2016                                                                | 12691058       | NON-EXPEDITED    |                    |                 | US-FRI-1000042781    |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                      | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Asthenia; Blood<br>Pressure Increased;<br>Decreased Appetite;     | Lexapro        |                  |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                                                            | Lexapro        |                  |                    | S               | Oral                 | 20mg                 |                 | Forest       |                |

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|                                                               |                                                              |             |      |        |  |  |  |                                              |
|---------------------------------------------------------------|--------------------------------------------------------------|-------------|------|--------|--|--|--|----------------------------------------------|
| Dizziness; Nausea; Panic Attack; Somnolence; Weight Increased | Synthroid<br>Metformin<br>Hormone Replacement Therapy<br>Nos | C<br>C<br>C | Oral | 500 Mg |  |  |  | Not Reported<br>Not Reported<br>Not Reported |
|---------------------------------------------------------------|--------------------------------------------------------------|-------------|------|--------|--|--|--|----------------------------------------------|

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 26-Aug-2016                       | 12691068               | NON-EXPEDITED             |                             |                          | US-FRI-1000086858             |                               |                     | Female              | USA                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Drug Hypersensitivity          | Lexapro                 |                       |                     | S                    |                       |                             |                          | Forest              |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 26-Aug-2016                       | 12691069               | NON-EXPEDITED             |                             |                          | US-FRI-1000086159             |                               | 59 YR               | Female              | USA                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a>    |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|------------------------|
| Breast Tenderness              | Lexapro<br>Klonopin     |                       |                     | S<br>C               | Oral<br>Oral          | 5mg                         |                          | Forest<br>Not Reported |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 26-Aug-2016                       | 12691070               | NON-EXPEDITED             |                             |                          | US-FRI-1000086717             |                               | 61 YR               | Female              | USA                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Hypersensitivity               | Lexapro                 |                       |                     | S                    |                       |                             |                          | Forest              |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 26-Aug-2016                       | 12691071               | NON-EXPEDITED             |                             |                          | US-FRI-1000086001             |                               | 39 YR               | Female              | USA                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Withdrawal Syndrome            | Lexapro                 |                       |                     | S                    | Oral                  | 10mg                        |                          | Forest              |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 26-Aug-2016                       | 12691252               | EXPEDITED (15-DAY)        |                             | DE                       | DE-MYLANLABS-2016M1035212     |                               |                     | Unknown             | DEU                     |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                              | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>                                           | <u>Duration</u> | <u>Mfr</u>   |                |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|--------------------|--------------------|-----------------|---------------------------|--------------------------------------------------------------|-----------------|--------------|----------------|
| Asphyxia; Completed Suicide                                                                                                                                                                                                                                                                                                                                                        | Escitalopram       |                    |                    | S               | Oral                      | 10 Mg, Unk                                                   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                                                           | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>                                         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Aug-2016                                                                                                                                                                                                                                                                                                                                                                        | 12692085           | NON-EXPEDITED      |                    |                 | US-SHIRE-US201610467      |                                                              |                 | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                              | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>                                           | <u>Duration</u> | <u>Mfr</u>   |                |
| Bradyphrenia; Drug Ineffective; Inappropriate Schedule Of Product Administration; Prescribed Overdose; Vision Blurred                                                                                                                                                                                                                                                              | Adderall Xr        |                    |                    | S               | Oral                      | 25 Mg, Other (Take For 4 Days, Then Does Not Take For 3 Days |                 | Shire        |                |
|                                                                                                                                                                                                                                                                                                                                                                                    | Lexapro            |                    |                    | S               | Unknown                   | 2.5 Mg, Unknown                                              |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                    | Zyrtec             |                    |                    | C               | Unknown                   | Unk, Unknown                                                 |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                    | Flonase /00908302/ |                    |                    | C               | Unknown                   | Unk, Unknown                                                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                                                           | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>                                         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Aug-2016                                                                                                                                                                                                                                                                                                                                                                        | 10667374           | EXPEDITED (15-DAY) |                    | DS              | US-009507513-1110USA04072 |                                                              |                 | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                              | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>                                           | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Distension; Anxiety; Basilar Migraine; Blood Pressure Increased; Cholelithiasis; Cognitive Disorder; Dependence; Depression; Dry Skin; Ear Operation; Erectile Dysfunction; Exposure To Toxic Agent; Fatigue; Flatulence; Fracture; Frustration Tolerance Decreased; Hypogonadism; Hypopituitarism; Injury; Irritability; Libido Decreased; Memory Impairment; Migraine; | Propecia           |                    |                    | S               | Oral                      | 1 Mg, Qd                                                     |                 | Merck        |                |
|                                                                                                                                                                                                                                                                                                                                                                                    | Lexapro            |                    |                    | S               | Oral                      | Unk, Unknown                                                 |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Muscle Fatigue; Muscular Weakness; Nasal Congestion; Nasopharyngitis; Palpitations; Premature Ejaculation; Prostatic Specific Antigen Increased; Sedation Complication; Semen Volume Decreased; Sexual Dysfunction; Skin Lesion; Somnolence; Stress; Testicular Pain; Vision Blurred; Visual Impairment; Wheezing

| <u>FDA Received Date</u>       | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u>                                          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------|---------------------|--------------------|--------------------|-----------------|-------------------------------|---------------------------------------------------------------|-----------------|--------------|----------------|
| 29-Aug-2016                    | 12620604            | EXPEDITED (15-DAY) |                    | OT              | ZA-CIPLA LTD.-<br>2016ZA10134 |                                                               |                 | Unknown      | ZAF            |
| <u>Preferred Term</u>          | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>                                            | <u>Duration</u> | <u>Mfr</u>   |                |
| Dyspnoea; Heart Rate Irregular | Lexamil             |                    |                    | S               | Unknown                       | 10 Mg, Qd In The Morning<br>Started Just Over 2<br>Months Ago |                 | Invagen      |                |
| <u>FDA Received Date</u>       | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u>                                          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Aug-2016                    | 12693953            | EXPEDITED (15-DAY) |                    | OT              | CA-APOTEX-<br>2016AP010671    |                                                               | 75 YR           | Female       | CAN            |
| <u>Preferred Term</u>          | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>                                            | <u>Duration</u> | <u>Mfr</u>   |                |
| Glossodynia                    | Apo-Escitalopram    |                    |                    | S               | Oral                          | 10 Mg, Qd                                                     |                 | Apotex       |                |
|                                | Pantoloc /01263204/ |                    |                    | C               | Unknown                       |                                                               |                 | Not Reported |                |
| <u>FDA Received Date</u>       | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u>                                          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Aug-2016                    | 12695159            | EXPEDITED (15-DAY) |                    | HO              | CA-MYLANLABS-<br>2016M1035922 |                                                               |                 | Unknown      | CAN            |
| <u>Preferred Term</u>          | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>                                            | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                      |              |   |      |              |
|------------------------------------------------------|--------------|---|------|--------------|
| Drug Interaction;<br>Overdose; Serotonin<br>Syndrome | Bupropion    | S | Oral | Not Reported |
|                                                      | Escitalopram | S | Oral | Not Reported |
|                                                      | Olanzapine   | S | Oral | Not Reported |
|                                                      | Phenytoin    | S | Oral | Not Reported |
|                                                      | Quetiapine   | S | Oral | Not Reported |
|                                                      | Primidone    | S | Oral | Mylan        |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Aug-2016              | 12696192      | EXPEDITED (15-DAY) |                    | HO, OT          | JP-FRI-1000087131    |                      | 48 YR      | Male       | JPN            |

| <u>Preferred Term</u>                                                                                                                                                         | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Bipolar Disorder; Blood<br>Glucose Increased; Blood<br>Triglycerides Increased;<br>Insomnia; Low Density<br>Lipoprotein Increased;<br>Mania; Somnolence;<br>Suicidal Ideation | Escitalopram           |              |            | S           | Oral         | 10 Mg                         |                 | Forest       |
|                                                                                                                                                                               | Effexor                |              |            | S           | Oral         | 37.5 Mg                       |                 | Not Reported |
|                                                                                                                                                                               | Effexor                |              |            | S           | Oral         | 75 Mg                         |                 | Not Reported |
|                                                                                                                                                                               | Effexor                |              |            | S           | Oral         | 112.5 Mg                      |                 | Not Reported |
|                                                                                                                                                                               | Effexor                |              |            | S           | Oral         | 150 Mg                        |                 | Not Reported |
|                                                                                                                                                                               | Effexor                |              |            | S           | Oral         | 112.5 Mg 2 Times Per Day      |                 | Not Reported |
|                                                                                                                                                                               | Seniran                |              |            | C           | Oral         | 6 Mg                          |                 | Not Reported |
|                                                                                                                                                                               | Vegetamin-B            |              |            | C           | Oral         | 1 Df                          |                 | Not Reported |
|                                                                                                                                                                               | Sorentmin (Brotizolam) |              |            | C           | Oral         | 0.25 Mg                       |                 | Not Reported |
|                                                                                                                                                                               | Flunitrazepam          |              |            | C           | Oral         | 4 Mg                          |                 | Not Reported |
|                                                                                                                                                                               | Quetiapine             |              |            | C           | Oral         | 100 Mg                        |                 | Not Reported |
|                                                                                                                                                                               | Cystanin               |              |            | C           | Oral         | 900 Mg                        |                 | Not Reported |
|                                                                                                                                                                               | Alosenn (Senna)        |              |            | C           | Oral         | 4.5 Gram                      |                 | Not Reported |
|                                                                                                                                                                               | Pantethine             |              |            | C           | Oral         | 9 Gram                        |                 | Not Reported |
|                                                                                                                                                                               | Vemas                  |              |            | C           | Oral         | 2 Tablets Three Times Per Day |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 30-Aug-2016              | 12527607      | NON-EXPEDITED    |                    |                 | US-SHIRE-<br>US201607043 |                      | 63 YR      | Female     | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                             | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                                                                     | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|------------------------------|----------------------------------------------------------------------------------------|-----------------|--------------|----------------|
| Condition Aggravated;<br>Drug Ineffective; Product<br>Quality Issue; Therapeutic<br>Response Unexpected;<br>Weight Decreased; Weight<br>Increased | Vyvanse                |                    |                    | S               | Oral                         | 50 Mg, 1x/Day:Qd                                                                       |                 | Shire        |                |
|                                                                                                                                                   | Lexapro                |                    |                    | S               | Oral                         | 20 Mg, 1x/Day:Qd                                                                       |                 | Not Reported |                |
|                                                                                                                                                   | Losartan               |                    |                    | C               | Oral                         | 50 Mg, 1x/Day:Qd                                                                       |                 | Not Reported |                |
|                                                                                                                                                   | Pravastatin            |                    |                    | C               | Oral                         | 40 Mg, 1x/Day:Qd                                                                       |                 | Not Reported |                |
|                                                                                                                                                   | Aspirin /00002701/     |                    |                    | C               | Oral                         | 81 Mg, 1x/Day:Qd                                                                       |                 | Not Reported |                |
|                                                                                                                                                   | Vitamin B12 /00056201/ |                    |                    | C               | Oral                         | 5000 Mg, 1x/Day:Qd                                                                     |                 | Not Reported |                |
|                                                                                                                                                   | Ferro-Sequels          |                    |                    | C               | Oral                         | 50 Mg, 1x/Day:Qd                                                                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                          | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                                                                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Aug-2016                                                                                                                                       | 12645968               | NON-EXPEDITED      |                    |                 | US-PFIZER INC-<br>2016158220 |                                                                                        |                 | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                             | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                                                                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity                                                                                                                             | Erythromycin           |                    |                    | S               |                              | Unk                                                                                    |                 | Pfizer       |                |
|                                                                                                                                                   | Lexapro                |                    |                    | S               |                              | Unk                                                                                    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                          | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                                                                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Aug-2016                                                                                                                                       | 12690182               | EXPEDITED (15-DAY) |                    | HO              | CH-TEVA-686883ISR            |                                                                                        | 76 YR           | Male         | CHE            |
| <u>Preferred Term</u>                                                                                                                             | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                                                                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Extrapyramidal Disorder                                                                                                                           | Escitalopram Actavis   |                    |                    | S               | Oral                         | 10 Milligram Daily;                                                                    |                 | Ivax         |                |
|                                                                                                                                                   | Lithiofor              |                    |                    | S               | Oral                         | 1 Dosage Forms Daily; 0.5<br>Dosage Forms Each In<br>The Morning And In The<br>Evening |                 | Not Reported |                |
|                                                                                                                                                   | Lithiofor              |                    |                    | S               | Oral                         | .5 Dosage Forms Daily;<br>0.5 Dosage Forms In The<br>Evening                           |                 | Not Reported |                |
|                                                                                                                                                   | Lithiofor              |                    |                    | S               | Oral                         | 1320 Milligram Daily; 2<br>Dosage Forms Of 660 Mg<br>Each At Lunch Time                |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                |   |         |                                                        |              |
|----------------|---|---------|--------------------------------------------------------|--------------|
| Lithiofor      | S | Oral    | Dosage And Start Date<br>Unknown, Long-Term<br>Therapy | Not Reported |
| Tenoretic Mite | C | Oral    | 1 Df = 50 Mg Atenolol And<br>12,5 Mg Chlortalidone     | Not Reported |
| Kcl            | C | Unknown |                                                        | Not Reported |

| <u>FDA Received Date</u>         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|----------------------------------|----------------------|--------------------|--------------------|-----------------|-------------------------------------|----------------------|-----------------|------------|----------------|
| 30-Aug-2016                      | 12696408             | EXPEDITED (15-DAY) |                    | OT              | GB-AUROBINDO-AUR-<br>APL-2016-10662 |                      |                 | Female     | GBR            |
| <u>Preferred Term</u>            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Colitis Ulcerative;<br>Diarrhoea | Escitalopram Tablets |                    |                    | S               | Oral                                | 5 Mg, Daily          |                 | Aurobindo  |                |

| <u>FDA Received Date</u>         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|----------------------------------|----------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|-----------------|------------|----------------|
| 30-Aug-2016                      | 12696441       | EXPEDITED (15-DAY) |                    | OT              | GB-CIPLA LTD.-<br>2016GB17739 |                      |                 | Unknown    | GBR            |
| <u>Preferred Term</u>            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Colitis Ulcerative;<br>Diarrhoea | Escitalopram   |                    |                    | S               | Oral                          | 5 Mg, Daily          |                 | Invagen    |                |

| <u>FDA Received Date</u> | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|---------------------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| 30-Aug-2016              | 12696657                  | EXPEDITED (15-DAY) |                    | DE, OT          | CA-APOTEX-<br>2016AP010670 |                      | 62 YR           | Male         | CAN            |
| <u>Preferred Term</u>    | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Death                    | Apo-Escitalopram          |                    |                    | S               | Unknown                    |                      |                 | Apotex       |                |
|                          | Apo-Temazepam             |                    |                    | S               | Unknown                    |                      |                 | Not Reported |                |
|                          | Tylenol With Codeine No.3 |                    |                    | S               | Unknown                    |                      |                 | Not Reported |                |
|                          | Advair                    |                    |                    | C               | Unknown                    |                      |                 | Not Reported |                |
|                          | Atrovent                  |                    |                    | C               | Unknown                    |                      |                 | Not Reported |                |
|                          | Gabapentin                |                    |                    | C               | Unknown                    |                      |                 | Not Reported |                |
|                          | Naproxen                  |                    |                    | C               | Unknown                    |                      |                 | Not Reported |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                           |                  |                    |                    |                 |                        |                      |                 |              |                |
|---------------------------------------------------------------------------------------------------------------------------|------------------|--------------------|--------------------|-----------------|------------------------|----------------------|-----------------|--------------|----------------|
| Ranitidine                                                                                                                |                  |                    | C                  |                 | Unknown                |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                  | <u>Case #</u>    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Aug-2016                                                                                                               | 12696817         | EXPEDITED (15-DAY) |                    | LT, OT          | CA-APOTEX-2016AP010674 |                      |                 | Female       | CAN            |
| <u>Preferred Term</u>                                                                                                     | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anaphylactic Reaction                                                                                                     | Apo-Escitalopram |                    |                    | S               | Unknown                | 10 Mg, Unk           |                 | Apotex       |                |
| <u>FDA Received Date</u>                                                                                                  | <u>Case #</u>    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Aug-2016                                                                                                               | 12696963         | EXPEDITED (15-DAY) |                    | LT, OT          | CA-APOTEX-2016AP010672 |                      | 31 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                                                                                     | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Arthritis; Decreased Appetite; Diarrhoea; Drug Hypersensitivity; Fatigue; Headache; Hypersensitivity; Rhinitis; Urticaria | Apo-Escitalopram |                    |                    | S               | Oral                   | 20 Mg, Bid           |                 | Apotex       |                |
|                                                                                                                           | Apo-Escitalopram |                    |                    | S               |                        |                      |                 | Apotex       |                |
|                                                                                                                           | Clobazam         |                    |                    | C               | Unknown                |                      |                 | Not Reported |                |
|                                                                                                                           | Tegretol         |                    |                    | C               | Unknown                |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                  | <u>Case #</u>    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Aug-2016                                                                                                               | 12699133         | EXPEDITED (15-DAY) |                    | HO              | PHHY2016CA116225       |                      | 39 YR           | Male         | CAN            |
| <u>Preferred Term</u>                                                                                                     | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Overdose; Intentional Product Misuse; Serotonin Syndrome; Tachycardia                                         | Quetiapine       |                    |                    | S               | Unknown                |                      |                 | Novartis     |                |
|                                                                                                                           | Bupropion        |                    |                    | S               | Unknown                |                      |                 | Not Reported |                |
|                                                                                                                           | Olanzapine       |                    |                    | S               | Unknown                |                      |                 | Not Reported |                |
|                                                                                                                           | Phenytoin        |                    |                    | S               | Unknown                |                      |                 | Not Reported |                |
|                                                                                                                           | Escitalopram     |                    |                    | S               | Unknown                |                      |                 | Not Reported |                |
|                                                                                                                           | Primidone        |                    |                    | S               | Unknown                |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                  | <u>Case #</u>    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Aug-2016                                                                                                               | 12699567         | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000087142      |                      | 50 YR           | Female       | FRA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Poisoning Deliberate;<br>Toxicity To Various Agents | Escitalopram   |              |            | S           | Oral         |                    |                 | Forest       |
|                                                     | Tercian        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                     | Seresta        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                     | Advil          |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Aug-2016              | 12699573      | EXPEDITED (15-DAY) |                    | DS, HO          | FR-FRI-1000087148    |                      | 64 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                                | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cerebral Haemorrhage;<br>Extradural Haematoma;<br>Subdural Haematoma | Escitalopram            |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                                                      | Kardegic                |              |            | S           | Oral         | 160 Mg             |                 | Not Reported |
|                                                                      | Alepsal (Phenobarbital) |              |            | C           |              | 150 Mg             |                 | Not Reported |
|                                                                      | Atorvastatine           |              |            | C           |              | 40 Mg              |                 | Not Reported |
|                                                                      | Forlax                  |              |            | C           |              |                    |                 | Not Reported |
|                                                                      | Ramipril                |              |            | C           |              | 5 Mg               |                 | Not Reported |
|                                                                      | Tegretol Lp             |              |            | C           |              | 800 Mg             |                 | Not Reported |
|                                                                      | Travatan                |              |            | C           |              |                    |                 | Not Reported |
|                                                                      | Uvedose                 |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 30-Aug-2016              | 12699974      | EXPEDITED (15-DAY) |                    | HO              | FR-JNJFOC-20160825817 |                      | 82 YR      | Female     | FRA            |

| <u>Preferred Term</u>           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Agitation; Confusional<br>State | Ixprim         |              |            | S           | Oral         |                    |                 | Not Reported |
|                                 | Seroplex       |              |            | S           | Oral         |                    |                 | Not Reported |
|                                 | Seresta        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                 | Simvastatin    |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                 | Atacand        |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                 | Diffu K        |              |            | C           | Unknown      |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|           |   |         |              |
|-----------|---|---------|--------------|
| Tanakan   | C | Unknown | Not Reported |
| Imovane   | C | Unknown | Not Reported |
| Doliprane | C | Unknown | Not Reported |

| <u>FDA Received Date</u>                                   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------|----------------|------------------|--------------------|-----------------|--------------------------|-----------------------------------|-----------------|--------------|----------------|
| 30-Aug-2016                                                | 12700187       | NON-EXPEDITED    |                    |                 | US-SHIRE-<br>US201611231 |                                   |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                      | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |                |
| Apathy; Dizziness;                                         | Vyvanse        |                  |                    | S               | Oral                     | 40 Mg, Unknown                    |                 | Shire        |                |
| Headache; Incorrect Dose                                   | Vyvanse        |                  |                    | S               | Oral                     | 60 Unk, Unk                       |                 | Shire        |                |
| Administered; Malaise;                                     | Vyvanse        |                  |                    | S               | Oral                     | 40 Mg, 1x/Day:Qd (In The Morning) |                 | Shire        |                |
| Nausea; Negative Thoughts; Nervousness; Performance Status | Vyvanse        |                  |                    | S               | Oral                     | 20 Mg, Unknown                    |                 | Shire        |                |
| Decreased; Tinnitus; Vomiting                              | Lexapro        |                  |                    | S               | Unknown                  | 0.5 Df, Unknown                   |                 | Not Reported |                |
|                                                            | Cymbalta       |                  |                    | S               | Unknown                  | 30 Mg, 1x/Day:Qd                  |                 | Not Reported |                |
|                                                            | Abilify        |                  |                    | S               | Unknown                  | 1 Mg (Half Of A 2 Mg), 1x/Day:Qd  |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>           | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|-------------------------|------------------|--------------------|-----------------|------------------------|----------------------|-----------------|--------------|----------------|
| 31-Aug-2016              | 12701928                | NON-EXPEDITED    |                    |                 | US-JAZZ-2016-US-007450 |                      | 13 YR           | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u>          | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Cataplexy       | Xyrem                   |                  |                    | S               | Oral                   | 1.25 G, Bid          |                 | Jazz         |                |
|                          | Xyrem                   |                  |                    | S               | Oral                   | Dose Adjustments     |                 | Jazz         |                |
|                          | Xyrem                   |                  |                    | S               | Oral                   | 4.5 G, Bid           |                 | Jazz         |                |
|                          | Lexapro                 |                  |                    | S               |                        | Unk                  |                 | Not Reported |                |
|                          | Focalin                 |                  |                    | C               |                        |                      |                 | Not Reported |                |
|                          | Focalin Xr              |                  |                    | C               |                        |                      |                 | Not Reported |                |
|                          | Penicillin Vk           |                  |                    | C               |                        |                      |                 | Not Reported |                |
|                          | Tamiflu                 |                  |                    | C               |                        |                      |                 | Not Reported |                |
|                          | Acetaminophen W/Codeine |                  |                    | C               |                        |                      |                 | Not Reported |                |
|                          | Amitriptyline Hcl       |                  |                    | C               |                        |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                      | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                               | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|--------------------|--------------------|-----------------|----------------------------------------------------|---------------------------|-----------------|--------------|----------------|
| 31-Aug-2016                                                                                                                                   | 12702184                          | EXPEDITED (15-DAY) |                    | DE              | DE-AUROBINDO-AUR-APL-2016-10812                    |                           | 32 YR           | Male         | DEU            |
| <u>Preferred Term</u>                                                                                                                         | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                       | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |                |
| Asphyxia; Completed Suicide                                                                                                                   | Escitalopram 10 Mg                |                    |                    | S               | Oral                                               | 10 Mg, Unk                |                 | Aurobindo    |                |
| <u>FDA Received Date</u>                                                                                                                      | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                               | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-Aug-2016                                                                                                                                   | 12702980                          | EXPEDITED (15-DAY) |                    | HO              | PHHY2016DK116646                                   |                           |                 | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                                         | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                       | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |                |
| Depressed Mood; Intentional Overdose; Restlessness; Sedation; Social Avoidant Behaviour; Suicidal Ideation; Suicide Attempt; Weight Increased | Oxapax                            |                    |                    | S               | Oral                                               |                           |                 | Novartis     |                |
|                                                                                                                                               | Ciprallex /Den/                   |                    |                    | S               | Oral                                               | 10 Mg, Unk                |                 | Not Reported |                |
|                                                                                                                                               | Imoclon                           |                    |                    | S               | Oral                                               | 7.5 Mg, Unk               |                 | Not Reported |                |
|                                                                                                                                               | Seroquel                          |                    |                    | S               | Oral                                               |                           |                 | Not Reported |                |
|                                                                                                                                               | Seroquel                          |                    |                    | S               | Oral                                               | 200 Mg, Unk               |                 | Not Reported |                |
|                                                                                                                                               | Abilify                           |                    |                    | S               | Oral                                               | 10 Mg, Unk                |                 | Not Reported |                |
|                                                                                                                                               | Truxal                            |                    |                    | S               | Oral                                               | 265 Mg, Unk               |                 | Not Reported |                |
|                                                                                                                                               | Zeldox//Ziprasidone Hydrochloride |                    |                    | S               | Oral                                               | 80 Mg Stigende Til 160 Mg |                 | Not Reported |                |
|                                                                                                                                               | Solian                            |                    |                    | S               | Oral                                               |                           |                 | Not Reported |                |
|                                                                                                                                               | Risperidon Krka                   |                    |                    | S               | Oral                                               |                           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                      | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                               | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-Aug-2016                                                                                                                                   | 12703318                          | EXPEDITED (15-DAY) |                    | OT              | ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2016R1-117351 |                           | 71 YR           | Male         | ESP            |
| <u>Preferred Term</u>                                                                                                                         | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                       | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |                |
| Disease Recurrence                                                                                                                            | Escitalopram                      |                    |                    | S               | Unknown                                            | Unk                       |                 | Not Reported |                |
|                                                                                                                                               | Olanzapine                        |                    |                    | S               | Oral                                               | Unk                       |                 | Sun          |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Carbidopa/Levodopa  
Trazodone

S Unknown Unk  
S Unknown Unk

Ranbaxy  
Mutual

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-Aug-2016              | 12703940      | EXPEDITED (15-DAY) | HO                 |                 | CH-TEVA-677634ISR    |                      | 47 YR      | Male       | CHE            |

| <u>Preferred Term</u>                    | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                             | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------|--------------------|--------------|------------|-------------|--------------|----------------------------------------------------------------|-----------------|--------------|
| Abscess; Epistaxis;<br>Furuncle; Myalgia | Escitalopram-Mepha |              |            | S           | Unknown      |                                                                |                 | Ivax         |
|                                          | Escitalopram-Mepha |              |            | S           | Unknown      | 10 Milligram Daily;                                            |                 | Ivax         |
|                                          | Quetiapine Xr      |              |            | C           | Unknown      | 800 Milligram Daily; Two<br>Dose Forms Taken In The<br>Evening |                 | Not Reported |
|                                          | Cymbalta           |              |            | C           | Unknown      | 60 Milligram Daily; Take In<br>The Morning                     |                 | Not Reported |
|                                          | Pantozol           |              |            | C           |              | 40 Milligram Daily; Taken<br>In The Evening                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|------------|------------|----------------|
| 31-Aug-2016              | 12704122      | EXPEDITED (15-DAY) |                    | OT              | BR-009507513-<br>1608BRA014438 |                      | 39 YR      | Female     | BRA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                        | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                         | <u>Duration</u> | <u>Mfr</u>                   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|--------------|------------|-------------|--------------|------------------------------------------------------------|-----------------|------------------------------|
| Affective Disorder;<br>Anxiety; Anxiety;<br>Disturbance In Attention;<br>Dysgraphia;<br>Hypothyroidism; Insomnia;<br>Panic Disorder; Pregnancy<br>On Contraceptive;<br>Reading Disorder;<br>Therapeutic Product Effect<br>Decreased; Unintended<br>Pregnancy | Nuvaring           |              |            | S           |              | Unk, 3 Weeks With The<br>Vaginal Ring And One<br>Week Free |                 | Merck                        |
|                                                                                                                                                                                                                                                              | Nuvaring           |              |            | S           | Vaginal      | Unk,3 Weeks With The<br>Vaginal Ring And One<br>Week Free  |                 | Merck                        |
|                                                                                                                                                                                                                                                              | Nuvaring           |              |            | S           | Vaginal      | Unk,3 Weeks With The<br>Vaginal Ring And One<br>Week Free  |                 | Merck                        |
|                                                                                                                                                                                                                                                              | Pristiq            |              |            | S           |              | Unk                                                        |                 | Not Reported                 |
|                                                                                                                                                                                                                                                              | Pristiq<br>Lexapro |              |            | S<br>S      | Oral         | 10 Mg, Qd                                                  |                 | Not Reported<br>Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                              | Ritalin            |                    | S                  | Oral            | 80mg, 2 Tablets Daily      |                      |                 | Not Reported |                |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
|                                                                                                                                                                                              | Frontal            |                    | S                  | Oral            | 1 Df, Qd                   |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                     | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-Aug-2016                                                                                                                                                                                  | 12704326           | EXPEDITED (15-DAY) |                    | OT              | BR-009507513-1608BRA014429 |                      |                 | Female       | BRA            |
| <u>Preferred Term</u>                                                                                                                                                                        | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Pregnancy On Contraceptive; Therapeutic Product Effect Decreased; Unintended Pregnancy                                                                                                       | Nuvaring           |                    |                    | S               | Vaginal                    |                      |                 | Merck        |                |
|                                                                                                                                                                                              | Lexapro            |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                     | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-Aug-2016                                                                                                                                                                                  | 12704660           | EXPEDITED (15-DAY) |                    | HO              | FR-ASTRAZENECA-2016SE91376 |                      | 47 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                        | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Gamma-Glutamyltransferase Increased; Hepatitis Cholestatic; Ischaemic Stroke | Inexium            |                    |                    | S               | Oral                       |                      |                 | Astrazeneca  |                |
|                                                                                                                                                                                              | Advagraf           |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                                                                                                                                                              | Advagraf           |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                                                                                                                                                              | Advagraf           |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                                                                                                                                                              | Seroplex           |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                                                                                                                                                              | Xanax              |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                                                                                                                                                              | Tahor              |                    |                    | S               | Oral                       | 10.0mg Unknown       |                 | Not Reported |                |
|                                                                                                                                                                                              | Bisoprolol         |                    |                    | C               |                            |                      |                 | Not Reported |                |
|                                                                                                                                                                                              | Triatec (Ramipril) |                    |                    | C               |                            |                      |                 | Not Reported |                |
|                                                                                                                                                                                              | Kayexalate         |                    |                    | C               |                            |                      |                 | Not Reported |                |
| Cellcept                                                                                                                                                                                     |                    |                    | C                  |                 |                            |                      | Not Reported    |              |                |
| <u>FDA Received Date</u>                                                                                                                                                                     | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-Aug-2016                                                                                                                                                                                  | 12704854           | EXPEDITED (15-DAY) |                    | HO              | CH-MEDA-2016080104         |                      | 90 YR           | Female       | CHE            |
| <u>Preferred Term</u>                                                                                                                                                                        | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|      |                        |   |      |                    |              |
|------|------------------------|---|------|--------------------|--------------|
| Fall | Torem                  | S |      | ½-0-0-0            | Meda         |
|      | Cipralex               | S |      | 1-0-0-0            | Not Reported |
|      | Madopar                | S |      | 200/50 Mg; ½-½-½-0 | Not Reported |
|      | Lyrica                 | S | Oral | 0-0-0-½            | Not Reported |
|      | Lyrica                 | S | Oral | 0-0-0-1            | Not Reported |
|      | Temesta (Lorazepam)    | S | Oral | 0-0-0-½            | Not Reported |
|      | Acidum Folicum Streuli | C |      | 1-0-0-0            | Not Reported |
|      | Vitamin D3 Streuli     | C |      | Every Tuesday      | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-Aug-2016              | 12705058      | DIRECT           | Y                  |                 |                      |                      | 61 YR      | Female     | USA            |

| <u>Preferred Term</u>                      | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--------------------------------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Product Substitution Issue; Pruritus; Rash | Escitalopram, 10 Mg |              |            | S           | Oral         |                    |                 | Mylan      |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-Aug-2016              | 12705079      | DIRECT           |                    |                 |                      |                      | 33 YR      | Female     | USA            |

| <u>Preferred Term</u>                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------|----------------|--------------|------------|-------------|--------------|---------------------------------------|-----------------|--------------|
| Asthenia; Chills; Dizziness; Nausea; Presyncope | Escitalopram   |              |            | S           | Oral         | 1 Tablet(S) Once A Day Taken By Mouth |                 | Lupin        |
|                                                 | Magnesium      |              |            | C           |              |                                       |                 | Not Reported |
|                                                 | Probiotic      |              |            | C           |              |                                       |                 | Not Reported |
|                                                 | Multi Vitamin  |              |            | C           |              |                                       |                 | Not Reported |
|                                                 | Coenzyme Q 10  |              |            | C           |              |                                       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 01-Sep-2016              | 10684237      | EXPEDITED (15-DAY) |                    |                 | PL-JNJFOC-20141213366 |                      |            | Unknown    | POL            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction      | Paracetamol    |              |            | S           | Unknown      |                    |                 | Not Reported |

**FDA Adverse Event Reporting System  
Freedom of Information Act (FOIA)  
Detailed Report**

|                       |   |   |         |              |
|-----------------------|---|---|---------|--------------|
| Paracetamol           |   | S | Unknown | Not Reported |
| Fluconazole           | Y | S | Unknown | Not Reported |
| Acetyl Salicylic Acid | Y | S | Unknown | Not Reported |
| Ibuprofen             |   | S | Unknown | Not Reported |
| Ketoprofen            |   | S | Unknown | Not Reported |
| Erythromycin          |   | S | Unknown | Not Reported |
| Domperidone           |   | S | Unknown | Not Reported |
| Haloperidol           |   | S | Unknown | Not Reported |
| Clonazepam            |   | S | Unknown | Not Reported |
| Midazolam             |   | S | Unknown | Not Reported |
| Zopiclone             |   | S | Unknown | Not Reported |
| Zolpidem              |   | S | Unknown | Not Reported |
| Amitriptyline         |   | S | Unknown | Not Reported |
| Citalopram            |   | S | Unknown | Not Reported |
| Mirtazapine           |   | S | Unknown | Not Reported |
| Escitalopram          |   | S | Unknown | Not Reported |
| Sertraline            |   | S | Unknown | Not Reported |
| Paroxetine            |   | S | Unknown | Not Reported |
| Venlafaxine           |   | S | Unknown | Not Reported |
| Fluoxetine            |   | S | Unknown | Not Reported |
| Methylphenidate       |   | S | Unknown | Not Reported |
| Gabapentin            |   | S | Unknown | Not Reported |
| Pregabalin            |   | S | Unknown | Not Reported |
| Carbamazepine         |   | S | Unknown | Not Reported |
| Phenytoin             |   | S | Unknown | Not Reported |
| Oxcarbazepine         |   | S | Unknown | Not Reported |
| Levomepromazine       |   | S | Unknown | Not Reported |
| Chlorpromazine        |   | S | Unknown | Not Reported |
| Metoclopramide        |   | S | Unknown | Not Reported |



**FDA Adverse Event Reporting System**  
**Freedom of Information Act (FOIA)**  
**Detailed Report**

|                                      |   |         |              |
|--------------------------------------|---|---------|--------------|
| Ondansetron                          | S | Unknown | Not Reported |
| Granisetron                          | S | Unknown | Not Reported |
| Tropisetron                          | S | Unknown | Not Reported |
| Cyclizine                            | S | Unknown | Not Reported |
| Dimenhydrinate                       | S | Unknown | Not Reported |
| Hyoscine                             | S | Unknown | Not Reported |
| Lansoprazole                         | S | Unknown | Not Reported |
| Esomeprazole                         | S | Unknown | Not Reported |
| Pantoprazole                         | S | Unknown | Not Reported |
| Omeprazole                           | S | Unknown | Not Reported |
| Ranitidine                           | S | Unknown | Not Reported |
| Cimetidine                           | S | Unknown | Not Reported |
| Tramadol                             | S | Unknown | Not Reported |
| Penicillin                           | S | Unknown | Not Reported |
| Cephalosporins                       | S | Unknown | Not Reported |
| Ciprofloxacin                        | S | Unknown | Not Reported |
| Metronidazole                        | S | Unknown | Not Reported |
| Clarithromycin                       | S | Unknown | Not Reported |
| Acyclovir                            | S | Unknown | Not Reported |
| Heparin                              | S | Unknown | Not Reported |
| Warfarin                             | S | Unknown | Not Reported |
| Codeine                              | S | Unknown | Not Reported |
| Tranexamic Acid                      | S | Unknown | Not Reported |
| Statins                              | S | Unknown | Not Reported |
| Calcium Channel Blockers             | S | Unknown | Not Reported |
| Beta Adrenergic Receptor Antagonists | S | Unknown | Not Reported |
| Amiodarone                           | S | Unknown | Not Reported |
| Loop Diuretics                       | S | Unknown | Not Reported |
| Potassium-Sparing Agents             | S | Unknown | Not Reported |

**FDA Adverse Event Reporting System  
Freedom of Information Act (FOIA)  
Detailed Report**

|                             |   |         |              |
|-----------------------------|---|---------|--------------|
| Thiazides                   | S | Unknown | Not Reported |
| Allopurinol                 | S | Unknown | Not Reported |
| Oral Hypoglycemic Agents    | S | Unknown | Not Reported |
| Insulin                     | S | Unknown | Not Reported |
| Thyroxin                    | S | Unknown | Not Reported |
| Hormone Replacement Therapy | S | Unknown | Not Reported |
| Vitamins                    | S | Unknown | Not Reported |
| Herbal Medicines            | S | Unknown | Not Reported |
| Metamizole                  | S | Unknown | Not Reported |
| Diclofenac                  | S | Unknown | Not Reported |
| Megestrol Acetate           | S | Unknown | Not Reported |
| Oxazepam                    | S | Unknown | Not Reported |
| Dexamethasone               | S | Unknown | Not Reported |
| Prednisolone                | S | Unknown | Not Reported |
| Methylprednisolone          | S | Unknown | Not Reported |
| Betamethasone               | S | Unknown | Not Reported |
| Gabapentin                  | S | Unknown | Not Reported |
| Pregabalin                  | S | Unknown | Not Reported |
| Amitriptyline               | S | Unknown | Not Reported |
| Antiemetics                 | S |         | Not Reported |
| Laxatives                   | S | Unknown | Not Reported |
| Sulfamethoxazole            | S | Unknown | Not Reported |
| Morphine                    | S | Unknown | Not Reported |
| Fentanyl                    | S | Unknown | Not Reported |
| Oxycodone                   | S | Unknown | Not Reported |
| Hydromorphone               | S | Unknown | Not Reported |
| Methadone                   | S | Unknown | Not Reported |
| Buprenorphine               | S | Unknown | Not Reported |
| Levomethadone               | S | Unknown | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|            |   |         |              |
|------------|---|---------|--------------|
| Alprazolam | S | Unknown | Not Reported |
| Lorazepam  | S | Unknown | Not Reported |
| Diazepam   | S | Unknown | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Sep-2016              | 11218377      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000077696    |                      | 64 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u>                    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-----------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiac Failure       | Nebivolol                         |              |            | S           | Oral         |                    |                 | Forest       |
|                       | Escitalopram                      |              |            | S           | Oral         |                    |                 | Forest       |
|                       | Xagrid                            |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Hydrea                            |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Exjade                            |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Levothyrox                        |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Aspegic [Acetylsalicylate Lysine] |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Sep-2016              | 11227938      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000077785    |                      | 64 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u>                    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-----------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiac Failure       | Escitalopram                      |              |            | S           | Oral         |                    |                 | Forest       |
|                       | Nebilox                           |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Xagrid                            |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Hydrea                            |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Exjade                            |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Levothyrox                        |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Aspegic [Acetylsalicylate Lysine] |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------|----------------------|------------|------------|----------------|
| 01-Sep-2016              | 12627526      | EXPEDITED (15-DAY) |                    | HO, OT          | US-JAZZ-2016-US-014280 |                      |            | Female     | USA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Asthma; Drug Interaction;<br>Lung Disorder; Malaise | Xyrem          |              |            | S           | Oral         | 2.25 G, Bid        |                 | Jazz         |
|                                                     | Xyrem          |              |            | S           | Oral         | 2.25 G, Bid        |                 | Jazz         |
|                                                     | Xyrem          |              |            | S           | Oral         | Dose Adjustments   |                 | Jazz         |
|                                                     | Xyrem          |              |            | S           | Oral         | 3.75 G, Bid        |                 | Jazz         |
|                                                     | Lexapro        |              |            | S           |              | 20 Mg, Unk         |                 | Not Reported |
|                                                     | Lexapro        |              |            | S           |              | 10 Mg, Unk         |                 | Not Reported |
|                                                     | Wellbutrin     |              |            | S           |              | Unk                |                 | Not Reported |
|                                                     | Prozac         |              |            | C           |              | Unk                |                 | Not Reported |
|                                                     | Levofloxacin   |              |            | C           |              | Unk                |                 | Not Reported |
|                                                     | Xanax          |              |            | C           |              | 0.5 Mg, Unk        |                 | Not Reported |
|                                                     | Xanax          |              |            | C           |              | 0.25 Mg, Unk       |                 | Not Reported |
|                                                     | Adderall       |              |            | C           |              | Unk                |                 | Not Reported |
|                                                     | Advair         |              |            | C           |              | Unk                |                 | Not Reported |
|                                                     | Budesonide     |              |            | C           |              | Unk                |                 | Not Reported |
|                                                     | Celexa         |              |            | C           |              | Unk                |                 | Not Reported |
|                                                     | Celexa         |              |            | C           |              | Unk                |                 | Not Reported |
|                                                     | Claritin       |              |            | C           |              | Unk                |                 | Not Reported |
|                                                     | Modafinil      |              |            | C           |              | Unk                |                 | Not Reported |
|                                                     | Singulair      |              |            | C           |              | Unk                |                 | Not Reported |
|                                                     | Ventolin Hfa   |              |            | C           |              | Unk                |                 | Not Reported |
|                                                     | Medrol         |              |            | C           |              | Unk                |                 | Not Reported |
|                                                     | Prozac         |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 01-Sep-2016              | 12696619      | EXPEDITED (15-DAY) |                    | DE              | CN-BAUSCH-BL-2016-020482 |                      | 36 YR      | Female     | CHN            |

  

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Depression Suicidal   | Bupropion      |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Eszopiclone    |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| Escitalopram                                                                                                                                                                                   |                      |                    | S                  |                 |                          | Not Reported         |                 |              |                |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| <u>FDA Received Date</u>                                                                                                                                                                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Sep-2016                                                                                                                                                                                    | 12707170             | EXPEDITED (15-DAY) |                    | HO              | FR-PFIZER INC-2016399448 |                      | 47 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Cerebral Ischaemia; Gamma-Glutamyltransferase Increased; Hepatitis Cholestatic | Xanax                |                    |                    | S               | Oral                     | Unk                  |                 | Pfizer       |                |
|                                                                                                                                                                                                | Xanax                |                    |                    | S               | Oral                     | Increased Dose       |                 | Pfizer       |                |
|                                                                                                                                                                                                | Tahor                |                    |                    | S               | Oral                     | 10 Mg, 1x/Day        |                 | Pfizer       |                |
|                                                                                                                                                                                                | Advagraf             |                    |                    | S               | Oral                     | Unk                  |                 | Not Reported |                |
|                                                                                                                                                                                                | Advagraf             |                    |                    | S               | Oral                     | 2.5 Mg, 1x/Day       |                 | Not Reported |                |
|                                                                                                                                                                                                | Advagraf             |                    |                    | S               | Oral                     | Unk                  |                 | Not Reported |                |
|                                                                                                                                                                                                | Inexium              |                    |                    | S               | Oral                     | Unk                  |                 | Not Reported |                |
|                                                                                                                                                                                                | Inexium              |                    |                    | S               | Oral                     | 40 Mg, 1x/Day        |                 | Not Reported |                |
|                                                                                                                                                                                                | Seroplex             |                    |                    | S               | Oral                     | Unk                  |                 | Not Reported |                |
|                                                                                                                                                                                                | Seroplex             |                    |                    | S               | Oral                     | Increased Dose       |                 | Not Reported |                |
|                                                                                                                                                                                                | Bisoprolol           |                    |                    | C               |                          | Unk                  |                 | Not Reported |                |
|                                                                                                                                                                                                | Triatec (Ramipril)   |                    |                    | C               |                          | Unk                  |                 | Not Reported |                |
|                                                                                                                                                                                                | Kayexalate           |                    |                    | C               |                          | Unk                  |                 | Not Reported |                |
|                                                                                                                                                                                                | Cellcept             |                    |                    | C               |                          | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Sep-2016                                                                                                                                                                                    | 12707242             | EXPEDITED (15-DAY) |                    | HO              | DK-PFIZER INC-2016403435 |                      | 35 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depressed Mood; Intentional Overdose; Restlessness; Sedation; Social Avoidant Behaviour; Suicidal Ideation; Suicide Attempt; Weight Increased                                                  | Zeldox               |                    |                    | S               | Oral                     | 80 Mg, Unk           |                 | Pfizer       |                |
|                                                                                                                                                                                                | Zeldox               |                    |                    | S               | Oral                     | 160 Mg, Unk          |                 | Pfizer       |                |
|                                                                                                                                                                                                | Cipralext /01588501/ |                    |                    | S               | Oral                     | Strength: 10 Mg      |                 | Not Reported |                |
|                                                                                                                                                                                                | Imoclone             |                    |                    | S               | Oral                     | Strength: 7.5 Mg     |                 | Not Reported |                |
|                                                                                                                                                                                                | Imoclone             |                    |                    | S               | Oral                     | Strenght: 7.5mg      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                   |   |      |                  |              |
|-------------------|---|------|------------------|--------------|
| Oxapax            | S | Oral | Unk              | Not Reported |
| Oxapax            | S |      | Unk              | Not Reported |
| Seroquel          | S | Oral | Unk              | Not Reported |
| Seroquel          | S | Oral | Strength: 200 Mg | Not Reported |
| Abilify           | S | Oral | Strength: 10 Mg. | Not Reported |
| Truxal /00012101/ | S | Oral | 265 Mg, Unk      | Not Reported |
| Solian            | S | Oral | Unk              | Not Reported |
| Risperidon Krka   | S | Oral | Unk              | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 01-Sep-2016              | 12707452      | EXPEDITED (15-DAY) |                    | HO, LT, OT      | DK-ASTRAZENECA-2016SE91020 |                      |            | Male       | DNK            |

| <u>Preferred Term</u>                                                                                                                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|----------------------------|-----------------|--------------|
| Product Dose Omission;<br>Restlessness; Sedation;<br>Social Avoidant<br>Behaviour; Suicidal<br>Ideation; Suicide Attempt;<br>Weight Increased | Seroquel       |              |            | S           | Oral         | 100.0mg Unknown            |                 | Zeneca       |
|                                                                                                                                               | Seroquel       |              |            | S           | Oral         | 300.0mg Unknown            |                 | Zeneca       |
|                                                                                                                                               | Seroquel       |              |            | S           | Oral         | 200.0mg Unknown            |                 | Zeneca       |
|                                                                                                                                               | Abilify        |              |            | S           | Oral         | 10.0mg Unknown             |                 | Not Reported |
|                                                                                                                                               | Cipralelex     |              |            | S           | Oral         |                            |                 | Not Reported |
|                                                                                                                                               | Cipralelex     |              |            | S           | Oral         |                            |                 | Not Reported |
|                                                                                                                                               | Imoclone       |              |            | S           | Oral         |                            |                 | Not Reported |
|                                                                                                                                               | Imoclone       |              |            | S           | Oral         | 7.5mg Unknown              |                 | Not Reported |
|                                                                                                                                               | Oxapax         |              |            | S           | Oral         |                            |                 | Not Reported |
|                                                                                                                                               | Truxal         |              |            | S           | Oral         | 265.0mg Unknown            |                 | Not Reported |
|                                                                                                                                               | Zeldox         |              |            | S           | Oral         | 80 Mg Increasing To 160 Mg |                 | Not Reported |
|                                                                                                                                               | Solian         |              |            | S           | Oral         |                            |                 | Not Reported |
|                                                                                                                                               | Risperidon     |              |            | S           | Oral         |                            |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------|----------------------|------------|------------|----------------|
| 01-Sep-2016              | 12708938      | NON-EXPEDITED    |                    |                 | US-JAZZ-2016-US-008482 |                      |            | Male       | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Paranoia; Stress | Xyrem          |              |            | S           | Oral         | 2.25 G, Bid        |                 | Jazz         |
|                           | Xyrem          |              |            | S           | Oral         | Dose Adjustments   |                 | Jazz         |
|                           | Xyrem          |              |            | S           | Oral         | 4.5 G, Bid         |                 | Jazz         |
|                           | Lexapro        |              |            | S           |              | Unk                |                 | Not Reported |
|                           | Adderall       |              |            | C           |              |                    |                 | Not Reported |
|                           | Lorazepam      |              |            | C           |              |                    |                 | Not Reported |
|                           | Clonazepam     |              |            | C           |              |                    |                 | Not Reported |
|                           | Vyvanse        |              |            | C           |              |                    |                 | Not Reported |
|                           | Effexor        |              |            | C           |              |                    |                 | Not Reported |
|                           | Provigil       |              |            | C           |              |                    |                 | Not Reported |
|                           | Escitalopram   |              |            | C           |              |                    |                 | Not Reported |
|                           | Pristiq        |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 01-Sep-2016              | 12708959      | EXPEDITED (15-DAY) |                    | HO              | CH-ASTRAZENECA-2016SE90924 |                      | 96 YR      | Female     | CHE            |

| <u>Preferred Term</u>                                                                                                                                                                 | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Asthenia; Contusion; Craniocerebral Injury; Dizziness; Dizziness Postural; Face Injury; Fall; Gait Disturbance; Haemorrhage Intracranial; Hyponatraemia; Skin Injury; Skin Laceration | Ass Cardio            |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                                                                       | Beloc Zok             |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                                                       | Ciprallex             |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                                                                       | Torem                 |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                                                                       | Amiodaron-Mepha       |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                                                                       | Polystyrene Sulfonate |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Sep-2016              | 12710552      | DIRECT           | Y                  |                 |                      |                      | 42 YR      | Female     | USA            |

| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Ineffective; Vomiting | Escitalopram   |              |            | S           | Oral         |                    |                 | Not Reported |

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| <u>FDA Received Date</u>                                                                                                                           | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| 02-Sep-2016                                                                                                                                        | 11717721       | EXPEDITED (15-DAY) |                    | HO              | FR-ASTRAZENECA-2015SF07761 |                      | 84 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                              | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Fall; General Physical Health Deterioration; Hypokalaemia; Hyponatraemia                                                                           | Crestor        |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                                                                                                                    | Kardegic       |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                                                                                                                    | Cardensiel     |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                                                                                                                    | Levothyrox     |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                                                                                                                    | Seroplex       |                    |                    | S               | Unknown                    |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                           | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Sep-2016                                                                                                                                        | 12342733       | EXPEDITED (15-DAY) |                    | HO, OT          | US-PFIZER INC-2016242078   |                      | 63 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                              | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Amnesia; Anger; Condition Aggravated; Crying; Depression; Drug Ineffective; Loss Of Consciousness; Nervousness; Weight Increased; Weight Loss Poor | Effexor Xr     |                    |                    | S               | Oral                       | 75 Mg, 1x/Day        |                 | Pfizer       |                |
|                                                                                                                                                    | Effexor Xr     |                    |                    | S               | Oral                       | 10 Mg, 2x/Day        |                 | Pfizer       |                |
|                                                                                                                                                    | Effexor Xr     |                    |                    | S               |                            |                      |                 | Pfizer       |                |
|                                                                                                                                                    | Effexor Xr     |                    |                    | S               |                            |                      |                 | Pfizer       |                |
|                                                                                                                                                    | Escitalopram   |                    |                    | S               | Oral                       | 20 Mg, Daily         |                 | Not Reported |                |
|                                                                                                                                                    | Escitalopram   |                    |                    | S               | Oral                       | 10 Mg, 2x/Day        |                 | Not Reported |                |
|                                                                                                                                                    | Diazepam       |                    |                    | C               |                            | 10 Mg, 3x/Day        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                           | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Sep-2016                                                                                                                                        | 12696194       | EXPEDITED (15-DAY) |                    | OT              | IT-FRI-1000087125          |                      | 58 YR           | Male         | ITA            |
| <u>Preferred Term</u>                                                                                                                              | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Malaise; Nausea; Neck Pain                                                                                                                         | Escitalopram   |                    |                    | S               | Oral                       | 10 Mg                |                 | Forest       |                |



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| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Sep-2016              | 12711001      | EXPEDITED (15-DAY) |                    | HO              | DK-FRI-1000087230    |                      |            | Male       | DNK            |

| <u>Preferred Term</u>                                                                                                                                           | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|--------------|------------|-------------|--------------|-------------------------------------|-----------------|--------------|
| Depressed Mood;<br>Intentional Overdose;<br>Restlessness; Sedation;<br>Social Avoidant<br>Behaviour; Suicidal<br>Ideation; Suicide Attempt;<br>Weight Increased | Escitalopram      |              |            | S           | Unknown      |                                     |                 | Forest       |
|                                                                                                                                                                 | Escitalopram      |              |            | S           | Oral         |                                     |                 | Forest       |
|                                                                                                                                                                 | Imoclon           |              |            | S           | Unknown      |                                     |                 | Not Reported |
|                                                                                                                                                                 | Imoclon           |              |            | S           | Oral         |                                     |                 | Not Reported |
|                                                                                                                                                                 | Oxapax            |              |            | S           | Oral         |                                     |                 | Not Reported |
|                                                                                                                                                                 | Seroquel          |              |            | S           | Oral         |                                     |                 | Not Reported |
|                                                                                                                                                                 | Seroquel Prolong  |              |            | S           | Oral         |                                     |                 | Not Reported |
|                                                                                                                                                                 | Abilify           |              |            | S           | Oral         |                                     |                 | Not Reported |
|                                                                                                                                                                 | Truxal            |              |            | S           | Oral         |                                     |                 | Not Reported |
|                                                                                                                                                                 | Zeldox            |              |            | S           | Oral         | Dose: 80 Mg Increasing<br>To 160 Mg |                 | Not Reported |
|                                                                                                                                                                 | Solian            |              |            | S           | Oral         |                                     |                 | Not Reported |
|                                                                                                                                                                 | Risperidon "Krka" |              |            | S           | Oral         |                                     |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Sep-2016              | 12711205      | EXPEDITED (15-DAY) |                    | DS              | DK-FRI-1000087231    |                      |            | Male       | DNK            |

| <u>Preferred Term</u>                                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Headache; Photopsia;<br>Pollakiuria; Visual<br>Impairment | Escitalopram   |              |            | S           | Oral         |                    |                 | Forest       |
|                                                           | Escitalopram   |              |            | S           | Unknown      |                    |                 | Forest       |
|                                                           | Mianserin      |              |            | C           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------------------------------|----------------------|------------|------------|----------------|
| 05-Sep-2016              | 12572421      | EXPEDITED (15-DAY) |                    | HO              | IL-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>BMS-2016-057808 |                      | 79 YR      | Female     | ISR            |

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| <u>Preferred Term</u>                                                  | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>           |
|------------------------------------------------------------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------|
| General Physical Health<br>Deterioration; Hepatic<br>Function Abnormal | Eliquis             |              |            | S           | Unknown      | 5 Mg, Bid          |                 | Bristol Myers Squibb |
|                                                                        | Ciprexel /01588501/ |              |            | S           | Unknown      |                    |                 | Not Reported         |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 05-Sep-2016              | 12636499      | EXPEDITED (15-DAY) |                    | HO, OT          | US-BAUSCH-BL-2016-018916 |                      |            | Female     | USA            |

| <u>Preferred Term</u>                               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Asthma; Drug Interaction;<br>Lung Disorder; Malaise | Wellbutrin     |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                     | Xyrem          |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                     | Xyrem          |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                     | Xyrem          |              |            | S           | Oral         | Dose Adjustments   |                 | Not Reported |
|                                                     | Xyrem          |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                     | Lexapro        |              |            | S           |              |                    |                 | Not Reported |
|                                                     | Lexapro        |              |            | S           |              |                    |                 | Not Reported |
|                                                     | Prozac         |              |            | C           |              |                    |                 | Not Reported |
|                                                     | Prozac         |              |            | C           |              |                    |                 | Not Reported |
|                                                     | Levofloxacin   |              |            | C           |              |                    |                 | Not Reported |
|                                                     | Xanax          |              |            | C           |              |                    |                 | Not Reported |
|                                                     | Xanax          |              |            | C           |              |                    |                 | Not Reported |
|                                                     | Adderall       |              |            | C           |              |                    |                 | Not Reported |
|                                                     | Advair         |              |            | C           |              |                    |                 | Not Reported |
|                                                     | Budesonide     |              |            | C           |              |                    |                 | Not Reported |
|                                                     | Celexa         |              |            | C           |              |                    |                 | Not Reported |
|                                                     | Celexa         |              |            | C           |              |                    |                 | Not Reported |
|                                                     | Claritin       |              |            | C           |              |                    |                 | Not Reported |
|                                                     | Modafinil      |              |            | C           |              |                    |                 | Not Reported |
|                                                     | Singulair      |              |            | C           |              |                    |                 | Not Reported |
|                                                     | Ventolin Hfa   |              |            | C           |              |                    |                 | Not Reported |
|                                                     | Medrol         |              |            | C           |              |                    |                 | Not Reported |
|                                                     | Prozac         |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------|----------------------|------------|------------|----------------|
| 05-Sep-2016              | 12714485      | NON-EXPEDITED    |                    | OT              | US-JAZZ-2016-US-008898 |                      |            | Female     | USA            |

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| <u>Preferred Term</u>           | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Depression; Nausea;<br>Vomiting | Xyrem               |              |            | S           | Oral         | 4.5 G, Bid         |                 | Jazz         |
|                                 | Xyrem               |              |            | S           | Oral         | Dose Adjustments   |                 | Jazz         |
|                                 | Xyrem               |              |            | S           | Oral         | 5.5 G, Tid         |                 | Jazz         |
|                                 | Zoloft              |              |            | S           |              | Unk                |                 | Not Reported |
|                                 | Lexapro             |              |            | S           |              | Unknown Dose       |                 | Not Reported |
|                                 | Boost Calorie Smart |              |            | C           |              | Unk                |                 | Not Reported |
|                                 | Warfarin Sodium     |              |            | C           |              | 1 Mg, Unk          |                 | Not Reported |
|                                 | Warfarin Sodium     |              |            | C           |              | 5 Mg, Unk          |                 | Not Reported |
|                                 | Warfarin Sodium     |              |            | C           |              | 4 Mg, Unk          |                 | Not Reported |
|                                 | Warfarin Sodium     |              |            | C           |              | 2 Mg, Unk          |                 | Not Reported |
|                                 | Amlodipine Besylate |              |            | C           |              | Unk                |                 | Not Reported |
|                                 | Zofran              |              |            | C           |              | Unk                |                 | Not Reported |
|                                 | Lisinopril          |              |            | C           |              | Unk                |                 | Not Reported |
|                                 | Lovenox             |              |            | C           |              | Unk                |                 | Not Reported |
|                                 | Miralax             |              |            | C           |              | Unk                |                 | Not Reported |
|                                 | Prilosec            |              |            | C           |              | Unk                |                 | Not Reported |
|                                 | Amitiza             |              |            | C           |              | 8 Mg, Unk          |                 | Not Reported |
|                                 | Amitiza             |              |            | C           |              | 24 Mg, Unk         |                 | Not Reported |
|                                 | Methadone Hcl       |              |            | C           |              | Unk                |                 | Not Reported |
|                                 | Ambien Cr           |              |            | C           |              | Unk                |                 | Not Reported |
|                                 | Duragesic           |              |            | C           |              | Unk                |                 | Not Reported |
|                                 | Librax              |              |            | C           |              | Unk                |                 | Not Reported |
|                                 | Lipitor             |              |            | C           |              | Unk                |                 | Not Reported |
|                                 | Nexium              |              |            | C           |              | Unk                |                 | Not Reported |
|                                 | Percocet            |              |            | C           |              | Unk                |                 | Not Reported |
|                                 | Remeron             |              |            | C           |              |                    |                 | Not Reported |
|                                 | Xanax               |              |            | C           |              |                    |                 | Not Reported |

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| <u>FDA Received Date</u>                                                    | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|-----------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|------------------------------------------|----------------------|-----------------|----------------------|----------------|
| 05-Sep-2016                                                                 | 12714906       | EXPEDITED (15-DAY) |                    | HO              | FR-JNJFOC-20160902036                    |                      | 87 YR           | Female               | FRA            |
| <u>Preferred Term</u>                                                       | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Generalised Tonic-Clonic Seizure; Petit Mal Epilepsy                        | Durogesic      |                    |                    | S               | Transdermal                              |                      |                 | Not Reported         |                |
|                                                                             | Seroplex       |                    |                    | S               | Oral                                     |                      |                 | Not Reported         |                |
|                                                                             | Seroplex       |                    |                    | S               | Oral                                     |                      |                 | Not Reported         |                |
|                                                                             | Paracetamol    |                    |                    | C               | Unknown                                  |                      |                 | Not Reported         |                |
|                                                                             | Zopiclone      |                    |                    | C               | Unknown                                  |                      |                 | Not Reported         |                |
|                                                                             | Alprazolam     |                    |                    | C               | Unknown                                  |                      |                 | Not Reported         |                |
|                                                                             | Pantoprazole   |                    |                    | C               | Unknown                                  |                      |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                    | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 05-Sep-2016                                                                 | 12715148       | EXPEDITED (15-DAY) |                    | HO, LT, OT      | TR-MYLANLABS-2016M1037242                |                      |                 | Unknown              | TUR            |
| <u>Preferred Term</u>                                                       | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Drug Interaction; Intentional Overdose; Serotonin Syndrome; Suicide Attempt | Escitalopram   |                    |                    | S               | Unknown                                  | 1400mg               |                 | Not Reported         |                |
|                                                                             | Moclobemide    |                    |                    | S               | Unknown                                  | 6000mg               |                 | Mylan                |                |
| <u>FDA Received Date</u>                                                    | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 06-Sep-2016                                                                 | 6365722        | EXPEDITED (15-DAY) |                    | OT              | FR-BRISTOL-MYERS SQUIBB COMPANY-13853411 |                      | < 1 DAY         | Female               | FRA            |
| <u>Preferred Term</u>                                                       | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Foetal Exposure During Pregnancy; Premature Baby                            | Abilify        |                    |                    | S               | Transplacental                           | 15 Mg, Qd            |                 | Bristol Myers Squibb |                |
|                                                                             | Seroplex       |                    |                    | S               | Transplacental                           | 10 Mg, Qd            |                 | Not Reported         |                |
|                                                                             | Depamide       |                    |                    | S               | Transplacental                           | 1200 Mg, Qd          |                 | Not Reported         |                |
|                                                                             | Seresta        |                    |                    | S               | Transplacental                           | Unk                  |                 | Not Reported         |                |
|                                                                             | Largactil      |                    |                    | S               | Transplacental                           | 50 Mg, Qd            |                 | Not Reported         |                |

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| <u>FDA Received Date</u>                               | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|--------------------------------------------------------|--------------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|----------------------|----------------|
| 06-Sep-2016                                            | 6366492            | EXPEDITED (15-DAY) |                    | OT              | FR-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>13853429 |                      | < 1 DAY         | Female               | FRA            |
| <u>Preferred Term</u>                                  | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Foetal Exposure During<br>Pregnancy; Premature<br>Baby | Abilify            |                    |                    | S               | Transplacental                                  | 15 Mg, Qd            |                 | Bristol Myers Squibb |                |
|                                                        | Seroplex           |                    |                    | S               | Transplacental                                  | 10 Mg, Qd            |                 | Not Reported         |                |
|                                                        | Depamide           |                    |                    | S               | Transplacental                                  | 1200 Mg, Qd          |                 | Not Reported         |                |
|                                                        | Seresta            |                    |                    | S               | Transplacental                                  | Unk                  |                 | Not Reported         |                |
|                                                        | Largactil          |                    |                    | S               | Transplacental                                  | 50 Mg, Qd            |                 | Not Reported         |                |
| <u>FDA Received Date</u>                               | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 06-Sep-2016                                            | 12715998           | EXPEDITED (15-DAY) |                    | HO, OT          | CA-APOTEX-<br>2016AP010733                      |                      | 39 YR           | Male                 | CAN            |
| <u>Preferred Term</u>                                  | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Drug Interaction;<br>Overdose; Serotonin<br>Syndrome   | Apo-Escitalopram   |                    |                    | S               | Oral                                            | Unk                  |                 | Apotex               |                |
|                                                        | Apo-Olanzapine Odt |                    |                    | S               | Oral                                            | Unk                  |                 | Apotex               |                |
|                                                        | Apo-Quetiapine     |                    |                    | S               | Oral                                            | Unk                  |                 | Apotex               |                |
|                                                        | Primidone          |                    |                    | S               | Oral                                            | Unk                  |                 | Not Reported         |                |
|                                                        | Phenytoin          |                    |                    | S               | Oral                                            | Unk                  |                 | Not Reported         |                |
|                                                        | Bupropion          |                    |                    | S               | Oral                                            | Unk                  |                 | Not Reported         |                |
|                                                        | Clonidine          |                    |                    | C               | Unknown                                         | Unk                  |                 | Not Reported         |                |
|                                                        | Dexmedetomidine    |                    |                    | C               | Unknown                                         | Unk                  |                 | Not Reported         |                |
| <u>FDA Received Date</u>                               | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 06-Sep-2016                                            | 12716942           | EXPEDITED (15-DAY) |                    | HO              | CH-MEDA-2016080110                              |                      | 96 YR           | Female               | CHE            |
| <u>Preferred Term</u>                                  | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Fall                                                   | Torem              |                    |                    | S               |                                                 |                      |                 | Meda                 |                |
|                                                        | Cipralex           |                    |                    | S               |                                                 |                      |                 | Not Reported         |                |
|                                                        | Ass Cardio         |                    |                    | S               |                                                 |                      |                 | Not Reported         |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                              |   |              |
|------------------------------|---|--------------|
| Beloc Zok                    | S | Not Reported |
| Amiodaron-Mepha              | S | Not Reported |
| Sodium Polystyrene Sulfonate | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Sep-2016              | 12717274      | EXPEDITED (15-DAY) |                    | HO              | CH-TEVA-688424ISR    |                      | 96 YR      | Female     | CHE            |

| <u>Preferred Term</u> | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|--------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Fall                  | Ass Cardio Actavis |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Amiodaron-Mepha    |              |            | S           | Unknown      |                    |                 | Teva         |
|                       | Torem              |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Cipralex           |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Beloc Zok          |              |            | S           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 06-Sep-2016              | 12717570      | EXPEDITED (15-DAY) |                    | HO              | FR-JNJFOC-20160901173 |                      | 67 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                                  | <u>Product</u>   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                     | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------|------------------|--------------|------------|-------------|--------------|--------------------------------------------------------|-----------------|--------------|
| Hyponatraemia;<br>Inappropriate Antidiuretic<br>Hormone Secretion; Self-<br>Medication | Haldol           |              |            | S           | Oral         | 12 Drops Morning And<br>Midday And 13 Drops<br>Evening |                 | Not Reported |
|                                                                                        | Tarka            |              |            | S           | Unknown      | In Evening                                             |                 | Not Reported |
|                                                                                        | Aldactazine      |              |            | S           | Unknown      | Morning                                                |                 | Not Reported |
|                                                                                        | Seroplex         |              |            | S           | Unknown      |                                                        |                 | Not Reported |
|                                                                                        | Loperamide       |              |            | C           | Unknown      |                                                        |                 | Not Reported |
|                                                                                        | Spaglumeric Acid |              |            | C           | Unknown      | 19.6 Mg/0.4 MI 1<br>Instillation 2 To 6 Times<br>Daily |                 | Not Reported |
|                                                                                        | Lantus           |              |            | C           | Unknown      | Evening                                                |                 | Not Reported |
|                                                                                        | Xanax            |              |            | C           | Unknown      | Half Tablet 1 To 3 Times<br>Daily                      |                 | Not Reported |
|                                                                                        | Stagid           |              |            | C           | Unknown      | 1.5 Tab                                                |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |              |   |         |                                            |              |
|--|--------------|---|---------|--------------------------------------------|--------------|
|  | Stagid       | C | Unknown |                                            | Not Reported |
|  | Parkinane    | C | Unknown | Morning                                    | Not Reported |
|  | Atorvastatin | C | Unknown | Evening                                    | Not Reported |
|  | Levothyrox   | C | Unknown | Morning On An Empty Stomach                | Not Reported |
|  | Levothyrox   | C | Unknown | Half Tablet In Morning On An Empty Stomach | Not Reported |
|  | Omeprazole   | C | Unknown |                                            | Not Reported |
|  | Allergodil   | C | Nasal   | 1 Spritz In Each Nostril                   | Not Reported |
|  | Cetirizine   | C | Unknown | Evening For 3 Months                       | Not Reported |
|  | Uvedose      | C | Unknown | 1 Vial                                     | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Sep-2016              | 12724460      | DIRECT           |                    | OT              |                      |                      | 53 YR      | Female     | USA            |

  

| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u> |
|--------------------------|----------------|--------------|------------|-------------|--------------|-----------------------|-----------------|------------|
| Diplopia; Vision Blurred | Escitalpram    |              |            | S           | Oral         | 30 Tablets Daily Oral |                 | Teva       |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------|----------------------|------------|------------|----------------|
| 07-Sep-2016              | 9663411       | EXPEDITED (15-DAY) |                    | HO              | US-RANBAXY-2013US-74750 |                      | 16 YR      | Female     | USA            |

  

| <u>Preferred Term</u>                                                                                                    | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------|-------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Bundle Branch Block Right; Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Intentional Overdose | Escitalopram                  |              |            | S           | Oral         | 50 Df, Single      |                 | Not Reported |
|                                                                                                                          | Hydrocodone And Acetaminophen |              |            | S           | Oral         | Unk Unk, Single    |                 | Sun          |
|                                                                                                                          | Tramadol/Acetaminophen        |              |            | S           | Oral         | 25 Df, Single      |                 | Sun          |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Sep-2016              | 12623311      | EXPEDITED (15-DAY) |                    | HO, OT          | CA-TEVA-681942USA    |                      | 39 YR      | Male       | CAN            |

  

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                       |              |   |              |
|-----------------------|--------------|---|--------------|
| Drug Interaction;     | Escitalopram | S | Ivax         |
| Overdose; Serotonin   | Quetiapine   | S | Teva         |
| Syndrome; Toxicity To | Olanzapine   | S | Teva         |
| Various Agents        | Phenytoin    | S | Not Reported |
|                       | Primidone    | S | Not Reported |
|                       | Bupropion    | S | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------------------|----------------------|------------|------------|----------------|
| 07-Sep-2016              | 12640939      | EXPEDITED (15-DAY) |                    | HO, OT          | US-<br>GLAXOSMITHKLINE-<br>US2016GSK115302 |                      |            | Female     | USA            |

| <u>Preferred Term</u>     | <u>Product</u>               | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|---------------------------|------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Adverse Drug Reaction;    | Wellbutrin                   |              |            | S           |              | Unk                |                 | Glaxosmithkline |
| Asthma; Drug Interaction; | Xyrem                        |              |            | S           | Oral         | 2.25 G, Bid        |                 | Not Reported    |
| Lung Disorder; Malaise    | Xyrem                        |              |            | S           | Oral         | 2.25 G, Bid        |                 | Not Reported    |
|                           | Xyrem                        |              |            | S           | Oral         | Unk                |                 | Not Reported    |
|                           | Xyrem                        |              |            | S           | Oral         | 3.75 G, Bid        |                 | Not Reported    |
|                           | Lexapro                      |              |            | S           |              | 20 Mg, Unk         |                 | Not Reported    |
|                           | Lexapro                      |              |            | S           |              | 10 Mg, Unk         |                 | Not Reported    |
|                           | Prozac                       |              |            | C           |              | Unk                |                 | Not Reported    |
|                           | Levofloxacin                 |              |            | C           |              | Unk                |                 | Not Reported    |
|                           | Xanax                        |              |            | C           |              | 0.5 Mg, Unk        |                 | Not Reported    |
|                           | Xanax                        |              |            | C           |              | 0.25 Mg, Unk       |                 | Not Reported    |
|                           | Adderall                     |              |            | C           |              | Unk                |                 | Not Reported    |
|                           | Advair                       |              |            | C           |              | Unk                |                 | Glaxosmithkline |
|                           | Budesonide                   |              |            | C           |              | Unk                |                 | Not Reported    |
|                           | Celexa                       |              |            | C           |              | Unk                |                 | Not Reported    |
|                           | Celexa                       |              |            | C           |              | Unk                |                 | Not Reported    |
|                           | Claritin Tablet (Loratadine) |              |            | C           |              | Unk                |                 | Not Reported    |
|                           | Modafinil                    |              |            | C           |              | Unk                |                 | Not Reported    |
|                           | Singulair                    |              |            | C           |              | Unk                |                 | Not Reported    |
|                           | Ventolin Hfa                 |              |            | C           |              | Unk                |                 | Glaxosmithkline |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                                                                                                        |                         |                    |                    |                 |                                                      |                      |                         |                 |                |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|------------------------------------------------------|----------------------|-------------------------|-----------------|----------------|
| Medrol                                                                                                                                                                                                                                                                                 |                         |                    | C                  |                 |                                                      | Unk                  |                         | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                               | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                 | <u>503B Facility</u> | <u>Age</u>              | <u>Sex</u>      | <u>Country</u> |
| 07-Sep-2016                                                                                                                                                                                                                                                                            | 12720725                | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000087377                                    |                      | 84 YR                   | Female          | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                  | <u>Product</u>          |                    | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>                                          | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>     |
| Fall; General Physical Health Deterioration; Hypokalaemia; Hyponatraemia                                                                                                                                                                                                               | Escitalopram            |                    |                    |                 | S                                                    | Oral                 | Daily Dose Not Reported |                 | Forest         |
|                                                                                                                                                                                                                                                                                        | Cardensiel              |                    |                    |                 | S                                                    | Oral                 | Daily Dose Not Reported |                 | Not Reported   |
|                                                                                                                                                                                                                                                                                        | Kardegic                |                    |                    |                 | S                                                    | Oral                 | Daily Dose Not Reported |                 | Not Reported   |
|                                                                                                                                                                                                                                                                                        | Levothyrox              |                    |                    |                 | S                                                    | Oral                 | Daily Dose Not Reported |                 | Not Reported   |
|                                                                                                                                                                                                                                                                                        | Crestor                 |                    |                    |                 | S                                                    | Oral                 | Daily Dose Not Reported |                 | Not Reported   |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                               | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                 | <u>503B Facility</u> | <u>Age</u>              | <u>Sex</u>      | <u>Country</u> |
| 07-Sep-2016                                                                                                                                                                                                                                                                            | 12720748                | EXPEDITED (15-DAY) |                    | HO, OT          | CA-SCIEGEN<br>PHARMACEUTICALS<br>INC-2016SCILIT00402 |                      | 39 YR                   | Male            | CAN            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                  | <u>Product</u>          |                    | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>                                          | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>     |
| Agitation; Arrhythmia; Confusional State; Delirium; Device Related Sepsis; Hyperhidrosis; Hyperreflexia; Hyperthermia; Incoherent; Major Depression; Muscle Rigidity; Myoclonus; Neuroleptic Malignant Syndrome; Overdose; Pneumonia; Seizure; Serotonin Syndrome; Tachycardia; Tremor | Bupropion Hydrochloride |                    |                    |                 | S                                                    | Unknown              | Unk                     |                 | Sciegen        |
|                                                                                                                                                                                                                                                                                        | Escitalopram            |                    |                    |                 | S                                                    | Unknown              | Unk                     |                 | Not Reported   |
|                                                                                                                                                                                                                                                                                        | Olanzapine              |                    |                    |                 | S                                                    | Unknown              | Unk                     |                 | Not Reported   |
|                                                                                                                                                                                                                                                                                        | Phenytoin               |                    |                    |                 | S                                                    | Unknown              | Unk                     |                 | Not Reported   |
|                                                                                                                                                                                                                                                                                        | Primidone               |                    |                    |                 | S                                                    | Unknown              | Unk                     |                 | Not Reported   |
|                                                                                                                                                                                                                                                                                        | Quetapine               |                    |                    |                 | S                                                    | Unknown              | Unk                     |                 | Not Reported   |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                               | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                 | <u>503B Facility</u> | <u>Age</u>              | <u>Sex</u>      | <u>Country</u> |
| 07-Sep-2016                                                                                                                                                                                                                                                                            | 12720824                | EXPEDITED (15-DAY) |                    | HO, OT          | CA-SCIEGEN<br>PHARMACEUTICALS<br>INC-2016SCILIT00404 |                      | 39 YR                   | Male            | CAN            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                  | <u>Product</u>          |                    | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>                                          | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>     |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                                                                                                                                                                                                                                                                                            |                                                                                                                                         |                                |                                                                    |                                            |                                                                                             |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|--------------------------------------------------------------------|--------------------------------------------|---------------------------------------------------------------------------------------------|
| Agitation; Arrhythmia;<br>Confusional State;<br>Delirium; Device Related<br>Sepsis; Hyperhidrosis;<br>Hyperreflexia;<br>Hyperthermia; Incoherent;<br>Major Depression; Muscle<br>Rigidity; Myoclonus;<br>Neuroleptic Malignant<br>Syndrome; Overdose;<br>Pneumonia; Seizure;<br>Serotonin Syndrome;<br>Tachycardia; Tremor | Bupropion Hydrochloride<br>Extended-Release Tablets Usp,<br>150 Mg<br>Escitalopram<br>Olanzapine<br>Phenytoin<br>Primidone<br>Quetapine | S<br><br>S<br>S<br>S<br>S<br>S | Unknown<br><br>Unknown<br>Unknown<br>Unknown<br>Unknown<br>Unknown | Unk<br><br>Unk<br>Unk<br>Unk<br>Unk<br>Unk | Sciegen<br><br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|--------------------------------------------------------------------|--------------------------------------------|---------------------------------------------------------------------------------------------|

| <u>FDA Received Date</u>                                                                                                                              | <u>Case #</u>                                                                                                                                                                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>                                | <u>Mfr Control #</u>          | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>                                                                    | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|--------------------|------------------------------------------------|-------------------------------|-------------------------|-----------------|-------------------------------------------------------------------------------|----------------|
| 07-Sep-2016                                                                                                                                           | 12721751                                                                                                                                                                           | EXPEDITED (15-DAY) |                    | HO                                             | FR-MYLANLABS-<br>2016M1037675 |                         |                 | Unknown                                                                       | FRA            |
| <u>Preferred Term</u>                                                                                                                                 | <u>Product</u>                                                                                                                                                                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                                    | <u>Route</u>                  | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>                                                                    |                |
| Agranulocytosis; Blood<br>Sodium Increased;<br>Dehydration; General<br>Physical Health<br>Deterioration;<br>Hypokalaemia; Parotitis;<br>Renal Failure | Alprazolam Mylan 0.25 Mg,<br>Comprimé Sécable<br>Escitalopram Arrow<br>Cordarone<br>Lasilix /00032601/<br>Doliprane<br>Kardegic<br>Seresta<br>Levothyrox<br>Discotrine<br>Eupantol |                    |                    | S<br>S<br>C<br>C<br>C<br>C<br>C<br>C<br>C<br>C | Oral<br>Oral                  | 0.5 Df, Qd<br>10 Mg, Qd |                 | Mylan<br>Mylan<br>Mylan<br>Mylan<br>Mylan<br>Mylan<br>Mylan<br>Mylan<br>Mylan |                |

| <u>FDA Received Date</u> | <u>Case #</u>             | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------------------|------------------|--------------------|-----------------|-------------------------|----------------------|-----------------|------------|----------------|
| 07-Sep-2016              | 12721800                  | NON-EXPEDITED    |                    |                 | US-TORRENT-<br>00001244 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>            | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Eczema                   | Escitalopram Tablets, Usp |                  |                    | S               |                         | 1 Daily              |                 | Torrent    |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                                                                                             | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>              | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>        | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|--------------------|--------------------|-----------------|-----------------------------------|----------------------|-----------------|-------------------|----------------|
| 07-Sep-2016                                                                                                                                                                                                                                                                                                                                                                                                          | 12722413            | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000087242                 |                      | 47 YR           | Female            | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                                | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                      | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>        |                |
| Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Gamma-Glutamyltransferase Increased; Hepatitis Cholestatic                                                                                                                                                                                                                                           | Escitalopram        |                    |                    | S               | Oral                              |                      |                 | Forest            |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                      | Advagraf            |                    |                    | S               | Oral                              | 2.5 Mg               |                 | Not Reported      |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                      | Inexium             |                    |                    | S               | Oral                              | 40 Mg                |                 | Not Reported      |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                      | Xanax               |                    |                    | S               | Oral                              |                      |                 | Not Reported      |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                      | Tahor               |                    |                    | S               | Oral                              | 10 Mg                |                 | Not Reported      |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                                                                                             | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>              | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>        | <u>Country</u> |
| 08-Sep-2016                                                                                                                                                                                                                                                                                                                                                                                                          | 12649114            | EXPEDITED (15-DAY) |                    | DS, HO, OT      | US-SAOL THERAPEUTICS-2016SAO00367 |                      | 47 YR           | Female            | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                                | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                      | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>        |                |
| Alopecia; Bedridden; Cardiac Disorder; Catheter Site Swelling; Chest Discomfort; Chest Pain; Chills; Cognitive Disorder; Disturbance In Attention; Drug Withdrawal Syndrome; Dry Skin; Dyspnoea; Fall; Fatigue; General Physical Condition Abnormal; Headache; Heart Rate Increased; Hyperhidrosis; Influenza; Loss Of Consciousness; Malaise; Muscle Spasms; Muscle Spasticity; Muscular Weakness; Nasopharyngitis; | Baclofen            |                    |                    | S               | Intrathecal                       | 70 Mg, \Day          |                 | Saol Therapeutics |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                      | Baclofen            |                    |                    | S               |                                   | Unk Mg, Unk          |                 | Not Reported      |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                      | Compounded Baclofen |                    |                    | S               |                                   | 70 Mg, \Day          |                 | Saol Therapeutics |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                      | Dilaudid            |                    |                    | S               | Intrathecal                       | 3.78 Mg, \Day        |                 | Not Reported      |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                      | Fentanyl            |                    |                    | S               | Intrathecal                       | 630 Mg, \Day         |                 | Not Reported      |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                      | Bupivacaine         |                    |                    | S               | Intrathecal                       | 7.6 Mg, \Day         |                 | Not Reported      |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                      | Tizanidine          |                    |                    | S               |                                   | Unk                  |                 | Not Reported      |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                      | Remeron             |                    |                    | S               |                                   | Unk                  |                 | Not Reported      |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                      | Topamax             |                    |                    | S               |                                   |                      |                 | Not Reported      |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                      | Synthroid           |                    |                    | S               |                                   |                      |                 | Not Reported      |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                      | Midrin              |                    |                    | S               |                                   |                      |                 | Not Reported      |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                      | Lexapro             |                    |                    | S               |                                   |                      |                 | Not Reported      |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                      | Adderall            |                    |                    | S               |                                   |                      |                 | Not Reported      |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                      | Diazepam            |                    |                    | C               | Oral                              | 20 Mg, \Day          |                 | Not Reported      |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Nightmare; Off Label Use; Percocet  
Overdose; Pain;  
Paraesthesia;  
Performance Status  
Decreased; Post Lumbar  
Puncture Syndrome;  
Pruritus; Road Traffic  
Accident; Toxicity To  
Various Agents; Tremor;  
Vomiting

C Oral 40 Mg, \Day Not Reported

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------------------------------|----------------------|------------|------------|----------------|
| 08-Sep-2016              | 12709618      | EXPEDITED (15-DAY) |                    | OT              | DK-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>BMS-2016-071524 |                      |            | Male       | DNK            |

| <u>Preferred Term</u>                                                                                                                                           | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|----------------------|-----------------|----------------------|
| Depressed Mood;<br>Intentional Overdose;<br>Restlessness; Sedation;<br>Social Avoidant<br>Behaviour; Suicidal<br>Ideation; Suicide Attempt;<br>Weight Increased | Abilify              |              |            | S           | Oral         | 10 Mg, Unk           |                 | Bristol Myers Squibb |
|                                                                                                                                                                 | Cipralext /01588501/ |              |            | S           | Oral         | 10 Mg, Unk           |                 | Not Reported         |
|                                                                                                                                                                 | Imoclon              |              |            | S           | Oral         | 7.5 Mg, Unk          |                 | Not Reported         |
|                                                                                                                                                                 | Oxapax               |              |            | S           | Oral         | Unk                  |                 | Not Reported         |
|                                                                                                                                                                 | Seroquel             |              |            | S           | Oral         | 100 Mg, Unk          |                 | Not Reported         |
|                                                                                                                                                                 | Seroquel             |              |            | S           | Unknown      | 300 Mg, Unk          |                 | Not Reported         |
|                                                                                                                                                                 | Seroquel Prolong     |              |            | S           | Oral         | 200 Mg, Unk          |                 | Not Reported         |
|                                                                                                                                                                 | Truxal /00012101/    |              |            | S           | Oral         | 265 Mg, Unk          |                 | Not Reported         |
|                                                                                                                                                                 | Zeldox /01487002/    |              |            | S           | Oral         | 1 Df, Unk            |                 | Not Reported         |
|                                                                                                                                                                 | Solian               |              |            | S           | Oral         | 1 Df, Unk            |                 | Not Reported         |
|                                                                                                                                                                 | Solian               |              |            | S           | Unknown      | 50 Mg, Unk           |                 | Not Reported         |
|                                                                                                                                                                 | Risperidon           |              |            | S           | Oral         | Unk, 1/2 Mg At Night |                 | Not Reported         |
| Risperidon                                                                                                                                                      |                      |              | S          | Oral        | 1 Mg, Unk    |                      | Not Reported    |                      |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Sep-2016              | 12712018      | EXPEDITED (15-DAY) |                    | DS, HO, OT      | JP-FRI-1000087076    |                      | 50 YR      | Female     | JPN            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                               |                      |   |            |        |              |
|---------------------------------------------------------------|----------------------|---|------------|--------|--------------|
| Oculogyric Crisis;<br>Protrusion Tongue;<br>Seizure; Vomiting | Asenapine            | S | Sublingual | 10 Mg  | Forest       |
|                                                               | Lexapro              | S | Oral       | 20 Mg  | Forest       |
|                                                               | Quetiapine Fumarate  | S | Oral       | 100 Mg | Not Reported |
|                                                               | Quetiapine Fumarate  | S | Oral       | 175 Mg | Not Reported |
|                                                               | Quetiapine Fumarate  | S | Oral       | 300 Mg | Not Reported |
|                                                               | Tandospirone Citrate | C |            |        | Not Reported |
|                                                               | Brotizolam           | C |            |        | Not Reported |
|                                                               | Suvorexant           | C |            |        | Not Reported |
|                                                               | Yoku-Kan-San         | C |            |        | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Sep-2016              | 12723407      | EXPEDITED (15-DAY) |                    | HO              | CA-ROCHE-1827187     |                      | 54 YR      | Female     | CAN            |

| <u>Preferred Term</u>                                               | <u>Product</u>                     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------|------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Condition Aggravated;<br>Dehydration; Dysphagia;<br>Mental Disorder | Clonazepam                         |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                     | Acetaminophen/Codeine<br>Phosphate |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                     | Domperidone                        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                     | Escitalopram                       |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                     | Ferrous Sulfate                    |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                     | Gabapentin                         |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                     | Gabapentin                         |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                     | Temazepam                          |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                     | Wellbutrin                         |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 08-Sep-2016              | 12724251      | EXPEDITED (15-DAY) |                    | HO, LT          | ES-PFIZER INC-<br>2016417483 |                      | 69 YR      | Male       | ESP            |

| <u>Preferred Term</u>                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction; Upper<br>Gastrointestinal<br>Haemorrhage | Trangorex      |              |            | S           | Oral         | 200 Mg, Daily      |                 | Pfizer       |
|                                                            | Escitalopram   |              |            | S           | Oral         | 10 Mg, Daily       |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                        |   |         |     |              |
|----------------------------------------|---|---------|-----|--------------|
| Omeprazole                             | S | Unknown | Unk | Not Reported |
| Aldocumar                              | S | Oral    | Unk | Not Reported |
| Secalip                                | S | Unknown | Unk | Not Reported |
| Efferalgan /00020001/                  | S | Unknown | Unk | Not Reported |
| Tramadol                               | S |         | Unk | Not Reported |
| Nebivolol                              | C |         | Unk | Not Reported |
| Furosemide                             | C |         | Unk | Not Reported |
| Amlodipine                             | C |         | Unk | Not Reported |
| Metformin                              | C |         | Unk | Not Reported |
| Hydrochloride/Sitagliptin<br>Phosphate |   |         |     |              |
| Fluticasone/Salmeterol                 | C |         | Unk | Not Reported |
| Tiotropium                             | C |         | Unk | Not Reported |
| Salbutamol                             | C |         | Unk | Not Reported |
| Lormetazepam                           | C |         | Unk | Not Reported |
| Metamizole                             | C |         | Unk | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|------------|------------|----------------|
| 08-Sep-2016              | 12726075      | EXPEDITED (15-DAY) |                    | HO, LT          | ES-MYLANLABS-<br>2016M1036998 |                      |            | Unknown    | ESP            |

| <u>Preferred Term</u>                                                                                                                                  | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction; Gastric<br>Ulcer; Haematocrit<br>Decreased; International<br>Normalised Ratio<br>Increased; Upper<br>Gastrointestinal<br>Haemorrhage | Escitalopram          |              |            | S           | Oral         | 10 Mg, Qd          |                 | Not Reported |
|                                                                                                                                                        | Omeprazole            |              |            | S           |              | Unk                |                 | Not Reported |
|                                                                                                                                                        | Tramadol              |              |            | S           |              | Unk                |                 | Not Reported |
|                                                                                                                                                        | Secalip               |              |            | S           |              | Unk                |                 | Mylan        |
|                                                                                                                                                        | Aldocumar             |              |            | S           | Oral         | Unk                |                 | Mylan        |
|                                                                                                                                                        | Trangorex             |              |            | S           | Oral         | 200 Mg, Qd         |                 | Mylan        |
|                                                                                                                                                        | Efferalgan /00020001/ |              |            | S           |              | Unk                |                 | Mylan        |
|                                                                                                                                                        | Nebivolol             |              |            | C           |              |                    |                 | Mylan        |
|                                                                                                                                                        | Furosemide            |              |            | C           |              |                    |                 | Mylan        |
|                                                                                                                                                        | Amlodipine            |              |            | C           |              |                    |                 | Mylan        |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                  |   |       |
|----------------------------------|---|-------|
| Metformin Hydrochloride          | C | Mylan |
| W/Sitagliptin                    |   |       |
| Salmeterol/Fluticasonepropionate | C | Mylan |
| Tiotropium                       | C | Mylan |
| Salbutamol                       | C | Mylan |
| Lormetazepam                     | C | Mylan |
| Metamizole                       | C | Mylan |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-------------------------|----------------------|------------|------------|----------------|
| 08-Sep-2016              | 12726656      | NON-EXPEDITED    |                    |                 | US-TAKEDA-2016TUS015852 |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Ineffective      | Trintellix     |              |            | S           | Unknown      | Unk                |                 | Takeda       |
|                       | Lexapro        |              |            | S           | Unknown      | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Sep-2016              | 12729608      | DIRECT           | Y                  | OT              |                      |                      | 65 YR      | Female     | USA            |

| <u>Preferred Term</u>            | <u>Product</u>  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------|-----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Depressed Mood; Drug Ineffective | Generic Lexapro |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 09-Sep-2016              | 12695234      | EXPEDITED (15-DAY) |                    | DE, HO, LT      | CH-JNJFOC-20160819529 |                      | 60 YR      | Male       | CHE            |

| <u>Preferred Term</u>                                                                                                                                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anticoagulation Drug                                                                                                                                    | Xarelto        |              |            | S           | Oral         |                    |                 | Not Reported |
| Level Increased; Cardiac Arrest; Inhibitory Drug Interaction; Potentiating Drug Interaction; Sinus Node Dysfunction; Upper Gastrointestinal Haemorrhage | Xarelto        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                         | Ibrutinib      |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                         | Amiodarone     |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                         | Cipralex       |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                         | Nebivolol      |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                         | Atorvastatin   |              |            | C           | Oral         |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|            |   |      |              |
|------------|---|------|--------------|
| Ramipril   | C | Oral | Not Reported |
| Eplerenone | C | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 09-Sep-2016              | 12729087      | EXPEDITED (15-DAY) | HO                 |                 | FR-ABBVIE-16P-056-1722133-00 |                      | 67 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                             | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                             | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|------------------------------------------------|-----------------|--------------|
| Hyponatraemia;<br>Inappropriate Antidiuretic<br>Hormone Secretion | Tarka Er 4 Mg/240 Mg    |              |            | S           | Oral         | Daily Dose: 1 Df Once<br>Daily In The Evening  |                 | Not Reported |
|                                                                   | Aldactazine             |              |            | S           | Oral         | Daily Dose: 1 Df Once<br>Daily In The Morning  |                 | Not Reported |
|                                                                   | Haldol                  |              |            | S           | Oral         | 12 Drops Morning And<br>Noon, 13 Drops Evening |                 | Not Reported |
|                                                                   | Seroplex                |              |            | S           | Oral         | Daily Dose: 1 Df Daily In<br>The Morning       |                 | Not Reported |
|                                                                   | Stagid                  |              |            | C           |              |                                                |                 | Not Reported |
|                                                                   | Lantus                  |              |            | C           |              | 22 Units In The Evening                        |                 | Not Reported |
|                                                                   | Parkinane               |              |            | C           |              | 1 Fial Morning                                 |                 | Not Reported |
|                                                                   | Atorvastatin            |              |            | C           |              | 10 Mg Evening                                  |                 | Not Reported |
|                                                                   | Levothyrox              |              |            | C           |              | 1 Df Morning                                   |                 | Not Reported |
|                                                                   | Levothyrox              |              |            | C           |              | 1/2 Df Morning                                 |                 | Not Reported |
|                                                                   | Omeprazole              |              |            | C           |              |                                                |                 | Not Reported |
|                                                                   | Loperamide              |              |            | C           |              |                                                |                 | Not Reported |
|                                                                   | Proctolog               |              |            | C           |              | 1df; 1 Or 2 Times Daily                        |                 | Not Reported |
|                                                                   | Cetirizine              |              |            | C           |              | 1 Df Evening For 3 Months                      |                 | Not Reported |
|                                                                   | Allergodil              |              |            | C           |              | 1 Puff In Each Nostril 2<br>Times Daily        |                 | Not Reported |
|                                                                   | Naabak (Spaglumic Acid) |              |            | C           |              | Instillation, 2 Or 6 Times<br>Daily            |                 | Not Reported |
|                                                                   | Uvedose                 |              |            | C           |              |                                                |                 | Not Reported |
|                                                                   | Xanax                   |              |            | C           |              | 1/2 Df 1 To 3 Times Daily                      |                 | Not Reported |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                         | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>             | <u>Country</u> |
|----------------------------------------------------------------------------------|----------------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|------------------------|----------------|
| 09-Sep-2016                                                                      | 12729363                         | EXPEDITED (15-DAY) |                    | OT              | IT-JNJFOC-20160906098    |                      | 37 YR           | Male                   | ITA            |
| <u>Preferred Term</u>                                                            | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>             |                |
| Dry Mouth; Intentional Overdose; Intentional Self-Injury                         | Risperdal                        |                    |                    | S               | Oral                     |                      |                 | Not Reported           |                |
|                                                                                  | Risperdal                        |                    |                    | S               | Oral                     |                      |                 | Not Reported           |                |
|                                                                                  | Cipralelex                       |                    |                    | S               | Oral                     |                      |                 | Not Reported           |                |
|                                                                                  | Cipralelex                       |                    |                    | S               | Oral                     |                      |                 | Not Reported           |                |
| <u>FDA Received Date</u>                                                         | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>             | <u>Country</u> |
| 09-Sep-2016                                                                      | 12732182                         | DIRECT             | Y                  | OT              |                          |                      | 59 YR           | Male                   | USA            |
| <u>Preferred Term</u>                                                            | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>             |                |
| Aggression; Depression; Irritability; Nervousness; Obsessive-Compulsive Disorder | Escitalopram Oxalate 20mg, 20 Mg |                    |                    | S               | Oral                     |                      |                 | Bluepoint Laboratories |                |
| <u>FDA Received Date</u>                                                         | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>             | <u>Country</u> |
| 12-Sep-2016                                                                      | 9564677                          | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2013278375 |                      | 45 YR           | Female                 | USA            |
| <u>Preferred Term</u>                                                            | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>             |                |
| Drug Ineffective                                                                 | Phenytoin                        |                    |                    | S               |                          | Unk                  |                 | Pfizer                 |                |
|                                                                                  | Lamotrigine                      |                    |                    | S               |                          | Unk                  |                 | Not Reported           |                |
|                                                                                  | Levetiracetam                    |                    |                    | S               |                          | Unk                  |                 | Unknown                |                |
|                                                                                  | Sertraline Hcl                   |                    |                    | S               |                          | Unk                  |                 | Pfizer                 |                |
|                                                                                  | Phenobarbital                    |                    |                    | S               |                          | Unk                  |                 | Not Reported           |                |
|                                                                                  | Valproic Acid                    |                    |                    | S               |                          | Unk                  |                 | Not Reported           |                |
|                                                                                  | Carbamazepine                    |                    |                    | S               |                          | Unk                  |                 | Not Reported           |                |
|                                                                                  | Oxcarbazepine                    |                    |                    | S               |                          | Unk                  |                 | Not Reported           |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| Escitalopram                                             |                          |                    | S                  |                 | Unk                    |                            |                 | Not Reported |                |
|----------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|------------------------|----------------------------|-----------------|--------------|----------------|
| <u>FDA Received Date</u>                                 | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Sep-2016                                              | 12696191                 | EXPEDITED (15-DAY) |                    | OT              | MY-FRI-1000086877      |                            | 45 YR           | Male         | MYS            |
| <u>Preferred Term</u>                                    | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>   |                |
| Bipolar I Disorder; Drug Ineffective; Sexual Dysfunction | Citalopram               |                    |                    | S               | Unknown                | 20 Mg                      |                 | Forest       |                |
|                                                          | Escitalopram             |                    |                    | S               | Unknown                | 20 Mg                      |                 | Forest       |                |
|                                                          | Hypoglycemic Agent       |                    |                    | C               | Oral                   |                            |                 | Not Reported |                |
|                                                          | Sodium Valproate         |                    |                    | C               | Unknown                |                            |                 | Not Reported |                |
|                                                          | Mirtazapine              |                    |                    | C               | Oral                   |                            |                 | Not Reported |                |
|                                                          | Olanzapine               |                    |                    | C               | Unknown                |                            |                 | Not Reported |                |
|                                                          | Quetiapine Xr            |                    |                    | C               | Unknown                | Uptitrated To 400 Mg Daily |                 | Not Reported |                |
| <u>FDA Received Date</u>                                 | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Sep-2016                                              | 12731534                 | NON-EXPEDITED      |                    |                 | US-APOTEX-2016AP008293 |                            | 66 YR           | Male         | USA            |
| <u>Preferred Term</u>                                    | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>   |                |
| Adverse Drug Reaction; Drug Ineffective                  | Bupropion Hydrochloride  |                    |                    | S               |                        |                            |                 | Apotex       |                |
|                                                          | Citalopram               |                    |                    | S               |                        |                            |                 | Apotex       |                |
|                                                          | Paroxetine Hydrochloride |                    |                    | S               |                        |                            |                 | Apotex       |                |
|                                                          | Sertraline Hydrochloride |                    |                    | S               |                        |                            |                 | Apotex       |                |
|                                                          | Mirtazapine              |                    |                    | S               |                        |                            |                 | Apotex       |                |
|                                                          | Escitalopram Oxalate     |                    |                    | S               |                        |                            |                 | Apotex       |                |
|                                                          | Venlafaxine              |                    |                    | S               |                        |                            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                 | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Sep-2016                                              | 12731883                 | DIRECT             |                    | LT, OT          |                        |                            | 48 YR           | Female       | USA            |
| <u>Preferred Term</u>                                    | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>   |                |
| Anaphylactic Reaction; Reaction To Excipient             | Escitalopram             |                    |                    | S               | Oral                   |                            |                 | Torrent      |                |
|                                                          | Lexapro                  |                    |                    | C               |                        |                            |                 | Not Reported |                |
|                                                          | Atenolol                 |                    |                    | C               |                        |                            |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| Estradiol                   |                      | C                  |                    | Not Reported    |                      |                      |                 |            |                |
|-----------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| Vitamin C                   |                      | C                  |                    | Not Reported    |                      |                      |                 |            |                |
| <u>FDA Received Date</u>    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Sep-2016                 | 12738638             | DIRECT             |                    |                 |                      |                      |                 | Male       | USA            |
| <u>Preferred Term</u>       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Neck Pain                   | Escitalopram         |                    |                    | S               |                      |                      |                 |            | Not Reported   |
| <u>FDA Received Date</u>    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 13-Sep-2016                 | 12739302             | EXPEDITED (15-DAY) |                    | DS, HO, OT      | PHHY2016US048902     |                      |                 | Female     | USA            |
| <u>Preferred Term</u>       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Alopecia; Bedridden;        | Baclofen Intrathecal |                    |                    | S               | Intrathecal          | 70 Ug, Qd            |                 |            | Not Reported   |
| Cardiac Disorder; Catheter  | Baclofen             |                    |                    | S               | Unknown              | Unk Mg, Unk          |                 |            | Not Reported   |
| Site Swelling; Chest        | Baclofen Intrathecal |                    |                    | S               | Intrathecal          | 70 Ug, Qd            |                 |            | Not Reported   |
| Discomfort; Chest Pain;     | Tizanidine           |                    |                    | S               | Unknown              | , Unk                |                 |            | Novartis       |
| Chills; Cognitive Disorder; | Dilaudid             |                    |                    | S               | Intrathecal          | 3.78 Mg, Qd          |                 |            | Not Reported   |
| Disturbance In Attention;   | Fentanyl             |                    |                    | S               | Intrathecal          | 630 Mg, Qd           |                 |            | Not Reported   |
| Drug Withdrawal             | Bupivacaine          |                    |                    | S               | Intrathecal          | 7.6 Mg, Qd           |                 |            | Not Reported   |
| Syndrome; Dry Skin;         | Remeron              |                    |                    | S               | Unknown              | Unk, Unk             |                 |            | Not Reported   |
| Dyspnoea; Fall; Fatigue;    | Topamax              |                    |                    | S               | Unknown              | , Unk                |                 |            | Not Reported   |
| General Physical            | Midrin               |                    |                    | S               | Unknown              |                      |                 |            | Not Reported   |
| Condition Abnormal;         | Synthroid            |                    |                    | S               | Unknown              | , Unk                |                 |            | Not Reported   |
| Headache; Heart Rate        | Lexapro              |                    |                    | S               | Unknown              |                      |                 |            | Not Reported   |
| Increased; Hyperhidrosis;   | Adderall             |                    |                    | S               | Unknown              | , Unk                |                 |            | Not Reported   |
| Influenza; Loss Of          | Diazepam             |                    |                    | C               | Unknown              |                      |                 |            | Not Reported   |
| Consciousness; Malaise;     | Percocet             |                    |                    | C               | Unknown              |                      |                 |            | Not Reported   |
| Muscle Spasms; Muscle       |                      |                    |                    |                 |                      |                      |                 |            |                |
| Spasticity; Muscular        |                      |                    |                    |                 |                      |                      |                 |            |                |
| Weakness;                   |                      |                    |                    |                 |                      |                      |                 |            |                |
| Nasopharyngitis;            |                      |                    |                    |                 |                      |                      |                 |            |                |
| Nightmare; Off Label Use;   |                      |                    |                    |                 |                      |                      |                 |            |                |
| Overdose; Pain;             |                      |                    |                    |                 |                      |                      |                 |            |                |
| Paraesthesia;               |                      |                    |                    |                 |                      |                      |                 |            |                |
| Performance Status          |                      |                    |                    |                 |                      |                      |                 |            |                |
| Decreased; Post Lumbar      |                      |                    |                    |                 |                      |                      |                 |            |                |
| Puncture Syndrome;          |                      |                    |                    |                 |                      |                      |                 |            |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Pruritus; Road Traffic  
Accident; Toxicity To  
Various Agents; Tremor;  
Vomiting

| <u>FDA Received Date</u>                                                         | <u>Case #</u>                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------|------------------------------------------|--------------------|--------------------|-----------------|--------------------------------|--------------------------------|-----------------|--------------|----------------|
| 14-Sep-2016                                                                      | 12484432                                 | EXPEDITED (15-DAY) |                    | HO              | CH-PFIZER INC-<br>2016300987   |                                | 23 YR           | Female       | CHE            |
| <u>Preferred Term</u>                                                            | <u>Product</u>                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Epilepsy; Hyponatraemia;<br>Status Epilepticus                                   | Temesta (Lorazepam)                      |                    |                    | S               | Oral                           | 1 Mg, As Needed (Max<br>2/24h) |                 | Pfizer       |                |
|                                                                                  | Leponex                                  |                    |                    | S               | Oral                           | 100 Mg, 3x/Day                 |                 | Not Reported |                |
|                                                                                  | Leponex                                  |                    |                    | S               | Oral                           | 100 Mg, 4x/Day                 |                 | Not Reported |                |
|                                                                                  | Cipralex /01588501/                      |                    |                    | S               | Oral                           | 20 Mg, 1x/Day (1-0-0-0)        |                 | Not Reported |                |
|                                                                                  | Humulus Lupulus<br>Extract/Valerian Root |                    |                    | C               | Oral                           | 1 Df, 1x/Day                   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                         | <u>Case #</u>                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Sep-2016                                                                      | 12722862                                 | EXPEDITED (15-DAY) |                    | HO              | IT-ASTRAZENECA-<br>2016SE85801 |                                | 65 YR           | Male         | ITA            |
| <u>Preferred Term</u>                                                            | <u>Product</u>                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Glucose Increased;<br>Gingival Bleeding;<br>Petechiae;<br>Thrombocytopenia | Crestor                                  |                    |                    | S               | Oral                           |                                |                 | Not Reported |                |
|                                                                                  | Crestor                                  |                    |                    | S               | Oral                           |                                |                 | Not Reported |                |
|                                                                                  | Stiliden                                 |                    |                    | S               | Oral                           | 10 Mg/ML Oral Drops,<br>Daily  |                 | Not Reported |                |
|                                                                                  | Stiliden                                 |                    |                    | S               | Oral                           |                                |                 | Not Reported |                |
|                                                                                  | Cipralex                                 |                    |                    | S               | Oral                           | 20 Mg/ML Oral Drops,<br>Daily  |                 | Not Reported |                |
|                                                                                  | Diamox                                   |                    |                    | S               | Oral                           |                                |                 | Not Reported |                |
|                                                                                  | Omeprazole                               |                    |                    | C               | Oral                           | 20.0mg Unknown                 |                 | Not Reported |                |
|                                                                                  | Glucophage                               |                    |                    | C               | Oral                           | 1000.0mg Unknown               |                 | Not Reported |                |
|                                                                                  | Metformin                                |                    |                    | C               |                                |                                |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                      | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                       | <u>503B Facility</u>                    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|------------------------------------------------------------|-----------------------------------------|-----------------|--------------|----------------|
| 14-Sep-2016                                                                                                                   | 12740933               | EXPEDITED (15-DAY) |                    | HO              | TW-MACLEODS<br>PHARMACEUTICALS<br>US LTD-<br>MAC2016003099 |                                         |                 | Unknown      | TWN            |
| <u>Preferred Term</u>                                                                                                         | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                               | <u>Dosage Text</u>                      | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Disturbance<br>In Attention; Drug<br>Interaction; Euphoric<br>Mood; Insomnia; Mania;<br>Psychomotor Hyperactivity | Escitalopram Oxalate   |                    |                    | S               | Unknown                                                    | 15 Mg, Qd                               |                 | Macleods     |                |
|                                                                                                                               | Dextromethorphan       |                    |                    | S               | Oral                                                       | 30 Mg, Qid (Every 6<br>Hourly In A Day) |                 | Not Reported |                |
|                                                                                                                               | Paracetamol            |                    |                    | C               | Unknown                                                    | 325 Mg, Tid                             |                 | Not Reported |                |
|                                                                                                                               | Ambroxol               |                    |                    | C               | Unknown                                                    |                                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                      | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                       | <u>503B Facility</u>                    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Sep-2016                                                                                                                   | 12746119               | DIRECT             |                    | DS              |                                                            |                                         | 43 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                         | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                               | <u>Dosage Text</u>                      | <u>Duration</u> | <u>Mfr</u>   |                |
| Bedridden; Lactose<br>Intolerance; Malaise;<br>Reaction To Excipient                                                          | Escitalopram           |                    |                    | S               | Oral                                                       |                                         |                 | Camber       |                |
|                                                                                                                               | Escitalopram           |                    |                    | S               | Oral                                                       |                                         |                 | Aurobindo    |                |
|                                                                                                                               | Fentanyl Hydromorphone |                    |                    | C               |                                                            |                                         |                 | Not Reported |                |
|                                                                                                                               | Valium                 |                    |                    | C               |                                                            |                                         |                 | Not Reported |                |
|                                                                                                                               | Lexapro                |                    |                    | C               |                                                            |                                         |                 | Not Reported |                |
|                                                                                                                               | Tylenol                |                    |                    | C               |                                                            |                                         |                 | Not Reported |                |
|                                                                                                                               | Advil                  |                    |                    | C               |                                                            |                                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                      | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                       | <u>503B Facility</u>                    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Sep-2016                                                                                                                   | 12549259               | EXPEDITED (15-DAY) |                    | HO              | CA-IMPAX<br>LABORATORIES, INC-<br>2016-IPXL-00708          |                                         | 182 DAY         | Female       | CAN            |
| <u>Preferred Term</u>                                                                                                         | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                               | <u>Dosage Text</u>                      | <u>Duration</u> | <u>Mfr</u>   |                |
| Cyanosis; Drug<br>Interaction; Exposure Via<br>Breast Milk; Hypertonia;<br>Seizure Like Phenomena;<br>Sleep Disorder;         | Bupropion XI           |                    |                    | S               | Transmammary                                               | Unk                                     |                 | Impax        |                |
|                                                                                                                               | Escitalopram           |                    |                    | S               | Transmammary                                               | Unk                                     |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Somnolence; Staring;  
Unresponsive To Stimuli;  
Vomiting

| <u>FDA Received Date</u>                                                 | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 15-Sep-2016                                                              | 12746558       | DIRECT           |                    | OT              |                      |                      | 27 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anal Fissure;<br>Constipation;<br>Haemorrhage;<br>Haemorrhoids; Insomnia | Escitalopram   |                  |                    | S               | Oral                 | 1 Tablet Oral        |                 | Cipla        |                |
|                                                                          | Hydroxyzine    |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                          | Viorele        |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                          | Loratidine     |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                          | Calcium        |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                          | Flonase        |                  |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|--------------------------|------------------------|-----------------|--------------|----------------|
| 15-Sep-2016              | 12747509       | NON-EXPEDITED    |                    |                 | US-ASTELLAS-2016US031700 |                        | 60 YR           | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Tinnitus                 | Xtandi         |                  |                    | S               | Oral                     |                        |                 | Astellas     |                |
|                          | Escitalopram   |                  |                    | S               | Unknown                  | Unk Unk, Unknown Freq. |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                                                                                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|--------------------------|---------------------------|-----------------|--------------|----------------|
| 15-Sep-2016                                                                                                                                                                                             | 12747952             | EXPEDITED (15-DAY) |                    | OT              | DK-PFIZER INC-2016429406 |                           | 17 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain; Anger;<br>Anxiety; Asthenia;<br>Asthenia; Bronchitis;<br>Decreased Immune Responsiveness;<br>Delusion; Depressed Mood; Derealisation;<br>Diarrhoea; Disturbance In Sexual Arousal; Drug | Lyrica               |                    |                    | S               | Oral                     | Unk                       |                 | Pfizer       |                |
|                                                                                                                                                                                                         | Abilify              |                    |                    | S               |                          | Unk                       |                 | Not Reported |                |
|                                                                                                                                                                                                         | Ciprallex /01588501/ |                    |                    | S               | Oral                     | Unk                       |                 | Not Reported |                |
|                                                                                                                                                                                                         | Circadin             |                    |                    | S               | Oral                     | Unk                       |                 | Not Reported |                |
|                                                                                                                                                                                                         | Serdolect            |                    |                    | S               | Oral                     | Strength: 4 - 12 - 16 Mg. |                 | Not Reported |                |
|                                                                                                                                                                                                         | Seroquel Prolong     |                    |                    | S               | Oral                     | Unk                       |                 | Not Reported |                |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                 |                     |   |      |                |              |
|-----------------------------------------------------------------|---------------------|---|------|----------------|--------------|
| Ineffective; Fatigue;                                           | Solian              | S | Oral | Unk            | Not Reported |
| Fungal Infection;                                               | Truxal /00012102/   | S | Oral | Unk, As Needed | Not Reported |
| Gastrointestinal Disorder;                                      | Seroquel            | S | Oral | Unk, As Needed | Not Reported |
| Hallucination, Auditory;                                        | Zyprexa             | S | Oral | Unk, As Needed | Not Reported |
| Hallucination, Visual;                                          | Venlafaxin Actavis  | S | Oral | Unk            | Not Reported |
| Hypersomnia; Impaired Reasoning; Impulsive Behaviour; Insomnia; | Pulmicort           | C |      | Unk            | Not Reported |
| Irritable Bowel Syndrome;                                       | Bricanyl Turbuhaler | C |      | Unk            | Not Reported |
| Lung Infection;                                                 | Seretide            | C |      | Unk            | Not Reported |
| Nasopharyngitis; Nausea;                                        | Canesten            | C |      | Unk            | Not Reported |
| Nightmare; Otitis Media;                                        | Brentan /00310801/  | C |      | Unk            | Not Reported |
| Pain; Personality Change;                                       | Nizoral             | C |      | Unk            | Not Reported |
| Restlessness; Sleep Disorder; Sleep Paralysis;                  | Cetirizin Actavis   | C |      | Unk            | Not Reported |
| Suicidal Ideation;                                              | Telfast             | C |      | Unk            | Not Reported |
| Violence-Related Symptom; Weight Fluctuation; Weight Increased  | Depo-Medrol         | C |      | Unk            | Not Reported |
|                                                                 | Depo-Provera        | C |      | Unk            | Not Reported |
|                                                                 | Tradolan            | C | Oral | Unk            | Not Reported |
|                                                                 | Dolol /00020001/    | C | Oral | Unk            | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------------------------------------|----------------------|------------|------------|----------------|
| 16-Sep-2016              | 12717468      | EXPEDITED (15-DAY) |                    | DS              | JP-SUN<br>PHARMACEUTICAL<br>INDUSTRIES LTD-<br>2016RR-122221 |                      | 50 YR      | Female     | JPN            |

  

| <u>Preferred Term</u>                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                           | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------|----------------|--------------|------------|-------------|--------------|----------------------------------------------|-----------------|--------------|
| Inhibitory Drug Interaction;                  | Paroxetine     |              |            | S           | Unknown      | 40 Mg, Daily                                 |                 | Sun          |
| Off Label Use;                                | Sertraline     |              |            | S           | Unknown      | 100 Mg, Daily                                |                 | Sun          |
| Therapeutic Product                           | Clomipramine   |              |            | S           | Unknown      | 150 Mg, Daily                                |                 | Taro         |
| Ineffective; Therapeutic Response Unexpected; | Luvox          |              |            | S           | Unknown      | 100 Mg, Daily                                |                 | Not Reported |
| Urinary Incontinence                          | Luvox          |              |            | S           | Unknown      | 25 Mg, Daily                                 |                 | Not Reported |
|                                               | Lexapro        |              |            | S           | Unknown      | Dose Increased By 10<br>Mg/Day Every 4 Weeks |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                    | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|-------------------------------------------------------------|---------------------|--------------------|--------------------|-----------------|--------------------------------------------------------|----------------------|-----------------|----------------------|----------------|
| 16-Sep-2016                                                 | 12750358            | EXPEDITED (15-DAY) |                    | OT              | CA-CIPLA LTD.-<br>2016CA18458                          |                      |                 | Unknown              | CAN            |
| <u>Preferred Term</u>                                       | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Drug Interaction;<br>Electrocardiogram Qt<br>Prolonged      | Escitalopram        |                    |                    | S               | Unknown                                                | Unk                  |                 | Invagen              |                |
|                                                             | Haloperidol         |                    |                    | S               | Unknown                                                | Unk                  |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                    | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 16-Sep-2016                                                 | 12750748            | EXPEDITED (15-DAY) |                    | OT              | CA-CIPLA LTD.-<br>2016CA18456                          |                      |                 | Unknown              | CAN            |
| <u>Preferred Term</u>                                       | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Drug Interaction;<br>Electrocardiogram Qt<br>Prolonged      | Escitalopram        |                    |                    | S               | Unknown                                                | Unk                  |                 | Invagen              |                |
|                                                             | Fluconazole         |                    |                    | S               | Unknown                                                | Unk                  |                 | Cipla                |                |
| <u>FDA Received Date</u>                                    | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 17-Sep-2016                                                 | 12756791            | EXPEDITED (15-DAY) |                    | HO              | IT-AUROBINDO-AUR-<br>APL-2016-11710                    |                      | 32 YR           | Female               | ITA            |
| <u>Preferred Term</u>                                       | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Coma; Drug Abuse;<br>Psychomotor<br>Hyperactivity; Vomiting | Lorazepam           |                    |                    | S               | Oral                                                   | Total                |                 | Not Reported         |                |
|                                                             | Quetiapine          |                    |                    | S               | Oral                                                   | Total                |                 | Aurobindo            |                |
|                                                             | Entact              |                    |                    | S               | Oral                                                   | Total                |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                    | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 18-Sep-2016                                                 | 11833977            | EXPEDITED (15-DAY) |                    | OT              | CA-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>BMS-2015-084958 |                      | 63 YR           | Male                 | CAN            |
| <u>Preferred Term</u>                                       | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Serotonin Syndrome                                          | Abilify             |                    |                    | S               | Oral                                                   | 2 Mg, Qd             |                 | Bristol Myers Squibb |                |
|                                                             | Cipralex /01588501/ |                    |                    | S               | Unknown                                                | 30 Mg, Qd            |                 | Not Reported         |                |
|                                                             | Cipralex /01588501/ |                    |                    | S               | Unknown                                                | 20 Mg, Qd            |                 | Not Reported         |                |



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| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------|----------------|--------------------|--------------------|-----------------|---------------------------------------|----------------------|-----------------|--------------|----------------|
| 20-Sep-2016               | 10729012       | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2015026350              |                      | 44 YR           | Female       | USA            |
| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity     | Lyrica         |                    |                    | S               |                                       | Unk                  |                 | Pfizer       |                |
|                           | Amoxicillin    |                    |                    | S               |                                       | Unk                  |                 | Pfizer       |                |
|                           | Zyrtec         |                    |                    | S               |                                       | Unk                  |                 | Not Reported |                |
|                           | Biaxin         |                    |                    | S               |                                       | Unk                  |                 | Not Reported |                |
|                           | Lexapro        |                    |                    | S               |                                       | Unk                  |                 | Not Reported |                |
|                           | Penicillin Nos |                    |                    | S               |                                       | Unk                  |                 | Not Reported |                |
|                           | Cymbalta       |                    |                    | S               |                                       | Unk                  |                 | Not Reported |                |
|                           | Cipro          |                    |                    | S               |                                       | Unk                  |                 | Not Reported |                |
|                           | Acyclovir      |                    |                    | S               |                                       | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Sep-2016               | 12401577       | EXPEDITED (15-DAY) |                    | HO, LT          | FR-SA-2016SA098601                    |                      | 77 YR           | Female       | FRA            |
| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Interstitial Lung Disease | Rifadine       |                    |                    | S               | Intravenous (not otherwise specified) |                      |                 | Not Reported |                |
|                           | Calciparine    |                    |                    | S               | Subcutaneous                          |                      |                 | Not Reported |                |
|                           | Azactam        |                    |                    | S               | Intravenous (not otherwise specified) |                      |                 | Not Reported |                |
|                           | Cubicin        |                    |                    | S               | Intravenous (not otherwise specified) |                      |                 | Not Reported |                |
|                           | Metronidazole  |                    |                    | S               | Intravenous (not otherwise specified) |                      |                 | Not Reported |                |
|                           | Pravastatine   |                    |                    | S               | Unknown                               |                      |                 | Not Reported |                |
|                           | Pravastatine   |                    |                    | S               | Oral                                  |                      |                 | Not Reported |                |
|                           | Escitalopram   |                    |                    | S               | Unknown                               |                      |                 | Not Reported |                |

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|                                |   |         |             |              |
|--------------------------------|---|---------|-------------|--------------|
| Escitalopram                   | S | Oral    |             | Not Reported |
| Allopurinol                    | S | Unknown |             | Not Reported |
| Allopurinol                    | S | Oral    |             | Not Reported |
| Allopurinol                    | S | Oral    |             | Not Reported |
| Nebivolol                      | S | Oral    |             | Not Reported |
| Hydrochlorothiazide/Irbesartan | S | Oral    | 300/12.5mg  | Not Reported |
| Hydrochlorothiazide/Irbesartan | S | Oral    | 150/12.5 Mg | Not Reported |
| Simvastatin                    | C |         |             | Not Reported |
| Seresta                        | C |         |             | Not Reported |
| Inexium                        | C |         |             | Not Reported |
| Voltarene (Diclofenac Sodium)  | C |         |             | Not Reported |

| <u>FDA Received Date</u>                                                                                                                                                                       | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|--------------------|--------------------|-----------------|--------------------------|-------------------------------|-----------------|--------------|----------------|
| 20-Sep-2016                                                                                                                                                                                    | 12704283           | EXPEDITED (15-DAY) |                    | HO              | FR-ASTELLAS-2016US033394 |                               | 47 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                          | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Cerebral Ischaemia; Gamma-Glutamyltransferase Increased; Hepatitis Cholestatic | Advagraf           |                    |                    | S               | Oral                     | Unk Unk, Unknown Freq.        |                 | Astellas     |                |
|                                                                                                                                                                                                | Advagraf           |                    |                    | S               | Oral                     |                               |                 | Astellas     |                |
|                                                                                                                                                                                                | Advagraf           |                    |                    | S               | Oral                     | Unk Unk, Unknown Freq.        |                 | Astellas     |                |
|                                                                                                                                                                                                | Atorvastatin       |                    |                    | S               | Oral                     |                               |                 | Not Reported |                |
|                                                                                                                                                                                                | Xanax              |                    |                    | S               | Oral                     | Unk, Unknown Freq.            |                 | Not Reported |                |
|                                                                                                                                                                                                | Xanax              |                    |                    | S               | Oral                     | Increased Dose, Unknown Freq. |                 | Not Reported |                |
|                                                                                                                                                                                                | Inexium /01479302/ |                    |                    | S               | Oral                     | Unk Unk, Unknown Freq.        |                 | Not Reported |                |
|                                                                                                                                                                                                | Inexium /01479302/ |                    |                    | S               | Oral                     |                               |                 | Not Reported |                |
|                                                                                                                                                                                                | Seroplex           |                    |                    | S               | Oral                     | Unk, Unknown Freq.            |                 | Not Reported |                |
|                                                                                                                                                                                                | Seroplex           |                    |                    | S               | Oral                     | Increased Dose, Unknown Freq. |                 | Not Reported |                |
|                                                                                                                                                                                                | Bisoprolol         |                    |                    | C               | Unknown                  | Unk, Unknown Freq.            |                 | Not Reported |                |
|                                                                                                                                                                                                | Triatec /00885601/ |                    |                    | C               | Unknown                  | Unk Unk, Unknown Freq.        |                 | Not Reported |                |
|                                                                                                                                                                                                | Kayexalate         |                    |                    | C               | Unknown                  | Unk, Unknown Freq.            |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                     |                |                    |                    |                 |                            |                                   |                 |              |                |
|---------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------------|-----------------------------------|-----------------|--------------|----------------|
| Cellcept /01275104/                                                 |                |                    | C                  | Unknown         | Unk, Unknown Freq.         |                                   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Sep-2016                                                         | 12761048       | EXPEDITED (15-DAY) |                    | HO              | HR-ROCHE-1831565           |                                   |                 | Female       | HRV            |
| <u>Preferred Term</u>                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Overdose;<br>Poisoning; Suicide Attempt                 | Rivotril       |                    |                    | S               | Oral                       | 30-40 Tbl, Once, Strength Unknown |                 | Not Reported |                |
|                                                                     | Nozinan        |                    |                    | S               | Oral                       | 10 Tbl, Once, Strength Unknown    |                 | Not Reported |                |
|                                                                     | Sanval         |                    |                    | S               | Oral                       | 30 Tbl, Once, Strength Unknown    |                 | Not Reported |                |
|                                                                     | Citram         |                    |                    | S               | Oral                       | Once                              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Sep-2016                                                         | 12761665       | EXPEDITED (15-DAY) |                    | HO, OT          | FR-ASTRAZENECA-2016SE97384 |                                   | 84 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |                |
| Bile Duct Stone; Drug-Induced Liver Injury; Hepatic Mass; Hepatitis | Inexium        |                    |                    | S               | Oral                       |                                   |                 | Astrazeneca  |                |
|                                                                     | Seroplex       |                    |                    | S               | Oral                       |                                   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Sep-2016                                                         | 12762553       | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000087570          |                                   | 56 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |                |
| Seizure                                                             | Escitalopram   |                    |                    | S               | Oral                       | 5 Mg                              |                 | Forest       |                |
|                                                                     | Loperamide     |                    |                    | S               | Oral                       | 6 Mg                              |                 | Not Reported |                |
|                                                                     | Tanganil       |                    |                    | S               | Oral                       | 1500 Mg                           |                 | Not Reported |                |
|                                                                     | Doliprane      |                    |                    | S               | Oral                       | Daily Dose Not Reported           |                 | Not Reported |                |
|                                                                     | Kenacort       |                    |                    | S               | Unknown                    | Daily Dose Not Reported           |                 | Not Reported |                |
|                                                                     | Lemoxil Roche  |                    |                    | S               | Oral                       | Daily Dose Not Reported           |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                 | <u>Case #</u>                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------|---------------------------------------------|--------------------|--------------------|-----------------|-----------------------|-------------------------|-----------------|--------------|----------------|
| 20-Sep-2016                                              | 12762899                                    | EXPEDITED (15-DAY) |                    | HO, LT          | CH-JNJFOC-20160919838 |                         | 90 YR           | Male         | CHE            |
| <u>Preferred Term</u>                                    | <u>Product</u>                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Fall; Haematemesis; Potentiating Drug Interaction; Shock | Xarelto                                     |                    |                    | S               | Oral                  |                         |                 | Not Reported |                |
|                                                          | Torem                                       |                    |                    | S               | Oral                  |                         |                 | Not Reported |                |
|                                                          | Escitalopram                                |                    |                    | S               | Oral                  |                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                 | <u>Case #</u>                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Sep-2016                                              | 12763258                                    | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000087601     |                         | 94 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                    | <u>Product</u>                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Anaemia; Muscle Haemorrhage                              | Escitalopram                                |                    |                    | S               | Oral                  | Daily Dose Not Reported |                 | Forest       |                |
|                                                          | Previscan (Fluindione)                      |                    |                    | S               | Oral                  | Daily Dose Not Reported |                 | Not Reported |                |
|                                                          | Lansoprazole                                |                    |                    | C               | Unknown               | Daily Dose Not Reported |                 | Not Reported |                |
|                                                          | Levocetirizine                              |                    |                    | C               | Unknown               | Daily Dose Not Reported |                 | Not Reported |                |
|                                                          | Lorazepam                                   |                    |                    | C               | Unknown               | Daily Dose Not Reported |                 | Not Reported |                |
| <u>FDA Received Date</u>                                 | <u>Case #</u>                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Sep-2016                                              | 12763259                                    | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000087602     |                         | 87 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                    | <u>Product</u>                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Generalised Tonic-Clonic Seizure; Petit Mal Epilepsy     | Escitalopram                                |                    |                    | S               | Oral                  | 10 Mg                   |                 | Forest       |                |
|                                                          | Durogesic                                   |                    |                    | S               | Transdermal           | Daily Dose Not Reported |                 | Not Reported |                |
|                                                          | Alprazolam                                  |                    |                    | C               | Unknown               | Daily Dose Not Reported |                 | Not Reported |                |
|                                                          | Zopiclone                                   |                    |                    | C               | Unknown               | Daily Dose Not Reported |                 | Not Reported |                |
|                                                          | Pantoprazole                                |                    |                    | C               | Unknown               | Daily Dose Not Reported |                 | Not Reported |                |
|                                                          | Meteospasmyl (Alverine Citrate\Dimethicone) |                    |                    | C               | Unknown               | Daily Dose Not Reported |                 | Not Reported |                |
|                                                          | Paracetamol                                 |                    |                    | C               | Unknown               | Daily Dose Not Reported |                 | Not Reported |                |

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| <u>FDA Received Date</u>                  | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                               | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                 | <u>Country</u> |
|-------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------------------------------------|----------------------|-----------------|----------------------------|----------------|
| 20-Sep-2016                               | 12764358       | NON-EXPEDITED    |                    |                 | US-PRINSTON<br>PHARMACEUTICAL<br>INC.-2016PRN00147 |                      |                 | Male                       | USA            |
| <u>Preferred Term</u>                     | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                       | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                 |                |
| Product Substitution Issue;<br>Somnolence | Escitalopram   |                  |                    | S               |                                                    |                      |                 | Prinston<br>Pharmaceutical |                |

| <u>FDA Received Date</u>   | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------|---------------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|-----------------|--------------|----------------|
| 20-Sep-2016                | 12764523            | EXPEDITED (15-DAY) |                    | OT              | DK-ASTRAZENECA-<br>2016SE97037 |                      | 17 YR           | Female       | DNK            |
| <u>Preferred Term</u>      | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain; Anger;     | Seroquel            |                    |                    | S               | Oral                           |                      |                 | Zeneca       |                |
| Anxiety; Asthenia;         | Seroquel            |                    |                    | S               | Oral                           |                      |                 | Zeneca       |                |
| Asthenia; Bronchitis;      | Seroquel            |                    |                    | S               | Oral                           |                      |                 | Zeneca       |                |
| Decreased Immune           | Abilify             |                    |                    | S               | Unknown                        |                      |                 | Not Reported |                |
| Responsiveness;            | Venlafaxin          |                    |                    | S               | Oral                           |                      |                 | Not Reported |                |
| Depressed Mood;            | Ciprallex           |                    |                    | S               | Oral                           |                      |                 | Not Reported |                |
| Derealisation; Diarrhoea;  | Circadin            |                    |                    | S               | Oral                           |                      |                 | Not Reported |                |
| Disturbance In Sexual      | Lyrica              |                    |                    | S               | Oral                           |                      |                 | Not Reported |                |
| Arousal; Drug Ineffective; | Serdolect           |                    |                    | S               | Oral                           | 4 - 12 -16 Mg.       |                 | Not Reported |                |
| Fatigue; Fungal Infection; | Solian              |                    |                    | S               | Oral                           |                      |                 | Not Reported |                |
| Gastrointestinal Disorder; | Truxal              |                    |                    | S               | Oral                           |                      |                 | Not Reported |                |
| Hallucination;             | Zyprexa             |                    |                    | S               | Oral                           |                      |                 | Not Reported |                |
| Hallucination, Auditory;   | Pulmicort           |                    |                    | C               |                                |                      |                 | Not Reported |                |
| Hallucination, Visual;     | Bricanyl Turbuhaler |                    |                    | C               |                                |                      |                 | Not Reported |                |
| Hypersomnia; Impaired      | Seretide            |                    |                    | C               |                                |                      |                 | Not Reported |                |
| Reasoning; Impulsive       | Canesten            |                    |                    | C               |                                |                      |                 | Not Reported |                |
| Behaviour; Insomnia;       | Brentan             |                    |                    | C               |                                |                      |                 | Not Reported |                |
| Irritable Bowel Syndrome;  | Nizoral             |                    |                    | C               |                                |                      |                 | Not Reported |                |
| Lung Infection;            | Cetirizin           |                    |                    | C               |                                |                      |                 | Not Reported |                |
| Nasopharyngitis; Nausea;   | Telfast             |                    |                    | C               |                                |                      |                 | Not Reported |                |
| Nightmare; Otitis Media;   | Depo-Medrol         |                    |                    | C               |                                |                      |                 | Not Reported |                |
| Pain; Personality Change;  |                     |                    |                    |                 |                                |                      |                 |              |                |
| Restlessness; Sleep        |                     |                    |                    |                 |                                |                      |                 |              |                |
| Disorder; Sleep Paralysis; |                     |                    |                    |                 |                                |                      |                 |              |                |
| Suicidal Ideation;         |                     |                    |                    |                 |                                |                      |                 |              |                |
| Violence-Related           |                     |                    |                    |                 |                                |                      |                 |              |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                     |              |   |      |              |
|---------------------|--------------|---|------|--------------|
| Symptom; Weight     | Depo-Provera | C |      | Not Reported |
| Fluctuation; Weight | Tradolan     | C | Oral | Not Reported |
| Increased           | Dolol        | C | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 20-Sep-2016              | 12764607      | EXPEDITED (15-DAY) |                    | OT              | DK-<br>ELI_LILLY_AND_COMP<br>ANY-DK201609005087 |                      | 17 YR      | Female     | DNK            |

| <u>Preferred Term</u>       | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>       |
|-----------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------------|
| Abdominal Pain; Anger;      | Zyprexa              |              |            | S           | Oral         | Unk Unk, Prn       |                 | Eli Lilly And Co |
| Anxiety; Asthenia;          | Seroquel             |              |            | S           | Oral         | Unk, Prn           |                 | Not Reported     |
| Bronchitis; Decreased       | Truxal /00012101/    |              |            | S           | Oral         | Unk, Prn           |                 | Not Reported     |
| Immune Responsiveness;      | Serdolect            |              |            | S           | Oral         | Unk, Prn           |                 | Not Reported     |
| Depressed Mood;             | Serdolect            |              |            | S           | Oral         | 12 Mg, Prn         |                 | Not Reported     |
| Derealisation; Diarrhoea;   | Serdolect            |              |            | S           | Oral         | 16 Mg, Prn         |                 | Not Reported     |
| Disturbance In Sexual       | Solian               |              |            | S           | Oral         | Unk, Unknown       |                 | Not Reported     |
| Arousal; Drug Ineffective;  | Abilify              |              |            | S           | Unknown      | Unk, Unknown       |                 | Not Reported     |
| Fatigue; Fungal Skin        | Cipralext /01588501/ |              |            | S           | Oral         | Unk, Unknown       |                 | Not Reported     |
| Infection; Gastrointestinal | Circadin             |              |            | S           | Oral         | Unk, Unknown       |                 | Not Reported     |
| Disorder; General Physical  | Lyrica               |              |            | S           | Oral         | Unk, Unknown       |                 | Not Reported     |
| Condition Abnormal;         | Seroquel             |              |            | S           | Oral         | Unk, Prn           |                 | Not Reported     |
| Genital Infection Fungal;   | Venlafaxin Actavis   |              |            | S           | Oral         | Unk, Unknown       |                 | Not Reported     |
| Hallucination;              | Pulmicort            |              |            | C           | Unknown      | Unk, Unknown       |                 | Not Reported     |
| Hallucination, Auditory;    | Bricanyl Turbuhaler  |              |            | C           | Unknown      | Unk, Unknown       |                 | Not Reported     |
| Hallucination, Visual;      | Seretide             |              |            | C           | Unknown      | Unk, Unknown       |                 | Not Reported     |
| Hypersomnia; Impaired       | Canesten             |              |            | C           | Unknown      | Unk, Unknown       |                 | Not Reported     |
| Reasoning; Impulse-         | Brentan /00310801/   |              |            | C           | Unknown      | Unk, Unknown       |                 | Not Reported     |
| Control Disorder;           | Nizoral              |              |            | C           | Unknown      | Unk, Unknown       |                 | Not Reported     |
| Impulsive Behaviour;        | Cetirizin Actavis    |              |            | C           | Unknown      | Unk, Unknown       |                 | Not Reported     |
| Insomnia; Irritable Bowel   | Telfast              |              |            | C           | Unknown      | Unk, Unknown       |                 | Not Reported     |
| Syndrom; Libido             |                      |              |            |             |              |                    |                 |                  |
| Disorder; Lung Infection;   |                      |              |            |             |              |                    |                 |                  |
| Nasopharyngitis; Nausea;    |                      |              |            |             |              |                    |                 |                  |
| Nightmare; Otitis Media;    |                      |              |            |             |              |                    |                 |                  |
| Pain; Personality Change;   |                      |              |            |             |              |                    |                 |                  |
| Restlessness; Sleep         |                      |              |            |             |              |                    |                 |                  |
| Disorder; Sleep Paralysis;  |                      |              |            |             |              |                    |                 |                  |
| Suicidal Ideation;          |                      |              |            |             |              |                    |                 |                  |
| Violence-Related            |                      |              |            |             |              |                    |                 |                  |
| Symptom; Weight             |                      |              |            |             |              |                    |                 |                  |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                               |                  |   |         |              |              |
|-------------------------------|------------------|---|---------|--------------|--------------|
| Fluctuation; Weight Increased | Depo-Medrol      | C | Unknown | Unk, Unknown | Not Reported |
|                               | Depo-Provera     | C | Unknown | Unk, Unknown | Not Reported |
|                               | Tradolan         | C | Oral    | Unk, Unknown | Not Reported |
|                               | Dolol /00020001/ | C | Oral    | Unk, Unknown | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Sep-2016              | 12771537      | DIRECT           | Y                  |                 |                      |                      | 67 YR      | Male       | USA            |

| <u>Preferred Term</u>                          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Bradycardia;<br>Electrocardiogram Qt Prolonged | Escitalopram   |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Sep-2016              | 10467701      | EXPEDITED (15-DAY) |                    | LT              | FR-FRI-1000070838    |                      | 42 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                                                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|-------------------------|-----------------|--------------|
| Confusional State;<br>Hallucination; Intentional Overdose; Neuroleptic Malignant Syndrome | Escitalopram   |              |            | S           |              | Overdose Of 20 Df Once  |                 | Forest       |
|                                                                                           | Baclofene      |              |            | S           | Oral         | Overdose Of 140 Df Once |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Sep-2016              | 11239649      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000077877    |                      | 91 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                        | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------|-------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anaemia; Drug Interaction;<br>Gastric Ulcer;<br>Gastrointestinal Haemorrhage | Escitalopram      |              |            | S           | Oral         | 5 Mg               |                 | Forest       |
|                                                                              | Kardegic          |              |            | S           | Oral         | 75 Mg              |                 | Not Reported |
|                                                                              | Fosamax           |              |            | C           | Oral         | 70 Mg              |                 | Not Reported |
|                                                                              | Levothyrox        |              |            | C           | Oral         | 50 Microgram       |                 | Not Reported |
|                                                                              | Candesartan Mylan |              |            | C           | Oral         | 8 Mg               |                 | Not Reported |
|                                                                              | Bisoprolol Arrow  |              |            | C           | Oral         | 10 Mg              |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                    |   |      |       |              |
|------------------------------------|---|------|-------|--------------|
| Seresta                            | C | Oral | 10 Mg | Not Reported |
| Loxen (Niacardipine Hydrochloride) | C | Oral | 40 Mg | Not Reported |
| Inexium                            | C | Oral | 40 Mg | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Sep-2016              | 12365448      | EXPEDITED (15-DAY) |                    | HO, LT          | JP-FRI-1000083337    |                      | 82 YR      | Female     | JPN            |

| <u>Preferred Term</u>                                    | <u>Product</u>   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                          | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------|------------------|--------------|------------|-------------|---------------------------------------|--------------------|-----------------|--------------|
| Electrocardiogram Qt Prolonged; Ventricular Fibrillation | Escitalopram     |              |            | S           | Oral                                  | 10 Mg              |                 | Forest       |
|                                                          | Olmotec          |              |            | S           | Oral                                  | 20 Mg              |                 | Not Reported |
|                                                          | Myslee           |              |            | S           | Oral                                  | 10 Mg              |                 | Not Reported |
|                                                          | Depas (Etizolam) |              |            | S           | Oral                                  | 0.5 Mg             |                 | Not Reported |
|                                                          | Kakkonto         |              |            | C           | Oral                                  |                    |                 | Not Reported |
|                                                          | Calonal          |              |            | C           | Oral                                  |                    |                 | Not Reported |
|                                                          | Mohrus Tape      |              |            | C           | Transdermal                           |                    |                 | Not Reported |
|                                                          | Neurotropin      |              |            | C           | Intravenous (not otherwise specified) | Unit Dose: 3.6 Ut  |                 | Not Reported |
|                                                          | Claritin         |              |            | C           | Oral                                  |                    |                 | Not Reported |
|                                                          | Yokukansan       |              |            | C           | Oral                                  |                    |                 | Not Reported |
|                                                          | Meilax           |              |            | C           | Oral                                  |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Sep-2016              | 12627186      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000086671    |                      | 22 YR      | Female     | FRA            |

| <u>Preferred Term</u>         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------|----------------|--------------|------------|-------------|--------------|----------------------------------------|-----------------|--------------|
| Dry Mouth; Miosis; Somnolence | Escitalopram   |              |            | S           | Oral         | 10 Mg                                  |                 | Forest       |
|                               | Escitalopram   |              |            | S           | Oral         | Overdose: Escitalopram 280 Mg At Once. |                 | Forest       |
|                               | Doxylamine     |              |            | S           | Oral         |                                        |                 | Not Reported |
|                               | Nocertone      |              |            | S           | Oral         |                                        |                 | Not Reported |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|             |   |         |                                                          |
|-------------|---|---------|----------------------------------------------------------|
| Codeine     | S | Oral    | Not Reported                                             |
| Paracetamol | C | Oral    | Not Reported                                             |
| Ketoprofene | C | Oral    | Not Reported                                             |
| Ketoprofene | C | Oral    | Overdose: Ketoprofene<br>700 Mg At Once.<br>Not Reported |
| Jasminelle  | C | Unknown | Not Reported                                             |

| <u>FDA Received Date</u>                                               | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 21-Sep-2016                                                            | 12765260       | NON-EXPEDITED    |                    |                 | AU-LUPIN<br>PHARMACEUTICALS<br>INC.-2016-03254 |                      | 34 YR           | Male         | AUS            |
| <u>Preferred Term</u>                                                  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Dreams; Drug<br>Interaction; Sleep-Related<br>Eating Disorder | Zolpidem       |                  |                    | S               | Unknown                                        |                      |                 | Not Reported |                |
|                                                                        | Escitalopram   |                  |                    | S               | Unknown                                        |                      |                 | Not Reported |                |
|                                                                        | Zolpidem       |                  |                    | S               | Unknown                                        |                      |                 | Not Reported |                |
|                                                                        | Oxycodone      |                  |                    | C               | Unknown                                        |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                    | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------|---------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| 21-Sep-2016                                                 | 12766661            | EXPEDITED (15-DAY) |                    | HO              | IT-PFIZER INC-<br>2016431183 |                      | 32 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                       | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Coma; Drug Abuse;<br>Psychomotor<br>Hyperactivity; Vomiting | Lorazepam           |                    |                    | S               | Oral                         | Total                |                 | Pfizer       |                |
|                                                             | Quetiapine Fumarate |                    |                    | S               | Oral                         | Total                |                 | Not Reported |                |
|                                                             | Entact              |                    |                    | S               | Oral                         | Total                |                 | Not Reported |                |

| <u>FDA Received Date</u>                                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
| 21-Sep-2016                                                           | 12767770       | EXPEDITED (15-DAY) |                    | HO, LT          | CZ-JNJFOC-<br>20160811600 |                      | 82 YR           | Female       | CZE            |
| <u>Preferred Term</u>                                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Chest Wall Haematoma;<br>Dehydration; Fall;<br>Hyponatraemia; Syncope | Fentanyl       |                    |                    | S               | Transdermal               |                      |                 | Not Reported |                |
|                                                                       | Tramadol       |                    |                    | S               | Unknown                   | 1-0-1                |                 | Not Reported |                |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                            |   |         |                      |              |
|--------------------------------------------|---|---------|----------------------|--------------|
| Tiaprid                                    | S | Unknown | 0-0-0-1              | Not Reported |
| Metamizole                                 | S | Unknown | 2-2-2                | Not Reported |
| Nitrendipin                                | S | Unknown | 1-0-0                | Not Reported |
| Bromazepam                                 | S | Unknown | 1/2-0-0              | Not Reported |
| Omeprazole                                 | S | Unknown | 1-0-0                | Not Reported |
| Furosemide                                 | S | Unknown | 1-0-0                | Not Reported |
| Levothyroxine                              | S | Unknown | 1-0-0                | Not Reported |
| Escitalopram                               | S | Unknown | 1-0-0                | Not Reported |
| Atorvastatin                               | S | Unknown | 0-0-1/2              | Not Reported |
| Perindopril                                | S | Unknown | 1-0-1                | Not Reported |
| Isosorbid Dinitrate                        | S | Unknown |                      | Not Reported |
| Amiloride Hydrochloride<br>W/Chlortalidone | S | Unknown | 25 Mg/2.5 Mg (1-0-1) | Not Reported |
| Rivaroxaban                                | C | Unknown | 1-0-0                | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Sep-2016              | 12767789      | EXPEDITED (15-DAY) | HO                 |                 | FR-FRI-1000087628    |                      | 89 YR      | Female     | FRA            |

  

| <u>Preferred Term</u>                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------|----------------|--------------|------------|-------------|--------------|-------------------------|-----------------|--------------|
| Asthenia;<br>Hypochloraemia;<br>Hyponatraemia | Escitalopram   |              |            | S           | Oral         | 10 Mg                   |                 | Forest       |
|                                               | Valsartan      |              |            | S           | Oral         | Daily Dose Not Reported |                 | Not Reported |
|                                               | Eupantol       |              |            | S           | Oral         | 40 Mg                   |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Sep-2016              | 12767873      | EXPEDITED (15-DAY) | HO                 |                 | IT-FRI-1000087606    |                      | 66 YR      | Female     | ITA            |

  

| <u>Preferred Term</u>                                         | <u>Product</u>                             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------|--------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Coma; Drug Abuse;<br>Intentional Overdose;<br>Suicide Attempt | Escitalopram                               |              |            | S           | Oral         |                    |                 | Forest       |
|                                                               | Escitalopram                               |              |            | S           | Oral         | Overdose: 560 Mg   |                 | Forest       |
|                                                               | Minias 2.5 Mg/MI Gocce Orali,<br>Soluzione |              |            | S           | Oral         |                    |                 | Not Reported |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                          |   |      |                   |              |
|--------------------------------------------------------------------------|---|------|-------------------|--------------|
| Minias 2.5 Mg/ML Gocce Orali,<br>Soluzione                               | S | Oral | Overdose: 50 Mg   | Not Reported |
| Trittico 150 Mg Compresse<br>Rivestite Con Film A Rilascio<br>Prolungato | S | Oral |                   | Not Reported |
| Trittico 150 Mg Compresse<br>Rivestite Con Film A Rilascio<br>Prolungato | S | Oral | Overdose: 2100 Mg | Not Reported |
| Solian 200 Mg Compresse                                                  | C | Oral |                   | Not Reported |
| Solian 200 Mg Compresse                                                  | C | Oral |                   | Not Reported |
| Levopraid 25 Mg/ML Gocce Orali<br>Soluzione                              | C | Oral |                   | Not Reported |
| Vantavo 70 Mg/5600 Ui<br>Compresse                                       | C | Oral |                   | Not Reported |
| Vantavo 70 Mg/5600 Ui<br>Compresse                                       | C | Oral |                   | Not Reported |
| Tolep 300 Mg Compresse                                                   | C | Oral |                   | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Sep-2016              | 12767874      | EXPEDITED (15-DAY) |                    | OT              | SE-FRI-1000087590    |                      |            | Male       | SWE            |

  

| <u>Preferred Term</u>       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Inhibitory Drug Interaction | Escitalopram   |              |            | S           | Unknown      | 20 Mg              |                 | Forest       |
|                             | Corsodyl       |              |            | S           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Sep-2016              | 12768237      | EXPEDITED (15-DAY) |                    | HO, OT          | HR-TEVA-692643ACC    |                      |            | Female     | HRV            |

  

| <u>Preferred Term</u>                                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Intentional Overdose;<br>Somnolence; Suicide<br>Attempt | Ladiomil       |              |            | S           | Oral         |                    |                 | Actavis      |
|                                                         | Normabel       |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                         | Elicea         |              |            | S           | Oral         |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                       | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|------------------------------------------------|---------------------|--------------------|--------------------|-----------------|--------------------------------------------------------|----------------------|-----------------|----------------------|----------------|
| 21-Sep-2016                                    | 12768360            | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000087642                                      |                      | 38 YR           | Male                 | FRA            |
| <u>Preferred Term</u>                          | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Poisoning Deliberate;<br>Somnolence            | Escitalopram        |                    |                    | S               | Oral                                                   |                      |                 | Forest               |                |
|                                                | Alprazolam          |                    |                    | S               | Oral                                                   |                      |                 | Not Reported         |                |
| <u>FDA Received Date</u>                       | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 21-Sep-2016                                    | 12768610            | EXPEDITED (15-DAY) |                    | OT              | US-FRI-1000080935                                      |                      |                 | Male                 | USA            |
| <u>Preferred Term</u>                          | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Neuromyopathy; Suicidal<br>Ideation            | Escitalopram        |                    |                    | S               | Unknown                                                |                      |                 | Forest               |                |
|                                                | Escitalopram        |                    |                    | S               | Unknown                                                |                      |                 | Forest               |                |
| <u>FDA Received Date</u>                       | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 21-Sep-2016                                    | 12768614            | EXPEDITED (15-DAY) |                    |                 | JP-FRI-1000080680                                      |                      | 80 YR           | Female               | JPN            |
| <u>Preferred Term</u>                          | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Seizure                                        | Lexapro             |                    |                    | S               | Oral                                                   | 10 Mg                |                 | Forest               |                |
|                                                | Depas (Etizolam)    |                    |                    | C               | Oral                                                   |                      |                 | Not Reported         |                |
| <u>FDA Received Date</u>                       | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 22-Sep-2016                                    | 12414641            | EXPEDITED (15-DAY) |                    | HO, LT, OT      | FR-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>BMS-2016-040279 |                      | 77 YR           | Female               | FRA            |
| <u>Preferred Term</u>                          | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Interstitial Lung Disease;<br>Renal Impairment | Azactam             |                    |                    | S               | Intravenous (not<br>otherwise specified)               | 500 Mg, Tid          |                 | Bristol Myers Squibb |                |
|                                                | Rifadine /00146901/ |                    |                    | S               | Intravenous (not<br>otherwise specified)               | 600 Mg, Bid          |                 | Not Reported         |                |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                       |   |                                       |             |              |
|-----------------------|---|---------------------------------------|-------------|--------------|
| Calciparine           | S | Subcutaneous                          | 0.2 MI, Bid | Not Reported |
| Cubicin               | S | Intravenous (not otherwise specified) | Unk         | Not Reported |
| Metronidazole B Braun | S | Intravenous (not otherwise specified) | 500 Mg, Tid | Not Reported |
| Pravastatin Arrow     | S | Oral                                  | 20 Mg, Qd   | Not Reported |
| Escitalopram Arrow    | S | Oral                                  | 10 Mg, Qd   | Not Reported |
| Allopurinol Arrow     | S | Oral                                  | 200 Mg, Qd  | Not Reported |
| Allopurinol Arrow     | S | Oral                                  | 100 Mg, Qd  | Not Reported |
| Nebivolol Arrow       | S | Oral                                  | 2.5 Mg, Qd  | Not Reported |
| Simvastatine          | C | Unknown                               | 20 Mg, Qd   | Not Reported |
| Seresta               | C | Unknown                               | 10 Mg, Qd   | Not Reported |
| Inexium /01479302/    | C | Unknown                               | 20 Mg, Qd   | Not Reported |
| Voltarene /00372302/  | C | Unknown                               | 75 Mg, Qd   | Not Reported |

| <u>FDA Received Date</u>                                                                                                                                                                   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|---------------------------------------------|----------------------|-----------------|------------------|----------------|
| 22-Sep-2016                                                                                                                                                                                | 12439178             | EXPEDITED (15-DAY) |                    | DS, HO, LT, OT  | NO-ELI_LILLY_AND_COMP<br>ANY-NO201606000159 |                      | 28 YR           | Female           | NOR            |
| <u>Preferred Term</u>                                                                                                                                                                      | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |
| Breath Odour; Facial Asymmetry; Gait Disturbance; Head Discomfort; Muscle Spasms; Musculoskeletal Stiffness; Parkinson'S Disease; Personality Change; Shoulder Deformity; Weight Increased | Zyprexa Velotab      |                    |                    | S               | Unknown                                     | Unk, Unknown         |                 | Eli Lilly And Co |                |
|                                                                                                                                                                                            | Abilify              |                    |                    | S               | Unknown                                     | Unk, Unknown         |                 | Not Reported     |                |
|                                                                                                                                                                                            | Xeplion              |                    |                    | S               | Unknown                                     | Unk, Unknown         |                 | Not Reported     |                |
|                                                                                                                                                                                            | Ciprallex /01588501/ |                    |                    | S               | Unknown                                     | Unk, Unknown         |                 | Not Reported     |                |
|                                                                                                                                                                                            | Risperdal            |                    |                    | S               | Unknown                                     | Unk, Unknown         |                 | Not Reported     |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Sep-2016              | 12502305      | EXPEDITED (15-DAY) |                    | HO              | CH-FRI-1000085630    |                      | 23 YR      | Female     | CHE            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>   | <u>Product</u>                                                                                                                    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------|-----------------------------------------------------------------------------------------------------------------------------------|--------------|------------|-------------|--------------|---------------------|-----------------|--------------|
| Epilepsy; Hyponatraemia | Escitalopram                                                                                                                      |              |            | S           | Unknown      |                     |                 | Forest       |
|                         | Escitalopram                                                                                                                      |              |            | S           | Unknown      |                     |                 | Forest       |
|                         | Escitalopram                                                                                                                      |              |            | S           | Oral         | 20 Mg               |                 | Not Reported |
|                         | Temesta (Lorazepam)                                                                                                               |              |            | S           | Oral         | 2/24 H, As Required |                 | Not Reported |
|                         | Leponex (Clozapine)                                                                                                               |              |            | S           | Oral         | 300 Mg              |                 | Not Reported |
|                         | Leponex (Clozapine)                                                                                                               |              |            | S           | Unknown      | 400 Mg              |                 | Not Reported |
|                         | Linomed (Senna Alexandria/Linum Usitatissimum Seed/Rhamnus Frangula Ba Redormin (Valeriana Officinalis Root/Humulus Lupulus Hops) |              |            | C           | Oral         |                     |                 | Not Reported |
|                         |                                                                                                                                   |              |            | C           | Oral         | 1 Dosage Form       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 22-Sep-2016              | 12745011      | EXPEDITED (15-DAY) |                    | OT              | US-CIPLA LTD.-2016US05060 |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>                                                                                                                                                                       | <u>Product</u>  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|--------------|------------|-------------|--------------|--------------------------|-----------------|--------------|
| Amnesia; Anger; Crying; Depression; Drug Ineffective; Emotional Disorder; Fatigue; Feeling Abnormal; Loss Of Consciousness; Nervousness; Pain; Sedation; Weight Increased; Weight Loss Poor | Escitalopram    |              |            | S           | Oral         | Unk, Bid, 10 Mid         |                 | Invagen      |
|                                                                                                                                                                                             | Escitalopram    |              |            | S           | Oral         | 10 Mg, Qd                |                 | Invagen      |
|                                                                                                                                                                                             | Cyclobenzaprine |              |            | S           | Unknown      | Unk, Prn                 |                 | Invagen      |
|                                                                                                                                                                                             | Lyrica          |              |            | S           | Unknown      | 75 Mg, Bid, Two Capsules |                 | Not Reported |
|                                                                                                                                                                                             | Lyrica          |              |            | S           | Unknown      | 10 Mg, Bid               |                 | Not Reported |
|                                                                                                                                                                                             | Propranolol     |              |            | S           | Oral         | 10 Mg, Qd At Night       |                 | Not Reported |
|                                                                                                                                                                                             | Diazepam        |              |            | S           | Oral         | 10 Mg, Tid               |                 | Not Reported |
|                                                                                                                                                                                             | Singulair       |              |            | S           | Unknown      | Unk                      |                 | Not Reported |
|                                                                                                                                                                                             | Synthroid       |              |            | S           | Oral         | Unk, 1 Tablet, Qd        |                 | Not Reported |
|                                                                                                                                                                                             | Tramadol        |              |            | S           | Oral         | 50 Mg, 6 Hourly, Prn     |                 | Not Reported |
|                                                                                                                                                                                             | Effexor         |              |            | S           | Oral         | 10 Mg, Bid               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 22-Sep-2016              | 12769634      | EXPEDITED (15-DAY) |                    | HO, LT          | CA-ORCHID HEALTHCARE-1057560 |                      | 39 YR      | Male       | CAN            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                               | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Arrhythmia; Device<br>Related Sepsis; Overdose;<br>Pneumonia; Serotonin<br>Syndrome | Olanzapine          |              |            | S           | Unknown      |                    |                 | Orchid       |
|                                                                                     | Bupropion           |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                     | Escitalopram        |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                     | Quetiapine Fumarate |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                     | Phenytoin           |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                     | Primidone           |              |            | S           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Sep-2016              | 12769953      | EXPEDITED (15-DAY) |                    | HO              | TW-ACCORD-044138     |                      | 22 YR      | Female     | TWN            |

| <u>Preferred Term</u>   | <u>Product</u>                         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------|----------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction; Mania | Escitalopram                           |              |            | S           |              |                    |                 | Accord       |
|                         | Dextromethorphan                       |              |            | S           | Oral         |                    |                 | Not Reported |
|                         | Ambroxol/Ambroxol                      |              |            | C           |              |                    |                 | Not Reported |
|                         | Acefyllinate/Ambroxol<br>Hydrochloride |              |            |             |              |                    |                 |              |
|                         | Paracetamol                            |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Sep-2016              | 12772029      | EXPEDITED (15-DAY) |                    | OT              | DK-TEVA-693414ACC    |                      | 17 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                          | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|------------------------|-----------------|--------------|
| Abdominal Pain; Anger;<br>Anxiety; Asthenia;<br>Asthenia; Bronchitis;<br>Decreased Immune<br>Responsiveness;<br>Delusion; Depressed<br>Mood; Derealisation;<br>Diarrhoea; Disturbance In<br>Sexual Arousal; Drug<br>Ineffective; Fatigue;<br>Fungal Infection; | Venlafaxin "Actavis" |              |            | S           | Oral         |                        |                 | Teva         |
|                                                                                                                                                                                                                                                                | Abilify              |              |            | S           |              |                        |                 | Not Reported |
|                                                                                                                                                                                                                                                                | Cipralax             |              |            | S           | Oral         |                        |                 | Not Reported |
|                                                                                                                                                                                                                                                                | Circadin             |              |            | S           | Oral         |                        |                 | Not Reported |
|                                                                                                                                                                                                                                                                | Lyrica               |              |            | S           | Oral         |                        |                 | Not Reported |
|                                                                                                                                                                                                                                                                | Serdolect            |              |            | S           | Oral         | Styrke: 4 - 12 -16 Mg. |                 | Not Reported |
|                                                                                                                                                                                                                                                                | Seroquel Prolong     |              |            | S           | Oral         |                        |                 | Not Reported |
|                                                                                                                                                                                                                                                                | Solian               |              |            | S           | Oral         |                        |                 | Not Reported |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                         |                     |   |      |                  |              |
|-------------------------------------------------------------------------|---------------------|---|------|------------------|--------------|
| Gastrointestinal Disorder;<br>Hallucination;                            | Truxal              | S | Oral | Dosis: Ved Behov | Not Reported |
| Hallucination, Auditory;                                                | Seroquel            | S | Oral | Dosis: Ved Behov | Not Reported |
| Hallucination, Visual;                                                  | Zyprexa             | S | Oral | Dosis: Ved Behov | Not Reported |
| Hypersomnia; Impaired<br>Reasoning; Impulsive<br>Behaviour; Insomnia;   | Pulmicort           | C |      |                  | Not Reported |
| Irritable Bowel Syndrome;                                               | Bricanyl Turbuhaler | C |      |                  | Not Reported |
| Lung Infection;                                                         | Seretide            | C |      |                  | Not Reported |
| Nasopharyngitis; Nausea;                                                | Canesten            | C |      |                  | Not Reported |
| Nightmare; Otitis Media;                                                | Brentan             | C |      |                  | Not Reported |
| Pain; Personality Change;                                               | Nizoral             | C |      |                  | Not Reported |
| Restlessness; Sleep<br>Disorder; Sleep Paralysis;                       | Cetirizin "Actavis" | C |      |                  | Not Reported |
| Suicidal Ideation;                                                      | Telfast             | C |      |                  | Not Reported |
| Violence-Related<br>Symptom; Weight<br>Fluctuation; Weight<br>Increased | Depo-Medrol         | C |      |                  | Not Reported |
|                                                                         | Depo-Provera        | C |      |                  | Not Reported |
|                                                                         | Tradolan            | C | Oral |                  | Not Reported |
|                                                                         | Dolol               | C | Oral |                  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|------------|------------|----------------|
| 22-Sep-2016              | 12772352      | EXPEDITED (15-DAY) |                    | HO              | IT-MYLANLABS-<br>2016M1039648 |                      |            | Unknown    | ITA            |

| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Coma; Drug Abuse;       | Quetiapine     |              |            | S           | Oral         | Unk Unk, Total     |                 | Not Reported |
| Psychomotor             | Lorazepam      |              |            | S           | Oral         | Unk Unk, Total     |                 | Not Reported |
| Hyperactivity; Vomiting | Entact         |              |            | S           | Oral         | Unk Unk, Total     |                 | Mylan        |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|------------|------------|----------------|
| 23-Sep-2016              | 12413228      | EXPEDITED (15-DAY) |                    | LT              | FR-009507513-<br>1605FRA011514 |                      | 77 YR      | Female     | FRA            |

| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                             | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u> |
|---------------------------|----------------|--------------|------------|-------------|------------------------------------------|-----------------------------------|-----------------|------------|
| Interstitial Lung Disease | Daptomycin     |              |            | S           | Intravenous (not<br>otherwise specified) | 1000 Mg, Biw (Every Two<br>Weeks) |                 | Merck      |
|                           | Daptomycin     |              |            | S           | Intravenous (not<br>otherwise specified) | 1000 Mg, Qd                       |                 | Merck      |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                               |   |                                       |                                               |              |
|-------------------------------|---|---------------------------------------|-----------------------------------------------|--------------|
| Rifadin                       | S | Intravenous (not otherwise specified) | 600 Mg, (4 Capsules, Daily For Two Days), Bid | Not Reported |
| Metronidazole                 | S | Intravenous (not otherwise specified) | 500 Mg, Tid                                   | Not Reported |
| Azactam                       | S | Intravenous (not otherwise specified) | 1000 Mg, Once/Single                          | Not Reported |
| Azactam                       | S | Intravenous (not otherwise specified) | 500 Mg, Tid                                   | Not Reported |
| Pravastatin                   | S | Oral                                  | 20 Mg, Qd                                     | Not Reported |
| Pravastatin                   | S | Oral                                  | Unk                                           | Not Reported |
| Escitalopram Oxalate          | S | Oral                                  | 10 Mg, Qd                                     | Not Reported |
| Escitalopram Oxalate          | S | Oral                                  | Unk                                           | Not Reported |
| Allopurinol                   | S | Oral                                  | 200 Mg, Qd                                    | Not Reported |
| Allopurinol                   | S | Oral                                  | 100 Mg, Qd                                    | Not Reported |
| Allopurinol                   | S | Oral                                  | Unk                                           | Not Reported |
| Nebivolol Hydrochloride       | S | Oral                                  | 2.5 Mg, Qd                                    | Not Reported |
| Calciparine                   | S | Subcutaneous                          | 0.2 MI, Bid                                   | Not Reported |
| Calciparine                   | S | Subcutaneous                          | Unk                                           | Not Reported |
| Hydrochlorothiazide (+)       | S | Oral                                  | 300/12.5 Mg, Qd                               | Not Reported |
| Irbesartan                    |   |                                       |                                               |              |
| Hydrochlorothiazide (+)       | S | Oral                                  | 150/2.5 Mg, Qd                                | Not Reported |
| Irbesartan                    |   |                                       |                                               |              |
| Seresta                       | C |                                       |                                               | Not Reported |
| Inexium (Esomeprazole Sodium) | C |                                       |                                               | Not Reported |
| Voltarene (Diclofenac Sodium) | C |                                       |                                               | Not Reported |
| Simvastatin                   | C |                                       |                                               | Merck        |

| <u>FDA Received Date</u>                                                             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|--------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|--------------------------------------------------------|----------------------|-----------------|----------------------|----------------|
| 23-Sep-2016                                                                          | 12774380       | EXPEDITED (15-DAY) |                    | OT              | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>BMS-2016-077166 |                      |                 | Unknown              | USA            |
| <u>Preferred Term</u>                                                                | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Affective Disorder; Cardiac<br>Flutter; Feeling Abnormal;<br>Major Depression; Sleep | Abilify        |                    |                    | S               | Unknown                                                |                      |                 | Bristol Myers Squibb |                |
|                                                                                      | Wellbutrin     |                    |                    | S               | Unknown                                                |                      |                 | Not Reported         |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                             |         |   |         |              |
|-------------------------------------------------------------|---------|---|---------|--------------|
| Disorder; Suicidal Ideation; Therapeutic Response Decreased | Lexapro | S | Unknown | Not Reported |
|-------------------------------------------------------------|---------|---|---------|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Sep-2016              | 12775355      | EXPEDITED (15-DAY) |                    | HO              | IT-TEVA-693889ACC    |                      | 32 YR      | Female     | ITA            |

| <u>Preferred Term</u>                                 | <u>Product</u>                       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------|--------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Coma; Drug Abuse; Psychomotor Hyperactivity; Vomiting | Quetiapine                           |              |            | S           | Oral         |                    |                 | Teva         |
|                                                       | Lorazepam                            |              |            | S           | Oral         |                    |                 | Actavis      |
|                                                       | Entact - 10 Mg Comprese              |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                       | Rivestite Con Film - H. Lundbeck A/S |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 23-Sep-2016              | 12775573      | EXPEDITED (15-DAY) |                    | HO              | FR-PFIZER INC-2016439554 |                      | 89 YR      | Female     | FRA            |

| <u>Preferred Term</u>                   | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------|-------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Asthenia; Hypochloraemia; Hyponatraemia | Eupantol          |              |            | S           | Oral         | 40 Mg, Qd          |                 | Pfizer       |
|                                         | Valsartan         |              |            | S           | Oral         | Unk, Qd            |                 | Not Reported |
|                                         | Seroplex          |              |            | S           | Oral         | 10 Mg, Qd          |                 | Not Reported |
|                                         | Lyrica            |              |            | C           |              | Unk                |                 | Not Reported |
|                                         | Loxen /00639802/  |              |            | C           |              | Unk                |                 | Not Reported |
|                                         | Celiprolol        |              |            | C           |              | Unk                |                 | Not Reported |
|                                         | Atarax /00058402/ |              |            | C           |              | Unk                |                 | Not Reported |
|                                         | Foradil           |              |            | C           |              | Unk                |                 | Not Reported |
|                                         | Ceris             |              |            | C           |              | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Sep-2016              | 12759768      | EXPEDITED (15-DAY) |                    | CA, DE          | PHHY2016US128692     |                      | 4 DAY      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                      |              |   |                |                                          |
|----------------------------------------------------------------------|--------------|---|----------------|------------------------------------------|
| Cardiac Failure;<br>Congestive                                       | Ondansetron  | S | Transplacental | Not Reported                             |
| Cardiomyopathy; Foetal                                               | Sertraline   | S | Transplacental | Novartis                                 |
| Exposure During<br>Pregnancy; Multiple Organ<br>Dysfunction Syndrome | Escitalopram | S | Transplacental | Not Reported                             |
|                                                                      | Progesterone | S | Transplacental | Maternal Dose: High Dsoe<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Sep-2016              | 12777254      | EXPEDITED (15-DAY) |                    | HO              | IT-ACCORD-044189     |                      | 32 YR      | Female     | ITA            |

| <u>Preferred Term</u>                                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|------------------------------------|-----------------|--------------|
| Coma; Drug Abuse;<br>Psychomotor<br>Hyperactivity; Vomiting | Quetiapine     |              |            | S           | Oral         |                                    |                 | Accord       |
|                                                             | Entact         |              |            | S           | Oral         | Strength 10 Mg Dose:<br>Total Oral |                 | Not Reported |
|                                                             | Lorazepam      |              |            | S           | Oral         | Dose: Total                        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|------------|------------|----------------|
| 26-Sep-2016              | 12780046      | EXPEDITED (15-DAY) |                    | HO, LT          | TR-MYLANLABS-<br>2016M1040862 |                      |            | Unknown    | TUR            |

| <u>Preferred Term</u>                                                                                                                                                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Clonus; Coma; General<br>Physical Health<br>Deterioration;                                                                                                                | Escitalopram   |              |            | S           | Oral         |                    |                 | Not Reported |
| Hypertension;                                                                                                                                                             | Fluoxetine     |              |            | S           | Oral         |                    |                 | Not Reported |
| Hypertension;                                                                                                                                                             | Olanzapine     |              |            | S           | Oral         |                    |                 | Not Reported |
| Hypocalcaemia;<br>Leukopenia; Loss Of<br>Consciousness;<br>Respiratory Depression;<br>Sinus Tachycardia;<br>Somnolence; Suicide<br>Attempt; Toxicity To<br>Various Agents | Valproic Acid  |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 26-Sep-2016              | 12780578      | EXPEDITED (15-DAY) |                    | DE              | FR-PFIZER INC-<br>2016441329 |                      | 88 YR      | Female     | FRA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|--------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|--------------------------------------------------------------|----------------------|-----------------|--------------|----------------|
| Acute Respiratory Distress Syndrome; Bradycardia; Coma; Intentional Overdose; Pneumonia Aspiration; Toxicity To Various Agents | Amlor          |                    |                    | S               | Oral                                                         | Unk Unk, Single      |                 | Pfizer       |                |
|                                                                                                                                | Amlor          |                    |                    | S               |                                                              |                      |                 | Pfizer       |                |
|                                                                                                                                | Lyrica         |                    |                    | S               | Oral                                                         | Unk, Single          |                 | Pfizer       |                |
|                                                                                                                                | Lyrica         |                    |                    | S               |                                                              |                      |                 | Pfizer       |                |
|                                                                                                                                | Sectral        |                    |                    | S               | Oral                                                         | Unk, Single          |                 | Not Reported |                |
|                                                                                                                                | Sectral        |                    |                    | S               |                                                              |                      |                 | Not Reported |                |
|                                                                                                                                | Seroplex       |                    |                    | S               | Oral                                                         | Unk, Single          |                 | Not Reported |                |
|                                                                                                                                | Seroplex       |                    |                    | S               |                                                              |                      |                 | Not Reported |                |
|                                                                                                                                | Actiskenan     |                    |                    | S               | Oral                                                         | Unk, Single          |                 | Not Reported |                |
|                                                                                                                                | Actiskenan     |                    |                    | S               |                                                              |                      |                 | Not Reported |                |
|                                                                                                                                | Plavix         |                    |                    | C               |                                                              |                      |                 | Not Reported |                |
|                                                                                                                                | Crestor        |                    |                    | C               |                                                              |                      |                 | Not Reported |                |
|                                                                                                                                | Pariet         |                    |                    | C               |                                                              |                      |                 | Not Reported |                |
|                                                                                                                                | Doliprane      |                    |                    | C               |                                                              |                      |                 | Not Reported |                |
| Spasfon /00765801/                                                                                                             |                |                    | C                  |                 |                                                              |                      | Not Reported    |              |                |
| Movicol                                                                                                                        |                |                    | C                  |                 |                                                              |                      | Not Reported    |              |                |
| <u>FDA Received Date</u>                                                                                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Sep-2016                                                                                                                    | 12781267       | EXPEDITED (15-DAY) |                    | OT              | AU-SA-2016SA171157                                           |                      | 34 YR           | Male         | AUS            |
| <u>Preferred Term</u>                                                                                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Eating Disorder; Hallucination                                                                               | Zolpidem       |                    |                    | S               | Unknown                                                      |                      |                 | Not Reported |                |
|                                                                                                                                | Escitalopram   |                    |                    | S               | Unknown                                                      |                      |                 | Not Reported |                |
|                                                                                                                                | Oxycodone      |                    |                    | C               | Unknown                                                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Sep-2016                                                                                                                    | 12761992       | EXPEDITED (15-DAY) |                    | HO              | IT-SUN<br>PHARMACEUTICAL<br>INDUSTRIES LTD-<br>2016RR-124180 |                      | 32 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                                                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Coma; Drug Abuse; Psychomotor Hyperactivity; Vomiting                                                                          | Quetiapine     |                    |                    | S               | Oral                                                         | 1 Dosage Total       |                 | Sun          |                |
|                                                                                                                                | Lorazepam      |                    |                    | S               | Oral                                                         | Total                |                 | Sun          |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| Entact                                                                                                                                                         |                           |                  | S                  |                 | Oral                                           |                      | Total           |              | Not Reported   |  |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|------------------|--------------------|-----------------|------------------------------------------------|----------------------|-----------------|--------------|----------------|--|
| <u>FDA Received Date</u>                                                                                                                                       | <u>Case #</u>             | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |  |
| 27-Sep-2016                                                                                                                                                    | 12782000                  | NON-EXPEDITED    |                    | DE              | JP-LUPIN<br>PHARMACEUTICALS<br>INC.-2016-03180 |                      | 20 YR           | Female       | JPN            |  |
| <u>Preferred Term</u>                                                                                                                                          | <u>Product</u>            | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |  |
| Completed Suicide;<br>Overdose                                                                                                                                 | Mirtazapine               |                  |                    | S               | Unknown                                        |                      |                 | Not Reported |                |  |
|                                                                                                                                                                | Duloxetine                |                  |                    | S               | Unknown                                        |                      |                 | Not Reported |                |  |
|                                                                                                                                                                | Alprazolam                |                  |                    | S               | Unknown                                        |                      |                 | Not Reported |                |  |
|                                                                                                                                                                | Escitalopram              |                  |                    | S               | Unknown                                        |                      |                 | Not Reported |                |  |
| <u>FDA Received Date</u>                                                                                                                                       | <u>Case #</u>             | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |  |
| 27-Sep-2016                                                                                                                                                    | 12782852                  | DIRECT           |                    | OT              |                                                |                      | 50 YR           | Male         | USA            |  |
| <u>Preferred Term</u>                                                                                                                                          | <u>Product</u>            | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |  |
| Dizziness; Dizziness; Fall;<br>Fatigue; Product<br>Substitution Issue;<br>Scratch; Similar Reaction<br>On Previous Exposure To<br>Drug; Withdrawal<br>Syndrome | Escitalopram Oxalate      |                  |                    | S               | Oral                                           |                      |                 | Aurobindo    |                |  |
|                                                                                                                                                                | Generic Lexapro           |                  |                    | C               |                                                |                      |                 | Not Reported |                |  |
|                                                                                                                                                                | Prevacid                  |                  |                    | C               |                                                |                      |                 | Not Reported |                |  |
|                                                                                                                                                                | Allegra                   |                  |                    | C               |                                                |                      |                 | Not Reported |                |  |
|                                                                                                                                                                | Digestive Advantage Daily |                  |                    | C               |                                                |                      |                 | Not Reported |                |  |
|                                                                                                                                                                | Probiotic                 |                  |                    |                 |                                                |                      |                 |              |                |  |
| Vitamin D Nos                                                                                                                                                  |                           |                  | C                  |                 |                                                |                      | Not Reported    |              |                |  |
| <u>FDA Received Date</u>                                                                                                                                       | <u>Case #</u>             | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |  |
| 27-Sep-2016                                                                                                                                                    | 12783031                  | NON-EXPEDITED    |                    |                 | US-PFIZER INC-<br>2016449593                   |                      | 68 YR           | Female       | USA            |  |
| <u>Preferred Term</u>                                                                                                                                          | <u>Product</u>            | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |  |
| Drug Ineffective                                                                                                                                               | Zoloft                    |                  |                    | S               |                                                | Unk                  |                 | Pfizer       |                |  |
|                                                                                                                                                                | Lexapro                   |                  |                    | S               |                                                | Unk                  |                 | Not Reported |                |  |
|                                                                                                                                                                | Wellbutrin                |                  |                    | S               |                                                | Unk                  |                 | Not Reported |                |  |
|                                                                                                                                                                | Rexulti                   |                  |                    | C               | Oral                                           | Unk                  |                 | Not Reported |                |  |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                                                                                 | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|------------------------|----------------------|-----------------|--------------|----------------|
| 27-Sep-2016                                                                                                                                                                                                                                                              | 12783922                 | EXPEDITED (15-DAY) |                    | HO              | IT-ALLERGAN-1000087630 |                      | 32 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                    | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Coma; Drug Abuse; Psychomotor Hyperactivity; Refusal Of Treatment By Patient; Self-Medication; Vomiting                                                                                                                                                                  | Escitalopram Oxalate Unk |                    |                    | S               | Oral                   | 10 Mg, Unk           |                 | Allergan     |                |
|                                                                                                                                                                                                                                                                          | Quetiapine               |                    |                    | S               | Oral                   | Unk                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                          | Lorazepam                |                    |                    | S               | Oral                   | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                 | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Sep-2016                                                                                                                                                                                                                                                              | 12784826                 | EXPEDITED (15-DAY) |                    | HO, LT          | CH-MEDA-2016090062     |                      | 90 YR           | Male         | CHE            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                    | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Fall; Haematemesis; Potentiating Drug Interaction; Shock                                                                                                                                                                                                                 | Torem 5 Mg               |                    |                    | S               | Oral                   | 1-0-0                |                 | Meda         |                |
|                                                                                                                                                                                                                                                                          | Xarelto 20 Mg            |                    |                    | S               | Oral                   | 1-0-0                |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                          | Escitalopram             |                    |                    | S               | Oral                   | 1-0-0                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                 | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Sep-2016                                                                                                                                                                                                                                                              | 12786865                 | EXPEDITED (15-DAY) |                    | OT              | FR-ALLERGAN-1669878US  |                      | 75 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                    | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Distension; Abnormal Dreams; Acne; Arthralgia; Breast Swelling; Decreased Appetite; Diarrhoea; Dry Mouth; Insomnia; Myalgia; Nausea; Nightmare; Ocular Discomfort; Pruritus; Suicidal Ideation; Throat Irritation; Tinnitus; Tremor; Vertigo; Weight Decreased | Seroplex Tablets         |                    |                    | S               | Unknown                |                      |                 | Allergan     |                |
|                                                                                                                                                                                                                                                                          | Mylan-Risperidone        |                    |                    | S               | Unknown                | Unk                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                          | Permixon                 |                    |                    | C               | Unknown                |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                          | Nebivolol                |                    |                    | C               | Unknown                |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                          | Kardegic                 |                    |                    | C               | Unknown                |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                          | Doliprane                |                    |                    | C               | Unknown                |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------|----------------------|--------------------|--------------------|-----------------|------------------------|-------------------------|-----------------|--------------|----------------|
| 27-Sep-2016                | 12786972             | EXPEDITED (15-DAY) |                    | OT              | DK-ALLERGAN-1000087643 |                         | 17 YR           | Female       | DNK            |
| <u>Preferred Term</u>      | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain; Anger;     | Cipralext Tablets    |                    |                    | S               | Oral                   | Unk                     |                 | Allergan     |                |
| Anxiety; Asthenia;         | Abilify              |                    |                    | S               | Unknown                | Unk                     |                 | Not Reported |                |
| Asthenia; Bronchitis;      | Circadin             |                    |                    | S               | Oral                   | Unk                     |                 | Not Reported |                |
| Decreased Immune           | Lyrica               |                    |                    | S               | Oral                   | Unk                     |                 | Not Reported |                |
| Responsiveness;            | Serdolact            |                    |                    | S               | Oral                   | Strength: 4 - 12 -16 Mg |                 | Not Reported |                |
| Depressed Mood;            | Seroquel Prolong     |                    |                    | S               | Oral                   | Unk                     |                 | Not Reported |                |
| Derealisation; Diarrhoea;  | Solian               |                    |                    | S               | Oral                   | Unk                     |                 | Not Reported |                |
| Disturbance In Sexual      | Truxal               |                    |                    | S               | Oral                   | Unk Unk, Prn            |                 | Not Reported |                |
| Arousal; Drug Ineffective; | Seroquel             |                    |                    | S               | Oral                   | Unk, Prn                |                 | Not Reported |                |
| Fatigue; Fungal Infection; | Zyprexa              |                    |                    | S               | Oral                   | Unk, Prn                |                 | Not Reported |                |
| Gastrointestinal Disorder; | Venlafaxin "Actavis" |                    |                    | S               | Oral                   | Unk                     |                 | Not Reported |                |
| Hallucination;             | Pulmicort            |                    |                    | C               | Unknown                | Unk                     |                 | Not Reported |                |
| Hallucination, Auditory;   | Bricanyl Turbuhaler  |                    |                    | C               | Unknown                | Unk                     |                 | Not Reported |                |
| Hallucination, Visual;     | Seretide             |                    |                    | C               | Unknown                | Unk                     |                 | Not Reported |                |
| Hypersomnia; Impaired      | Canesten             |                    |                    | C               | Unknown                | Unk                     |                 | Not Reported |                |
| Reasoning; Impulsive       | Brentan              |                    |                    | C               | Unknown                | Unk                     |                 | Not Reported |                |
| Behaviour; Insomnia;       | Nizoral              |                    |                    | C               | Unknown                | Unk                     |                 | Not Reported |                |
| Irritable Bowel Syndrome;  | Cetirizin "Actavis"  |                    |                    | C               | Unknown                | Unk                     |                 | Not Reported |                |
| Lung Infection;            | Telfast              |                    |                    | C               | Unknown                | Unk                     |                 | Not Reported |                |
| Nasopharyngitis; Nausea;   | Depo-Medrol          |                    |                    | C               | Unknown                | Unk                     |                 | Not Reported |                |
| Nightmare; Otitis Media;   | Depo-Provera         |                    |                    | C               | Unknown                | Unk                     |                 | Not Reported |                |
| Pain; Personality Change;  | Tradolan             |                    |                    | C               | Oral                   | Unk                     |                 | Not Reported |                |
| Product Use Issue;         | Dolol                |                    |                    | C               | Oral                   | Unk                     |                 | Not Reported |                |
| Restlessness; Sleep        |                      |                    |                    |                 |                        |                         |                 |              |                |
| Disorder; Sleep Paralysis; |                      |                    |                    |                 |                        |                         |                 |              |                |
| Suicidal Ideation;         |                      |                    |                    |                 |                        |                         |                 |              |                |
| Violence-Related           |                      |                    |                    |                 |                        |                         |                 |              |                |
| Symptom; Weight            |                      |                    |                    |                 |                        |                         |                 |              |                |
| Fluctuation; Weight        |                      |                    |                    |                 |                        |                         |                 |              |                |
| Increased                  |                      |                    |                    |                 |                        |                         |                 |              |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|-----------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|------------------------------------------------------|----------------------|-----------------|----------------------|----------------|
| 28-Sep-2016                                               | 12788687                 | DIRECT             |                    | HO, LT          |                                                      |                      | 20 YR           | Male                 | USA            |
| <u>Preferred Term</u>                                     | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Inappropriate Schedule Of Product Administration; Seizure | Lexapro                  |                    |                    | S               | Oral                                                 |                      |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 28-Sep-2016                                               | 12790093                 | EXPEDITED (15-DAY) |                    | OT              | FR-B.I. PHARMACEUTICALS, I NC./RIDGEFIELD-2016-BI-62 |                      | 53 YR           | Female               | FRA            |
| <u>Preferred Term</u>                                     | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Hepatitis                                                 | Sifrol                   |                    |                    | S               | Oral                                                 | 0.7 Mg               |                 | Boehringer Ingelheim |                |
|                                                           | Arava                    |                    |                    | S               | Oral                                                 | 1 Anz                |                 | Not Reported         |                |
|                                                           | Seroplex                 |                    |                    | S               | Oral                                                 | 10 Mg                |                 | Not Reported         |                |
|                                                           | Femara                   |                    |                    | S               | Oral                                                 |                      |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 28-Sep-2016                                               | 12790250                 | EXPEDITED (15-DAY) |                    | OT              | AU-ALLERGAN-1000087634                               |                      | 45 YR           | Male                 | AUS            |
| <u>Preferred Term</u>                                     | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Abdominal Pain Upper;                                     | Escitalopram Oxalate Unk |                    |                    | S               | Unknown                                              | 10 Mg, Qd            |                 | Allergan             |                |
| Abdominal Pain Upper;                                     | Escitalopram Oxalate Unk |                    |                    | S               |                                                      |                      |                 | Allergan             |                |
| Abnormal Dreams;                                          | Escitalopram Oxalate Unk |                    |                    | S               |                                                      |                      |                 | Allergan             |                |
| Abnormal Dreams;                                          | Alepam / Oxazepam        |                    |                    | C               | Unknown                                              | 15 Mg, Unk           |                 | Not Reported         |                |
| Confusional State;                                        | Panadol / Paracetamol    |                    |                    | C               | Unknown                                              | Unk                  |                 | Not Reported         |                |
| Diarrhoea; Dizziness;                                     |                          |                    |                    |                 |                                                      |                      |                 |                      |                |
| Fatigue; Feeling                                          |                          |                    |                    |                 |                                                      |                      |                 |                      |                |
| Abnormal; Headache;                                       |                          |                    |                    |                 |                                                      |                      |                 |                      |                |
| Hyperhidrosis; Insomnia;                                  |                          |                    |                    |                 |                                                      |                      |                 |                      |                |
| Lethargy; Memory                                          |                          |                    |                    |                 |                                                      |                      |                 |                      |                |
| Impairment; Muscle                                        |                          |                    |                    |                 |                                                      |                      |                 |                      |                |
| Disorder; Yawning                                         |                          |                    |                    |                 |                                                      |                      |                 |                      |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|------------|------------|----------------|
| 29-Sep-2016              | 12431684      | EXPEDITED (15-DAY) |                    | LT              | FR-AUROBINDO-AUR-APL-2016-06519 |                      | 77 YR      | Female     | FRA            |

| <u>Preferred Term</u>     | <u>Product</u>                     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                          | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|------------------------------------|--------------|------------|-------------|---------------------------------------|-------------------------|-----------------|--------------|
| Interstitial Lung Disease | Allopurinol Arrow                  |              |            | S           | Oral                                  | 100 Mg, Once A Day      |                 | Not Reported |
|                           | Escitalopram Arrow 10 Mg           |              |            | S           | Oral                                  | 10 Mg, Once A Day       |                 | Aurobindo    |
|                           | Nebivolol Arrow                    |              |            | S           | Oral                                  | 2.5 Mg, Once A Day      |                 | Not Reported |
|                           | Pravastatin Arrow 20mg             |              |            | S           | Oral                                  | 20 Mg, Once A Day       |                 | Not Reported |
|                           | Azactam                            |              |            | S           | Intravenous (not otherwise specified) | 500 Mg, 3 Times A Day   |                 | Not Reported |
|                           | Cubicin                            |              |            | S           | Intravenous (not otherwise specified) | Unk                     |                 | Not Reported |
|                           | Irbesartan And Hydrochlorothiazide |              |            | S           | Oral                                  | Unk, Once A Day         |                 | Not Reported |
|                           | Metronidazole B Braun              |              |            | S           | Intravenous (not otherwise specified) | 500 Mg, 3 Times A Day   |                 | Not Reported |
|                           | Rifadine /00146901/                |              |            | S           | Intravenous (not otherwise specified) | 600 Mg, Two Times A Day |                 | Not Reported |
|                           | Heparin Calcium                    |              |            | S           | Subcutaneous                          | 0.2 MI, Two Times A Day |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 29-Sep-2016              | 12525609      | NON-EXPEDITED    |                    | OT              | US-JNJFOC-20160615361 |                      | 50 YR      | Female     | USA            |

| <u>Preferred Term</u>                  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Bradycardia; Irritability; Mood Swings | Invega         |              |            | S           | Oral         |                    |                 | Not Reported |
|                                        | Invega         |              |            | S           | Oral         |                    |                 | Not Reported |
|                                        | Lexapro        |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                        | Lexapro        |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                        | Wellbutrin     |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                        | Wellbutrin     |              |            | S           | Unknown      |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                     | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|-----------------|--------------|----------------|
| 29-Sep-2016                                                                                                                  | 12791492                             | EXPEDITED (15-DAY) |                    | OT              | US-CIPLA LTD.-<br>2016US18916 |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                                                                        | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Contact Lens Acute Red<br>Eye; Disturbance In<br>Attention; Feeling<br>Abnormal; Headache;<br>Insomnia; Ocular<br>Discomfort | Escitalopram                         |                    |                    | S               | Oral                          | 10 Mg, Qd            |                 | Invagen      |                |
|                                                                                                                              | Tylenol                              |                    |                    | C               | Unknown                       | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                     | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Sep-2016                                                                                                                  | 12791753                             | EXPEDITED (15-DAY) |                    | OT              | PHHY2016FR131308              |                      | 53 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                        | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hepatitis; Hepatitis<br>Cholestatic                                                                                          | Femara                               |                    |                    | S               | Oral                          | Unk                  |                 | Novartis     |                |
|                                                                                                                              | Arava                                |                    |                    | S               | Oral                          | 1 Df, Qd             |                 | Not Reported |                |
|                                                                                                                              | Seroplex                             |                    |                    | S               | Oral                          | 10 Mg, Unk           |                 | Not Reported |                |
|                                                                                                                              | Sifrol                               |                    |                    | S               | Unknown                       | 0.7 Mg, Qd           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                     | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Sep-2016                                                                                                                  | 12795769                             | EXPEDITED (15-DAY) |                    | DE              | PHHY2016CH133717              |                      | 75 YR           | Female       | CHE            |
| <u>Preferred Term</u>                                                                                                        | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cerebral Haemorrhage;<br>Drug Interaction; Drug<br>Interaction                                                               | Voltaren Retard                      |                    |                    | S               | Oral                          | 75 Mg, Bid           |                 | Novartis     |                |
|                                                                                                                              | Escitalopram                         |                    |                    | S               | Oral                          | 10 Mg, Qd            |                 | Not Reported |                |
|                                                                                                                              | Symfona N (Ginkgo Biloba<br>Extract) |                    |                    | S               | Oral                          | 120 Mg, Bid          |                 | Not Reported |                |
|                                                                                                                              | Marcoumar                            |                    |                    | S               | Oral                          | Unk                  |                 | Not Reported |                |
|                                                                                                                              | Omeprazole                           |                    |                    | C               | Oral                          | 20 Mg, Bid           |                 | Not Reported |                |
|                                                                                                                              | Novalgine (Metamizole Sodium)        |                    |                    | C               | Oral                          | 500 Mg, Qid          |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                                                                                                                |                          |                    |                    |                 |                                                 |                      |                 |              |                |  |
|------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|--------------|----------------|--|
| Lexotanil                                                                                                                                      |                          |                    | C                  |                 | Oral                                            |                      | 1.5 Mg, Tid     |              | Not Reported   |  |
| <u>FDA Received Date</u>                                                                                                                       | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |  |
| 29-Sep-2016                                                                                                                                    | 12797000                 | EXPEDITED (15-DAY) |                    | HO, LT          | FR-ALLERGAN-1670193US                           |                      | 31 YR           | Female       | FRA            |  |
| <u>Preferred Term</u>                                                                                                                          | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |  |
| Altered State Of Consciousness; Overdose; Pneumonia Aspiration                                                                                 | Escitalopram Oxalate Unk |                    |                    | S               | Oral                                            | 50 Df, Single        |                 | Allergan     |                |  |
|                                                                                                                                                | Seresta                  |                    |                    | S               | Oral                                            | 30 Df, Single        |                 | Not Reported |                |  |
|                                                                                                                                                | Moclamine                |                    |                    | S               | Oral                                            | 50 Df, Single        |                 | Not Reported |                |  |
|                                                                                                                                                | Teralithe                |                    |                    | S               | Oral                                            | 3 Unk, Unk           |                 | Not Reported |                |  |
| <u>FDA Received Date</u>                                                                                                                       | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |  |
| 29-Sep-2016                                                                                                                                    | 12797016                 | EXPEDITED (15-DAY) |                    | HO              | DE-ALLERGAN-1670190US                           |                      | 67 YR           | Female       | DEU            |  |
| <u>Preferred Term</u>                                                                                                                          | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |  |
| Eructation; Platelet Disorder; Post Procedural Haemorrhage; Procedural Haemorrhage; Withdrawal Syndrome                                        | Escitalopram Oxalate Unk |                    |                    | S               | Unknown                                         | 10 Mg, Qd            |                 | Allergan     |                |  |
|                                                                                                                                                | Escitalopram Oxalate Unk |                    |                    | S               | Unknown                                         | 5 Mg, Qd             |                 | Allergan     |                |  |
| <u>FDA Received Date</u>                                                                                                                       | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |  |
| 30-Sep-2016                                                                                                                                    | 12660404                 | EXPEDITED (15-DAY) |                    | HO, LT, OT      | CA-VALIDUS PHARMACEUTICALS LLC-CA-2016VAL002418 |                      | 54 YR           | Female       | CAN            |  |
| <u>Preferred Term</u>                                                                                                                          | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |  |
| Agitation; Body Temperature Increased; Diarrhoea; Flushing; Hallucination, Auditory; Hallucination, Visual; Insomnia; Rash; Serotonin Syndrome | Meperidine Hydrochloride |                    |                    | S               | Oral                                            | Unk                  |                 | Validus      |                |  |
|                                                                                                                                                | Atasol (Acetaminophen)   |                    |                    | S               | Oral                                            | Unk                  |                 | Not Reported |                |  |
|                                                                                                                                                | Cipralext                |                    |                    | S               | Oral                                            | 1.5 Df, Qd           |                 | Not Reported |                |  |
|                                                                                                                                                | Cipralext                |                    |                    | S               | Unknown                                         | Unk                  |                 | Not Reported |                |  |
|                                                                                                                                                | Cipralext                |                    |                    | S               |                                                 | Unk                  |                 | Not Reported |                |  |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                  |   |                                       |           |              |
|------------------|---|---------------------------------------|-----------|--------------|
| Concerta         | S | Oral                                  | 18 Mg, Qd | Not Reported |
| Morphine Sulfate | S | Intravenous (not otherwise specified) | Unk       | Not Reported |
| Diprosone        | C | Unknown                               | Unk       | Not Reported |
| Docusate Sodium  | C | Unknown                               | Unk       | Not Reported |
| Glucagon         | C | Unknown                               | Unk       | Not Reported |
| Lantus           | C | Unknown                               | Unk       | Not Reported |
| Metformin        | C | Unknown                               | Unk       | Not Reported |
| Phisohex         | C | Unknown                               | Unk       | Not Reported |
| Proctodan Hc     | C | Unknown                               | Unk       | Not Reported |
| Proctosol Hc     | C | Unknown                               | Unk       | Not Reported |
| Ramipril         | C | Unknown                               | Unk       | Not Reported |
| Simvastatin      | C | Unknown                               | Unk       | Not Reported |
| Tecta            | C | Unknown                               | Unk       | Not Reported |

| <u>FDA Received Date</u>                              | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|------------------------|----------------------|-----------------|--------------|----------------|
| 30-Sep-2016                                           | 12780888                    | EXPEDITED (15-DAY) |                    | HO, OT          | IT-APOTEX-2016AP011948 |                      | 32 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                 | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Coma; Drug Abuse; Psychomotor Hyperactivity; Vomiting | Quetiapina Doc Generici     |                    |                    | S               | Oral                   | Unk                  |                 | Apotex       |                |
|                                                       | Comprese Rivestite Con Film |                    |                    | S               | Oral                   | Unk                  |                 | Not Reported |                |
|                                                       | Lorazepam                   |                    |                    | S               | Oral                   | Unk                  |                 | Not Reported |                |
|                                                       | Entact                      |                    |                    | S               | Oral                   | Unk                  |                 | Not Reported |                |

| <u>FDA Received Date</u>                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|-----------------------------------------|----------------------|--------------------|--------------------|-----------------|--------------------------------------------------|----------------------|-----------------|------------|----------------|
| 30-Sep-2016                             | 12797986             | EXPEDITED (15-DAY) |                    | OT              | SA-MACLEODS PHARMACEUTICALS US LTD-MAC2016003164 |                      |                 | Unknown    | SAU            |
| <u>Preferred Term</u>                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                     | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Angle Closure Glaucoma; Drug Withdrawal | Escitalopram Oxalate |                    |                    | S               | Unknown                                          | Unk                  |                 | Macleods   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Syndrome; Headache;  
Photophobia; Vision  
Blurred; Vomiting

| <u>FDA Received Date</u>                                          | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>             | <u>Country</u> |
|-------------------------------------------------------------------|--------------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------------------|----------------|
| 30-Sep-2016                                                       | 12798325                       | EXPEDITED (15-DAY) |                    | OT              | FR-ACCORD-044399          |                      | 55 YR           | Female                 | FRA            |
| <u>Preferred Term</u>                                             | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>             |                |
| Eosinophilia;<br>Hepatocellular Injury;<br>Influenza Like Illness | Escitalopram<br>Chlorpromazine |                    |                    | S<br>C          |                           |                      |                 | Accord<br>Not Reported |                |
| <u>FDA Received Date</u>                                          | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>             | <u>Country</u> |
| 30-Sep-2016                                                       | 12799027                       | EXPEDITED (15-DAY) |                    | OT              | IT-JNJFOC-<br>20160929410 |                      | 35 YR           | Male                   | ITA            |
| <u>Preferred Term</u>                                             | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>             |                |
| Intentional Overdose;<br>Intentional Self-Injury                  | Risperdal                      |                    |                    | S               | Oral                      |                      |                 | Not Reported           |                |
|                                                                   | Risperdal                      |                    |                    | S               | Oral                      |                      |                 | Not Reported           |                |
|                                                                   | Cipralext                      |                    |                    | S               | Oral                      |                      |                 | Not Reported           |                |
| <u>FDA Received Date</u>                                          | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>             | <u>Country</u> |
| 30-Sep-2016                                                       | 12800021                       | EXPEDITED (15-DAY) |                    | OT              | FR-SA-2016SA178461        |                      | 53 YR           | Female                 | FRA            |
| <u>Preferred Term</u>                                             | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>             |                |
| Hepatitis                                                         | Arava                          |                    |                    | S               | Oral                      |                      |                 | Not Reported           |                |
|                                                                   | Seroplex                       |                    |                    | S               | Oral                      |                      |                 | Not Reported           |                |
|                                                                   | Sifrol                         |                    |                    | S               | Unknown                   |                      |                 | Not Reported           |                |
|                                                                   | Femara                         |                    |                    | S               | Oral                      |                      |                 | Not Reported           |                |
| <u>FDA Received Date</u>                                          | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>             | <u>Country</u> |
| 30-Sep-2016                                                       | 12801921                       | DIRECT             |                    |                 |                           |                      | 91 YR           | Female                 | USA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                                                                 | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
|-----------------------------------------------------------------------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|----------------------|------------------------|-----------------|--------------|----------------|
| Anxiety                                                                                                               | Escitalopram Oxalate 5 Mg Tab |                    |                    | S               | Oral                 | Quantity:1 Tablet(S);  |                 | Not Reported |                |
|                                                                                                                       | Ac                            |                    |                    |                 |                      |                        |                 |              |                |
|                                                                                                                       | Vitamin C                     |                    |                    | C               |                      |                        |                 | Not Reported |                |
|                                                                                                                       | Vitamin D Nos                 |                    |                    | C               |                      |                        |                 | Not Reported |                |
|                                                                                                                       | Unspecified Ingredient        |                    |                    | C               |                      |                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                              | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Oct-2016                                                                                                           | 12805631                      | DIRECT             |                    | LT              |                      |                        | 30 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                 | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Product Substitution Issue; Suicidal Ideation                                                             | Lexapro                       |                    |                    | S               | Oral                 | Quantity:90 Tablet(S); |                 | Not Reported |                |
|                                                                                                                       | Levothyroxin                  |                    |                    | C               |                      |                        |                 | Not Reported |                |
|                                                                                                                       | Lexapro                       |                    |                    | C               |                      |                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                              | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Oct-2016                                                                                                           | 12643483                      | EXPEDITED (15-DAY) |                    | DS              | IT-FRI-1000086765    |                        | 59 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                                                                 | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Complex Regional Pain Syndrome; Complex Regional Pain Syndrome; Hyperhidrosis; Nausea; Night Sweats; Weight Increased | Entact Oral Drops             |                    |                    | S               | Oral                 | 20 Mg, Qd              |                 | Allergan     |                |
|                                                                                                                       | Cipralext Tablets             |                    |                    | S               | Oral                 | 10 Mg, Qd              |                 | Allergan     |                |
|                                                                                                                       | Cipralext Tablets             |                    |                    | S               |                      | Unk                    |                 | Allergan     |                |
|                                                                                                                       | Inderal                       |                    |                    | C               | Oral                 | 40 Mg, Qd              |                 | Not Reported |                |
|                                                                                                                       | Inderal                       |                    |                    | C               |                      |                        |                 | Not Reported |                |
|                                                                                                                       | Deursil                       |                    |                    | C               | Oral                 | 450 Mg, Bid            |                 | Not Reported |                |
|                                                                                                                       | Tavor [Lorazepam]             |                    |                    | C               | Oral                 | 1 Mg, Qd               |                 | Not Reported |                |
|                                                                                                                       | Tavor                         |                    |                    | C               | Oral                 | 1 Mg, Prn              |                 | Not Reported |                |
|                                                                                                                       | Diclofenac                    |                    |                    | C               | Intramuscular        | Unk Unk, Unk           |                 | Not Reported |                |
|                                                                                                                       | Diclofenac                    |                    |                    | C               | Unknown              | 50 Mg, Prn             |                 | Not Reported |                |
|                                                                                                                       | Muscoril                      |                    |                    | C               | Intramuscular        | As Reuired             |                 | Not Reported |                |
|                                                                                                                       | Aciclovir                     |                    |                    | C               | Unknown              | Unk                    |                 | Not Reported |                |
|                                                                                                                       | Pantoprazole                  |                    |                    | C               | Oral                 | 20 Mg, Unk             |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                                                  |                                      |                    |                    |                 |                                            |                      |                 |                 |                |  |
|----------------------------------------------------------------------------------|--------------------------------------|--------------------|--------------------|-----------------|--------------------------------------------|----------------------|-----------------|-----------------|----------------|--|
| Didrogyl                                                                         |                                      |                    | C                  |                 | Oral                                       |                      | 3 Gtt, Qd       |                 | Not Reported   |  |
| <u>FDA Received Date</u>                                                         | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |  |
| 03-Oct-2016                                                                      | 12802851                             | EXPEDITED (15-DAY) |                    | DE, OT          | CH-<br>GLAXOSMITHKLINE-<br>CH2016GSK143660 |                      | 75 YR           | Female          | CHE            |  |
| <u>Preferred Term</u>                                                            | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |  |
| Cerebral Haemorrhage;<br>Drug Interaction; Drug<br>Interaction                   | Voltaren Retard                      |                    |                    | S               | Oral                                       | 75 Mg, Bid           |                 | Glaxosmithkline |                |  |
|                                                                                  | Escitalopram                         |                    |                    | S               | Oral                                       | 10 Mg, Qd            |                 | Not Reported    |                |  |
|                                                                                  | Symfona N (Ginkgo Biloba<br>Extract) |                    |                    | S               | Oral                                       | 120 Mg, Bid          |                 | Not Reported    |                |  |
|                                                                                  | Marcoumar                            |                    |                    | S               | Oral                                       | Unk                  |                 | Not Reported    |                |  |
|                                                                                  | Omeprazole                           |                    |                    | C               |                                            |                      |                 | Not Reported    |                |  |
|                                                                                  | Novalgine (Metamizole Sodium)        |                    |                    | C               |                                            | Unk                  |                 | Not Reported    |                |  |
|                                                                                  | Lexotanil                            |                    |                    | C               |                                            |                      |                 | Not Reported    |                |  |
| <u>FDA Received Date</u>                                                         | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |  |
| 03-Oct-2016                                                                      | 12802877                             | NON-EXPEDITED      |                    |                 | US-DRREDDYS-<br>USA/USA/15/0053042         |                      |                 | Female          | USA            |  |
| <u>Preferred Term</u>                                                            | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |  |
| Pain; Peripheral Swelling                                                        | Augmentin                            |                    |                    | S               | Unknown                                    |                      |                 | Not Reported    |                |  |
|                                                                                  | Prevnar 13                           |                    |                    | S               | Unknown                                    |                      |                 | Not Reported    |                |  |
|                                                                                  | Lexapro                              |                    |                    | S               | Unknown                                    |                      |                 | Not Reported    |                |  |
| <u>FDA Received Date</u>                                                         | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |  |
| 03-Oct-2016                                                                      | 12803276                             | EXPEDITED (15-DAY) |                    | HO, OT          | PHHY2016HR134895                           |                      | 53 YR           | Male            | HRV            |  |
| <u>Preferred Term</u>                                                            | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |  |
| Bundle Branch Block<br>Right; Drug Interaction;<br>Electrocardiogram<br>Abnormal | Quetiapine                           |                    |                    | S               | Unknown                                    | 800 Mg, Qd           |                 | Novartis        |                |  |
|                                                                                  | Quetiapine                           |                    |                    | S               | Unknown                                    | 400 Mg, Qd           |                 | Novartis        |                |  |
|                                                                                  | Quetiapine                           |                    |                    | S               | Unknown                                    | 100 Mg, Qd           |                 | Novartis        |                |  |
|                                                                                  | Escitalopram                         |                    |                    | S               | Unknown                                    | 20 Mg, Qd            |                 | Not Reported    |                |  |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|           |   |         |             |              |
|-----------|---|---------|-------------|--------------|
| Valproate | C | Unknown | 1500 Mg, Qd | Not Reported |
| Valproate | C |         |             | Not Reported |
| Diazepam  | C | Unknown | 30 Mg, Qd   | Not Reported |
| Diazepam  | C |         |             | Not Reported |
| Zolpidem  | C | Unknown | 10 Mg, Qd   | Not Reported |
| Zolpidem  | C |         |             | Not Reported |
| Biperiden | C | Unknown | 1 Mg, Qd    | Not Reported |
| Biperiden | C |         |             | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 03-Oct-2016              | 12804570      | EXPEDITED (15-DAY) |                    | DE              | FR-ALLERGAN-1670490US |                      | 88 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                        | <u>Product</u>                                    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------|---------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Acute Respiratory Distress Syndrome; Bradycardia; Coma; Pneumonia Aspiration | Seroplex Tablets                                  |              |            | S           | Oral         | Unk                |                 | Allergan     |
|                                                                              | Sectral                                           |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                                                                              | Amlor                                             |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                                                                              | Lyrica                                            |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                                                                              | Actiskenan                                        |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                                                                              | Plavix                                            |              |            | C           |              | Unk                |                 | Not Reported |
|                                                                              | Crestor                                           |              |            | C           |              | Unk                |                 | Not Reported |
|                                                                              | Pariet                                            |              |            | C           |              | Unk                |                 | Not Reported |
|                                                                              | Doliprane                                         |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                              | Spasfon (Phloroglucinol, Trimethylphloroglucinol) |              |            | C           |              | Unk                |                 | Not Reported |
|                                                                              | Movicol                                           |              |            | C           |              | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 03-Oct-2016              | 12804581      | EXPEDITED (15-DAY) |                    | DE              | FR-ALLERGAN-1670499US |                      | 89 YR      | Female     | FRA            |

| <u>Preferred Term</u>                           | <u>Product</u>   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-------------------------------------------------|------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Anaemia; Drug Interaction; Haematemesis; Rectal | Seroplex Tablets |              |            | S           | Oral         | 10 Mg, Qd          |                 | Allergan   |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|             |                           |   |      |                                     |              |
|-------------|---------------------------|---|------|-------------------------------------|--------------|
| Haemorrhage | Kardegic                  | S | Oral | 75 Mg, Qd                           | Not Reported |
|             | Coaprovel                 | C |      | 150 Mg/12.5 Mg, Qam                 | Not Reported |
|             | Imovane                   | C |      | 7.5 Mg, Qhs                         | Not Reported |
|             | Transipeg (Macrogol 3350) | C | Oral | Unk, Bid (Morning And Night)        | Not Reported |
|             | Inofer                    | C |      | 2 Df, Qam                           | Not Reported |
|             | Paracetamol               | C |      | 1g, Prn (Morning And Night If Pain) | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|------------|------------|----------------|
| 04-Oct-2016              | 12628056      | EXPEDITED (15-DAY) |                    | OT              | FR-AUROBINDO-AUR-APL-2016-09895 |                      | 55 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                                                                                           | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Alanine Aminotransferase Increased; Drug Interaction; Eosinophilia; Hepatocellular Injury; Influenza Like Illness; Liver Function Test Abnormal | Escitalopram 10 Mg |              |            | S           | Unknown      | 10 Mg, Unk         |                 | Aurobindo    |
|                                                                                                                                                 | Chlorpromazine     |              |            | C           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-------------------------|----------------------|------------|------------|----------------|
| 04-Oct-2016              | 12805247      | NON-EXPEDITED    |                    |                 | US-TAKEDA-2016TUS017023 |                      | 49 YR      | Female     | USA            |

| <u>Preferred Term</u>                                         | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abdominal Pain Lower; Abdominal Pain Upper; Diarrhoea; Nausea | Trintellix          |              |            | S           | Oral         | 10 Mg, Qd          |                 | Takeda       |
|                                                               | Trintellix          |              |            | S           | Oral         | 20 Mg, Qd          |                 | Takeda       |
|                                                               | Lexapro             |              |            | S           | Oral         | 20 Mg, Qd          |                 | Not Reported |
|                                                               | Lexapro             |              |            | S           | Oral         | 10 Mg, Qd          |                 | Not Reported |
|                                                               | Verapamil Er        |              |            | C           | Oral         | 180 Mg, Qd         |                 | Not Reported |
|                                                               | Hydrochlorothiazide |              |            | C           | Oral         | 25 Mg, Qd          |                 | Not Reported |
|                                                               | Trazodone           |              |            | C           | Oral         | 100 Mg, Qd         |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|              |   |      |          |              |
|--------------|---|------|----------|--------------|
| Alprazolam   | C | Oral | 2 Mg, Qd | Not Reported |
| Carisoprodol | C | Oral | Unk, Qd  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 04-Oct-2016              | 12808367      | EXPEDITED (15-DAY) |                    | HO              | US-ALLERGAN-1670486US |                      | 27 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                            | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>               |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------------------|
| Abdominal Pain Upper;<br>Acne; Anaemia;<br>Decreased Appetite;<br>Diastolic Dysfunction;<br>Epistaxis; Haemorrhagic<br>Pneumonia; Hypertension;<br>Hypotension; Nausea;<br>Oliguria; Peripheral<br>Swelling;<br>Thrombocytopenia | Lexapro<br>Sirolimus |              |            | S<br>S      | Oral         | Unk                |                 | Allergan<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 04-Oct-2016              | 12808537      | EXPEDITED (15-DAY) |                    | OT              | FR-MYLANLABS-2016M1042404 |                      |            | Unknown    | FRA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                         | <u>Product</u>                                                                  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>                | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                                         |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------|--------------|------------|----------------------------|--------------|--------------------|-----------------|----------------------------------------------------|
| Abdominal Distension;<br>Abnormal Dreams; Acne;<br>Breast Swelling;<br>Decreased Appetite;<br>Diarrhoea; Dizziness; Dry<br>Mouth; Dyspepsia; Erectile<br>Dysfunction;<br>Gynaecomastia; Insomnia;<br>Nausea; Nightmare;<br>Paraesthesia; Pruritus;<br>Rash; Suicidal Ideation;<br>Throat Irritation; Tinnitus;<br>Tremor; Weight<br>Decreased | Mylan-Risperidone<br>Seroplex<br>Permixon<br>Nebivolol<br>Kardegic<br>Doliprane |              |            | S<br>S<br>C<br>C<br>C<br>C |              | Unk<br>Unk         |                 | Mylan<br>Mylan<br>Mylan<br>Mylan<br>Mylan<br>Mylan |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                               | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|--------------------------|------------------------------------------------|-----------------|--------------|----------------|
| 04-Oct-2016                                                                                                                                                                                                            | 12809117                 | EXPEDITED (15-DAY) |                    | DS              | FR-ALLERGAN-1670503US    |                                                | 4 YR            | Male         | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                                                  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                             | <u>Duration</u> | <u>Mfr</u>   |                |
| Autism Spectrum Disorder; Autism Spectrum Disorder; Foetal Exposure During Pregnancy                                                                                                                                   | Seroplex Tablets         |                    |                    | S               | Transplacental           | 10 Mg, Qd                                      |                 | Allergan     |                |
| <u>FDA Received Date</u>                                                                                                                                                                                               | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Oct-2016                                                                                                                                                                                                            | 12809141                 | EXPEDITED (15-DAY) |                    | OT              | SE-ALLERGAN-1670893US    |                                                |                 | Male         | SWE            |
| <u>Preferred Term</u>                                                                                                                                                                                                  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                             | <u>Duration</u> | <u>Mfr</u>   |                |
| Appetite Disorder; Cognitive Disorder; Decreased Interest; Depressed Mood; Disturbance In Attention; Fatigue; Feelings Of Worthlessness; Intentional Self-Injury; Irritability; Suicidal Behaviour; Weight Fluctuation | Escitalopram Oxalate Unk |                    |                    | S               | Unknown                  | Unknown                                        |                 | Allergan     |                |
| <u>FDA Received Date</u>                                                                                                                                                                                               | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Oct-2016                                                                                                                                                                                                            | 12680461                 | EXPEDITED (15-DAY) |                    | HO              | CH-PFIZER INC-2016389753 |                                                | 90 YR           | Female       | CHE            |
| <u>Preferred Term</u>                                                                                                                                                                                                  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                             | <u>Duration</u> | <u>Mfr</u>   |                |
| Fall                                                                                                                                                                                                                   | Temesta (Lorazepam)      |                    |                    | S               | Oral                     | 0.5 Mg, 1x/Day (1mg, 0-0-0-1/2)                |                 | Pfizer       |                |
|                                                                                                                                                                                                                        | Lyrica                   |                    |                    | S               | Oral                     | 62.5 Mg, 1x/Day                                |                 | Pfizer       |                |
|                                                                                                                                                                                                                        | Madopar                  |                    |                    | S               |                          | 100mg/25mg, 3x/Day (200mg/50mg, 1/2-1/2-1/2-0) |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                        |   |                                  |              |
|------------------------|---|----------------------------------|--------------|
| Cipralex /01588501/    | S | 10 Mg, 1x/Day (1-0-0-0)          | Not Reported |
| Torem /01036501/       | S | 2.5 Mg, 1x/Day (5 Mg, 1/2-0-0-0) | Not Reported |
| Acidum Folicum Streuli | C | 5 Mg, 1x/Day                     | Not Reported |
| Vitamin D3 Streuli     | C | Gtt, Every Tuesday               | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------------------------|----------------------|------------|------------|----------------|
| 05-Oct-2016              | 12809966      | EXPEDITED (15-DAY) |                    | HO, LT          | TR-LUPIN<br>PHARMACEUTICALS<br>INC.-2016-04424 |                      | 24 YR      | Female     | TUR            |

| <u>Preferred Term</u>                          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Coma; Hypernatraemia;                          | Valproic Acid  |              |            | S           | Oral         |                    |                 | Not Reported |
| Hypocalcaemia;                                 | Olanzapine     |              |            | S           | Oral         |                    |                 | Not Reported |
| Leukopenia; Respiratory                        | Escitalopram   |              |            | S           | Oral         |                    |                 | Not Reported |
| Depression; Somnolence;                        | Fluoxetine     |              |            | S           | Oral         |                    |                 | Not Reported |
| Suicide Attempt; Toxicity<br>To Various Agents |                |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 05-Oct-2016              | 12810100      | NON-EXPEDITED    |                    |                 | US-PFIZER INC-<br>2016461280 |                      | 49 YR      | Female     | USA            |

| <u>Preferred Term</u>               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Depression; Disease                 | Effexor        |              |            | S           | Oral         | 75 Mg, 1x/Day      |                 | Pfizer       |
| Progression; Menopausal<br>Symptoms | Lexapro        |              |            | S           | Oral         | 10 Mg, 1x/Day      |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 05-Oct-2016              | 12818168      | EXPEDITED (15-DAY) |                    | OT              | TW-ALLERGAN-<br>1000087611 |                      | 27 YR      | Male       | TWN            |

| <u>Preferred Term</u> | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Sexual Dysfunction    | Escitalopram Oxalate Unk |              |            | S           | Unknown      | Unk                |                 | Allergan   |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 05-Oct-2016              | 12818197      | EXPEDITED (15-DAY) |                    | OT              | FI-ALLERGAN-<br>1670899US |                      |            | Female     | FIN            |

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| <u>Preferred Term</u>                                                                                                                    | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
|------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|--------------------|--------------------|-----------------|------------------------------|-----------------------|-----------------|--------------|----------------|
| Decreased Interest;<br>Depressed Mood; Fatigue;<br>Intentional Self-Injury;<br>Irritability; Negative<br>Thoughts; Suicidal<br>Behaviour | Escitalopram Oxalate Unk              |                    |                    | S               | Unknown                      |                       |                 | Allergan     |                |
| <u>FDA Received Date</u>                                                                                                                 | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Oct-2016                                                                                                                              | 12818023                              | DIRECT             |                    | DE              |                              |                       | 62 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                    | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Therapy Change                                                                                                     | Escitalopram 20mg Tablet<br>(Lexapro) |                    |                    | S               | Oral                         | Quantity:1 Tablet(S); |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                                 | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Oct-2016                                                                                                                              | 12818102                              | NON-EXPEDITED      |                    |                 | US-PFIZER INC-<br>2016463328 |                       | 57 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                    | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity                                                                                                                    | Lyrica                                |                    |                    | S               |                              | Unk                   |                 | Pfizer       |                |
|                                                                                                                                          | Lexapro                               |                    |                    | S               |                              | Unk                   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                 | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Oct-2016                                                                                                                              | 12821713                              | EXPEDITED (15-DAY) |                    | LT, OT          | PHHY2016TR134298             |                       | 24 YR           | Female       | TUR            |
| <u>Preferred Term</u>                                                                                                                    | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Loss Of Consciousness;<br>Suicide Attempt                                                                                                | Olanzapine                            |                    |                    | S               | Unknown                      |                       |                 | Novartis     |                |
|                                                                                                                                          | Valproic Acid                         |                    |                    | S               | Unknown                      |                       |                 | Not Reported |                |
|                                                                                                                                          | Escitalopram                          |                    |                    | S               | Unknown                      |                       |                 | Not Reported |                |
|                                                                                                                                          | Fluoxetine                            |                    |                    | S               | Unknown                      |                       |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                                                   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|------------------|----------------|
| 06-Oct-2016                                                                                                | 12823392                 | EXPEDITED (15-DAY) |                    | OT              | US-<br>ELI_LILLY_AND_COMP<br>ANY-US201609009641 |                      |                 | Male             | USA            |
| <u>Preferred Term</u>                                                                                      | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |
| Hepatic Steatosis;<br>Hepatomegaly;<br>Pancytopenia;<br>Splenomegaly                                       | Cymbalta                 |                    |                    | S               | Unknown                                         | Unk, Unknown         |                 | Eli Lilly And Co |                |
|                                                                                                            | Qudexy                   |                    |                    | S               | Unknown                                         | 200 Df, Qd           |                 | Not Reported     |                |
|                                                                                                            | Lexapro                  |                    |                    | S               | Unknown                                         | Unk, Unknown         |                 | Not Reported     |                |
|                                                                                                            | Cyclobenzaprine          |                    |                    | S               | Unknown                                         | Unk, Unknown         |                 | Not Reported     |                |
|                                                                                                            | Tazetol                  |                    |                    | S               | Unknown                                         | Unk, Unknown         |                 | Not Reported     |                |
|                                                                                                            | Proton /00661201/        |                    |                    | S               | Unknown                                         | Unk, Unknown         |                 | Not Reported     |                |
|                                                                                                            | Calcium                  |                    |                    | C               | Unknown                                         | Unk, Unknown         |                 | Not Reported     |                |
|                                                                                                            | Bentyl                   |                    |                    | C               | Unknown                                         | Unk, Unknown         |                 | Not Reported     |                |
|                                                                                                            | Vitamin D /00107901/     |                    |                    | C               | Unknown                                         | Unk, Unknown         |                 | Not Reported     |                |
|                                                                                                            | Prevacid                 |                    |                    | C               | Unknown                                         | Unk, Unknown         |                 | Not Reported     |                |
|                                                                                                            | Trazodone                |                    |                    | C               | Unknown                                         | Unk, Unknown         |                 | Not Reported     |                |
|                                                                                                            | Zofran /00955301/        |                    |                    | C               | Unknown                                         | Unk, Unknown         |                 | Not Reported     |                |
|                                                                                                            | Ativan                   |                    |                    | C               | Unknown                                         | Unk, Unknown         |                 | Not Reported     |                |
|                                                                                                            | Norco                    |                    |                    | C               | Unknown                                         | Unk, Unknown         |                 | Not Reported     |                |
|                                                                                                            | Lyrica                   |                    |                    | C               | Unknown                                         | Unk, Unknown         |                 | Not Reported     |                |
| <u>FDA Received Date</u>                                                                                   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 07-Oct-2016                                                                                                | 12510191                 | EXPEDITED (15-DAY) |                    | LT              | FR-FRI-1000085621                               |                      | 68 YR           | Female           | FRA            |
| <u>Preferred Term</u>                                                                                      | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |
| Brain Oedema; Drug<br>Interaction; Loss Of<br>Consciousness; Lung<br>Disorder; Subarachnoid<br>Haemorrhage | Escitalopram Oxalate Unk |                    |                    | S               | Oral                                            | 20 Mg, Qd            |                 | Allergan         |                |
|                                                                                                            | Eliquis                  |                    |                    | S               | Oral                                            | 5 Mg, Bid            |                 | Not Reported     |                |
|                                                                                                            | Cordarone                |                    |                    | S               | Oral                                            | 200 Mg, Qd           |                 | Not Reported     |                |
|                                                                                                            | Micardis                 |                    |                    | C               | Oral                                            | 1 Df, Qd             |                 | Not Reported     |                |

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|                      |   |                          |             |              |
|----------------------|---|--------------------------|-------------|--------------|
| Pariet               | C | Oral                     | 20 Mg, Qd   | Not Reported |
| Singulair            | C | Oral                     | 10 Mg, Qd   | Not Reported |
| Symbicort Turbuhaler | C | Respiratory (inhalation) | 1 Df, Bid   | Not Reported |
| Lasilix Faible       | C | Oral                     | 20 Mg, Qd   | Not Reported |
| Euphylline L.A.      | C | Oral                     | 200 Mg, Bid | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|------------|------------|----------------|
| 07-Oct-2016              | 12633613      | EXPEDITED (15-DAY) |                    | HO, OT          | CA-AUROBINDO-AUR-APL-2016-10217 |                      | 39 YR      | Male       | CAN            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                   | <u>Product</u>                    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Agitation; Autonomic Nervous System Imbalance; Body Temperature Increased; Clonus; Condition Aggravated; Confusional State; Drug Interaction; Hyperhidrosis; Hyperreflexia; Hyperthermia; Mental Status Changes; Muscle Rigidity; Myoclonus; Overdose; Serotonin Syndrome; Tachycardia; Tachycardia; Toxicity To Various Agents; Tremor | Escitalopram Tablets              |              |            | S           | Unknown      | Unk                |                 | Aurobindo    |
|                                                                                                                                                                                                                                                                                                                                         | Olanzapine Oraldispersible Tablet |              |            | S           | Unknown      | Unk                |                 | Aurobindo    |
|                                                                                                                                                                                                                                                                                                                                         | Quetiapine Film-Coated Tablet     |              |            | S           | Unknown      | Unk                |                 | Aurobindo    |
|                                                                                                                                                                                                                                                                                                                                         | Phenytoin                         |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                         | Bupropion                         |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                         | Primidone                         |              |            | S           | Unknown      | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 07-Oct-2016              | 12661665      | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2016388581 |                      | 62 YR      | Female     | USA            |

| <u>Preferred Term</u>                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Hypersensitivity; Headache; Vomiting | Effexor Xr     |              |            | S           |              | Unk                |                 | Pfizer       |
|                                           | Flagyl         |              |            | S           |              | Unk                |                 | Pfizer       |
|                                           | Lexapro        |              |            | S           |              | Unk                |                 | Not Reported |

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| <u>FDA Received Date</u>                                                                                                                                                                              | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|--------------------------------------------------------|----------------------|-----------------|----------------------|----------------|
| 07-Oct-2016                                                                                                                                                                                           | 12770805                 | EXPEDITED (15-DAY) |                    |                 | DK-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>BMS-2016-076151 |                      | 26 YR           | Male                 | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                 | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Drug Interaction; Product<br>Prescribing Error                                                                                                                                                        | Abilify                  |                    |                    | S               | Oral                                                   | 30 Mg, Qd            |                 | Bristol Myers Squibb |                |
|                                                                                                                                                                                                       | Propranolol              |                    |                    | S               | Oral                                                   | 80 Mg, Qd            |                 | Not Reported         |                |
|                                                                                                                                                                                                       | Citalopram               |                    |                    | S               | Oral                                                   | 40 Mg, Qd            |                 | Not Reported         |                |
|                                                                                                                                                                                                       | Escitalopram             |                    |                    | S               | Oral                                                   | 30 Mg, Qd            |                 | Not Reported         |                |
|                                                                                                                                                                                                       | Olanzapine               |                    |                    | S               | Oral                                                   | 10 Mg, Qd            |                 | Not Reported         |                |
|                                                                                                                                                                                                       | Quetiapine               |                    |                    | S               | Oral                                                   | 900 Mg, Qd           |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                                                                                                                                              | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 10-Oct-2016                                                                                                                                                                                           | 12831747                 | EXPEDITED (15-DAY) |                    | OT              | US-CIPLA LTD.-<br>2016US19165                          |                      |                 | Unknown              | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                 | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Lactose Intolerance;<br>Product Substitution Issue                                                                                                                                                    | Escitalopram             |                    |                    | S               | Unknown                                                | 20 Mg, Unk           |                 | Invagen              |                |
| <u>FDA Received Date</u>                                                                                                                                                                              | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 10-Oct-2016                                                                                                                                                                                           | 12834303                 | EXPEDITED (15-DAY) |                    | OT              | NO-ALLERGAN-<br>1671499US                              |                      |                 | Female               | NOR            |
| <u>Preferred Term</u>                                                                                                                                                                                 | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Cognitive Disorder;<br>Decreased Interest;<br>Depressed Mood;<br>Disturbance In Attention;<br>Drug Ineffective; Fatigue;<br>Feelings Of<br>Worthlessness; Negative<br>Thoughts; Suicidal<br>Behaviour | Escitalopram Oxalate Unk |                    |                    | S               | Unknown                                                |                      |                 | Allergan             |                |



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| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                              | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>        | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|--------------------|--------------------|-----------------|------------------------------------------|----------------------|-----------------|-------------------|----------------|
| 11-Oct-2016                                                                                                                                                                                                                                                                                                                           | 12763280                   | EXPEDITED (15-DAY) |                    | HO, OT          | US-SAOL<br>THERAPEUTICS-<br>2016SAO00659 |                      | 61 YR           | Female            | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                 | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>        |                |
| Altered State Of Consciousness; Anxiety; Aphasia; Confusional State; Disturbance In Attention; Dysarthria; Gait Inability; Malaise; Memory Impairment; Migraine; Multiple Sclerosis Relapse; Muscle Tightness; Seizure; Sepsis; Substance-Induced Psychotic Disorder; Ulcer Haemorrhage; Urinary Tract Infection; Withdrawal Syndrome | Lioresal                   |                    |                    | S               | Intrathecal                              | 101.78 Mg, \Day      |                 | Saol Therapeutics |                |
|                                                                                                                                                                                                                                                                                                                                       | Lioresal                   |                    |                    | S               |                                          | Unk                  |                 | Saol Therapeutics |                |
|                                                                                                                                                                                                                                                                                                                                       | "Steroids"                 |                    |                    | S               |                                          |                      |                 | Not Reported      |                |
|                                                                                                                                                                                                                                                                                                                                       | Intravenous Immunoglobulin |                    |                    | S               |                                          |                      |                 | Not Reported      |                |
|                                                                                                                                                                                                                                                                                                                                       | Lexapro                    |                    |                    | S               |                                          |                      |                 | Not Reported      |                |
|                                                                                                                                                                                                                                                                                                                                       | Topamax                    |                    |                    | S               |                                          |                      |                 | Not Reported      |                |
|                                                                                                                                                                                                                                                                                                                                       | Rebif                      |                    |                    | S               |                                          |                      |                 | Not Reported      |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                              | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>        | <u>Country</u> |
| 11-Oct-2016                                                                                                                                                                                                                                                                                                                           | 12768350                   | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000087639                        |                      | 41 YR           | Female            | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                 | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>        |                |
| Diarrhoea; Hepatitis; Jaundice; Pyrexia                                                                                                                                                                                                                                                                                               | Escitalopram Oxalate Unk   |                    |                    | S               | Oral                                     | Unk                  |                 | Allergan          |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                              | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>        | <u>Country</u> |
| 11-Oct-2016                                                                                                                                                                                                                                                                                                                           | 12835583                   | NON-EXPEDITED      |                    |                 | US-TAKEDA-<br>2016TUS018355              |                      |                 | Female            | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                 | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>        |                |
| Nausea; Respiratory Tract Congestion; Throat Irritation; Vomiting                                                                                                                                                                                                                                                                     | Trintellix                 |                    |                    | S               | Unknown                                  | Unk                  |                 | Takeda            |                |
|                                                                                                                                                                                                                                                                                                                                       | Escitalopram               |                    |                    | S               | Unknown                                  | Unk                  |                 | Not Reported      |                |

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|  |                     |   |              |            |              |
|--|---------------------|---|--------------|------------|--------------|
|  | Humira              | S | Subcutaneous | 40mg/0.8ml | Not Reported |
|  | Lamictal            | S | Unknown      | Unk        | Not Reported |
|  | Zyprexa             | S | Unknown      |            | Not Reported |
|  | Ativan              | C | Unknown      | Unk        | Not Reported |
|  | Prilosec /00661201/ | C | Unknown      | Unk        | Not Reported |

| <u>FDA Received Date</u>                                                | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------|-----------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 11-Oct-2016                                                             | 12837321              | EXPEDITED (15-DAY) |                    | HO              | FR-ALLERGAN-1671483US |                      | 41 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                   | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Bilirubin Increased;<br>Drug Dependence;<br>Hepatitis Cholestatic | Seroplex Tablets      |                    |                    | S               | Unknown               |                      |                 | Allergan     |                |
|                                                                         | Codeine               |                    |                    | S               | Unknown               |                      |                 | Not Reported |                |
|                                                                         | Paracetamol           |                    |                    | S               |                       |                      |                 | Not Reported |                |
|                                                                         | Ursodesoxycholic Acid |                    |                    | C               |                       | Unk                  |                 | Not Reported |                |
|                                                                         | Atarax                |                    |                    | C               |                       | Unk                  |                 | Not Reported |                |

| <u>FDA Received Date</u>       | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------------|-------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|------------|----------------|
| 11-Oct-2016                    | 12837323          | EXPEDITED (15-DAY) |                    | OT              | IT-ALLERGAN-1671481US |                      | 50 YR           | Female     | ITA            |
| <u>Preferred Term</u>          | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Medication Overuse<br>Headache | Cipralext Tablets |                    |                    | S               | Oral                  |                      |                 | Allergan   |                |

| <u>FDA Received Date</u>       | <u>Case #</u>    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------|------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 12-Oct-2016                    | 12830867         | EXPEDITED (15-DAY) |                    | OT              | FR-ALLERGAN-1671247US |                      |                 | Female       | FRA            |
| <u>Preferred Term</u>          | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Pregnancy; Premature<br>Labour | Seroplex Tablets |                    |                    | S               | Transplacental        |                      |                 | Allergan     |                |
|                                | Abilify          |                    |                    | S               | Transplacental        |                      |                 | Not Reported |                |
|                                | Depamide         |                    |                    | S               | Transplacental        |                      |                 | Not Reported |                |
|                                | Seresta          |                    |                    | S               | Transplacental        |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Largactil

S

Transplacental

Not Reported

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Oct-2016              | 12838173      | EXPEDITED (15-DAY) |                    | HO, OT          | PHHY2016BR028121     |                      | 53 YR      | Female     | BRA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abdominal Discomfort;                                                                                                                                                                                                                                                                                                                                                                         | Gilenya        |              |            | S           | Oral         | 0.5 Mg, Qd         |                 | Novartis     |
| Abdominal Pain Lower;                                                                                                                                                                                                                                                                                                                                                                         | Gilenya        |              |            | S           | Oral         | 0.5 Mg, Qd         |                 | Novartis     |
| Anxiety; Asthenia; Back Pain; Bacteriuria; Central Nervous System Lesion; Concomitant Disease                                                                                                                                                                                                                                                                                                 | Escitalopram   |              |            | S           | Unknown      | 10 Mg, Unk         |                 | Not Reported |
| Aggravated; Crying; Decreased Activity; Decreased Interest; Depression; Headache; Hemiparesis; Hypoaesthesia; Limb Injury; Memory Impairment; Micturition Urgency; Mobility Decreased; Musculoskeletal Discomfort; Neck Pain; Pain; Paraesthesia; Peripheral Swelling; Sensory Disturbance; Urinary Incontinence; Urinary Tract Infection; Weight Increased; White Blood Cell Count Decreased | Folic Acid     |              |            | C           | Unknown      | 1 Df, Qd           |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                               | Amitriptilina  |              |            | C           | Oral         | 1 Df, Qd           |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                               | Glifage        |              |            | C           | Oral         | 2 Df, Qd           |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 12-Oct-2016              | 12838182      | EXPEDITED (15-DAY) |                    | HO, OT          | TR-HETERO LABS LTD-1058246 |                      | 24 YR      | Female     | TUR            |

| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Suicide Attempt; Toxicity | Escitalopram   |              |            | S           | Unknown      |                    |                 | Hetero     |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                   |               |   |              |
|-------------------|---------------|---|--------------|
| To Various Agents | Valproic Acid | S | Not Reported |
|                   | Olanzapine    | S | Not Reported |
|                   | Olanzapine    | S | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Oct-2016              | 12839155      | EXPEDITED (15-DAY) |                    | HO              | CH-SA-2016SA184754   |                      | 81 YR      | Male       | CHE            |

| <u>Preferred Term</u> | <u>Product</u>                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|--------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Haematoma; Syncope    | Triatec (Ramipril)             |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Plavix                         |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Torem                          |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Cipralex                       |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Temesta (Lorazepam)            |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Pantozol (Pantoprazole Sodium) |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Aspirin Cardio                 |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Haldol                         |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Hydromorphone Hydrochloride    |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Circadin                       |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 12-Oct-2016              | 12839970      | EXPEDITED (15-DAY) |                    | DE, OT          | CH-ALLERGAN-1671466US |                      | 75 YR      | Female     | CHE            |

| <u>Preferred Term</u>                                       | <u>Product</u>                    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------|-----------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cerebral Haemorrhage;<br>Drug Interaction; Drug Interaction | Escitalopram Oxalate Unk          |              |            | S           | Oral         |                    |                 | Allergan     |
|                                                             | Symfona N (Ginkgo Biloba Extract) |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                             | Voltaren                          |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                             | Marcoumar                         |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                             | Omeprazol                         |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                             | Novalgine (Metamizole Sodium)     |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                             | Lexotanil                         |              |            | C           | Oral         |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                             | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------|--------------------------------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|-----------------|--------------|----------------|
| 13-Oct-2016                                                                                                          | 12237183                             | EXPEDITED (15-DAY) |                    | HO              | IT-AUROBINDO-AUR-APL-2015-11354 |                      | 81 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                                                                | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Macule; Papule; Skin Lesion; Telangiectasia                                                                          | Escitalopram 10 Mg                   |                    |                    | S               | Oral                            | 10 Mg, Daily         |                 | Aurobindo    |                |
| <u>FDA Received Date</u>                                                                                             | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Oct-2016                                                                                                          | 12836741                             | EXPEDITED (15-DAY) |                    | OT              | FI-ALLERGAN-1671473US           |                      |                 | Female       | FIN            |
| <u>Preferred Term</u>                                                                                                | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cognitive Disorder; Decreased Interest; Depressed Mood; Fatigue; Irritability; Negative Thoughts; Suicidal Behaviour | Escitalopram Oxalate Unk             |                    |                    | S               |                                 |                      |                 | Allergan     |                |
| <u>FDA Received Date</u>                                                                                             | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Oct-2016                                                                                                          | 12843081                             | EXPEDITED (15-DAY) |                    | HO              | CH-BAYER-2016-192809            |                      | 81 YR           | Male         | CHE            |
| <u>Preferred Term</u>                                                                                                | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Fall; Haematoma; Syncope                                                                                             | Aspirin Cardio                       |                    |                    | S               |                                 | 100 Mg, Qd           |                 | Bayer        |                |
|                                                                                                                      | Hydromorphoni Hydrochloridum Streuli |                    |                    | S               |                                 | 10 MI, Qid           |                 | Not Reported |                |
|                                                                                                                      | Circadin                             |                    |                    | S               | Oral                            | 10 Mg, Qd            |                 | Not Reported |                |
|                                                                                                                      | Torem                                |                    |                    | S               | Oral                            | 200 Mg, Qd           |                 | Not Reported |                |
|                                                                                                                      | Cipralex                             |                    |                    | S               |                                 | 10 Mg, Qd            |                 | Not Reported |                |
|                                                                                                                      | Temesta (Lorazepam)                  |                    |                    | S               | Oral                            | 1 Mg, Bid            |                 | Not Reported |                |
|                                                                                                                      | Pantozol (Pantoprazole Sodium)       |                    |                    | S               |                                 | 20 Mg, Qd            |                 | Not Reported |                |
|                                                                                                                      | Triatec (Ramipril)                   |                    |                    | S               |                                 | 2.5 Mg, Qd           |                 | Not Reported |                |
|                                                                                                                      | Plavix                               |                    |                    | S               | Oral                            | 75 Mg, Qd            |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Haldol  
Insulin Novomix

S  
S

28 -0 -14-0

Not Reported  
Not Reported

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                 | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------------------------------|----------------------|------------|------------|----------------|
| 13-Oct-2016              | 12845076      | EXPEDITED (15-DAY) |                    | HO, OT          | TR-SCIEGEN<br>PHARMACEUTICALS<br>INC-2016SCILIT00451 |                      | 24 YR      | Female     | TUR            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Acidosis; Clonus; Coma;<br>General Physical Health<br>Deterioration;<br>Hypercapnia;<br>Hypernatraemia;<br>Hypocalcaemia;<br>Leukopenia; Loss Of<br>Consciousness;<br>Respiratory Depression;<br>Sinus Tachycardia;<br>Somnolence; Suicide<br>Attempt; Toxicity To<br>Various Agents | Fluoxetine Capsules, Usp |              |            | S           | Oral         | Unk                |                 | Sciegen      |
|                                                                                                                                                                                                                                                                                      | Valproic Acid            |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                                                                                                                                                                                                                                                                                      | Olanzapine               |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                                                                                                                                                                                                                                                                                      | Escitalopram             |              |            | S           | Oral         | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Oct-2016              | 12495991      | EXPEDITED (15-DAY) |                    | HO              | JP-FRI-1000085481    |                      | 49 YR      | Female     | JPN            |

| <u>Preferred Term</u>                                                                                         | <u>Product</u>  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------|-----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Atrioventricular Block<br>Complete;<br>Electrocardiogram Qt<br>Prolonged; Syncope;<br>Ventricular Tachycardia | Lexapro Tablets |              |            | S           | Oral         | 10 Mg, Qd          |                 | Allergan     |
|                                                                                                               | Lexapro Tablets |              |            | S           | Oral         | 15 Mg, Qd          |                 | Allergan     |
|                                                                                                               | Lexapro Tablets |              |            | S           | Oral         | 20 Mg, Qd          |                 | Allergan     |
|                                                                                                               | Lexapro Tablets |              |            | S           | Oral         | 5 Mg, Qd           |                 | Allergan     |
|                                                                                                               | Tryptanol       |              |            | S           | Oral         | 75 Mg, Unk         |                 | Not Reported |
|                                                                                                               | Wypax           |              |            | C           | Oral         | 115 Mg             |                 | Not Reported |
|                                                                                                               | Rohypnol        |              |            | C           | Oral         | 2 Mg               |                 | Not Reported |

# FDA Adverse Event Reporting System

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| <u>FDA Received Date</u>                                                    | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 14-Oct-2016                                                                 | 12561805                    | EXPEDITED (15-DAY) |                    | OT              | AU-PFIZER INC-2016343305 |                      | 66 YR           | Male         | AUS            |
| <u>Preferred Term</u>                                                       | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Electrocardiogram Qt Prolonged; Hypokalaemia; Hypomagnesaemia               | Escitalopram                |                    |                    | S               |                          | 10 Mg, 1x/Day        |                 | Not Reported |                |
|                                                                             | Atenolol                    |                    |                    | C               |                          |                      |                 | Not Reported |                |
|                                                                             | Lercanidipine Hydrochloride |                    |                    | C               |                          |                      |                 | Not Reported |                |
|                                                                             | Pantoprazole                |                    |                    | C               |                          |                      |                 | Not Reported |                |
|                                                                             | Rosuvastatin Calcium        |                    |                    | C               |                          |                      |                 | Not Reported |                |
|                                                                             | Perindopril                 |                    |                    | C               |                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                    | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Oct-2016                                                                 | 12847559                    | EXPEDITED (15-DAY) |                    | HO              | FR-ALLERGAN-1671948US    |                      | 49 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                       | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Coma; Hypotension; Suicide Attempt; Tachycardia; Toxicity To Various Agents | Seroplex Tablets            |                    |                    | S               | Oral                     | 30 Df, Single        |                 | Allergan     |                |
|                                                                             | Efferalgan Codeine          |                    |                    | S               | Unknown                  | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                    | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Oct-2016                                                                 | 12850790                    | EXPEDITED (15-DAY) |                    | HO              | FR-ALLERGAN-1672118US    |                      | 63 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                       | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bradycardia; Chest Pain; Hyponatraemia; Long Qt Syndrome                    | Escitalopram Oxalate - Bp   |                    |                    | S               | Oral                     | 5 Mg, Qd             |                 | Allergan     |                |
| <u>FDA Received Date</u>                                                    | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Oct-2016                                                                 | 12850915                    | EXPEDITED (15-DAY) |                    | HO, LT, OT      | PL-TEVA-699054ISR        |                      |                 | Unknown      | POL            |
| <u>Preferred Term</u>                                                       | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Overdose; Toxicity To Various Agents                                        | Sulpiride                   |                    |                    | S               | Unknown                  |                      |                 | Not Reported |                |

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Freedom of Information Act (FOIA)  
Detailed Report**

|                      |   |         |              |
|----------------------|---|---------|--------------|
| Olanzapine           | S | Unknown | Teva         |
| Risperidone          | S | Unknown | Pliva        |
| Hydroxyzine          | S | Unknown | Barr         |
| Zolpidem             | S | Unknown | Teva         |
| Sertraline           | S | Unknown | Not Reported |
| Escitalopram         | S | Unknown | Ivax         |
| Venlafaxine          | S | Unknown | Teva         |
| Carbamazepine        | S | Unknown | Not Reported |
| Lamotrigine          | S | Unknown | Teva         |
| Topiramate           | S | Unknown | Teva         |
| Donepezil            | S | Unknown | Barr         |
| Paracetamol          | S | Unknown | Not Reported |
| Ibuprofen            | S | Unknown | Ivax         |
| Acetylsalicylic Acid | S | Unknown | Not Reported |
| Diclofenac           | S | Unknown | Not Reported |
| Morphine             | S | Unknown | Not Reported |
| Bisoprolol           | S | Unknown | Duramed      |
| Metoprolol           | S | Unknown | Teva         |
| Amlodipine           | S | Unknown | Teva         |
| Ramipril             | S | Unknown | Teva         |
| Indapamide           | S | Unknown | Ivax         |
| Valsartan            | S | Unknown | Teva         |
| Simvastatin          | S | Unknown | Ivax         |
| Atorvastatin         | S | Unknown | Teva         |
| Rosuvastatin         | S | Unknown | Teva         |
| Dextromethorphan     | S | Unknown | Not Reported |
| Metformin            | S | Unknown | Not Reported |
| Omeprazole           | S | Unknown | Actavis      |



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### Detailed Report

| <u>FDA Received Date</u>  | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                         | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|---------------------------|--------------------|--------------------|--------------------|-----------------|--------------------------------------------------------------|------------------------|-----------------|----------------------|----------------|
| 15-Oct-2016               | 12780860           | NON-EXPEDITED      |                    |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>BMS-2016-078321       |                        | 44 YR           | Male                 | USA            |
| <u>Preferred Term</u>     | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                 | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>           |                |
| Confusional State;        | Abilify            |                    |                    | S               | Unknown                                                      | Unk                    |                 | Bristol Myers Squibb |                |
| Dizziness; Dyskinesia;    | Lexapro            |                    |                    | S               | Unknown                                                      |                        |                 | Not Reported         |                |
| Memory Impairment;        | Depakote           |                    |                    | C               | Unknown                                                      |                        |                 | Not Reported         |                |
| Tardive Dyskinesia;       | Klonopin           |                    |                    | C               | Unknown                                                      |                        |                 | Not Reported         |                |
| Weight Increased          |                    |                    |                    |                 |                                                              |                        |                 |                      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                         | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 15-Oct-2016               | 12852581           | DIRECT             |                    |                 |                                                              |                        | 27 YR           | Male                 | USA            |
| <u>Preferred Term</u>     | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                 | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>           |                |
| Joint Stiffness           | Escitalopram 10 Mg |                    |                    | S               | Oral                                                         | Quantity:30 Tablet(S); |                 | Camber               |                |
| <u>FDA Received Date</u>  | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                         | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 17-Oct-2016               | 12556768           | EXPEDITED (15-DAY) |                    | OT              | US-WEST-WARD<br>PHARMACEUTICALS<br>CORP.-US-H14001-16-<br>01 |                        | 68 YR           | Female               | USA            |
| <u>Preferred Term</u>     | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                 | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>           |                |
| Autoimmune Hepatitis;     | Escitalopram       |                    |                    | S               | Unknown                                                      |                        |                 | Hikma                |                |
| Drug-Induced Liver Injury | Diazepam           |                    |                    | C               | Unknown                                                      |                        |                 | Not Reported         |                |
|                           | Lorazepam          |                    |                    | C               | Unknown                                                      |                        |                 | Not Reported         |                |
|                           | Zolpidem           |                    |                    | C               | Unknown                                                      |                        |                 | Not Reported         |                |
|                           | Fexofenadine       |                    |                    | C               | Unknown                                                      |                        |                 | Not Reported         |                |
| <u>FDA Received Date</u>  | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                         | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 17-Oct-2016               | 12837711           | EXPEDITED (15-DAY) |                    | OT              | US-GILEAD-2016-<br>0224117                                   |                        | 66 YR           | Male                 | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abdominal Discomfort; | Ambrisentan    |              |            | S           | Unknown      | 10 Mg, Qd          |                 | Gilead       |
| Diarrhoea; Epistaxis; | Lexapro        |              |            | S           | Unknown      |                    |                 | Not Reported |
| Gingival Bleeding;    | Zoloft         |              |            | S           | Unknown      |                    |                 | Not Reported |
| Melaena; Rectal       | Revatio        |              |            | C           |              |                    |                 | Not Reported |
| Haemorrhage; Skin     |                |              |            |             |              |                    |                 |              |
| Haemorrhage           |                |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 17-Oct-2016              | 12853020      | EXPEDITED (15-DAY) |                    | OT              | NO-ALLERGAN-1672502US |                      | 20 YR      | Male       | NOR            |

| <u>Preferred Term</u>                                                                                                                                                                            | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Decreased Interest;<br>Depressed Mood;<br>Disturbance In Attention;<br>Fatigue; Feelings Of<br>Worthlessness; Negative<br>Thoughts; Sleep Disorder;<br>Suicidal Behaviour;<br>Weight Fluctuation | Escitalopram Oxalate - Bp |              |            | S           | Unknown      | Unknown            |                 | Allergan   |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 17-Oct-2016              | 12855211      | EXPEDITED (15-DAY) |                    | OT              | NO-MYLANLABS-2016M1043614 |                      |            | Unknown    | NOR            |

| <u>Preferred Term</u>                                                                                                                                                                                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cognitive Disorder;<br>Decreased Interest;<br>Depressed Mood;<br>Disturbance In Attention;<br>Drug Ineffective; Fatigue;<br>Feelings Of<br>Worthlessness; Negative<br>Thoughts; Suicidal<br>Behaviour | Escitalopram   |              |            | S           | Unknown      | Unk                |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                             | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|----------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|--------------------------------------------------------|----------------------|-----------------|----------------------|----------------|
| 17-Oct-2016                                                          | 12855348                  | EXPEDITED (15-DAY) |                    | HO, OT          | FR-ALLERGAN-1672433US                                  |                      | 82 YR           | Male                 | FRA            |
| <u>Preferred Term</u>                                                | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Cerebellar Syndrome;<br>Cognitive Disorder                           | Escitalopram Oxalate - Bp |                    |                    | S               | Oral                                                   |                      |                 | Allergan             |                |
|                                                                      | Crestor                   |                    |                    | C               | Unknown                                                | 5 Mg, Unk            |                 | Not Reported         |                |
|                                                                      | Rivastigmine              |                    |                    | C               | Unknown                                                | Unk                  |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                             | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 18-Oct-2016                                                          | 12612177                  | NON-EXPEDITED      |                    |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>BMS-2016-060580 |                      | 44 YR           | Female               | USA            |
| <u>Preferred Term</u>                                                | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Hepatic Enzyme<br>Increased; Product Use In<br>Unapproved Indication | Eliquis                   |                    |                    | S               | Oral                                                   | 5 Mg, Bid            |                 | Bristol Myers Squibb |                |
|                                                                      | Lexapro                   |                    |                    | S               | Unknown                                                | 10 Mg, Unk           |                 | Not Reported         |                |
|                                                                      | Lexapro                   |                    |                    | S               |                                                        |                      |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                             | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 19-Oct-2016                                                          | 12576853                  | NON-EXPEDITED      |                    |                 | US-OTSUKA-2016_011586                                  |                      | 77 YR           | Female               | USA            |
| <u>Preferred Term</u>                                                | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Discomfort; Off Label Use;<br>Panic Attack                           | Rexulti                   |                    |                    | S               | Oral                                                   | 0.5 Mg, Qd           |                 | Otsuka               |                |
|                                                                      | Lexapro                   |                    |                    | S               | Unknown                                                | Unk                  |                 | Not Reported         |                |
|                                                                      | Xanax                     |                    |                    | C               | Unknown                                                | Unk                  |                 | Not Reported         |                |
|                                                                      | Trazodone                 |                    |                    | C               | Unknown                                                | Unk, Qd (At Bedtime) |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                             | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 19-Oct-2016                                                          | 12576947                  | NON-EXPEDITED      |                    |                 | US-OTSUKA-2016_016047                                  |                      | 60 YR           | Female               | USA            |
| <u>Preferred Term</u>                                                | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                          |          |   |         |             |              |
|--------------------------|----------|---|---------|-------------|--------------|
| Hallucination;           | Rexulti  | S | Oral    | 0.5 Mg, Qd  | Otsuka       |
| Hallucination, Visual;   | Lexapro  | S | Unknown | 60 Mg, Unk  | Not Reported |
| Hyperhidrosis; Migraine; | Lexapro  | S | Unknown | 0.5 Mg, Unk | Not Reported |
| Nausea; Vertigo;         | Lexapro  | S | Oral    | 20 Mg, Unk  | Not Reported |
| Withdrawal Syndrome      | Lexapro  | S | Unknown | 15 Mg, Unk  | Not Reported |
|                          | Cymbalta | C | Unknown | Unk         | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 19-Oct-2016              | 12577049      | NON-EXPEDITED    |                    |                 | US-OTSUKA-2016_014948 |                      | 26 YR      | Male       | USA            |

| <u>Preferred Term</u>         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Apathy; Feeling Abnormal;     | Rexulti        |              |            | S           | Oral         | 0.5 Mg, Qd         |                 | Otsuka       |
| Laziness; Off Label Use;      | Lexapro        |              |            | S           | Unknown      | Unk                |                 | Not Reported |
| Pollakiuria; Weight Decreased | Xanax          |              |            | C           | Unknown      | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 19-Oct-2016              | 12843567      | EXPEDITED (15-DAY) |                    | HO, OT          | CH-PFIZER INC-2016466511 |                      | 81 YR      | Male       | CHE            |

| <u>Preferred Term</u>    | <u>Product</u>                       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|--------------------------------------|--------------|------------|-------------|--------------|-----------------------------|-----------------|--------------|
| Fall; Haematoma; Syncope | Temesta (Lorazepam)                  |              |            | S           | Oral         | 1 Mg, 2x/Day (1-0-1-0)      |                 | Pfizer       |
|                          | Triatec (Ramipril)                   |              |            | S           | Unknown      | 2.5 Mg, Daily (1/2-0-1/2-0) |                 | Pfizer       |
|                          | Hydromorphoni Hydrochloridum Streuli |              |            | S           | Unknown      | 10 Ml, 4x/Day               |                 | Not Reported |
|                          | Circadin                             |              |            | S           | Oral         | 10 Mg, Daily                |                 | Not Reported |
|                          | Torem /01036501/                     |              |            | S           | Oral         | 200 Mg, Daily (1/4-0-0-0)   |                 | Not Reported |
|                          | Cipralext /01588501/                 |              |            | S           | Unknown      | 10 Mg, Daily (1-0-0-0)      |                 | Not Reported |
|                          | Pantozol /01263204/                  |              |            | S           | Unknown      | 20 Mg, Daily (1-0-0-0)      |                 | Not Reported |
|                          | Aspirin Cardio                       |              |            | S           | Unknown      | 100 Mg, Daily (1-0-0-0)     |                 | Not Reported |
|                          | Plavix                               |              |            | S           | Oral         | 75 Mg, Daily (1-0-0-0)      |                 | Not Reported |
|                          | Haldol                               |              |            | S           | Unknown      | 5 Gtt, 2x/Day (1gtt= 2.0    |                 | Not Reported |

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|                                        |                           |                    |                    |                       |                           |                      |                 |              |                |
|----------------------------------------|---------------------------|--------------------|--------------------|-----------------------|---------------------------|----------------------|-----------------|--------------|----------------|
| Insulin                                |                           | C                  |                    | Mg/MI)<br>Unk, 2x/Day |                           | Not Reported         |                 |              |                |
| <u>FDA Received Date</u>               | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>       | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Oct-2016                            | 12860858                  | EXPEDITED (15-DAY) |                    | HO                    | US-SUNOVION-2016SUN002559 |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                  | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>           | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Malaise; Mania;<br>Withdrawal Syndrome | Latuda                    |                    |                    | S                     | Oral                      | 20 Mg, Unk           |                 | Sunovion     |                |
|                                        | Latuda                    |                    |                    | S                     | Oral                      | 60 Mg, Qd            |                 | Sunovion     |                |
|                                        | Lexapro                   |                    |                    | S                     |                           | Unk                  |                 | Not Reported |                |
|                                        | Lexapro                   |                    |                    | S                     |                           | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>               | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>       | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Oct-2016                            | 12862811                  | EXPEDITED (15-DAY) |                    | OT                    | SG-ALLERGAN-1672780US     |                      | 29 YR           | Female       | SGP            |
| <u>Preferred Term</u>                  | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>           | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypoaesthesia; Tongue Biting           | Escitalopram Oxalate - Bp |                    |                    | S                     | Unknown                   |                      |                 | Allergan     |                |
| <u>FDA Received Date</u>               | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>       | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Oct-2016                            | 12862841                  | EXPEDITED (15-DAY) |                    | HO                    | SG-ALLERGAN-1672786US     |                      | 49 YR           | Female       | SGP            |
| <u>Preferred Term</u>                  | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>           | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Photosensitivity Reaction              | Escitalopram Oxalate - Bp |                    |                    | S                     | Oral                      |                      |                 | Allergan     |                |
| <u>FDA Received Date</u>               | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>       | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Oct-2016                            | 12863045                  | EXPEDITED (15-DAY) |                    | OT                    | SG-ALLERGAN-1672793US     |                      | 19 YR           | Female       | SGP            |
| <u>Preferred Term</u>                  | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>           | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Oculogyric Crisis                      | Escitalopram Oxalate - Bp |                    |                    | S                     | Unknown                   | Unk                  |                 | Allergan     |                |

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| <u>FDA Received Date</u>                                                 | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|--------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|----------------------|----------------|
| 19-Oct-2016                                                              | 12863242                  | EXPEDITED (15-DAY) |                    | HO              | SG-ALLERGAN-1672795US                           |                      | 39 YR           | Female               | SGP            |
| <u>Preferred Term</u>                                                    | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Hyponatraemia; Seizure                                                   | Escitalopram Oxalate - Bp |                    |                    | S               | Unknown                                         | Unk                  |                 | Allergan             |                |
| <u>FDA Received Date</u>                                                 | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 19-Oct-2016                                                              | 12863251                  | NON-EXPEDITED      |                    |                 | US-OTSUKA-2016_017508                           |                      |                 | Female               | USA            |
| <u>Preferred Term</u>                                                    | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Weight Increased                                                         | Rexulti                   |                    |                    | S               | Unknown                                         | Unk                  |                 | Otsuka               |                |
|                                                                          | Rexulti                   |                    |                    | S               |                                                 |                      |                 | Otsuka               |                |
|                                                                          | Lexapro                   |                    |                    | S               | Unknown                                         | Unk                  |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                 | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 19-Oct-2016                                                              | 12865590                  | DIRECT             | Y                  | LT              |                                                 |                      | 64 YR           | Male                 | USA            |
| <u>Preferred Term</u>                                                    | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Suicidal Ideation                                                        | Escitalopram              |                    |                    | S               | Oral                                            |                      |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                 | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 20-Oct-2016                                                              | 12488540                  | EXPEDITED (15-DAY) |                    | HO, LT, OT      | FR-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-048646 |                      | 68 YR           | Female               | FRA            |
| <u>Preferred Term</u>                                                    | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Aneurysm Repair; Carotid Artery Aneurysm; Labelled Drug-Drug Interaction | Eliquis                   |                    |                    | S               | Oral                                            | 5 Mg, Bid            |                 | Bristol Myers Squibb |                |
| Medication Error;                                                        | Cordarone                 |                    |                    | S               | Oral                                            | 200 Mg, Daily        |                 | Not Reported         |                |
| Pneumonia Aspiration;                                                    | Seroplex                  |                    |                    | S               | Oral                                            | 20 Mg, Daily         |                 | Not Reported         |                |
| Subarachnoid                                                             | Micardis                  |                    |                    | C               | Oral                                            | 1 Df, Qd             |                 | Not Reported         |                |
| Haemorrhage                                                              | Pariet                    |                    |                    | C               | Oral                                            | 20 Mg, Qd            |                 | Not Reported         |                |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                 |   |                          |             |              |
|-----------------|---|--------------------------|-------------|--------------|
| Singulair       | C | Oral                     | 1 Df, Qd    | Not Reported |
| Symbicort       | C | Respiratory (inhalation) | 200 Mg, Bid | Not Reported |
| Lasilix Faible  | C | Oral                     | 1 Df, Qd    | Not Reported |
| Euphylline L.A. | C | Oral                     | 1 Df, Bid   | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Oct-2016              | 12685028      | EXPEDITED (15-DAY) |                    | OT              | US-FRI-1000086663    |                      | 66 YR      | Male       | USA            |

| <u>Preferred Term</u>                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abdominal Discomfort;                | Lexapro        |              |            | S           |              | Unk                |                 | Allergan     |
| Diarrhoea; Epistaxis;                | Ambrisentan    |              |            | S           |              | 10 Mg, Qd          |                 | Not Reported |
| Gingival Bleeding;                   | Zoloft         |              |            | S           |              |                    |                 | Not Reported |
| Melaena; Off Label Use;              | Revatio        |              |            | C           |              |                    |                 | Not Reported |
| Rectal Haemorrhage; Skin Haemorrhage |                |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 20-Oct-2016              | 12834239      | EXPEDITED (15-DAY) |                    |                 | NL-ALLERGAN-1671494US |                      | 20 YR      | Female     | NLD            |

| <u>Preferred Term</u> | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| No Adverse Event      | Escitalopram Oxalate Unk |              |            | S           |              |                    |                 | Allergan   |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 20-Oct-2016              | 12867383      | EXPEDITED (15-DAY) |                    | HO, OT          | AT-MYLANLABS-2016M1044373 |                      |            | Unknown    | AUT            |

| <u>Preferred Term</u>                                                                                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cognitive Disorder; Depression; Dysphoria; Insomnia; Mania; Paranoia; Psychomotor Hyperactivity; Social Avoidant Behaviour | Escitalopram   |              |            | S           | Unknown      | 10 Mg, Unk         |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                  | <u>Case #</u>                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|------------------------------|----------------|
| 21-Oct-2016                                                                                                                               | 12476328                                    | EXPEDITED (15-DAY) |                    | OT              | FR-PFIZER INC-2016298678 |                      | 24 YR           | Female                       | FRA            |
| <u>Preferred Term</u>                                                                                                                     | <u>Product</u>                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Obsessive-Compulsive Disorder                                                                                                             | Xanax                                       |                    |                    | S               | Oral                     | 0.5 Mg, Unk          |                 | Pfizer                       |                |
|                                                                                                                                           | Lamictal                                    |                    |                    | S               | Oral                     | Unk                  |                 | Not Reported                 |                |
|                                                                                                                                           | Lamictal                                    |                    |                    | S               | Oral                     | 200 Mg, Daily        |                 | Not Reported                 |                |
|                                                                                                                                           | Theralene                                   |                    |                    | S               | Oral                     | Unk                  |                 | Not Reported                 |                |
|                                                                                                                                           | Imovane                                     |                    |                    | S               | Oral                     | 1 Df, 1x/Day         |                 | Not Reported                 |                |
|                                                                                                                                           | Seroplex                                    |                    |                    | S               | Oral                     | Unk                  |                 | Not Reported                 |                |
|                                                                                                                                           | Optilova                                    |                    |                    | C               |                          | Unk                  |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                                                                                                                  | <u>Case #</u>                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 21-Oct-2016                                                                                                                               | 12492419                                    | EXPEDITED (15-DAY) |                    | HO, LT, OT      | FR-PFIZER INC-2016312120 |                      | 68 YR           | Female                       | FRA            |
| <u>Preferred Term</u>                                                                                                                     | <u>Product</u>                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Aneurysm Repair; Carotid Artery Aneurysm; Labelled Drug-Drug Interaction Medication Error; Pneumonia Aspiration; Subarachnoid Haemorrhage | Cordarone                                   |                    |                    | S               | Oral                     | 200 Mg, 1x/Day       |                 | Pfizer                       |                |
|                                                                                                                                           | Eliquis                                     |                    |                    | S               | Oral                     | 5 Mg, 2x/Day         |                 | Not Reported                 |                |
|                                                                                                                                           | Eliquis                                     |                    |                    | S               |                          |                      |                 | Not Reported                 |                |
|                                                                                                                                           | Seroplex                                    |                    |                    | S               | Oral                     | 20 Mg, 1x/Day        |                 | Not Reported                 |                |
|                                                                                                                                           | Micardis                                    |                    |                    | C               | Oral                     | 1 Df, 1x/Day         |                 | Not Reported                 |                |
|                                                                                                                                           | Pariet                                      |                    |                    | C               | Oral                     | 20 Mg, 1x/Day        |                 | Not Reported                 |                |
|                                                                                                                                           | Singulair                                   |                    |                    | C               | Oral                     | 1 Df, 1x/Day         |                 | Not Reported                 |                |
|                                                                                                                                           | Symbicort                                   |                    |                    | C               | Respiratory (inhalation) | 200 Mg, 2x/Day       |                 | Not Reported                 |                |
|                                                                                                                                           | Lasilix Faible                              |                    |                    | C               | Oral                     | 1 Df, 1x/Day         |                 | Not Reported                 |                |
|                                                                                                                                           | Euphylline L.A.                             |                    |                    | C               | Oral                     | 1 Df, 2x/Day         |                 | Not Reported                 |                |
|                                                                                                                                           | Lasilix /00032601/<br>Euphylline /00003701/ |                    |                    | C<br>C          |                          |                      |                 | Not Reported<br>Not Reported |                |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                    | <u>Case #</u>                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u>                         | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>                                             | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|--------------------|--------------------|------------------|----------------------------------------------|------------------------------------|-----------------|--------------------------------------------------------|----------------|
| 21-Oct-2016                                                                                                                 | 12691382                                    | EXPEDITED (15-DAY) |                    | OT               | CA-VERTEX<br>PHARMACEUTICALS-<br>2016-004943 |                                    | 35 YR           | Female                                                 | CAN            |
| <u>Preferred Term</u>                                                                                                       | <u>Product</u>                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>                                 | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>                                             |                |
| Drug Interaction;<br>Increased Appetite;<br>Nausea; Suicidal Ideation                                                       | Orkambi<br>Cipralex                         |                    |                    | S<br>S           | Oral<br>Oral                                 | 400-250 Mg, Bid<br>20 Mg, Qd       |                 | Vertex<br>Not Reported                                 |                |
| <u>FDA Received Date</u>                                                                                                    | <u>Case #</u>                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u>                         | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>                                             | <u>Country</u> |
| 21-Oct-2016                                                                                                                 | 12827017                                    | EXPEDITED (15-DAY) |                    | HO               | JP-ALLERGAN-<br>1000087604                   |                                    | 1 DAY           | Male                                                   | JPN            |
| <u>Preferred Term</u>                                                                                                       | <u>Product</u>                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>                                 | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>                                             |                |
| Drug Withdrawal<br>Syndrome Neonatal;<br>Foetal Exposure During<br>Pregnancy                                                | Lexapro Tablets                             |                    |                    | S                | Transplacental                               | 10 Mg, Single                      |                 | Allergan                                               |                |
| <u>FDA Received Date</u>                                                                                                    | <u>Case #</u>                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u>                         | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>                                             | <u>Country</u> |
| 21-Oct-2016                                                                                                                 | 12855084                                    | EXPEDITED (15-DAY) |                    | OT               | US-PFIZER INC-<br>2016478596                 |                                    | 66 YR           | Male                                                   | USA            |
| <u>Preferred Term</u>                                                                                                       | <u>Product</u>                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>                                 | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>                                             |                |
| Abdominal Discomfort;<br>Diarrhoea; Epistaxis;<br>Gingival Bleeding;<br>Melaena; Rectal<br>Haemorrhage; Skin<br>Haemorrhage | Zoloft<br>Ambrisentan<br>Lexapro<br>Revatio |                    |                    | S<br>S<br>S<br>C |                                              | Unk<br>10 Mg, 1x/Day<br>Unk<br>Unk |                 | Pfizer<br>Not Reported<br>Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                                                    | <u>Case #</u>                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u>                         | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>                                             | <u>Country</u> |
| 21-Oct-2016                                                                                                                 | 12870487                                    | EXPEDITED (15-DAY) |                    | CA, HO           | NL-AUROBINDO-AUR-<br>APL-2014-02025          |                                    |                 | Unknown                                                | NLD            |
| <u>Preferred Term</u>                                                                                                       | <u>Product</u>                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>                                 | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>                                             |                |
| Coarctation Of The Aorta;                                                                                                   | Sertraline Aurobindo                        |                    |                    | S                | Transplacental                               | 50 Mg,Once A Day,                  |                 | Aurobindo                                              |                |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                        |                               |                                                   |                    |                 |                       |                      |                 |              |                |
|--------------------------------------------------------|-------------------------------|---------------------------------------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| Foetal Exposure During Pregnancy; Respiratory Failure  |                               | Filmomhulde Tabletten 50mg Escitalopram Aurobindo |                    | S               | Transplacental        | 10 Mg, Once A Day,   |                 | Aurobindo    |                |
|                                                        |                               | Filmomhulde Tabletten 10mg Folic Acid             |                    | C               | Unknown               | Unk Unk, Unk,        |                 | Not Reported |                |
| <u>FDA Received Date</u>                               | <u>Case #</u>                 | <u>Case Type</u>                                  | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Oct-2016                                            | 12871536                      | DIRECT                                            |                    |                 |                       |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                  | <u>Product</u>                | <u>Comp.</u>                                      | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Physical Product Label Issue; Product Dispensing Error | Escitalopram Oxalate          |                                                   |                    | S               |                       |                      |                 | Not Reported |                |
|                                                        | Escitalopram                  |                                                   |                    |                 |                       |                      |                 |              |                |
|                                                        | Enalapril Maleate Enalaprilat |                                                   |                    | S               |                       |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                               | <u>Case #</u>                 | <u>Case Type</u>                                  | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Oct-2016                                            | 12871670                      | DIRECT                                            | Y                  |                 |                       |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                  | <u>Product</u>                | <u>Comp.</u>                                      | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Product Dispensing Error; Product Selection Error      | Atorvastatin Calcium          |                                                   |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                        | Atorvastatin                  |                                                   |                    |                 |                       |                      |                 |              |                |
|                                                        | Escitalopram Oxalate          |                                                   |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                        | Escitalopram                  |                                                   |                    |                 |                       |                      |                 |              |                |
| <u>FDA Received Date</u>                               | <u>Case #</u>                 | <u>Case Type</u>                                  | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Oct-2016                                            | 12874213                      | EXPEDITED (15-DAY)                                |                    | OT              | US-ALLERGAN-1672886US |                      | 60 YR           | Female       | USA            |
| <u>Preferred Term</u>                                  | <u>Product</u>                | <u>Comp.</u>                                      | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Crying;                                    | Lexapro                       |                                                   |                    | S               | Oral                  | 20 Mg, Unk           |                 | Allergan     |                |
| Hallucination; Mood Swings; Muscle Spasms;             | Lexapro                       |                                                   |                    | S               | Oral                  | 40 Mg, Unk           |                 | Allergan     |                |
| Staphylococcal Infection;                              | Norco                         |                                                   |                    | C               | Oral                  | Unk, Prn             |                 | Not Reported |                |
| Suicidal Ideation; Tremor                              | Gabapentin                    |                                                   |                    | C               | Oral                  | Unk, Tid             |                 | Not Reported |                |
|                                                        | Lisinopril                    |                                                   |                    | C               | Oral                  | 20 Mg, Qd            |                 | Not Reported |                |
|                                                        | Lisinopril                    |                                                   |                    | C               |                       |                      |                 | Not Reported |                |
|                                                        | Topiramate                    |                                                   |                    | C               | Oral                  | Unk Unk, Bid         |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                         |   |      |                             |              |
|-------------------------|---|------|-----------------------------|--------------|
| Clonopin                | C | Oral | 0.1 Mg, Prn                 | Not Reported |
| Memantine Hydrochloride | C | Oral | 10 (Units Not Provided), Qd | Not Reported |
| Atorvastatin            | C | Oral | 40 Mg, Qd                   | Not Reported |
| Ms Contin               | C | Oral | Unk, Tid                    | Not Reported |

| <u>FDA Received Date</u>                                         | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 21-Oct-2016                                                      | 12874485                  | EXPEDITED (15-DAY) |                    | OT              | FI-ALLERGAN-1673150US |                      | 17 YR           | Female       | FIN            |
| <u>Preferred Term</u>                                            | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Overdose; Poisoning; Product Use Issue; Suicide Attempt | Escitalopram Oxalate - Bp |                    |                    | S               | Oral                  | 10 Mg, Qd            |                 | Allergan     |                |
|                                                                  | Escitalopram Oxalate - Bp |                    |                    | S               |                       | 50 Mg, Single        |                 | Allergan     |                |
|                                                                  | Paracetamol               |                    |                    | S               | Unknown               | Overdose 15 G        |                 | Not Reported |                |

| <u>FDA Received Date</u>                                 | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|------------------------|----------------------|-----------------|--------------|----------------|
| 21-Oct-2016                                              | 12874645                  | EXPEDITED (15-DAY) |                    | HO, OT          | CH-ALLERGAN-1000087584 |                      | 32 YR           | Female       | CHE            |
| <u>Preferred Term</u>                                    | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Exposure During Pregnancy; Suicidal Ideation | Escitalopram Oxalate - Bp |                    |                    | S               | Oral                   | 20 Mg, Qd            |                 | Allergan     |                |
|                                                          | Zoloft                    |                    |                    | S               | Oral                   | 25 Mg, Qd            |                 | Not Reported |                |
|                                                          | Seresta                   |                    |                    | S               | Oral                   | 15 Mg, Bid           |                 | Not Reported |                |
|                                                          | Seresta                   |                    |                    | S               | Oral                   | 30 Mg, Qd            |                 | Not Reported |                |
|                                                          | Seroquel                  |                    |                    | S               | Unknown                | 100 Mg, Qd           |                 | Not Reported |                |
|                                                          | Anxiolit                  |                    |                    | S               | Unknown                | 60 Mg, Qd            |                 | Not Reported |                |
|                                                          | Temesta (Lorazepam)       |                    |                    | S               | Unknown                | 2.5 Mg, Qd           |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|------------------------------------|----------------------|-----------------|------------|----------------|
| 24-Oct-2016              | 12473452       | EXPEDITED (15-DAY) |                    | OT              | FR-GLAXOSMITHKLINE-FR2016GSK085431 |                      | 23 YR           | Female     | FRA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                       | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                                     |           |   |      |             |                 |
|---------------------------------------------------------------------|-----------|---|------|-------------|-----------------|
| Obsessive-Compulsive Disorder; Product Use In Unapproved Indication | Lamictal  | S | Oral | Unk         | Glaxosmithkline |
|                                                                     | Xanax     | S | Oral | 0.5 Mg, Unk | Glaxosmithkline |
|                                                                     | Imovane   | S | Oral | 1 Df, Qd    | Glaxosmithkline |
|                                                                     | Seroplex  | S | Oral | Unk         | Glaxosmithkline |
|                                                                     | Theralene | S | Oral | Unk         | Not Reported    |
|                                                                     | Optilova  | C |      |             | Not Reported    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Oct-2016              | 12875612      | EXPEDITED (15-DAY) |                    | OT              | DK-ACCORD-045043     |                      | 26 YR      | Male       | DNK            |

| <u>Preferred Term</u>                  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|----------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Intercepted Medication Error; Overdose | Escitalopram   |              |            | S           | Oral         |                    |                 | Accord     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------|----------------------|------------|------------|----------------|
| 24-Oct-2016              | 12875823      | NON-EXPEDITED    |                    |                 | US-JAZZ-2016-US-014878 |                      | 14 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Initial Insomnia      | Xyrem          |              |            | S           | Oral         | 2.25 G, Bid        |                 | Jazz         |
|                       | Xyrem          |              |            | S           | Oral         | Dose Adjustments   |                 | Jazz         |
|                       | Xyrem          |              |            | S           | Oral         | 4.5 G, Bid         |                 | Jazz         |
|                       | Xyrem          |              |            | S           | Oral         | 4.5 G, Bid         |                 | Jazz         |
|                       | Lexapro        |              |            | S           |              | Unknown Dose       |                 | Not Reported |
|                       | Alvesco        |              |            | C           |              |                    |                 | Not Reported |
|                       | Nuvigil        |              |            | C           |              |                    |                 | Not Reported |
|                       | Veramyst       |              |            | C           |              |                    |                 | Not Reported |
|                       | Zyrtec         |              |            | C           |              |                    |                 | Not Reported |
|                       | Melatonin      |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Oct-2016              | 12877651      | EXPEDITED (15-DAY) |                    | HO, LT, OT      | PL-SA-2016SA193820   |                      |            | Unknown    | POL            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

**FDA Adverse Event Reporting System  
Freedom of Information Act (FOIA)  
Detailed Report**

|                                         |                                  |   |         |              |
|-----------------------------------------|----------------------------------|---|---------|--------------|
| Overdose; Toxicity To<br>Various Agents | Ramipril                         | S | Unknown | Not Reported |
|                                         | Metformin                        | S | Unknown | Not Reported |
|                                         | Diclofenac Salt Not Specified    | S | Unknown | Not Reported |
|                                         | Risperidone                      | S | Unknown | Not Reported |
|                                         | Hydroxyzine                      | S | Unknown | Not Reported |
|                                         | Zolpidem                         | S | Unknown | Not Reported |
|                                         | Topiramate                       | S | Unknown | Not Reported |
|                                         | Donepezil Hydrochloride          | S | Unknown | Not Reported |
|                                         | Bisoprolol Fumarate              | S | Unknown | Not Reported |
|                                         | Metoprolol Salt Not Specified    | S | Unknown | Not Reported |
|                                         | Amlodipine (Salt Not Specified)  | S | Unknown | Not Reported |
|                                         | Simvastatin                      | S | Unknown | Not Reported |
|                                         | Atorvastatin                     | S | Unknown | Not Reported |
|                                         | Rosuvastatin                     | S | Unknown | Not Reported |
|                                         | Dextromethorphan<br>Hydrobromide | S | Unknown | Not Reported |
|                                         | Omeprazole                       | S | Unknown | Not Reported |
|                                         | Lamotrigine                      | S | Unknown | Not Reported |
|                                         | Valsartan                        | S | Unknown | Not Reported |
|                                         | Venlafaxine                      | S | Unknown | Not Reported |
|                                         | Olanzapine                       | S | Unknown | Not Reported |
|                                         | Escitalopram                     | S | Unknown | Not Reported |
|                                         | Indapamide                       | S | Unknown | Not Reported |
|                                         | Morphine Hydrochloride           | S | Unknown | Not Reported |
|                                         | Acetylsalicylic Acid             | S | Unknown | Not Reported |
|                                         | Carbamazepine                    | S | Unknown | Not Reported |
|                                         | Sertraline                       | S | Unknown | Not Reported |
|                                         | Sulpiride                        | S | Unknown | Not Reported |
|                                         | Ibuprofen                        | S | Unknown | Not Reported |
|                                         | Paracetamol                      | S | Unknown | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                  | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------|------------------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 24-Oct-2016                                               | 12877921                     | EXPEDITED (15-DAY) |                    | DE              | AT-ALLERGAN-1673371US |                      | 70 YR           | Female       | AUT            |
| <u>Preferred Term</u>                                     | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Tachycardia                                               | Escitalopram Oxalate - Bp    |                    |                    | S               | Oral                  | 10 Mg, Qd            |                 | Allergan     |                |
|                                                           | Marcumar / Phenprocoumon     |                    |                    | C               |                       | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                  | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Oct-2016                                               | 12878331                     | EXPEDITED (15-DAY) |                    | HO, OT          | FR-ALLERGAN-1673364US |                      | 75 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                     | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anaemia; Fall; Haematoma                                  | Escitalopram Oxalate - Bp    |                    |                    | S               | Oral                  |                      |                 | Allergan     |                |
|                                                           | Arixtra                      |                    |                    | S               | Subcutaneous          | 7.5mg/0.6ml          |                 | Not Reported |                |
|                                                           | Exelon                       |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |
|                                                           | Cibadrex                     |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |
|                                                           | Tahor                        |                    |                    | C               |                       |                      |                 | Not Reported |                |
|                                                           | Lactulose                    |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |
|                                                           | Doliprane                    |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |
|                                                           | Esomeprazole                 |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                  | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Oct-2016                                               | 12878401                     | EXPEDITED (15-DAY) |                    | DE, HO          | FR-ALLERGAN-1673370US |                      | 87 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                     | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Eyelid Haematoma; Periorbital Haematoma | Escitalopram Oxalate - Bp    |                    |                    | S               | Oral                  |                      |                 | Allergan     |                |
|                                                           | Kardegic                     |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                           | Clopidogrel                  |                    |                    | S               | Oral                  | 75 Mg, Qd            |                 | Not Reported |                |
|                                                           | Atorvastatin Arrow           |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |
|                                                           | Perindopril Arginine Servier |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |                   |   |         |               |              |
|--|-------------------|---|---------|---------------|--------------|
|  | Nebivolol Actavis | C | Unknown |               | Not Reported |
|  | Seretide          | C | Unknown | 250/25µg      | Not Reported |
|  | Fosavance         | C | Unknown | 70mg/28000 Ui | Not Reported |
|  | Uvedose           | C | Unknown |               | Not Reported |
|  | Doliprane         | C | Unknown |               | Not Reported |

| <u>FDA Received Date</u>                                                                                                                                                                         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
| 24-Oct-2016                                                                                                                                                                                      | 12878611       | EXPEDITED (15-DAY) |                    | OT              | NO-MYLANLABS-2016M1044639 |                      |                 | Unknown      | NOR            |
| <u>Preferred Term</u>                                                                                                                                                                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Decreased Interest;<br>Depressed Mood;<br>Disturbance In Attention;<br>Fatigue; Feelings Of<br>Worthlessness; Negative<br>Thoughts; Sleep Disorder;<br>Suicidal Behaviour;<br>Weight Fluctuation | Escitalopram   |                    |                    | S               | Unknown                   | Unk                  |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 24-Oct-2016              | 12878661                | EXPEDITED (15-DAY) |                    | DE              | PHHY2016US144408     |                      | 42 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide        | Metoprolol              |                    |                    | S               | Oral                 |                      |                 | Novartis     |                |
|                          | Oxycodone Hydrochloride |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                          | Zolpidem                |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                          | Diazepam                |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                          | Escitalopram            |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 24-Oct-2016              | 12878906       | EXPEDITED (15-DAY) |                    | HO              | FR-MYLANLABS-2016M1045674 |                      |                 | Unknown    | FRA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                             |                   |   |              |            |              |
|-----------------------------|-------------------|---|--------------|------------|--------------|
| Anaemia; Fall;<br>Haematoma | Fondaparinux      | S | Subcutaneous | 7.5 Mg, Qd | Not Reported |
|                             | Seroplex          | S | Oral         | 20 Mg, Qd  | Mylan        |
|                             | Exelon /01383201/ | C |              | 4.6 Mg, Qd | Mylan        |
|                             | Cibadrex          | C |              | Unk        | Mylan        |
|                             | Tahor             | C |              | Unk        | Mylan        |
|                             | Lactulose         | C |              | Unk        | Mylan        |
|                             | Doliprane         | C |              | Unk        | Mylan        |
|                             | Esomeprazole      | C |              | Unk        | Mylan        |

| <u>FDA Received Date</u>                      | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------|----------------|------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 25-Oct-2016                                   | 10971154       | NON-EXPEDITED    |                    |                 | US-JNJFOC-20150313235 |                      | 8 YR            | Male         | USA            |
| <u>Preferred Term</u>                         | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Emotional Distress;<br>Gynaecomastia; Obesity | Risperdal      |                  |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                               | Risperdal      |                  |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                               | Lexapro        |                  |                    | S               | Unknown               |                      |                 | Not Reported |                |
|                                               | Catapres       |                  |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                               | Depakote Er    |                  |                    | C               | Oral                  |                      |                 | Not Reported |                |
|                                               | Zoloft         |                  |                    | C               | Oral                  |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                    | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 25-Oct-2016                                                                                                                                 | 11020901       | NON-EXPEDITED    |                    |                 | US-JNJFOC-20150404210 |                      |                 | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                       | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Weight Gain;<br>Galactorrhoea;<br>Gynaecomastia;<br>Hyperprolactinaemia; Off<br>Label Use; Product Use In<br>Unapproved Indication | Risperdal      |                  |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                                                             | Risperdal      |                  |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                                                             | Risperidone    |                  |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                                                             | Lexapro        |                  |                    | S               | Oral                  |                      |                 | Not Reported |                |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Oct-2016              | 11880691      | EXPEDITED (15-DAY) |                    | HO, LT          | JP-FRI-1000081924    |                      | 73 YR      | Female     | JPN            |

| <u>Preferred Term</u>         | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Autoimmune Haemolytic Anaemia | Lexapro Tablets         |              |            | S           | Oral         | 1/2 Tablet Daily   |                 | Allergan     |
|                               | Lexapro Tablets         |              |            | S           | Oral         | 10mg Daily         |                 | Allergan     |
|                               | Trazodone Hydrochloride |              |            | C           | Oral         | 25 Mg, Qd          |                 | Not Reported |
|                               | Lexotan (Bromazepam)    |              |            | C           | Oral         | 1 Mg, Qd           |                 | Not Reported |
|                               | Wypax                   |              |            | C           | Oral         | Unknown            |                 | Not Reported |
|                               | Norvasc                 |              |            | C           |              |                    |                 | Not Reported |
|                               | Selectol                |              |            | C           |              |                    |                 | Not Reported |
|                               | Diovan                  |              |            | C           |              |                    |                 | Not Reported |
|                               | Sermion                 |              |            | C           |              |                    |                 | Not Reported |
|                               | Aricept                 |              |            | C           |              |                    |                 | Not Reported |
|                               | Nexium                  |              |            | C           |              |                    |                 | Not Reported |
|                               | Desyrel                 |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 25-Oct-2016              | 12449865      | NON-EXPEDITED    |                    |                 | US-JNJFOC-20160505909 |                      | 8 YR       | Male       | USA            |

| <u>Preferred Term</u>                                                                              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------------|-----------------|--------------|
| Emotional Distress; Gynaecomastia; Off Label Use; Overweight; Product Use In Unapproved Indication | Risperdal      |              |            | S           | Oral         | 0.5 (Unit Not Specified) |                 | Not Reported |
|                                                                                                    | Risperdal      |              |            | S           | Oral         | 0.5 (Unit Not Specified) |                 | Not Reported |
|                                                                                                    | Abilify        |              |            | S           | Unknown      |                          |                 | Not Reported |
|                                                                                                    | Abilify        |              |            | S           | Unknown      |                          |                 | Not Reported |
|                                                                                                    | Abilify        |              |            | S           | Unknown      |                          |                 | Not Reported |
|                                                                                                    | Lexapro        |              |            | S           | Unknown      |                          |                 | Not Reported |
|                                                                                                    | Lexapro        |              |            | S           | Unknown      |                          |                 | Not Reported |
|                                                                                                    | Lexapro        |              |            | S           | Unknown      |                          |                 | Not Reported |
|                                                                                                    | Lexapro        |              |            | S           | Unknown      |                          |                 | Not Reported |
|                                                                                                    | Strattera      |              |            | S           | Oral         |                          |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                               | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|--------------------|--------------------|-----------------|--------------------------------------------------------|----------------------|-----------------|----------------------|----------------|
| 25-Oct-2016                                                                                                                                                                            | 12879422              | EXPEDITED (15-DAY) |                    | OT              | DE-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>BMS-2016-088348 |                      | 34 YR           | Female               | DEU            |
| <u>Preferred Term</u>                                                                                                                                                                  | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Aggression; Alopecia;<br>Bronchitis; Depression;<br>Gastrointestinal Infection;<br>General Physical Health<br>Deterioration;<br>Haematoma; Insomnia;<br>Nausea; Sinusitis;<br>Vomiting | Entecavir             |                    |                    | S               | Unknown                                                |                      |                 | Bristol Myers Squibb |                |
|                                                                                                                                                                                        | Peginterferon Alfa-2a |                    |                    | S               | Subcutaneous                                           | 180 Mg, Qwk          |                 | Not Reported         |                |
|                                                                                                                                                                                        | Cipralext /01588501/  |                    |                    | S               | Unknown                                                |                      |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                                                                                                                               | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 25-Oct-2016                                                                                                                                                                            | 12879447              | EXPEDITED (15-DAY) |                    |                 | US-CIPLA LTD.-<br>2016US07014                          |                      |                 | Unknown              | USA            |
| <u>Preferred Term</u>                                                                                                                                                                  | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Insomnia; Palpitations                                                                                                                                                                 | Escitalopram          |                    |                    | S               | Oral                                                   | 20 Mg, Qd            |                 | Invagen              |                |
| <u>FDA Received Date</u>                                                                                                                                                               | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 25-Oct-2016                                                                                                                                                                            | 12879453              | EXPEDITED (15-DAY) |                    |                 | US-CIPLA LTD.-<br>2016US04595                          |                      |                 | Unknown              | USA            |
| <u>Preferred Term</u>                                                                                                                                                                  | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Hypersensitivity                                                                                                                                                                       | Escitalopram          |                    |                    | S               |                                                        | 10 Mg, Unk           |                 | Invagen              |                |
| <u>FDA Received Date</u>                                                                                                                                                               | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 25-Oct-2016                                                                                                                                                                            | 12879454              | EXPEDITED (15-DAY) |                    |                 | US-CIPLA LTD.-<br>2016US07024                          |                      |                 | Unknown              | USA            |
| <u>Preferred Term</u>                                                                                                                                                                  | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Eye Swelling                                                                                                                                                                           | Escitalopram          |                    |                    | S               | Oral                                                   | 10 Mg, Qd, 3 Weeks   |                 | Invagen              |                |

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| <u>FDA Received Date</u>                                          | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u>                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|-------------------------------|-------------------------------------------|-----------------|--------------|----------------|
| 25-Oct-2016                                                       | 12879560       | EXPEDITED (15-DAY) |                    | OT              | DK-ACCORD-045045              |                                           | 26 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                             | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>                        | <u>Duration</u> | <u>Mfr</u>   |                |
| Intercepted Medication<br>Error; Potentiating Drug<br>Interaction | Escitalopram   |                    |                    | S               | Oral                          |                                           |                 | Accord       |                |
|                                                                   | Olanzapine     |                    |                    | S               | Oral                          |                                           |                 | Accord       |                |
|                                                                   | Propranolol    |                    |                    | S               | Oral                          |                                           |                 | Not Reported |                |
|                                                                   | Abilify        |                    |                    | S               | Oral                          |                                           |                 | Not Reported |                |
|                                                                   | Seroquel       |                    |                    | S               | Oral                          |                                           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                          | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u>                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Oct-2016                                                       | 12879585       | EXPEDITED (15-DAY) |                    |                 | US-CIPLA LTD.-<br>2016US07038 |                                           |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                             | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>                        | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State                                                 | Escitalopram   |                    |                    | S               | Oral                          | 10 Mg, Unk                                |                 | Invagen      |                |
|                                                                   | Escitalopram   |                    |                    | S               |                               |                                           |                 | Invagen      |                |
|                                                                   | Aricept        |                    |                    | C               | Unknown                       | 10 Mg, Qd                                 |                 | Not Reported |                |
|                                                                   | Actonel        |                    |                    | C               | Unknown                       | 35 Mg, Once A Week                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                          | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u>                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Oct-2016                                                       | 12879588       | EXPEDITED (15-DAY) |                    |                 | US-CIPLA LTD.-<br>2016US07031 |                                           |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                             | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>                        | <u>Duration</u> | <u>Mfr</u>   |                |
| Headache; Sleep Disorder                                          | Escitalopram   |                    |                    | S               | Oral                          | 10 Mg, Every Other Day,<br>Since 10 Years |                 | Invagen      |                |
|                                                                   | Verapamil      |                    |                    | C               | Unknown                       | 80 Mg, Qd                                 |                 | Not Reported |                |
|                                                                   | Zyrtec         |                    |                    | C               | Unknown                       | 10 Mg, Qd                                 |                 | Not Reported |                |
|                                                                   | Multi Vitamins |                    |                    | C               | Unknown                       | Unk, Qd                                   |                 | Not Reported |                |
|                                                                   | Chantix        |                    |                    | C               | Unknown                       | 1 Mg, Bid                                 |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                               | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------|--------------------|--------------------|--------------------|-----------------|-------------------------------|------------------------|-----------------|--------------|----------------|
| 25-Oct-2016                                                            | 12879590           | EXPEDITED (15-DAY) |                    |                 | US-CIPLA LTD.-<br>2016US07059 |                        |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                  | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Headache                                                               | Escitalopram       |                    |                    | S               | Oral                          | 5 Mg, Qd               |                 | Invagen      |                |
|                                                                        | Metoprolol         |                    |                    | C               | Unknown                       | Half Tablet Once Daily |                 | Not Reported |                |
| <u>FDA Received Date</u>                                               | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Oct-2016                                                            | 12879591           | EXPEDITED (15-DAY) |                    |                 | US-CIPLA LTD.-<br>2016US07042 |                        |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                  | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Diplopia; Erythema;<br>Headache; Swelling Of<br>Eyelid; Vision Blurred | Escitalopram       |                    |                    | S               |                               | 5 Mg, Qd               |                 | Invagen      |                |
|                                                                        | Escitalopram       |                    |                    | S               |                               |                        |                 | Invagen      |                |
|                                                                        | Aspirin            |                    |                    | C               | Unknown                       | 81 Mg, Unk             |                 | Not Reported |                |
|                                                                        | Potassium Chloride |                    |                    | C               | Unknown                       | 10 Meq, Bid            |                 | Not Reported |                |
|                                                                        | Synthroid          |                    |                    | C               | Unknown                       | 100 Mcg, Unk           |                 | Not Reported |                |
|                                                                        | Metoprolol         |                    |                    | C               | Unknown                       | 50 Mg, Unk             |                 | Not Reported |                |
|                                                                        | Furosemide         |                    |                    | C               | Unknown                       | 20 Mg, Unk             |                 | Not Reported |                |
|                                                                        | Lisinopril         |                    |                    | C               | Unknown                       | 5 Mg, Unk              |                 | Not Reported |                |
|                                                                        | Allegra            |                    |                    | C               | Unknown                       | 100 Mg, Unk            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                               | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Oct-2016                                                            | 12879592           | EXPEDITED (15-DAY) |                    |                 | US-CIPLA LTD.-<br>2016US07032 |                        |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                  | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Alopecia                                                               | Escitalopram       |                    |                    | S               | Oral                          | 5 Mg, Qd               |                 | Invagen      |                |
| <u>FDA Received Date</u>                                               | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Oct-2016                                                            | 12879594           | EXPEDITED (15-DAY) |                    |                 | US-CIPLA LTD.-<br>2016US06577 |                        |                 | Unknown      | USA            |

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| <u>Preferred Term</u>                           | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>                                                        | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------------------|-----------------|--------------------|--------------------|-----------------|-------------------------------|---------------------------------------------------------------------------|-----------------|--------------|----------------|
| Feeling Abnormal;<br>Hallucination; Nausea      | Escitalopram    |                    |                    | S               | Oral                          | 10 Mg, Qd                                                                 |                 | Invagen      |                |
|                                                 | Escitalopram    |                    |                    | S               | Oral                          | 2 More Pills,Unk                                                          |                 | Invagen      |                |
|                                                 | Escitalopram    |                    |                    | S               | Oral                          | 2 More Pills, Unk                                                         |                 | Invagen      |                |
|                                                 | Pravacid 24 Hrs |                    |                    | C               | Unknown                       | Unk, Qd                                                                   |                 | Not Reported |                |
| <u>FDA Received Date</u>                        | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u>                                                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Oct-2016                                     | 12879605        | EXPEDITED (15-DAY) |                    |                 | US-CIPLA LTD.-<br>2016US07081 |                                                                           |                 | Unknown      | USA            |
| <u>Preferred Term</u>                           | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>                                                        | <u>Duration</u> | <u>Mfr</u>   |                |
| Pruritus; Rash; Urticaria                       | Escitalopram    |                    |                    | S               | Oral                          | 20 Mg, Qd                                                                 |                 | Invagen      |                |
|                                                 | Lipitor         |                    |                    | C               | Unknown                       | 20 Mg, Qd                                                                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                        | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u>                                                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Oct-2016                                     | 12879612        | EXPEDITED (15-DAY) |                    |                 | US-CIPLA LTD.-<br>2016US09590 |                                                                           |                 | Unknown      | USA            |
| <u>Preferred Term</u>                           | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>                                                        | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective; Product<br>Substitution Issue | Escitalopram    |                    |                    | S               | Unknown                       | 20 Mg, Qd                                                                 |                 | Invagen      |                |
| <u>FDA Received Date</u>                        | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u>                                                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Oct-2016                                     | 12879747        | EXPEDITED (15-DAY) |                    |                 | US-CIPLA LTD.-<br>2016US17365 |                                                                           |                 | Unknown      | USA            |
| <u>Preferred Term</u>                           | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>                                                        | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective                                | Escitalopram    |                    |                    | S               | Unknown                       | 5 Mg, Qd, (10mg Tablet<br>Broken Into 5mg Half<br>Consumed Every Morning) |                 | Invagen      |                |
| <u>FDA Received Date</u>                        | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u>                                                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Oct-2016                                     | 12879757        | EXPEDITED (15-DAY) |                    |                 | US-CIPLA LTD.-<br>2016US17837 |                                                                           |                 | Unknown      | USA            |

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| <a href="#">Preferred Term</a>     | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
|------------------------------------|--------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Fatigue                            | Escitalopram             |                           |                             | S                        | Oral                          | 5 Mg, Unk                     |                          | Invagen             |                         |
|                                    | Escitalopram             |                           |                             | S                        | Oral                          | 10 Mg, Unk                    |                          | Invagen             |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 25-Oct-2016                        | 12879760                 | EXPEDITED (15-DAY)        |                             |                          | US-CIPLA LTD.-<br>2016US18095 |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>     | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Alopecia                           | Escitalopram             |                           |                             | S                        | Oral                          | 10 Mg, Qd                     |                          | Invagen             |                         |
|                                    | Provera                  |                           |                             | S                        | Unknown                       | 100 Mg, Qd                    |                          | Not Reported        |                         |
|                                    | Minivelle Estrogen Patch |                           |                             | S                        | Unknown                       | 0.025 Mg, Twice A Week        |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 25-Oct-2016                        | 12879768                 | EXPEDITED (15-DAY)        |                             |                          | US-CIPLA LTD.-<br>2016US18225 |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>     | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Ineffective                   | Escitalopram             |                           |                             | S                        | Unknown                       | 20 Mg, Qd                     |                          | Invagen             |                         |
|                                    | Escitalopram             |                           |                             | S                        |                               |                               |                          | Invagen             |                         |
|                                    | Nature Thyroid           |                           |                             | C                        | Unknown                       | 65 Mg, 1 Grain                |                          | Not Reported        |                         |
|                                    | Xolair                   |                           |                             | C                        | Unknown                       | Unk                           |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 25-Oct-2016                        | 12879775                 | EXPEDITED (15-DAY)        |                             |                          | US-CIPLA LTD.-<br>2016US17000 |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>     | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Adverse Reaction; Drug Ineffective | Escitalopram             |                           |                             | S                        | Unknown                       | 20 Mg, Unk                    |                          | Invagen             |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 25-Oct-2016                        | 12882417                 | EXPEDITED (15-DAY)        |                             | DE                       |                               | PHHY2016US144437              | 14 YR                    | Male                | USA                     |

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| <u>Preferred Term</u>                            | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|--------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| Completed Suicide                                | Metoprolol                |                    |                    | S               | Oral                  |                      |                 | Novartis     |                |
|                                                  | Escitalopram              |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                  | Bupropion                 |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Oct-2016                                      | 12882652                  | EXPEDITED (15-DAY) |                    | DE              | PHHY2016US144568      |                      | 53 YR           | Female       | USA            |
| <u>Preferred Term</u>                            | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                | Baclofen                  |                    |                    | S               | Oral                  | Unk                  |                 | Not Reported |                |
|                                                  | Duloxetine                |                    |                    | S               | Oral                  | Unk                  |                 | Not Reported |                |
|                                                  | Clonazepam                |                    |                    | S               | Oral                  |                      |                 | Novartis     |                |
|                                                  | Escitalopram              |                    |                    | S               | Oral                  | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Oct-2016                                      | 12883279                  | EXPEDITED (15-DAY) |                    | OT              | AU-ALLERGAN-1673372US |                      | 34 YR           | Male         | AUS            |
| <u>Preferred Term</u>                            | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Eating Disorder; Hallucination | Escitalopram Oxalate - Bp |                    |                    | S               | Unknown               |                      |                 | Allergan     |                |
|                                                  | Zolpidem                  |                    |                    | S               | Unknown               |                      |                 | Not Reported |                |
|                                                  | Oxycodone                 |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Oct-2016                                      | 12883304                  | EXPEDITED (15-DAY) |                    | OT              | CH-ALLERGAN-1673519US |                      | 31 YR           | Female       | CHE            |
| <u>Preferred Term</u>                            | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Exposure During Pregnancy; Normal Foetus         | Escitalopram Oxalate - Bp |                    |                    | S               | Oral                  | 10 Mg, Qd            |                 | Allergan     |                |

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| <u>FDA Received Date</u>                                                          | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 26-Oct-2016                                                                       | 12227357                 | EXPEDITED (15-DAY) |                    | HO, LT          | ES-FRI-1000083688    |                      | 84 YR           | Female       | ESP            |
| <u>Preferred Term</u>                                                             | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Electrocardiogram Qt Prolonged; Hypokalaemia; Hypomagnesaemia; Torsade De Pointes | Escitalopram Oxalate Unk |                    |                    | S               | Unknown              | Unk                  |                 | Allergan     |                |
|                                                                                   | Digoxin                  |                    |                    | S               | Unknown              | Unk                  |                 | Not Reported |                |
|                                                                                   | Simvastatin              |                    |                    | S               | Unknown              | Unk                  |                 | Not Reported |                |
|                                                                                   | Sulpiride                |                    |                    | S               | Unknown              | Unk                  |                 | Not Reported |                |
|                                                                                   | Solifenacin              |                    |                    | S               | Unknown              | Unk                  |                 | Not Reported |                |
|                                                                                   | Levofloxacin             |                    |                    | S               | Unknown              | Unk                  |                 | Not Reported |                |
|                                                                                   | Amiodarone               |                    |                    | S               | Unknown              | Unk                  |                 | Not Reported |                |
|                                                                                   | Acenocoumarol            |                    |                    | C               | Unknown              | Unk                  |                 | Not Reported |                |
|                                                                                   | Furosemide               |                    |                    | C               | Unknown              | Unk                  |                 | Not Reported |                |
|                                                                                   | Candesartan              |                    |                    | C               | Unknown              | Unk                  |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                                                                                                                                    | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|------------------------|----------------------|-----------------|--------------|----------------|
| 26-Oct-2016                                                                                                                                                                                                                                                 | 12798920       | EXPEDITED (15-DAY) |                    | HO, LT, OT      | TR-APOTEX-2016AP012422 |                      | 24 YR           | Female       | TUR            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                       | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Clonus; Coma; Depressed Level Of Consciousness; General Physical Health Deterioration; Hypernatraemia; Hypocalcaemia; Leukopenia; Loss Of Consciousness; Respiratory Depression; Sinus Tachycardia; Somnolence; Suicide Attempt; Toxicity To Various Agents | Olanzapine     |                    |                    | S               | Oral                   | Unk                  |                 | Apotex       |                |
|                                                                                                                                                                                                                                                             | Valproic Acid  |                    |                    | S               | Oral                   | Unk                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                                             | Escitalopram   |                    |                    | S               | Oral                   | Unk                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                                             | Fluoxetine     |                    |                    | S               | Oral                   | Unk                  |                 | Not Reported |                |



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### Detailed Report

| <u>FDA Received Date</u>                                         | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|-----------------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 26-Oct-2016                                                      | 12865899                | EXPEDITED (15-DAY) |                    | DE              | CH-JNJFOC-20161016796                                     |                      | 89 YR           | Male         | CHE            |
| <u>Preferred Term</u>                                            | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aphasia; Basal Ganglia<br>Haemorrhage; Dysphagia;<br>Hemiparesis | Xarelto                 |                    |                    | S               | Oral                                                      |                      |                 | Not Reported |                |
|                                                                  | Escitalopram            |                    |                    | S               | Oral                                                      |                      |                 | Not Reported |                |
|                                                                  | Candesartan             |                    |                    | C               | Oral                                                      |                      |                 | Not Reported |                |
|                                                                  | Espasmo Canulase        |                    |                    | C               | Oral                                                      |                      |                 | Not Reported |                |
|                                                                  | Sirdalud                |                    |                    | C               | Oral                                                      |                      |                 | Not Reported |                |
|                                                                  | Tamsulosin              |                    |                    | C               | Oral                                                      |                      |                 | Not Reported |                |
|                                                                  | Magnesiocard            |                    |                    | C               | Oral                                                      |                      |                 | Not Reported |                |
|                                                                  | Vitamin D3              |                    |                    | C               | Oral                                                      |                      |                 | Not Reported |                |
|                                                                  | Povidone                |                    |                    | C               |                                                           |                      |                 | Not Reported |                |
|                                                                  | Amlodipine              |                    |                    | C               | Oral                                                      |                      |                 | Not Reported |                |
|                                                                  | Metoprolol Succinate    |                    |                    | C               | Oral                                                      |                      |                 | Not Reported |                |
|                                                                  | Atorvastatin            |                    |                    | C               | Oral                                                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                         | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Oct-2016                                                      | 12886261                | EXPEDITED (15-DAY) |                    | DE              | US-VALIDUS<br>PHARMACEUTICALS<br>LLC-US-<br>2016VAL002873 |                      | 42 YR           | Female       | USA            |
| <u>Preferred Term</u>                                            | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                                | Metoprolol Tartrate     |                    |                    | S               | Oral                                                      | Unk                  |                 | Validus      |                |
|                                                                  | Oxycodone Hydrochloride |                    |                    | S               | Oral                                                      | Unk                  |                 | Not Reported |                |
|                                                                  | Zolpidem                |                    |                    | S               | Oral                                                      | Unk                  |                 | Not Reported |                |
|                                                                  | Diazepam                |                    |                    | S               | Oral                                                      | Unk                  |                 | Not Reported |                |
|                                                                  | Escitalopram            |                    |                    | S               | Oral                                                      | Unk                  |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                    | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u>                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|-------------------------------|---------------------------------------------|-----------------|--------------|----------------|
| 27-Oct-2016                                                 | 12509968                  | EXPEDITED (15-DAY) |                    | OT              | FR-FRI-1000085623             |                                             | 25 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                       | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Obsessive-Compulsive Disorder                               | Escitalopram Oxalate - Bp |                    |                    | S               | Oral                          | Unk                                         |                 | Allergan     |                |
|                                                             | Lamictal                  |                    |                    | S               | Oral                          | 200 Mg, Unk                                 |                 | Not Reported |                |
|                                                             | Theralene                 |                    |                    | S               | Oral                          | Unk                                         |                 | Not Reported |                |
|                                                             | Xanax                     |                    |                    | S               | Oral                          | Unk                                         |                 | Not Reported |                |
|                                                             | Imovane                   |                    |                    | S               | Oral                          | 1 Df, Qd                                    |                 | Not Reported |                |
|                                                             | Optilova                  |                    |                    | C               | Unknown                       | Unk                                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                    | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u>                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Oct-2016                                                 | 12888332                  | EXPEDITED (15-DAY) |                    |                 | US-CIPLA LTD.-<br>2016US07078 |                                             |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                       | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Diarrhoea; Hypertension; Nausea; Polyuria; Weight Decreased | Escitalopram              |                    |                    | S               | Oral                          | 5 Mg, Unknown Date Since 5 Years To Ongoing |                 | Invagen      |                |
|                                                             | Escitalopram              |                    |                    | S               |                               |                                             |                 | Invagen      |                |
|                                                             | Metoprolol                |                    |                    | C               | Unknown                       | 25 Mg, Qd                                   |                 | Not Reported |                |
|                                                             | Vitamin-D                 |                    |                    | C               | Unknown                       | 400 Iu, Bid                                 |                 | Not Reported |                |
|                                                             | Aspirin                   |                    |                    | C               | Unknown                       | 81 Mg, Qd                                   |                 | Not Reported |                |
|                                                             | Crestor                   |                    |                    | C               | Unknown                       | Unk, Qd                                     |                 | Not Reported |                |
|                                                             | Xanax                     |                    |                    | C               | Unknown                       | 0.25 Mg, Tid                                |                 | Not Reported |                |
|                                                             | Tylenol                   |                    |                    | C               | Unknown                       | 1000 Mg, Qd                                 |                 | Not Reported |                |
|                                                             | Restasis                  |                    |                    | C               | Unknown                       | 0.5 Mg, Bid                                 |                 | Not Reported |                |
|                                                             | Oxycodone                 |                    |                    | C               | Unknown                       | Unk, Prn                                    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                    | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u>                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Oct-2016                                                 | 12889682                  | EXPEDITED (15-DAY) |                    | OT              | DE-ALLERGAN-<br>1673732US     |                                             | 54 YR           | Male         | DEU            |

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| <u>Preferred Term</u>                            | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|--------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
| Liver Injury                                     | Escitalopram Oxalate - Bp |                    |                    | S               | Oral                      | 10 Mg, Qd            |                 | Allergan     |                |
|                                                  | Escitalopram Oxalate - Bp |                    |                    | S               |                           |                      |                 | Allergan     |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Oct-2016                                      | 12889987                  | EXPEDITED (15-DAY) |                    | HO              | JP-ALLERGAN-1673890US     |                      |                 | Unknown      | JPN            |
| <u>Preferred Term</u>                            | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Pancreatitis                                     | Escitalopram Oxalate - Bp |                    |                    | S               | Oral                      | Unk                  |                 | Allergan     |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Oct-2016                                      | 12890339                  | EXPEDITED (15-DAY) |                    | HO, OT          | HR-MYLANLABS-2016M1046323 |                      |                 | Unknown      | HRV            |
| <u>Preferred Term</u>                            | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Coma; Suicide Attempt                            | Leponex                   |                    |                    | S               | Oral                      | Unk                  |                 | Mylan        |                |
|                                                  | Elicea /01588501/         |                    |                    | S               | Oral                      | Unk                  |                 | Mylan        |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Oct-2016                                      | 12890696                  | NON-EXPEDITED      |                    | OT              | US-JAZZ-2016-US-015788    |                      | 31 YR           | Female       | USA            |
| <u>Preferred Term</u>                            | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Decreased Appetite; Depression; Weight Decreased | Xyrem                     |                    |                    | S               | Oral                      | 2.25 G, Bid          |                 | Jazz         |                |
|                                                  | Xyrem                     |                    |                    | S               | Oral                      | Dose Adjustments     |                 | Jazz         |                |
|                                                  | Xyrem                     |                    |                    | S               | Oral                      | 4.5 G, Bid           |                 | Jazz         |                |
|                                                  | Lexapro                   |                    |                    | S               |                           | Unk                  |                 | Not Reported |                |
|                                                  | Lexapro                   |                    |                    | S               |                           |                      |                 | Not Reported |                |
|                                                  | Lexapro                   |                    |                    | S               |                           |                      |                 | Not Reported |                |
|                                                  | Ritalin                   |                    |                    | C               |                           | Unk                  |                 | Not Reported |                |
|                                                  | Adderall                  |                    |                    | C               |                           | Unk                  |                 | Not Reported |                |
|                                                  | Nuvigil                   |                    |                    | C               |                           | 150 Mg, Unk          |                 | Not Reported |                |

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|                                                                                                                   |   |             |              |
|-------------------------------------------------------------------------------------------------------------------|---|-------------|--------------|
| Nuvigil                                                                                                           | C | 250 Mg, Unk | Not Reported |
| Robaxin                                                                                                           | C | Unk         | Not Reported |
| 5 Hour Energy                                                                                                     | C | Unk         | Not Reported |
| Ibuprofen                                                                                                         | C | Unk         | Not Reported |
| Nyquil Cold & Flu                                                                                                 | C | Unk         | Not Reported |
| Tylenol Extra-Strength                                                                                            | C | Unk         | Not Reported |
| Epipen 2-Pak                                                                                                      | C | Unk         | Not Reported |
| Modafinil                                                                                                         | C | Unk         | Not Reported |
| Vitamin B Complex                                                                                                 | C | Unk         | Not Reported |
| Theraflu Cold & Cough<br>[Dextromethorphan<br>Hydrobromide\Pheniramine<br>Maleate\Phenylephrine<br>Hydrochloride] | C |             | Not Reported |

| <u>FDA Received Date</u>                        | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 27-Oct-2016                                     | 12893553       | DIRECT           | Y                  |                 |                      |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                           | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective; Malaise;<br>Suicidal Ideation | Escitalopram   |                  |                    | S               | Oral                 |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|---------------------|--------------------|--------------------|-----------------|-----------------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 28-Oct-2016              | 12892262            | EXPEDITED (15-DAY) |                    | DE              | US-VALIDUS<br>PHARMACEUTICALS<br>LLC-US-<br>2016VAL002881 |                      | 14 YR           | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide        | Metoprolol Tartrate |                    |                    | S               | Oral                                                      | Unk                  |                 | Validus      |                |
|                          | Escitalopram        |                    |                    | S               | Oral                                                      | Unk                  |                 | Not Reported |                |
|                          | Bupropion           |                    |                    | S               | Oral                                                      | Unk                  |                 | Not Reported |                |

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| <u>FDA Received Date</u> | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|------------|----------------|
| 28-Oct-2016              | 12892782                  | EXPEDITED (15-DAY) |                    | OT              | TR-ALLERGAN-1673906US |                      |                 | Unknown    | TUR            |
| <u>Preferred Term</u>    | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Dependence               | Escitalopram Oxalate - Bp |                    |                    | S               | Unknown               |                      |                 | Allergan   |                |

| <u>FDA Received Date</u> | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|-----------------------|--------------------|--------------------|-----------------|---------------------------------------|----------------------|-----------------|--------------|----------------|
| 28-Oct-2016              | 12893124              | EXPEDITED (15-DAY) |                    | HO              | FR-PFIZER INC-2016493027              |                      | 76 YR           | Female       | FRA            |
| <u>Preferred Term</u>    | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agranulocytosis          | Fragmine              |                    |                    | S               | Subcutaneous                          | 5000 Iu, Daily       |                 | Pfizer       |                |
|                          | Ceftriaxone Panpharma |                    |                    | S               | Intravenous (not otherwise specified) | 1 G, Daily           |                 | Not Reported |                |
|                          | Ceftriaxone Panpharma |                    |                    | S               | Intravenous (not otherwise specified) | 2 G, Daily           |                 | Not Reported |                |
|                          | Esidrex               |                    |                    | S               | Oral                                  | 12.5 Mg, Daily       |                 | Not Reported |                |
|                          | Esidrex               |                    |                    | S               | Oral                                  | 25 Mg, Daily         |                 | Not Reported |                |
|                          | Escitalopram Arrow    |                    |                    | S               | Oral                                  | 20 Mg, Daily         |                 | Not Reported |                |
|                          | Oxazepam              |                    |                    | C               |                                       | 10 Mg, 3x/Day        |                 | Not Reported |                |
|                          | Amlodipine            |                    |                    | C               |                                       | 10 Mg, Daily         |                 | Not Reported |                |
|                          | Simvastatin           |                    |                    | C               |                                       | 10 Mg, Daily         |                 | Not Reported |                |
|                          | Paracetamol           |                    |                    | C               |                                       | Unk Unk, As Needed   |                 | Not Reported |                |
|                          | Phloroglucinol        |                    |                    | C               |                                       |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                     | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------|----------------------|--------------------|--------------------|-----------------|-------------------------------------------|----------------------|-----------------|--------------|----------------|
| 28-Oct-2016                                  | 12894062             | EXPEDITED (15-DAY) |                    | HO              | HR-LANNETT COMPANY, INC.-HR-2016LAN001716 |                      | 53 YR           | Male         | HRV            |
| <u>Preferred Term</u>                        | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bundle Branch Block Right; Electrocardiogram | Escitalopram Oxalate |                    |                    | S               |                                           | 20 Mg, Qd            |                 | Lannett      |                |
|                                              | Quetiapine Xr        |                    |                    | S               |                                           | 800 Mg, Qd           |                 | Not Reported |                |

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|              |               |   |             |              |
|--------------|---------------|---|-------------|--------------|
| Qt Prolonged | Quetiapine Xr | S | 400 Mg, Qd  | Not Reported |
|              | Quetiapine Xr | S | 100 Mg, Qd  | Not Reported |
|              | Valproate     | C | 1500 Mg, Qd | Not Reported |
|              | Diazepam      | C | 30 Mg, Qd   | Not Reported |
|              | Zolpidem      | C | 10 Mg, Qd   | Not Reported |
|              | Biperiden     | C | 1 Mg, Qd    | Not Reported |
|              |               |   |             |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 28-Oct-2016              | 12894799      | EXPEDITED (15-DAY) |                    | OT              | TR-MYLANLABS-2016M1046438 |                      |            | Unknown    | TUR            |

| <u>Preferred Term</u>                                          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                      | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|-----------------------------------------|-----------------|--------------|
| Abortion Spontaneous;<br>Maternal Exposure During<br>Pregnancy | Escitalopram   |              |            | S           | Unknown      | 10 Mg/Day (In 4-6<br>Gestation Weeks)   |                 | Not Reported |
|                                                                | Levothyroxine  |              |            | S           | Unknown      | 1000 Mcg/Day                            |                 | Not Reported |
|                                                                | Cefprozil      |              |            | S           | Unknown      | 1000 Mg/Day (In 4-6<br>Gestation Weeks) |                 | Mylan        |
|                                                                | Dexketoprofen  |              |            | S           | Unknown      | 25 Mg/Day (In 4-6<br>Gestation Weeks)   |                 | Mylan        |
|                                                                | Trimetazidine  |              |            | S           | Unknown      | 40 Mg/Day (In 4-6<br>Gestation Weeks)   |                 | Mylan        |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 28-Oct-2016              | 12894800      | EXPEDITED (15-DAY) |                    | OT              | TR-MYLANLABS-2016M1046441 |                      |            | Unknown    | TUR            |

| <u>Preferred Term</u>                                          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|---------------------------------------|-----------------|--------------|
| Abortion Spontaneous;<br>Maternal Exposure During<br>Pregnancy | Escitalopram   |              |            | S           | Unknown      | 10 Mg/Day (In 0-5<br>Gestation Weeks) |                 | Not Reported |
|                                                                | Nifedipine     |              |            | S           | Unknown      | 30 Mg/Day (In 0-5<br>Gestation Weeks) |                 | Not Reported |
|                                                                | Zofenopril     |              |            | S           | Unknown      | 30 Mg/Day (In 0-5<br>Gestation Weeks) |                 | Mylan        |
|                                                                | Trimetazidine  |              |            | S           | Unknown      | 40 Mg/Day (In 0-5<br>Gestation Weeks) |                 | Mylan        |

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| Gestation Weeks)                                                                              |                                                   |                    |                    |                 |                          |                      |                 |              |                |
|-----------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| <u>FDA Received Date</u>                                                                      | <u>Case #</u>                                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Oct-2016                                                                                   | 12894835                                          | EXPEDITED (15-DAY) |                    | DE, OT          | CH-ALLERGAN-1674040US    |                      | 89 YR           | Unknown      | CHE            |
| <u>Preferred Term</u>                                                                         | <u>Product</u>                                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aphasia; Basal Ganglia Haemorrhage; Dysphagia; Dyspnoea; Hemiparesis; Hypertonia; Tachycardia | Escitalopram Oxalate - Bp                         |                    |                    | S               | Oral                     |                      |                 | Allergan     |                |
|                                                                                               | Xarelto (Rivaroxaban)                             |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                                                                                               | Meto Zerok (Metoprolol Succinate)                 |                    |                    | C               | Oral                     | 25 Mg, Qd            |                 | Not Reported |                |
|                                                                                               | Amlodipin (Amlodipine)                            |                    |                    | C               | Oral                     | 5 Mg, Qd             |                 | Not Reported |                |
|                                                                                               | Candesartan (Candesartan)                         |                    |                    | C               | Oral                     | 8 Mg, Qd             |                 | Not Reported |                |
|                                                                                               | Atorvastatin (Atorvastatin)                       |                    |                    | C               | Oral                     | 40 Mg, Qd            |                 | Not Reported |                |
|                                                                                               | Sirdalud (Tizanidine Hydrochloride)               |                    |                    | C               | Oral                     | 4 Mg, Qd             |                 | Not Reported |                |
|                                                                                               | Tamsulosin (Tamsulosin)                           |                    |                    | C               | Oral                     | 4 Mg, Qd             |                 | Not Reported |                |
|                                                                                               | Magnesioncard (Magnesium Aspartate Hydrochloride) |                    |                    | C               | Oral                     | 5 Mmol, Qd           |                 | Not Reported |                |
|                                                                                               | Vitamin D3 (Colecalciferol)                       |                    |                    | C               | Oral                     | 1 Df, Qd             |                 | Not Reported |                |
|                                                                                               | Oculac (Povidone)                                 |                    |                    | C               |                          |                      |                 | Not Reported |                |
|                                                                                               | Spasmo Canulase (Glutamic Acid Hydrochloride)     |                    |                    | C               | Oral                     | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                      | <u>Case #</u>                                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-Oct-2016                                                                                   | 12091208                                          | EXPEDITED (15-DAY) |                    | HO, OT          | AU-BAUSCH-BL-2016-004085 |                      | 70 YR           | Female       | AUS            |
| <u>Preferred Term</u>                                                                         | <u>Product</u>                                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Akathisia; Inappropriate Antidiuretic Hormone Secretion                                       | Bupropion                                         |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                                                                                               | Ramipril                                          |                    |                    | S               | Unknown                  |                      |                 | Not Reported |                |
|                                                                                               | Escitalopram                                      |                    |                    | S               | Unknown                  |                      |                 | Not Reported |                |
|                                                                                               | Dothiepin                                         |                    |                    | S               | Unknown                  |                      |                 | Not Reported |                |
|                                                                                               | Dothiepin                                         |                    |                    | S               | Unknown                  |                      |                 | Not Reported |                |
|                                                                                               | Quetiapine                                        |                    |                    | C               |                          |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|              |   |              |
|--------------|---|--------------|
| Lamotrigine  | C | Not Reported |
| Oestradiol   | C | Not Reported |
| Glipizide    | C | Not Reported |
| Metformin    | C | Not Reported |
| Lantus       | C | Not Reported |
| Atorvastatin | C | Not Reported |
| Aspirin      | C | Not Reported |
| Norfloxacin  | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-Oct-2016              | 12896268      | EXPEDITED (15-DAY) |                    | DE              | BR-TORRENT-00003640  |                      |            | Male       | BRA            |

| <u>Preferred Term</u>                                                  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                           | <u>Duration</u> | <u>Mfr</u> |
|------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|----------------------------------------------|-----------------|------------|
| Disease Progression; Off Label Use; Off Label Use; Parkinson'S Disease | Menelat        |              |            | S           | Oral         | Once Daily/ Oral                             |                 | Torrent    |
|                                                                        | Espran         |              |            | S           | Oral         | Once Daily/ Oral                             |                 | Torrent    |
|                                                                        | Clomenac       |              |            | C           | Oral         | Number Of Units In Interval Is Unknown/ Oral |                 | Actavis    |
|                                                                        | Kitapen        |              |            | C           | Oral         | Number Of Units In Interval Is Unknown/ Oral |                 | Actavis    |
|                                                                        | Prolopa        |              |            | C           | Oral         | Unk/ Oral                                    |                 | Roche      |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|------------|------------|----------------|
| 31-Oct-2016              | 12896763      | EXPEDITED (15-DAY) |                    | OT              | AU-GLAXOSMITHKLINE-AU2016158851 |                      | 70 YR      | Female     | AUS            |

| <u>Preferred Term</u>                                                                                     | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|-----------------------------------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Drug Interaction; Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion; Toxicity To Various Agents | Escitalopram            |              |            | S           |              |                    |                 | Glaxosmithkline |
|                                                                                                           | Bupropion               |              |            | S           |              | 75 Mg Po Mane      |                 | Glaxosmithkline |
|                                                                                                           | Ramipril                |              |            | S           |              |                    |                 | Glaxosmithkline |
|                                                                                                           | Norfloxacin             |              |            | C           |              |                    |                 | Not Reported    |
|                                                                                                           | Dothiepin Hydrochloride |              |            | S           |              |                    |                 | Not Reported    |
|                                                                                                           | Dothiepin Hydrochloride |              |            | S           |              |                    |                 | Not Reported    |
|                                                                                                           | Dothiepin Hydrochloride |              |            | S           |              |                    |                 | Not Reported    |
|                                                                                                           | Quetiapine              |              |            | C           |              | 400 Mg At Night    |                 | Not Reported    |
|                                                                                                           | Lamotrigine             |              |            | C           |              |                    |                 | Not Reported    |
|                                                                                                           | Oestradiol              |              |            | C           |              |                    |                 | Not Reported    |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                      |   |              |
|----------------------|---|--------------|
| Glipizide            | C | Not Reported |
| Metformin            | C | Not Reported |
| Insulin Lantus       | C | Not Reported |
| Atorvastatin         | C | Not Reported |
| Acetylsalicylic Acid | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------|----------------------|------------|------------|----------------|
| 31-Oct-2016              | 12897718      | EXPEDITED (15-DAY) |                    | OT              | US-LUNDBECK-DKLU2021900 |                      | 18 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                      | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------|-----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Inappropriate Schedule Of Product Administration; Product Dose Omission; Suicidal Ideation | Lexapro Film-Coated Tablets |              |            | S           | Unknown      |                    |                 | Forest       |
|                                                                                            | Abilify                     |              |            | S           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 31-Oct-2016              | 12897958      | EXPEDITED (15-DAY) |                    | OT              | FR-ALLERGAN-1674208US |                      | 58 YR      | Male       | FRA            |

| <u>Preferred Term</u>         | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-------------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Anxiety; Nausea; Pancreatitis | Escitalopram Oxalate - Bp |              |            | S           | Oral         |                    |                 | Allergan   |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 01-Nov-2016              | 12522017      | EXPEDITED (15-DAY) |                    | OT              | JP-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-053742 |                      | 26 YR      | Male       | JPN            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>           |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------|
| Hypothermia; Malaise  | Abilify        |              |            | S           | Oral         | 1.5 Mg, Qd         |                 | Bristol Myers Squibb |
|                       | Abilify        |              |            | S           | Oral         | 0.75 Mg, Qd        |                 | Bristol Myers Squibb |
|                       | Lexapro        |              |            | S           | Oral         | 10 Mg, Qd          |                 | Not Reported         |
|                       | Lexapro        |              |            | S           | Oral         | 20 Mg, Qd          |                 | Not Reported         |
|                       | Lendormin      |              |            | C           | Oral         | 0.25 Mg, Qd        |                 | Not Reported         |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|--------------------------|-------------------------------|-----------------|--------------|----------------|
| 01-Nov-2016                                                  | 12900339       | EXPEDITED (15-DAY) |                    | HO              | PHHY2016HR147687         |                               |                 | Female       | HRV            |
| <u>Preferred Term</u>                                        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Overdose;<br>Suicide Attempt                     | Trileptal      |                    |                    | S               | Oral                     | 30 Df, Once/Single            |                 | Novartis     |                |
|                                                              | Elicea         |                    |                    | S               | Oral                     | 20 Df, Once/Single            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Nov-2016                                                  | 12900350       | EXPEDITED (15-DAY) |                    | OT              | PHHY2016TR149408         |                               |                 | Unknown      | TUR            |
| <u>Preferred Term</u>                                        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Foetal Exposure During<br>Pregnancy; Premature<br>Delivery   | Escitalopram   |                    |                    | S               | Transplacental           | Maternal Dose: 10 Mg/Day      |                 | Not Reported |                |
|                                                              | Levofloxacin   |                    |                    | S               | Transplacental           | Maternal Dose: 500<br>Mg/Day  |                 | Novartis     |                |
|                                                              | Cefprozil      |                    |                    | S               | Transplacental           | Maternal Dose: 1000<br>Mg/Day |                 | Not Reported |                |
|                                                              | Etodolac       |                    |                    | S               | Transplacental           | Maternal Dose: 300<br>Mg/Day  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Nov-2016                                                  | 12900352       | EXPEDITED (15-DAY) |                    | OT              | PHHY2016TR149407         |                               | 21 YR           | Female       | TUR            |
| <u>Preferred Term</u>                                        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Maternal Exposure During<br>Pregnancy; Premature<br>Delivery | Escitalopram   |                    |                    | S               | Unknown                  | 10 Mg, Qd                     |                 | Not Reported |                |
|                                                              | Levofloxacin   |                    |                    | S               | Unknown                  | 500 Mg, Qd                    |                 | Novartis     |                |
|                                                              | Cefprozil      |                    |                    | S               | Unknown                  | 1000 Mg, Qd                   |                 | Not Reported |                |
|                                                              | Etodolac       |                    |                    | S               | Unknown                  | 300 Mg, Qd                    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Nov-2016                                                  | 12083886       | EXPEDITED (15-DAY) |                    | OT              | AU-SUN<br>PHARMACEUTICAL |                               |                 | Unknown      | AUS            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

INDUSTRIES LTD-  
2016RR-111658

| <u>Preferred Term</u>                                                                                                         | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Akathisia; Drug Interaction;<br>Hyponatraemia;<br>Inappropriate Antidiuretic Hormone Secretion;<br>Toxicity To Various Agents | Escitalopram            |              |            | S           | Unknown      | 30 Mg, Daily       |                 | Not Reported |
|                                                                                                                               | Bupropion               |              |            | S           | Oral         | 75 Mg Po Mane      |                 | Sun          |
|                                                                                                                               | Ramipril                |              |            | S           | Unknown      | Unk                |                 | Ranbaxy      |
|                                                                                                                               | Dothiepin Hydrochloride |              |            | S           | Unknown      | 225 Mg, Unk        |                 | Not Reported |
|                                                                                                                               | Dothiepin Hydrochloride |              |            | S           | Unknown      | 175 Mg, Unk        |                 | Not Reported |
|                                                                                                                               | Dothiepin Hydrochloride |              |            | S           | Unknown      | 175 Mg, Unk        |                 | Not Reported |
|                                                                                                                               | Norfloxacin             |              |            | C           | Oral         | 400 Mg, Bid        |                 | Not Reported |
|                                                                                                                               | Quetiapine              |              |            | C           | Unknown      | 400 Mg At Night    |                 | Not Reported |
|                                                                                                                               | Lamotrigine             |              |            | C           | Unknown      | 75 Mg, Bid         |                 | Not Reported |
|                                                                                                                               | Oestradiol              |              |            | C           | Unknown      | Unk                |                 | Not Reported |
|                                                                                                                               | Glipizide               |              |            | C           | Unknown      | Unk                |                 | Not Reported |
|                                                                                                                               | Metformin               |              |            | C           | Unknown      | Unk                |                 | Not Reported |
|                                                                                                                               | Lantus Insulin          |              |            | C           | Unknown      | Unk                |                 | Not Reported |
|                                                                                                                               | Atorvastatin            |              |            | C           | Unknown      | Unk                |                 | Not Reported |
|                                                                                                                               | Acetylsalicylic Acid    |              |            | C           | Unknown      | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------|----------------------|------------|------------|----------------|
| 02-Nov-2016              | 12903850      | EXPEDITED (15-DAY) |                    | HO, OT          | CH-ALLERGAN-1000087249 |                      | 96 YR      | Female     | CHE            |

| <u>Preferred Term</u>                                                                                                              | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Asthenia; Contusion;<br>Craniocerebral Injury;<br>Dizziness; Face Injury;<br>Fall; Gait Disturbance;<br>Hyponatraemia; Skin Lesion | Escitalopram Oxalate - Bp |              |            | S           | Unknown      | Unk                |                 | Allergan     |
|                                                                                                                                    | Ass Cardio                |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                                                                                                                                    | Beloc Zok                 |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                                                                                                                                    | Amiodaron-Mepha           |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                                                                                                                                    | Torem                     |              |            | S           | Unknown      | Unk                |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|-------------------------|-----------------------|-----------------|--------------|----------------|
| 02-Nov-2016                                                                    | 12904636             | EXPEDITED (15-DAY) |                    | OT              | JP-TEVA-2016-JP-002282J |                       | 35 YR           | Female       | JPN            |
| <u>Preferred Term</u>                                                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Pemphigoid                                                                     | Eurodin 2mg. Tablets |                    |                    | S               | Oral                    |                       |                 | Actavis      |                |
|                                                                                | Risperdal            |                    |                    | S               | Oral                    |                       |                 | Not Reported |                |
|                                                                                | Lexapro              |                    |                    | S               | Oral                    |                       |                 | Not Reported |                |
|                                                                                | Primperan            |                    |                    | C               | Unknown                 |                       |                 | Not Reported |                |
|                                                                                | Laxoberon            |                    |                    | C               | Oral                    |                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Nov-2016                                                                    | 12916593             | DIRECT             |                    | DS              |                         |                       | 32 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypersensitivity                                                               | Escitalopram         |                    |                    | S               | Oral                    | Quantity:1 Tablet(S); |                 | Not Reported |                |
|                                                                                | Jolessa              |                    |                    | C               |                         |                       |                 | Not Reported |                |
|                                                                                | Prednisone           |                    |                    | C               |                         |                       |                 | Not Reported |                |
|                                                                                | Hydroxyzine Hcl      |                    |                    | C               |                         |                       |                 | Not Reported |                |
|                                                                                | Multi Vitamin        |                    |                    | C               |                         |                       |                 | Not Reported |                |
|                                                                                | Vitamin D Nos        |                    |                    | C               |                         |                       |                 | Not Reported |                |
|                                                                                | Biotin               |                    |                    | C               |                         |                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Nov-2016                                                                    | 12939595             | DIRECT             | Y                  |                 |                         |                       | 43 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated;<br>Depression; Drug<br>Intolerance; Treatment<br>Failure | Escitalopram Oxalate |                    |                    | S               | Oral                    |                       |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                   | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
| 03-Nov-2016                                                                                                                | 12906818                  | EXPEDITED (15-DAY) |                    | DS              | GB-ALLERGAN-1674520US     |                      | 26 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                                                                      | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Disturbance In Sexual Arousal; Female Orgasmic Disorder; Female Sexual Dysfunction; Libido Decreased; Vulvovaginal Dryness | Escitalopram Oxalate - Bp |                    |                    | S               | Oral                      |                      |                 | Allergan     |                |
|                                                                                                                            | Cetirizine Hydrochloride  |                    |                    | C               | Unknown                   |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                   | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Nov-2016                                                                                                                | 12907990                  | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2016M1046624 |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                                                                      | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aphasia; Food Craving; Hepatic Fibrosis; Non-Alcoholic Steatohepatitis; Weight Increased                                   | Sertraline                |                    |                    | S               | Unknown                   | 50mg Daily           |                 | Not Reported |                |
|                                                                                                                            | Cyclobenzaprine           |                    |                    | S               | Unknown                   |                      |                 | Not Reported |                |
|                                                                                                                            | Clonazepam                |                    |                    | S               | Unknown                   |                      |                 | Not Reported |                |
|                                                                                                                            | Lorazepam                 |                    |                    | S               | Unknown                   | 0.5mg As Needed      |                 | Not Reported |                |
|                                                                                                                            | Lithium                   |                    |                    | S               | Unknown                   |                      |                 | Not Reported |                |
|                                                                                                                            | Escitalopram              |                    |                    | S               | Unknown                   |                      |                 | Not Reported |                |
|                                                                                                                            | Bupropion                 |                    |                    | S               | Unknown                   |                      |                 | Not Reported |                |
|                                                                                                                            | Methylphenidate           |                    |                    | S               | Unknown                   |                      |                 | Not Reported |                |
|                                                                                                                            | Quetiapine                |                    |                    | S               | Unknown                   |                      |                 | Not Reported |                |
|                                                                                                                            | Metformin                 |                    |                    | S               | Unknown                   |                      |                 | Not Reported |                |
|                                                                                                                            | Pregabalin                |                    |                    | S               | Unknown                   |                      |                 | Mylan        |                |
|                                                                                                                            | Aripiprazole              |                    |                    | S               | Unknown                   |                      |                 | Mylan        |                |
|                                                                                                                            | Lamotrigine               |                    |                    | C               | Unknown                   |                      |                 | Mylan        |                |
|                                                                                                                            | Oxcarbazepine             |                    |                    | C               | Unknown                   |                      |                 | Mylan        |                |
|                                                                                                                            | Docusate Sodium           |                    |                    | C               | Unknown                   |                      |                 | Mylan        |                |
|                                                                                                                            | Acetylcysteine            |                    |                    | C               | Unknown                   |                      |                 | Mylan        |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                      |   |         |       |
|----------------------|---|---------|-------|
| Clonidine            | C | Unknown | Mylan |
| Levothyroxine Sodium | C | Unknown | Mylan |
| Diphenhydramine      | C | Unknown | Mylan |
| Topiramate           | C | Unknown | Mylan |
| Ondansetron          | C | Unknown | Mylan |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 03-Nov-2016              | 12908376      | EXPEDITED (15-DAY) |                    | HO              | FR-ALLERGAN-1674403US |                      | 38 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                        | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Intentional Overdose; Somnolence; Toxicity To Various Agents | Escitalopram Oxalate - Bp |              |            | S           | Oral         | 14 Df, Unk         |                 | Allergan     |
|                                                              | Temesta (Lorazepam)       |              |            | S           | Oral         | Unk Unk, Single    |                 | Not Reported |
|                                                              | Temesta                   |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                              | Alprazolam                |              |            | S           | Oral         | 14 Df, Unk         |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Nov-2016              | 12916258      | DIRECT           |                    |                 |                      |                      | 48 YR      | Female     | USA            |

| <u>Preferred Term</u>               | <u>Product</u>   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------|------------------|--------------|------------|-------------|--------------|-----------------------|-----------------|--------------|
| Food Interaction; Rash Erythematous | Escitalopram     |              |            | S           | Oral         | Quantity:1 Tablet(S); |                 | Aurobindo    |
|                                     | Vitamin B        |              |            | C           |              |                       |                 | Not Reported |
|                                     | Vitamin C        |              |            | C           |              |                       |                 | Not Reported |
|                                     | Vitamin E        |              |            | C           |              |                       |                 | Not Reported |
|                                     | Calcium          |              |            | C           |              |                       |                 | Not Reported |
|                                     | Baby Aspirin     |              |            | C           |              |                       |                 | Not Reported |
|                                     | Generic Claritin |              |            | C           |              |                       |                 | Not Reported |
|                                     | Fish Oil         |              |            | C           |              |                       |                 | Not Reported |
|                                     | Methyl Folate    |              |            | C           |              |                       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Nov-2016              | 12283472      | EXPEDITED (15-DAY) |                    | OT              | US-SA-2015SA177732   |                      | 38 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |            |   |                  |              |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|---|------------------|--------------|
| Asthenia; Balance Disorder; Balance Disorder; Blood Pressure Increased; Cd4                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Lemtrada   | S | Intravenous drip | Not Reported |
| Lymphocytes Decreased; Chest Discomfort; Chills; Cognitive Disorder; Cold Sweat; Condition Aggravated; Condition Aggravated; Cough; Crystal Urine; Decreased Immune Responsiveness; Depression; Dermatitis; Dizziness; Dysphagia; Emotional Disorder; Fatigue; Fatigue; Gait Disturbance; Gait Disturbance; Headache; Hemiparesis; Influenza Like Illness; Laboratory Test Abnormal; Malaise; Multiple Sclerosis Relapse; Muscle Spasticity; Muscular Weakness; Musculoskeletal Disorder; Nasopharyngitis; Nausea; Oral Mucosal Exfoliation; Oral Pain; Pruritus; Pyrexia; Seizure; Skin Discolouration; Skin Disorder; Somnolence; Stomatitis; T-Lymphocyte Count Abnormal; Temperature Intolerance; Tremor; Tremor; Visual Impairment | Solumedrol | S | Intravenous drip | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Solumedrol | S | Intravenous drip | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Lexapro    | S | Unknown          | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Lexapro    | S | Unknown          | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Acyclovir  | C |                  | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Symmetrel  | C |                  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|------------|------------|----------------|
| 04-Nov-2016              | 12912969      | EXPEDITED (15-DAY) |                    | HO              | US-GLENMARK<br>PHARMACEUTICALS |                      | 50 YR      | Female     | USA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

EUROPE LIMITED-  
2016GMK

| <u>Preferred Term</u>                                                                    | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
|------------------------------------------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|----------------------|----------------|
| Drug Interaction; Drug Reaction With Eosinophilia And Systemic Symptoms; Viral Infection | Lamotrigine                   |                    |                    | S               | Unknown                                         | Unk                  |                 | Glenmark             |                |
|                                                                                          | Cyclobenzaprine               |                    |                    | S               | Unknown                                         | 10 Mg, Tid           |                 | Not Reported         |                |
|                                                                                          | Escitalopram                  |                    |                    | S               | Unknown                                         | 10 Mg, Od            |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                                 | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 04-Nov-2016                                                                              | 12913645                      | EXPEDITED (15-DAY) |                    | OT              | US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-093614 |                      | 18 YR           | Female               | USA            |
| <u>Preferred Term</u>                                                                    | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Product Dose Omission; Suicidal Ideation; Treatment Noncompliance                        | Abilify                       |                    |                    | S               | Unknown                                         | 10 Mg, Qd            |                 | Bristol Myers Squibb |                |
|                                                                                          | Lexapro                       |                    |                    | S               | Unknown                                         | 10 Mg, Qd            |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                                 | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 05-Nov-2016                                                                              | 12913816                      | NON-EXPEDITED      |                    |                 | US-AUROBINDO-AUR-APU-2015-08341                 |                      |                 | Unknown              | USA            |
| <u>Preferred Term</u>                                                                    | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Dizziness                                                                                | Escitalopram Tablets Usp 10mg |                    |                    | S               | Unknown                                         | 10 Mg, Unk           |                 | Aurobindo            |                |
| <u>FDA Received Date</u>                                                                 | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 05-Nov-2016                                                                              | 12913823                      | NON-EXPEDITED      |                    |                 | US-AUROBINDO-AUR-APU-2016-05874                 |                      | 62 YR           | Female               | USA            |
| <u>Preferred Term</u>                                                                    | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Abdominal Distension                                                                     | Escitalopram Tablets Usp 10mg |                    |                    | S               | Unknown                                         | One Tablet Daily     |                 | Aurobindo            |                |
|                                                                                          | Valsartan                     |                    |                    | C               | Unknown                                         |                      |                 | Not Reported         |                |
|                                                                                          | Metoprolol                    |                    |                    | C               | Unknown                                         | 75 Mg, Unk           |                 | Not Reported         |                |
|                                                                                          | Bupropion                     |                    |                    | C               | Unknown                                         |                      |                 | Not Reported         |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Clarityn /00082102/

C

Unknown

Not Reported

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|---------------------------------|----------------------|------------|------------|----------------|
| 05-Nov-2016              | 12913828      | NON-EXPEDITED    |                    |                 | US-AUROBINDO-AUR-APU-2015-10219 |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Rash                  | Escitalopram Tablets Usp 10mg |              |            | S           | Oral         | 1 Df, Once A Day   |                 | Aurobindo    |
|                       | Trazodone                     |              |            | C           | Unknown      |                    |                 | Not Reported |
|                       | Folic Acid                    |              |            | C           | Unknown      | 1 Mg, Unk          |                 | Not Reported |
|                       | Mono Linyah                   |              |            | C           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|---------------------------------|----------------------|------------|------------|----------------|
| 05-Nov-2016              | 12913841      | NON-EXPEDITED    |                    |                 | US-AUROBINDO-AUR-APU-2015-07954 |                      | 64 YR      | Female     | USA            |

| <u>Preferred Term</u>        | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------|-------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Dizziness; Drug Ineffective; | Escitalopram Tablets Usp 10mg |              |            | S           | Unknown      | 10 Mg, Daily       |                 | Aurobindo    |
| Hypoaesthesia;               | Escitalopram Tablets Usp 10mg |              |            | S           |              |                    |                 | Aurobindo    |
| Medication Error             | Escitalopram Tablets Usp 10mg |              |            | S           |              |                    |                 | Aurobindo    |
|                              | Escitalopram Tablets Usp 10mg |              |            | S           |              |                    |                 | Aurobindo    |
|                              | Stalevo                       |              |            | C           | Unknown      | 200 Mg, Unk        |                 | Not Reported |
|                              | Metoprolol                    |              |            | C           | Unknown      |                    |                 | Not Reported |
|                              | Parcopa                       |              |            | C           | Unknown      |                    |                 | Not Reported |
|                              | Clonazepam                    |              |            | C           | Unknown      | 0.5 Mg, Unk        |                 | Not Reported |
|                              | Ropinirole                    |              |            | C           | Unknown      |                    |                 | Not Reported |
|                              | Tylenol /00020001/            |              |            | C           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|---------------------------------|----------------------|------------|------------|----------------|
| 05-Nov-2016              | 12914075      | NON-EXPEDITED    |                    |                 | US-AUROBINDO-AUR-APU-2016-02306 |                      | 53 YR      | Male       | USA            |

| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Anxiety; Disturbance In | Escitalopram Tablets |              |            | S           | Unknown      | 10 Mg, Once A Day  |                 | Aurobindo  |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                       |                      |   |         |                   |              |
|-----------------------|----------------------|---|---------|-------------------|--------------|
| Attention; Somnolence | Escitalopram Tablets | S | Unknown | 20 Mg, Once A Day | Aurobindo    |
|                       | Bupropion            | C | Unknown |                   | Not Reported |
|                       | Wellbutrin XL        | C | Unknown | 300 Mg, Unk       | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Nov-2016              | 12920304      | DIRECT           |                    | DS, HO          |                      |                      | 51 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|-----------------------|-----------------|--------------|
| Balance Disorder;<br>Confusional State;<br>Dizziness; Fall; Motor<br>Dysfunction; Rib Fracture | Escitalopram   |              |            | S           | Oral         | Quantity:1 Tablet(S); |                 | Not Reported |
|                                                                                                | Ibuprofen      |              |            | C           |              |                       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-------------------------------------|----------------------|------------|------------|----------------|
| 06-Nov-2016              | 12915764      | NON-EXPEDITED    |                    |                 | US-AUROBINDO-AUR-<br>APU-2016-09706 |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|-------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Diarrhoea; Nausea     | Escitalopram Tablets Usp 20mg |              |            | S           | Unknown      | 1/2 Tab            |                 | Aurobindo  |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-------------------------------------|----------------------|------------|------------|----------------|
| 06-Nov-2016              | 12915767      | NON-EXPEDITED    |                    |                 | US-AUROBINDO-AUR-<br>APU-2016-08536 |                      |            | Female     | USA            |

| <u>Preferred Term</u>                    | <u>Product</u>               | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------|------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Diarrhoea; Feeling<br>Abnormal; Headache | Escitalopram Tablets Usp 5mg |              |            | S           | Unknown      | 5 Mg, Once A Day   |                 | Aurobindo    |
|                                          | Methotrexate                 |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                          | Prednisone                   |              |            | C           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-------------------------------------|----------------------|------------|------------|----------------|
| 06-Nov-2016              | 12915773      | NON-EXPEDITED    |                    |                 | US-AUROBINDO-AUR-<br>APU-2016-09758 |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                  |                               |   |         |            |           |
|------------------|-------------------------------|---|---------|------------|-----------|
| Adverse Reaction | Escitalopram Tablets Usp 20mg | S | Unknown | 20 Mg, Unk | Aurobindo |
|------------------|-------------------------------|---|---------|------------|-----------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Nov-2016              | 11618608      | EXPEDITED (15-DAY) |                    | HO, OT          | AU-ACCORD-034376     |                      | 70 YR      | Female     | AUS            |

| <u>Preferred Term</u>                                                                                                                                             | <u>Product</u>                    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|--------------|------------|-------------|--------------|----------------------------|-----------------|--------------|
| Confusional State; Drug Interaction; Escherichia Urinary Tract Infection; Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion; Toxicity To Various Agents | Escitalopram                      |              |            | S           |              |                            |                 | Accord       |
|                                                                                                                                                                   | Ramipril                          |              |            | S           |              |                            |                 | Accord       |
|                                                                                                                                                                   | Bupropion/Bupropion Hydrochloride |              |            | S           | Oral         | In The Mroning             |                 | Not Reported |
|                                                                                                                                                                   | Dosulepin                         |              |            | S           |              | Previously Received 225 Mg |                 | Not Reported |
|                                                                                                                                                                   | Quetiapine/Quetiapine Fumarate    |              |            | C           |              | At Night                   |                 | Not Reported |
|                                                                                                                                                                   | Lamotrigine                       |              |            | C           |              |                            |                 | Not Reported |
|                                                                                                                                                                   | Estradiol                         |              |            | C           |              |                            |                 | Not Reported |
|                                                                                                                                                                   | Glipizide                         |              |            | C           |              |                            |                 | Not Reported |
|                                                                                                                                                                   | Metformin                         |              |            | C           |              |                            |                 | Not Reported |
|                                                                                                                                                                   | Lantus                            |              |            | C           |              |                            |                 | Not Reported |
|                                                                                                                                                                   | Atorvastatin                      |              |            | C           |              |                            |                 | Not Reported |
|                                                                                                                                                                   | Acetylsalicylic Acid              |              |            | C           |              |                            |                 | Not Reported |
|                                                                                                                                                                   | Norfloxacin                       |              |            | C           |              |                            |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 07-Nov-2016              | 12253083      | EXPEDITED (15-DAY) |                    | OT              | PT-PFIZER INC-2016138816 |                      | 66 YR      | Male       | PRT            |

| <u>Preferred Term</u>                                                                                                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Amnesia; Carotid Arteriosclerosis; Insomnia; Intentional Product Misuse; Nightmare; Poor Quality Sleep; Visual Impairment | Xanax Xr       |              |            | S           | Oral         | 1 Mg, 2x/Day       |                 | Pfizer       |
|                                                                                                                           | Xanax Xr       |              |            | S           | Oral         | 0.5 Mg, Daily      |                 | Pfizer       |
|                                                                                                                           | Xanax Xr       |              |            | S           | Oral         | 0.25 Mg, Daily     |                 | Pfizer       |
|                                                                                                                           | Ciprallex      |              |            | S           |              | Unk                |                 | Not Reported |
|                                                                                                                           | Aspirina       |              |            | C           |              | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Nov-2016              | 12915873      | NON-EXPEDITED    |                    |                 | US-ACCORD-034742     |                      |            | Male       | USA            |

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| <u>Preferred Term</u>                                                                                               | <u>Product</u>      | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                   | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------------------------------------------------------------------------|---------------------|------------------|--------------------|-----------------|----------------------|----------------------------------------------------------------------|-----------------|--------------|----------------|
| Drug Ineffective                                                                                                    | Escitalopram Accord |                  |                    | S               |                      |                                                                      |                 | Accord       |                |
| <u>FDA Received Date</u>                                                                                            | <u>Case #</u>       | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Nov-2016                                                                                                         | 12915874            | NON-EXPEDITED    |                    |                 | US-ACCORD-034750     |                                                                      | 54 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                               | <u>Product</u>      | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Arthralgia; Insomnia;<br>Musculoskeletal Pain;<br>Musculoskeletal Stiffness;<br>Myalgia; Pain; Product<br>Complaint | Escitalopram Accord |                  |                    | S               | Oral                 |                                                                      |                 | Accord       |                |
|                                                                                                                     | Dicycloverine       |                  |                    | C               |                      |                                                                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                            | <u>Case #</u>       | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Nov-2016                                                                                                         | 12915875            | NON-EXPEDITED    |                    |                 | US-ACCORD-035136     |                                                                      | 13 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                               | <u>Product</u>      | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated;<br>Drug Ineffective                                                                           | Escitalopram Accord |                  |                    | S               | Oral                 |                                                                      |                 | Accord       |                |
|                                                                                                                     | Pristiq             |                  |                    | S               | Oral                 | 35mg Orally By Mouth,<br>Once A Day. Then Dose<br>Increased To 50mg, |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                            | <u>Case #</u>       | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Nov-2016                                                                                                         | 12915877            | NON-EXPEDITED    |                    |                 | US-ACCORD-035306     |                                                                      | 49 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                               | <u>Product</u>      | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective; Product<br>Substitution Issue;<br>Withdrawal Syndrome                                             | Escitalopram Accord |                  |                    | S               | Oral                 | Strength: 10 Mg. 30<br>Tablets                                       |                 | Accord       |                |
| <u>FDA Received Date</u>                                                                                            | <u>Case #</u>       | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Nov-2016                                                                                                         | 12915880            | NON-EXPEDITED    |                    | DS, HO, OT      | US-ACCORD-035307     |                                                                      | 63 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                               | <u>Product</u>      | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                   | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                    |                                          |   |      |                 |              |
|--------------------------------------------------------------------|------------------------------------------|---|------|-----------------|--------------|
| Cerebrovascular Accident;<br>Depression; Headache;<br>Hypertension | Escitalopram                             | S | Oral | Strength: 10 Mg | Accord       |
|                                                                    | Lexapro                                  | S |      | 5 Tablets       | Not Reported |
|                                                                    | Meloxicam                                | C |      |                 | Not Reported |
|                                                                    | Clonazepam                               | C |      |                 | Not Reported |
|                                                                    | Paxil                                    | C |      |                 | Not Reported |
|                                                                    | Terbinafine/Terbinafine<br>Hydrochloride | C |      | 250             | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Nov-2016              | 12915885      | NON-EXPEDITED    |                    |                 | US-ACCORD-037013     |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>                                                                     | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-------------------------------------------------------------------------------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Adverse Event; Drug<br>Ineffective; Product<br>Substitution Issue;<br>Withdrawal Syndrome | Escitalopram Accord |              |            | S           |              | Strength: 5 Mg     |                 | Accord     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Nov-2016              | 12915893      | NON-EXPEDITED    |                    |                 | US-ACCORD-037425     |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                    | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|----------------------------------------------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Abdominal Discomfort;<br>Arthralgia; Weight<br>Decreased | Escitalopram Accord |              |            | S           |              | Strength: 5 Mg     |                 | Accord     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Nov-2016              | 12915927      | NON-EXPEDITED    |                    | OT              | US-ACCORD-037743     |                      | 23 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                          | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|---------------------|--------------|------------|-------------|--------------|-----------------------------------------------------------------------------|-----------------|--------------|
| Contusion             | Escitalopram Accord |              |            | S           | Oral         | Strenght: 20 Mg<br>Previously Received 10<br>Mg In Oct-2015 Or Nov-<br>2015 |                 | Accord       |
|                       | Ibuprofen           |              |            | C           |              | Ibuprofen Prn                                                               |                 | Not Reported |
|                       | Ergocalciferol      |              |            | C           |              |                                                                             |                 | Not Reported |

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| <a href="#">FDA Received Date</a>                  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>                                                                        | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|----------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|------------------------------------------------------------------------------------------------------|--------------------------|---------------------|-------------------------|
| 07-Nov-2016                                        | 12915941                | NON-EXPEDITED             |                             |                          | US-ACCORD-040130              |                                                                                                      |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>                     | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>                                                                          | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Hypersensitivity                                   | Escitalopram            |                           |                             | S                        |                               | Strength: 10 Mg                                                                                      |                          | Accord              |                         |
| <a href="#">FDA Received Date</a>                  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>                                                                        | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 07-Nov-2016                                        | 12915943                | NON-EXPEDITED             |                             |                          | US-ACCORD-040413              |                                                                                                      | 16 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                     | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>                                                                          | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Chest Discomfort;<br>Hypopnoea;<br>Nasopharyngitis | Escitalopram            |                           |                             | S                        | Oral                          | Strength: 10 Mg 2.5 Mg<br>Once Daily At Bed Time,<br>Then Increased To 5 Mg,<br>10 Mg And Then 15 Mg |                          | Accord              |                         |
| <a href="#">FDA Received Date</a>                  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>                                                                        | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 07-Nov-2016                                        | 12915945                | NON-EXPEDITED             |                             |                          | US-ACCORD-041977              |                                                                                                      |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>                     | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>                                                                          | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Ineffective; Product<br>Substitution Issue    | Escitalopram Accord     |                           |                             | S                        |                               | Pills                                                                                                |                          | Accord              |                         |
| <a href="#">FDA Received Date</a>                  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>                                                                        | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 07-Nov-2016                                        | 12915953                | NON-EXPEDITED             |                             |                          | US-ACCORD-041978              |                                                                                                      | 45 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                     | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>                                                                          | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Chest Discomfort;<br>Thinking Abnormal             | Escitalopram            |                           |                             | S                        | Oral                          | 20 Mg Once Daily 7<br>Weeks Ago                                                                      |                          | Accord              |                         |
| <a href="#">FDA Received Date</a>                  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>                                                                        | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 07-Nov-2016                                        | 12915966                | NON-EXPEDITED             |                             |                          | US-ACCORD-043051              |                                                                                                      |                          | Male                | USA                     |

# FDA Adverse Event Reporting System

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| <u>Preferred Term</u>               | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                     | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------|----------------------------------|--------------------|--------------------|-----------------|----------------------|--------------------------------------------------------|-----------------|--------------|----------------|
| Anger; Drug Ineffective; Headache   | Escitalopram                     |                    |                    | S               |                      | Started At 10 Mg, 20 Mg Pill To Reach Prescribed Doses |                 | Accord       |                |
| <u>FDA Received Date</u>            | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Nov-2016                         | 12915974                         | NON-EXPEDITED      |                    | OT              | US-ACCORD-043111     |                                                        | 21 YR           | Female       | USA            |
| <u>Preferred Term</u>               | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Menorrhagia                         | Escitalopram                     |                    |                    | S               | Oral                 | Strength: 10 Mg                                        |                 | Accord       |                |
| <u>FDA Received Date</u>            | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Nov-2016                         | 12915977                         | NON-EXPEDITED      |                    |                 | US-ACCORD-042500     |                                                        | 50 YR           | Male         | USA            |
| <u>Preferred Term</u>               | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective                    | Escitalopram                     |                    |                    | S               | Oral                 | Dose/Strength: 10 Mg                                   |                 | Accord       |                |
| <u>FDA Received Date</u>            | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Nov-2016                         | 12915980                         | NON-EXPEDITED      |                    |                 | US-ACCORD-043574     |                                                        | 71 YR           | Female       | USA            |
| <u>Preferred Term</u>               | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Insomnia; Weight Decreased | Escitalopram                     |                    |                    | S               | Oral                 | Strength 10 Mg                                         |                 | Accord       |                |
|                                     | Ergocalciferol                   |                    |                    | C               |                      |                                                        |                 | Not Reported |                |
|                                     | Chondroitin Sulfate              |                    |                    | C               |                      |                                                        |                 | Not Reported |                |
|                                     | Sodium/Glucosamine Hydrochloride |                    |                    |                 |                      |                                                        |                 |              |                |
|                                     | Chondroitin/Glucosamine          |                    |                    | C               |                      |                                                        |                 | Not Reported |                |
|                                     | Calcium Gluconate                |                    |                    | C               |                      |                                                        |                 | Not Reported |                |
| <u>FDA Received Date</u>            | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Nov-2016                         | 12916435                         | EXPEDITED (15-DAY) |                    | OT              | US-ZYDUS-012665      |                                                        | 17 YR           | Female       | USA            |
| <u>Preferred Term</u>               | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                     | <u>Duration</u> | <u>Mfr</u>   |                |

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|                                                                                                                                                                                                             |                                   |   |         |              |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|---|---------|--------------|
| Alanine Aminotransferase Increased; Aphasia; Aphasia; Aspartate Aminotransferase Increased; Body Mass Index Increased; Hepatic Fibrosis; Hepatic Steatosis; Non-Alcoholic Steatohepatitis; Weight Increased | Bupropion/Bupropion Hydrochloride | S | Unknown | Zyklus Pharm |
|                                                                                                                                                                                                             | Escitalopram                      | S | Unknown | Zyklus Pharm |
|                                                                                                                                                                                                             | Sertraline                        | S | Unknown | Zyklus Pharm |
|                                                                                                                                                                                                             | Lorazepam                         | S | Unknown | Not Reported |
|                                                                                                                                                                                                             | Cyclobenzaprine                   | S | Unknown | Not Reported |
|                                                                                                                                                                                                             | Clonazepam                        | S | Unknown | Not Reported |
|                                                                                                                                                                                                             | Aripiprazole                      | S | Unknown | Not Reported |
|                                                                                                                                                                                                             | Lithium                           | S | Unknown | Not Reported |
|                                                                                                                                                                                                             | Methylphenidate                   | S | Unknown | Not Reported |
|                                                                                                                                                                                                             | Pregabalin                        | S | Unknown | Not Reported |
|                                                                                                                                                                                                             | Quetiapine/Quetiapine Fumarate    | S | Unknown | Not Reported |
|                                                                                                                                                                                                             | Topiramate                        | C | Unknown | Not Reported |
|                                                                                                                                                                                                             | Metformin                         | C | Unknown | Not Reported |
|                                                                                                                                                                                                             | Lamotrigine                       | C | Unknown | Not Reported |
|                                                                                                                                                                                                             | Oxcarbazepine                     | C | Unknown | Not Reported |
|                                                                                                                                                                                                             | Docusate                          | C | Unknown | Not Reported |
|                                                                                                                                                                                                             | Acetylcysteine                    | C | Unknown | Not Reported |
|                                                                                                                                                                                                             | Clonidine                         | C | Unknown | Not Reported |
|                                                                                                                                                                                                             | Levothyroxine                     | C | Unknown | Not Reported |
|                                                                                                                                                                                                             | Melatonin                         | C | Unknown | Not Reported |
|                                                                                                                                                                                                             | Ondansetron                       | C | Unknown | Not Reported |
|                                                                                                                                                                                                             | Diphenhydramine                   | C | Unknown | Not Reported |
|                                                                                                                                                                                                             | Dexamfetamine                     | C | Unknown | Not Reported |
|                                                                                                                                                                                                             | Minocycline                       | C | Unknown | Not Reported |
|                                                                                                                                                                                                             | Ethinylestradiol/Norgestimate     | C | Unknown | Not Reported |
|                                                                                                                                                                                                             | Lurasidone                        | C | Unknown | Not Reported |
|                                                                                                                                                                                                             | Polyethylene Glycol               | C | Unknown | Not Reported |



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| <u>FDA Received Date</u>                                                                 | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 07-Nov-2016                                                                              | 12917338                      | EXPEDITED (15-DAY) |                    | DS, HO          | JP-ALLERGAN-1675036US |                      | 67 YR           | Female       | JPN            |
| <u>Preferred Term</u>                                                                    | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Nausea; Serotonin Syndrome; Therapeutic Response Decreased             | Escitalopram Oxalate - Bp     |                    |                    | S               | Oral                  | 10 Mg, Qd            |                 | Allergan     |                |
|                                                                                          | Escitalopram Oxalate - Bp     |                    |                    | S               | Oral                  | 20 Mg, Qd            |                 | Allergan     |                |
|                                                                                          | Escitalopram Oxalate - Bp     |                    |                    | S               | Oral                  | 10 Mg, Qd            |                 | Allergan     |                |
|                                                                                          | Linezolid                     |                    |                    | S               | Oral                  | 1200 Mg, Qd          |                 | Not Reported |                |
|                                                                                          | Sulpiride                     |                    |                    | C               | Unknown               | 100 Mg, Qd           |                 | Not Reported |                |
|                                                                                          | Etizolam                      |                    |                    | C               | Oral                  | 2 Mg, Qd             |                 | Not Reported |                |
|                                                                                          | Trazodone Hydrochloride       |                    |                    | C               | Oral                  | 50 Mg, Qd            |                 | Not Reported |                |
|                                                                                          | Mirtazapine                   |                    |                    | C               | Oral                  | 3.75 Mg, Qd          |                 | Not Reported |                |
|                                                                                          | Mirtazapine                   |                    |                    | C               |                       | 45 Mg, Qd            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                 | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Nov-2016                                                                              | 12917342                      | EXPEDITED (15-DAY) |                    | OT              | US-TEVA-709629USA     |                      | 17 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                    | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aphasia; Food Craving; Hepatic Fibrosis; Non-Alcoholic Steatohepatitis; Weight Increased | Clonazepam                    |                    |                    | S               | Unknown               |                      |                 | Teva         |                |
|                                                                                          | Lorazepam                     |                    |                    | S               | Unknown               | 0.5mg As Needed      |                 | Actavis      |                |
|                                                                                          | Aripiprazole                  |                    |                    | S               | Unknown               |                      |                 | Teva         |                |
|                                                                                          | Bupropion Extended Release XI |                    |                    | S               | Unknown               |                      |                 | Actavis      |                |
|                                                                                          | Escitalopram                  |                    |                    | S               | Unknown               |                      |                 | Ivax         |                |
|                                                                                          | Methylphenidate Hydrochloride |                    |                    | S               | Unknown               |                      |                 | Barr         |                |
|                                                                                          | Quetiapine Fumarate           |                    |                    | S               | Unknown               |                      |                 | Teva         |                |
|                                                                                          | Sertraline                    |                    |                    | S               | Unknown               | 50mg Daily           |                 | Not Reported |                |
|                                                                                          | Cyclobenzaprine               |                    |                    | S               | Unknown               |                      |                 | Not Reported |                |
|                                                                                          | Lithium                       |                    |                    | S               | Unknown               |                      |                 | Not Reported |                |
|                                                                                          | Pregabalin                    |                    |                    | S               | Unknown               |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                      |   |         |              |
|----------------------|---|---------|--------------|
| Metformin            | S | Unknown | Not Reported |
| Lamotrigine          | C | Unknown | Not Reported |
| Oxcarbazepine        | C | Unknown | Not Reported |
| Docusate Sodium      | C | Unknown | Not Reported |
| Acetylcysteine       | C | Unknown | Not Reported |
| Clonidine            | C | Unknown | Not Reported |
| Levothyroxine Sodium | C | Unknown | Not Reported |
| Diphenhydramine      | C | Unknown | Not Reported |
| Topiramate           | C | Unknown | Not Reported |
| Ondansetron          | C | Unknown | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 07-Nov-2016              | 12917441      | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2016517517 |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Ineffective      | Alprazolam     |              |            | S           |              |                    |                 | Pfizer       |
|                       | Escitalopram   |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 07-Nov-2016              | 12917490      | EXPEDITED (15-DAY) |                    | OT              | PT-ALLERGAN-1674843US |                      | 71 YR      | Female     | PRT            |

| <u>Preferred Term</u>                                   | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Dry Mouth; Eyelid Oedema; Oedema Peripheral; Polydipsia | Escitalopram Oxalate - Bp |              |            | S           | Oral         |                    |                 | Allergan     |
|                                                         | Somazina                  |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                         | Acutil                    |              |            | C           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------|----------------------|------------|------------|----------------|
| 07-Nov-2016              | 12918308      | NON-EXPEDITED    |                    |                 | US-APOTEX-2016AP008106 |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                          |                      |                    |                    |                 |                                                               |                      |                 |            |                  |
|--------------------------|----------------------|--------------------|--------------------|-----------------|---------------------------------------------------------------|----------------------|-----------------|------------|------------------|
| Hypersensitivity         | Escitalopram Oxalate |                    | S                  | Unknown         |                                                               | Unk                  |                 | Apotex     |                  |
| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u>   |
| 07-Nov-2016              | 12918367             | NON-EXPEDITED      |                    |                 | US-B.I.<br>PHARMACEUTICALS,I<br>NC./RIDGEFIELD-2016-<br>BI-07 |                      | 78 YR           | Male       | USA              |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                  |
| Torticollis              | Busco Ibuprofen      |                    |                    | S               | Unknown                                                       |                      |                 |            | Not Reported     |
|                          | Busco Omeprazole     |                    |                    | S               | Unknown                                                       |                      |                 |            | Not Reported     |
|                          | Tamsulosin           |                    |                    | S               | Unknown                                                       |                      |                 |            | Not Reported     |
|                          | Escitalopram         |                    |                    | S               | Unknown                                                       |                      |                 |            | Not Reported     |
|                          | Escitalopram         |                    |                    | S               | Unknown                                                       |                      |                 |            | Not Reported     |
|                          | Escitalopram         |                    |                    | S               | Unknown                                                       |                      |                 |            | Not Reported     |
|                          | Amlodipine           |                    |                    | C               | Unknown                                                       |                      |                 |            | Not Reported     |
|                          | Celecoxib            |                    |                    | C               | Unknown                                                       |                      |                 |            | Not Reported     |
|                          | Clonazepam           |                    |                    | C               | Unknown                                                       |                      |                 |            | Not Reported     |
| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u>   |
| 07-Nov-2016              | 12918509             | EXPEDITED (15-DAY) |                    | OT              | ZA-<br>ELI_LILLY_AND_COMP<br>ANY-ZA201610009040               |                      |                 | Female     | ZAF              |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                  |
| Hypoaesthesia            | Prozac               |                    |                    | S               | Oral                                                          | 20 Mg, Qd            |                 |            | Eli Lilly And Co |
|                          | Prozac               |                    |                    | S               | Oral                                                          | 20 Mg, Qd            |                 |            | Eli Lilly And Co |
|                          | Lexamil              |                    |                    | S               | Oral                                                          | 5 Mg, Qd             |                 |            | Not Reported     |
|                          | Lexamil              |                    |                    | S               |                                                               |                      |                 |            | Not Reported     |
|                          | Cortisone            |                    |                    | C               | Other                                                         | Unk, Unknown         |                 |            | Not Reported     |
| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u>   |
| 08-Nov-2016              | 12827020             | EXPEDITED (15-DAY) |                    | HO              | TW-ALLERGAN-<br>1000087603                                    |                      | 22 YR           | Female     | TWN              |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                           | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|------------------------|-------------------------|-----------------|--------------|----------------|
| Aggression; Drug Interaction; Mania                                             | Escitalopram Oxalate - Bp |                    |                    | S               | Unknown                | 15 Mg, Daily            |                 | Allergan     |                |
|                                                                                 | Dextromethorphan          |                    |                    | S               | Oral                   | 30 Mg, Q6hr             |                 | Not Reported |                |
|                                                                                 | Ambroxol                  |                    |                    | C               | Unknown                | 30 Mg, Unk              |                 | Not Reported |                |
|                                                                                 | Paracetamol               |                    |                    | C               |                        | 325 Mg, Tid             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                        | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Nov-2016                                                                     | 12889421                  | EXPEDITED (15-DAY) |                    | LT              | FR-ALLERGAN-1673902US  |                         | 74 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                           | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Intraventricular Haemorrhage                                                    | Escitalopram Oxalate - Bp |                    |                    | S               | Oral                   | 10 Mg, Qd               |                 | Allergan     |                |
|                                                                                 | Kardegic                  |                    |                    | S               | Oral                   | 160 Mg, Qd              |                 | Not Reported |                |
|                                                                                 | Glucophage                |                    |                    | C               | Unknown                | Daily Dose Not Reported |                 | Not Reported |                |
|                                                                                 | Novonorm                  |                    |                    | C               | Unknown                | Daily Dose Not Reported |                 | Not Reported |                |
|                                                                                 | Modopar                   |                    |                    | C               | Unknown                | Daily Dose Not Reported |                 | Not Reported |                |
|                                                                                 | Zaldiar                   |                    |                    | C               | Unknown                | Daily Dose Not Reported |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                        | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Nov-2016                                                                     | 12919372                  | EXPEDITED (15-DAY) |                    | OT              | US-APOTEX-2016AP014063 |                         | 17 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                           | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Food Craving; Hepatic Fibrosis; Non-Alcoholic Steatohepatitis; Weight Increased | Sertraline Hydrochloride  |                    |                    | S               | Unknown                | 50 Mg, Qd               |                 | Apotex       |                |
|                                                                                 | Clonazepam Tablets Usp    |                    |                    | S               | Unknown                |                         |                 | Apotex       |                |
|                                                                                 | Aripiprazole Tablets      |                    |                    | S               | Unknown                |                         |                 | Apotex       |                |
|                                                                                 | Escitalopram Oxalate      |                    |                    | S               | Unknown                |                         |                 | Apotex       |                |
|                                                                                 | Bupropion Hydrochloride   |                    |                    | S               | Unknown                |                         |                 | Apotex       |                |
|                                                                                 | Metformin Hydrochloride   |                    |                    | S               | Unknown                |                         |                 | Apotex       |                |
|                                                                                 | Quetiapine Fumarate       |                    |                    | S               | Unknown                |                         |                 | Apotex       |                |
|                                                                                 | Lithium Carbonate         |                    |                    | S               | Unknown                |                         |                 | Apotex       |                |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                      |   |         |                  |              |
|----------------------|---|---------|------------------|--------------|
| Lorazepam            | S | Unknown | 0.5 Mg As Needed | Not Reported |
| Methylphenidate      | S | Unknown |                  | Not Reported |
| Pregabalin           | S | Unknown |                  | Not Reported |
| Cyclobenzaprine      | C | Unknown |                  | Not Reported |
| Lamotrigine          | C | Unknown |                  | Not Reported |
| Oxcarbazepine        | C | Unknown |                  | Not Reported |
| Docusate Sodium      | C | Unknown |                  | Not Reported |
| Acetylcysteine       | C | Unknown |                  | Not Reported |
| Clonidine            | C | Unknown |                  | Not Reported |
| Levothyroxine Sodium | C | Unknown |                  | Not Reported |
| Diphenhydramine      | C | Unknown |                  | Not Reported |
| Topiramate           | C | Unknown |                  | Not Reported |
| Ondansetron          | C | Unknown |                  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 08-Nov-2016              | 12919431      | EXPEDITED (15-DAY) |                    | OT              | SE-SHIRE-<br>SE201615905 |                      | 28 YR      | Male       | SWE            |

| <u>Preferred Term</u>                | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Ineffective; Serotonin Syndrome | Elvanse              |              |            | S           | Oral         | 30 Mg, 1x/Day:Qd   |                 | Shire        |
|                                      | Ciprallex /01588501/ |              |            | S           | Unknown      | Unk, Unknown       |                 | Not Reported |
|                                      | Mirtazapine          |              |            | S           | Unknown      | Unk, Unknown       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|------------|------------|----------------|
| 08-Nov-2016              | 12926994      | EXPEDITED (15-DAY) |                    | OT              | US-CIPLA LTD.-<br>2016US04757 |                      |            | Unknown    | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Hypersensitivity      | Escitalopram   |              |            | S           | Oral         | 10 Mg, Unk         |                 | Invagen    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 09-Nov-2016              | 12886454      | EXPEDITED (15-DAY) |                    | OT              | FR-ALLERGAN-<br>1673736US |                      | 75 YR      | Male       | FRA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u> | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Akinesia; Tremor      | Escitalopram Oxalate - Bp |              |            | S           | Oral         | 5 Mg, Qd           |                 | Allergan     |
|                       | Escitalopram Oxalate - Bp |              |            | S           | Oral         | 15 Mg, Qd          |                 | Allergan     |
|                       | Escitalopram Oxalate - Bp |              |            | S           | Oral         | 10 Mg, Qd          |                 | Allergan     |
|                       | Kardegic                  |              |            | C           | Unknown      | 75 Mg, Unk         |                 | Not Reported |
|                       | Temerit                   |              |            | C           | Unknown      | Unk, Unknown       |                 | Not Reported |
|                       | Fumafer                   |              |            | C           | Unknown      | Unk, Unknown       |                 | Not Reported |
|                       | Xanax                     |              |            | C           | Unknown      | Unk, Unknown       |                 | Not Reported |
|                       | Inexium                   |              |            | C           | Unknown      | Unk, Unknown       |                 | Not Reported |
|                       | Perindopril               |              |            | C           | Unknown      | Unk, Unknown       |                 | Not Reported |
|                       | Eliquis                   |              |            | C           | Unknown      | Unk, Unknown       |                 | Not Reported |
|                       | Repaglinide               |              |            | C           | Unknown      | Unk, Unknown       |                 | Not Reported |
|                       | Daonil                    |              |            | C           | Unknown      | Unk, Unknown       |                 | Not Reported |
|                       | Seresta                   |              |            | C           | Unknown      | Unk Unk, Unknown   |                 | Not Reported |
|                       | Lasilix                   |              |            | C           | Unknown      | Unk, Unknown       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 09-Nov-2016              | 12894851      | EXPEDITED (15-DAY) |                    | OT              | NL-ALLERGAN-1673908US |                      | 57 YR      | Male       | NLD            |

| <u>Preferred Term</u>                                              | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--------------------------------------------------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Incorrect Dose Administered; Product Use Issue; Serotonin Syndrome | Escitalopram Oxalate - Bp |              |            | S           | Oral         | 15 Mg, Qd          |                 | Allergan   |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Nov-2016              | 12922545      | EXPEDITED (15-DAY) |                    | OT              | US-CIPLA-2016US04490 |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Drug Ineffective; Tremor | Escitalopram   |              |            | S           | Oral         | 30 Mg, Qd, Tablet  |                 | Invagen    |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|         |   |      |                   |              |
|---------|---|------|-------------------|--------------|
| Pristiq | S | Oral | 50 Mg, Qd, Tablet | Not Reported |
| Benicar | C |      | 10 Mg, Unk        | Not Reported |
| Zocor   | C |      | 40 Mg, Unk        | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 09-Nov-2016              | 12923633      | EXPEDITED (15-DAY) |                    | DE              | FR-PFIZER INC-2016511426 |                      | 55 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                                                                                                                                               | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Acute Kidney Injury; Acute Respiratory Distress Syndrome; Cardiogenic Shock; Hepatic Failure; Hypovolaemic Shock; Inflammation; Multiple Organ Dysfunction Syndrome; Rhabdomyolysis | Tahor                 |              |            | S           | Oral         | Unk                |                 | Pfizer       |
|                                                                                                                                                                                     | Alprazolam            |              |            | S           | Oral         | Unk                |                 | Pfizer       |
|                                                                                                                                                                                     | Atenolol              |              |            | S           | Oral         | 10 Mg, 1x/Day      |                 | Not Reported |
|                                                                                                                                                                                     | Bipreterax /01421201/ |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                                                                                                                                                                                     | Kardegic              |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                                                                                                                                                                                     | Seroplex              |              |            | S           | Oral         | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 09-Nov-2016              | 12925608      | EXPEDITED (15-DAY) |                    | HO              | FR-ALLERGAN-1675082US |                      | 34 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                             | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Agitation; Drug Abuser; Drug Dependence; Hypokalaemia; Toxicity To Various Agents | Escitalopram Oxalate - Bp |              |            | S           | Oral         |                    |                 | Allergan     |
|                                                                                   | Cannabis And Resin        |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                   | Tobacco Powder            |              |            | S           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 09-Nov-2016              | 12926611      | EXPEDITED (15-DAY) |                    | HO              | FR-ALLERGAN-1675192US |                      | 42 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                              | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Bradypnoea; Coma; Inappropriate Schedule Of Product Administration | Escitalopram Oxalate - Bp |              |            | S           | Oral         |                    |                 | Allergan     |
|                                                                    | Alprazolam                |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                    | Abilify                   |              |            | C           | Unknown      | 5 Mg, Unk          |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                   | Atarax                               |                    | C                  | Unknown         | 25 Mg, Tid               |                      |                 | Not Reported |                |
|---------------------------------------------------|--------------------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
|                                                   | Revvia                               |                    | C                  | Unknown         | 50 Mg, Qd                |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                          | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Nov-2016                                       | 12927093                             | EXPEDITED (15-DAY) |                    | HO              | FR-ALLERGAN-1675031US    |                      | 74 YR           | Female       | FRA            |
| <u>Preferred Term</u>                             | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Neuropsychiatric Lupus; Photosensitivity Reaction | Escitalopram Oxalate - Bp            |                    |                    | S               | Oral                     |                      |                 | Allergan     |                |
|                                                   | Levothyrox                           |                    |                    | C               | Unknown                  |                      |                 | Not Reported |                |
|                                                   | Kardegic                             |                    |                    | C               | Unknown                  |                      |                 | Not Reported |                |
|                                                   | Novopulm                             |                    |                    | C               | Unknown                  |                      |                 | Not Reported |                |
|                                                   | Orocal D3                            |                    |                    | C               | Unknown                  |                      |                 | Not Reported |                |
|                                                   | Preservision                         |                    |                    | C               | Unknown                  |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                          | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Nov-2016                                       | 12168487                             | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2016139951 |                      | 82 YR           | Female       | USA            |
| <u>Preferred Term</u>                             | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity                             | Xanax                                |                    |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                                                   | Norvasc                              |                    |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                                                   | Amoxicillin                          |                    |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                                                   | Calcium Carbonate                    |                    |                    | S               |                          | 600 Mg, Unk          |                 | Pfizer       |                |
|                                                   | Homatropine                          |                    |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                                                   | Methylbromide/Hydrocodone Bitartrate |                    |                    |                 |                          |                      |                 |              |                |
|                                                   | Naproxen Sodium                      |                    |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                                                   | Zoloft                               |                    |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                                                   | Effexor Xr                           |                    |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                                                   | Sonata                               |                    |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                                                   | Zithromax                            |                    |                    | S               |                          | Unk                  |                 | Pfizer       |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                     |   |     |              |
|-------------------------------------|---|-----|--------------|
| Furosemide                          | S | Unk | Not Reported |
| Prednisone                          | S | Unk | Not Reported |
| Trazodone Hcl                       | S | Unk | Not Reported |
| Aspirin                             | S | Unk | Not Reported |
| Cefuroxime Sodium                   | S | Unk | Not Reported |
| Diovan                              | S | Unk | Not Reported |
| Dyrenium                            | S | Unk | Not Reported |
| Ketek                               | S | Unk | Not Reported |
| Lexapro                             | S | Unk | Not Reported |
| Proventil                           | S | Unk | Not Reported |
| Prozac                              | S | Unk | Not Reported |
| Qvar                                | S | Unk | Not Reported |
| Rhinocort Aqua                      | S | Unk | Not Reported |
| Tramadol                            | S | Unk | Not Reported |
| Triamterene And Hydrochlorothiazide | S | Unk | Not Reported |
| Ultram                              | S | Unk | Not Reported |
| Wellbutrin                          | S | Unk | Not Reported |
| Biaxin                              | S | Unk | Not Reported |
| Lisinopril                          | S | Unk | Not Reported |
| Toprol XL                           | S | Unk | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------------|----------------------|------------|------------|----------------|
| 10-Nov-2016              | 12172063      | NON-EXPEDITED    |                    | OT              | US-GLAXOSMITHKLINE-US2016GSK033600 |                      | 76 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                     | <u>Product</u>                                   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                          | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|-----------------------------------------------------------------------------------------------------------|--------------------------------------------------|--------------|------------|-------------|---------------------------------------|--------------------|-----------------|-----------------|
| Abdominal Pain Upper; Accidental Exposure To Product; Blood Glucose Increased; Device Leakage; Device Use | Tanzeum Solution For Injection In Pre-Filled Pen |              |            | S           | Intravenous (not otherwise specified) | 30 Mg, We          |                 | Glaxosmithkline |
|                                                                                                           | Tanzeum Solution For Injection In Pre-Filled Pen |              |            | S           | Intravenous (not otherwise specified) | 30 Mg, We          |                 | Glaxosmithkline |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                                                                                                                                                              |                                                     |   |                                          |           |                 |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------|---|------------------------------------------|-----------|-----------------|
| Error; Dry Mouth;<br>Headache; Hypophagia;<br>Ill-Defined Disorder;<br>Increased Appetite;<br>Labelled Drug-Disease<br>Interaction Medication<br>Error; Limb Operation;<br>Product Preparation Issue;<br>Pruritus; Skin Burning<br>Sensation; Squamous Cell<br>Carcinoma Of Skin;<br>Stress; Urinary Tract<br>Infection; Weight<br>Increased | Tanzeum Solution For Injection<br>In Pre-Filled Pen | S | Intravenous (not<br>otherwise specified) | 30 Mg, We | Glaxosmithkline |
|                                                                                                                                                                                                                                                                                                                                              | Escitalopram                                        | S |                                          | Unk       | Glaxosmithkline |

| <u>FDA Received Date</u>                     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
|----------------------------------------------|----------------|--------------------|--------------------|-----------------|-------------------------------------------------|-----------------------|-----------------|------------------|----------------|
| 10-Nov-2016                                  | 12928743       | EXPEDITED (15-DAY) |                    | HO, LT, OT      | ES-<br>ELI_LILLY_AND_COMP<br>ANY-ES201611002272 |                       | 42 YR           | Male             | ESP            |
| <u>Preferred Term</u>                        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>       |                |
| Acute Kidney Injury; Drug<br>Interaction;    | Zyprexa        |                    |                    | S               | Oral                                            | 10 Mg, Qd             |                 | Eli Lilly And Co |                |
| Hepatomegaly;                                | Zyprexa        |                    |                    | S               | Oral                                            | 140 Mg, Qd            |                 | Eli Lilly And Co |                |
| Neuroleptic Malignant<br>Syndrome; Overdose; | Haloperidol    |                    |                    | S               | Oral                                            | 5 Mg, Tid             |                 | Not Reported     |                |
| Pleural Effusion; Suicide<br>Attempt         | Haloperidol    |                    |                    | S               | Oral                                            | 150 Mg, Qd            |                 | Not Reported     |                |
|                                              | Escitalopram   |                    |                    | S               | Oral                                            | 20 Mg, Qd             |                 | Not Reported     |                |
|                                              | Escitalopram   |                    |                    | S               | Oral                                            | 400 Mg, Qd            |                 | Not Reported     |                |
|                                              | Xeplion        |                    |                    | C               | Intramuscular                                   | 150 Mg, Monthly (1/M) |                 | Not Reported     |                |
|                                              | Alcohol        |                    |                    | C               | Unknown                                         | 2 Beers A Day         |                 | Not Reported     |                |
|                                              | Cocaine        |                    |                    | C               | Respiratory<br>(inhalation)                     | Unk, Unknown          |                 | Not Reported     |                |
|                                              | Cocaine        |                    |                    | C               | Intravenous (not<br>otherwise specified)        | Unk, Unknown          |                 | Not Reported     |                |
| <u>FDA Received Date</u>                     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 10-Nov-2016                                  | 12930595       | EXPEDITED (15-DAY) |                    | HO              | FR-ALLERGAN-<br>1675324US                       |                       | 39 YR           | Female           | FRA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <a href="#">Preferred Term</a>                                                            | <a href="#">Product</a>   | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>                                           | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
|-------------------------------------------------------------------------------------------|---------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-----------------------------------------------------------------------|--------------------------|---------------------|-------------------------|
| Coma; Contraindicated Product Administered; Overdose; Poisoning Deliberate                | Escitalopram Oxalate - Bp |                           |                             | S                        | Oral                          | 240 Mg, Single                                                        |                          | Allergan            |                         |
| <a href="#">FDA Received Date</a>                                                         | <a href="#">Case #</a>    | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>                                         | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 10-Nov-2016                                                                               | 12930808                  | EXPEDITED (15-DAY)        |                             | OT                       | CN-JNJFOC-20161104369         |                                                                       | 43 YR                    | Male                | CHN                     |
| <a href="#">Preferred Term</a>                                                            | <a href="#">Product</a>   | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>                                           | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Off Label Use; Product Use In Unapproved Indication; Suicidal Ideation; Thinking Abnormal | Risperdal                 |                           |                             | S                        | Oral                          |                                                                       |                          | Not Reported        |                         |
|                                                                                           | Risperdal                 |                           |                             | S                        | Oral                          |                                                                       |                          | Not Reported        |                         |
|                                                                                           | Lexapro                   |                           |                             | S                        | Unknown                       |                                                                       |                          | Not Reported        |                         |
|                                                                                           | Lexapro                   |                           |                             | S                        | Unknown                       | 2 Tablets Per Morning                                                 |                          | Not Reported        |                         |
|                                                                                           | Lexapro                   |                           |                             | S                        | Unknown                       | 2 Tablets Per Morning, 2 Tablets Per Noon, 1 Tablet At Every 16:00 Pm |                          | Not Reported        |                         |
|                                                                                           | Clonazepam                |                           |                             | C                        | Oral                          |                                                                       |                          | Not Reported        |                         |
|                                                                                           | Clonazepam                |                           |                             | C                        | Oral                          | Half Dosage Currently Compared With Before                            |                          | Not Reported        |                         |
|                                                                                           | Stilnox                   |                           |                             | C                        | Unknown                       |                                                                       |                          | Not Reported        |                         |
|                                                                                           | Stilnox                   |                           |                             | C                        | Unknown                       | Half Dosage Currently Compared With Before                            |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                         | <a href="#">Case #</a>    | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>                                         | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 10-Nov-2016                                                                               | 12931209                  | NON-EXPEDITED             |                             |                          | US-JAZZ-2016-US-018025        |                                                                       |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                            | <a href="#">Product</a>   | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>                                           | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Night Sweats; Unevaluable Event; Weight Increased                                         | Xyrem                     |                           |                             | S                        | Oral                          | 2.25 G, Bid                                                           |                          | Jazz                |                         |
|                                                                                           | Xyrem                     |                           |                             | S                        | Oral                          | Dose Adjustments                                                      |                          | Jazz                |                         |
|                                                                                           | Xyrem                     |                           |                             | S                        | Oral                          | Unknown Dose                                                          |                          | Jazz                |                         |
|                                                                                           | Escitalopram              |                           |                             | S                        |                               |                                                                       |                          | Not Reported        |                         |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                         |   |              |
|-------------------------|---|--------------|
| Buspirone Hcl           | C | Not Reported |
| Ceftina                 | C | Not Reported |
| Minastrin 24 Fe         | C | Not Reported |
| Nuvigil                 | C | Not Reported |
| Excedrin Extra Strength | C | Not Reported |
| Ibuprofen               | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Nov-2016              | 12931433      | EXPEDITED (15-DAY) |                    | HO              | GXKR2016DE005071     |                      |            | Unknown    | DEU            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hyponatraemia         | Metoprolol     |              |            | S           | Oral         | 23.75 Mg, Qd       |                 | Novartis     |
|                       | Ciprallex      |              |            | S           | Oral         | 10 Mg, Qd          |                 | Not Reported |
|                       | L-Thyroxine    |              |            | C           | Oral         | 37.5 Ug, Qd        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------------------------|----------------------|------------|------------|----------------|
| 11-Nov-2016              | 12932561      | EXPEDITED (15-DAY) |                    | OT              | US-LUPIN<br>PHARMACEUTICALS<br>INC.-2016-04995 |                      | 17 YR      | Female     | USA            |

| <u>Preferred Term</u>                                         | <u>Product</u>  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------|-----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Food Craving; Non-Alcoholic Steatohepatitis; Weight Increased | Sertraline      |              |            | S           | Unknown      | 50 Mg              |                 | Not Reported |
|                                                               | Cyclobenzaprine |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                               | Clonazepam      |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                               | Lorazepam       |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                               | Aripiprazole    |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                               | Lithium         |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                               | Escitalopram    |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                               | Bupropion       |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                               | Methylphenidate |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                               | Pregabalin      |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                               | Quetiapine      |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                               | Metformin       |              |            | S           | Unknown      |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                         | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                              | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|---------------------------------------------------|-------------------------|-----------------|--------------|----------------|
| 11-Nov-2016                                                                                                                      | 12934429                  | EXPEDITED (15-DAY) |                    | DE              | FR-ALLERGAN-1675512US                             |                         | 55 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                                            | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                      | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiogenic Shock;<br>Hypovolaemic Shock;<br>Multiple Organ<br>Dysfunction Syndrome                                              | Escitalopram Oxalate - Bp |                    |                    | S               | Oral                                              | 10 Mg, Unk              |                 | Allergan     |                |
|                                                                                                                                  | Atenolol                  |                    |                    | S               | Oral                                              | 10 Mg, Qd               |                 | Not Reported |                |
|                                                                                                                                  | Bipreterax                |                    |                    | S               | Oral                                              | 5mg/1.25mg              |                 | Not Reported |                |
|                                                                                                                                  | Kardegic                  |                    |                    | S               | Oral                                              | 75 Mg, Unk              |                 | Not Reported |                |
|                                                                                                                                  | Tahor                     |                    |                    | S               | Oral                                              | 80 Mg, Unk              |                 | Not Reported |                |
|                                                                                                                                  | Alprazolam                |                    |                    | S               | Oral                                              |                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                         | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                              | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Nov-2016                                                                                                                      | 12629078                  | EXPEDITED (15-DAY) |                    | HO, OT          | FR-ALEMBIC PHARMACUETICALS LIMITED-2016SCAL000635 |                         |                 | Unknown      | FRA            |
| <u>Preferred Term</u>                                                                                                            | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                      | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State;<br>Electrocardiogram Qt<br>Prolonged;<br>Hypoglycaemia;<br>Nystagmus; Overdose;<br>Toxicity To Various Agents | Venlafaxine Hydrochloride |                    |                    | S               |                                                   | 7875 Mg, Unk            |                 | Alembic      |                |
|                                                                                                                                  | Escitalopram              |                    |                    | S               |                                                   | 840 Mg, Unk             |                 | Not Reported |                |
|                                                                                                                                  | Bromazepam                |                    |                    | S               |                                                   | 180 Mg, Unk             |                 | Not Reported |                |
|                                                                                                                                  | Lormetazepam              |                    |                    | S               |                                                   | 14 Mg, Unk              |                 | Not Reported |                |
|                                                                                                                                  |                           |                    |                    |                 |                                                   |                         |                 |              |                |
| <u>FDA Received Date</u>                                                                                                         | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                              | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Nov-2016                                                                                                                      | 12791120                  | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2016455897                          |                         | 76 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                            | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                      | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Amnesia; Wrong Dose                                                                                                              | Lyrica                    |                    |                    | S               |                                                   | 50 Mg, Unk              |                 | Pfizer       |                |
|                                                                                                                                  | Clonazepam                |                    |                    | S               |                                                   | 4 Mg, Unk               |                 | Not Reported |                |
|                                                                                                                                  | Clonazepam                |                    |                    | S               | Oral                                              | 0.5 Mg, 1x/Day At Night |                 | Not Reported |                |
|                                                                                                                                  | Escitalopram              |                    |                    | S               | Oral                                              | 20 Mg, 1x/Day At Night  |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|          |   |      |                        |              |
|----------|---|------|------------------------|--------------|
| Seroquel | S |      | 100 Mg, Unk            | Not Reported |
| Seroquel | S | Oral | 50 Mg, 1x/Day At Night | Not Reported |
| Klonopin | S |      | Unk                    | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------------------------------------|----------------------|------------|------------|----------------|
| 14-Nov-2016              | 12893951      | EXPEDITED (15-DAY) |                    | HO              | FR-IPSEN<br>BIOPHARMACEUTICAL<br>S, INC.-2016-09150 |                      |            | Male       | FRA            |

| <u>Preferred Term</u>                                                                                                                                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>  | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|---------------|--------------------|-----------------|--------------|
| Asthenia; Faecal Vomiting;<br>Intestinal Obstruction;<br>Muscular Weakness;<br>Neuromuscular Toxicity;<br>Respiratory Failure;<br>Urinary Retention;<br>Vomiting | Dysport        |              |            | S           | Intramuscular | 100 lu             |                 | Not Reported |
|                                                                                                                                                                  | Dysport        |              |            | S           |               |                    |                 | Not Reported |
|                                                                                                                                                                  | Gutron         |              |            | S           | Oral          |                    |                 | Not Reported |
|                                                                                                                                                                  | Seroplex       |              |            | S           | Oral          |                    |                 | Not Reported |
|                                                                                                                                                                  | Xanax          |              |            | S           | Oral          |                    |                 | Not Reported |
|                                                                                                                                                                  | Gaviscon       |              |            | S           | Oral          |                    |                 | Not Reported |
|                                                                                                                                                                  | Inipomp        |              |            | S           | Oral          |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|------------|------------|----------------|
| 14-Nov-2016              | 12935726      | EXPEDITED (15-DAY) |                    | DE              | US-CIPLA LTD.-<br>2016US20958 |                      |            | Unknown    | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|---------------------|-----------------|------------|
| Death                 | Escitalopram   |              |            | S           |              | More Than 20 Mg, Qd |                 | Invagen    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|------------|------------|----------------|
| 14-Nov-2016              | 12935811      | EXPEDITED (15-DAY) |                    | DE              | US-CIPLA LTD.-<br>2016US20959 |                      |            | Unknown    | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|----------------------|-----------------|------------|
| Death                 | Escitalopram   |              |            | S           | Unknown      | More Than 20mg Daily |                 | Invagen    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|------------|------------|----------------|
| 14-Nov-2016              | 12935977      | EXPEDITED (15-DAY) |                    | DE              | US-CIPLA LTD.-<br>2016US20986 |                      |            | Unknown    | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                    | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>   |                |
|------------------------------------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|------------------------------------------------|--------------------------------------|-----------------|--------------|----------------|
| Sudden Cardiac Death                                                                     | Escitalopram                |                    |                    | S               | Unknown                                        | Unk, >20 Mg                          |                 | Invagen      |                |
| <u>FDA Received Date</u>                                                                 | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u>                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Nov-2016                                                                              | 12937475                    | EXPEDITED (15-DAY) |                    | OT              | US-LUPIN<br>PHARMACEUTICALS<br>INC.-2016-05064 |                                      | 12 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                    | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Irritability;<br>Restlessness; Sleep<br>Disorder                             | Escitalopram                |                    |                    | S               | Unknown                                        |                                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                 | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u>                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Nov-2016                                                                              | 12939519                    | DIRECT             |                    | HO              |                                                |                                      | 85 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                    | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Behaviour;<br>Abnormal Dreams;<br>Delirium; Hallucination;<br>Thinking Abnormal | Citalopram                  |                    |                    | S               | Oral                                           | Quantity:1 Tablet(S);<br>Daily; Oral |                 | Not Reported |                |
|                                                                                          | Escitalopram                |                    |                    | S               |                                                |                                      |                 | Not Reported |                |
|                                                                                          | Pravastatin                 |                    |                    | C               |                                                |                                      |                 | Not Reported |                |
|                                                                                          | Ramipril                    |                    |                    | C               |                                                |                                      |                 | Not Reported |                |
|                                                                                          | Vitamin D3                  |                    |                    | C               |                                                |                                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                 | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u>                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Nov-2016                                                                              | 12940388                    | EXPEDITED (15-DAY) |                    | OT              | US-DRREDDYS-<br>USA/USA/16/0084703             |                                      | 17 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                    | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aphasia; Non-Alcoholic<br>Steatohepatitis                                                | Sertraline Hydrochloride    |                    |                    | S               | Unknown                                        |                                      |                 | Not Reported |                |
|                                                                                          | Quetiapine Fumarate Tablets |                    |                    | S               | Unknown                                        |                                      |                 | Not Reported |                |
|                                                                                          | Lorazepam                   |                    |                    | S               | Unknown                                        |                                      |                 | Not Reported |                |
|                                                                                          | Cyclobenzaprine             |                    |                    | S               | Unknown                                        |                                      |                 | Not Reported |                |
|                                                                                          | Clonazepam                  |                    |                    | S               | Unknown                                        |                                      |                 | Not Reported |                |
|                                                                                          | Lithium Carbonate           |                    |                    | S               | Unknown                                        |                                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                   |   |         |              |
|-------------------|---|---------|--------------|
| Escitalopram      | S | Unknown | Not Reported |
| Aripiprazole      | S | Unknown | Not Reported |
| Bupropion         | S |         | Not Reported |
| Methylphenidate   | S | Unknown | Not Reported |
| Pregabalin        | S | Unknown | Not Reported |
| Cetirizine        | C | Unknown | Not Reported |
| Naproxen          | C | Unknown | Not Reported |
| Paracetamol       | C | Unknown | Not Reported |
| Vitamin B Complex | C | Unknown | Not Reported |
| Cholecalciferol   | C | Unknown | Not Reported |
| Melatonin         | C | Unknown | Not Reported |
| Tizanidine        | C | Unknown | Not Reported |
| Lamotrigine       | C | Unknown | Not Reported |
| Oxcarbazepine     | C | Unknown | Not Reported |
| Levothyroxine     | C | Unknown | Not Reported |
| Ondansetron       | C | Unknown | Not Reported |
| Clonidine         | C | Unknown | Not Reported |
| Diphenhydramine   | C | Unknown | Not Reported |
| Docusate Sodium   | C | Unknown | Not Reported |
| Acetylcysteine    | C | Unknown | Not Reported |
| Minocycline       | C | Unknown | Not Reported |
| Lurasidone        | C | Unknown | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 15-Nov-2016              | 12943136      | EXPEDITED (15-DAY) |                    | DE, HO, OT      | US-PFIZER INC-2016522408 |                      |            | Female     | USA            |

| <u>Preferred Term</u>                        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------|----------------|--------------|------------|-------------|----------------|----------------------|-----------------|--------------|
| Agitation Neonatal; Drug Withdrawal Syndrome | Vistaril       |              |            | S           | Transplacental | 50 Mg, 2x/Day        |                 | Pfizer       |
| Neonatal; Irritability;                      | Gabapentin     |              |            | S           | Transplacental | Unk Unk, 1x/Day (Qd) |                 | Pfizer       |
| Maternal Exposure During                     | Suboxone       |              |            | S           | Transplacental | 10 Mg, Daily         |                 | Not Reported |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                       |               |   |                |                      |              |
|-----------------------------------------------------------------------|---------------|---|----------------|----------------------|--------------|
| Pregnancy; Neonatal Aspiration; Oral Candidiasis; Poor Feeding Infant | Buprenorphine | S | Transplacental | Various Doses        | Not Reported |
|                                                                       | Lexapro       | S | Transplacental | 20 Mg, 1x/Day (Qd)   | Not Reported |
|                                                                       | Buprenorphine | S | Transplacental | 10 Mg, 1x/Day (Qd)   | Not Reported |
|                                                                       | Nicotine      | S | Transplacental | 40 Cigarettes, Daily | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 15-Nov-2016              | 12944206      | EXPEDITED (15-DAY) |                    | OT              | CN-ALLERGAN-1675831US |                      | 43 YR      | Male       | CHN            |

| <u>Preferred Term</u>                                      | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                    | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------|---------------------------|--------------|------------|-------------|--------------|-----------------------------------------------------------------------|-----------------|--------------|
| Intentional Product Use Issue; Overdose; Suicidal Ideation | Escitalopram Oxalate - Bp |              |            | S           | Unknown      | 2 Df, Qam                                                             |                 | Allergan     |
|                                                            | Escitalopram Oxalate - Bp |              |            | S           | Unknown      | 2 Tablets Per Morning, 2 Tablets Per Noon And 1 Tablet At Every 16:00 |                 | Allergan     |
|                                                            | Escitalopram Oxalate - Bp |              |            | S           | Unknown      | 1 Df, Qd                                                              |                 | Allergan     |
|                                                            | Risperdal                 |              |            | S           | Unknown      |                                                                       |                 | Not Reported |
|                                                            | Risperdal                 |              |            | S           | Unknown      | 0.5 Df, Qd                                                            |                 | Not Reported |
|                                                            | Clonazepam                |              |            | C           | Unknown      | Half Dosage Compared With Before.                                     |                 | Not Reported |
|                                                            | Stilnox                   |              |            | C           | Unknown      | Half Dosage Currently Compared With Before.                           |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------------|----------------------|------------|------------|----------------|
| 16-Nov-2016              | 12484991      | NON-EXPEDITED    |                    |                 | US-GLAXOSMITHKLINE-US2016GSK087253 |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                                                                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|----------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Back Disorder; Back Pain; Exostosis; Fall; Hypoaesthesia; Musculoskeletal Pain; Nausea; Pain In Extremity; Spinal Disorder | Wellbutrin     |              |            | S           |              | 150 Mg, Bid        |                 | Glaxosmithkline |
|                                                                                                                            | Methadone      |              |            | S           |              | 5 Mg, Bid          |                 | Glaxosmithkline |
|                                                                                                                            | Lexapro        |              |            | S           |              | 10 Mg, Qd          |                 | Not Reported    |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 16-Nov-2016                       | 12944717                | EXPEDITED (15-DAY)        |                             | DE                       | US-CIPLA LTD.-<br>2016US20987 |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Sudden Cardiac Death              | Escitalopram            |                           |                             | S                        | Unknown                       | Unk, > 20 Mg                  |                          | Invagen             |                         |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 16-Nov-2016                       | 12944746                | EXPEDITED (15-DAY)        |                             | DE                       | US-CIPLA LTD.-<br>2016US20989 |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Sudden Cardiac Death              | Escitalopram            |                           |                             | S                        | Unknown                       | Unk, > 20 Mg                  |                          | Invagen             |                         |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 16-Nov-2016                       | 12944780                | EXPEDITED (15-DAY)        |                             | DE                       | US-CIPLA LTD.-<br>2016US20988 |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Sudden Cardiac Death              | Escitalopram            |                           |                             | S                        | Unknown                       | Unk, >20 Mg                   |                          | Invagen             |                         |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 16-Nov-2016                       | 12944843                | EXPEDITED (15-DAY)        |                             | DE                       | US-CIPLA LTD.-<br>2016US20991 |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Sudden Death                      | Escitalopram            |                           |                             | S                        | Unknown                       | Unk, >20 Mg                   |                          | Invagen             |                         |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 16-Nov-2016                       | 12944846                | EXPEDITED (15-DAY)        |                             | DE                       | US-CIPLA LTD.-<br>2016US20992 |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Sudden Death                      | Escitalopram            |                           |                             | S                        | Unknown                       | Unk, > 20 Mg                  |                          | Invagen             |                         |

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| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|-----------------|------------|----------------|
| 16-Nov-2016              | 12944850       | EXPEDITED (15-DAY) |                    | DE              | US-CIPLA LTD.-<br>2016US20990 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Sudden Death             | Escitalopram   |                    |                    | S               | Unknown                       | Unk, > 20 Mg         |                 | Invagen    |                |

| <u>FDA Received Date</u>                     | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                         | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------|-----------------|--------------------|--------------------|-----------------|--------------------------------------------------------------|----------------------------------------|-----------------|--------------|----------------|
| 16-Nov-2016                                  | 12945856        | EXPEDITED (15-DAY) |                    | HO, OT          | RO-SUN<br>PHARMACEUTICAL<br>INDUSTRIES LTD-<br>2016RR-127636 |                                        | 38 YR           | Male         | ROM            |
| <u>Preferred Term</u>                        | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                 | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Insomnia; Treatment<br>Noncompliance; Tremor | Amisulpride     |                    |                    | S               | Unknown                                                      | 600 Mg, Daily                          |                 | Not Reported |                |
|                                              | Valproic Acid   |                    |                    | S               | Unknown                                                      | 1200 Mg, Daily                         |                 | Sun          |                |
|                                              | Valproic Acid   |                    |                    | S               | Unknown                                                      | 1000 Mg, Daily                         |                 | Sun          |                |
|                                              | Diazepam        |                    |                    | S               | Unknown                                                      | 20 Mg, Daily                           |                 | Not Reported |                |
|                                              | Quetiapine      |                    |                    | S               | Unknown                                                      | 400 Mg, Daily                          |                 | Sun          |                |
|                                              | Quetiapine      |                    |                    | S               | Unknown                                                      | 600 Mg, Daily                          |                 | Sun          |                |
|                                              | Quetiapine      |                    |                    | S               | Unknown                                                      | 400 Mg, Daily                          |                 | Sun          |                |
|                                              | Levomepromazine |                    |                    | S               | Unknown                                                      | 50 Mg, Daily                           |                 | Not Reported |                |
|                                              | Clonazepam      |                    |                    | S               | Unknown                                                      | 2 Mg, Daily                            |                 | Sun          |                |
|                                              | Bromazepam      |                    |                    | S               | Unknown                                                      | 6 Mg, Daily                            |                 | Not Reported |                |
|                                              | Zopiclone       |                    |                    | S               | Unknown                                                      | 7.5 Mg, Daily                          |                 | Not Reported |                |
|                                              | Escitalopram    |                    |                    | S               | Unknown                                                      | 10 Mg, Daily                           |                 | Not Reported |                |
|                                              | Zolpidem        |                    |                    | S               | Unknown                                                      | 10 Mg, Daily                           |                 | Sun          |                |
|                                              | Risperidone     |                    |                    | S               | Unknown                                                      | 4 MI, Daily                            |                 | Not Reported |                |
|                                              | Siofor          |                    |                    | C               | Unknown                                                      | 1000 Mg, Bid (1-0-1)                   |                 | Not Reported |                |
|                                              | Mixtard         |                    |                    | C               | Subcutaneous                                                 | 100 Ui/MI, 18u-0-10ui,<br>Before Meals |                 | Not Reported |                |
|                                              | Metoprolol      |                    |                    | C               | Unknown                                                      | 50 Mg, Daily                           |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                        | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|----------------------------|------------------------------------------------------------|-----------------|--------------|----------------|
| 16-Nov-2016                                     | 12947282                  | EXPEDITED (15-DAY) |                    | HO              | DE-MYLANLABS-2016M1048921  |                                                            |                 | Unknown      | DEU            |
| <u>Preferred Term</u>                           | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyponatraemia                                   | Metoprolol                |                    |                    | S               | Oral                       | 23.75 Mg, Qd (Daily Dose: 23.75 Mg Milligram(S) Every Day) |                 | Not Reported |                |
|                                                 | Cipralext                 |                    |                    | S               | Oral                       | 10 Mg, Qd (Daily Dose: 10 Mg Milligram(S) Every Day)       |                 | Mylan        |                |
|                                                 | L-Thyroxin                |                    |                    | C               | Oral                       | 37.5 Mg, Qd (Daily Dose: 37.5 Mg Microgram(S) Every Day)   |                 | Mylan        |                |
| <u>FDA Received Date</u>                        | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Nov-2016                                     | 12950144                  | EXPEDITED (15-DAY) |                    | HO              | CN-ALLERGAN-1676420US      |                                                            | 47 YR           | Male         | CHN            |
| <u>Preferred Term</u>                           | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Off Label Use; White Blood Cell Count Decreased | Escitalopram Oxalate - Bp |                    |                    | S               | Oral                       | 5-10 Mg Daily                                              |                 | Allergan     |                |
|                                                 | Seroquel                  |                    |                    | S               | Oral                       | 12.5 Mg, Qd                                                |                 | Not Reported |                |
| <u>FDA Received Date</u>                        | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Nov-2016                                     | 12950975                  | EXPEDITED (15-DAY) |                    | CA              | FR-ASTRAZENECA-2016SF19499 |                                                            |                 | Unknown      | FRA            |
| <u>Preferred Term</u>                           | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Exposure During Pregnancy; Talipes              | Xeroquel                  |                    |                    | S               | Transplacental             |                                                            |                 | Not Reported |                |
|                                                 | Xeroquel                  |                    |                    | S               | Transplacental             |                                                            |                 | Not Reported |                |
|                                                 | Seroplex                  |                    |                    | S               | Transplacental             |                                                            |                 | Not Reported |                |
| <u>FDA Received Date</u>                        | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Nov-2016                                     | 12951674                  | EXPEDITED (15-DAY) |                    | HO              | FR-ELI_LILLY_AND_COMP      |                                                            | 38 YR           | Female       | FRA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

ANY-FR201611005693

| <u>Preferred Term</u>   | <u>Product</u>  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>       |
|-------------------------|-----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------------|
| Oedematous Pancreatitis | Prozac          |              |            | S           | Unknown      | Unk, Unknown       |                 | Eli Lilly And Co |
|                         | Seroplex        |              |            | S           | Unknown      | Unk, Unknown       |                 | Not Reported     |
|                         | Dafalgan Codein |              |            | S           | Oral         | Unk, Unknown       |                 | Not Reported     |
|                         | Xanax           |              |            | C           | Unknown      | Unk, Unknown       |                 | Not Reported     |
|                         | Stilnox         |              |            | C           | Unknown      | Unk, Unknown       |                 | Not Reported     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 17-Nov-2016              | 12953484      | EXPEDITED (15-DAY) |                    | DE              | CH-ALLERGAN-1676655US |                      |            | Male       | CHE            |

| <u>Preferred Term</u> | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Poisoning             | Escitalopram Oxalate - Bp |              |            | S           | Unknown      |                    |                 | Allergan     |
|                       | Zolpidem                  |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Alprazolam                |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Varenicline               |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Mirtazapine               |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Phenylephrine             |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Dimetindene               |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Bisacodyl                 |              |            | S           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Nov-2016              | 12954776      | DIRECT           | Y                  |                 |                      |                      | 10 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|----------------------|-----------------|--------------|
| Agitation             | Lexapro        |              |            | S           | Oral         | 5 Mg At Bedtime Oral |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                                         | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|--------------------------------------------------------|----------------------|-----------------|----------------------|----------------|
| 18-Nov-2016                                                                                                                                                                                                                      | 12438133                  | EXPEDITED (15-DAY) |                    | DS, HO, LT, OT  | NO-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>BMS-2016-043148 |                      | 28 YR           | Female               | NOR            |
| <u>Preferred Term</u>                                                                                                                                                                                                            | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Breath Odour; Facial Asymmetry; Gait Disturbance; Head Discomfort; Muscle Spasms; Musculoskeletal Stiffness; Parkinson'S Disease; Personality Change; Product Use In Unapproved Indication; Shoulder Deformity; Weight Increased | Abilify                   |                    |                    | S               | Unknown                                                |                      |                 | Bristol Myers Squibb |                |
|                                                                                                                                                                                                                                  | Cipralex /01588501/       |                    |                    | S               | Unknown                                                |                      |                 | Not Reported         |                |
|                                                                                                                                                                                                                                  | Xeplion                   |                    |                    | S               | Unknown                                                |                      |                 | Not Reported         |                |
|                                                                                                                                                                                                                                  | Zyprexa                   |                    |                    | S               | Unknown                                                |                      |                 | Not Reported         |                |
|                                                                                                                                                                                                                                  | Risperdal                 |                    |                    | S               | Unknown                                                |                      |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                         | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 18-Nov-2016                                                                                                                                                                                                                      | 12918414                  | EXPEDITED (15-DAY) |                    | HO              | JP-ALLERGAN-<br>1674813US                              |                      | 73 YR           | Female               | JPN            |
| <u>Preferred Term</u>                                                                                                                                                                                                            | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Hepatic Function Abnormal; Hypertension; Product Use In Unapproved Indication                                                                                                                                                    | Escitalopram Oxalate - Bp |                    |                    | S               | Oral                                                   | 10 Mg, Qd            |                 | Allergan             |                |
|                                                                                                                                                                                                                                  | Escitalopram Oxalate - Bp |                    |                    | S               | Oral                                                   | 20 Mg, Qd            |                 | Allergan             |                |
|                                                                                                                                                                                                                                  | Escitalopram Oxalate - Bp |                    |                    | S               | Oral                                                   | 10 Mg, Qd            |                 | Allergan             |                |
|                                                                                                                                                                                                                                  | Ferromia                  |                    |                    | C               | Oral                                                   |                      |                 | Not Reported         |                |
|                                                                                                                                                                                                                                  | Edirol                    |                    |                    | C               | Oral                                                   |                      |                 | Not Reported         |                |
|                                                                                                                                                                                                                                  | Alfacalcidol              |                    |                    | C               | Oral                                                   |                      |                 | Not Reported         |                |
|                                                                                                                                                                                                                                  | Mucosta                   |                    |                    | C               | Oral                                                   |                      |                 | Not Reported         |                |
|                                                                                                                                                                                                                                  | Rozerem                   |                    |                    | C               | Oral                                                   |                      |                 | Not Reported         |                |
|                                                                                                                                                                                                                                  | Chlomy                    |                    |                    | C               | Vaginal                                                |                      |                 | Not Reported         |                |
|                                                                                                                                                                                                                                  | Belsomra                  |                    |                    | C               | Oral                                                   | Unk                  |                 | Not Reported         |                |
|                                                                                                                                                                                                                                  | Seroquel                  |                    |                    | C               | Oral                                                   |                      |                 | Not Reported         |                |

# FDA Adverse Event Reporting System

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| <u>FDA Received Date</u> | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|---------------------------|--------------------|--------------------|-----------------|------------------------------------------|----------------------|-----------------|--------------|----------------|
| 18-Nov-2016              | 12925630                  | EXPEDITED (15-DAY) |                    | HO              | FR-ALLERGAN-1675029US                    |                      | 65 YR           | Male         | FRA            |
| <u>Preferred Term</u>    | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Dysphagia;     | Escitalopram Oxalate - Bp |                    |                    | S               |                                          | 10 Mg, Qd            |                 | Allergan     |                |
| Faecal Vomiting;         | Dysport                   |                    |                    | S               | Intramuscular                            | 100 Iu, Single       |                 | Not Reported |                |
| Hypercapnia; Hypoxia;    | Gutron                    |                    |                    | S               |                                          | 10 Mg, Qd            |                 | Not Reported |                |
| Intestinal Obstruction;  | Xanax                     |                    |                    | S               |                                          | 0.5 Mg, Bid          |                 | Not Reported |                |
| Malaise; Respiratory     | Gaviscon                  |                    |                    | S               |                                          |                      |                 | Not Reported |                |
| Disorder; Speech         | Inipomp                   |                    |                    | S               |                                          |                      |                 | Not Reported |                |
| Disorder; Urinary        |                           |                    |                    |                 |                                          |                      |                 |              |                |
| Retention; Vomiting      |                           |                    |                    |                 |                                          |                      |                 |              |                |
| <u>FDA Received Date</u> | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Nov-2016              | 12954436                  | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2016534207                 |                      | 20 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity    | Zoloft                    |                    |                    | S               |                                          | Unk                  |                 | Pfizer       |                |
|                          | Paxil                     |                    |                    | S               |                                          | Unk                  |                 | Not Reported |                |
|                          | Lexapro                   |                    |                    | S               |                                          | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Nov-2016              | 12954964                  | EXPEDITED (15-DAY) |                    | OT              | SA-LUPIN PHARMACEUTICALS INC.-2016-05098 |                      | 45 YR           | Female       | SAU            |
| <u>Preferred Term</u>    | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Angle Closure Glaucoma;  | Escitalopram              |                    |                    | S               | Unknown                                  |                      |                 | Not Reported |                |
| Drug Withdrawal          |                           |                    |                    |                 |                                          |                      |                 |              |                |
| Syndrome                 |                           |                    |                    |                 |                                          |                      |                 |              |                |
| <u>FDA Received Date</u> | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Nov-2016              | 12955676                  | EXPEDITED (15-DAY) |                    | OT              | CA-MYLANLABS-2016M1049838                |                      |                 | Unknown      | CAN            |
| <u>Preferred Term</u>    | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

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|                                                     |                      |   |         |                                                                                          |              |
|-----------------------------------------------------|----------------------|---|---------|------------------------------------------------------------------------------------------|--------------|
| Hypoglycaemia;<br>Hyponatraemia; Lactic<br>Acidosis | Escitalopram         | S | Unknown | Initial Dose Not Stated;<br>Eventually The Dose Was<br>Increased To 1gram Twice<br>A Day | Not Reported |
|                                                     | Gliclazide           | S | Unknown |                                                                                          | Not Reported |
|                                                     | Metformin            | S | Unknown |                                                                                          | Not Reported |
|                                                     | Hydrochlorothiazide  | S | Unknown |                                                                                          | Not Reported |
|                                                     | Insulin              | S | Unknown |                                                                                          | Mylan        |
|                                                     | Levothyroxine Sodium | C | Unknown |                                                                                          | Mylan        |
|                                                     | Telmisartan          | C | Unknown |                                                                                          | Mylan        |
|                                                     | Trazodone            | C | Unknown |                                                                                          | Mylan        |

| <u>FDA Received Date</u> | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|---------------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 18-Nov-2016              | 12957616                  | EXPEDITED (15-DAY) | CA                 |                 | FR-ALLERGAN-1676709US |                      |                 | Unknown      | FRA            |
| <u>Preferred Term</u>    | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Talipes                  | Escitalopram Oxalate - Bp |                    |                    | S               | Transplacental        |                      |                 | Allergan     |                |
|                          | Xeroquel                  |                    |                    | S               | Transplacental        | 300 Mg, Unk          |                 | Not Reported |                |
|                          | Xeroquel                  |                    |                    | S               | Transplacental        | 50 Mg, Unk           |                 | Not Reported |                |

| <u>FDA Received Date</u>                   | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------|-----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 21-Nov-2016                                | 12579610        | EXPEDITED (15-DAY) | HO                 |                 | JP-FRI-1000086131    |                      | 31 YR           | Male         | JPN            |
| <u>Preferred Term</u>                      | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Eosinophilia; Hepatic<br>Function Abnormal | Lexapro Tablets |                    |                    | S               | Oral                 | 10 Mg, Qd            |                 | Allergan     |                |
|                                            | Meilax          |                    |                    | S               | Oral                 | 1 Mg, Qd             |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                    | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------------------------------|----------------------|------------|------------|----------------|
| 21-Nov-2016              | 12619335      | EXPEDITED (15-DAY) | HO, OT             |                 | AU-SYMLMED<br>PHARMACEUTICALS-<br>2016SYMLMED00028<br>4 |                      |            | Unknown    | AUS            |



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| <u>Preferred Term</u>                                                                                         | <u>Product</u>                       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------|--------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Electrocardiogram Qt<br>Prolonged; Hypokalaemia;<br>Hypomagnesaemia;<br>Orthostatic Hypotension;<br>Poisoning | Perindopril                          |              |            | S           | Unknown      | 10 Mg, Qd          |                 | Unknown      |
|                                                                                                               | Rosuvastatin Calcium                 |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                                                                                                               | Escitalopram Oxalate                 |              |            | S           | Unknown      | 10 Mg, Qd          |                 | Not Reported |
|                                                                                                               | Lercanidipine Hydrochloride          |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                                                                                                               | Pantoprazole Sodium<br>Sesquihydrate |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                                                                                                               | Atenolol                             |              |            | S           | Unknown      | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------|----------------------|------------|------------|----------------|
| 21-Nov-2016              | 12649964      | EXPEDITED (15-DAY) |                    | HO, OT          | PT-AUROBINDO-AUR-<br>APL-2016-10491 |                      | 23 YR      | Female     | PRT            |

| <u>Preferred Term</u>                                                                                                                             | <u>Product</u>                           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------|--------------|------------|-------------|--------------|-------------------------|-----------------|------------|
| Abdominal Pain; Carcinoid<br>Syndrome; Flushing;<br>Metastases To Liver;<br>Nausea; Pancreatic<br>Neuroendocrine Tumour;<br>Tachycardia; Vomiting | Escitalopram 10 Mg Film-Coated<br>Tablet |              |            | S           | Unknown      | 10 Mg, One 10 Mg Tablet |                 | Aurobindo  |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 21-Nov-2016              | 12825508      | EXPEDITED (15-DAY) |                    | DE, HO          | SI-JNJFOC-<br>20161004315 |                      | 79 YR      | Male       | SVN            |

| <u>Preferred Term</u>                                                                                                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>  | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|---------------|--------------------|-----------------|--------------|
| Aggression; Agitation;<br>Condition Aggravated;<br>Confusional State; Fear;<br>Insomnia; Pain;<br>Personality Change | Durogesic      |              |            | S           | Transdermal   |                    |                 | Not Reported |
|                                                                                                                      | Haldol         |              |            | S           | Intramuscular |                    |                 | Not Reported |
|                                                                                                                      | Cipralext      |              |            | S           | Oral          |                    |                 | Not Reported |
|                                                                                                                      | Cymbalta       |              |            | S           | Oral          |                    |                 | Not Reported |
|                                                                                                                      | Kventiax       |              |            | S           | Oral          |                    |                 | Not Reported |
|                                                                                                                      | Arcoxia        |              |            | S           | Oral          |                    |                 | Not Reported |
|                                                                                                                      | Triptorelin    |              |            | C           | Intramuscular |                    |                 | Not Reported |

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| <u>FDA Received Date</u>                                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|-----------------|------------|----------------|
| 21-Nov-2016                                                | 12958544       | EXPEDITED (15-DAY) |                    | CA              | GB-CIPLA LTD.-<br>2016GB21705 |                      |                 | Unknown    | GBR            |
| <u>Preferred Term</u>                                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Congenital Anomaly;<br>Foetal Exposure During<br>Pregnancy | Escitalopram   |                    |                    | S               | Transplacental                | Unk                  |                 | Invagen    |                |
| <u>FDA Received Date</u>                                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 21-Nov-2016                                                | 12958765       | EXPEDITED (15-DAY) |                    | CA              | GB-CIPLA LTD.-<br>2016GB21935 |                      |                 | Unknown    | GBR            |
| <u>Preferred Term</u>                                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Congenital Anomaly;<br>Foetal Exposure During<br>Pregnancy | Escitalopram   |                    |                    | S               | Transplacental                | Unk                  |                 | Invagen    |                |
| <u>FDA Received Date</u>                                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 21-Nov-2016                                                | 12958776       | EXPEDITED (15-DAY) |                    | CA              | GB-CIPLA LTD.-<br>2016GB21934 |                      |                 | Unknown    | GBR            |
| <u>Preferred Term</u>                                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Congenital Anomaly;<br>Foetal Exposure During<br>Pregnancy | Escitalopram   |                    |                    | S               | Transplacental                | Unk                  |                 | Invagen    |                |
| <u>FDA Received Date</u>                                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 21-Nov-2016                                                | 12958787       | EXPEDITED (15-DAY) |                    | CA              | GB-CIPLA LTD.-<br>2016GB21933 |                      |                 | Unknown    | GBR            |
| <u>Preferred Term</u>                                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Congenital Anomaly;<br>Foetal Exposure During<br>Pregnancy | Escitalopram   |                    |                    | S               | Transplacental                | Unk                  |                 | Invagen    |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|-----------------|------------|----------------|
| 21-Nov-2016                                                      | 12958814       | EXPEDITED (15-DAY) |                    | CA              | DK-CIPLA LTD.-<br>2016DK21718 |                      |                 | Unknown    | DNK            |
| <u>Preferred Term</u>                                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Foetal Exposure During<br>Pregnancy; Heart Disease<br>Congenital | Escitalopram   |                    |                    | S               | Transplacental                | Unk                  |                 | Invagen    |                |
| <u>FDA Received Date</u>                                         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 21-Nov-2016                                                      | 12958841       | EXPEDITED (15-DAY) |                    | CA              | DK-CIPLA LTD.-<br>2016DK21655 |                      |                 | Unknown    | DNK            |
| <u>Preferred Term</u>                                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Congenital Anomaly;<br>Foetal Exposure During<br>Pregnancy       | Escitalopram   |                    |                    | S               | Transplacental                | Unk                  |                 | Invagen    |                |
| <u>FDA Received Date</u>                                         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 21-Nov-2016                                                      | 12959284       | EXPEDITED (15-DAY) |                    | CA              | DK-CIPLA LTD.-<br>2016DK21890 |                      |                 | Unknown    | DNK            |
| <u>Preferred Term</u>                                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Congenital Anomaly;<br>Foetal Exposure During<br>Pregnancy       | Escitalopram   |                    |                    | S               | Transplacental                | Unk                  |                 | Invagen    |                |
| <u>FDA Received Date</u>                                         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 21-Nov-2016                                                      | 12959285       | EXPEDITED (15-DAY) |                    | CA              | DK-CIPLA LTD.-<br>2016DK21891 |                      |                 | Unknown    | DNK            |
| <u>Preferred Term</u>                                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Congenital Anomaly;<br>Foetal Exposure During<br>Pregnancy       | Escitalopram   |                    |                    | S               | Transplacental                | Unk                  |                 | Invagen    |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                    | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 21-Nov-2016                                                                                 | 12959309               | EXPEDITED (15-DAY) |                    | HO              | DE-AUROBINDO-AUR-APL-2016-14294                 |                      | 67 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                                                       | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyponatraemia                                                                               | Metoprolol             |                    |                    | S               | Oral                                            | 23.75 Mg, Unk        |                 | Aurobindo    |                |
|                                                                                             | Ciprallex /01588501/   |                    |                    | S               | Oral                                            | 10 Mg, Daily         |                 | Not Reported |                |
|                                                                                             | L-Thyroxin             |                    |                    | C               | Oral                                            | 37.5 Mcg, Unk        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                    | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Nov-2016                                                                                 | 12959539               | EXPEDITED (15-DAY) |                    | HO              | US-ABBVIE-16P-163-1737590-00                    |                      | 64 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                       | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Angina Pectoris; Cellulitis; Depression; Electrolyte Imbalance; Hypertension; Hyponatraemia | Humira 40mg/0.8ml      |                    |                    | S               | Subcutaneous                                    |                      |                 | Not Reported |                |
|                                                                                             | Humira 40mg/0.8ml      |                    |                    | S               |                                                 |                      |                 | Not Reported |                |
|                                                                                             | Hydrochlorothiazide    |                    |                    | S               | Oral                                            |                      |                 | Not Reported |                |
|                                                                                             | Lexapro                |                    |                    | S               | Unknown                                         |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                    | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Nov-2016                                                                                 | 12961407               | EXPEDITED (15-DAY) |                    | HO              | DE-VALIDUS PHARMACEUTICALS LLC-DE-2016VAL002982 |                      | 67 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                                                       | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyponatraemia                                                                               | Metoprolol Tartrate    |                    |                    | S               | Oral                                            | 23.75 Mg, Qd         |                 | Validus      |                |
|                                                                                             | Ciprallex /01588502/   |                    |                    | S               | Oral                                            | 10 Mg, Qd            |                 | Not Reported |                |
|                                                                                             | L-Thyroxine /00068001/ |                    |                    | C               |                                                 | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                    | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Nov-2016                                                                                 | 12961835               | EXPEDITED (15-DAY) |                    | OT              | JP-PFIZER INC-2016538154                        |                      | 76 YR           | Female       | JPN            |
| <u>Preferred Term</u>                                                                       | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                        |         |   |      |              |              |
|----------------------------------------|---------|---|------|--------------|--------------|
| Decreased Appetite;<br>Suicide Attempt | Effexor | S | Oral | 75 Mg, Daily | Pfizer       |
|                                        | Lexapro | S | Oral | Unk          | Not Reported |
|                                        | Limas   | S | Oral | Unk          | Not Reported |

| <u>FDA Received Date</u>                                  | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|-----------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|------------|----------------|
| 21-Nov-2016                                               | 12962138                  | EXPEDITED (15-DAY) |                    | DS              | IT-ALLERGAN-1676907US |                      | 22 YR           | Male       | ITA            |
| <u>Preferred Term</u>                                     | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Anhedonia; Disturbance In Attention; Erectile Dysfunction | Escitalopram Oxalate - Bp |                    |                    | S               | Oral                  |                      |                 | Allergan   |                |

| <u>FDA Received Date</u>                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|--------------------------------------------|----------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|----------------------|----------------|
| 22-Nov-2016                                | 12801525       | EXPEDITED (15-DAY) |                    | OT              | US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-080352 |                      | 18 YR           | Female               | USA            |
| <u>Preferred Term</u>                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Suicidal Ideation; Treatment Noncompliance | Abilify        |                    |                    | S               | Unknown                                         | 10 Mg, Qd            |                 | Bristol Myers Squibb |                |
|                                            | Lexapro        |                    |                    | S               | Unknown                                         | 10 Mg, Qd            |                 | Not Reported         |                |

| <u>FDA Received Date</u>                                                                                                                                                                                 | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|--------------------|--------------------|-----------------|--------------------------|---------------------------------|-----------------|--------------|----------------|
| 22-Nov-2016                                                                                                                                                                                              | 12918407           | EXPEDITED (15-DAY) |                    | HO, OT          | FR-PFIZER INC-2016500352 |                                 | 65 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                                    | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Faecal Vomiting; Fatigue; General Physical Health Deterioration; Hypercapnia; Hypoxia; Intestinal Obstruction; Miosis; Respiratory Disorder; Urinary Incontinence; Urinary Retention; Vomiting | Xanax              |                    |                    | S               |                          | 0.25 Mg Per Two Tablet Daily    |                 | Pfizer       |                |
|                                                                                                                                                                                                          | Inipomp            |                    |                    | S               |                          | 40 Mg Per Two Dosage Form Daily |                 | Pfizer       |                |
|                                                                                                                                                                                                          | Gutron             |                    |                    | S               | Other                    | 2.5 Mg Per Four Tablet Daily    |                 | Not Reported |                |
|                                                                                                                                                                                                          | Dysport /01136801/ |                    |                    | S               | Intramuscular            | 100 Iu, Single                  |                 | Not Reported |                |
|                                                                                                                                                                                                          | Seroplex           |                    |                    | S               |                          | 10 Mg, Qd                       |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Gaviscon /00237601/

S

1 Df, Daily

Not Reported

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|------------|------------|----------------|
| 22-Nov-2016              | 12963093      | EXPEDITED (15-DAY) |                    | CA              | NO-CIPLA LTD.-<br>2016NO21684 |                      |            | Unknown    | NOR            |

| <u>Preferred Term</u>                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|------------|
| Congenital Anomaly;<br>Foetal Exposure During<br>Pregnancy | Escitalopram   |              |            | S           | Transplacental | Unk                |                 | Invagen    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|------------|------------|----------------|
| 22-Nov-2016              | 12963095      | EXPEDITED (15-DAY) |                    | CA              | NO-CIPLA LTD.-<br>2016NO21919 |                      |            | Unknown    | NOR            |

| <u>Preferred Term</u>                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|------------|
| Congenital Anomaly;<br>Foetal Exposure During<br>Pregnancy | Escitalopram   |              |            | S           | Transplacental | Unk                |                 | Invagen    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|------------|------------|----------------|
| 22-Nov-2016              | 12963166      | EXPEDITED (15-DAY) |                    | CA              | NO-CIPLA LTD.-<br>2016NO21920 |                      |            | Unknown    | NOR            |

| <u>Preferred Term</u>                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|------------|
| Congenital Anomaly;<br>Foetal Exposure During<br>Pregnancy | Escitalopram   |              |            | S           | Transplacental | Unk                |                 | Invagen    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|------------|------------|----------------|
| 22-Nov-2016              | 12963172      | EXPEDITED (15-DAY) |                    | CA              | NO-CIPLA LTD.-<br>2016NO21921 |                      |            | Unknown    | NOR            |

| <u>Preferred Term</u>                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|------------|
| Congenital Anomaly;<br>Foetal Exposure During<br>Pregnancy | Escitalopram   |              |            | S           | Transplacental | Unk                |                 | Invagen    |

# FDA Adverse Event Reporting System

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### Detailed Report

| <u>FDA Received Date</u>                                         | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------|---------------------|--------------------|--------------------|-----------------|------------------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 22-Nov-2016                                                      | 12963360            | EXPEDITED (15-DAY) |                    | CA              | DK-CIPLA LTD.-<br>2016DK21959                              |                      |                 | Unknown      | DNK            |
| <u>Preferred Term</u>                                            | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Foetal Exposure During<br>Pregnancy; Heart Disease<br>Congenital | Escitalopram        |                    |                    | S               | Transplacental                                             | Unk                  |                 | Invagen      |                |
| <u>FDA Received Date</u>                                         | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Nov-2016                                                      | 12963367            | EXPEDITED (15-DAY) |                    | CA              | DK-CIPLA LTD.-<br>2016DK21958                              |                      |                 | Unknown      | DNK            |
| <u>Preferred Term</u>                                            | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Foetal Exposure During<br>Pregnancy; Heart Disease<br>Congenital | Escitalopram        |                    |                    | S               | Transplacental                                             | Unk                  |                 | Invagen      |                |
| <u>FDA Received Date</u>                                         | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Nov-2016                                                      | 12963370            | EXPEDITED (15-DAY) |                    | CA              | DK-CIPLA LTD.-<br>2016DK21889                              |                      |                 | Unknown      | DNK            |
| <u>Preferred Term</u>                                            | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Congenital Anomaly;<br>Foetal Exposure During<br>Pregnancy       | Escitalopram        |                    |                    | S               | Transplacental                                             | Unk                  |                 | Invagen      |                |
| <u>FDA Received Date</u>                                         | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Nov-2016                                                      | 12965489            | EXPEDITED (15-DAY) |                    | HO              | CA-UNICHEM<br>LABORATORIES<br>LIMITED-UCM201611-<br>000259 |                      | 77 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                            | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Inappropriate Antidiuretic<br>Hormone Secretion                  | Hydrochlorothiazide |                    |                    | S               |                                                            |                      |                 | Unichem      |                |
|                                                                  | Escitalopram        |                    |                    | S               |                                                            |                      |                 | Not Reported |                |
|                                                                  | L-Thyroxine         |                    |                    | C               |                                                            |                      |                 | Not Reported |                |
|                                                                  | Telmisartan         |                    |                    | C               |                                                            |                      |                 | Not Reported |                |
|                                                                  | Trazadone           |                    |                    | C               |                                                            |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                   |                | Gliclazide Mr      |                    | C               |                        |                      |                 |              | Not Reported   |
|---------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|------------------------|----------------------|-----------------|--------------|----------------|
|                                                                                                                                                   |                | Metformin          |                    | C               |                        |                      |                 |              | Not Reported   |
|                                                                                                                                                   |                | Insulin            |                    | C               |                        |                      |                 |              | Not Reported   |
| <u>FDA Received Date</u>                                                                                                                          | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Nov-2016                                                                                                                                       | 12970104       | DIRECT             | Y                  |                 |                        |                      | 66 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                             | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Rash                                                                                                                                              | Escitalopram   |                    |                    | S               | Oral                   |                      |                 |              | Not Reported   |
| <u>FDA Received Date</u>                                                                                                                          | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Nov-2016                                                                                                                                       | 11482534       | NON-EXPEDITED      |                    |                 | US-JAZZ-2014-US-014545 |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                             | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hunger; Hyperhidrosis; Hyperphagia; Hypersensitivity; Night Sweats; Pruritus; Scratch; Weight Increased; Wrong Technique In Product Usage Process | Xyrem          |                    |                    | S               | Oral                   | 2.25 G, Bid          |                 | Jazz         |                |
|                                                                                                                                                   | Xyrem          |                    |                    | S               | Oral                   | Dose Adjustments     |                 | Jazz         |                |
|                                                                                                                                                   | Xyrem          |                    |                    | S               | Oral                   | 4.5 G, Bid           |                 | Jazz         |                |
|                                                                                                                                                   | Cymbalta       |                    |                    | S               |                        |                      |                 | Not Reported |                |
|                                                                                                                                                   | Lexapro        |                    |                    | S               |                        | 20 G, Qd             |                 | Not Reported |                |
|                                                                                                                                                   | Brintellix     |                    |                    | S               |                        | 10mg, Qd             |                 | Not Reported |                |
|                                                                                                                                                   | Brintellix     |                    |                    | S               | Oral                   | 20 Mg, Qd            |                 | Not Reported |                |
|                                                                                                                                                   | Clonazepam     |                    |                    | C               |                        |                      |                 | Not Reported |                |
|                                                                                                                                                   | Propranolol    |                    |                    | C               |                        |                      |                 | Not Reported |                |
|                                                                                                                                                   | Propranolol    |                    |                    | C               |                        |                      |                 | Not Reported |                |
|                                                                                                                                                   | Claritin       |                    |                    | C               |                        |                      |                 | Not Reported |                |
|                                                                                                                                                   | Flixonase      |                    |                    | C               |                        |                      |                 | Not Reported |                |
|                                                                                                                                                   | Fetzima        |                    |                    | C               |                        |                      |                 | Not Reported |                |
|                                                                                                                                                   | Vitamin D3     |                    |                    | C               |                        |                      |                 | Not Reported |                |
|                                                                                                                                                   | Deplin         |                    |                    | C               |                        |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                          | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Nov-2016                                                                                                                                       | 11655276       | EXPEDITED (15-DAY) |                    | HO              | JP-JNJFOC-20151015732  |                      | 78 YR           | Female       | JPN            |
| <u>Preferred Term</u>                                                                                                                             | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                          |              |   |         |              |
|--------------------------|--------------|---|---------|--------------|
| Bradykinesia;            | Risperidone  | S | Unknown | Not Reported |
| Dehydration; Somnolence; | Risperidone  | S | Unknown | Not Reported |
| Urinary Tract Infection  | Risperidone  | S | Unknown | Not Reported |
|                          | Escitalopram | S | Unknown | Not Reported |
|                          | Escitalopram | S | Unknown | Not Reported |
|                          | Escitalopram | S | Unknown | Not Reported |
|                          | Escitalopram | S | Unknown | Not Reported |
|                          | Escitalopram | S | Unknown | Not Reported |
|                          | Mirtazapine  | C | Unknown | Not Reported |
|                          | Nitrazepam   | C | Unknown | Not Reported |

| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|----------------------------|----------------|------------------|--------------------|-----------------|--------------------------------------------|----------------------|-----------------|-----------------|----------------|
| 23-Nov-2016                | 12164036       | NON-EXPEDITED    |                    |                 | US-<br>GLAXOSMITHKLINE-<br>US2016GSK033637 |                      | 56 YR           | Male            | USA            |
| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Adverse Drug Reaction;     | Paxil          |                  |                    | S               |                                            |                      |                 | Glaxosmithkline |                |
| Anxiety; Depression; Drug  | Paxil          |                  |                    | S               |                                            |                      |                 | Glaxosmithkline |                |
| Ineffective; Ejaculation   | Wellbutrin     |                  |                    | S               |                                            | 150 Mg, Qd           |                 | Glaxosmithkline |                |
| Failure; Emotional         | Wellbutrin     |                  |                    | S               |                                            |                      |                 | Glaxosmithkline |                |
| Disorder; Emotional        | Cymbalta       |                  |                    | S               |                                            | 60 Mg, Unk           |                 | Glaxosmithkline |                |
| Distress; Feeling          | Cymbalta       |                  |                    | S               |                                            |                      |                 | Glaxosmithkline |                |
| Abnormal; Headache;        | Lexapro        |                  |                    | S               |                                            |                      |                 | Not Reported    |                |
| Hypertension; Potentiating | Lexapro        |                  |                    | S               |                                            |                      |                 | Not Reported    |                |
| Drug Interaction; Sexual   |                |                  |                    |                 |                                            |                      |                 |                 |                |
| Dysfunction; Tinnitus;     |                |                  |                    |                 |                                            |                      |                 |                 |                |
| Unevaluable Event          |                |                  |                    |                 |                                            |                      |                 |                 |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|-----------------|------------|----------------|
| 23-Nov-2016              | 12967745       | EXPEDITED (15-DAY) |                    | CA              | FI-CIPLA LTD.-<br>2016FI21819 |                      |                 | Unknown    | FIN            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Foetal Exposure During   | Escitalopram   |                    |                    | S               | Transplacental                | Unk                  |                 | Invagen    |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Pregnancy; Ventricular  
Septal Defect

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 23-Nov-2016              | 12968699       | DIRECT           |                    |                 |                      |                      | 75 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dry Mouth; Fatigue       | Lexapro        |                  |                    | S               | Oral                 |                      |                 | Mylan        |                |
|                          | Levothyroxine  |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Pantoprazole   |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Cranberry      |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Zinc           |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Vitamin D3     |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Lactaid        |                  |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|------------------------|-----------------|--------------|----------------|
| 23-Nov-2016              | 12970517       | EXPEDITED (15-DAY) |                    | HO              | DE-TEVA-711295GER    |                        | 67 YR           | Female       | DEU            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyponatraemia            | Metoprolol     |                    |                    | S               | Oral                 | 23.75 Milligram Daily; |                 | Not Reported |                |
|                          | Ciprallex      |                    |                    | S               | Oral                 | 10 Milligram Daily;    |                 | Not Reported |                |
|                          | L-Thyroxin     |                    |                    | C               | Oral                 | 37.5 Microgram Daily;  |                 | Not Reported |                |

| <u>FDA Received Date</u>            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                               | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                 | <u>Country</u> |
|-------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------------------------------------|----------------------|-----------------|----------------------------|----------------|
| 23-Nov-2016                         | 12970625       | EXPEDITED (15-DAY) |                    | HO              | GR-PRINSTON<br>PHARMACEUTICAL<br>INC.-2016PRN00322 |                      | 76 YR           | Male                       | GRC            |
| <u>Preferred Term</u>               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                       | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                 |                |
| Prostatectomy; Urinary<br>Retention | Escitalopram   |                    |                    | S               |                                                    | 10 Mg, 1x/Day        |                 | Prinston<br>Pharmaceutical |                |
|                                     | Escitalopram   |                    |                    | S               |                                                    | 20 Mg, 1x/Day        |                 | Prinston<br>Pharmaceutical |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                  | <u>Case #</u>       | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------|---------------------|------------------|--------------------|-----------------|------------------------|----------------------|-----------------|--------------|----------------|
| 23-Nov-2016                                                                               | 12970979            | NON-EXPEDITED    |                    |                 | US-JAZZ-2015-US-003581 |                      | 37 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                     | <u>Product</u>      | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Anger; Anxiety; Fatigue; Feeling Abnormal                                      | Xyrem               |                  |                    | S               | Oral                   | 2.25 G, Bid          |                 | Jazz         |                |
|                                                                                           | Xyrem               |                  |                    | S               | Oral                   | Dose Adjustments     |                 | Jazz         |                |
|                                                                                           | Xyrem               |                  |                    | S               | Oral                   | 4.5 G, Bid           |                 | Jazz         |                |
|                                                                                           | Lexapro             |                  |                    | S               | Oral                   | Unk                  |                 | Not Reported |                |
|                                                                                           | Nuvigil             |                  |                    | C               | Oral                   | Unk                  |                 | Not Reported |                |
|                                                                                           | Latuda              |                  |                    | C               | Oral                   | Unk                  |                 | Not Reported |                |
|                                                                                           | Adderall            |                  |                    | C               | Oral                   | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                  | <u>Case #</u>       | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Nov-2016                                                                               | 12971500            | NON-EXPEDITED    |                    | OT              | US-JAZZ-2016-US-019629 |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                     | <u>Product</u>      | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Cataplexy; Headache; Hepatic Enzyme Increased; Hypersensitivity; Sinus Disorder | Xyrem               |                  |                    | S               | Oral                   | 2.25 G, Bid          |                 | Jazz         |                |
|                                                                                           | Xyrem               |                  |                    | S               | Oral                   | 2.25 G, Bid          |                 | Jazz         |                |
|                                                                                           | Xyrem               |                  |                    | S               | Oral                   | Dose Adjustments     |                 | Jazz         |                |
|                                                                                           | Xyrem               |                  |                    | S               | Oral                   | 3 G, Bid             |                 | Jazz         |                |
|                                                                                           | Lexapro             |                  |                    | S               |                        |                      |                 | Not Reported |                |
|                                                                                           | Excedrin /00110301/ |                  |                    | S               |                        |                      |                 | Not Reported |                |
|                                                                                           | Flonase /00908302/  |                  |                    | C               |                        | Unk                  |                 | Not Reported |                |
|                                                                                           | Imitrex /01044801/  |                  |                    | C               |                        | Unk                  |                 | Not Reported |                |
|                                                                                           | Pramipexole         |                  |                    | C               |                        | Unk                  |                 | Not Reported |                |
|                                                                                           | Prevacid            |                  |                    | C               |                        | 15 Mg, Unk           |                 | Not Reported |                |
|                                                                                           | Prevacid            |                  |                    | C               |                        | 30 Mg, Unk           |                 | Not Reported |                |
|                                                                                           | Provent             |                  |                    | C               |                        | Unk                  |                 | Not Reported |                |
|                                                                                           | Provigil /01265601/ |                  |                    | C               |                        | Unk                  |                 | Not Reported |                |
|                                                                                           | Singulair           |                  |                    | C               |                        |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                      |   |     |              |
|--------------------------------------|---|-----|--------------|
| Sudafed /00076302/                   | C | Unk | Not Reported |
| Vitamin C /00008001/                 | C | Unk | Not Reported |
| Vitamin D /00107901/                 | C | Unk | Not Reported |
| Nyquil Cold & Flu                    | C | Unk | Not Reported |
| Hydrocodone/Acetaminophen /00607101/ | C | Unk | Not Reported |
| Colon Herbal Cleanser                | C |     | Not Reported |
| Multivitamins /00116001/             | C |     | Not Reported |
| Vitamin D3                           | C | Unk | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Nov-2016              | 12975185      | DIRECT           | Y                  | OT              |                      |                      | 52 YR      | Female     | USA            |

| <u>Preferred Term</u>      | <u>Product</u>                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|--------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Balance Disorder; | Lexapro                        |              |            | S           | Oral         |                    | 9 MTH           | Not Reported |
| Blood Thyroid Stimulating  | Abilify                        |              |            | S           | Oral         |                    | 1 YR            | Torrent      |
| Hormone Increased;         | Aripiprazole                   |              |            | C           |              |                    |                 | Not Reported |
| Delusion Of Grandeur;      | Escitalopram                   |              |            | C           |              |                    |                 | Not Reported |
| Derealisation;             | Meloxicam                      |              |            | C           |              |                    |                 | Not Reported |
| Electrocardiogram Qt       | Cefdinir                       |              |            | C           |              |                    |                 | Not Reported |
| Prolonged; Head Injury;    | Levothyroxine                  |              |            | C           |              |                    |                 | Not Reported |
| Restless Legs Syndrome;    | Mupirocin                      |              |            | C           |              |                    |                 | Not Reported |
| Victim Of Crime            | Calcium Citrate With Vitamin D |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|------------|------------|----------------|
| 24-Nov-2016              | 12971964      | EXPEDITED (15-DAY) |                    | CA              | FI-CIPLA LTD.-<br>2016FI21817 |                      |            | Unknown    | FIN            |

| <u>Preferred Term</u>                                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|----------------------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|------------|
| Foetal Exposure During Pregnancy; Left Ventricle Outflow Tract Obstruction | Escitalopram   |              |            | S           | Transplacental | Unk                |                 | Invagen    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Nov-2016              | 12972112      | EXPEDITED (15-DAY) |                    | DE, HO          | FR-ACCORD-045762     |                      | 74 YR      | Male       | FRA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                             | <u>Product</u>   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                           | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------|------------------|--------------|------------|-------------|--------------|----------------------------------------------|-----------------|--------------|
| Condition Aggravated;<br>Drug Ineffective;<br>Psychiatric Symptom | Clonazepam       |              |            | S           |              | Reintroduced 0.6 Mg/D In<br>Jun-2015         |                 | Accord       |
|                                                                   | Escitalopram     |              |            | S           |              |                                              |                 | Accord       |
|                                                                   | Tetrabenazine    |              |            | S           |              | 25 Mg/D Was Finally<br>Reintroduced Mar-2015 |                 | Not Reported |
|                                                                   | Baclofen         |              |            | S           |              |                                              |                 | Not Reported |
|                                                                   | Mianserin        |              |            | C           |              |                                              |                 | Not Reported |
|                                                                   | Hydroxycarbamide |              |            | C           |              |                                              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Nov-2016              | 12972288      | EXPEDITED (15-DAY) |                    | HO, LT          | FR-ZYDUS-012780      |                      | 83 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                      | <u>Product</u>                   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                             | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------|----------------------------------|--------------|------------|-------------|------------------------------------------|--------------------|-----------------|--------------|
| Drug Interaction;<br>Dyspnoea; Fall; Serotonin<br>Syndrome | Escitalopram                     |              |            | S           | Unknown                                  |                    |                 | Not Reported |
|                                                            | Tramadol                         |              |            | S           | Unknown                                  |                    |                 | Zydu Pharm   |
|                                                            | Fluindione                       |              |            | S           | Unknown                                  |                    |                 | Not Reported |
|                                                            | Pantoprazole                     |              |            | S           | Unknown                                  |                    |                 | Not Reported |
|                                                            | Perindopril/Perindopril Erbumine |              |            | S           | Unknown                                  |                    |                 | Not Reported |
|                                                            | Bisoprolol                       |              |            | S           | Unknown                                  |                    |                 | Not Reported |
|                                                            | Spironolactone                   |              |            | S           | Unknown                                  |                    |                 | Not Reported |
|                                                            | Rosuvastatin/Rosuvastatin        |              |            | S           | Unknown                                  |                    |                 | Not Reported |
|                                                            | Calcium                          |              |            |             |                                          |                    |                 |              |
|                                                            | Paracetamol                      |              |            | S           | Intravenous (not<br>otherwise specified) |                    |                 | Not Reported |
|                                                            | Furosemide                       |              |            | S           | Unknown                                  |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|------------|------------|----------------|
| 25-Nov-2016              | 12974220      | EXPEDITED (15-DAY) |                    | CA              | FI-CIPLA LTD.-<br>2016FI22168 |                      |            | Unknown    | FIN            |

| <u>Preferred Term</u>                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|------------|
| Foetal Exposure During<br>Pregnancy; Ventricular | Escitalopram   |              |            | S           | Transplacental | Unk                |                 | Invagen    |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Septal Defect

| <u>FDA Received Date</u>                                          | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|-------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|-----------------|------------|----------------|
| 25-Nov-2016                                                       | 12974231       | EXPEDITED (15-DAY) |                    | CA              | FI-CIPLA LTD.-<br>2016FI22167 |                      |                 | Unknown    | FIN            |
| <u>Preferred Term</u>                                             | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Foetal Exposure During<br>Pregnancy; Ventricular<br>Septal Defect | Escitalopram   |                    |                    | S               | Transplacental                | Unk                  |                 | Invagen    |                |

| <u>FDA Received Date</u>                                          | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|-------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|-----------------|------------|----------------|
| 25-Nov-2016                                                       | 12974246       | EXPEDITED (15-DAY) |                    | CA              | FI-CIPLA LTD.-<br>2016FI22166 |                      |                 | Unknown    | FIN            |
| <u>Preferred Term</u>                                             | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Foetal Exposure During<br>Pregnancy; Ventricular<br>Septal Defect | Escitalopram   |                    |                    | S               | Transplacental                | Unk                  |                 | Invagen    |                |

| <u>FDA Received Date</u>                | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------|----------------|--------------------|--------------------|-----------------|------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 25-Nov-2016                             | 12974809       | EXPEDITED (15-DAY) |                    | HO              | FR-LUPIN<br>PHARMACEUTICALS<br>INC.-2016-05181 |                      | 83 YR           | Male         | FRA            |
| <u>Preferred Term</u>                   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;<br>Serotonin Syndrome | Escitalopram   |                    |                    | S               | Unknown                                        |                      |                 | Not Reported |                |
|                                         | Tramadol       |                    |                    | S               | Unknown                                        |                      |                 | Not Reported |                |
|                                         | Fluindione     |                    |                    | C               | Unknown                                        |                      |                 | Not Reported |                |
|                                         | Pantoprazole   |                    |                    | C               | Unknown                                        |                      |                 | Not Reported |                |
|                                         | Perindopril    |                    |                    | C               | Unknown                                        |                      |                 | Not Reported |                |
|                                         | Bisoprolol     |                    |                    | C               | Unknown                                        |                      |                 | Not Reported |                |
|                                         | Spironolactone |                    |                    | C               | Unknown                                        |                      |                 | Not Reported |                |
|                                         | Rosuvastatin   |                    |                    | C               | Unknown                                        |                      |                 | Not Reported |                |
|                                         | Paracetamol    |                    |                    | C               | Unknown                                        |                      |                 | Not Reported |                |
|                                         | Furosemide     |                    |                    | C               | Unknown                                        |                      |                 | Not Reported |                |

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| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------------------------------------|----------------------|------------|------------|----------------|
| 26-Nov-2016              | 12474882      | EXPEDITED (15-DAY) |                    | HO, OT          | FR-PAR<br>PHARMACEUTICAL<br>COMPANIES-<br>2016SCPR015544 |                      |            | Unknown    | FRA            |

| <u>Preferred Term</u>                                                                                                                                                                                              | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Clonus; Confusional State;<br>Electrocardiogram Qt<br>Prolonged;<br>Hypoglycaemia; Loss Of<br>Consciousness;<br>Nystagmus; Overdose;<br>Psychomotor Retardation;<br>Suicide Attempt; Toxicity<br>To Various Agents | Venlafaxine Hydrochloride |              |            | S           | Oral         | 7875 Mg, Unknown   |                 | Par          |
|                                                                                                                                                                                                                    | Escitalopram              |              |            | S           | Oral         | 840 Mg, Unknown    |                 | Not Reported |
|                                                                                                                                                                                                                    | Bromazepam                |              |            | S           | Oral         | 180 Mg, Unknown    |                 | Not Reported |
|                                                                                                                                                                                                                    | Lormetazepam              |              |            | S           | Oral         | 14 Mg, Unknown     |                 | Not Reported |
|                                                                                                                                                                                                                    | Alcohol                   |              |            | S           | Oral         | Unk Unk, Unknown   |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Nov-2016              | 12976052      | EXPEDITED (15-DAY) |                    | DS, HO          | GXKR2016DE005290     |                      |            | Unknown    | DEU            |

| <u>Preferred Term</u> | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Fall                  | Olanzapin             |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Olanzapin             |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Mirtazapine           |              |            | S           | Oral         |                    |                 | Novartis     |
|                       | Escitalopram Lundbeck |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Escitalopram Lundbeck |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Tavor (Lorazepam)     |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Tavor (Lorazepam)     |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Tavor (Lorazepam)     |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | L-Thyroxine           |              |            | C           | Oral         |                    |                 | Not Reported |
|                       | Aprovel               |              |            | C           | Oral         |                    |                 | Not Reported |
|                       | Urivesc               |              |            | C           | Oral         |                    |                 | Not Reported |
|                       | Felodipin             |              |            | C           | Oral         |                    |                 | Not Reported |
|                       | Kalium-Duriles        |              |            | C           | Oral         |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                        | <u>Case #</u>                                                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                         | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------|--------------------|--------------------|-----------------|----------------------------------------------|-----------------------|-----------------|--------------|----------------|
| 26-Nov-2016                                                                                                                                                                                                                                                                                     | 12978075                                                             | DIRECT             |                    | LT, OT          |                                              |                       | 41 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                           | <u>Product</u>                                                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                 | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Pressure Increased; Dizziness; Dysarthria; Feeling Drunk; Heart Rate Increased; Multi-Organ Disorder; Muscular Weakness; Musculoskeletal Discomfort; Musculoskeletal Stiffness; Nausea; Paraesthesia; Paraesthesia; Respiratory Rate Increased; Syncope; Tremor; Vision Blurred; Vomiting | Etalopro 5mg Escitalopram Oxalate Clonmel Healthcare Methlyphenidate |                    |                    | S               | Oral                                         | Quantity:1 Tablet(S); |                 | Clonmel      |                |
|                                                                                                                                                                                                                                                                                                 |                                                                      |                    |                    | C               |                                              |                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                        | <u>Case #</u>                                                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                         | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Nov-2016                                                                                                                                                                                                                                                                                     | 12978186                                                             | DIRECT             |                    | OT              |                                              |                       | 34 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                           | <u>Product</u>                                                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                 | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State; Gastrointestinal Disorder; Muscle Rigidity; Mydriasis; Palpitations; Product Substitution Issue; Serotonin Syndrome                                                                                                                                                          | Lexapro 10mg                                                         | Y                  |                    | S               | Oral                                         | Quantity:1 Tablet(S); |                 | Cipla        |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                        | <u>Case #</u>                                                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                         | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Nov-2016                                                                                                                                                                                                                                                                                     | 12976629                                                             | EXPEDITED (15-DAY) |                    | HO              | GR-JUBILANT<br>GENERICIS LIMITED-<br>1060074 |                       | 76 YR           | Male         | GRC            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                           | <u>Product</u>                                                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                 | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Prostatectomy; Urinary                                                                                                                                                                                                                                                                          | Escitalopram Oxalate                                                 |                    |                    | S               |                                              |                       |                 | Jubilant     |                |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Retention

| <u>FDA Received Date</u>                                                                      | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|---------------------------------|------------------------------------|-----------------|--------------|----------------|
| 28-Nov-2016                                                                                   | 12834903                  | EXPEDITED (15-DAY) |                    | HO, LT          | CN-ALLERGAN-1671476US           |                                    |                 | Unknown      | CHN            |
| <u>Preferred Term</u>                                                                         | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Shock; Suspected Counterfeit Product                                                          | Lexapro Tablets           |                    |                    | S               | Oral                            | Unk                                |                 | Allergan     |                |
|                                                                                               | Lexapro Tablets           |                    |                    | S               | Oral                            | Unk                                |                 | Allergan     |                |
| <u>FDA Received Date</u>                                                                      | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Nov-2016                                                                                   | 12885642                  | EXPEDITED (15-DAY) |                    | OT              | ZA-ALLERGAN-1673737US           |                                    |                 | Female       | ZAF            |
| <u>Preferred Term</u>                                                                         | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Gastric Bypass; Prescribed Overdose; Weight Decreased                                         | Escitalopram Oxalate - Bp |                    |                    | S               | Unknown                         | 30 Mg, Qd                          |                 | Allergan     |                |
|                                                                                               | Fluanxol                  |                    |                    | S               | Unknown                         | 05. Mg, Twice A Day Or When Needed |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                      | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Nov-2016                                                                                   | 12959137                  | EXPEDITED (15-DAY) |                    | HO              | US-AUROBINDO-AUR-APL-2016-14063 |                                    | 17 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                         | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Aphasia; Body Mass Index Increased; Fibrosis; Non-Alcoholic Steatohepatitis; Weight Increased | Aripiprazole              |                    |                    | S               | Unknown                         | 2.5 Mg, At Night                   |                 | Aurobindo    |                |
|                                                                                               | Cyclobenzaprine           |                    |                    | S               | Unknown                         |                                    |                 | Aurobindo    |                |
|                                                                                               | Escitalopram              |                    |                    | S               |                                 |                                    |                 | Aurobindo    |                |
|                                                                                               | Quetiapine                |                    |                    | S               | Unknown                         |                                    |                 | Aurobindo    |                |
|                                                                                               | Sertraline 50mg           |                    |                    | S               | Unknown                         | 50 Mg, Daily                       |                 | Aurobindo    |                |
|                                                                                               | Bupropion                 |                    |                    | S               | Unknown                         |                                    |                 | Not Reported |                |
|                                                                                               | Clonazepam                |                    |                    | S               | Unknown                         |                                    |                 | Not Reported |                |
|                                                                                               | Lithium                   |                    |                    | S               | Unknown                         |                                    |                 | Not Reported |                |
|                                                                                               | Lorazepam                 |                    |                    | S               | Unknown                         | 0.5 Mg, Unk                        |                 | Not Reported |                |
|                                                                                               | Methylphenidate           |                    |                    | S               | Unknown                         |                                    |                 | Not Reported |                |

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|                                                                     |                |                    |                    |                 |                                    |                      |                 |              |                |
|---------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|------------------------------------|----------------------|-----------------|--------------|----------------|
| Pregabalin                                                          |                |                    | S                  |                 | Unknown                            |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Nov-2016                                                         | 12963400       | EXPEDITED (15-DAY) |                    | HO, OT          | US-DRREDDYS-<br>USA/USA/16/0084876 |                      |                 | Male         | USA            |
| <u>Preferred Term</u>                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                       | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Suicide Attempt; Thinking Abnormal                                  | Zenatane       |                    |                    | S               | Unknown                            |                      |                 |              | Not Reported   |
|                                                                     | Lexapro        |                    |                    | S               | Unknown                            |                      |                 |              | Not Reported   |
| <u>FDA Received Date</u>                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Nov-2016                                                         | 12976894       | EXPEDITED (15-DAY) |                    | CA              | NO-CIPLA LTD.-<br>2016NO21850      |                      |                 | Unknown      | NOR            |
| <u>Preferred Term</u>                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                       | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Congenital Cardiovascular Anomaly; Foetal Exposure During Pregnancy | Citalopram     |                    |                    | S               | Transplacental                     | Unk                  |                 |              | Invagen        |
|                                                                     | Escitalopram   |                    |                    | S               | Transplacental                     | Unk                  |                 |              | Invagen        |
|                                                                     | Folic Acid     |                    |                    | S               | Transplacental                     | Unk                  |                 |              | Invagen        |
| <u>FDA Received Date</u>                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Nov-2016                                                         | 12976997       | EXPEDITED (15-DAY) |                    | CA              | NO-CIPLA LTD.-<br>2016NO21851      |                      |                 | Unknown      | NOR            |
| <u>Preferred Term</u>                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                       | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Congenital Cardiovascular Anomaly; Foetal Exposure During Pregnancy | Citalopram     |                    |                    | S               | Transplacental                     | Unk                  |                 |              | Invagen        |
|                                                                     | Escitalopram   |                    |                    | S               | Transplacental                     | Unk                  |                 |              | Invagen        |
|                                                                     | Folic Acid     |                    |                    | S               | Transplacental                     | Unk                  |                 |              | Invagen        |
| <u>FDA Received Date</u>                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Nov-2016                                                         | 12977006       | EXPEDITED (15-DAY) |                    | CA              | NO-CIPLA LTD.-<br>2016NO21858      |                      |                 | Unknown      | NOR            |
| <u>Preferred Term</u>                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                       | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Congenital Anomaly; Foetal Exposure During                          | Citalopram     |                    |                    | S               | Transplacental                     | Unk                  |                 |              | Invagen        |

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|                                                            |                |                    |                    |                 |                               |                      |                    |                 |                |
|------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|--------------------|-----------------|----------------|
| Pregnancy                                                  | Escitalopram   |                    | S                  | Transplacental  | Unk                           |                      |                    | Invagen         |                |
|                                                            | Folic Acid     |                    | S                  | Transplacental  | Unk                           |                      |                    | Invagen         |                |
| <u>FDA Received Date</u>                                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |
| 28-Nov-2016                                                | 12977478       | EXPEDITED (15-DAY) |                    | CA              | SE-CIPLA LTD.-<br>2016SE22073 |                      |                    | Unknown         | SWE            |
| <u>Preferred Term</u>                                      | <u>Product</u> |                    | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>                   | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>     |
| Congenital Anomaly;<br>Foetal Exposure During<br>Pregnancy | Escitalopram   |                    |                    |                 | S                             | Transplacental       | Unk                |                 | Invagen        |
| <u>FDA Received Date</u>                                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |
| 28-Nov-2016                                                | 12977494       | EXPEDITED (15-DAY) |                    | CA              | SE-CIPLA LTD.-<br>2016SE22074 |                      |                    | Unknown         | SWE            |
| <u>Preferred Term</u>                                      | <u>Product</u> |                    | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>                   | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>     |
| Congenital Anomaly;<br>Foetal Exposure During<br>Pregnancy | Escitalopram   |                    |                    |                 | S                             | Transplacental       | Unk                |                 | Invagen        |
| <u>FDA Received Date</u>                                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |
| 28-Nov-2016                                                | 12977510       | EXPEDITED (15-DAY) |                    | CA              | SE-CIPLA LTD.-<br>2016SE22076 |                      |                    | Unknown         | SWE            |
| <u>Preferred Term</u>                                      | <u>Product</u> |                    | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>                   | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>     |
| Congenital Anomaly;<br>Foetal Exposure During<br>Pregnancy | Escitalopram   |                    |                    |                 | S                             | Transplacental       | Unk                |                 | Invagen        |
| <u>FDA Received Date</u>                                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |
| 28-Nov-2016                                                | 12977651       | EXPEDITED (15-DAY) |                    | CA              | NO-CIPLA LTD.-<br>2016NO21857 |                      |                    | Unknown         | NOR            |
| <u>Preferred Term</u>                                      | <u>Product</u> |                    | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>                   | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>     |
| Congenital Anomaly;<br>Foetal Exposure During<br>Pregnancy | Citalopram     |                    |                    |                 | S                             | Transplacental       | Unk                |                 | Invagen        |
|                                                            | Escitalopram   |                    |                    |                 | S                             | Transplacental       | Unk                |                 | Invagen        |

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|                          |                   |                    |                    |                 |                            |                      |                 |              |                |
|--------------------------|-------------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| Folic Acid               |                   |                    | S                  |                 | Transplacental             | Unk                  | Invagen         |              |                |
| <u>FDA Received Date</u> | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Nov-2016              | 12977983          | EXPEDITED (15-DAY) |                    | DS, HO          | DE-009507513-1611DEU010185 |                      | 74 YR           | Male         | DEU            |
| <u>Preferred Term</u>    | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Fall                     | Mirtazapine       |                    |                    | S               | Oral                       | 30 Mg, Qd            |                 | Merck        |                |
|                          | Escitalopram      |                    |                    | S               | Oral                       | 10 Mg, Qd            |                 | Not Reported |                |
|                          | Escitalopram      |                    |                    | S               | Oral                       | 20 Mg, Qd            |                 | Not Reported |                |
|                          | Olanzapine        |                    |                    | S               | Oral                       | 2.5 Mg, Qd           |                 | Not Reported |                |
|                          | Olanzapine        |                    |                    | S               | Oral                       | 5 Mg, Qd             |                 | Not Reported |                |
|                          | Tavor (Lorazepam) |                    |                    | S               | Oral                       | 3 Mg, Qd             |                 | Not Reported |                |
|                          | Tavor (Lorazepam) |                    |                    | S               | Oral                       | 2 Mg, Qd             |                 | Not Reported |                |
|                          | Tavor (Lorazepam) |                    |                    | S               | Oral                       | 1.5 Mg, Qd           |                 | Not Reported |                |
|                          | L-Thyroxin        |                    |                    | C               | Oral                       | 100 Microgram, Qd    |                 | Not Reported |                |
|                          | Aprovel           |                    |                    | C               | Oral                       | 300 Mg, Qd           |                 | Not Reported |                |
|                          | Urivesc           |                    |                    | C               | Oral                       | 60 Mg, Qd            |                 | Not Reported |                |
|                          | Felodipine        |                    |                    | C               | Oral                       | 10 Mg, Qd            |                 | Not Reported |                |
|                          | Kalium-Duriles    |                    |                    | C               | Oral                       | 3 Df, Qd             |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Nov-2016              | 12978376          | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2016543031   |                      | 69 YR           | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction         | Zoloft            |                    |                    | S               |                            | Unk                  |                 | Pfizer       |                |
|                          | Desyrel           |                    |                    | S               |                            | Unk                  |                 | Not Reported |                |
|                          | Celexa            |                    |                    | S               |                            | Unk                  |                 | Not Reported |                |
|                          | Lexapro           |                    |                    | S               |                            | Unk                  |                 | Not Reported |                |
|                          | Wellbutrin        |                    |                    | S               |                            | Unk                  |                 | Not Reported |                |

# FDA Adverse Event Reporting System

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| <u>FDA Received Date</u>                                                                                         | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 28-Nov-2016                                                                                                      | 12980468                  | EXPEDITED (15-DAY) |                    | HO              | SE-ALLERGAN-1677990US |                      | 78 YR           | Male         | SWE            |
| <u>Preferred Term</u>                                                                                            | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Lethargy; Suicide Attempt; Toxicity To Various Agents                                                            | Escitalopram Oxalate - Bp |                    |                    | S               | Oral                  | Unk                  |                 | Allergan     |                |
|                                                                                                                  | Mirtazapin Actavis        |                    |                    | S               | Oral                  | Unk                  |                 | Not Reported |                |
|                                                                                                                  | Sobril                    |                    |                    | S               | Oral                  | Unk                  |                 | Not Reported |                |
|                                                                                                                  | Imovane                   |                    |                    | S               | Oral                  | Unk                  |                 | Not Reported |                |
|                                                                                                                  | Metoprolol Gea Retard     |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |
|                                                                                                                  | Inderal                   |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |
|                                                                                                                  | Oralovite                 |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                         | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Nov-2016                                                                                                      | 12980492                  | EXPEDITED (15-DAY) |                    | HO              | FR-ALLERGAN-1677986US |                      | 81 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                            | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated; Confusional State; Incorrect Dose Administered; Medication Error                           | Escitalopram Oxalate - Bp |                    |                    | S               | Oral                  | 2 Df, Once           |                 | Allergan     |                |
|                                                                                                                  | Temesta (Lorazepam)       |                    |                    | S               | Oral                  | 2 Df, Once           |                 | Not Reported |                |
|                                                                                                                  | Zolpidem                  |                    |                    | S               | Oral                  | 2 Df, Once           |                 | Not Reported |                |
|                                                                                                                  | Piracetam                 |                    |                    | S               | Oral                  | 2 Df, Once           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                         | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Nov-2016                                                                                                      | 12827338                  | EXPEDITED (15-DAY) |                    | HO              | TR-TEVA-698138ISR     |                      | 24 YR           | Female       | TUR            |
| <u>Preferred Term</u>                                                                                            | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Clonus; General Physical Health Deterioration; Hypernatraemia; Hypocalcaemia; Leukopenia; Loss Of Consciousness; | Fluoxetine                |                    |                    | S               | Oral                  |                      |                 | Barr         |                |
|                                                                                                                  | Valproic Acid             |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                                  | Olanzapine                |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                                  | Escitalopram              |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |

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Respiratory Depression;  
Sinus Tachycardia;  
Somnolence; Suicide  
Attempt; Toxicity To  
Various Agents

| <u>FDA Received Date</u>                                                                                         | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|------------------------|----------------------|-----------------|--------------|----------------|
| 29-Nov-2016                                                                                                      | 12900878                  | EXPEDITED (15-DAY) |                    | HO, OT          | JP-ALLERGAN-1000086346 |                      | 72 YR           | Female       | JPN            |
| <u>Preferred Term</u>                                                                                            | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Gastroesophageal Reflux Disease; Long Qt Syndrome; Off Label Use; Serotonin Syndrome; Transient Ischaemic Attack | Escitalopram Oxalate - Bp |                    |                    | S               | Oral                   | 10 Mg, Qd            |                 | Allergan     |                |
|                                                                                                                  | Mystan                    |                    |                    | S               | Oral                   | 5 Mg, Bid            |                 | Not Reported |                |
|                                                                                                                  | Lendormin                 |                    |                    | S               | Oral                   | .25 Mg, Qd           |                 | Not Reported |                |
|                                                                                                                  | Belsomra                  |                    |                    | S               | Oral                   | 20 Mg, Qd            |                 | Not Reported |                |
|                                                                                                                  | Milmag                    |                    |                    | C               | Oral                   | 300 Mg, Unk          |                 | Not Reported |                |
|                                                                                                                  | Malfa                     |                    |                    | C               | Oral                   | Unk                  |                 | Not Reported |                |
|                                                                                                                  | Micardis                  |                    |                    | C               | Oral                   | 1 Df, Unk            |                 | Not Reported |                |
|                                                                                                                  | Madopar                   |                    |                    | C               |                        |                      |                 | Not Reported |                |
|                                                                                                                  | Pariet                    |                    |                    | C               |                        |                      |                 | Not Reported |                |
|                                                                                                                  | Gasmotin                  |                    |                    | C               |                        |                      |                 | Not Reported |                |
|                                                                                                                  | Hangekobokuto             |                    |                    | C               |                        |                      |                 | Not Reported |                |
|                                                                                                                  | Micamlo                   |                    |                    | C               |                        | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                         | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Nov-2016                                                                                                      | 12962570                  | EXPEDITED (15-DAY) |                    | OT              | TR-ALLERGAN-1676995US  |                      | 29 YR           | Female       | TUR            |
| <u>Preferred Term</u>                                                                                            | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abortion Spontaneous; Pregnancy                                                                                  | Escitalopram Oxalate Unk  |                    |                    | S               | Oral                   | 10 Mg, Qd            |                 | Allergan     |                |
|                                                                                                                  | Cefprozil                 |                    |                    | C               |                        | 1000 Mg, Qd          |                 | Not Reported |                |
|                                                                                                                  | Dexketoprofen             |                    |                    | C               |                        | 25 Mg, Qd            |                 | Not Reported |                |
|                                                                                                                  | Trimetazidine             |                    |                    | C               |                        | 40 Mg, Qd            |                 | Not Reported |                |
|                                                                                                                  | Levothyroxine             |                    |                    | C               |                        | 1000 Mg, Qd          |                 | Not Reported |                |

# FDA Adverse Event Reporting System

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| <u>FDA Received Date</u>           | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------|--------------------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|-----------------|--------------|----------------|
| 29-Nov-2016                        | 12962579                 | EXPEDITED (15-DAY) |                    | OT              | TR-ALLERGAN-1676996US           |                      | 39 YR           | Female       | TUR            |
| <u>Preferred Term</u>              | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abortion Spontaneous;<br>Pregnancy | Escitalopram Oxalate Unk |                    |                    | S               | Oral                            | 10 Mg, Qd            |                 | Allergan     |                |
|                                    | Zofenopril               |                    |                    | C               |                                 | 30 Mg, Qd            |                 | Not Reported |                |
|                                    | Trimetazidine            |                    |                    | C               |                                 | 40 Mg, Qd            |                 | Not Reported |                |
|                                    | Nifedipine               |                    |                    | C               |                                 | 30 Mg, Qd            |                 | Not Reported |                |
| <u>FDA Received Date</u>           | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Nov-2016                        | 12967159                 | EXPEDITED (15-DAY) |                    | OT              | PT-ACCORD-045639                |                      | 23 YR           | Female       | PRT            |
| <u>Preferred Term</u>              | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Metastases To Liver                | Escitalopram             |                    |                    | S               |                                 | One 10 Mg Tablet     |                 | Accord       |                |
| <u>FDA Received Date</u>           | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Nov-2016                        | 12981863                 | EXPEDITED (15-DAY) |                    | OT              | DE-AUROBINDO-AUR-APL-2016-14850 |                      | 74 YR           | Male         | DEU            |
| <u>Preferred Term</u>              | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Fall                               | Olanzapine 2.5mg         |                    |                    | S               | Oral                            | 2.5 Mg, Once A Day   |                 | Aurobindo    |                |
|                                    | Olanzapine 2.5mg         |                    |                    | S               |                                 | 5 Mg, Once A Day     |                 | Aurobindo    |                |
|                                    | Mirtazapine 30mg         |                    |                    | S               |                                 | 30 Mg, Unk           |                 | Aurobindo    |                |
|                                    | Escitalopram Lundbeck    |                    |                    | S               |                                 | 10 Mg, Once A Day    |                 | Not Reported |                |
|                                    | Escitalopram Lundbeck    |                    |                    | S               |                                 | 20 Mg, Once A Day    |                 | Not Reported |                |
|                                    | Tavor /00273201/         |                    |                    | S               |                                 | 3 Mg, Once A Day     |                 | Not Reported |                |
|                                    | Tavor /00273201/         |                    |                    | S               |                                 | 2 Mg, Once A Day     |                 | Not Reported |                |
|                                    | Tavor /00273201/         |                    |                    | S               |                                 | 1.5 Mg, Once A Day   |                 | Not Reported |                |
|                                    | Thyroxin                 |                    |                    | C               |                                 | 100 Mcg, Once A Day  |                 | Not Reported |                |
|                                    | Aprovel                  |                    |                    | C               |                                 | 300 Mg, Once A Day   |                 | Not Reported |                |

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|                                                              | Urisec                    |                    | C                  | Oral            | 60 Mg, Once A Day        |                      |                 | Not Reported |                |
|--------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
|                                                              | Felodin                   |                    | C                  | Oral            | 10 Mg, Once A Day        |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Nov-2016                                                  | 12982129                  | EXPEDITED (15-DAY) |                    | DE, OT          | CN-ALLERGAN-1677971US    |                      |                 | Unknown      | CHN            |
| <u>Preferred Term</u>                                        | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Foetal Exposure During Pregnancy; Foetal Heart Rate Abnormal | Escitalopram Oxalate - Bp |                    |                    | S               | Transplacental           | 5 Mg, Qd             |                 | Allergan     |                |
|                                                              | Escitalopram Oxalate - Bp |                    |                    | S               | Transplacental           | 10 Mg, Qd            |                 | Allergan     |                |
|                                                              | Escitalopram Oxalate - Bp |                    |                    | S               | Transplacental           | 15 Mg, Qd            |                 | Allergan     |                |
|                                                              | Escitalopram Oxalate - Bp |                    |                    | S               | Transplacental           | 20 Mg, Qd            |                 | Allergan     |                |
|                                                              | Propylthiouracil          |                    |                    | C               | Transplacental           |                      |                 | Not Reported |                |
|                                                              | Alprazolam                |                    |                    | C               | Transplacental           |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Nov-2016                                                  | 12982548                  | EXPEDITED (15-DAY) |                    | DS, HO          | DE-PFIZER INC-2016544022 |                      | 74 YR           | Male         | DEU            |
| <u>Preferred Term</u>                                        | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cervical Vertebral Fracture; Dizziness; Fall                 | Tavor [Lorazepam]         |                    |                    | S               | Oral                     | 3 Mg, 1x/Day         |                 | Pfizer       |                |
|                                                              | Tavor                     |                    |                    | S               | Oral                     | 2 Mg, 1x/Day         |                 | Pfizer       |                |
|                                                              | Tavor                     |                    |                    | S               | Oral                     | 1.5 Mg, 1x/Day       |                 | Pfizer       |                |
|                                                              | Escitalopram Lundbeck     |                    |                    | S               | Oral                     | 10 Mg, 1x/Day        |                 | Not Reported |                |
|                                                              | Escitalopram Lundbeck     |                    |                    | S               | Oral                     | 20 Mg, 1x/Day        |                 | Not Reported |                |
|                                                              | Olanzapin                 |                    |                    | S               | Oral                     | 2.5 Mg, 1x/Day       |                 | Not Reported |                |
|                                                              | Olanzapin                 |                    |                    | S               | Oral                     | 5 Mg, 1x/Day         |                 | Not Reported |                |
|                                                              | Mirtazapin                |                    |                    | S               | Oral                     | 30 Mg, 1x/Day        |                 | Not Reported |                |
|                                                              | L-Thyroxin                |                    |                    | C               | Oral                     | 100 Ug, 1x/Day       |                 | Not Reported |                |
|                                                              | Aprovel                   |                    |                    | C               | Oral                     | 300 Mg, 1x/Day       |                 | Not Reported |                |
|                                                              | Urivesc                   |                    |                    | C               | Oral                     | 60 Mg, 1x/Day        |                 | Not Reported |                |
|                                                              | Felodipin                 |                    |                    | C               | Oral                     | 10 Mg, 1x/Day        |                 | Not Reported |                |



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|                                                                                                                                                               |                             |                    |                    |                 |                            |                                     |                 |              |                |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|----------------------------|-------------------------------------|-----------------|--------------|----------------|
| Kalium Durule                                                                                                                                                 |                             |                    | C                  | Oral            | 3 Df, 1x/Day               |                                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                      | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Nov-2016                                                                                                                                                   | 12982826                    | EXPEDITED (15-DAY) |                    | HO              | IT-PFIZER INC-2016553276   |                                     | 45 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                                                                                                         | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Abuse; Hypotension; Myoclonus; Somnolence; Tremor; Vomiting                                                                                              | Lorazepam                   |                    |                    | S               | Oral                       | 5 Df, Total                         |                 | Pfizer       |                |
|                                                                                                                                                               | Escitalopram                |                    |                    | S               | Oral                       | 10 Df, Total                        |                 | Not Reported |                |
|                                                                                                                                                               | Sodium Valproate            |                    |                    | S               | Oral                       | 2 Df, Total                         |                 | Not Reported |                |
|                                                                                                                                                               | Eutirox                     |                    |                    | C               | Oral                       |                                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                      | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Nov-2016                                                                                                                                                   | 12982851                    | EXPEDITED (15-DAY) |                    | OT              | CN-ALLERGAN-1677977US      |                                     | 39 YR           | Female       | CHN            |
| <u>Preferred Term</u>                                                                                                                                         | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Abortion; Drug Ineffective; Exposure During Pregnancy; Feeling Abnormal; Heart Rate Increased; Nasopharyngitis; Restlessness; Sensation Of Blood Flow; Tremor | Escitalopram Oxalate - Bp   |                    |                    | S               | Unknown                    |                                     |                 | Allergan     |                |
|                                                                                                                                                               | Escitalopram Oxalate - Bp   |                    |                    | S               | Unknown                    |                                     |                 | Allergan     |                |
|                                                                                                                                                               | Escitalopram Oxalate - Bp   |                    |                    | S               | Unknown                    |                                     |                 | Allergan     |                |
|                                                                                                                                                               | Escitalopram Oxalate - Bp   |                    |                    | S               | Unknown                    |                                     |                 | Allergan     |                |
|                                                                                                                                                               | Escitalopram Oxalate - Bp   |                    |                    | S               | Unknown                    |                                     |                 | Allergan     |                |
|                                                                                                                                                               | Escitalopram Oxalate - Bp   |                    |                    | S               | Unknown                    |                                     |                 | Allergan     |                |
|                                                                                                                                                               | Escitalopram Oxalate - Bp   |                    |                    | S               | Unknown                    |                                     |                 | Allergan     |                |
|                                                                                                                                                               | Propylthiouracil            |                    |                    | C               | Unknown                    |                                     |                 | Not Reported |                |
|                                                                                                                                                               | Alprazolam                  |                    |                    | C               | Unknown                    |                                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                      | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Nov-2016                                                                                                                                                   | 12983065                    | NON-EXPEDITED      |                    |                 | US-MALLINCKRODT-T201602641 |                                     | 68 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                         | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective; Pain; Weight Increased                                                                                                                      | Fentanyl Transdermal System |                    |                    | S               | Transdermal                | 50 Mcg/MI, One Patch Every 72 Hours |                 | Mallinckrodt |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|          |   |         |                                              |              |
|----------|---|---------|----------------------------------------------|--------------|
| Lexapro  | S | Unknown | 30 Mg (Unknown Frequency)                    | Not Reported |
| Lexapro  | S | Unknown | 40 Mg (Unknown Frequency)                    | Not Reported |
| Fentanyl | C |         | 37 Mcg/Hr (One 25 Mcg/Hr Plus One 12 Mcg/Hr) | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 29-Nov-2016              | 12983282      | EXPEDITED (15-DAY) |                    | DS, HO          | DE-MYLANLABS-2016M1051301 |                      |            | Unknown    | DEU            |

| <u>Preferred Term</u> | <u>Product</u>   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Fall                  | Escitalopram     |              |            | S           | Oral         | 10 Mg, Qd          |                 | Not Reported |
|                       | Escitalopram     |              |            | S           | Oral         | 20 Mg, Qd          |                 | Not Reported |
|                       | Olanzapine       |              |            | S           | Oral         | 2.5 Mg, Qd         |                 | Not Reported |
|                       | Olanzapine       |              |            | S           | Oral         | 5 Mg, Qd           |                 | Not Reported |
|                       | Mirtazapine      |              |            | S           | Oral         | 30 Mg, Qd          |                 | Not Reported |
|                       | Tavor /00273201/ |              |            | S           | Oral         | 3 Mg, Qd           |                 | Mylan        |
|                       | Tavor /00273201/ |              |            | S           | Oral         | 2 Mg, Qd           |                 | Mylan        |
|                       | Tavor /00273201/ |              |            | S           | Oral         | 1.5 Mg, Qd         |                 | Mylan        |
|                       | L-Thyroxin       |              |            | C           | Oral         | 100 Mg, Qd         |                 | Mylan        |
|                       | Aprovel          |              |            | C           | Oral         | 300 Mg, Qd         |                 | Mylan        |
|                       | Urivesc          |              |            | C           | Oral         | 60 Mg, Qd          |                 | Mylan        |
|                       | Felodipin        |              |            | C           | Oral         | 10 Mg, Qd          |                 | Mylan        |
|                       | Kalium Durule    |              |            | C           | Oral         | 3 Df, Qd           |                 | Mylan        |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                              | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|---------------------------------------------------|----------------------|------------|------------|----------------|
| 29-Nov-2016              | 12985212      | NON-EXPEDITED    |                    |                 | US-ALEMBIC PHARMACUETICALS LIMITED-2015SCAL000843 |                      |            | Unknown    | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                        |                     |   |      |                                                     |              |
|--------------------------------------------------------|---------------------|---|------|-----------------------------------------------------|--------------|
| Depression; Fall; Fatigue;<br>Feeling Abnormal; Tremor | Modafinil           | S | Oral | 200 Mg, Bid, At 6am And<br>One Tablet At Noon Daily | Qualitest    |
|                                                        | Modafinil           | S |      |                                                     | Qualitest    |
|                                                        | Modafinil           | S |      |                                                     | Qualitest    |
|                                                        | Modafinil           | S |      |                                                     | Qualitest    |
|                                                        | Lexapro             | S | Oral | 10 Mg, Unk                                          | Not Reported |
|                                                        | Benadryl /00000402/ | C |      | Unk                                                 | Not Reported |
|                                                        | Allegra             | C |      | Unk                                                 | Not Reported |

| <u>FDA Received Date</u>                                                                                                                                                                               | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| 30-Nov-2016                                                                                                                                                                                            | 12271646              | EXPEDITED (15-DAY) |                    | DE, HO, OT      | IE-PFIZER INC-<br>2016209765 |                      | 63 YR           | Female       | IRL            |
| <u>Preferred Term</u>                                                                                                                                                                                  | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Altered State Of<br>Consciousness; Blood<br>Test Abnormal;                                                                                                                                  | Sertraline Hcl        |                    |                    | S               |                              | 50 Mg, Unk           |                 | Pfizer       |                |
| Coagulopathy; Completed<br>Suicide; Contusion;                                                                                                                                                         | Sertraline Hcl        |                    |                    | S               |                              | 100 Mg, Unk          |                 | Pfizer       |                |
| Electrocardiogram<br>Abnormal;                                                                                                                                                                         | Sertraline Hcl        |                    |                    | S               |                              | 50 Mg, Unk           |                 | Pfizer       |                |
| Electrocardiogram Qt<br>Prolonged;                                                                                                                                                                     | Zispin                |                    |                    | S               |                              | 15 Mg, Unk           |                 | Not Reported |                |
| Electrocardiogram St<br>Segment Elevation; Fall;                                                                                                                                                       | Zispin                |                    |                    | S               |                              | 30 Mg, Unk           |                 | Not Reported |                |
| Fall; Fear; Fear Of Death;<br>Haemorrhage; Head<br>Injury; Hepatic Enzyme<br>Abnormal; Hyponatraemia;<br>Liver Function Test<br>Abnormal; Negative<br>Thoughts; Panic Reaction;<br>Withdrawal Syndrome | Lexapro               |                    |                    | S               |                              | Unk                  |                 | Not Reported |                |
|                                                                                                                                                                                                        | Diazepam              |                    |                    | C               |                              | 5 Mg, Unk            |                 | Not Reported |                |
|                                                                                                                                                                                                        | Diazepam              |                    |                    | C               |                              | 2 Mg, Unk            |                 | Not Reported |                |
|                                                                                                                                                                                                        | Temazepam             |                    |                    | C               |                              | 20 Mg At Night       |                 | Not Reported |                |
|                                                                                                                                                                                                        | Solpadeine /00154101/ |                    |                    | C               |                              | Unk                  |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 30-Nov-2016              | 12938396       | EXPEDITED (15-DAY) |                    | HO, OT          | PT-TEVA-711070ISR    |                      | 23 YR           | Female     | PRT            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                                                    |                |                                          |                    |                 |                               |                      |                 |            |                |
|------------------------------------------------------------------------------------|----------------|------------------------------------------|--------------------|-----------------|-------------------------------|----------------------|-----------------|------------|----------------|
| Carcinoid Syndrome;<br>Metastases To Liver;<br>Pancreatic<br>Neuroendocrine Tumour |                | Escitalopram 10 Mg Film-Coated<br>Tablet |                    | S               |                               | 10 Milligram Daily;  |                 | Ivax       |                |
| <u>FDA Received Date</u>                                                           | <u>Case #</u>  | <u>Case Type</u>                         | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 30-Nov-2016                                                                        | 12977380       | EXPEDITED (15-DAY)                       |                    | CA              | NO-CIPLA LTD.-<br>2016NO21852 |                      |                 | Unknown    | NOR            |
| <u>Preferred Term</u>                                                              | <u>Product</u> | <u>Comp.</u>                             | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Congenital Cardiovascular<br>Anomaly; Foetal Exposure<br>During Pregnancy          | Citalopram     |                                          |                    | S               | Transplacental                | Unk                  |                 | Invagen    |                |
|                                                                                    | Escitalopram   |                                          |                    | S               | Transplacental                | Unk                  |                 | Invagen    |                |
|                                                                                    | Folic Acid     |                                          |                    | S               | Transplacental                | Unk                  |                 | Invagen    |                |
| <u>FDA Received Date</u>                                                           | <u>Case #</u>  | <u>Case Type</u>                         | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 30-Nov-2016                                                                        | 12977633       | EXPEDITED (15-DAY)                       |                    | CA              | NO-CIPLA LTD.-<br>2016NO21856 |                      |                 | Unknown    | NOR            |
| <u>Preferred Term</u>                                                              | <u>Product</u> | <u>Comp.</u>                             | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Congenital Anomaly;<br>Foetal Exposure During<br>Pregnancy                         | Citalopram     |                                          |                    | S               | Transplacental                | Unk                  |                 | Invagen    |                |
|                                                                                    | Escitalopram   |                                          |                    | S               | Transplacental                | Unk                  |                 | Invagen    |                |
|                                                                                    | Folic Acid     |                                          |                    | S               | Transplacental                | Unk                  |                 | Invagen    |                |
| <u>FDA Received Date</u>                                                           | <u>Case #</u>  | <u>Case Type</u>                         | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 30-Nov-2016                                                                        | 12977642       | EXPEDITED (15-DAY)                       |                    | CA              | NO-CIPLA LTD.-<br>2016NO21855 |                      |                 | Unknown    | NOR            |
| <u>Preferred Term</u>                                                              | <u>Product</u> | <u>Comp.</u>                             | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Congenital Anomaly;<br>Foetal Exposure During<br>Pregnancy                         | Citalopram     |                                          |                    | S               | Transplacental                | Unk                  |                 | Invagen    |                |
|                                                                                    | Escitalopram   |                                          |                    | S               | Transplacental                | Unk                  |                 | Invagen    |                |
|                                                                                    | Folic Acid     |                                          |                    | S               | Transplacental                | Unk                  |                 | Invagen    |                |
| <u>FDA Received Date</u>                                                           | <u>Case #</u>  | <u>Case Type</u>                         | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 30-Nov-2016                                                                        | 12985361       | EXPEDITED (15-DAY)                       |                    | OT              | US-CIPLA LTD.-<br>2016US22254 |                      |                 | Unknown    | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                      | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>                                                                            | <u>Duration</u> | <u>Mfr</u>   |                |
|------------------------------------------------------------|----------------------------------|--------------------|--------------------|-----------------|---------------------------------------|-----------------------------------------------------------------------------------------------|-----------------|--------------|----------------|
| Adverse Event; Product Substitution Issue                  | Escitalopram                     |                    |                    | S               | Oral                                  | 10 Mg, Unk, Camber Distributed                                                                |                 | Invagen      |                |
|                                                            | Escitalopram                     |                    |                    | S               | Oral                                  | 10 Mg, Unk, Cipla Distributed                                                                 |                 | Invagen      |                |
| <u>FDA Received Date</u>                                   | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>                                                                          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Nov-2016                                                | 12985672                         | EXPEDITED (15-DAY) |                    | HO, LT, OT      | FR-ACCORD-045909                      |                                                                                               | 83 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                      | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>                                                                            | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Serotonin Syndrome                       | Tramadol/Tramadol Hydrochloride  |                    |                    | S               |                                       | January 19th: Prescription And Administration Of One Dose Of Tramadol Extended Release 100 Mg |                 | Accord       |                |
|                                                            | Escitalopram                     |                    |                    | S               |                                       |                                                                                               |                 | Accord       |                |
|                                                            | Fluindione                       |                    |                    | C               |                                       |                                                                                               |                 | Not Reported |                |
|                                                            | Pantoprazole                     |                    |                    | C               |                                       |                                                                                               |                 | Not Reported |                |
|                                                            | Perindopril/Perindopril Erbumine |                    |                    | C               |                                       |                                                                                               |                 | Not Reported |                |
|                                                            | Bisoprolol                       |                    |                    | C               |                                       |                                                                                               |                 | Not Reported |                |
|                                                            | Spironolactone                   |                    |                    | C               |                                       |                                                                                               |                 | Not Reported |                |
|                                                            | Rosuvastatin/Rosuvastatin        |                    |                    | C               |                                       |                                                                                               |                 | Not Reported |                |
|                                                            | Calcium                          |                    |                    |                 |                                       |                                                                                               |                 |              |                |
|                                                            | Paracetamol                      |                    |                    | C               | Intravenous (not otherwise specified) |                                                                                               |                 | Not Reported |                |
| Furosemide                                                 |                                  |                    | C                  |                 |                                       |                                                                                               | Not Reported    |              |                |
| <u>FDA Received Date</u>                                   | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>                                                                          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Nov-2016                                                | 12986091                         | EXPEDITED (15-DAY) |                    | HO, OT          | IT-009507513-1611ITA012807            |                                                                                               | 45 YR           | Male         | ITA            |
| <u>Preferred Term</u>                                      | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>                                                                            | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Product Misuse; Intentional Self-Injury; Sopor | Lortaan 12,5 Mg Compresse        |                    |                    | S               | Oral                                  | 28 Dose Unit, Total, Oral                                                                     |                 | Merck        |                |
|                                                            | Rivestite Con Film               |                    |                    |                 |                                       |                                                                                               |                 |              |                |
|                                                            | Escitalopram Oxalate             |                    |                    | S               | Oral                                  | 30 MI, Total, Oral Drops                                                                      |                 | Not Reported |                |
|                                                            | Zolpidem Tartrate                |                    |                    | S               | Oral                                  | 30 MI, Total, Oral Drops                                                                      |                 | Not Reported |                |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                      | Anafranil                 |                    | S                  | Oral            |                            | 20 Dose Unit, Total Oral |                 |              | Not Reported   |
|--------------------------------------|---------------------------|--------------------|--------------------|-----------------|----------------------------|--------------------------|-----------------|--------------|----------------|
|                                      | Levoxacin                 |                    | S                  | Oral            |                            | 5 Dose Unit, Total, Oral |                 |              | Not Reported   |
|                                      | Bentelan                  |                    | S                  | Oral            |                            | 10 Mg Total              |                 |              | Not Reported   |
| <u>FDA Received Date</u>             | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Nov-2016                          | 12987265                  | EXPEDITED (15-DAY) |                    | HO              | FR-ALLERGAN-1677804US      |                          |                 | Female       | FRA            |
| <u>Preferred Term</u>                | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Adverse Event; Fall; Spinal Fracture | Escitalopram Oxalate - Bp |                    |                    | S               | Oral                       | 10 Mg, Qd                |                 | Allergan     |                |
| <u>FDA Received Date</u>             | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Nov-2016                          | 12987272                  | EXPEDITED (15-DAY) |                    | HO              | FR-ALLERGAN-1677801US      |                          | 89 YR           | Female       | FRA            |
| <u>Preferred Term</u>                | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State; Urinary Retention | Escitalopram Oxalate - Bp |                    |                    | S               | Oral                       | 10 Mg, Qd                |                 | Allergan     |                |
|                                      | Escitalopram Oxalate - Bp |                    |                    | S               | Oral                       | 5 Mg, Qd                 |                 | Allergan     |                |
| <u>FDA Received Date</u>             | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Nov-2016                          | 12988673                  | EXPEDITED (15-DAY) |                    | HO              | DE-ASTRAZENECA-2016SF25665 |                          | 21 YR           | Male         | DEU            |
| <u>Preferred Term</u>                | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Circulatory Collapse                 | Quetiapine                |                    |                    | S               | Oral                       | 50.0mg As Required       |                 | Zeneca       |                |
|                                      | Escitalopram              |                    |                    | S               | Oral                       |                          |                 | Not Reported |                |
|                                      | Escitalopram              |                    |                    | S               | Oral                       |                          |                 | Not Reported |                |
| <u>FDA Received Date</u>             | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Dec-2016                          | 11786950                  | EXPEDITED (15-DAY) |                    | OT              | CH-JNJFOC-20151123767      |                          | 17 YR           | Female       | CHE            |
| <u>Preferred Term</u>                | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Abortion Induced;                    | Topamax                   |                    |                    | S               | Oral                       | 25-0-50mg/ Day           |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                           |            |   |      |              |
|---------------------------|------------|---|------|--------------|
| Exposure During           | Lyrica     | S | Oral | Not Reported |
| Pregnancy; Off Label Use; | Cipralex   | S | Oral | Not Reported |
| Product Use In            | Aspirin    | S | Oral | Not Reported |
| Unapproved Indication     | Omeprazole | S | Oral | Not Reported |

| <u>FDA Received Date</u>                                                | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------|---------------------|--------------------|--------------------|-----------------|------------------------|----------------------|-----------------|--------------|----------------|
| 01-Dec-2016                                                             | 12968064            | EXPEDITED (15-DAY) |                    | HO, OT          | IT-APOTEX-2016AP014926 |                      | 65 YR           | Male         | ITA            |
| <u>Preferred Term</u>                                                   | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Gingival Bleeding; Immune Thrombocytopenic Purpura; Petechiae; Tinnitus | Paxil Tablets       |                    |                    | S               | Unknown                | 20 Mg, Qd            |                 | Apotex       |                |
|                                                                         | Glucophage          |                    |                    | S               | Unknown                | 500 Mg, Qd           |                 | Not Reported |                |
|                                                                         | Crestor             |                    |                    | S               | Unknown                | 10 Mg, Qd            |                 | Not Reported |                |
|                                                                         | Cipralex /01588501/ |                    |                    | S               | Unknown                | 4 Mg, Qd             |                 | Not Reported |                |
|                                                                         | Esopral /01479302/  |                    |                    | S               | Unknown                | 20 Mg, Qd            |                 | Not Reported |                |
|                                                                         | Esopral /01479302/  |                    |                    | S               |                        |                      |                 | Not Reported |                |
|                                                                         | Diamox /00016901/   |                    |                    | S               | Unknown                | 250 Mg, Qd           |                 | Not Reported |                |
|                                                                         | Muscoril            |                    |                    | S               | Unknown                | 4 Mg, Qd             |                 | Not Reported |                |
|                                                                         | Sereupin            |                    |                    | S               | Unknown                | Unk                  |                 | Not Reported |                |

| <u>FDA Received Date</u>     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------|----------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 01-Dec-2016                  | 12979613       | EXPEDITED (15-DAY) |                    | HO              | IN-JNJFOC-20161124242 |                      |                 | Unknown      | IND            |
| <u>Preferred Term</u>        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Arrhythmia; Drug Interaction | Risperidone    |                    |                    | S               | Unknown               |                      |                 | Not Reported |                |
|                              | Escitalopram   |                    |                    | S               | Unknown               |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 01-Dec-2016              | 12989233       | EXPEDITED (15-DAY) |                    | OT              | TR-ACCORD-045926     |                      | 21 YR           | Female     | TUR            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                        |                                    |   |              |
|--------------------------------------------------------|------------------------------------|---|--------------|
| Maternal Exposure During Pregnancy; Premature Delivery | Escitalopram                       | S | Accord       |
|                                                        | Levofloxacin/Levofloxacin Mesylate | C | Not Reported |
|                                                        | Cefprozil                          | C | Not Reported |
|                                                        | Etodolac                           | C | Not Reported |
|                                                        |                                    |   |              |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 01-Dec-2016                       | 12990748               | EXPEDITED (15-DAY)        |                             | OT                       | AU-APOTEX-2015AP007370        |                               | 43 YR               | Female              | AUS                     |

| <a href="#">Preferred Term</a>                                                                                                     | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|------------------------------------------------------------------------------------------------------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Coordination Abnormal;<br>Depressed Level Of Consciousness;<br>Disturbance In Attention;<br>Feeling Abnormal;<br>Memory Impairment | Escitalopram            |                       |                     | S                    | Unknown               | Unk                         |                          | Apotex              |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 01-Dec-2016                       | 12991346               | EXPEDITED (15-DAY)        |                             | HO, OT                   | DE-MYLANLABS-2016M1051660     |                               |                     | Unknown             | DEU                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Circulatory Collapse           | Escitalopram            |                       |                     | S                    | Oral                  | 10 Mg, Qd                   |                          | Not Reported        |
|                                | Escitalopram            |                       |                     | S                    | Oral                  | 5 Mg, Qd                    |                          | Not Reported        |
|                                | Quetiapine              |                       |                     | S                    | Oral                  |                             |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 01-Dec-2016                       | 12991670               | EXPEDITED (15-DAY)        |                             | OT                       | ZA-ALLERGAN-1678356US         |                               |                     | Unknown             | ZAF                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a>   | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|---------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Seizure                        | Escitalopram Oxalate - Bp |                       |                     | S                    | Unknown               |                             |                          | Allergan            |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 01-Dec-2016                       | 12991683               | EXPEDITED (15-DAY)        |                             | DS                       | FR-ALLERGAN-1678557US         |                               | 75 YR               | Female              | FRA                     |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                     | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anaemia; Haematoma;<br>Haemothorax; Muscle<br>Haemorrhage | Escitalopram Oxalate - Bp |              |            | S           | Oral         | 10 Mg, Qd          |                 | Allergan     |
|                                                           | Xarelto                   |              |            | S           | Oral         | 20 Mg, Qd          |                 | Not Reported |
|                                                           | Valsartan                 |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                           | Betahistine               |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                           | Tanganil                  |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                           | Cordarone                 |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                           | Metformine                |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                           | Tahor                     |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                           | Lexomil                   |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                           | Amlodipine                |              |            | C           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|------------|------------|----------------|
| 01-Dec-2016              | 12992061      | EXPEDITED (15-DAY) |                    | HO              | DE-009507513-<br>1611DEU013996 |                      | 77 YR      | Female     | DEU            |

| <u>Preferred Term</u> | <u>Product</u>               | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Delirium              | Nacom 100 Mg/25 Mg Tabletten |              |            | S           | Oral         | 100/25 Mg Daily    |                 | Merck        |
|                       | Nacom 100 Mg/25 Mg Tabletten |              |            | S           | Oral         | 400/100 Mg Daily   |                 | Merck        |
|                       | Nacom 100 Mg/25 Mg Tabletten |              |            | S           | Oral         | 600/150 Mg Daily   |                 | Merck        |
|                       | Nacom 100 Mg/25 Mg Tabletten |              |            | S           | Oral         | 300/75 Mg Daily    |                 | Merck        |
|                       | Nacom 100 Mg/25 Mg Tabletten |              |            | S           | Oral         | 150/37.5 Mg Daily  |                 | Merck        |
|                       | Amitriptyline Hydrochloride  |              |            | S           | Oral         | 25 Mg, Qd          |                 | Merck        |
|                       | Amitriptyline Hydrochloride  |              |            | S           | Oral         | 50 Mg, Qd          |                 | Merck        |
|                       | Amitriptyline Hydrochloride  |              |            | S           | Oral         | 75 Mg, Qd          |                 | Merck        |
|                       | Amitriptyline Hydrochloride  |              |            | S           | Oral         | 50 Mg, Qd          |                 | Merck        |
|                       | Amitriptyline Hydrochloride  |              |            | S           | Oral         | 25 Mg, Qd          |                 | Merck        |
|                       | Escitalopram                 |              |            | S           | Oral         | 5 Mg, 1 Day        |                 | Not Reported |
|                       | Escitalopram                 |              |            | S           | Oral         | 10 Mg, Qd          |                 | Not Reported |
|                       | Escitalopram                 |              |            | S           | Oral         | 15 Mg, Qd          |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                     |                           | Eliquis            | C                  | Oral            | 5 Mg, Qd                   |                      |                 | Not Reported |                |
|---------------------------------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
|                                                                                                                     |                           | Metformin          | C                  | Oral            | 2 G, Unk                   |                      |                 | Not Reported |                |
|                                                                                                                     |                           | Lorazepam          | C                  | Oral            | 1 Mg, Qd                   |                      |                 | Not Reported |                |
|                                                                                                                     |                           | Lorazepam          | C                  | Oral            | 1.5 Mg, Qd                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                            | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Dec-2016                                                                                                         | 12993500                  | DIRECT             | Y                  |                 |                            |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                               | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Discomfort;<br>Nausea; Vomiting                                                                           | Generic Escitalopram 10.5 |                    |                    | S               | Oral                       |                      |                 |              | Not Reported   |
| <u>FDA Received Date</u>                                                                                            | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Dec-2016                                                                                                         | 12325817                  | EXPEDITED (15-DAY) |                    | OT              | US-CIPLA-<br>2016US04333   |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                                                               | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Haemorrhage; Intentional<br>Product Misuse; Overdose                                                                | Warfarin                  |                    |                    | S               | Unknown                    | Unk                  |                 |              | Invagen        |
|                                                                                                                     | Escitalopram              |                    |                    | S               | Unknown                    | Unk                  |                 |              | Invagen        |
|                                                                                                                     | Comet Cleaner             |                    |                    | S               | Unknown                    | Unk                  |                 |              | Not Reported   |
| <u>FDA Received Date</u>                                                                                            | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Dec-2016                                                                                                         | 12933440                  | EXPEDITED (15-DAY) |                    | HO, OT          | PT-ALLERGAN-<br>1000084606 |                      | 23 YR           | Female       | PRT            |
| <u>Preferred Term</u>                                                                                               | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Metastases To Liver;<br>Metastasis; Pancreatic<br>Neuroendocrine Tumour;<br>Product Use In<br>Unapproved Indication | Escitalopram Oxalate - Bp |                    |                    | S               |                            | 10 Mg, Qd            |                 |              | Allergan       |
| <u>FDA Received Date</u>                                                                                            | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Dec-2016                                                                                                         | 12970711                  | EXPEDITED (15-DAY) |                    | OT              | IT-ALLERGAN-<br>1677579US  |                      | 33 YR           | Female       | ITA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                       | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
|-----------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|----------------------|----------------|
| Asthenia; Drug Abuse; Overdose                                              | Escitalopram Oxalate Unk |                    |                    | S               | Oral                                            |                      |                 | Allergan             |                |
|                                                                             | Escitalopram Oxalate Unk |                    |                    | S               |                                                 |                      |                 | Allergan             |                |
| <u>FDA Received Date</u>                                                    | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 02-Dec-2016                                                                 | 12993971                 | EXPEDITED (15-DAY) |                    | OT              | AU-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-101489 |                      | 40 YR           | Female               | AUS            |
| <u>Preferred Term</u>                                                       | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Abortion Spontaneous; Maternal Exposure During Pregnancy; Product Use Issue | Abilify                  |                    |                    | S               | Oral                                            | 20 Mg, Qd            |                 | Bristol Myers Squibb |                |
|                                                                             | Escitalopram /01588502/  |                    |                    | S               | Oral                                            | 10 Mg, Qd            |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                    | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 02-Dec-2016                                                                 | 12994254                 | EXPEDITED (15-DAY) |                    | DS, HO          | DE-TEVA-714641GER                               |                      | 74 YR           | Male                 | DEU            |
| <u>Preferred Term</u>                                                       | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Fall                                                                        | Olanzapin                |                    |                    | S               | Oral                                            |                      |                 | Not Reported         |                |
|                                                                             | Olanzapin                |                    |                    | S               | Oral                                            |                      |                 | Not Reported         |                |
|                                                                             | Mirtazapine              |                    |                    | S               | Oral                                            |                      |                 | Teva                 |                |
|                                                                             | Escitalopram             |                    |                    | S               | Oral                                            |                      |                 | Not Reported         |                |
|                                                                             | Escitalopram             |                    |                    | S               | Oral                                            |                      |                 | Not Reported         |                |
|                                                                             | Tavor [Lorazepam]        |                    |                    | S               | Oral                                            |                      |                 | Not Reported         |                |
|                                                                             | Tavor                    |                    |                    | S               | Oral                                            |                      |                 | Not Reported         |                |
|                                                                             | Tavor                    |                    |                    | S               | Oral                                            |                      |                 | Not Reported         |                |
|                                                                             | L-Thyroxin               |                    |                    | C               | Oral                                            |                      |                 | Not Reported         |                |
|                                                                             | Aprovel                  |                    |                    | C               | Oral                                            |                      |                 | Not Reported         |                |
|                                                                             | Urivesc                  |                    |                    | C               | Oral                                            |                      |                 | Not Reported         |                |
|                                                                             | Felodipin                |                    |                    | C               | Oral                                            |                      |                 | Not Reported         |                |
|                                                                             | Kalium Duriles           |                    |                    | C               | Oral                                            |                      |                 | Not Reported         |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                 | <u>Case #</u>                                                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------|--------------------------------------------------------------------|--------------------|--------------------|-----------------|------------------------|----------------------|-----------------|--------------|----------------|
| 02-Dec-2016                                              | 12994458                                                           | EXPEDITED (15-DAY) |                    | HO              | DE-TEVA-714916GER      |                      | 21 YR           | Male         | DEU            |
| <u>Preferred Term</u>                                    | <u>Product</u>                                                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Circulatory Collapse                                     | Escitalopram                                                       |                    |                    | S               | Oral                   |                      |                 | Ivax         |                |
|                                                          | Escitalopram                                                       |                    |                    | S               | Oral                   |                      |                 | Ivax         |                |
|                                                          | Quetiapine                                                         |                    |                    | S               | Oral                   |                      |                 | Teva         |                |
| <u>FDA Received Date</u>                                 | <u>Case #</u>                                                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Dec-2016                                              | 12995011                                                           | EXPEDITED (15-DAY) |                    | OT              | CH-ALLERGAN-1000081643 |                      | 17 YR           | Female       | CHE            |
| <u>Preferred Term</u>                                    | <u>Product</u>                                                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abortion Induced; Exposure During Pregnancy              | Escitalopram Oxalate Unk                                           |                    |                    | S               | Oral                   | 20 Mg, Qd            |                 | Allergan     |                |
|                                                          | Aspirin Cardio                                                     |                    |                    | S               | Oral                   | 100 Mg, Qd           |                 | Not Reported |                |
|                                                          | Omeprazole                                                         |                    |                    | S               | Oral                   | 20 Mg, Qd            |                 | Not Reported |                |
|                                                          | Topamax Migraene                                                   |                    |                    | S               | Oral                   | 25 Mg, Tid           |                 | Not Reported |                |
|                                                          | Lyrica                                                             |                    |                    | S               | Oral                   | 100 Mg, Bid          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                 | <u>Case #</u>                                                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Dec-2016                                              | 12995466                                                           | EXPEDITED (15-DAY) |                    | OT              | TR-ALLERGAN-1678838US  |                      | 56 YR           | Male         | TUR            |
| <u>Preferred Term</u>                                    | <u>Product</u>                                                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Choking; Cough; Nausea; Off Label Use; Throat Irritation | Escitalopram Oxalate - Bp                                          |                    |                    | S               | Oral                   |                      |                 | Allergan     |                |
|                                                          | Cibadrex (5 Mg Benazepril Hidroklorür Ve 6,25 Mg Hidroklorotiyazid |                    |                    | S               | Unknown                |                      |                 | Not Reported |                |
|                                                          |                                                                    |                    |                    |                 |                        |                      |                 |              |                |
| <u>FDA Received Date</u>                                 | <u>Case #</u>                                                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Dec-2016                                              | 12995553                                                           | EXPEDITED (15-DAY) |                    | HO              | SE-TEVA-714655ACC      |                      | 78 YR           | Male         | SWE            |
| <u>Preferred Term</u>                                    | <u>Product</u>                                                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                          |                       |   |      |              |
|----------------------------------------------------------|-----------------------|---|------|--------------|
| Lethargy; Suicide Attempt;<br>Toxicity To Various Agents | Mirtazapin Actavis    | S | Oral | Teva         |
|                                                          | Imovane               | S | Oral | Not Reported |
|                                                          | Cipralext             | S | Oral | Not Reported |
|                                                          | Sobril                | S | Oral | Not Reported |
|                                                          | Metoprolol Gea Retard | C |      | Not Reported |
|                                                          | Inderal               | C |      | Not Reported |
|                                                          | Oralovite             | C |      | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 02-Dec-2016              | 12995904      | EXPEDITED (15-DAY) |                    | DS, HO          | DE-<br>ELI_LILLY_AND_COMP<br>ANY-DE201611007882 |                      | 74 YR      | Male       | DEU            |

| <u>Preferred Term</u>                                                                                 | <u>Product</u>   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>       |
|-------------------------------------------------------------------------------------------------------|------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------------|
| Cervical Vertebral<br>Fracture; Dizziness; Drug<br>Interaction; Fall; Subgaleal<br>Haematoma; Syncope | Olanzapine       |              |            | S           | Oral         | 2.5 Mg, Qd         |                 | Eli Lilly And Co |
|                                                                                                       | Olanzapine       |              |            | S           | Oral         | 5 Mg, Qd           |                 | Eli Lilly And Co |
|                                                                                                       | Escitalopram     |              |            | S           | Oral         | 10 Mg, Qd          |                 | Not Reported     |
|                                                                                                       | Escitalopram     |              |            | S           | Oral         | 20 Mg, Qd          |                 | Not Reported     |
|                                                                                                       | Mirtazapin       |              |            | S           | Oral         | 30 Mg, Qd          |                 | Not Reported     |
|                                                                                                       | Tavor /00273201/ |              |            | S           | Oral         | 3 Mg, Qd           |                 | Not Reported     |
|                                                                                                       | Tavor /00273201/ |              |            | S           | Oral         | 2 Mg, Qd           |                 | Not Reported     |
|                                                                                                       | Tavor /00273201/ |              |            | S           | Oral         | 1.5 Mg, Unknown    |                 | Not Reported     |
|                                                                                                       | L-Thyroxin       |              |            | C           | Oral         | 100 Ug, Qd         |                 | Not Reported     |
|                                                                                                       | Aprovel          |              |            | C           | Oral         | 300 Mg, Qd         |                 | Not Reported     |
|                                                                                                       | Urivesc          |              |            | C           | Oral         | 60 Mg, Qd          |                 | Not Reported     |
|                                                                                                       | Felodipin        |              |            | C           | Oral         | 10 Mg, Qd          |                 | Not Reported     |
|                                                                                                       | Kalium Durule    |              |            | C           | Oral         | 3 Df, Qd           |                 | Not Reported     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 02-Dec-2016              | 12995954      | EXPEDITED (15-DAY) |                    | LT              | AU-ALLERGAN-<br>1678833US |                      | 37 YR      | Female     | AUS            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                               |                           |   |              |              |
|-----------------------------------------------|---------------------------|---|--------------|--------------|
| Breast Feeding;                               | Escitalopram Oxalate - Bp | S | Unknown      | Allergan     |
| Gestational Diabetes;                         | Seroquel Xr / Quetiapine  | S | Unknown      | Not Reported |
| Maternal Exposure During Pregnancy; Overdose; | Elevit                    | C | Unknown      | Not Reported |
| Pregnancy                                     | Vitamin C                 | C | Endocervical | Not Reported |

| <u>FDA Received Date</u>                                             | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 02-Dec-2016                                                          | 12995963                  | EXPEDITED (15-DAY) |                    | HO              | IT-ALLERGAN-1679032US |                      | 45 YR           | Male         | ITA            |
| <u>Preferred Term</u>                                                | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Product Misuse; Intentional Self-Injury; Overdose; Sopor | Escitalopram Oxalate - Bp |                    |                    | S               | Oral                  | 30 MI, Unk           |                 | Allergan     |                |
|                                                                      | Zolpidem Tartrate         |                    |                    | S               | Oral                  | 30 MI, Unk           |                 | Not Reported |                |
|                                                                      | Anafranil                 |                    |                    | S               | Oral                  | 20 Df, Unk           |                 | Not Reported |                |
|                                                                      | Levoxacin                 |                    |                    | S               | Oral                  | 5 Df, Unk            |                 | Not Reported |                |
|                                                                      | Bentelan                  |                    |                    | S               | Oral                  | 10 Mg, Unk           |                 | Not Reported |                |
|                                                                      | Lortaan                   |                    |                    | S               | Oral                  | 28 Df, Unk           |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| 02-Dec-2016              | 12995968         | EXPEDITED (15-DAY) |                    | HO              | IT-ABBVIE-16P-083-1799096-00 |                      | 45 YR           | Female       | ITA            |
| <u>Preferred Term</u>    | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Abuse;              | Valproate Sodium |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
| Hypertension; Myoclonus; | Escitalopram     |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
| Somnolence; Tremor;      | Lorazepam        |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
| Vomiting                 | Eutirox          |                    |                    | C               |                              |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------------------------------|----------------------|-----------------|------------|----------------|
| 02-Dec-2016              | 12996021       | EXPEDITED (15-DAY) |                    | HO              | PT-PRINSTON PHARMACEUTICAL INC.-2016PRN00328 |                      | 23 YR           | Female     | PRT            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Carcinoid Syndrome       | Escitalopram   |                    |                    | S               | Oral                                         | 10 Mg, Unk           |                 | Prinston   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Anti-Inflammatories C Unknown Pharmaceutical Not Reported

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 02-Dec-2016              | 12996051      | EXPEDITED (15-DAY) |                    | HO              | AU-ALLERGAN-1679015US |                      | 1 DAY      | Female     | AUS            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                          | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Blood Glucose Decreased; Caesarean Section; Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Hyperreflexia; Maternal Drugs Affecting Foetus; Maternal Exposure During Breast Feeding; Neonatal Respiratory Distress; Respiratory Distress; Somnolence; Withdrawal Syndrome | Escitalopram Oxalate - Bp |              |            | S           | Transplacental |                    |                 | Allergan     |
|                                                                                                                                                                                                                                                                                                | Seroquel Xr / Quetiapine  |              |            | S           | Transplacental |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                | Elevit                    |              |            | C           | Transplacental |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                | Vitamin C                 |              |            | C           | Transplacental |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Dec-2016              | 12997387      | DIRECT           |                    | OT              |                      |                      | 45 YR      | Female     | USA            |

| <u>Preferred Term</u>                                        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Depressed Mood; Drug Ineffective; Product Substitution Issue | Escitalopram   |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------------|----------------------|------------|------------|----------------|
| 05-Dec-2016              | 12893781      | NON-EXPEDITED    |                    |                 | US-GLAXOSMITHKLINE-US2016GSK158285 |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|-----------------------|-----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| III-Defined Disorder  | Wellbutrin                  |              |            | S           |              | Unk                |                 | Glaxosmithkline |
|                       | Escitalopram Oxalate Tablet |              |            | S           |              | 20 Mg, Unk         |                 | Not Reported    |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|------------|------------|----------------|
| 05-Dec-2016              | 12998035      | EXPEDITED (15-DAY) |                    | HO, LT          | CA-NAPPMUNDI-CAN-2016-0007237 |                      | 52 YR      | Male       | CAN            |

| <u>Preferred Term</u>    | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Creatine           | Oxycodone Hydrochloride   |              |            | S           | Unknown      | Unk                |                 | Purdue       |
| Phosphokinase Increased; | Oxycodone Hydrochloride   |              |            | S           | Oral         | 20 Mg, Unk         |                 | Purdue       |
| Blood Creatinine         | Oxycodone Hydrochloride   |              |            | S           | Oral         | Unk                |                 | Purdue       |
| Increased; Blood         | Oxycodone Hydrochloride   |              |            | S           | Unknown      | 10 Mg, Unk         |                 | Purdue       |
| Potassium Increased;     | Oxycodone Hydrochloride   |              |            | S           | Unknown      | 9500 Mg, Unk       |                 | Purdue       |
| Blood Pressure           | Morphine Sulfate          |              |            | S           | Unknown      | 420 Mg, Unk        |                 | Purdue       |
| Decreased; Bradycardia;  | Morphine Sulfate          |              |            | S           | Unknown      | 2640 Mg, Unk       |                 | Purdue       |
| Coma; Coma Scale         | Morphine Sulfate          |              |            | S           | Oral         | 30 Mg, Unk         |                 | Purdue       |
| Abnormal; Drug           | Morphine Sulfate          |              |            | S           | Oral         | Unk                |                 | Purdue       |
| Interaction;             | Morphine Sulfate          |              |            | S           | Oral         | 30 Mg, Daily       |                 | Purdue       |
| Electrocardiogram        | Morphine Sulfate          |              |            | S           | Unknown      | 15 Mg, Unk         |                 | Purdue       |
| Abnormal;                | Morphine Sulfate          |              |            | S           | Unknown      | 100 Mg, Unk        |                 | Purdue       |
| Electrocardiogram Qt     | Morphine Sulfate          |              |            | S           | Unknown      | Unk                |                 | Not Reported |
| Prolonged; Heart Rate    | Morphine Sulfate          |              |            | S           | Unknown      | 10 Mg, Unk         |                 | Not Reported |
| Decreased;               | Morphine Sulfate          |              |            | S           | Unknown      | 10 Mg, Daily       |                 | Not Reported |
| Hyperkalaemia;           | Morphine Sulfate          |              |            | S           | Unknown      | Unk                |                 | Not Reported |
| Hypotension; Intentional | Morphine Sulfate          |              |            | S           | Unknown      | 10 Mg, Unk         |                 | Not Reported |
| Overdose; Loss Of        | Altace                    |              |            | C           | Unknown      | Unk                |                 | Not Reported |
| Consciousness;           | Ciprallex                 |              |            | S           | Unknown      | 140 Mg, Unk        |                 | Not Reported |
| Mechanical Ventilation;  | Ciprallex                 |              |            | S           | Unknown      | 10 Mg, Daily       |                 | Not Reported |
| Opiates Positive;        | Ciprallex                 |              |            | S           | Unknown      | Unk                |                 | Not Reported |
| Overdose; Oxygen         | Ciprallex                 |              |            | S           | Unknown      | 10 Mg, Unk         |                 | Not Reported |
| Saturation Decreased;    | Citalopram                |              |            | S           | Unknown      | 1800 Mg, Unk       |                 | Not Reported |
| Sinus Tachycardia;       | Citalopram                |              |            | S           | Unknown      | Unk                |                 | Not Reported |
| Suicide Attempt          | Diazepam                  |              |            | S           | Unknown      | 30 Mg, Unk         |                 | Not Reported |
|                          | Diazepam                  |              |            | S           | Unknown      | 10 Unk, Unk        |                 | Not Reported |
|                          | Diazepam                  |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                          | Lorazepam                 |              |            | S           | Unknown      | 7.5 Mg, Unk        |                 | Not Reported |
|                          | Lorazepam                 |              |            | S           | Unknown      | 187.5 Mg, Unk      |                 | Not Reported |
|                          | Oxycodone / Acetaminophen |              |            | S           | Unknown      |                    |                 |              |
|                          | Zopiclone                 |              |            | S           | Unknown      |                    |                 |              |
|                          | Zopiclone                 |              |            | S           | Unknown      |                    |                 |              |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|           |   |      |              |              |
|-----------|---|------|--------------|--------------|
| Zopiclone | S | Oral | 15 Mg, Daily | Not Reported |
|-----------|---|------|--------------|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|------------|------------|----------------|
| 05-Dec-2016              | 12998412      | EXPEDITED (15-DAY) |                    | DS, HO, OT      | DE-DRREDDYS-GER/GER/16/0085045 |                      | 74 YR      | Male       | DEU            |

| <u>Preferred Term</u>                                                       | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| C-Reactive Protein Increased; Dizziness; Fall; Liver Function Test Abnormal | Olanzapine           |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                             | Olanzapine           |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                             | Mirtazapine          |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                             | Escitalopram         |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                             | Escitalopram         |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                             | Tavor [Lorazepam]    |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                             | Tavor                |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                             | Tavor                |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                             | Levothyroxine Sodium |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                             | Aprovel              |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                             | Urivesc              |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                             | Felodipin            |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                             | Potassium Chloride   |              |            | C           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|------------|------------|----------------|
| 05-Dec-2016              | 12999380      | EXPEDITED (15-DAY) |                    | HO, OT          | DE-DRREDDYS-GER/GER/16/0085106 |                      | 21 YR      | Male       | DEU            |

| <u>Preferred Term</u>                          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Circulatory Collapse; Discomfort; Palpitations | Quetiapine     |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                | Escitalopram   |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                | Escitalopram   |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 06-Dec-2016              | 9837009       | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2014018541 |                      | 57 YR      | Female     | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                               | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |                |
|-----------------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|---------------------------|-----------------------------------|-----------------|--------------|----------------|
| Drug Hypersensitivity;<br>Product Use In<br>Unapproved Indication                                   | Neurontin                 |                    |                    | S               | Oral                      | Unk, Daily                        |                 | Pfizer       |                |
|                                                                                                     | Amitriptyline             |                    |                    | S               | Oral                      | Unk                               |                 | Not Reported |                |
|                                                                                                     | Cymbalta                  |                    |                    | S               | Oral                      | Unk, 1x/Day                       |                 | Not Reported |                |
|                                                                                                     | Prozac                    |                    |                    | S               |                           | Unk                               |                 | Not Reported |                |
|                                                                                                     | Lexapro                   |                    |                    | S               |                           | Unk                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                            | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Dec-2016                                                                                         | 12984442                  | EXPEDITED (15-DAY) |                    | DE, HO, LT      | FR-DSJP-DSE-2016-139401   |                                   |                 | Unknown      | FRA            |
| <u>Preferred Term</u>                                                                               | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |                |
| Bezoar; Completed<br>Suicide; Intestinal<br>Ischaemia; Skin Necrosis;<br>Toxicity To Various Agents | Sevikar                   |                    |                    | S               | Oral                      | 129 Df (5.16 G/1.29 G),<br>Single |                 | Daiichi      |                |
|                                                                                                     | Atarax /00058401/         |                    |                    | S               | Oral                      | 700 Mg, Single                    |                 | Not Reported |                |
|                                                                                                     | Lysanxia                  |                    |                    | S               | Oral                      | 420 Mg, Single                    |                 | Not Reported |                |
|                                                                                                     | Seroplex                  |                    |                    | S               | Oral                      | 280 Mg, Single                    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                            | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Dec-2016                                                                                         | 13000324                  | NON-EXPEDITED      |                    | HO              | SG-LUNDBECK-DKLU2021199   |                                   | 27 YR           | Female       | SGP            |
| <u>Preferred Term</u>                                                                               | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |                |
| Stevens-Johnson<br>Syndrome                                                                         | Escitalopram-Form-Unknown |                    |                    | S               | Unknown                   |                                   |                 | Not Reported |                |
|                                                                                                     | Clobazam                  |                    |                    | S               | Unknown                   |                                   |                 | Lundbeck     |                |
|                                                                                                     | Sertraline                |                    |                    | S               | Unknown                   |                                   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                            | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Dec-2016                                                                                         | 13000629                  | EXPEDITED (15-DAY) |                    | HO              | US-CIPLA LTD.-2016US22315 |                                   |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                                               | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Angioedema;                                                                              | Lisinopril                |                    |                    | S               | Oral                      | 5 Mg, At 11 Am In The             |                 | Invagen      |                |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                            |               |   |         |                                               |              |
|--------------------------------------------|---------------|---|---------|-----------------------------------------------|--------------|
| Concussion; Disease<br>Recurrence; Syncope | Carvedilol    | S | Oral    | Morning<br>6.25 Mg At 11 Am In The<br>Morning | Cipla        |
|                                            | Levetiracetam | S | Oral    | Unk                                           | Invagen      |
|                                            | Escitalopram  | S | Oral    | 10 Mg, Qd                                     | Invagen      |
|                                            | Aspirin       | C | Unknown | Unk                                           | Not Reported |
|                                            | Rosuvastatin  | C | Unknown | Unk                                           | Not Reported |
|                                            | Lorazepam     | C | Unknown | Unk                                           | Not Reported |
|                                            | Hydromorphone | C | Unknown | Unk, Prn                                      | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------------------------------------|----------------------|------------|------------|----------------|
| 06-Dec-2016              | 13000662      | EXPEDITED (15-DAY) |                    | CA, OT          | DE-MACLEODS<br>PHARMACEUTICALS<br>US LTD-<br>MAC2016003617 |                      |            | Unknown    | DEU            |

| <u>Preferred Term</u>                                             | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u>                           | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------|-----------------------|--------------|------------|-------------|----------------|----------------------------------------------|-----------------|--------------|
| Foetal Exposure During<br>Pregnancy; Ventricular<br>Septal Defect | Escitalopram          |              |            | S           | Transplacental | 10 Mg, Qd (0.-<br>38.5.Gestational Week)     |                 | Macleods     |
|                                                                   | Paracetamol           |              |            | C           | Transplacental | 500 Mg, Qd (14.0 - 17.0<br>Gestational Week) |                 | Not Reported |
|                                                                   | Thyronajod            |              |            | C           | Transplacental | (50 ?G/D) And (150<br>?G/D)Qd                |                 | Not Reported |
|                                                                   | Folio Forte (Jodfrei) |              |            | C           | Transplacental | 0.8 Mg, Qd                                   |                 | Not Reported |
|                                                                   | Ibuprofen Lysinate    |              |            | C           | Transplacental | Unk, Bid (Twice, Dosage)                     |                 | Not Reported |
|                                                                   | Korodin               |              |            | C           | Transplacental | Unk,1-3x Per Week                            |                 | Not Reported |
|                                                                   | Opipramol             |              |            | C           | Transplacental | 50 Mg, Qd                                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------------------------------------|----------------------|------------|------------|----------------|
| 06-Dec-2016              | 13000931      | EXPEDITED (15-DAY) |                    | DS, HO          | DE-SUN<br>PHARMACEUTICAL<br>INDUSTRIES LTD-<br>2016RR-128647 |                      | 74 YR      | Male       | DEU            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|      |                       |   |      |               |              |
|------|-----------------------|---|------|---------------|--------------|
| Fall | Mirtazapine           | S | Oral | 30 Mg, Daily  | Sun          |
|      | Olanzapine            | S | Oral | 2.5 Mg, Daily | Sun          |
|      | Olanzapine            | S | Oral | 5 Mg, Daily   | Sun          |
|      | Escitalopram Lundbeck | S | Oral | 10 Mg, Daily  | Not Reported |
|      | Escitalopram Lundbeck | S | Oral | 20 Mg, Daily  | Not Reported |
|      | Tavor [Lorazepam]     | S | Oral | 3 Mg, Daily   | Not Reported |
|      | Tavor                 | S | Oral | 2 Mg, Daily   | Not Reported |
|      | Tavor                 | S | Oral | 1.5 Mg, Daily | Not Reported |
|      | I-Thyroxin            | C | Oral | 100 Mg, Daily | Not Reported |
|      | Aprovel               | C | Oral | 60 Mg, Daily  | Not Reported |
|      | Felodipin             | C | Oral | 10 Mg, Daily  | Not Reported |
|      | Kalium Duriles        | C | Oral | 10 Mg, Daily  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------------------------------------|----------------------|------------|------------|----------------|
| 06-Dec-2016              | 13000952      | EXPEDITED (15-DAY) |                    | HO              | DE-SUN<br>PHARMACEUTICAL<br>INDUSTRIES LTD-<br>2016RR-128570 |                      | 21 YR      | Male       | DEU            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Circulatory Collapse  | Escitalopram   |              |            | S           | Oral         | 10 Mg, Daily       |                 | Not Reported |
|                       | Escitalopram   |              |            | S           | Oral         | 5 Mg, Daily        |                 | Not Reported |
|                       | Quetiapine     |              |            | S           | Oral         | 50 Mg, Unk         |                 | Sun          |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------|----------------------|------------|------------|----------------|
| 06-Dec-2016              | 13000986      | EXPEDITED (15-DAY) |                    | HO              | DE-AUROBINDO-AUR-<br>APL-2016-14659 |                      | 21 YR      | Male       | DEU            |

| <u>Preferred Term</u>                                                                            | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--------------------------------------------------------------------------------------------------|--------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Bradycardia; Circulatory Collapse;<br>Electrocardiogram Qt Prolonged; Palpitations; Restlessness | Escitalopram 10 Mg |              |            | S           | Oral         | 10 Mg, Once A Day  |                 | Aurobindo  |
|                                                                                                  | Escitalopram 10 Mg |              |            | S           | Oral         | 5 Mg, Once A Day   |                 | Aurobindo  |
|                                                                                                  | Quetiapine         |              |            | S           | Oral         | 50 Mg, Unk         |                 | Aurobindo  |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------------------------------------------|-----------------|--------------|----------------|
| 06-Dec-2016              | 13001028       | EXPEDITED (15-DAY) |                    | HO              | DE-ACCORD-046312     |                                                          | 21 YR           | Male         | DEU            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                       | <u>Duration</u> | <u>Mfr</u>   |                |
| Circulatory Collapse     | Escitalopram   |                    |                    | S               | Oral                 | Dose Reduced To 5 Mg/Day From 30-May-2016 To 04-May-2016 |                 | Not Reported |                |
|                          | Quetiapine     |                    |                    | S               | Oral                 |                                                          |                 | Accord       |                |

| <u>FDA Received Date</u>                                              | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|-------------------------|----------------------|-----------------|--------------|----------------|
| 06-Dec-2016                                                           | 13003034                    | EXPEDITED (15-DAY) |                    | HO, OT          | JP-LUNDBECK-DKLU2016560 |                      | 71 YR           | Female       | JPN            |
| <u>Preferred Term</u>                                                 | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Gastroesophageal Reflux Disease; Long Qt Syndrome; Serotonin Syndrome | Lexapro Film-Coated Tablets |                    |                    | S               | Oral                    |                      |                 | Not Reported |                |
|                                                                       | Mystan                      |                    |                    | S               | Oral                    |                      |                 | Lundbeck     |                |
|                                                                       | Lendormin                   |                    |                    | S               | Oral                    |                      |                 | Not Reported |                |
|                                                                       | Belsomra                    |                    |                    | S               | Oral                    |                      |                 | Not Reported |                |
|                                                                       | Milmag                      |                    |                    | C               | Oral                    |                      |                 | Not Reported |                |
|                                                                       | Malfa                       |                    |                    | C               | Oral                    |                      |                 | Not Reported |                |
|                                                                       | Micardis                    |                    |                    | C               | Oral                    |                      |                 | Not Reported |                |
|                                                                       | Madopar                     |                    |                    | C               | Oral                    |                      |                 | Not Reported |                |
|                                                                       | Pariet                      |                    |                    | C               | Oral                    |                      |                 | Not Reported |                |
|                                                                       | Gasmotin                    |                    |                    | C               | Oral                    |                      |                 | Not Reported |                |
|                                                                       | Hangekobokuto               |                    |                    | C               | Oral                    |                      |                 | Not Reported |                |
|                                                                       | Micamlo                     |                    |                    | C               | Oral                    |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 06-Dec-2016              | 13003113       | EXPEDITED (15-DAY) |                    | HO              | IT-MYLANLABS-2016M1052809 |                      |                 | Unknown    | ITA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                      |                   |   |      |              |              |
|----------------------------------------------------------------------|-------------------|---|------|--------------|--------------|
| Intentional Product Misuse; Intentional Self-Injury; Overdose; Sopor | Escitalopram      | S | Oral | 30 MI, Total | Not Reported |
|                                                                      | Bentelan          | S | Oral | 10 Mg, Total | Mylan        |
|                                                                      | Anafranil         | S | Oral | 20 Df, Total | Mylan        |
|                                                                      | Levoxacin         | S | Oral | 5 Df, Total  | Mylan        |
|                                                                      | Lortaan           | S | Oral | 28 Df, Total | Mylan        |
|                                                                      | Zolpidem Tartrate | S | Oral | 30 MI, Total | Mylan        |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
| 06-Dec-2016              | 13003119       | EXPEDITED (15-DAY) |                    | OT              | IT-MYLANLABS-2016M1052817 |                      |                 | Unknown      | ITA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Abuse; Sopor        | Escitalopram   |                    |                    | S               | Oral                      | Unk                  |                 | Not Reported |                |
|                          | Delorazepam    |                    |                    | S               | Oral                      | Unk                  |                 | Mylan        |                |

| <u>FDA Received Date</u>                                         | <u>Case #</u>    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------|------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
| 06-Dec-2016                                                      | 13003120         | EXPEDITED (15-DAY) |                    | HO              | IT-MYLANLABS-2016M1052800 |                      |                 | Unknown      | ITA            |
| <u>Preferred Term</u>                                            | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Abuse; Hypotension; Myoclonus; Somnolence; Tremor; Vomiting | Escitalopram     |                    |                    | S               | Oral                      | 10 Df, Total         |                 | Not Reported |                |
|                                                                  | Lorazepam        |                    |                    | S               | Oral                      | 5 Df, Total          |                 | Not Reported |                |
|                                                                  | Valproate Sodium |                    |                    | S               | Oral                      | 2 Df, Total          |                 | Mylan        |                |
|                                                                  | Eutirox          |                    |                    | C               | Oral                      | Unk                  |                 | Mylan        |                |

| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------|----------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
| 06-Dec-2016               | 13003336       | EXPEDITED (15-DAY) |                    | CA              | DE-MYLANLABS-2016M1052932 |                      |                 | Unknown      | DEU            |
| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Ventricular Septal Defect | Escitalopram   |                    |                    | S               | Transplacental            | 10 [Mg/D ]           |                 | Not Reported |                |
|                           | Thyronajod     |                    |                    | C               | Transplacental            | 50/150               |                 | Mylan        |                |
|                           | Folio Forte    |                    |                    | C               | Transplacental            | 0.8 [Mg/D ]          |                 | Mylan        |                |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                    |   |                |                                      |       |
|--------------------|---|----------------|--------------------------------------|-------|
| Ibuprofen Lysinate | C | Transplacental | Twice, Dosage Unknown                | Mylan |
| Paracetamol        | C | Transplacental | 500 [Mg/D ]/ 2-3 Times, If Necessary | Mylan |
| Korodin /08256501/ | C | Transplacental | Unk Unk, 3xw                         | Mylan |
| Opi Pramol         | C | Transplacental | 50 [Mg/D ]                           | Mylan |

| <u>FDA Received Date</u> | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|--------------------------|--------------------|--------------------|-----------------|-----------------------|------------------------|-----------------|--------------|----------------|
| 06-Dec-2016              | 13003357                 | EXPEDITED (15-DAY) |                    | HO, OT          | IT-ALLERGAN-1679280US |                        | 25 YR           | Female       | ITA            |
| <u>Preferred Term</u>    | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Abuse; Sopor        | Escitalopram Oxalate Unk |                    |                    | S               | Oral                  | Unk                    |                 | Allergan     |                |
|                          | Delorazepam              |                    |                    | S               | Oral                  | Overdose: Unknown Dose |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u>                             | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
|------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|---------------------------------------------|--------------------------------------------------|-----------------|------------------|----------------|
| 07-Dec-2016                                                                              | 13006748       | EXPEDITED (15-DAY) |                    | HO              | JP-ELI_LILLY_AND_COMP<br>ANY-JP201611003204 |                                                  | 85 YR           | Female           | JPN            |
| <u>Preferred Term</u>                                                                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                | <u>Dosage Text</u>                               | <u>Duration</u> | <u>Mfr</u>       |                |
| Altered State Of Consciousness; Off Label Use; Off Label Use; Portal Vein Flow Decreased | Zyprexa        |                    |                    | S               | Oral                                        | 10 Mg, Qd                                        |                 | Eli Lilly And Co |                |
|                                                                                          | Zyprexa        |                    |                    | S               | Oral                                        | 2.5mg Tab In The Morning; 5mg Tab In The Evening |                 | Eli Lilly And Co |                |
|                                                                                          | Tramcet        |                    |                    | S               | Unknown                                     | 2 Df, Bid (Morning And Evening)                  |                 | Not Reported     |                |
|                                                                                          | Reminyl        |                    |                    | S               |                                             | 12 Mg, Qd (Morning)                              |                 | Not Reported     |                |
|                                                                                          | Lexapro        |                    |                    | S               | Unknown                                     | 10 Mg, Qd (Evening)                              |                 | Not Reported     |                |
|                                                                                          | Desyrel        |                    |                    | S               | Unknown                                     | 25 Mg, Qd (Before Bedtime)                       |                 | Not Reported     |                |
|                                                                                          | Lunesta        |                    |                    | S               | Unknown                                     | 1 Mg, Qd (Before Bedtime)                        |                 | Not Reported     |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Dec-2016              | 13007335      | EXPEDITED (15-DAY) |                    | HO              | PHHY2016IT164398     |                      | 45 YR      | Female     | ITA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                                                           | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                           | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|--------------------------------------------------------|-----------------------|-----------------|--------------|----------------|
| Drug Abuse; Hypotension;<br>Myoclonus; Somnolence;<br>Tremor; Vomiting                                                                                                                          | Escitalopram              |                    |                    | S               | Oral                                                   | 10 Df, Once/Single    |                 | Not Reported |                |
|                                                                                                                                                                                                 | Lorazepam                 |                    |                    | S               | Oral                                                   | 5 Df, Once/Single     |                 | Novartis     |                |
|                                                                                                                                                                                                 | Sodium Valproate          |                    |                    | S               | Oral                                                   | 2 Df, Once/Single     |                 | Not Reported |                |
|                                                                                                                                                                                                 | Eutirox                   |                    |                    | C               | Oral                                                   |                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                        | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Dec-2016                                                                                                                                                                                     | 13010299                  | DIRECT             |                    | OT              |                                                        |                       | 69 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                           | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                           | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Paraesthesia                                                                                                                                                                                    | Lexapro                   |                    |                    | S               | Oral                                                   | Quantity:1 Tablet(S); |                 | Cipla        |                |
|                                                                                                                                                                                                 | Evista                    |                    |                    | C               |                                                        |                       |                 | Not Reported |                |
|                                                                                                                                                                                                 | Magnesium Trace Minerals  |                    |                    | C               |                                                        |                       |                 | Not Reported |                |
|                                                                                                                                                                                                 | D3                        |                    |                    | C               |                                                        |                       |                 | Not Reported |                |
|                                                                                                                                                                                                 | B12                       |                    |                    | C               |                                                        |                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                        | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Dec-2016                                                                                                                                                                                     | 12874215                  | EXPEDITED (15-DAY) |                    | HO              | JP-ALLERGAN-1672915US                                  |                       | 53 YR           | Male         | JPN            |
| <u>Preferred Term</u>                                                                                                                                                                           | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                           | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Hyposmosis; Blood<br>Osmolarity Increased;<br>Blood Sodium Increased;<br>Dizziness; Feeling<br>Abnormal; Inappropriate<br>Antidiuretic Hormone<br>Secretion; Muscular<br>Weakness; Nausea | Escitalopram Oxalate - Bp |                    |                    | S               | Oral                                                   | 20 Mg, Unk            |                 | Allergan     |                |
|                                                                                                                                                                                                 | Risperdal                 |                    |                    | S               | Oral                                                   | 5 Mg, Bid             |                 | Not Reported |                |
|                                                                                                                                                                                                 | Anafranil                 |                    |                    | S               | Oral                                                   | 50 Mg, Unk            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                        | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Dec-2016                                                                                                                                                                                     | 12928183                  | NON-EXPEDITED      |                    |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>BMS-2016-095103 |                       | 71 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                           | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                           | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                               |              |   |         |     |                      |
|-----------------------------------------------|--------------|---|---------|-----|----------------------|
| Anxiety; Product Use In Unapproved Indication | Abilify      | S | Unknown | Unk | Bristol Myers Squibb |
|                                               | Abilify      | S | Unknown |     | Bristol Myers Squibb |
|                                               | Aripiprazole | S | Unknown | Unk | Not Reported         |
|                                               | Lexapro      | S | Unknown | Unk | Not Reported         |

| <u>FDA Received Date</u>                     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------|----------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|-----------------|--------------|----------------|
| 08-Dec-2016                                  | 13008367       | EXPEDITED (15-DAY) |                    | OT              | IT-AUROBINDO-AUR-APL-2016-15010 |                      | 25 YR           | Female       | ITA            |
| <u>Preferred Term</u>                        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Abuse; Psychomotor Hyperactivity; Sopor | Delorazepam    |                    |                    | S               | Oral                            | Unk                  |                 | Not Reported |                |
|                                              | Escitalopram   |                    |                    | S               | Oral                            | Unk                  |                 | Aurobindo    |                |

| <u>FDA Received Date</u>                                         | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------|----------------------------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|-----------------|--------------|----------------|
| 08-Dec-2016                                                      | 13008487                         | EXPEDITED (15-DAY) |                    | HO              | IT-AUROBINDO-AUR-APL-2016-15016 |                      | 45 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                            | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Abuse; Hypotension; Myoclonus; Somnolence; Tremor; Vomiting | Escitalopram Film-Coated Tablets |                    |                    | S               | Oral                            | 10 Df, Total         |                 | Aurobindo    |                |
|                                                                  | Lorazepam Tablets                |                    |                    | S               | Oral                            | 5 Df, Total          |                 | Not Reported |                |
|                                                                  | Sodium Valproate                 |                    |                    | S               | Oral                            | 2 Df, Total          |                 | Not Reported |                |
|                                                                  | Eutirox                          |                    |                    | C               | Oral                            |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                     | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------|---------------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 08-Dec-2016                                  | 13008744                  | EXPEDITED (15-DAY) |                    | OT              | KR-ALLERGAN-1679373US |                      | 62 YR           | Female       | KOR            |
| <u>Preferred Term</u>                        | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Discomfort; Hyperhidrosis; Seizure | Escitalopram Oxalate - Bp |                    |                    | S               |                       | 1 Tab                |                 | Allergan     |                |
|                                              | Clonazepam                |                    |                    | S               |                       | 1 Tab                |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Dec-2016              | 13008832      | EXPEDITED (15-DAY) |                    | OT              | TW-RECKITT           |                      | 22 YR      | Female     | TWN            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

BENCKISER  
HEALTHCARE INT  
LIMITED-RB-936

| <u>Preferred Term</u>                                                                                                                                | <u>Product</u>                            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|--------------|------------|-------------|--------------|----------------------|-----------------|--------------|
| Aggression; Distractibility;<br>Euphoric Mood; Mania;<br>Product Use In<br>Unapproved Indication;<br>Psychomotor<br>Hyperactivity; Sleep<br>Disorder | Unspecified Dextromethorphan Hydrobromide |              |            | S           | Oral         | 30 Mg, Every 6 Hours |                 | Not Reported |
|                                                                                                                                                      | Unspecified Dextromethorphan Hydrobromide |              |            | S           |              |                      |                 | Not Reported |
|                                                                                                                                                      | Escitalopram                              |              |            | S           | Unknown      | 15 Mg, Qd (A Day)    |                 | Not Reported |
|                                                                                                                                                      | Ambroxol                                  |              |            | C           | Unknown      | 30 Mg, Tid           |                 | Not Reported |
|                                                                                                                                                      | Acetaminophen                             |              |            | C           | Unknown      | 325 Mg, Tid          |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                 | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------------------------------|----------------------|------------|------------|----------------|
| 08-Dec-2016              | 13009123      | EXPEDITED (15-DAY) |                    | HO              | CA-SCIEGEN<br>PHARMACEUTICALS<br>INC-2016SCILIT00608 |                      | 77 YR      | Female     | CAN            |

| <u>Preferred Term</u>                                                                                                   | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------|-----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Asthenia; Confusional<br>State; Fall;<br>Hyponatraemia;<br>Inappropriate Antidiuretic<br>Hormone Secretion;<br>Lethargy | Hydrochlorothiazide Tablets |              |            | S           | Unknown      | Unk                |                 | Sciegen      |
|                                                                                                                         | Escitalopram                |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                                                                                                                         | Metformin                   |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                                                                                                                         | Gliclazide                  |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                                                                                                                         | Insulin                     |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                                                                                                                         | L-Thyroxine                 |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                                                                                                                         | Telmisartan                 |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                                                                                                                         | Trazadone                   |              |            | S           | Unknown      | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 08-Dec-2016              | 13009837      | EXPEDITED (15-DAY) |                    | HO              | FR-ALLERGAN-<br>1679560US |                      | 77 YR      | Female     | FRA            |

| <u>Preferred Term</u>    | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Cerebral Haematoma; Fall | Escitalopram Oxalate - Bp |              |            | S           | Oral         | 20 Mg, Qd          |                 | Allergan   |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                          |                           |                           |                             |                          |                               |                               |                                    |                          |                         |  |
|------------------------------------------------------------------------------------------|---------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|------------------------------------|--------------------------|-------------------------|--|
| Zolpidem                                                                                 |                           |                           | S                           |                          | Oral                          |                               | 0.5 Mg, Qd                         |                          | Not Reported            |  |
| <a href="#">FDA Received Date</a>                                                        | <a href="#">Case #</a>    | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>                | <a href="#">Sex</a>      | <a href="#">Country</a> |  |
| 08-Dec-2016                                                                              | 13009838                  | EXPEDITED (15-DAY)        |                             | HO                       | FR-ALLERGAN-1679564US         |                               | 75 YR                              | Male                     | FRA                     |  |
| <a href="#">Preferred Term</a>                                                           | <a href="#">Product</a>   |                           | <a href="#">Comp.</a>       | <a href="#">OTC</a>      | <a href="#">Role</a>          | <a href="#">Route</a>         | <a href="#">Dosage Text</a>        | <a href="#">Duration</a> | <a href="#">Mfr</a>     |  |
| Hallucination, Visual; Overdose; Product Administration Error                            | Escitalopram Oxalate - Bp |                           |                             |                          | S                             | Oral                          | Overdose: Escitalopram 40 Mg Daily |                          | Allergan                |  |
| <a href="#">FDA Received Date</a>                                                        | <a href="#">Case #</a>    | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>                | <a href="#">Sex</a>      | <a href="#">Country</a> |  |
| 08-Dec-2016                                                                              | 13010863                  | EXPEDITED (15-DAY)        |                             | HO                       | IT-MYLANLABS-2016M1053925     |                               |                                    | Unknown                  | ITA                     |  |
| <a href="#">Preferred Term</a>                                                           | <a href="#">Product</a>   |                           | <a href="#">Comp.</a>       | <a href="#">OTC</a>      | <a href="#">Role</a>          | <a href="#">Route</a>         | <a href="#">Dosage Text</a>        | <a href="#">Duration</a> | <a href="#">Mfr</a>     |  |
| Dehydration; Diarrhoea                                                                   | Escitalopram              |                           |                             |                          | S                             | Oral                          | 10 Mg Daily                        |                          | Not Reported            |  |
|                                                                                          | Cardioaspirin             |                           |                             |                          | C                             | Oral                          |                                    |                          | Mylan                   |  |
|                                                                                          | Serenase (Haloperidol)    |                           |                             |                          | C                             | Oral                          |                                    |                          | Mylan                   |  |
|                                                                                          | Quetiapine                |                           |                             |                          | C                             | Oral                          | 25 Mg                              |                          | Mylan                   |  |
|                                                                                          | Enalapril                 |                           |                             |                          | C                             | Oral                          | 20 Mg                              |                          | Mylan                   |  |
| <a href="#">FDA Received Date</a>                                                        | <a href="#">Case #</a>    | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>                | <a href="#">Sex</a>      | <a href="#">Country</a> |  |
| 08-Dec-2016                                                                              | 13010933                  | EXPEDITED (15-DAY)        |                             | OT                       | IT-ALLERGAN-1679750US         |                               | 23 YR                              | Female                   | ITA                     |  |
| <a href="#">Preferred Term</a>                                                           | <a href="#">Product</a>   |                           | <a href="#">Comp.</a>       | <a href="#">OTC</a>      | <a href="#">Role</a>          | <a href="#">Route</a>         | <a href="#">Dosage Text</a>        | <a href="#">Duration</a> | <a href="#">Mfr</a>     |  |
| Aggression; Drug Abuse; Hyperventilation; Overdose; Product Use In Unapproved Indication | Escitalopram Oxalate Unk  |                           |                             |                          | S                             | Oral                          | 10 Mg, Qd                          |                          | Allergan                |  |
| <a href="#">FDA Received Date</a>                                                        | <a href="#">Case #</a>    | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>                | <a href="#">Sex</a>      | <a href="#">Country</a> |  |
| 08-Dec-2016                                                                              | 13012961                  | DIRECT                    |                             |                          |                               |                               | 23 YR                              | Female                   | USA                     |  |
| <a href="#">Preferred Term</a>                                                           | <a href="#">Product</a>   |                           | <a href="#">Comp.</a>       | <a href="#">OTC</a>      | <a href="#">Role</a>          | <a href="#">Route</a>         | <a href="#">Dosage Text</a>        | <a href="#">Duration</a> | <a href="#">Mfr</a>     |  |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                             |              |   |      |                       |              |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|---|------|-----------------------|--------------|
| Abdominal Discomfort;<br>Abdominal Pain Upper;<br>Bedridden; Dizziness;<br>Facial Paralysis; Influenza;<br>Loss Of Personal<br>Independence In Daily<br>Activities; Nausea;<br>Paraesthesia | Escitalopram | S | Oral | Quantity:1 Tablet(S); | Not Reported |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|---|------|-----------------------|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Dec-2016              | 13017028      | DIRECT           |                    | DS, HO, RI, OT  |                      |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>                                                                                                                          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Chest Pain; Eating<br>Disorder; Impaired Work<br>Ability; Mental Disorder;<br>Panic Attack; Product<br>Substitution Issue; Weight<br>Decreased | Paxil          |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                | Fluoxetine     |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                | Escitalopram   |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 09-Dec-2016              | 12980664      | EXPEDITED (15-DAY) |                    | HO              | FR-ALLERGAN-<br>1677983US |                      | 81 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                                                                                         | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Osmolarity<br>Decreased; Confusional<br>State; General Physical<br>Health Deterioration;<br>Hyponatraemia; Off Label<br>Use; Somnolence | Escitalopram Oxalate - Bp |              |            | S           | Oral         | 5 Mg, Qd           |                 | Allergan     |
|                                                                                                                                               | Moducen                   |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                                               | Laroxyl                   |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                                               | Zopiclone                 |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                                                               | Alprazolam                |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                                                               | Theralene                 |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                                                               | Atarax                    |              |            | C           | Oral         | 25 Mg, Qd          |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|------------|------------|----------------|
| 09-Dec-2016              | 13011314      | EXPEDITED (15-DAY) |                    | OT              | IT-CIPLA LTD.-<br>2016IT22782 |                      |            | Unknown    | ITA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|--------------------------|----------------|--------------------|--------------------|-----------------|--------------------------------------------------------------|----------------------|-----------------|--------------|----------------|
| Drug Abuse; Sopor        | Escitalopram   |                    |                    | S               | Oral                                                         | Unk                  |                 | Invagen      |                |
|                          | Delorazepam    |                    |                    | S               | Oral                                                         | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Dec-2016              | 13011691       | EXPEDITED (15-DAY) |                    | HO              | DE-SUN<br>PHARMACEUTICAL<br>INDUSTRIES LTD-<br>2016RR-129032 |                      | 77 YR           | Female       | DEU            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Delirium                 | Escitalopram   |                    |                    | S               | Oral                                                         | 10 Mg, Daily         |                 | Not Reported |                |
|                          | Escitalopram   |                    |                    | S               | Oral                                                         | 15 Mg, Daily         |                 | Not Reported |                |
|                          | Escitalopram   |                    |                    | S               | Oral                                                         | 20 Mg, Daily         |                 | Not Reported |                |
|                          | Amitriptyline  |                    |                    | S               | Oral                                                         | 25 Mg, Daily         |                 | Sun          |                |
|                          | Amitriptyline  |                    |                    | S               | Oral                                                         | 50 Mg, Daily         |                 | Sun          |                |
|                          | Amitriptyline  |                    |                    | S               | Oral                                                         | 75 Mg, Daily         |                 | Sun          |                |
|                          | Amitriptyline  |                    |                    | S               | Oral                                                         | 50 Mg, Daily         |                 | Sun          |                |
|                          | Amitriptyline  |                    |                    | S               | Oral                                                         | 25 Mg, Daily         |                 | Sun          |                |
|                          | Amitriptyline  |                    |                    | S               |                                                              | Unk                  |                 | Sun          |                |
|                          | Tramadol       |                    |                    | S               | Oral                                                         | 50 Mg, Daily         |                 | Sun          |                |
|                          | Eliquis        |                    |                    | C               | Oral                                                         | 5 Mg, Daily          |                 | Not Reported |                |
|                          | Metformin      |                    |                    | C               | Oral                                                         | 2 G, Daily           |                 | Not Reported |                |
|                          | Lorazepam      |                    |                    | C               | Oral                                                         | 1 Mg, Daily          |                 | Not Reported |                |
|                          | Lorazepam      |                    |                    | C               | Oral                                                         | 1.5 Mg, Daily        |                 | Not Reported |                |
|                          | Diclofenac     |                    |                    | C               | Unknown                                                      | 150 Mg, Daily        |                 | Not Reported |                |
|                          | Ibuprofen      |                    |                    | C               | Oral                                                         | 1200 Mg, Daily       |                 | Not Reported |                |
|                          | Ramipril       |                    |                    | C               | Oral                                                         | 5 Mg, Daily          |                 | Not Reported |                |
|                          | Escitalopram   |                    |                    | C               |                                                              | Unk                  |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                               | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                         | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|--------------------------------------------------------------|--------------------------------|-----------------|--------------|----------------|
| 09-Dec-2016                                                                            | 13011723                | EXPEDITED (15-DAY) |                    | HO              | IT-SUN<br>PHARMACEUTICAL<br>INDUSTRIES LTD-<br>2016RR-128750 |                                | 45 YR           | Male         | ITA            |
| <u>Preferred Term</u>                                                                  | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                 | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Product<br>Misuse; Intentional Self-<br>Injury; Sopor                      | Escitalopram            |                    |                    | S               | Oral                                                         | 30 MI Total                    |                 | Not Reported |                |
|                                                                                        | Zolpidem                |                    |                    | S               | Oral                                                         | 30 MI Total                    |                 | Sun          |                |
|                                                                                        | Bentelan 1 Mg           |                    |                    | S               | Oral                                                         | 10 Mg Total                    |                 | Not Reported |                |
|                                                                                        | Anafranil               |                    |                    | S               | Oral                                                         | 20 Df Total                    |                 | Not Reported |                |
|                                                                                        | Levoxacin               |                    |                    | S               | Oral                                                         | 5 Df Total                     |                 | Not Reported |                |
|                                                                                        | Lortaan                 |                    |                    | S               | Oral                                                         | 28 Df Total                    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                               | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                         | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Dec-2016                                                                            | 13011755                | EXPEDITED (15-DAY) |                    | HO, OT          | DE-MACLEODS<br>PHARMACEUTICALS<br>US LTD-<br>MAC2016003615   |                                |                 | Unknown      | DEU            |
| <u>Preferred Term</u>                                                                  | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                 | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State;<br>Delirium; Depressed Level<br>Of Consciousness;<br>Disorientation | Tramadol Hydrochloride  |                    |                    | S               | Oral                                                         | 50 Mg, Qd                      |                 | Macleods     |                |
|                                                                                        | Escitalopram            |                    |                    | S               | Oral                                                         | 5 Mg, Qd                       |                 | Macleods     |                |
|                                                                                        | Escitalopram            |                    |                    | S               | Oral                                                         | 10 Mg, Qd                      |                 | Macleods     |                |
|                                                                                        | Escitalopram            |                    |                    | S               | Oral                                                         | 15 Mg, Qd                      |                 | Macleods     |                |
|                                                                                        | Escitalopram            |                    |                    | S               | Oral                                                         | 20 Mg, Qd                      |                 | Macleods     |                |
|                                                                                        | Amitriptylin            |                    |                    | S               | Oral                                                         | 25 Mg, Qd                      |                 | Not Reported |                |
|                                                                                        | Amitriptylin            |                    |                    | S               | Oral                                                         | 50 Mg, Qd                      |                 | Not Reported |                |
|                                                                                        | Amitriptylin            |                    |                    | S               | Oral                                                         | 75 Mg, Qd                      |                 | Not Reported |                |
|                                                                                        | Amitriptylin            |                    |                    | S               | Oral                                                         | 50 Mg, Qd                      |                 | Not Reported |                |
|                                                                                        | Amitriptylin            |                    |                    | S               | Oral                                                         | 25 Mg, Qd                      |                 | Not Reported |                |
|                                                                                        | Metformin Hydrochloride |                    |                    | C               | Unknown                                                      | 2 G, Qd (For Year -<br>B.A.W.) |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|            |   |         |                        |              |
|------------|---|---------|------------------------|--------------|
| Eliquis    | C | Oral    | 5 Mg, Qd               | Not Reported |
| Lorazepam  | C | Oral    | 1 Mg, Unk (For Months) | Not Reported |
| Lorazepam  | C | Oral    | 1.5 Mg, Qd             | Not Reported |
| Diclofenac | C | Unknown | 150 Mg, Qd             | Not Reported |
| Ramipril   | C | Oral    | 5 Mg, Qd (B.A.W)       | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|------------|------------|----------------|
| 09-Dec-2016              | 13011762      | EXPEDITED (15-DAY) |                    | HO              | IT-CIPLA LTD.-<br>2016IT22727 |                      |            | Unknown    | ITA            |

| <u>Preferred Term</u>                                                  | <u>Product</u>   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------|------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Abuse; Hypotension;<br>Myoclonus; Somnolence;<br>Tremor; Vomiting | Escitalopram     |              |            | S           | Oral         | 10 Df Total        |                 | Invagen      |
|                                                                        | Sodium Valproate |              |            | S           | Oral         | 2 Df Total         |                 | Not Reported |
|                                                                        | Lorazepam        |              |            | S           | Oral         | 5 Df Total         |                 | Not Reported |
|                                                                        | Eutirox          |              |            | C           | Oral         | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------------------------------------|----------------------|------------|------------|----------------|
| 09-Dec-2016              | 13011942      | EXPEDITED (15-DAY) |                    | HO              | IT-SUN<br>PHARMACEUTICAL<br>INDUSTRIES LTD-<br>2016RR-128940 |                      | 45 YR      | Female     | ITA            |

| <u>Preferred Term</u>                                                  | <u>Product</u>   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------|------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Abuse; Hypotension;<br>Myoclonus; Somnolence;<br>Tremor; Vomiting | Escitalopram     |              |            | S           | Oral         | 10 Df Total        |                 | Not Reported |
|                                                                        | Lorazepam        |              |            | S           | Oral         | 5 Df Total         |                 | Sun          |
|                                                                        | Sodium Valproate |              |            | S           | Oral         | 2 Df Total         |                 | Not Reported |
|                                                                        | Eutirox          |              |            | C           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 09-Dec-2016              | 13014235      | EXPEDITED (15-DAY) |                    | OT              | JP-ALLERGAN-<br>1679723US |                      | 87 YR      | Female     | JPN            |

| <u>Preferred Term</u> | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Seizure               | Escitalopram Oxalate - Bp |              |            | S           | Oral         | Unk                |                 | Allergan   |

# FDA Adverse Event Reporting System

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| <u>FDA Received Date</u>                                    | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 09-Dec-2016                                                 | 13014366                  | EXPEDITED (15-DAY) |                    | HO              | IT-ALLERGAN-1679742US |                      | 79 YR           | Male         | ITA            |
| <u>Preferred Term</u>                                       | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dehydration; Diarrhoea                                      | Escitalopram Oxalate - Bp |                    |                    | S               | Oral                  |                      |                 | Allergan     |                |
|                                                             | Cardioaspirin             |                    |                    | C               | Oral                  |                      |                 | Not Reported |                |
|                                                             | Serenzase                 |                    |                    | C               |                       |                      |                 | Not Reported |                |
|                                                             | Quetiapine                |                    |                    | C               | Oral                  |                      |                 | Not Reported |                |
|                                                             | Enalapril                 |                    |                    | C               | Oral                  |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                    | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Dec-2016                                                 | 13014371                  | EXPEDITED (15-DAY) |                    | HO              | GR-ALLERGAN-1674405US |                      | 76 YR           | Male         | GRC            |
| <u>Preferred Term</u>                                       | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Benign Prostatic Hyperplasia; Urinary Retention             | Escitalopram Oxalate - Bp |                    |                    | S               | Unknown               | 10 Mg, Qd            |                 | Allergan     |                |
|                                                             | Escitalopram Oxalate - Bp |                    |                    | S               | Unknown               | 20 Mg, Qd            |                 | Allergan     |                |
| <u>FDA Received Date</u>                                    | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Dec-2016                                                 | 13014377                  | EXPEDITED (15-DAY) |                    | CA, HO          | DE-ALLERGAN-1679730US |                      | 1 DAY           | Female       | DEU            |
| <u>Preferred Term</u>                                       | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Foetal Exposure During Pregnancy; Ventricular Septal Defect | Escitalopram Oxalate - Bp |                    |                    | S               | Transplacental        | 10 Mg, Qd            |                 | Allergan     |                |
|                                                             | Thyronajod                |                    |                    | C               | Transplacental        | 50 Mg, Unk           |                 | Not Reported |                |
|                                                             | Thyronajod                |                    |                    | C               | Transplacental        | 150 Mg, Unk          |                 | Not Reported |                |
|                                                             | Folio Forte               |                    |                    | C               | Transplacental        |                      |                 | Not Reported |                |
|                                                             | Ibuprofen Lysinate        |                    |                    | C               | Transplacental        |                      |                 | Not Reported |                |
|                                                             | Paracetamol               |                    |                    | C               | Transplacental        |                      |                 | Not Reported |                |
|                                                             | Korodin                   |                    |                    | C               | Transplacental        |                      |                 | Not Reported |                |
|                                                             | Opipramol                 |                    |                    | C               | Transplacental        |                      |                 | Not Reported |                |



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| <u>FDA Received Date</u>                                                       | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
|--------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|------------------|----------------|
| 10-Dec-2016                                                                    | 13015006                 | EXPEDITED (15-DAY) |                    | CA, OT          | DE-STRIDES ARCOLAB<br>LIMITED-<br>2016SP019063  |                      |                 | Unknown          | DEU            |
| <u>Preferred Term</u>                                                          | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |
| Foetal Exposure During<br>Pregnancy; Oesophageal<br>Atresia; Premature Baby    | Mycophenolate Mofetil    |                    |                    | S               | Transplacental                                  | Unk                  |                 | Strides          |                |
|                                                                                | Escitalopram             |                    |                    | S               | Transplacental                                  | Unk                  |                 | Not Reported     |                |
|                                                                                | Zolpidem                 |                    |                    | S               | Transplacental                                  | Unk                  |                 | Not Reported     |                |
|                                                                                | Lorazepam                |                    |                    | S               | Transplacental                                  | Unk                  |                 | Not Reported     |                |
| <u>FDA Received Date</u>                                                       | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 11-Dec-2016                                                                    | 13015151                 | NON-EXPEDITED      |                    | OT              | US-<br>ELI_LILLY_AND_COMP<br>ANY-US201612001349 |                      |                 | Female           | USA            |
| <u>Preferred Term</u>                                                          | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |
| Dizziness; Drug<br>Ineffective; Fatigue;<br>Seizure; Tremor; Vision<br>Blurred | Cymbalta                 |                    |                    | S               | Oral                                            | 20 Mg, Qd            |                 | Eli Lilly And Co |                |
|                                                                                | Cymbalta                 |                    |                    | S               | Oral                                            | 30 Mg, Qd            |                 | Eli Lilly And Co |                |
|                                                                                | Duloxetine Hydrochloride |                    |                    | S               | Oral                                            | 20 Mg, Qd            |                 | Eli Lilly And Co |                |
|                                                                                | Duloxetine Hydrochloride |                    |                    | S               | Oral                                            | 30 Mg, Qd            |                 | Eli Lilly And Co |                |
|                                                                                | Lexapro                  |                    |                    | S               | Unknown                                         | Unk Unk, Unknown     |                 | Not Reported     |                |
|                                                                                | Nefazodone               |                    |                    | S               | Unknown                                         | Unk Unk, Unknown     |                 | Not Reported     |                |
|                                                                                | Ventolin /00139501/      |                    |                    | C               | Unknown                                         | Unk Unk, Unknown     |                 | Not Reported     |                |
|                                                                                | Flovent                  |                    |                    | C               | Unknown                                         | Unk Unk, Unknown     |                 | Not Reported     |                |
|                                                                                | Seasonique               |                    |                    | C               | Unknown                                         | Unk Unk, Unknown     |                 | Not Reported     |                |
| <u>FDA Received Date</u>                                                       | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 12-Dec-2016                                                                    | 12554596                 | EXPEDITED (15-DAY) |                    | HO              | PHHY2016FR094517                                |                      | 57 YR           | Female           | FRA            |
| <u>Preferred Term</u>                                                          | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |
| Abdominal Pain Upper;<br>Drug Reaction With                                    | Tegretol                 |                    |                    | S               | Oral                                            | 200 Mg, Qd           |                 | Novartis         |                |

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|                                                                                                                                                                                           |          |   |      |           |              |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|---|------|-----------|--------------|
| Eosinophilia And Systemic Symptoms; Eosinophilia; Lymphadenopathy; Lymphocyte Morphology Abnormal; Pruritus; Pyrexia; Rash Maculo-Papular; Transaminases Increased; Vulvovaginal Erythema | Seroplex | S | Oral | 20 Mg, Qd | Not Reported |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|---|------|-----------|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Dec-2016              | 12680104      | EXPEDITED (15-DAY) |                    | OT              | US-FRI-1000083397    |                      | 42 YR      | Male       | USA            |

| <u>Preferred Term</u>                                            | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Paraesthesia; Serotonin Syndrome; Wrong Patient Received Product | Escitalopram Oxalate Unk |              |            | S           | Oral         | 20 Mg, Qd          |                 | Allergan     |
|                                                                  | Escitalopram Oxalate Unk |              |            | S           |              |                    |                 | Allergan     |
|                                                                  | Benazepril               |              |            | S           |              | 20 Mg, Unk         |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Dec-2016              | 12681747      | NON-EXPEDITED    |                    |                 | US-FRI-1000082596    |                      | 67 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                             | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Gastric Disorder; Nausea; Off Label Use; Wrong Technique In Product Usage Process | Escitalopram Oxalate - Bp |              |            | S           |              | 10 Mg, Unk         |                 | Allergan     |
|                                                                                   | Cozaar                    |              |            | C           |              | Unk                |                 | Not Reported |
|                                                                                   | Hydrochlorothiazide       |              |            | C           |              | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Dec-2016              | 12681762      | NON-EXPEDITED    |                    |                 | US-FRI-1000082609    |                      |            | Female     | USA            |

| <u>Preferred Term</u>              | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|------------------------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Drug Ineffective; Feeling Abnormal | Escitalopram Oxalate Unk |              |            | S           |              | Unk                |                 | Allergan   |

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| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|--------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 12-Dec-2016                       | 12682319                 | NON-EXPEDITED             |                             |                          | US-FRI-1000083598             |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Headache                          | Escitalopram Oxalate Unk |                           |                             | S                        |                               | Unk                           |                          | Allergan            |                         |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 12-Dec-2016                       | 12682320                 | NON-EXPEDITED             |                             |                          | US-FRI-1000083184             |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Feeling Abnormal; Off Label Use   | Escitalopram Oxalate Unk |                           |                             | S                        | Oral                          | 20 Mg, Qd                     |                          | Allergan            |                         |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 12-Dec-2016                       | 12682337                 | NON-EXPEDITED             |                             |                          | US-FRI-1000082292             |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Burning Sensation                 | Lexapro                  |                           |                             | S                        |                               | Unk                           |                          | Allergan            |                         |
|                                   | Lexapro                  |                           |                             | S                        |                               | Unk                           |                          | Allergan            |                         |
|                                   | Escitalopram Oxalate Unk |                           |                             | S                        |                               | Unk                           |                          | Allergan            |                         |
|                                   | Escitalopram Oxalate Unk |                           |                             | S                        |                               | Unk                           |                          | Allergan            |                         |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 12-Dec-2016                       | 12683825                 | NON-EXPEDITED             |                             |                          | US-FRI-1000083914             |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Chest Pain                        | Escitalopram Oxalate Unk |                           |                             | S                        |                               | Unk                           |                          | Allergan            |                         |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 12-Dec-2016                       | 12683827                 | NON-EXPEDITED             |                             |                          | US-FRI-1000084123             |                               |                          | Female              | USA                     |

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| <u>Preferred Term</u>                                    | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                     | <u>Duration</u> | <u>Mfr</u>   |                |
|----------------------------------------------------------|--------------------------|------------------|--------------------|-----------------|----------------------|--------------------------------------------------------|-----------------|--------------|----------------|
| Abdominal Pain Upper;<br>Diarrhoea; Therapy<br>Cessation | Lexapro Tablets          |                  |                    | S               |                      | 10 Mg, Unk                                             |                 | Allergan     |                |
| <u>FDA Received Date</u>                                 | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Dec-2016                                              | 12684357                 | NON-EXPEDITED    |                    |                 | US-FRI-1000085417    |                                                        |                 | Female       | USA            |
| <u>Preferred Term</u>                                    | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Drug Ineffective;<br>Panic Attack               | Escitalopram Oxalate Unk |                  |                    | S               | Oral                 | 20 Mg, Qd                                              |                 | Allergan     |                |
|                                                          | Lorazepam                |                  |                    | C               |                      | Unk                                                    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                 | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Dec-2016                                              | 12684358                 | NON-EXPEDITED    |                    |                 | US-FRI-1000084567    |                                                        |                 | Female       | USA            |
| <u>Preferred Term</u>                                    | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Amnesia                                                  | Lexapro Tablets          |                  |                    | S               |                      | Unk                                                    |                 | Allergan     |                |
| <u>FDA Received Date</u>                                 | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Dec-2016                                              | 12684359                 | NON-EXPEDITED    |                    |                 | US-FRI-1000084381    |                                                        |                 | Female       | USA            |
| <u>Preferred Term</u>                                    | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness                                                | Escitalopram Oxalate Unk |                  |                    | S               | Oral                 | 10 Mg, Qd                                              |                 | Allergan     |                |
|                                                          | Sinemet                  |                  |                    | C               | Oral                 | Unk Unk, Qd                                            |                 | Not Reported |                |
|                                                          | Sinemet                  |                  |                    | C               | Oral                 | Unk Unk, Frequency<br>2,Freq_Time 4,Freq Unit<br>Hours |                 | Not Reported |                |
|                                                          | Lorazepam                |                  |                    | C               |                      | "Takes Carefully"                                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                 | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Dec-2016                                              | 12684366                 | NON-EXPEDITED    |                    |                 | US-FRI-1000085354    |                                                        |                 | Female       | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                    | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|------------------------------------------|--------------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Depression                               | Lexapro Tablets          |                  |                    | S               |                      | Unk                  |                 | Allergan     |                |
| <u>FDA Received Date</u>                 | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Dec-2016                              | 12684517                 | NON-EXPEDITED    |                    |                 | US-FRI-1000085774    |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                    | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective                         | Escitalopram Oxalate Unk |                  |                    | S               | Oral                 | 20 Mg, Qd            |                 | Allergan     |                |
|                                          | Escitalopram Oxalate Unk |                  |                    | S               |                      |                      |                 | Allergan     |                |
| <u>FDA Received Date</u>                 | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Dec-2016                              | 12685939                 | NON-EXPEDITED    |                    |                 | US-FRI-1000082799    |                      |                 | Male         | USA            |
| <u>Preferred Term</u>                    | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Insomnia; Weight Gain Poor               | Escitalopram Oxalate Unk |                  |                    | S               | Oral                 | 10 Mg, Qd            |                 | Allergan     |                |
| <u>FDA Received Date</u>                 | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Dec-2016                              | 12688931                 | NON-EXPEDITED    |                    |                 | US-FRI-1000081812    |                      | 82 YR           | Male         | USA            |
| <u>Preferred Term</u>                    | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Contusion; Hostility                     | Escitalopram Oxalate Unk |                  |                    | S               | Oral                 | 20 Mg, Qd            |                 | Allergan     |                |
|                                          | Baby Aspirin             |                  |                    | C               | Oral                 | Unk Unk, Qd          |                 | Not Reported |                |
| <u>FDA Received Date</u>                 | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Dec-2016                              | 12688935                 | NON-EXPEDITED    |                    |                 | US-FRI-1000081996    |                      | 44 YR           | Female       | USA            |
| <u>Preferred Term</u>                    | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Altered State Of Consciousness; Anxiety; | Lexapro                  |                  |                    | S               | Oral                 | 20 Mg, Qd            |                 | Allergan     |                |
| Depression; Dizziness;                   | Escitalopram Oxalate Unk |                  |                    | S               | Oral                 | 20 Mg, Qd            |                 | Allergan     |                |
| Drug Ineffective;                        | Escitalopram Oxalate Unk |                  |                    | S               |                      |                      |                 | Allergan     |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                    |                 |   |            |            |              |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|---|------------|------------|--------------|
| Dyssomnia; Energy Increased; Insomnia; Irritability; Mental Disorder; Mental Disorder; Paraesthesia; Photophobia; Post-Traumatic Stress Disorder; Psychotic Behaviour; Tremor; Withdrawal Syndrome | Lamotrigine     | C | Oral       | 100 Mg, Qd | Not Reported |
|                                                                                                                                                                                                    | Multivitamins   | C | Oral       | Unk        | Not Reported |
|                                                                                                                                                                                                    | Mepron          | C | Oral       | Unk        | Not Reported |
|                                                                                                                                                                                                    | Mepron          | C |            |            | Not Reported |
|                                                                                                                                                                                                    | Nystatin        | C | Oral       | Unk        | Not Reported |
|                                                                                                                                                                                                    | Nystatin        | C |            |            | Not Reported |
|                                                                                                                                                                                                    | Tindamax        | C | Oral       | Unk        | Not Reported |
|                                                                                                                                                                                                    | Tindamax        | C |            |            | Not Reported |
|                                                                                                                                                                                                    | Biaxin          | C | Oral       | Unk        | Not Reported |
|                                                                                                                                                                                                    | Biaxin          | C |            |            | Not Reported |
|                                                                                                                                                                                                    | Advil           | C | Oral       | Unk        | Not Reported |
|                                                                                                                                                                                                    | Cetirizine      | C | Oral       | 10 Mg, Qd  | Not Reported |
|                                                                                                                                                                                                    | Deplin          | C | Oral       | 7 Mg, Qd   | Not Reported |
|                                                                                                                                                                                                    | Diflucan        | C | Oral       | Unk        | Not Reported |
|                                                                                                                                                                                                    | Diflucan        | C |            |            | Not Reported |
|                                                                                                                                                                                                    | Methylcobalamin | C | Sublingual | Unk        | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Dec-2016              | 12690374      | NON-EXPEDITED    |                    |                 | US-FRI-1000084376    |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Hypersensitivity      | Escitalopram Oxalate Unk |              |            | S           |              | 10 Mg, Unk         |                 | Allergan   |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Dec-2016              | 12690381      | NON-EXPEDITED    |                    |                 | US-FRI-1000084013    |                      | 40 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                  | <u>Product</u>  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|----------------------------------------------------------------------------------------------------------------------------------------|-----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Anticholinergic Syndrome; Anxiety; Confusional State; Drug Withdrawal Syndrome; Flushing; Headache; Hyperacusis; Insomnia; Intentional | Lexapro Tablets |              |            | S           | Oral         | 10 Mg, Qd          |                 | Allergan   |
|                                                                                                                                        | Lexapro Tablets |              |            | S           | Oral         | 5 Mg, Qd           |                 | Allergan   |
|                                                                                                                                        | Lexapro Tablets |              |            | S           | Oral         | 7.5 Mg, Qd         |                 | Allergan   |
|                                                                                                                                        | Lexapro Tablets |              |            | S           | Oral         | 5 Mg, Qd           |                 | Allergan   |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Product Misuse; Nausea;  
Off Label Use; Pyrexia;  
Tinnitus; Visual  
Impairment

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Dec-2016              | 12690383      | NON-EXPEDITED    |                    |                 | US-FRI-1000084092    |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                                                          | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|------------------------------------------------------------------------------------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Drug Ineffective;<br>Dyspnoea; Headache; Off<br>Label Use; Pollakiuria;<br>Snoring; Somnolence | Escitalopram Oxalate Unk |              |            | S           | Oral         | 10 Mg, Qd          |                 | Allergan   |
|                                                                                                | Escitalopram Oxalate Unk |              |            | S           | Oral         | 5 Mg, Qd           |                 | Allergan   |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Dec-2016              | 12690388      | NON-EXPEDITED    |                    |                 | US-FRI-1000084100    |                      |            | Female     | USA            |

| <u>Preferred Term</u>                              | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Depressed Mood;<br>Depressed Mood; Mood<br>Altered | Lexapro                  |              |            | S           | Oral         | 10 Mg, Qd          |                 | Allergan     |
|                                                    | Lexapro                  |              |            | S           | Oral         | 20 Mg, Qd          |                 | Allergan     |
|                                                    | Lexapro                  |              |            | S           | Oral         | 10 Mg, Bid         |                 | Allergan     |
|                                                    | Lexapro                  |              |            | S           | Oral         | 10 Mg, Bid         |                 | Allergan     |
|                                                    | Lexapro                  |              |            | S           | Oral         | 20 Mg, Qd          |                 | Allergan     |
|                                                    | Lexapro                  |              |            | S           | Oral         | 10 Mg, Bid         |                 | Allergan     |
|                                                    | Escitalopram Oxalate Unk |              |            | S           | Oral         | 10 Mg, Unk         |                 | Allergan     |
|                                                    | Escitalopram Oxalate Unk |              |            | S           | Oral         | 20 Mg, Unk         |                 | Allergan     |
|                                                    | Steroids                 |              |            | C           | Oral         | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Dec-2016              | 12690396      | NON-EXPEDITED    |                    |                 | US-FRI-1000084236    |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                 |                 |   |            |          |
|-----------------------------------------------------------------------------------------------------------------|-----------------|---|------------|----------|
| Drug Titration Error; Dry Mouth; Fatigue; Feeling Abnormal; Paraesthesia; Product Dose Omission; Taste Disorder | Lexapro Tablets | S | 10 Mg, Unk | Allergan |
|                                                                                                                 | Lexapro Tablets | S | 5 Mg, Unk  | Allergan |

| <u>FDA Received Date</u> | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|--------------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 12-Dec-2016              | 12690406                 | NON-EXPEDITED    |                    |                 | US-FRI-1000083433    |                      | 61 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Lacrimation Increased    | Escitalopram Oxalate Unk |                  |                    | S               | Oral                 | 10 Mg, Unk           |                 | Allergan     |                |
|                          | Asa                      |                  |                    | C               | Oral                 | Prn                  |                 | Not Reported |                |
|                          | Ibuprofen                |                  |                    | C               | Oral                 | Prn                  |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                                              | <u>Case #</u>   | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 12-Dec-2016                                                                                                                                                           | 12690428        | NON-EXPEDITED    |                    |                 | US-FRI-1000085136    |                      | 57 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                 | <u>Product</u>  | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain Upper; Anal Incontinence; Bladder Disorder; Influenza Like Illness; Intentional Product Use Issue; Muscle Spasms; Pain In Extremity; Urinary Retention | Lexapro Tablets |                  |                    | S               | Oral                 | 10 Mg, Qd            |                 | Allergan     |                |
|                                                                                                                                                                       | Alprazolam      |                  |                    | C               | Oral                 | 1 Mg, Qid            |                 | Not Reported |                |
|                                                                                                                                                                       | Bupropion       |                  |                    | C               | Oral                 | 300 Mg, Qd           |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                  | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|-------------------------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 12-Dec-2016                                                                               | 12690804       | NON-EXPEDITED    |                    |                 | US-FRI-1000085579    |                      | 52 YR           | Male       | USA            |
| <u>Preferred Term</u>                                                                     | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Intolerance; Feeling Abnormal; Paraesthesia; Peripheral Coldness; Therapy Cessation; | Lexapro        |                  |                    | S               | Oral                 | 5 Mg, Unk            |                 | Allergan   |                |
|                                                                                           | Lexapro        |                  |                    | S               |                      |                      |                 | Allergan   |                |
|                                                                                           | Lexapro        |                  |                    | S               | Oral                 | 5 Mg, Unk            |                 | Allergan   |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                     |                          |   |      |  |            |  |              |
|---------------------|--------------------------|---|------|--|------------|--|--------------|
| Withdrawal Syndrome | Lexapro                  | S |      |  |            |  | Allergan     |
|                     | Escitalopram Oxalate Unk | S |      |  | Unk        |  | Allergan     |
|                     | Verapamil                | C | Oral |  | 40 Mg, Bid |  | Not Reported |
|                     | Verapamil                | C |      |  |            |  | Not Reported |
|                     | Verapamil                | C |      |  |            |  | Not Reported |
|                     | Lorazepam                | C | Oral |  | 0.2-1 Mg   |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------------------------------------------|----------------------|------------|------------|----------------|
| 12-Dec-2016              | 12981772      | EXPEDITED (15-DAY) |                    | HO              | LT-ORION<br>CORPORATION ORION<br>PHARMA-ESCI2016-<br>0002 |                      |            | Male       | LTU            |

| <u>Preferred Term</u>                                                                                           | <u>Product</u>                     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------|------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Asthenia; Dizziness; Gait<br>Disturbance; Nausea;<br>Product Dispensing Error;<br>Wrong Product<br>Administered | Escitalopram Orion                 |              |            | S           | Oral         | Not Used           |                 | Not Reported |
|                                                                                                                 | Entacapone (Trade Name<br>Unknown) |              |            | S           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------------------------------------|----------------------|------------|------------|----------------|
| 12-Dec-2016              | 13015724      | EXPEDITED (15-DAY) |                    | OT              | TR-MACLEODS<br>PHARMACEUTICALS<br>US LTD-<br>MAC2016004015 |                      |            | Unknown    | TUR            |

| <u>Preferred Term</u>                 | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Carcinoembryonic Antigen<br>Increased | Escitalopram Oxalate |              |            | S           | Unknown      | Unk                |                 | Macleods   |
|                                       | Escitalopram Oxalate |              |            | S           |              |                    |                 | Macleods   |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------|----------------------|------------|------------|----------------|
| 12-Dec-2016              | 13015775      | EXPEDITED (15-DAY) |                    | HO, LT, OT      | FR-AUROBINDO-AUR-<br>APL-2016-14497 |                      | 83 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                                                    | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u> |
|------------------------------------------------------------------------------------------|--------------------|--------------|------------|-------------|--------------|-----------------------------|-----------------|------------|
| Clonic Convulsion; Drug<br>Interaction; Dyspnoea;<br>Extensor Plantar<br>Response; Fall; | Escitalopram 10 Mg |              |            | S           | Unknown      | 10 Mg, Unk                  |                 | Aurobindo  |
|                                                                                          | Tramadol 100mg     |              |            | S           | Unknown      | 100 Mg, Extended<br>Release |                 | Aurobindo  |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                     |                                                                                                                            |                                      |                                                                 |     |                                                                                                              |
|---------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------|--------------------------------------|-----------------------------------------------------------------|-----|--------------------------------------------------------------------------------------------------------------|
| Musculoskeletal Stiffness;<br>Myoclonic Epilepsy;<br>Postictal State; Pyrexia;<br>Serotonin Syndrome;<br>Somnolence | Fluindione<br>Pantoprazole<br>Perindopril<br>Bisoprolol<br>Spironolactone<br>Rosuvastatin<br>Paracetamol<br><br>Furosemide | C<br>C<br>C<br>C<br>C<br>C<br>C<br>C | Unknown<br><br><br><br>Intravenous (not<br>otherwise specified) | Unk | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |
|                                                                                                                     |                                                                                                                            |                                      |                                                                 |     | Not Reported                                                                                                 |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Dec-2016              | 13015822      | EXPEDITED (15-DAY) | HO                 |                 | IT-ACCORD-046284     |                      | 45 YR      | Female     | ITA            |

| <u>Preferred Term</u>                                                  | <u>Product</u>                                        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>      | <u>Route</u>                 | <u>Dosage Text</u>                      | <u>Duration</u> | <u>Mfr</u>                                             |
|------------------------------------------------------------------------|-------------------------------------------------------|--------------|------------|------------------|------------------------------|-----------------------------------------|-----------------|--------------------------------------------------------|
| Drug Abuse; Hypotension;<br>Myoclonus; Somnolence;<br>Tremor; Vomiting | Escitalopram<br>Valproic Acid<br>Lorazepam<br>Eutirox |              |            | S<br>S<br>S<br>C | Oral<br>Oral<br>Oral<br>Oral | 10 Df Total<br>2 Df Total<br>5 Df Total |                 | Accord<br>Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------------------------|----------------------|------------|------------|----------------|
| 12-Dec-2016              | 13016669      | EXPEDITED (15-DAY) | HO                 |                 | DE-LUPIN<br>PHARMACEUTICALS<br>INC.-E2B_00006748 |                      | 21 YR      | Male       | DEU            |

| <u>Preferred Term</u> | <u>Product</u>                             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                                   |
|-----------------------|--------------------------------------------|--------------|------------|-------------|----------------------|--------------------|-----------------|----------------------------------------------|
| Circulatory Collapse  | Escitalopram<br>Escitalopram<br>Quetiapine |              |            | S<br>S<br>S | Oral<br>Oral<br>Oral |                    |                 | Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------------------------|----------------------|------------|------------|----------------|
| 12-Dec-2016              | 13016679      | EXPEDITED (15-DAY) |                    | DS, HO          | DE-LUPIN<br>PHARMACEUTICALS<br>INC.-E2B_00006756 |                      | 74 YR      | Male       | DEU            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                             |                   |   |      |              |
|-----------------------------|-------------------|---|------|--------------|
| Fall; Loss Of Consciousness | Escitalopram      | S | Oral | Not Reported |
|                             | Escitalopram      | S | Oral | Not Reported |
|                             | Olanzapine        | S | Oral | Not Reported |
|                             | Olanzapine        | S | Oral | Not Reported |
|                             | Mirtazapine       | S | Oral | Not Reported |
|                             | Tavor [Lorazepam] | S | Oral | Not Reported |
|                             | Tavor [Lorazepam] | S | Oral | Not Reported |
|                             | Tavor             | S | Oral | Not Reported |
|                             | L-Thyroxin        | C | Oral | Not Reported |
|                             | Aprovel           | C | Oral | Not Reported |
|                             | Urivesc           | C | Oral | Not Reported |
|                             | Felodipine        | C | Oral | Not Reported |
|                             | Kalium Duriles    | C | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|------------|------------|----------------|
| 12-Dec-2016              | 13016897      | EXPEDITED (15-DAY) |                    | CA, OT          | DE-AUROBINDO-AUR-APL-2016-15136 |                      | 1 DAY      | Female     | DEU            |

| <u>Preferred Term</u>                                       | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------|--------------------|--------------|------------|-------------|----------------|---------------------|-----------------|--------------|
| Foetal Exposure During Pregnancy; Ventricular Septal Defect | Escitalopram 10 Mg |              |            | S           | Transplacental | 10 Mg, Once A Day   |                 | Aurobindo    |
|                                                             | Thyronajod         |              |            | C           | Transplacental | 150 Unk, Once A Day |                 | Not Reported |
|                                                             | Folio Forte        |              |            | C           | Transplacental | 0.8 Mg, Once A Day  |                 | Not Reported |
|                                                             | Ibuprofen Lysinate |              |            | C           | Transplacental |                     |                 | Not Reported |
|                                                             | Paracetamol        |              |            | C           | Transplacental | 500 Mg, Once A Day  |                 | Not Reported |
|                                                             | Korodin /00642501/ |              |            | C           | Transplacental |                     |                 | Not Reported |
|                                                             | Opipramol          |              |            | C           | Transplacental | 50 Mg, Once A Day   |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 12-Dec-2016              | 13017964      | EXPEDITED (15-DAY) |                    | HO              | FR-JNJFOC-20161207503 |                      | 75 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                              |                    |   |      |              |
|------------------------------|--------------------|---|------|--------------|
| Cerebellar Haemorrhage;      | Imbruvica          | S | Oral | Not Reported |
| Craniocerebral Injury;       | Pantoprazole       | S | Oral | Not Reported |
| Dizziness; Fall; Orthostatic | Losartan Potassium | S | Oral | Not Reported |
| Hypotension                  | Seroplex           | S | Oral | Not Reported |
|                              | Cordarone          | S | Oral | Not Reported |
|                              | Zelitrex           | S | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Dec-2016              | 13018188      | EXPEDITED (15-DAY) |                    | HO              | IT-TEVA-717784ACC    |                      | 45 YR      | Male       | ITA            |

| <u>Preferred Term</u>                                      | <u>Product</u>                                            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------|-----------------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Intentional Product Misuse; Intentional Self-Injury; Sopor | Escitalopram Oxalate                                      |              |            | S           | Oral         | 30 MI Total        |                 | Ivax         |
|                                                            | Bentelan -1 Mg Compresse Effervescenti                    |              |            | S           | Oral         | 10 Mg Total        |                 | Not Reported |
|                                                            | Anafranil - Sigma-Tau Industrie Farmaceutiche Riunite Spa |              |            | S           | Oral         | 20 Df Total        |                 | Not Reported |
|                                                            | Levoxacin - Glaxosmithkline S.P.A.                        |              |            | S           | Oral         | 5 Df Total         |                 | Not Reported |
|                                                            | Lortaan - Msd Italia S.R.L.                               |              |            | S           | Oral         | 28 Df Total        |                 | Not Reported |
|                                                            | Zolpidem Tartrate                                         |              |            | S           | Oral         | 30 MI Total        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Dec-2016              | 13018985      | EXPEDITED (15-DAY) |                    | HO              | IT-TEVA-717792ACC    |                      | 45 YR      | Female     | ITA            |

| <u>Preferred Term</u>                                            | <u>Product</u>   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------|------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Abuse; Hypotension; Myoclonus; Somnolence; Tremor; Vomiting | Valproate Sodium |              |            | S           | Oral         | 2 Df Total         |                 | Not Reported |
|                                                                  | Lorazepam        |              |            | S           | Oral         | 5 Df Total         |                 | Actavis      |
|                                                                  | Escitalopram     |              |            | S           | Oral         | 10 Df Total        |                 | Not Reported |
|                                                                  | Eutirox          |              |            | C           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Dec-2016              | 13020187      | EXPEDITED (15-DAY) |                    | CA              | DE-TEVA-716197GER    |                      | 1 DAY      | Female     | DEU            |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                       | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|---------------------------------------------|-------------------------------------|-----------------|--------------|----------------|
| Foetal Exposure During Pregnancy; Ventricular Septal Defect | Escitalopram              |                    |                    | S               | Transplacental                              | 10 Milligram Daily;                 |                 | Ivax         |                |
|                                                             | Thyronajod                |                    |                    | C               | Transplacental                              | 50 (Microg/D ) 150 (Microg/D )      |                 | Not Reported |                |
|                                                             | Folio Forte (Iodine-Free) |                    |                    | C               | Transplacental                              | .8 Milligram Daily;                 |                 | Not Reported |                |
|                                                             | Ibuprofen Lysinate        |                    |                    | C               | Transplacental                              | Twice, Dosage Unknown               |                 | Not Reported |                |
|                                                             | Paracetamol               |                    |                    | C               | Transplacental                              | 500 (Mg/D)/ 2-3 Times, If Necessary |                 | Not Reported |                |
|                                                             | Korodin                   |                    |                    | C               | Transplacental                              | 1-3x Per Week                       |                 | Not Reported |                |
|                                                             | Opipramol                 |                    |                    | C               | Transplacental                              | 50 Milligram Daily;                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                    | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Dec-2016                                                 | 13020247                  | EXPEDITED (15-DAY) |                    | DE, HO          | CA-ALLERGAN-1679977US                       |                                     | 73 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                       | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Death                                                       | Escitalopram Oxalate - Bp |                    |                    | S               | Unknown                                     |                                     |                 | Allergan     |                |
| <u>FDA Received Date</u>                                    | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Dec-2016                                                 | 13020259                  | EXPEDITED (15-DAY) |                    | OT              | IN-ELI_LILLY_AND_COMP<br>ANY-IN201612001739 |                                     | 37 YR           | Female       | IND            |
| <u>Preferred Term</u>                                       | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain; Gastric Ph Decreased; Gastritis             | Fluoxetine Hydrochloride  |                    |                    | S               | Unknown                                     | Unk, Unknown                        |                 | Not Reported |                |
|                                                             | Escitalopram              |                    |                    | S               | Unknown                                     | Unk, Unknown                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                    | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Dec-2016                                                 | 13020626                  | NON-EXPEDITED      |                    |                 | US-ALLERGAN-1669901US                       |                                     |                 | Male         | USA            |
| <u>Preferred Term</u>                                       | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Ejaculation Disorder                                        | Lexapro                   |                    |                    | S               | Oral                                        |                                     |                 | Allergan     |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <a href="#">FDA Received Date</a>                      | <a href="#">Case #</a>    | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|--------------------------------------------------------|---------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 12-Dec-2016                                            | 13020627                  | NON-EXPEDITED             |                             |                          | US-ALLERGAN-1677976US         |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>                         | <a href="#">Product</a>   | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Hypersensitivity                                       | Escitalopram Oxalate - Bp |                           |                             | S                        |                               |                               |                          | Allergan            |                         |
| <a href="#">FDA Received Date</a>                      | <a href="#">Case #</a>    | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 12-Dec-2016                                            | 13020630                  | NON-EXPEDITED             |                             |                          | US-ALLERGAN-1674900US         |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>                         | <a href="#">Product</a>   | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Chills; Nausea                                         | Escitalopram Oxalate Unk  |                           |                             | S                        |                               | 5 Mg, Qhs                     |                          | Allergan            |                         |
| <a href="#">FDA Received Date</a>                      | <a href="#">Case #</a>    | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 12-Dec-2016                                            | 13020631                  | NON-EXPEDITED             |                             |                          | US-ALLERGAN-1677930US         |                               | 31 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                         | <a href="#">Product</a>   | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Vomiting                                               | Escitalopram Oxalate - Bp |                           |                             | S                        | Unknown                       |                               |                          | Allergan            |                         |
| <a href="#">FDA Received Date</a>                      | <a href="#">Case #</a>    | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 12-Dec-2016                                            | 13020632                  | EXPEDITED (15-DAY)        |                             | OT                       | DK-ALLERGAN-1000085293        |                               | 29 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                         | <a href="#">Product</a>   | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Product Use In Unapproved Indication; Weight Increased | Escitalopram Oxalate Unk  |                           |                             | S                        | Unknown                       | Unk                           |                          | Allergan            |                         |
|                                                        | Xenazine                  |                           |                             | S                        | Oral                          | 25 Mg, Tid                    |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                      | <a href="#">Case #</a>    | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 12-Dec-2016                                            | 13020637                  | NON-EXPEDITED             |                             |                          | US-FRI-1000085575             |                               |                          | Male                | USA                     |
| <a href="#">Preferred Term</a>                         | <a href="#">Product</a>   | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Rash                                                   | Lexapro                   |                           |                             | S                        | Oral                          | Unk                           |                          | Allergan            |                         |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                    | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|------------------------|----------------------|-----------------|--------------|----------------|
| 12-Dec-2016                                                                 | 13020638                 | NON-EXPEDITED      |                    |                 | US-ALLERGAN-1000085040 |                      | 73 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                       | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Arthritis; Insomnia; Musculoskeletal Pain; Off Label Use; Pain; Pain In Jaw | Armour Thyroid 15 Mg     |                    |                    | S               | Oral                   | 30 Mg, Qod           |                 | Allergan     |                |
|                                                                             | Armour Thyroid 15 Mg     |                    |                    | S               | Oral                   | 60 Mg, Qod           |                 | Allergan     |                |
|                                                                             | Escitalopram Oxalate Unk |                    |                    | S               |                        | Unk                  |                 | Allergan     |                |
| <u>FDA Received Date</u>                                                    | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Dec-2016                                                                 | 13020639                 | NON-EXPEDITED      |                    |                 | US-ALLERGAN-1000087482 |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                       | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Expired Product Administered; Nervousness                                   | Escitalopram Oxalate Unk |                    |                    | S               | Oral                   | 10 Mg, Qd            |                 | Allergan     |                |
|                                                                             | Escitalopram Oxalate Unk |                    |                    | S               |                        |                      |                 | Allergan     |                |
| <u>FDA Received Date</u>                                                    | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Dec-2016                                                                 | 13020640                 | EXPEDITED (15-DAY) |                    | OT              | DK-ALLERGAN-1000086504 |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                       | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Nausea; Serotonin Syndrome                                                  | Escitalopram Oxalate Unk |                    |                    | S               | Oral                   | 10 Mg, Unk           |                 | Allergan     |                |
|                                                                             | Trintellix               |                    |                    | S               | Oral                   | 5 Mg, Qd             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                    | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Dec-2016                                                                 | 13020641                 | NON-EXPEDITED      |                    |                 | US-ALLERGAN-1674005US  |                      |                 | Male         | USA            |
| <u>Preferred Term</u>                                                       | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective; Drug Metabolising Enzyme Decreased; Off Label Use         | Escitalopram Oxalate Unk |                    |                    | S               | Unknown                | Unk                  |                 | Allergan     |                |
|                                                                             | Pristiq                  |                    |                    | C               | Oral                   | 25 Mg, Qd            |                 | Not Reported |                |
|                                                                             | Pristiq                  |                    |                    | C               | Oral                   | 50 Mg, Qd            |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                 |   |         |                     |              |
|-----------------|---|---------|---------------------|--------------|
| Methylphenidate | C | Unknown | 5 Mg, Qam           | Not Reported |
| Methylphenidate | C | Unknown | 36 Mg, Qam          | Not Reported |
| Hgh             | C | Unknown | 1.4 Unspecified, Qd | Not Reported |
| Trazodone       | C | Unknown | 50 Mg, Qhs          | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Dec-2016              | 13020643      | NON-EXPEDITED    |                    |                 | US-FRI-1000082821    |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Anxiety; Dizziness; Drug Ineffective; Irritability; Restlessness | Lexapro        |              |            | S           | Oral         | 1mg/ML             |                 | Allergan   |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------|----------------------|------------|------------|----------------|
| 12-Dec-2016              | 13020644      | EXPEDITED (15-DAY) |                    | HO              | DK-ALLERGAN-1000079019 |                      | 43 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety               | Lexapro Tablets |              |            | S           | Oral         | 20 Mg, Unk         |                 | Allergan     |
|                       | Luaf41156       |              |            | S           | Oral         | 3 Mg, Qd           |                 | Not Reported |
|                       | Estradiol Unk   |              |            | C           | Oral         | 2 Mg, Unk          |                 | Allergan     |
|                       | Maxzide         |              |            | C           | Oral         | 37.5/25 Mg         |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 12-Dec-2016              | 13020875      | EXPEDITED (15-DAY) |                    | HO              | IT-ALLERGAN-1679953US |                      | 60 YR      | Female     | ITA            |

| <u>Preferred Term</u>          | <u>Product</u>                                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------|------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Abuse; Overdose; Vomiting | Escitalopram Oxalate - Bp                      |              |            | S           | Unknown      | 49 Df, Unk         |                 | Allergan     |
|                                | Co Efferalgan/ Paracetamol + Codeine Phosphate |              |            | S           | Unknown      | 24 Df, Unk         |                 | Not Reported |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u>               | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|-----------------------------|------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 13-Dec-2016              | 11916951                    | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2015465806 |                      | 64 YR           | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u>              | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity    | Neurontin                   |                  |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                          | Lyrica                      |                  |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                          | Lipitor                     |                  |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                          | Nifedipine                  |                  |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                          | Cymbalta                    |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                          | Crestor                     |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                          | Lexapro                     |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                          | Toprol                      |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                          | Fish Oil                    |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                          | Iberet                      |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                          | Teva                        |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                          | Alendronate/Cholecalciferol |                  |                    |                 |                          |                      |                 |              |                |

| <u>FDA Received Date</u>                     | <u>Case #</u>    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|----------------------------------------------|------------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|----------------------|----------------|
| 13-Dec-2016                                  | 12550663         | EXPEDITED (15-DAY) |                    | OT              | CH-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-053945 |                      | 27 YR           | Male                 | CHE            |
| <u>Preferred Term</u>                        | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Anxiety; Suicidal Ideation; Weight Increased | Abilify          |                    |                    | S               | Oral                                            | 15 Mg, Unk           |                 | Bristol Myers Squibb |                |
|                                              | Escitalopram     |                    |                    | S               | Unknown                                         | Unk                  |                 | Not Reported         |                |
|                                              | Zuclopenthixol   |                    |                    | S               | Intramuscular                                   | Unk                  |                 | Not Reported         |                |
|                                              | Zuclopenthixol   |                    |                    | S               | Intramuscular                                   | Unk                  |                 | Not Reported         |                |
|                                              | Abilify Maintena |                    |                    | S               | Intramuscular                                   | Unk                  |                 | Not Reported         |                |
|                                              | Risperidone      |                    |                    | S               | Unknown                                         | Unk                  |                 | Not Reported         |                |
|                                              | Olanzapine       |                    |                    | S               | Intramuscular                                   | Unk                  |                 | Not Reported         |                |
|                                              | Haloperidol      |                    |                    | S               | Intramuscular                                   | Unk                  |                 | Not Reported         |                |

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|  |              |   |         |             |              |
|--|--------------|---|---------|-------------|--------------|
|  | Paliperidone | S | Oral    | Unk         | Not Reported |
|  | Paliperidone | S | Unknown |             | Not Reported |
|  | Paliperidone | S | Unknown | Unk         | Not Reported |
|  | Clozapine    | S | Unknown | 100 Mg, Bid | Not Reported |
|  | Fluvoxamine  | S | Unknown | 50 Mg, Unk  | Not Reported |
|  | Lorazepam    | C | Unknown | 4 Mg, Unk   | Not Reported |
|  | Lorazepam    | C | Unknown | 2 Mg, Unk   | Not Reported |

| <u>FDA Received Date</u>                                                                 | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 13-Dec-2016                                                                              | 12923023                  | EXPEDITED (15-DAY) |                    | HO              | JP-ALLERGAN-1675185US |                      | 1 DAY           | Male         | JPN            |
| <u>Preferred Term</u>                                                                    | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Hair Colour Changes | Escitalopram Oxalate - Bp |                    |                    | S               | Transplacental        | 10 Mg, Qd            |                 | Allergan     |                |
|                                                                                          | Escitalopram Oxalate - Bp |                    |                    | S               | Transplacental        | 20 Mg, Qd            |                 | Allergan     |                |
|                                                                                          | Wypax                     |                    |                    | C               | Transplacental        | 1.5 Mg, Qd           |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|--------------------------|-----------------|--------------|----------------|
| 13-Dec-2016                                                                                         | 12989941       | EXPEDITED (15-DAY) |                    | HO              | PHHY2016LT164547     |                          |                 | Male         | LTU            |
| <u>Preferred Term</u>                                                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Dizziness; Gait Disturbance; Nausea; Product Dispensing Error; Wrong Product Administered | Entacapone     |                    |                    | S               | Unknown              | 200 Mg, Qd,For Some Time |                 | Novartis     |                |
|                                                                                                     | Escitalopram   |                    |                    | S               | Oral                 | Not Used                 |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 13-Dec-2016              | 13021400       | EXPEDITED (15-DAY) |                    | OT              | IT-ACCORD-046272     |                      | 25 YR           | Female     | ITA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Abuse; Sopor        | Escitalopram   |                    |                    | S               | Oral                 |                      |                 | Accord     |                |

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| Delorazepam                                                                                |                                       |                    |                    | S               | Oral                                           |                                                    |                 |              | Not Reported   |
|--------------------------------------------------------------------------------------------|---------------------------------------|--------------------|--------------------|-----------------|------------------------------------------------|----------------------------------------------------|-----------------|--------------|----------------|
| <u>FDA Received Date</u>                                                                   | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u>                               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Dec-2016                                                                                | 13021421                              | EXPEDITED (15-DAY) |                    | HO              | IT-ACCORD-046276                               |                                                    | 45 YR           | Male         | ITA            |
| <u>Preferred Term</u>                                                                      | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>                                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Overdose;<br>Intentional Product<br>Misuse; Intentional Self-<br>Injury; Sopor | Escitalopram                          |                    |                    | S               | Oral                                           | 30 MI Total                                        |                 | Accord       |                |
|                                                                                            | Bentelan                              |                    |                    | S               | Oral                                           | 10 Mg Total Strength: 1<br>Mg Effervescent Tablets |                 | Not Reported |                |
|                                                                                            | Anafranil Sigma-Tau Industrie         |                    |                    | S               | Oral                                           | 20 Df Total                                        |                 | Sigma Tau    |                |
|                                                                                            | Farmaceutiche Riunite Spa             |                    |                    | S               | Oral                                           | 5 Df Total                                         |                 | Not Reported |                |
|                                                                                            | Levoxacin - Glaxosmithkline<br>S.P.A. |                    |                    | S               | Oral                                           | 28 Df Total                                        |                 | Not Reported |                |
|                                                                                            | Lortaan - Msd Italia S.R.L.           |                    |                    | S               | Oral                                           | 30 MI Total                                        |                 | Not Reported |                |
|                                                                                            | Zolpidem                              |                    |                    | S               | Oral                                           |                                                    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                   | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u>                               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Dec-2016                                                                                | 13021458                              | EXPEDITED (15-DAY) |                    | OT              | IN-LUPIN<br>PHARMACEUTICALS<br>INC.-2016-05442 |                                                    | 37 YR           | Female       | IND            |
| <u>Preferred Term</u>                                                                      | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>                                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain;<br>Dyspepsia; Gastritis                                                    | Escitalopram                          |                    |                    | S               | Unknown                                        |                                                    |                 | Not Reported |                |
|                                                                                            | Fluoxetine                            |                    |                    | S               | Unknown                                        |                                                    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                   | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u>                               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Dec-2016                                                                                | 13023308                              | EXPEDITED (15-DAY) |                    | LT              | FR-ALLERGAN-<br>1680129US                      |                                                    | 31 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                      | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>                                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Anaphylactic Reaction                                                                      | Escitalopram Oxalate - Bp             |                    |                    | S               | Oral                                           | 3 Mg, Single                                       |                 | Allergan     |                |
| <u>FDA Received Date</u>                                                                   | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u>                               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Dec-2016                                                                                | 13025797                              | EXPEDITED (15-DAY) |                    | HO              | IT-AUROBINDO-AUR-<br>APL-2016-15216            |                                                    | 79 YR           | Male         | ITA            |

# FDA Adverse Event Reporting System

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### Detailed Report

| <u>Preferred Term</u>    | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|--------------------------|----------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Dehydration; Diarrhoea   | Escitalopram Film-Coated Tablets |                    |                    | S               | Oral                 | 10 Mg, Daily         |                 | Aurobindo    |                |
|                          | Cardioaspirin                    |                    |                    | C               | Oral                 | Unk                  |                 | Not Reported |                |
|                          | Serenase /00027401/              |                    |                    | C               | Oral                 | Unk                  |                 | Not Reported |                |
|                          | Quetiapine                       |                    |                    | C               | Oral                 | 25 Mg, Unk           |                 | Not Reported |                |
|                          | Enalapril                        |                    |                    | C               | Oral                 | 20 Mg, Unk           |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Dec-2016              | 13026811                         | DIRECT             | Y                  | LT              |                      |                      | 29 YR           | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Suicide Attempt          | Escitalopram                     |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Dec-2016              | 13027158                         | EXPEDITED (15-DAY) |                    | HO              | IT-TEVA-718854ACC    |                      | 79 YR           | Male         | ITA            |
| <u>Preferred Term</u>    | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dehydration; Diarrhoea   | Escitalopram Oxalate             |                    |                    | S               | Oral                 |                      |                 | Ivax         |                |
|                          | Cardioaspirin                    |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |
|                          | Serenase (Haloperidol)           |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |
|                          | Quetiapine                       |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |
|                          | Enalapril                        |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Dec-2016              | 13029471                         | EXPEDITED (15-DAY) |                    | HO              | IT-ACCORD-046410     |                      | 79 YR           | Male         | ITA            |
| <u>Preferred Term</u>    | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dehydration; Diarrhoea   | Escitalopram                     |                    |                    | S               | Oral                 | Escitalopram Oxalate |                 | Accord       |                |
|                          | Cardioaspirin                    |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |

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|                                |   |      |              |
|--------------------------------|---|------|--------------|
| Serenase (Haloperidol)         | C | Oral | Not Reported |
| Quetiapine/Quetiapine Fumarate | C | Oral | Not Reported |
| Enalapril                      | C | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Dec-2016              | 13030120      | EXPEDITED (15-DAY) |                    | HO              | PHHY2016FR170380     |                      | 76 YR      | Male       | FRA            |

| <u>Preferred Term</u>         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                             | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------|----------------|--------------|------------|-------------|--------------|----------------------------------------------------------------|-----------------|--------------|
| Aggression; Confusional State | Stalevo        |              |            | S           | Oral         | 3 Df, Qd (Entacapone 100 Mg, Levodopa 25 Mg, Carbidopa 200 Mg) |                 | Novartis     |
|                               | Mantadix       |              |            | S           | Oral         | 1 Df, Qd                                                       |                 | Not Reported |
|                               | Azilect        |              |            | S           | Oral         | 1 Df, Qd                                                       |                 | Not Reported |
|                               | Escitalopram   |              |            | S           | Oral         | 1 Df, Qd                                                       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------------|----------------------|------------|------------|----------------|
| 15-Dec-2016              | 13031218      | EXPEDITED (15-DAY) |                    | HO, OT          | FR-GLAXOSMITHKLINE-FR2016GSK182461 |                      | 75 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|-----------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Cerebellar Haemorrhage; Craniocerebral Injury; Dizziness; Fall; Orthostatic Hypotension | Zelitrex       |              |            | S           | Oral         | 1000 Mg, Qd        |                 | Glaxosmithkline |
|                                                                                         | Pantoprazole   |              |            | S           | Oral         | 40 Mg, Qd          |                 | Glaxosmithkline |
|                                                                                         | Losartan       |              |            | S           | Oral         | 50 Mg, Qd          |                 | Glaxosmithkline |
|                                                                                         | Seroplex       |              |            | S           | Oral         | 20 Mg, Qd          |                 | Glaxosmithkline |
|                                                                                         | Cordarone      |              |            | S           | Oral         | 200 Mg, Qd         |                 | Not Reported    |
|                                                                                         | Imbruvica      |              |            | S           | Oral         | 420 Mg, Qd         |                 | Not Reported    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Dec-2016              | 12569926      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000086191    |                      | 57 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                                                                                   |                           |   |      |            |              |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|---|------|------------|--------------|
| Abdominal Pain Upper;<br>Drug Reaction With<br>Eosinophilia And Systemic<br>Symptoms; Eosinophilia;<br>Lymphadenopathy;<br>Lymphocyte Morphology<br>Abnormal; Pruritus;<br>Pyrexia; Rash Maculo-<br>Papular; Transaminases<br>Increased; Vulvovaginal<br>Erythema | Escitalopram Oxalate - Bp | S | Oral | 20 Mg, Qd  | Allergan     |
|                                                                                                                                                                                                                                                                   | Tegretol                  | S | Oral | 200 Mg, Qd | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 16-Dec-2016              | 12994718      | EXPEDITED (15-DAY) |                    | OT              | FR-ALLERGAN-<br>1678850US |                      | 75 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                 | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Breast Cancer;<br>Contraindicated Product<br>Administered; Depression | Escitalopram Oxalate - Bp |              |            | S           | Oral         |                    |                 | Allergan     |
|                                                                       | Tamoxifene                |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                       | Femara                    |              |            | S           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 16-Dec-2016              | 13013440      | EXPEDITED (15-DAY) |                    | DE, OT          | US-PFIZER INC-<br>2016569034 |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                             | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------|----------------------|--------------|------------|-------------|------------------------------------------|--------------------|-----------------|--------------|
| Cardiopulmonary Failure;<br>Cervix Cancer Metastatic | Pantoprazole         |              |            | S           | Unknown                                  | Unk                |                 | Pfizer       |
|                                                      | Estradiol            |              |            | S           | Unknown                                  | Unk                |                 | Pfizer       |
|                                                      | Metoclopramide Hcl   |              |            | S           | Unknown                                  | Unk                |                 | Pfizer       |
|                                                      | Ondansetron          |              |            | S           | Unknown                                  | Unk                |                 | Pfizer       |
|                                                      | Morphine Sulfate     |              |            | S           | Unknown                                  | Unk                |                 | Pfizer       |
|                                                      | Escitalopram Oxalate |              |            | S           | Unknown                                  | Unk                |                 | Not Reported |
|                                                      | Oxycodone Hcl        |              |            | S           | Unknown                                  | Unk                |                 | Not Reported |
|                                                      | Pembrolizumab        |              |            | S           | Intravenous (not<br>otherwise specified) | 200 Mg, Q3weeks    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                         |                                                   | Buspirone                 | S                  | Unknown         | Unk                                      |                      |                 | Not Reported |                |
|-----------------------------------------------------------------------------------------|---------------------------------------------------|---------------------------|--------------------|-----------------|------------------------------------------|----------------------|-----------------|--------------|----------------|
|                                                                                         |                                                   | Polyethylene Glycol       | S                  | Unknown         | Unk                                      |                      |                 | Not Reported |                |
|                                                                                         |                                                   | Hyoscyamine Sulfate       | S                  | Unknown         | Unk                                      |                      |                 | Not Reported |                |
|                                                                                         |                                                   | Carboplatin W/Gemcitabine | S                  | Unknown         | Unk                                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                | <u>Case #</u>                                     | <u>Case Type</u>          | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Dec-2016                                                                             | 13033940                                          | EXPEDITED (15-DAY)        |                    | HO, OT          | DE-HETERO LABS LTD-1060895               |                      | 21 YR           | Male         | DEU            |
| <u>Preferred Term</u>                                                                   | <u>Product</u>                                    | <u>Comp.</u>              | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Circulatory Collapse                                                                    | Escitalopram                                      |                           |                    | S               | Oral                                     |                      |                 | Hetero       |                |
|                                                                                         | Quetiapine Fumarate                               |                           |                    | S               | Oral                                     |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                | <u>Case #</u>                                     | <u>Case Type</u>          | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Dec-2016                                                                             | 13034030                                          | EXPEDITED (15-DAY)        |                    | DE, HO, LT      | FR-LUPIN PHARMACEUTICALS INC.-2016-05547 |                      | 63 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                   | <u>Product</u>                                    | <u>Comp.</u>              | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bezoar; Overdose; Toxicity To Various Agents                                            | Sevikar                                           |                           |                    | S               | Unknown                                  | 129 Units            |                 | Not Reported |                |
|                                                                                         | Atarax                                            |                           |                    | S               | Unknown                                  | 28 Tablets           |                 | Not Reported |                |
|                                                                                         | Lysanxia                                          |                           |                    | S               | Unknown                                  | 42 Tablets           |                 | Not Reported |                |
|                                                                                         | Escitalopram                                      |                           |                    | S               | Unknown                                  | 28 Tablet            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                | <u>Case #</u>                                     | <u>Case Type</u>          | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Dec-2016                                                                             | 13035234                                          | EXPEDITED (15-DAY)        |                    | HO, OT          | FR-009507513-1612FRA006256               |                      | 75 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                   | <u>Product</u>                                    | <u>Comp.</u>              | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cerebellar Haemorrhage; Craniocerebral Injury; Dizziness; Fall; Orthostatic Hypotension | Losartan Zentiva 50mg, Comprimé Pelliculé Sécable |                           |                    | S               | Oral                                     | 50 Mg, Qd            |                 | Merck        |                |
|                                                                                         | Pantoprazole                                      |                           |                    | S               | Oral                                     | 40 Mg, Qd            |                 | Not Reported |                |
|                                                                                         | Cordarone                                         |                           |                    | S               | Oral                                     | 200 Mg, Qd           |                 | Not Reported |                |
|                                                                                         | Seroplex                                          |                           |                    | S               | Oral                                     | 20 Mg, Qd            |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|           |   |      |             |              |
|-----------|---|------|-------------|--------------|
| Zelitrex  | S | Oral | Unk Unk, Qd | Not Reported |
| Imbruvica | S | Oral | 420 Mg, Qd  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 16-Dec-2016              | 13035903      | EXPEDITED (15-DAY) | HO                 |                 | CH-ALLERGAN-1680890US |                      | 94 YR      | Male       | CHE            |

| <u>Preferred Term</u>                                           | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------|-------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Haemoglobin Decreased;<br>Upper Gastrointestinal<br>Haemorrhage | Escitalopram Oxalate - Bp     |              |            | S           | Unknown      | 10 Mg, Qd          |                 | Allergan     |
|                                                                 | Xarelto                       |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                 | Xarelto                       |              |            | S           |              |                    |                 | Not Reported |
|                                                                 | Aspirin Cardio 100            |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                 | Casodex                       |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                 | Casodex                       |              |            | S           |              |                    |                 | Not Reported |
|                                                                 | Novalgine (Metamizole Sodium) |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                 | Pantoprazol                   |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                 | Macrogol                      |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                 | Calcium D3                    |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                 | Torem                         |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                 | Micardis                      |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                 | Dafalgan                      |              |            | C           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 16-Dec-2016              | 13036405      | EXPEDITED (15-DAY) | HO                 |                 | JP-ALLERGAN-1680694US |                      | 35 YR      | Female     | JPN            |

| <u>Preferred Term</u>                    | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Overdose; Somnolence;<br>Suicide Attempt | Escitalopram Oxalate - Bp |              |            | S           | Oral         | Unk Unk, Qd        |                 | Allergan     |
|                                          | Escitalopram Oxalate - Bp |              |            | S           | Oral         | Overdose           |                 | Allergan     |
|                                          | Alprazolam                |              |            | S           | Oral         | Overdose           |                 | Not Reported |
|                                          | Norvasc                   |              |            | S           | Oral         | Overdose           |                 | Not Reported |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                      | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| 16-Dec-2016                                                                                                   | 13036433                  | EXPEDITED (15-DAY) |                    | HO              | FR-ALLERGAN-1680897US      |                      | 75 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                         | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cerebellar Haemorrhage;<br>Craniocerebral Injury;<br>Dizziness; Face Injury;<br>Fall; Orthostatic Hypotension | Escitalopram Oxalate - Bp |                    |                    | S               | Oral                       | 20 Mg, Qd            |                 | Allergan     |                |
|                                                                                                               | Pantoprazole              |                    |                    | S               | Oral                       | 40 Mg, Qd            |                 | Not Reported |                |
|                                                                                                               | Losartan Potassique       |                    |                    | S               | Oral                       | 50 Mg, Qd            |                 | Not Reported |                |
|                                                                                                               | Cordarone                 |                    |                    | S               | Oral                       | 200 Mg, Qd           |                 | Not Reported |                |
|                                                                                                               | Zelitrex                  |                    |                    | S               | Oral                       | 1000 Mg, Qd          |                 | Not Reported |                |
|                                                                                                               | Imbruvica                 |                    |                    | S               | Oral                       | 420 Mg, Qd           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                      | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Dec-2016                                                                                                   | 13036479                  | EXPEDITED (15-DAY) |                    | HO              | CA-ALLERGAN-1680900US      |                      | 65 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                                                                         | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hospitalisation                                                                                               | Escitalopram Oxalate - Bp |                    |                    | S               |                            | 20 Mg, Unknown       |                 | Allergan     |                |
| <u>FDA Received Date</u>                                                                                      | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Dec-2016                                                                                                   | 13037505                  | EXPEDITED (15-DAY) |                    | CA              | DE-HETERO LABS LTD-1060935 |                      | 1 DAY           | Female       | DEU            |
| <u>Preferred Term</u>                                                                                         | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Foetal Exposure During Pregnancy; Ventricular Septal Defect                                                   | Escitalopram              |                    |                    | S               |                            |                      |                 | Hetero       |                |
|                                                                                                               | Thyronajod                |                    |                    | C               |                            |                      |                 | Not Reported |                |
|                                                                                                               | Folio Forte               |                    |                    | C               | Transplacental             |                      |                 | Not Reported |                |
|                                                                                                               | Ibuprofen Lysinate        |                    |                    | C               | Transplacental             |                      |                 | Not Reported |                |
|                                                                                                               | Paracetamol               |                    |                    | C               |                            |                      |                 | Not Reported |                |
|                                                                                                               | Korodin                   |                    |                    | C               | Transplacental             |                      |                 | Not Reported |                |
|                                                                                                               | Opipramol                 |                    |                    | C               | Transplacental             |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                 | <u>Case #</u>   | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                               | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                 | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|------------------|--------------------|-----------------|----------------------------------------------------|----------------------|-----------------|----------------------------|----------------|
| 17-Dec-2016                                                                                                                                                                                              | 13037733        | NON-EXPEDITED    |                    |                 | US-PRINSTON<br>PHARMACEUTICAL<br>INC.-2016PRN00278 |                      |                 | Female                     | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                    | <u>Product</u>  | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                       | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                 |                |
| Feeling Abnormal;<br>Intentional Product Use<br>Issue; Therapeutic<br>Product Effect Incomplete                                                                                                          | Escitalopram    |                  |                    | S               |                                                    | 10 Mg, Unk           |                 | Prinston<br>Pharmaceutical |                |
|                                                                                                                                                                                                          | Escitalopram    |                  |                    | S               |                                                    | 20 Mg, Unk           |                 | Prinston<br>Pharmaceutical |                |
|                                                                                                                                                                                                          | Escitalopram    |                  |                    | S               |                                                    | 30 Mg, Unk           |                 | Prinston<br>Pharmaceutical |                |
|                                                                                                                                                                                                          | Wellbutrin      |                  |                    | S               |                                                    |                      |                 | Not Reported               |                |
| <u>FDA Received Date</u>                                                                                                                                                                                 | <u>Case #</u>   | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                               | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                 | <u>Country</u> |
| 17-Dec-2016                                                                                                                                                                                              | 13040315        | DIRECT           | Y                  | HO, RI          |                                                    |                      | 37 YR           | Male                       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                    | <u>Product</u>  | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                       | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                 |                |
| Anxiety; Confusional<br>State; Depression;<br>Diarrhoea; Dizziness;<br>Headache; Hot Flush;<br>Hypertension; Irritability;<br>Nausea; Serotonin<br>Syndrome; Vision Blurred;<br>Vision Blurred; Vomiting | Tramadol        |                  |                    | S               | Oral                                               |                      |                 | Not Reported               |                |
|                                                                                                                                                                                                          | Escitalopram    |                  |                    | S               | Oral                                               |                      |                 | Not Reported               |                |
| <u>FDA Received Date</u>                                                                                                                                                                                 | <u>Case #</u>   | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                               | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                 | <u>Country</u> |
| 19-Dec-2016                                                                                                                                                                                              | 13038223        | NON-EXPEDITED    |                    |                 | US-AUROBINDO-AUR-<br>APL-2016-02692                |                      |                 | Male                       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                    | <u>Product</u>  | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                       | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                 |                |
| Gynaecomastia                                                                                                                                                                                            | Finasteride 5mg |                  |                    | S               | Oral                                               | Unk                  |                 | Aurobindo                  |                |
|                                                                                                                                                                                                          | Lexapro         |                  |                    | S               | Oral                                               | 5 Mg, Once A Day     |                 | Not Reported               |                |
|                                                                                                                                                                                                          | Lexapro         |                  |                    | S               | Oral                                               | 10 Mg, Once A Day    |                 | Not Reported               |                |
|                                                                                                                                                                                                          | Lexapro         |                  |                    | S               | Oral                                               | 5 Mg, Once A Day     |                 | Not Reported               |                |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                   |   |         |                        |              |
|-------------------|---|---------|------------------------|--------------|
| Spironolactone    | S | Oral    | 25 Mg, Once A Day      | Not Reported |
| Vitamin D3        | C | Unknown |                        | Not Reported |
| Lisinopril        | C | Oral    | 2.5 Mg, Every 12 Hours | Not Reported |
| Imdur             | C | Oral    | 30 Mg, Unk             | Not Reported |
| Lasix /00032601/  | C | Oral    | 20 Mg, Four Times/Day  | Not Reported |
| Metropololtraat A | C | Oral    | 100 Mg, Once A Day     | Not Reported |
| Digoxin           | C | Oral    | 125 Mcg, Once A Day    | Not Reported |
| Loratadin         | C | Oral    | 10 Mg, Unk             | Not Reported |
| Simvastatin       | C | Oral    | 20 Mg, Once A Day      | Not Reported |
| Tamsulosin        | C | Oral    | 0.4 Mg, Once A Day     | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------------------------------------------|----------------------|------------|------------|----------------|
| 19-Dec-2016              | 13038691      | EXPEDITED (15-DAY) |                    | HO              | FR-ORION<br>CORPORATION ORION<br>PHARMA-ENTC2016-<br>0742 |                      | 76 YR      | Male       | FRA            |

| <u>Preferred Term</u>         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------|----------------|--------------|------------|-------------|--------------|-------------------------|-----------------|--------------|
| Aggression; Confusional State | Stalevo        |              |            | S           | Oral         | Strength: 25/100/200 Mg |                 | Not Reported |
|                               | Sifrol         |              |            | S           | Oral         | Strength: 0.52 Mg       |                 | Not Reported |
|                               | Mantadix       |              |            | S           | Oral         | Strength: 100 Mg        |                 | Not Reported |
|                               | Escitalopram   |              |            | S           | Oral         | Strength: 5 Mg          |                 | Not Reported |
|                               | Azilect        |              |            | S           | Oral         | Strength: 1 Mg          |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 19-Dec-2016              | 13042213      | NON-EXPEDITED    |                    |                 | US-PFIZER INC-<br>2016587067 |                      | 19 YR      | Male       | USA            |

| <u>Preferred Term</u>                  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------|----------------|--------------|------------|-------------|--------------|------------------------------|-----------------|--------------|
| Erectile Dysfunction; Libido Decreased | Zolof          |              |            | S           |              | Three Tablets In The Morning |                 | Pfizer       |
|                                        | Lexapro        |              |            | S           | Oral         | Unk, 1x/Day                  |                 | Not Reported |
|                                        | Oxcarbazepine  |              |            | S           |              | Unk                          |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|          |   |                                        |              |
|----------|---|----------------------------------------|--------------|
| Seroquel | S | 100 Mg Or 200 Mg Once<br>At Night Time | Not Reported |
| Benadryl | C | Unk, Once At Night                     | Not Reported |

| <u>FDA Received Date</u>   | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------|---------------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 19-Dec-2016                | 13042336                  | EXPEDITED (15-DAY) | DE                 |                 | FR-ALLERGAN-1681367US |                      | 76 YR           | Female       | FRA            |
| <u>Preferred Term</u>      | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cerebral Haematoma;        | Escitalopram Oxalate - Bp |                    |                    | S               | Oral                  |                      |                 | Allergan     |                |
| Drug Interaction; Subdural | Kardegic                  |                    |                    | S               | Oral                  | 75 Mg, Qd            |                 | Not Reported |                |
| Haematoma                  | Tahor                     |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>                 | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|-------------------------------|------------------|--------------------|-----------------|--------------------------------|----------------------|-----------------|--------------|----------------|
| 20-Dec-2016              | 13046053                      | NON-EXPEDITED    | HO                 |                 | US-DRREDDYS-USA/USA/15/0055105 |                      | 72 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>                | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Suicide Attempt          | Olanzapine Film-Coated Tablet |                  |                    | S               | Unknown                        |                      |                 | Not Reported |                |
|                          | Escitalopram                  |                  |                    | S               | Unknown                        |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
| 20-Dec-2016              | 13048168             | EXPEDITED (15-DAY) | OT                 |                 | IT-MYLANLABS-2016M1056273 |                      |                 | Unknown      | ITA            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Abuse; Poisoning;   | Simvastatin          |                    |                    | S               | Oral                      | 14 Df, Total         |                 | Not Reported |                |
| Sopor                    | Rivotril             |                    |                    | S               | Oral                      | 10 MI, Total         |                 | Mylan        |                |
|                          | Entact               |                    |                    | S               | Oral                      | 28 Df, Total         |                 | Mylan        |                |
|                          | Torvast              |                    |                    | S               | Oral                      | 8 Df, Total          |                 | Mylan        |                |
|                          | Deursil              |                    |                    | S               | Oral                      | 10 Df, Total         |                 | Mylan        |                |
|                          | Igroton              |                    |                    | S               | Oral                      | 15 Df, Total         |                 | Mylan        |                |
|                          | Acetylsalicylic Acid |                    |                    | S               | Oral                      | 20 Df, Total         |                 | Mylan        |                |

# FDA Adverse Event Reporting System

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| <u>FDA Received Date</u>                                                                                                  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|---------------------------------------------|----------------------|-----------------|------------------|----------------|
| 21-Dec-2016                                                                                                               | 11291680             | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2015242014                    |                      | 46 YR           | Female           | USA            |
| <u>Preferred Term</u>                                                                                                     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |
| Abdominal Discomfort;<br>Drug Hypersensitivity;<br>Drug Ineffective; Pruritus                                             | Effexor              |                    |                    | S               |                                             | Unk                  |                 | Pfizer           |                |
|                                                                                                                           | Zoloft               |                    |                    | S               |                                             | Unk                  |                 | Pfizer           |                |
|                                                                                                                           | Diclofenac Epolamine |                    |                    | S               |                                             | Unk                  |                 | Unknown          |                |
|                                                                                                                           | Venlafaxine Hcl      |                    |                    | S               |                                             | Unk                  |                 | Pfizer           |                |
|                                                                                                                           | Sertraline Hcl       |                    |                    | S               |                                             | Unk                  |                 | Pfizer           |                |
|                                                                                                                           | Methadone            |                    |                    | S               |                                             | Unk                  |                 | Not Reported     |                |
|                                                                                                                           | Lexapro              |                    |                    | S               |                                             | Unk                  |                 | Not Reported     |                |
|                                                                                                                           | Escitalopram Oxalate |                    |                    | S               |                                             | Unk                  |                 | Not Reported     |                |
| <u>FDA Received Date</u>                                                                                                  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 21-Dec-2016                                                                                                               | 12636816             | EXPEDITED (15-DAY) |                    | HO, OT          | FR-ELI_LILLY_AND_COMP<br>ANY-FR201608001055 |                      | 54 YR           | Male             | FRA            |
| <u>Preferred Term</u>                                                                                                     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |
| Alanine Aminotransferase<br>Increased; Aspartate<br>Aminotransferase<br>Increased; Hepatitis;<br>Hepatocellular Carcinoma | Trulicity            |                    |                    | S               | Subcutaneous                                | Unk, Weekly (1/W)    |                 | Eli Lilly And Co |                |
|                                                                                                                           | Okimus               |                    |                    | S               | Oral                                        | Unk, Unknown         |                 | Not Reported     |                |
|                                                                                                                           | Mysoline             |                    |                    | S               | Oral                                        | 125 Mg, Bid          |                 | Not Reported     |                |
|                                                                                                                           | Repaglinide          |                    |                    | S               | Oral                                        | 7 Mg, Qd             |                 | Not Reported     |                |
|                                                                                                                           | Perindopril          |                    |                    | S               | Oral                                        | 2.5 Mg, Qd           |                 | Not Reported     |                |
|                                                                                                                           | Tranxene             |                    |                    | S               | Oral                                        | 5 Mg, Qd             |                 | Not Reported     |                |
|                                                                                                                           | Escitalopram         |                    |                    | S               | Oral                                        | 5 Mg, Qd             |                 | Not Reported     |                |
|                                                                                                                           | Propranolol          |                    |                    | C               | Unknown                                     | Unk                  |                 | Not Reported     |                |
|                                                                                                                           | Stagid               |                    |                    | C               | Unknown                                     | Unk                  |                 | Not Reported     |                |
|                                                                                                                           | Lantus               |                    |                    | C               | Unknown                                     | Unk                  |                 | Not Reported     |                |
|                                                                                                                           | Omeprazole           |                    |                    | C               | Unknown                                     | Unk                  |                 | Not Reported     |                |

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| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 21-Dec-2016              | 12738629      | NON-EXPEDITED    |                    | HO              | US-PFIZER INC-2016422933 |                      | 71 YR      | Female     | USA            |

| <u>Preferred Term</u>                               | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Ineffective; Sleep Disorder; Suicidal Ideation | Zoloft                   |              |            | S           |              | Unk                |                 | Pfizer       |
|                                                     | Zoloft                   |              |            | S           |              |                    |                 | Pfizer       |
|                                                     | Ativan                   |              |            | S           |              | 1 Mg, 1x/Day       |                 | Pfizer       |
|                                                     | Ativan                   |              |            | S           |              |                    |                 | Pfizer       |
|                                                     | Buspar                   |              |            | S           |              | Unk                |                 | Not Reported |
|                                                     | Quetiapine Fumarate      |              |            | S           |              | Unk                |                 | Not Reported |
|                                                     | Quetiapine Fumarate      |              |            | S           |              |                    |                 | Not Reported |
|                                                     | Mirtazapine              |              |            | S           |              | 7.5 Mg, Unk        |                 | Not Reported |
|                                                     | Mirtazapine              |              |            | S           |              | 30 Mg, 1x/Day      |                 | Not Reported |
|                                                     | Fluoxetine Hydrochloride |              |            | S           |              | 25 Mg, 1x/Day      |                 | Not Reported |
|                                                     | Fluoxetine Hydrochloride |              |            | S           |              | 40 Mg, 1x/Day      |                 | Not Reported |
|                                                     | Fluoxetine Hydrochloride |              |            | S           |              |                    |                 | Not Reported |
|                                                     | Cymbalta                 |              |            | S           |              | Unk                |                 | Not Reported |
|                                                     | Cymbalta                 |              |            | S           |              |                    |                 | Not Reported |
|                                                     | Lexapro                  |              |            | S           |              | 10 Mg, Unk         |                 | Not Reported |
|                                                     | Lexapro                  |              |            | S           |              | 20 Mg, Unk         |                 | Not Reported |
|                                                     | Lexapro                  |              |            | S           |              | 30 Unk, Unk        |                 | Not Reported |
|                                                     | Trazodone                |              |            | C           |              | 25 Mg, 2x/Day      |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Dec-2016              | 13014865      | EXPEDITED (15-DAY) |                    | DE, HO, OT      | PHHY2016FR165138     |                      | 63 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                                                  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Acute Kidney Injury; Anuria; Bezoar; Cardiogenic Shock; Gastrointestinal Necrosis; Hyperlactacidaemia; | Zolpidem       |              |            | S           | Unknown      |                    |                 | Novartis     |
|                                                                                                        | Sevikar        |              |            | S           | Unknown      | 129 Df, Unk        |                 | Not Reported |
|                                                                                                        | Atarax         |              |            | S           | Unknown      | 28 Df, Unk         |                 | Not Reported |

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|                                                                                                                           |             |   |         |            |              |
|---------------------------------------------------------------------------------------------------------------------------|-------------|---|---------|------------|--------------|
| Intestinal Ischaemia;<br>Multiple Organ<br>Dysfunction Syndrome;<br>Toxicity To Various<br>Agents; Vasoplegia<br>Syndrome | Lysanxia    | S | Unknown | 42 Df, Unk | Not Reported |
|                                                                                                                           | Seroplex    | S | Unknown | 28 Df, Unk | Not Reported |
|                                                                                                                           | Nordiazepam | C | Unknown |            | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 21-Dec-2016              | 13030555      | EXPEDITED (15-DAY) |                    | HO, OT          | FR-PFIZER INC-<br>2016579642 |                      | 75 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                                            | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------|--------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cerebellar Haemorrhage;<br>Craniocerebral Injury;<br>Dizziness; Fall; Orthostatic<br>Hypotension | Cordarone          |              |            | S           | Oral         | 200 Mg, 1x/Day     |                 | Pfizer       |
|                                                                                                  | Pantoprazole       |              |            | S           | Oral         | 40 Mg, 1x/Day      |                 | Pfizer       |
|                                                                                                  | Losartan Potassium |              |            | S           | Oral         | 50 Mg, 1x/Day      |                 | Not Reported |
|                                                                                                  | Seroplex           |              |            | S           | Oral         | 20 Mg, 1x/Day      |                 | Not Reported |
|                                                                                                  | Zelitrex           |              |            | S           | Oral         | 1000 Mg, 1x/Day    |                 | Not Reported |
|                                                                                                  | Imbruvica          |              |            | S           | Oral         | 420 Mg, 1x/Day     |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 21-Dec-2016              | 13047381      | EXPEDITED (15-DAY) |                    | HO, LT          | US-ALLERGAN-<br>1681483US |                      | 60 YR      | Female     | USA            |

| <u>Preferred Term</u>                   | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction;<br>Serotonin Syndrome | Escitalopram Oxalate Unk |              |            | S           | Unknown      |                    |                 | Allergan     |
|                                         | Methylene Blue           |              |            | S           | Unknown      | 7.5 Mg/Kg, Unk     |                 | Not Reported |
|                                         | Isoflurane               |              |            | C           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-------------------------|----------------------|------------|------------|----------------|
| 21-Dec-2016              | 13048706      | NON-EXPEDITED    |                    | DE, HO, LT      | MX-TORRENT-<br>00000083 |                      | 81 YR      | Female     | MEX            |

| <u>Preferred Term</u>                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u> |
|--------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------------|-----------------|------------|
| Peptic Ulcer<br>Haemorrhage;<br>Thrombocytopenia | Memantine      |              |            | S           | Oral         | One 10 Mg Tablet Per Day |                 | Torrent    |
|                                                  | Donepezil      |              |            | S           | Oral         | One 10 Mg Tablet Per Day |                 | Torrent    |

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|                 |   |      |                           |         |
|-----------------|---|------|---------------------------|---------|
| Escitalopram    | S | Oral | One 10 Mg Tablet Per Day  | Torrent |
| Aspirin Protect | C |      | One 100 Mg Tablet Per Day | Bayer   |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 21-Dec-2016              | 13048755      | EXPEDITED (15-DAY) |                    | OT              | CH-AMGEN-CHESP2016177394 |                      | 74 YR      | Female     | CHE            |

| <u>Preferred Term</u>                                                       | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|-----------------------|-----------------|--------------|
| Bone Density Decreased;<br>Pelvic Fracture; Rebound Effect; Spinal Fracture | Prolia               |              |            | S           | Unknown      | 60 Mg, Q6mo           |                 | Amgen        |
|                                                                             | Prolia               |              |            | S           | Unknown      | Unk                   |                 | Amgen        |
|                                                                             | Pantoprazole Actavis |              |            | S           | Unknown      | 20 Mg, Qd             |                 | Not Reported |
|                                                                             | Cipralex             |              |            | S           | Unknown      | 10 Mg, Unk            |                 | Not Reported |
|                                                                             | Bekunis Bisacodyl    |              |            | C           |              | Unk Unk, Bid          |                 | Not Reported |
|                                                                             | Kalcipos D3          |              |            | C           |              | Unk Unk, Qd           |                 | Not Reported |
|                                                                             | Lexotanil            |              |            | C           |              | 3 Mg, Qd              |                 | Not Reported |
|                                                                             | Losartan             |              |            | C           |              | 50 Mg, Unk            |                 | Not Reported |
|                                                                             | Metoprolol           |              |            | C           |              | 50 Mg, Qd             |                 | Not Reported |
|                                                                             | Ponstan              |              |            | C           |              | Unk Unk, As Necessary |                 | Not Reported |
|                                                                             | Simvastatin          |              |            | C           |              |                       |                 | Not Reported |
|                                                                             | Targin               |              |            | C           |              | Unk Unk, Bid          |                 | Not Reported |
|                                                                             | Vi-De 3              |              |            | C           |              | 50 Drops/Qwk          |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 21-Dec-2016              | 13049216      | EXPEDITED (15-DAY) |                    | HO              | US-ALLERGAN-1680849US |                      |            | Female     | USA            |

| <u>Preferred Term</u>               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Malaise; Mania; Withdrawal Syndrome | Lexapro        |              |            | S           | Unknown      | Unk Unk, Unknown   |                 | Allergan     |
|                                     | Latuda         |              |            | S           | Oral         | 20 Mg, Unknown     |                 | Not Reported |
|                                     | Latuda         |              |            | S           | Oral         | 60 Mg, Qd          |                 | Not Reported |



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| <u>FDA Received Date</u>                                                                                                          | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|--------------------------------|-----------------------|-----------------|--------------|----------------|
| 21-Dec-2016                                                                                                                       | 13049703                  | NON-EXPEDITED      |                    | HO, OT          | US-DRREDDYS-USA/USA/15/0055081 |                       | 25 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                             | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Chest Pain; Palpitations; Rhabdomyolysis                                                                                          | Risperidone               |                    |                    | S               |                                | 0.5 Mg Qhs            |                 | Not Reported |                |
|                                                                                                                                   | Risperidone               |                    |                    | S               | Unknown                        |                       |                 | Not Reported |                |
|                                                                                                                                   | Escitalopram              |                    |                    | S               | Unknown                        |                       |                 | Not Reported |                |
|                                                                                                                                   | Escitalopram              |                    |                    | S               |                                |                       |                 | Not Reported |                |
|                                                                                                                                   | Mirtazapine               |                    |                    | C               |                                | 15 Mg Qhs             |                 | Not Reported |                |
|                                                                                                                                   | Mirtazapine               |                    |                    | C               |                                |                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                          | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Dec-2016                                                                                                                       | 13051380                  | DIRECT             |                    | DS              |                                |                       | 49 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                             | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Anorgasmia; Orgasm Abnormal; Orgasm Abnormal                                                                                      | Escitalopram 10 Mg        |                    |                    | S               | Oral                           | Quantity:1 Tablet(S); |                 | Camber       |                |
|                                                                                                                                   | D3                        |                    |                    | C               |                                |                       |                 | Not Reported |                |
|                                                                                                                                   | Multi                     |                    |                    | C               |                                |                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                          | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Dec-2016                                                                                                                       | 13051862                  | EXPEDITED (15-DAY) |                    | OT              | ES-ALLERGAN-1681765US          |                       |                 | Female       | ESP            |
| <u>Preferred Term</u>                                                                                                             | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Depressed Mood; Disorientation; Dizziness; Irritability; Nervousness; Thinking Abnormal; Wrong Technique In Product Usage Process | Escitalopram Oxalate - Bp |                    |                    | S               | Oral                           | 10 Mg, Unk            |                 | Allergan     |                |
| <u>FDA Received Date</u>                                                                                                          | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Dec-2016                                                                                                                       | 13052316                  | EXPEDITED (15-DAY) |                    | OT              | CH-TEVA-720748ISR              |                       | 74 YR           | Female       | CHE            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                          | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                                | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------|---------------------|--------------|------------|-------------|--------------|-----------------------------------------------------------------------------------|-----------------|--------------|
| Bone Density Decreased;<br>Pelvic Fracture; Rebound<br>Effect; Spinal Fracture | Pantoprazol-Actavis |              |            | S           | Oral         | 20 Milligram Daily; Enteric,<br>Strength: 20mg, Start Date<br>Unknown, Continuous |                 | Teva         |
|                                                                                | Prolia              |              |            | S           | Subcutaneous |                                                                                   |                 | Not Reported |
|                                                                                | Prolia              |              |            | S           | Subcutaneous | Continuous- Last Injection<br>In Oct 2016)                                        |                 | Not Reported |
|                                                                                | Cipralext           |              |            | S           | Oral         | 5 Milligram Daily; Strength:<br>10mg, Start Date<br>Unknown, Therapy<br>Ongoing   |                 | Not Reported |
|                                                                                | Bekunis Bisacodyl   |              |            | C           | Oral         | 6 Dosage Forms Daily; No<br>Details Available                                     |                 | Not Reported |
|                                                                                | Kalcipos D3         |              |            | C           | Oral         | 1 Dosage Forms Daily; No<br>Details Available                                     |                 | Not Reported |
|                                                                                | Lexotanil           |              |            | C           | Oral         | 3 Milligram Daily; Strength:<br>3mg, No Details Available                         |                 | Not Reported |
|                                                                                | Losartan            |              |            | C           | Oral         | 25 Milligram Daily; No<br>Details Available, Strength<br>50 Mg                    |                 | Not Reported |
|                                                                                | Metoprolol          |              |            | C           | Oral         | 50 Milligram Daily; No<br>Details Available                                       |                 | Not Reported |
|                                                                                | Ponstan             |              |            | C           | Oral         | 1 Dosage Forms Daily; No<br>Details Available                                     |                 | Not Reported |
|                                                                                | Simvastatin         |              |            | C           | Oral         | .5 Dosage Forms Daily;<br>No Details Available                                    |                 | Not Reported |
|                                                                                | Targin              |              |            | C           | Oral         | 2 Dosage Forms Daily; No<br>Details Available                                     |                 | Not Reported |
|                                                                                | Vi-De 3             |              |            | C           | Oral         | No Details Available                                                              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 22-Dec-2016              | 12194581      | NON-EXPEDITED    |                    |                 | US-PFIZER INC-<br>2016153668 |                      | 57 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

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|                       |              |   |     |              |
|-----------------------|--------------|---|-----|--------------|
| Drug Hypersensitivity | Neurontin    | S | Unk | Pfizer       |
|                       | Atenolol     | S | Unk | Pfizer       |
|                       | Levofloxacin | S | Unk | Pfizer       |
|                       | Levaquin     | S | Unk | Not Reported |
|                       | Avelox       | S | Unk | Not Reported |
|                       | Paxil        | S | Unk | Not Reported |
|                       | Prozac       | S | Unk | Not Reported |
|                       | Lisinopril   | S | Unk | Not Reported |
|                       | Prednisone   | S | Unk | Not Reported |
|                       | Lexapro      | S | Unk | Not Reported |
|                       | Cymbalta     | S | Unk | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 22-Dec-2016              | 12962580      | EXPEDITED (15-DAY) | LT                 |                 | FR-ALLERGAN-1676965US |                      | 83 YR      | Male       | FRA            |

| <u>Preferred Term</u>                   | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                          | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------|--------------------------|--------------|------------|-------------|---------------------------------------|--------------------|-----------------|--------------|
| Drug Interaction;<br>Serotonin Syndrome | Escitalopram Oxalate Unk |              |            | S           | Oral                                  | 10 Mg, Unk         |                 | Allergan     |
|                                         | Tramadol                 |              |            | S           | Oral                                  | 100 Mg, Unk        |                 | Not Reported |
|                                         | Fluindione               |              |            | C           |                                       |                    |                 | Not Reported |
|                                         | Pantoprazole             |              |            | C           |                                       |                    |                 | Not Reported |
|                                         | Perindopril              |              |            | C           |                                       |                    |                 | Not Reported |
|                                         | Bisoprolol               |              |            | C           |                                       |                    |                 | Not Reported |
|                                         | Spirolactone             |              |            | C           |                                       |                    |                 | Not Reported |
|                                         | Rosuvastatin             |              |            | C           |                                       |                    |                 | Not Reported |
|                                         | Paracetamol              |              |            | C           | Intravenous (not otherwise specified) |                    |                 | Not Reported |
|                                         | Furosemide               |              |            | C           |                                       |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Dec-2016              | 13054057      | DIRECT           | Y                  |                 |                      |                      |            | Unknown    | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

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|                                                               |                                                                                                                                                                                                                                     |                    |                    |                                 |                                                      |                        |                 |                                                                                                      |                |
|---------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|--------------------|---------------------------------|------------------------------------------------------|------------------------|-----------------|------------------------------------------------------------------------------------------------------|----------------|
| Product Dispensing Error                                      | Latuda Latuda 160<br>Lexapro Lexapro                                                                                                                                                                                                | S<br>S             |                    |                                 |                                                      |                        |                 | Not Reported<br>Not Reported                                                                         |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>                                                                                                                                                                                                                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>                 | <u>Mfr Control #</u>                                 | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>                                                                                           | <u>Country</u> |
| 22-Dec-2016                                                   | 13054570                                                                                                                                                                                                                            | EXPEDITED (15-DAY) |                    | OT                              | FR-ALLERGAN-1681780US                                |                        | 58 YR           | Female                                                                                               | FRA            |
| <u>Preferred Term</u>                                         | <u>Product</u>                                                                                                                                                                                                                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                     | <u>Route</u>                                         | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>                                                                                           |                |
| Dyspnoea; Fall; Injury; Malaise                               | Escitalopram Oxalate - Bp                                                                                                                                                                                                           |                    |                    | S                               | Oral                                                 | Unk                    |                 | Allergan                                                                                             |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>                                                                                                                                                                                                                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>                 | <u>Mfr Control #</u>                                 | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>                                                                                           | <u>Country</u> |
| 22-Dec-2016                                                   | 13054719                                                                                                                                                                                                                            | DIRECT             |                    | OT                              |                                                      |                        | 76 YR           | Female                                                                                               | USA            |
| <u>Preferred Term</u>                                         | <u>Product</u>                                                                                                                                                                                                                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                     | <u>Route</u>                                         | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>                                                                                           |                |
| Anxiety; Disturbance In Attention; Feeling Abnormal; Insomnia | Escitalopram<br>Ramipril<br>Lexapro<br>Vit D3                                                                                                                                                                                       |                    |                    | S<br>C<br>C<br>C                | Oral                                                 | Quantity:90 Tablet(S); |                 | Torrent<br>Not Reported<br>Not Reported<br>Not Reported                                              |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>                                                                                                                                                                                                                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>                 | <u>Mfr Control #</u>                                 | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>                                                                                           | <u>Country</u> |
| 22-Dec-2016                                                   | 13055498                                                                                                                                                                                                                            | EXPEDITED (15-DAY) |                    | OT                              | IT-TEVA-722519ACC                                    |                        | 26 YR           | Female                                                                                               | ITA            |
| <u>Preferred Term</u>                                         | <u>Product</u>                                                                                                                                                                                                                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                     | <u>Route</u>                                         | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>                                                                                           |                |
| Drug Abuse; Poisoning; Sopor                                  | Simvastatin<br>Acetylsalicylic Acid<br>Rivotril - 2,5mg/ML Gocce Orali<br>Soluzione - Roche S.P.A.<br>Entact - H. Lundbeck A/S<br>Torvast - Pfizer Limited<br>Deursil - Cheplapharm<br>Arzneimittel GmbH<br>Igroton - Amdipharm Ltd |                    |                    | S<br>S<br>S<br>S<br>S<br>S<br>S | Oral<br>Oral<br>Oral<br>Oral<br>Oral<br>Oral<br>Oral | 10 ML Total            |                 | Ivax<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |                |

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| <u>FDA Received Date</u>                                                     | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 22-Dec-2016                                                                  | 13055594                  | EXPEDITED (15-DAY) |                    | OT              | IT-ALLERGAN-1682076US |                      | 26 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                        | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Abuse; Overdose; Poisoning; Product Use In Unapproved Indication; Sopor | Escitalopram Oxalate Unk  |                    |                    | S               | Oral                  | 28 Df, Unk           |                 | Allergan     |                |
|                                                                              | Acetylsalicylic Acid      |                    |                    | S               | Oral                  | Unk Df, Unk          |                 | Not Reported |                |
|                                                                              | Rivotril                  |                    |                    | S               | Oral                  | 10 MI, Unk           |                 | Not Reported |                |
|                                                                              | Simvastatin               |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                              | Torvast                   |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                              | Deursil                   |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                              | Igroton                   |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                     | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Dec-2016                                                                  | 13056427                  | EXPEDITED (15-DAY) |                    | OT              | JP-ALLERGAN-1681761US |                      | 30 YR           | Female       | JPN            |
| <u>Preferred Term</u>                                                        | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Seizure                                                                      | Escitalopram Oxalate - Bp |                    |                    | S               | Oral                  | 10 Mg, Qd            |                 | Allergan     |                |
|                                                                              | Biken Ha                  |                    |                    | S               | Subcutaneous          | 0.5 MI, Single       |                 | Not Reported |                |
|                                                                              | Triazolam                 |                    |                    | C               | Unknown               | 0.25 Mg, Qd          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                     | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Dec-2016                                                                  | 13056464                  | EXPEDITED (15-DAY) |                    | HO              | FR-ALLERGAN-1681776US |                      | 77 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                        | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cough; Dyspnoea; Interstitial Lung Disease                                   | Escitalopram Oxalate - Bp |                    |                    | S               | Oral                  | 10 Mg, Qd            |                 | Allergan     |                |
|                                                                              | Detensiel                 |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                              | Kardegic                  |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                              | Amlor                     |                    |                    | C               | Oral                  |                      |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>        | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|-----------------------------|----------------------|-----------------|--------------|----------------|
| 22-Dec-2016                                                             | 13056484                    | EXPEDITED (15-DAY) |                    | HO              | FR-ALLERGAN-1681773US       |                      | 29 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                   | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Accidental Poisoning;<br>Drug Dependence; Wrong<br>Product Administered | Escitalopram Oxalate - Bp   |                    |                    | S               | Oral                        |                      |                 | Allergan     |                |
|                                                                         | Tobacco Powder              |                    |                    | S               | Respiratory<br>(inhalation) | 5 Packs/Year         |                 | Not Reported |                |
|                                                                         | Alcohol                     |                    |                    | S               | Oral                        | 1 Beer A Day         |                 | Not Reported |                |
|                                                                         | Methadone                   |                    |                    | S               | Oral                        |                      |                 | Not Reported |                |
|                                                                         | Subutex                     |                    |                    | S               | Oral                        |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>        | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Dec-2016                                                             | 13057068                    | EXPEDITED (15-DAY) |                    | OT              | PHHY2016IT173643            |                      | 26 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                   | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Abuse; Sopor;<br>Toxicity To Various Agents                        | Simvastatin                 |                    |                    | S               | Oral                        | 14 Df, Once/Single   |                 | Novartis     |                |
|                                                                         | Acetylsalicylic Acid Sandoz |                    |                    | S               | Oral                        | 20 Df, Once/Single   |                 | Not Reported |                |
|                                                                         | Igroton                     |                    |                    | S               | Oral                        | 15 Df, Once/Single   |                 | Not Reported |                |
|                                                                         | Rivotril                    |                    |                    | S               | Oral                        | 10 MI, Once/Single   |                 | Not Reported |                |
|                                                                         | Deursil                     |                    |                    | S               | Oral                        | 10 Df, Once/Single   |                 | Not Reported |                |
|                                                                         | Torvast                     |                    |                    | S               | Oral                        | 8 Df, Once/Single    |                 | Not Reported |                |
|                                                                         | Entact                      |                    |                    | S               | Oral                        | 28 Df, Once/Single   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>        | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Dec-2016                                                             | 13057833                    | EXPEDITED (15-DAY) |                    | OT              | US-CIPLA LTD.-2016US23663   |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                   | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Adverse Drug Reaction                                                   | Escitalopram                |                    |                    | S               | Unknown                     | 10 Mg, Unk           |                 | Invagen      |                |

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|------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 23-Dec-2016                                          | 13058123                    | DIRECT             | Y                  |                 |                          |                      | 50 YR           | Male         | USA            |
| <u>Preferred Term</u>                                | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Iritis; Scleritis                                    | Fluoxetine                  |                    |                    | S               | Oral                     |                      | 4 MTH           | Not Reported |                |
|                                                      | Lexapro                     |                    |                    | S               |                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                             | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Dec-2016                                          | 13059736                    | EXPEDITED (15-DAY) |                    | OT              | CH-PFIZER INC-2016578939 |                      | 26 YR           | Female       | CHE            |
| <u>Preferred Term</u>                                | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Headache; Malaise; Palpitations; Withdrawal Syndrome | Temesta (Lorazepam)         |                    |                    | S               | Oral                     | 1 Mg, As Needed      |                 | Pfizer       |                |
|                                                      | Escitalopram                |                    |                    | S               | Oral                     | 10 Mg, 1x/Day        |                 | Not Reported |                |
|                                                      | Escitalopram                |                    |                    | S               |                          | 5 Mg, Daily          |                 | Not Reported |                |
| <u>FDA Received Date</u>                             | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Dec-2016                                          | 13060065                    | EXPEDITED (15-DAY) |                    | HO              | FR-ALLERGAN-1682050US    |                      | 69 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cerebral Haemorrhage; Drug Interaction               | Escitalopram Oxalate - Bp   |                    |                    | S               | Oral                     |                      |                 | Allergan     |                |
|                                                      | Plavix                      |                    |                    | S               | Oral                     | 1 Df, Qd             |                 | Not Reported |                |
|                                                      | Tahor                       |                    |                    | C               | Oral                     |                      |                 | Not Reported |                |
|                                                      | Lamictal                    |                    |                    | C               | Oral                     |                      |                 | Not Reported |                |
|                                                      | Renitec [Enalapril Maleate] |                    |                    | C               | Oral                     |                      |                 | Not Reported |                |
|                                                      | Diffu K                     |                    |                    | C               | Oral                     |                      |                 | Not Reported |                |
|                                                      | Movicol                     |                    |                    | C               | Oral                     |                      |                 | Not Reported |                |
|                                                      | Paracetamol                 |                    |                    | C               | Oral                     |                      |                 | Not Reported |                |

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|-------------------------------------------|--------------------|------------------|--------------------|-----------------|--------------------------------------------|----------------------|-----------------|-----------------|----------------|
| 23-Dec-2016                               | 13060171           | NON-EXPEDITED    |                    |                 | US-<br>GLAXOSMITHKLINE-<br>US2016GSK190288 |                      | 20 YR           | Male            | USA            |
| <u>Preferred Term</u>                     | <u>Product</u>     | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Drug Screen Positive;<br>Feeling Abnormal | Wellbutrin         |                  |                    | S               |                                            | Unk                  |                 | Glaxosmithkline |                |
|                                           | Wellbutrin         |                  |                    | S               |                                            |                      |                 | Glaxosmithkline |                |
|                                           | Escitalopram       |                  |                    | S               | Oral                                       | 10 Mg, Qd            |                 | Not Reported    |                |
|                                           | Escitalopram       |                  |                    | S               |                                            |                      |                 | Not Reported    |                |
|                                           | Flax Seed Oil      |                  |                    | C               |                                            |                      |                 | Not Reported    |                |
|                                           | Tramadol           |                  |                    | C               |                                            |                      |                 | Not Reported    |                |
|                                           | Melatonin          |                  |                    | C               |                                            |                      |                 | Not Reported    |                |
|                                           | Zyrtec-D           |                  |                    | C               |                                            |                      |                 | Not Reported    |                |
|                                           | Theraflu - Unknown |                  |                    | C               |                                            |                      |                 | Glaxosmithkline |                |

| <u>FDA Received Date</u>                | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------|---------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
| 23-Dec-2016                             | 13060245                  | EXPEDITED (15-DAY) |                    | HO              | FR-ALLERGAN-<br>1682055US |                      | 71 YR           | Female       | FRA            |
| <u>Preferred Term</u>                   | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Loss Anaemia;<br>Haematoma Muscle | Escitalopram Oxalate - Bp |                    |                    | S               | Oral                      | 5 Mg, Qd             |                 | Allergan     |                |
|                                         | Coumadine                 |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                                         | Letrozole                 |                    |                    | C               | Unknown                   |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                                                  | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
| 24-Dec-2016                                                                                                                                                               | 8920401               | EXPEDITED (15-DAY) |                    | HO              | DE-JNJFOC-<br>20121103783 |                      | 22 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                                                                                                                                     | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aspiration; Drug Diversion;<br>Dysarthria;<br>Electrocardiogram Qt<br>Prolonged; Overdose;<br>Seizure; Somnolence;<br>Staring; Suicide Attempt;<br>Systolic Hypertension; | Dipiperon             |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                                                                                                                                                                           | Diphenhydramine       |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                                                                                                                                                                           | Ciprallex             |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                                                                                                                                                                           | Sycrest               |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                                                                                                                                                                           | Dominal (Prothipendyl |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |



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|                       |                |  |   |      |  |  |  |  |              |
|-----------------------|----------------|--|---|------|--|--|--|--|--------------|
| Tachycardia; Vomiting | Hydrochloride) |  |   |      |  |  |  |  |              |
|                       | Buscopan       |  | S | Oral |  |  |  |  | Not Reported |
|                       | Paracetamol    |  | S | Oral |  |  |  |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------|----------------------|------------|------------|----------------|
| 26-Dec-2016              | 13061466      | EXPEDITED (15-DAY) |                    | OT              | IT-AUROBINDO-AUR-<br>APL-2016-15586 |                      | 26 YR      | Female     | ITA            |

| <u>Preferred Term</u>           | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Abuse; Poisoning;<br>Sopor | Simvastatin Tablet   |              |            | S           | Oral         | 14 Df, Unk         |                 | Aurobindo    |
|                                 | Acetylsalicylic Acid |              |            | S           | Oral         | 20 Df, Unk         |                 | Not Reported |
|                                 | Entact               |              |            | S           | Oral         | 28 Df, Unk         |                 | Not Reported |
|                                 | Torvast              |              |            | S           | Oral         | 8 Df, Unk          |                 | Not Reported |
|                                 | Deursil              |              |            | S           | Oral         | 10 Df, Unk         |                 | Not Reported |
|                                 | Igroton              |              |            | S           | Oral         | 15 Df, Unk         |                 | Not Reported |
|                                 | Rivotril             |              |            | S           | Oral         | 10 MI, Unk         |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------------------------------------|----------------------|------------|------------|----------------|
| 26-Dec-2016              | 13061753      | EXPEDITED (15-DAY) |                    | OT              | IT-SUN<br>PHARMACEUTICAL<br>INDUSTRIES LTD-<br>2016RR-129702 |                      | 26 YR      | Female     | ITA            |

| <u>Preferred Term</u>           | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Abuse; Poisoning;<br>Sopor | Simvastatin          |              |            | S           | Oral         | 14 Df Total        |                 | Sun          |
|                                 | Acetylsalicylic Acid |              |            | S           | Oral         | 20 Df Total        |                 | Sun          |
|                                 | Rivotril 2,5mg/MI    |              |            | S           | Oral         | 10 MI Total        |                 | Not Reported |
|                                 | Igroton              |              |            | S           | Oral         | 15 Df Total        |                 | Not Reported |
|                                 | Deursil              |              |            | S           | Oral         | 10 Df Total        |                 | Not Reported |
|                                 | Torvast              |              |            | S           | Oral         | 8 Df Total         |                 | Not Reported |
|                                 | Entact               |              |            | S           | Oral         | 28 Df Total        |                 | Not Reported |

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| <u>FDA Received Date</u>            | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|-------------------------------------|---------------------------|--------------------|--------------------|-----------------|--------------------------------------------------------|----------------------|-----------------|----------------------|----------------|
| 26-Dec-2016                         | 13062432                  | EXPEDITED (15-DAY) |                    | HO, LT, OT      | FR-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>BMS-2016-108889 |                      | 91 YR           | Female               | FRA            |
| <u>Preferred Term</u>               | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Fall; Haemorrhagic Stroke           | Eliquis                   |                    |                    | S               | Oral                                                   | 2.5 Mg, Bid          |                 | Bristol Myers Squibb |                |
|                                     | Seroplex                  |                    |                    | S               | Oral                                                   | 1 Df, Qd             |                 | Not Reported         |                |
|                                     | Tanakan                   |                    |                    | C               | Unknown                                                |                      |                 | Not Reported         |                |
|                                     | Levothyrox                |                    |                    | C               | Unknown                                                |                      |                 | Not Reported         |                |
|                                     | Xanax                     |                    |                    | C               | Unknown                                                |                      |                 | Not Reported         |                |
|                                     | Cordarone                 |                    |                    | C               | Unknown                                                |                      |                 | Not Reported         |                |
| <u>FDA Received Date</u>            | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 26-Dec-2016                         | 13062513                  | EXPEDITED (15-DAY) |                    | HO              | US-ALLERGAN-<br>1682180US                              |                      | 33 YR           | Female               | USA            |
| <u>Preferred Term</u>               | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Drug Ineffective;<br>Pregnancy      | Escitalopram Oxalate - Bp |                    |                    | S               | Unknown                                                | 10 Mg, Qd            |                 | Allergan             |                |
|                                     | Olanzapine                |                    |                    | C               | Unknown                                                | 10 Mg, Qd            |                 | Not Reported         |                |
|                                     | Olanzapine                |                    |                    | C               | Unknown                                                | 20 Mg, Qd            |                 | Not Reported         |                |
| <u>FDA Received Date</u>            | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 26-Dec-2016                         | 13062718                  | EXPEDITED (15-DAY) |                    | HO              | PHHY2016FR175977                                       |                      | 71 YR           | Female               | FRA            |
| <u>Preferred Term</u>               | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Hypokalaemia; Torsade<br>De Pointes | Cotareg                   |                    |                    | S               | Oral                                                   | Unk Unk, Qd          |                 | Novartis             |                |
|                                     | Seroplex                  |                    |                    | S               | Oral                                                   | 10 Mg, Qd            |                 | Not Reported         |                |
|                                     | Stagid                    |                    |                    | S               | Oral                                                   | 700 Mg, Tid          |                 | Not Reported         |                |
|                                     | Mediatensyl               |                    |                    | S               | Oral                                                   | 60 Mg, Qd            |                 | Not Reported         |                |
|                                     | Symbicort                 |                    |                    | C               | Unknown                                                | (400/12), Bid        |                 | Not Reported         |                |
|                                     | Levothyrox                |                    |                    | C               | Unknown                                                | 75 Unk, Qd           |                 | Not Reported         |                |

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| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------------------------------------|----------------------|------------|------------|----------------|
| 27-Dec-2016              | 12967024      | EXPEDITED (15-DAY) |                    | HO, LT, OT      | FR-SUN<br>PHARMACEUTICAL<br>INDUSTRIES LTD-<br>2016RR-127980 |                      | 83 YR      | Male       | FRA            |

| <u>Preferred Term</u>                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                             | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------|----------------|--------------|------------|-------------|------------------------------------------|--------------------|-----------------|--------------|
| Drug Interaction;<br>Serotonin Syndrome | Escitalopram   |              |            | S           | Unknown                                  | 10 Mg, Unk         |                 | Not Reported |
|                                         | Tramadol       |              |            | S           | Unknown                                  | Extended Release   |                 | Sun          |
|                                         | Perindopril    |              |            | C           | Unknown                                  | Unk                |                 | Not Reported |
|                                         | Rosuvastatin   |              |            | C           | Unknown                                  | Unk                |                 | Not Reported |
|                                         | Spironolactone |              |            | C           | Unknown                                  | Unk                |                 | Not Reported |
|                                         | Furosemide     |              |            | C           | Unknown                                  | Unk                |                 | Not Reported |
|                                         | Fluindione     |              |            | C           | Unknown                                  | Unk                |                 | Not Reported |
|                                         | Paracetamol    |              |            | C           | Intravenous (not<br>otherwise specified) | Unk                |                 | Not Reported |
|                                         | Pantoprazole   |              |            | C           | Unknown                                  | Unk                |                 | Not Reported |
|                                         | Bisoprolol     |              |            | C           | Unknown                                  | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Dec-2016              | 13063042      | EXPEDITED (15-DAY) |                    | OT              | IT-ROCHE-1871356     |                      | 46 YR      | Male       | ITA            |

| <u>Preferred Term</u>                                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                            | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------|----------------|--------------|------------|-------------|--------------|-------------------------------------------------------------------------------|-----------------|--------------|
| Depressed Mood; Drug<br>Abuse; Psychomotor<br>Retardation | Valium         |              |            | S           | Oral         | 5 Mg/ML Oral Drops,<br>Solution' Bottle Containing<br>20 Oral Drops, Solution |                 | Not Reported |
|                                                           | Cipralext      |              |            | S           | Oral         | 14 X 5 Mg Film-Coated<br>Tablets                                              |                 | Not Reported |
|                                                           | Tavor (Italy)  |              |            | S           | Oral         | 2.5 Mg Tablets' 20 Tablets                                                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 27-Dec-2016              | 13066889      | EXPEDITED (15-DAY) |                    | HO              | FR-ALLERGAN-<br>1682353US |                      | 53 YR      | Female     | FRA            |

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| <u>Preferred Term</u>                                                                                       | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| Alcohol Poisoning; Coma Scale Abnormal; Hypokalaemia; Mydriasis; Pco2 Increased; Toxicity To Various Agents | Escitalopram Oxalate - Bp |                    |                    | S               | Oral                  | 28 Df, Single        |                 | Allergan     |                |
|                                                                                                             | Stilnox                   |                    |                    | S               | Oral                  | 12 Df, Single        |                 | Not Reported |                |
|                                                                                                             | Raloxifene Base           |                    |                    | S               | Oral                  | 60 Df, Single        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                    | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Dec-2016                                                                                                 | 13066891                  | EXPEDITED (15-DAY) |                    | HO              | FR-ALLERGAN-1682357US |                      | 14 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                       | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Miosis; Off Label Use; Somnolence; Toxicity To Various Agents                                               | Escitalopram Oxalate - Bp |                    |                    | S               | Oral                  | 4 Df, Single         |                 | Allergan     |                |
|                                                                                                             | Lysanxia                  |                    |                    | S               | Oral                  | 10 Df, Single        |                 | Not Reported |                |
|                                                                                                             | Largactil                 |                    |                    | S               | Oral                  | 6 Df, Single         |                 | Not Reported |                |
|                                                                                                             | Atarax                    |                    |                    | S               | Oral                  | 10 Df, Single        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                    | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Dec-2016                                                                                                 | 13066892                  | EXPEDITED (15-DAY) |                    | HO, LT          | FR-ALLERGAN-1682359US |                      | 91 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                       | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Haemorrhagic Stroke                                                                                         | Escitalopram Oxalate - Bp |                    |                    | S               | Oral                  | 10 Mg, Qd            |                 | Allergan     |                |
|                                                                                                             | Eliquis                   |                    |                    | S               | Oral                  | 5 Mg, Qd             |                 | Not Reported |                |
|                                                                                                             | Tanakan                   |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |
|                                                                                                             | Levothyrox                |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |
|                                                                                                             | Xanax                     |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |
|                                                                                                             | Cordarone                 |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                    | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Dec-2016                                                                                                 | 13066897                  | EXPEDITED (15-DAY) |                    | HO              | FR-ALLERGAN-1682355US |                      | 61 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                       | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

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|                        |                           |   |         |           |              |
|------------------------|---------------------------|---|---------|-----------|--------------|
| Tonic Clonic Movements | Escitalopram Oxalate - Bp | S | Oral    | 20 Mg, Qd | Allergan     |
|                        | Escitalopram Oxalate - Bp | S | Oral    | Unk       | Allergan     |
|                        | Crestor                   | C | Unknown |           | Not Reported |
|                        | Depakine Chrono           | C | Unknown |           | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|------------|----------------|
| 27-Dec-2016              | 13066898                  | EXPEDITED (15-DAY) |                    | HO              | NL-ALLERGAN-1682335US |                      | 60 DAY          | Unknown    | NLD            |
| <u>Preferred Term</u>    | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Premature Baby           | Escitalopram Oxalate - Bp |                    |                    | S               | Transplacental        | 5 Mg                 |                 | Allergan   |                |

| <u>FDA Received Date</u>                    | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---------------------------------------------|---------------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|------------|----------------|
| 27-Dec-2016                                 | 13066899                  | EXPEDITED (15-DAY) |                    | OT              | NL-ALLERGAN-1682189US |                      | 37 YR           | Female     | NLD            |
| <u>Preferred Term</u>                       | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Exposure During Pregnancy; Premature Labour | Escitalopram Oxalate - Bp |                    |                    | S               | Oral                  | 09-2016 -> 5mg       |                 | Allergan   |                |

| <u>FDA Received Date</u>                                                                          | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
| 27-Dec-2016                                                                                       | 13067238                | EXPEDITED (15-DAY) |                    | HO              | IT-CIPLA LTD.-2016IT23831 |                      |                 | Unknown      | ITA            |
| <u>Preferred Term</u>                                                                             | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Adjustment Disorder With Mixed Anxiety And Depressed Mood; Anhedonia; Insomnia; Suicidal Ideation | Escitalopram            |                    |                    | S               | Unknown                   | 20 Mg, Total         |                 | Invagen      |                |
|                                                                                                   | Valproic Acid           |                    |                    | S               | Unknown                   | 300 Mg, Total        |                 | Cipla        |                |
|                                                                                                   | Venlafaxine             |                    |                    | S               | Unknown                   | 300 Mg, Total        |                 | Cipla        |                |
|                                                                                                   | Quetiapine              |                    |                    | S               | Unknown                   | Unk, Total           |                 | Not Reported |                |
|                                                                                                   | Alprazolam              |                    |                    | S               | Unknown                   | 1.5 Mg, Total        |                 | Cipla        |                |
|                                                                                                   | Trazodone Hydrochloride |                    |                    | S               | Unknown                   | 75 Mg, Total         |                 | Not Reported |                |
|                                                                                                   | Clonazepam              |                    |                    | S               | Unknown                   | 0.5 Mg, Total        |                 | Not Reported |                |

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| <u>FDA Received Date</u>              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------|----------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| 28-Dec-2016                           | 10882280       | EXPEDITED (15-DAY) |                    | DS              | FR-ABBVIE-15P-056-1354299-00 |                      | 61 YR           | Female       | FRA            |
| <u>Preferred Term</u>                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Action Tremor; Dementia; Parkinsonism | Depakote       |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                       | Depakote       |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                       | Depakote       |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                       | Seroplex       |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                       | Crestor        |                    |                    | C               |                              |                      |                 | Not Reported |                |
|                                       | Lasilix        |                    |                    | C               |                              |                      |                 | Not Reported |                |
|                                       | Kardegic       |                    |                    | C               |                              |                      |                 | Not Reported |                |
|                                       | Plaquenil      |                    |                    | C               |                              |                      |                 | Not Reported |                |
|                                       | Preterax       |                    |                    | C               |                              |                      |                 | Not Reported |                |
|                                       | Abufene        |                    |                    | C               |                              |                      |                 | Not Reported |                |
|                                       | Inexium        |                    |                    | C               |                              |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                               | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 28-Dec-2016                                                                          | 13000493       | EXPEDITED (15-DAY) |                    | DE, HO          | FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2016RR-128854 |                      | 63 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                       | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bezoar; Gastrointestinal Ischaemia; Shock; Skin Necrosis; Toxicity To Various Agents | Sevikar        |                    |                    | S               | Unknown                                            | 10 Mg, 129 Tablets   |                 | Not Reported |                |
|                                                                                      | Atarax         |                    |                    | S               | Unknown                                            | 25 Mg, 28 Tablets    |                 | Not Reported |                |
|                                                                                      | Lysanxia       |                    |                    | S               | Unknown                                            | 420 Mg, 42 Tablets   |                 | Not Reported |                |
|                                                                                      | Seroplex       |                    |                    | S               | Unknown                                            | 280 Mg, 28 Tablets   |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|--------------------------------------------------|----------------------|-----------------|------------|----------------|
| 28-Dec-2016              | 13067650       | EXPEDITED (15-DAY) |                    | OT              | DE-MACLEODS PHARMACEUTICALS US LTD-MAC2016004103 |                      |                 | Unknown    | DEU            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                     | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                       |              |   |                |                                     |              |
|-------------------------------------------------------------------------------------------------------|--------------|---|----------------|-------------------------------------|--------------|
| Foetal Exposure During Pregnancy; Premature Baby; Respiratory Disorder Neonatal; Small For Dates Baby | Escitalopram | S | Transplacental | 10 Mg, Qd (0-35.5 Gestational Week) | Macleods     |
|                                                                                                       | Folsaure     | C | Transplacental | Unk                                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 28-Dec-2016              | 13069042      | EXPEDITED (15-DAY) |                    | HO              | IT-ASTRAZENECA-2016SF35403 |                      | 65 YR      | Male       | ITA            |

| <u>Preferred Term</u>                     | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------|-------------------|--------------|------------|-------------|--------------|-----------------------|-----------------|--------------|
| Immune Thrombocytopenic Purpura; Tinnitus | Crestor           |              |            | S           | Oral         |                       |                 | Not Reported |
|                                           | Glucophage Unidie |              |            | S           | Oral         |                       |                 | Not Reported |
|                                           | Eutimil           |              |            | S           | Oral         |                       |                 | Not Reported |
|                                           | Eutimil           |              |            | S           | Unknown      | Sereupin              |                 | Not Reported |
|                                           | Cipralext         |              |            | S           | Unknown      |                       |                 | Not Reported |
|                                           | Esopral           |              |            | C           | Oral         | 20.0mg Unknown        |                 | Not Reported |
|                                           | Diamox            |              |            | C           | Oral         | 250.0mg Unknown       |                 | Not Reported |
|                                           | Muscoril          |              |            | C           | Oral         | 4.0mg Unknown         |                 | Not Reported |
|                                           | Stiliden          |              |            | C           | Oral         | 10 Mg/MI Oral Unknown |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Dec-2016              | 13069826      | EXPEDITED (15-DAY) |                    | HO, LT          | PHHY2016IN174860     |                      | 19 YR      | Female     | IND            |

| <u>Preferred Term</u>                               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------|----------------|--------------|------------|-------------|--------------|------------------------|-----------------|--------------|
| Dizziness; Headache; Hypoglycaemia; Suicide Attempt | Clonazepam     |              |            | S           | Unknown      | Unk Unk, Qd            |                 | Novartis     |
|                                                     | Clonazepam     |              |            | S           | Oral         | Ingested 10-15 Tablets |                 | Novartis     |
|                                                     | Escitalopram   |              |            | S           | Unknown      | Unk Unk, Qd            |                 | Not Reported |
|                                                     | Escitalopram   |              |            | S           | Oral         | Ingested 10-15 Tablets |                 | Not Reported |
|                                                     | Venlafaxine    |              |            | S           | Unknown      | 1 Df, Qd               |                 | Not Reported |
|                                                     | Venlafaxine    |              |            | S           | Oral         | Ingested 10-15 Tablets |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                        | <u>Case #</u>                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 29-Dec-2016                                                                                                                                                                                                     | 11120390                                   | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2015167081 |                      | 69 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                           | <u>Product</u>                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity                                                                                                                                                                                           | Celebrex                                   |                    |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                                                                                                                                                                                                                 | Ibuprofen                                  |                    |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                                                                                                                                                                                                                 | Lisinopril                                 |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                                                                                                                                                                                                                 | Omnicef                                    |                    |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                                                                                                                                                                                                                 | Lexapro                                    |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                        | <u>Case #</u>                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Dec-2016                                                                                                                                                                                                     | 12389853                                   | EXPEDITED (15-DAY) |                    | DE, HO, OT      | IE-FRI-1000071177        |                      | 63 YR           | Female       | IRL            |
| <u>Preferred Term</u>                                                                                                                                                                                           | <u>Product</u>                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Altered State Of Consciousness; Blood Test Abnormal;                                                                                                                                                            | Lexapro Tablets                            |                    |                    | S               | Oral                     | Unk                  |                 | Allergan     |                |
| Coagulopathy; Completed Suicide; Contusion; Electrocardiogram Abnormal;                                                                                                                                         | Zispin                                     |                    |                    | S               | Unknown                  | 30 Mg, Unk           |                 | Not Reported |                |
| Electrocardiogram St Segment Elevation; Fall; Fear; Fear Of Death; Haemorrhage; Head Injury; Hepatic Enzyme Abnormal; Hyponatraemia; Negative Thoughts; Panic Reaction; Psychotic Disorder; Withdrawal Syndrome | Zispin                                     |                    |                    | S               | Unknown                  | 30 Mg, Unk           |                 | Not Reported |                |
|                                                                                                                                                                                                                 | Sertraline                                 |                    |                    | S               | Unknown                  | 100 Mg, Unk          |                 | Not Reported |                |
|                                                                                                                                                                                                                 | Sertraline                                 |                    |                    | S               | Unknown                  | 100 Mg               |                 | Not Reported |                |
|                                                                                                                                                                                                                 | Sertraline                                 |                    |                    | S               | Unknown                  | 50 Mg, Unk           |                 | Not Reported |                |
|                                                                                                                                                                                                                 | Sertraline                                 |                    |                    | S               | Unknown                  | 50 Mg, Unk           |                 | Not Reported |                |
|                                                                                                                                                                                                                 | Temazepam                                  |                    |                    | C               | Unknown                  | 20 Mg, Unk           |                 | Not Reported |                |
|                                                                                                                                                                                                                 | Solpadeine                                 |                    |                    | C               |                          |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                 | (Acetaminophen\Caffeine\Codeine Phosphate) |                    |                    |                 |                          |                      |                 |              |                |
|                                                                                                                                                                                                                 | Solpadeine                                 |                    |                    | C               |                          |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                 | (Acetaminophen\Caffeine\Codeine Phosphate) |                    |                    |                 |                          |                      |                 |              |                |
|                                                                                                                                                                                                                 | Paracetamol                                |                    |                    | C               |                          |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                 | Diazepam                                   |                    |                    | C               |                          | Unk                  |                 | Not Reported |                |
|                                                                                                                                                                                                                 | Diazepam                                   |                    |                    | C               |                          | Unk                  |                 | Not Reported |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| Sudafed                                                                                                                     |                           |                    | C                  |                 | Unknown                    |                      |                 | Not Reported |                |
|-----------------------------------------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| <u>FDA Received Date</u>                                                                                                    | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Dec-2016                                                                                                                 | 12649667                  | EXPEDITED (15-DAY) |                    | HO              | IT-FRI-1000086792          |                      | 65 YR           | Male         | ITA            |
| <u>Preferred Term</u>                                                                                                       | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Gingival Bleeding;<br>Immune<br>Thrombocytopenic<br>Purpura; Petechiae;<br>Tinnitus                                         | Escitalopram Oxalate - Bp |                    |                    | S               | Oral                       | 4 Gtt, Qd            |                 | Allergan     |                |
|                                                                                                                             | Escitalopram Oxalate - Bp |                    |                    | S               | Oral                       | 5 Gtt, Qd            |                 | Allergan     |                |
|                                                                                                                             | Crestor                   |                    |                    | S               | Oral                       | 10 Mg, Qd            |                 | Not Reported |                |
|                                                                                                                             | Eutimil                   |                    |                    | S               | Oral                       | 20 Mg, Unk           |                 | Not Reported |                |
|                                                                                                                             | Sereupin                  |                    |                    | S               | Oral                       | Unk                  |                 | Not Reported |                |
|                                                                                                                             | Glucophage                |                    |                    | S               | Oral                       | 500 Mg, Bid          |                 | Not Reported |                |
|                                                                                                                             | Stiliden                  |                    |                    | C               | Oral                       | 40 Gtt, Qd           |                 | Not Reported |                |
|                                                                                                                             | Stiliden                  |                    |                    | C               | Oral                       | 35 Gtt, Qd           |                 | Not Reported |                |
|                                                                                                                             | Stiliden                  |                    |                    | C               | Oral                       | 30 Gtt, Qd           |                 | Not Reported |                |
|                                                                                                                             | Muscoril                  |                    |                    | C               | Oral                       | 1 Df, Bid            |                 | Not Reported |                |
|                                                                                                                             | Muscoril                  |                    |                    | C               |                            |                      |                 | Not Reported |                |
|                                                                                                                             | Diamox                    |                    |                    | C               | Oral                       | 1 Df, Qd             |                 | Not Reported |                |
|                                                                                                                             | Paroxetine                |                    |                    | C               | Oral                       | 20 Mg, Qd            |                 | Not Reported |                |
|                                                                                                                             | Esopral                   |                    |                    | C               |                            | 20 Mg, Unk           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                    | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Dec-2016                                                                                                                 | 13049284                  | EXPEDITED (15-DAY) |                    | HO              | LB-APOTEX-<br>2016AP015906 |                      | 50 YR           | Female       | LBN            |
| <u>Preferred Term</u>                                                                                                       | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;<br>Dysgeusia; Nausea;<br>Polyuria; Salivary<br>Hypersecretion; Toxicity<br>To Various Agents;<br>Vomiting | Valsartan 160             |                    |                    | S               | Unknown                    | 160 Mg, Qd           |                 | Not Reported |                |
|                                                                                                                             | Valsartan 160             |                    |                    | S               |                            |                      |                 | Not Reported |                |
|                                                                                                                             | Apo-Olanzapine            |                    |                    | S               | Unknown                    | 15 Mg, Qd            |                 | Apotex       |                |
|                                                                                                                             | Apo-Olanzapine            |                    |                    | S               | Unknown                    | 5 Mg, Qd             |                 | Apotex       |                |
|                                                                                                                             | Fluoxetine                |                    |                    | S               | Unknown                    | 20 Mg, Qd            |                 | Apotex       |                |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |                         |   |         |             |              |
|--|-------------------------|---|---------|-------------|--------------|
|  | Diazepam                | S | Unknown | 10 Mg, Qd   | Not Reported |
|  | Diazepam                | S | Unknown | 15 Mg, Qd   | Not Reported |
|  | Lithium Carbonate       | S | Unknown | 400 Mg, Qd  | Not Reported |
|  | Lithium Carbonate       | S | Unknown | 600 Mg, Qd  | Not Reported |
|  | Lithium Carbonate       | S | Unknown | 400 Mg, Bid | Not Reported |
|  | Lithium Carbonate       | S | Unknown | 800 Mg, Qd  | Not Reported |
|  | Escitalopram /01588502/ | S | Unknown | 10 Mg, Qd   | Not Reported |
|  | Quetiapine /01270902/   | S | Unknown | 100 Mg, Qd  | Not Reported |
|  | Quetiapine /01270902/   | S | Unknown | 300 Mg, Qd  | Not Reported |
|  | Levothyroxine Sodium    | C | Unknown | 100 Mg, Qd  | Not Reported |

  

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------------------------------|----------------------|------------|------------|----------------|
| 29-Dec-2016              | 13071263      | EXPEDITED (15-DAY) |                    | HO, OT          | FR-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>BMS-2016-108894 |                      | 71 YR      | Female     | FRA            |

  

| <u>Preferred Term</u>                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>           |
|------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------|
| Adenocarcinoma; Blood<br>Loss Anaemia;<br>Haematoma Muscle | Coumadine      |              |            | S           | Oral         | 3 Mg, Qd           |                 | Bristol Myers Squibb |
|                                                            | Seroplex       |              |            | S           | Oral         | 5 Mg, Unk          |                 | Not Reported         |
|                                                            | Letrozole      |              |            | S           | Unknown      |                    |                 | Not Reported         |

  

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Dec-2016              | 13075489      | DIRECT           |                    | HO              |                      |                      | 51 YR      | Female     | USA            |

  

| <u>Preferred Term</u>                                                                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                         | <u>Duration</u> | <u>Mfr</u> |
|---------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------------------------------|-----------------|------------|
| Anxiety; Depressed Mood;<br>Product Substitution Issue;<br>Suicidal Behaviour;<br>Suicide Attempt | Lexapro        |              |            | S           | Oral         | Quantity:30 Tablet(S); At<br>Bedtime; Oral |                 | Forest     |

  

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Dec-2016              | 10891769      | EXPEDITED (15-DAY) |                    | DS              | FR-FRI-1000075006    |                      | 66 YR      | Female     | FRA            |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                             | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|----------------------------|----------------------------|-----------------|--------------|----------------|
| Action Tremor; Dementia; Parkinsonism                             | Escitalopram Oxalate - Bp |                    |                    | S               | Oral                       | 20 Mg, Qd                  |                 | Allergan     |                |
|                                                                   | Depakote                  |                    |                    | S               | Oral                       | 1500 Mg, Qd                |                 | Not Reported |                |
|                                                                   | Depakote                  |                    |                    | S               | Oral                       | 1000 Mg, Unk               |                 | Not Reported |                |
|                                                                   | Depakote                  |                    |                    | S               | Oral                       | 500 Mg, Unk                |                 | Not Reported |                |
|                                                                   | Crestor                   |                    |                    | C               | Oral                       | 5 Mg, Unk                  |                 | Not Reported |                |
|                                                                   | Lasilix                   |                    |                    | C               | Oral                       | 40 Mg, Unk                 |                 | Not Reported |                |
|                                                                   | Kardegic                  |                    |                    | C               | Oral                       | 75 Mg, Unk                 |                 | Not Reported |                |
|                                                                   | Plaquenil                 |                    |                    | C               | Oral                       | 200 Mg, Unk                |                 | Not Reported |                |
|                                                                   | Preterax                  |                    |                    | C               |                            | Unk                        |                 | Not Reported |                |
|                                                                   | Abufene                   |                    |                    | C               | Oral                       | 400 Mg, Unk                |                 | Not Reported |                |
|                                                                   | Inexium                   |                    |                    | C               |                            | Unk                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                          | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Dec-2016                                                       | 12772303                  | EXPEDITED (15-DAY) |                    | HO, OT          | JP-FRI-1000087629          |                            | 74 YR           | Female       | JPN            |
| <u>Preferred Term</u>                                             | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Loss Of Consciousness; Sinus Node Dysfunction; Syncope | Escitalopram Oxalate Unk  |                    |                    | S               | Oral                       | Unk                        |                 | Allergan     |                |
|                                                                   | Donepezil Hydrochloride   |                    |                    | C               | Oral                       | 5 Mg, Qd                   |                 | Not Reported |                |
|                                                                   | Zopiclone                 |                    |                    | C               | Oral                       | 7.5 Mg, Qd                 |                 | Not Reported |                |
|                                                                   | Yokukansan                |                    |                    | C               | Oral                       | 2.5 G, Bid                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                          | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Dec-2016                                                       | 13034180                  | EXPEDITED (15-DAY) |                    | OT              | IT-009507513-1612ITA007161 |                            | 26 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                             | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Abuse; Poisoning; Sopor                                      | Simvastatin               |                    |                    | S               | Oral                       | 14 Dose Units, Total       |                 | Merck        |                |
|                                                                   | Aspirin                   |                    |                    | S               | Oral                       | 20 Dose Units, Total       |                 | Not Reported |                |
|                                                                   | Rivotril                  |                    |                    | S               | Oral                       | Strength: 2.5 Mg/ML, 10 ML |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|         |   |      | Total                |              |
|---------|---|------|----------------------|--------------|
| Entact  | S | Oral | 28 Dose Units, Total | Not Reported |
| Torvast | S | Oral | 8 Dose Units, Total  | Not Reported |
| Deursil | S | Oral | 10 Dose Units, Total | Not Reported |
| Igroton | S | Oral | 15 Dose Units, Total | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 30-Dec-2016              | 13037708      | EXPEDITED (15-DAY) |                    | HO, OT          | FR-ASTRAZENECA-2016SF31955 |                      | 90 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                                 | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Acute Cutaneous Lupus Erythematosus; Anaemia; Lymphopenia; Toxic Epidermal Necrolysis | Inexium                |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                       | Aprovel                |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                       | Aerius (Desloratadine) |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                       | Aerius (Desloratadine) |              |            | S           | Oral         | Doubled Dose       |                 | Not Reported |
|                                                                                       | Gaviscon               |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                       | Eliquis                |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                       | Eliquis                |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                       | Seroplex               |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                       | Hemigoxine Nativelle   |              |            | S           | Oral         | 0.125mg Unknown    |                 | Not Reported |
|                                                                                       | Loperamide             |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------|----------------------|------------|------------|----------------|
| 30-Dec-2016              | 13074408      | EXPEDITED (15-DAY) |                    | HO              | IT-APOTEX-2016AP016119 |                      | 58 YR      | Female     | ITA            |

| <u>Preferred Term</u>                                                                                                                              | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Adjustment Disorder With Mixed Anxiety And Depressed Mood; Anhedonia; Insomnia; Labelled Drug-Drug Interaction Medication Error; Suicidal Ideation | Venlafaxina Doc Generici    |              |            | S           | Unknown      | 300 Mg, Total      |                 | Apotex       |
|                                                                                                                                                    | Quetiapina Doc Generici     |              |            | S           | Unknown      | 200 Mg/Kg, Total   |                 | Apotex       |
|                                                                                                                                                    | Comprime Rivestite Con Film |              |            | S           | Unknown      | 75 Mg, Total       |                 | Not Reported |
|                                                                                                                                                    | Trazodone Hydrochloride     |              |            | S           | Unknown      | 20 Mg, Total       |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                        | Clonazepam                              |                    | S                  | Unknown         | 0.5 Mg, Total                                  |                      | Not Reported    |                              |                |
|------------------------------------------------------------------------|-----------------------------------------|--------------------|--------------------|-----------------|------------------------------------------------|----------------------|-----------------|------------------------------|----------------|
|                                                                        | Valproic Acid                           |                    | S                  | Unknown         | 300 Mg, Total                                  |                      | Not Reported    |                              |                |
|                                                                        | Alprazolam                              |                    | S                  | Unknown         | 1.5 Mg, Total                                  |                      | Not Reported    |                              |                |
| <u>FDA Received Date</u>                                               | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 30-Dec-2016                                                            | 13074612                                | EXPEDITED (15-DAY) |                    | OT              | PT-LUPIN<br>PHARMACEUTICALS<br>INC.-2016-05799 |                      | 23 YR           | Female                       | PRT            |
| <u>Preferred Term</u>                                                  | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Carcinoid Syndrome                                                     | Escitalopram                            |                    |                    | S               | Unknown                                        |                      |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                                               | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 30-Dec-2016                                                            | 13076078                                | DIRECT             | Y                  |                 |                                                |                      |                 | Female                       | USA            |
| <u>Preferred Term</u>                                                  | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Product Dispensing Error                                               | Buspar<br>Escitalopram Oxalate          |                    |                    | S<br>S          |                                                |                      |                 | Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                               | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 30-Dec-2016                                                            | 13076769                                | EXPEDITED (15-DAY) |                    | HO, LT, OT      | JP-ALLERGAN-<br>1680117US                      |                      | 16 YR           | Female                       | JPN            |
| <u>Preferred Term</u>                                                  | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Activation Syndrome;<br>Intentional Self-Injury;<br>Suicidal Behaviour | Escitalopram Oxalate - Bp               |                    |                    | S               | Oral                                           | 10 Mg, Qd            |                 | Allergan                     |                |
| <u>FDA Received Date</u>                                               | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 30-Dec-2016                                                            | 13076773                                | EXPEDITED (15-DAY) |                    | OT              | CH-ALLERGAN-<br>1682568US                      |                      | 34 YR           | Female                       | CHE            |
| <u>Preferred Term</u>                                                  | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Abortion Spontaneous;<br>Pregnancy                                     | Escitalopram Oxalate - Bp<br>Folic Acid |                    |                    | S<br>C          | Unknown<br>Unknown                             | 15 Mg, Qd            |                 | Allergan<br>Not Reported     |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                   | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 30-Dec-2016                                                                                                                                                | 13076782                      | EXPEDITED (15-DAY) |                    | OT              | IT-ALLERGAN-1682626US |                      | 46 YR           | Male         | ITA            |
| <u>Preferred Term</u>                                                                                                                                      | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depressed Mood; Drug Abuse; Psychomotor Retardation                                                                                                        | Escitalopram Oxalate - Bp     |                    |                    | S               | Oral                  | Unk Gtt, Unk         |                 | Allergan     |                |
|                                                                                                                                                            | Valium                        |                    |                    | S               | Oral                  | Unk Gtt, Unk         |                 | Not Reported |                |
|                                                                                                                                                            | Tavor [Lorazepam]             |                    |                    | S               | Oral                  | Unk Df, Unk          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                   | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Dec-2016                                                                                                                                                | 13077318                      | EXPEDITED (15-DAY) |                    | DE, OT          | US-JNJFOC-20161225121 |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                      | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                                                                                                                          | Loperamide                    |                    | Y                  | S               | Unknown               |                      |                 | Not Reported |                |
|                                                                                                                                                            | Loperamide                    |                    |                    | S               | Unknown               |                      |                 | Not Reported |                |
|                                                                                                                                                            | Escitalopram                  |                    |                    | S               | Unknown               |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                   | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Dec-2016                                                                                                                                                | 13088725                      | DIRECT             |                    |                 |                       |                      | 41 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                      | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Sensation In Eye; Balance Disorder; Dizziness; Feeling Abnormal; Headache; Muscle Spasticity; Nausea; Paraesthesia; Tinnitus; Withdrawal Syndrome | Escitalopram                  |                    |                    | S               |                       |                      |                 | Not Reported |                |
|                                                                                                                                                            | Synthroid                     |                    |                    | C               |                       |                      |                 | Not Reported |                |
|                                                                                                                                                            | B-Complex                     |                    |                    | C               |                       |                      |                 | Not Reported |                |
|                                                                                                                                                            | Vitd                          |                    |                    | C               |                       |                      |                 | Not Reported |                |
|                                                                                                                                                            | Fish Oil                      |                    |                    | C               |                       |                      |                 | Not Reported |                |
|                                                                                                                                                            | Digestive Advantage Probiotic |                    |                    | C               |                       |                      |                 | Not Reported |                |
|                                                                                                                                                            | Metamucil                     |                    |                    | C               |                       |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                   | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Jan-2017                                                                                                                                                | 13084248                      | DIRECT             |                    | HO              |                       |                      | 30 YR           | Male         | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>                           | <u>Duration</u> | <u>Mfr</u>   |                |
|--------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|---------------------------------|----------------------------------------------|-----------------|--------------|----------------|
| Condition Aggravated                                                                                                                 | Risperdal            |                    |                    | S               | Oral                            | Quantity:30 Tablet(S);                       |                 | Not Reported |                |
|                                                                                                                                      | Lexapro              |                    |                    | S               | Oral                            | Quantity:30 Tablet(S);                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                             | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u>                         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Jan-2017                                                                                                                          | 13033368             | EXPEDITED (15-DAY) |                    | OT              | IT-ROCHE-1867275                |                                              | 26 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                                                                                | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>                           | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Abuse; Poisoning; Sopor                                                                                                         | Rivotril             |                    |                    | S               | Oral                            | 2.5 Mg/ML Oral Drops, Solution' 10 ML Bottle |                 | Not Reported |                |
|                                                                                                                                      | Simvastatin          |                    |                    | S               | Oral                            |                                              |                 | Not Reported |                |
|                                                                                                                                      | Simvastatin          |                    |                    | S               | Oral                            |                                              |                 | Not Reported |                |
|                                                                                                                                      | Acetylsalicylic Acid |                    |                    | S               | Unknown                         |                                              |                 | Not Reported |                |
|                                                                                                                                      | Entact               |                    |                    | S               | Oral                            |                                              |                 | Not Reported |                |
|                                                                                                                                      | Torvast              |                    |                    | S               | Oral                            |                                              |                 | Not Reported |                |
|                                                                                                                                      | Deursil              |                    |                    | S               | Oral                            |                                              |                 | Not Reported |                |
|                                                                                                                                      | Igroton              |                    |                    | S               | Oral                            |                                              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                             | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u>                         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Jan-2017                                                                                                                          | 13078433             | EXPEDITED (15-DAY) |                    | LT              | IT-TEVA-725220ACC               |                                              | 63 YR           | Male         | ITA            |
| <u>Preferred Term</u>                                                                                                                | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>                           | <u>Duration</u> | <u>Mfr</u>   |                |
| Depressed Level Of Consciousness; Labelled Drug-Drug Interaction Medication Error; Musculoskeletal Stiffness; Rhabdomyolysis; Tremor | Escitalopram Oxalate |                    |                    | S               |                                 |                                              |                 | Ivax         |                |
|                                                                                                                                      | Lithium              |                    |                    | S               |                                 |                                              |                 | Barr         |                |
| <u>FDA Received Date</u>                                                                                                             | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u>                         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Jan-2017                                                                                                                          | 10903110             | EXPEDITED (15-DAY) |                    | OT              | IN-AUROBINDO-AUR-APL-2015-01872 |                                              | 50 YR           | Male         | IND            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                                                                                                    | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| Altered State Of Consciousness;<br>Electroencephalogram Abnormal;<br>Hypochloraemia;<br>Hypokalaemia;<br>Hyponatraemia;<br>Inappropriate Antidiuretic Hormone Secretion;<br>Metabolic Encephalopathy; Urine Sodium Abnormal;<br>Vomiting | Escitalopram 10 Mg        |                    |                    | S               | Unknown                  | 10 Mg, Unk           |                 | Aurobindo    |                |
|                                                                                                                                                                                                                                          | Telmisartan               |                    |                    | C               | Unknown                  | 80 Mg, Unk           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                 | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Jan-2017                                                                                                                                                                                                                              | 13042576                  | EXPEDITED (15-DAY) |                    | OT              | TR-ALLERGAN-1680921US    |                      | 52 YR           | Male         | TUR            |
| <u>Preferred Term</u>                                                                                                                                                                                                                    | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Carcinoembryonic Antigen Increased                                                                                                                                                                                                       | Escitalopram Oxalate - Bp |                    |                    | S               | Unknown                  | Unk                  |                 | Allergan     |                |
|                                                                                                                                                                                                                                          | Escitalopram Oxalate - Bp |                    |                    | S               |                          | Unk                  |                 | Allergan     |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                 | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Jan-2017                                                                                                                                                                                                                              | 13060246                  | EXPEDITED (15-DAY) |                    | HO, LT, OT      | IN-ALLERGAN-1682186US    |                      | 19 YR           | Female       | IND            |
| <u>Preferred Term</u>                                                                                                                                                                                                                    | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Headache;<br>Hypoglycaemia;<br>Intentional Overdose;<br>Respiratory Rate Increased; Suicidal Ideation; Suicide Attempt                                                                                                        | Escitalopram Oxalate - Bp |                    |                    | S               | Oral                     | 1 Df, Qd             |                 | Allergan     |                |
|                                                                                                                                                                                                                                          | Venlafaxine               |                    |                    | S               | Oral                     | 1 Df, Qd             |                 | Not Reported |                |
|                                                                                                                                                                                                                                          | Venlafaxine               |                    |                    | S               | Oral                     | 10-15 Tablets        |                 | Not Reported |                |
|                                                                                                                                                                                                                                          | Clonazepam                |                    |                    | S               | Oral                     | 1 Df, Qd             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                 | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Jan-2017                                                                                                                                                                                                                              | 13060254                  | EXPEDITED (15-DAY) |                    | HO, LT, OT      | IN-BAUSCH-BL-2016-032279 |                      | 19 YR           | Female       | IND            |



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| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Dizziness; Headache;      | Venlafaxine    |              |            | S           | Oral         |                    |                 | Not Reported |
| Hypoglycaemia;            | Venlafaxine    |              |            | S           | Oral         |                    |                 | Not Reported |
| Intentional Overdose;     | Clonazepam     |              |            | S           | Oral         |                    |                 | Not Reported |
| Respiratory Rate          | Clonazepam     |              |            | S           | Oral         |                    |                 | Not Reported |
| Increased; Suicidal       | Clonazepam     |              |            | S           | Oral         |                    |                 | Not Reported |
| Ideation; Suicide Attempt | Escitalopram   |              |            | S           | Oral         |                    |                 | Not Reported |
|                           | Escitalopram   |              |            | S           | Oral         |                    |                 | Not Reported |

  

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Jan-2017              | 13082165      | EXPEDITED (15-DAY) |                    | OT              | DE-TEVA-723599GER    |                      | 1 DAY      | Male       | DEU            |

  

| <u>Preferred Term</u>                                                                                              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|---------------------|-----------------|--------------|
| <div> Foetal Exposure During Pregnancy; Premature Baby; Respiratory Disorder Neonatal; Small For Dates Baby </div> | Escitalopram   |              |            | S           | Transplacental | 10 Milligram Daily; |                 | Ivax         |
|                                                                                                                    | Folsaeure      |              |            | C           | Transplacental |                     |                 | Not Reported |

  

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 03-Jan-2017              | 13082345      | EXPEDITED (15-DAY) |                    | OT              | DE-MYLANLABS-2016M1058599 |                      |            | Unknown    | DEU            |

  

| <u>Preferred Term</u>                                                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| <div> Premature Baby; Respiratory Disorder Neonatal; Small For Dates Baby </div> | Escitalopram   |              |            | S           | Transplacental | 10 Mg, Qd          |                 | Not Reported |
|                                                                                  | Folsaeure      |              |            | C           | Transplacental |                    |                 | Mylan        |

  

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Jan-2017              | 13085506      | DIRECT           |                    | OT              |                      |                      | 63 YR      | Female     | USA            |

  

| <u>Preferred Term</u>                    | <u>Product</u>                                   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u> |
|------------------------------------------|--------------------------------------------------|--------------|------------|-------------|--------------|-----------------------|-----------------|------------|
| Balance Disorder; Depression; Dizziness; | Escitalopram 10 Mg Tablet - Oval Aurobindo Pharm |              |            | S           | Oral         | Quantity:1 Tablet(S); |                 | Aurobindo  |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                              |                |   |              |
|------------------------------|----------------|---|--------------|
| Mood Swings; Product         | Synthroid      | C | Not Reported |
| Substitution Issue; Pruritus | Varapamil      | C | Not Reported |
| Generalised; Therapy         | Creon          | C | Not Reported |
| Cessation                    | Protonix       | C | Not Reported |
|                              | B-12           | C | Not Reported |
|                              | Levocetirizine | C | Not Reported |
|                              | Biotin         | C | Not Reported |
|                              | Vitamin D Nos  | C | Not Reported |
|                              | Benedril       | C | Not Reported |
|                              | Baby Aspirin   | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| 04-Jan-2017              | 10777637       | NON-EXPEDITED    |                    |                 | US-PFIZER INC-<br>2015047139 |                      | 48 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity    | Xanax          |                  |                    | S               |                              | Unk                  |                 | Pfizer       |                |
|                          | Estradiol      |                  |                    | S               |                              | Unk                  |                 | Not Reported |                |
|                          | Lexapro        |                  |                    | S               |                              | Unk                  |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|-----------------|------------|----------------|
| 04-Jan-2017              | 13083159       | EXPEDITED (15-DAY) |                    | DS, HO, LT      | SE-CIPLA LTD.-<br>2016SE24278 |                      |                 | Unknown    | SWE            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Epilepsy; Muscle Spasms  | Escitalopram   |                    |                    | S               | Unknown                       | Unk                  |                 | Invagen    |                |

| <u>FDA Received Date</u>    | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------|----------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|-----------------|--------------|----------------|
| 04-Jan-2017                 | 13083342       | EXPEDITED (15-DAY) |                    | OT              | SE-CIPLA LTD.-<br>2016SE24326 |                      |                 | Unknown      | SWE            |
| <u>Preferred Term</u>       | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Inhibitory Drug Interaction | Escitalopram   |                    |                    | S               | Unknown                       | Unk                  |                 | Invagen      |                |
|                             | Corsodyl 1 %   |                    |                    | S               | Unknown                       | Unk                  |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|--------------------------------------------|----------------------|-----------------|-----------------|----------------|
| 04-Jan-2017                                                                                            | 13083893       | EXPEDITED (15-DAY) |                    | OT              | FR-ROCHE-1873603                           |                      | 4 YR            | Male            | FRA            |
| <u>Preferred Term</u>                                                                                  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Behaviour Disorder;<br>Developmental Delay;<br>Foetal Exposure During<br>Pregnancy; Speech<br>Disorder | Rivotril       |                    |                    | S               | Transplacental                             |                      |                 | Not Reported    |                |
|                                                                                                        | Seroplex       |                    |                    | S               | Transplacental                             |                      |                 | Not Reported    |                |
|                                                                                                        | Stilnox        |                    |                    | S               | Transplacental                             |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 04-Jan-2017                                                                                            | 13084314       | EXPEDITED (15-DAY) |                    | DE, HO, OT      | US-<br>GLAXOSMITHKLINE-<br>US2016GSK193561 |                      | 22 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                                                  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Completed Suicide                                                                                      | Bupropion      |                    |                    | S               | Oral                                       | Unk                  |                 | Glaxosmithkline |                |
|                                                                                                        | Escitalopram   |                    |                    | S               | Oral                                       | Unk                  |                 | Glaxosmithkline |                |
|                                                                                                        | Ethanol        |                    |                    | S               | Oral                                       |                      |                 | Glaxosmithkline |                |
|                                                                                                        | Clonazepam     |                    |                    | S               | Oral                                       |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 04-Jan-2017                                                                                            | 13084318       | EXPEDITED (15-DAY) |                    | DE, OT          | US-<br>GLAXOSMITHKLINE-<br>US2016GSK194052 |                      | 59 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                                                  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Completed Suicide                                                                                      | Duloxetine     |                    |                    | S               | Oral                                       |                      |                 | Glaxosmithkline |                |
|                                                                                                        | Bupropion      |                    |                    | S               | Oral                                       |                      |                 | Glaxosmithkline |                |
|                                                                                                        | Escitalopram   |                    |                    | S               | Oral                                       |                      |                 | Glaxosmithkline |                |
| <u>FDA Received Date</u>                                                                               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 04-Jan-2017                                                                                            | 13084805       | EXPEDITED (15-DAY) |                    | HO, LT          | IT-TEVA-2010005656                         |                      | 63 YR           | Male            | ITA            |
| <u>Preferred Term</u>                                                                                  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                   |              |   |      |                      |              |
|-----------------------------------|--------------|---|------|----------------------|--------------|
| Depressed Level Of Consciousness; | Carbolithium | S | Oral | 900 Milligram Daily; | Barr         |
| Musculoskeletal Stiffness;        | Carbolithium | S | Oral |                      | Barr         |
| Rhabdomyolysis; Tremor            | Zyprexa      | S | Oral | 10 Milligram Daily;  | Not Reported |
|                                   | Zyprexa      | S |      |                      | Not Reported |
|                                   | Cipralext    | S | Oral | 15 Milligram Daily;  | Not Reported |
|                                   | Lorazepam    | C |      |                      | Not Reported |
|                                   | Bisoprololo  | C |      |                      | Not Reported |
|                                   | Lansoprazolo | C |      |                      | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Jan-2017              | 13084886      | EXPEDITED (15-DAY) |                    | OT              | FR-SA-2017SA000752   |                      | 4 YR       | Male       | FRA            |

| <u>Preferred Term</u>                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Behaviour Disorder;                               | Stilnox        |              |            | S           | Transplacental |                    |                 | Not Reported |
| Developmental Delay;                              | Seroplex       |              |            | S           | Transplacental |                    |                 | Not Reported |
| Foetal Exposure During Pregnancy; Speech Disorder | Rivotril       |              |            | S           | Transplacental |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 04-Jan-2017              | 13085394      | EXPEDITED (15-DAY) |                    | DE, HO          | US-JNJFOC-20170100166 |                      | 41 YR      | Male       | USA            |

| <u>Preferred Term</u>      | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide;         | Tramadol                  |              |            | S           | Oral         |                    |                 | Not Reported |
| Toxicity To Various Agents | Baclofen                  |              |            | S           | Oral         |                    |                 | Not Reported |
|                            | Clonazepam                |              |            | S           | Oral         |                    |                 | Not Reported |
|                            | Escitalopram              |              |            | S           | Oral         |                    |                 | Not Reported |
|                            | Hydrocodone/Acetaminophen |              |            | S           | Oral         |                    |                 | Not Reported |
|                            | Alprazolam                |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 04-Jan-2017              | 13086088      | EXPEDITED (15-DAY) |                    | HO              | US-ALLERGAN-1700119US |                      | 20 YR      | Female     | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                             | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|-------------------------------------|----------------------|-----------------|--------------|----------------|
| Caesarean Section;<br>Overdose; Pregnancy;<br>Premature Labour                                                    | Escitalopram Oxalate - Bp |                    |                    | S               | Unknown                             | 30 Mg, Qd            |                 | Allergan     |                |
|                                                                                                                   | Bupropion                 |                    |                    | S               | Unknown                             | 200 Mg, Qd           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                          | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Jan-2017                                                                                                       | 13086151                  | EXPEDITED (15-DAY) |                    | HO              | IT-MYLANLABS-<br>2016M1058974       |                      |                 | Unknown      | ITA            |
| <u>Preferred Term</u>                                                                                             | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Haemolysis; Self-Medication                                                                                       | Escitalopram              |                    |                    | S               |                                     | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                          | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Jan-2017                                                                                                       | 13087577                  | EXPEDITED (15-DAY) |                    | OT              | DE-AUROBINDO-AUR-<br>APL-2016-16141 |                      | 1 DAY           | Male         | DEU            |
| <u>Preferred Term</u>                                                                                             | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Foetal Exposure During<br>Pregnancy; Premature<br>Baby; Respiratory<br>Disorder Neonatal; Small<br>For Dates Baby | Escitalopram 10 Mg        |                    |                    | S               | Transplacental                      | 10 Mg, Once A Day    |                 | Aurobindo    |                |
|                                                                                                                   | Folsaeure                 |                    |                    | C               | Transplacental                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                          | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Jan-2017                                                                                                       | 13088860                  | EXPEDITED (15-DAY) |                    | OT              | FR-MYLANLABS-<br>2016M1058714       |                      |                 | Unknown      | FRA            |
| <u>Preferred Term</u>                                                                                             | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Pemphigoid                                                                                                        | Metformin                 |                    |                    | S               | Unknown                             |                      |                 | Not Reported |                |
|                                                                                                                   | Risperidone               |                    |                    | S               | Unknown                             |                      |                 | Not Reported |                |
|                                                                                                                   | Escitalopram              |                    |                    | S               | Unknown                             |                      |                 | Not Reported |                |
|                                                                                                                   | Vildagliptin              |                    |                    | S               | Unknown                             |                      |                 | Mylan        |                |
| <u>FDA Received Date</u>                                                                                          | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Jan-2017                                                                                                       | 13088897                  | EXPEDITED (15-DAY) |                    | OT              | DE-ALLERGAN-<br>1700292US           |                      | 1 DAY           | Male         | DEU            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                                         | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| Premature Baby;<br>Respiratory Disorder<br>Neonatal; Small For Dates<br>Baby                                                                                                                                                                                                                                                                                                                                                  | Escitalopram Oxalate - Bp |                    |                    | S               | Transplacental        | 10 Mg, Qd            |                 | Allergan     |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                               | Folsaeure                 |                    |                    | C               | Transplacental        | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                                                                                                      | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Jan-2017                                                                                                                                                                                                                                                                                                                                                                                                                   | 13089156                  | EXPEDITED (15-DAY) |                    | HO              | IT-TEVA-725022ACC     |                      | 78 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                                         | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Haemolysis; Self-Medication                                                                                                                                                                                                                                                                                                                                                                                                   | Escitalopram              |                    |                    | S               |                       |                      |                 | Ivax         |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                                                                                                      | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Jan-2017                                                                                                                                                                                                                                                                                                                                                                                                                   | 13089791                  | EXPEDITED (15-DAY) |                    | HO, LT, OT      | US-ALLERGAN-1700298US |                      |                 | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                                         | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Distension; C-Reactive Protein Increased; Drug Withdrawal Syndrome<br>Neonatal; Foetal Exposure During Pregnancy;<br>Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Necrosis; Haematochezia; Hypertonia; Hypocalcaemia; Hypoglycaemia; Hyponatraemia; Hypothermia; Irritability; Leukopenia; Necrotising Colitis; Pneumatosis; Polycythaemia; Thrombocytopenia; Tremor; Vomiting | Escitalopram Oxalate - Bp |                    |                    | S               | Transplacental        | 30 Mg, Qd            |                 | Allergan     |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                               | Bupropion                 |                    |                    | S               | Transplacental        | 200 Mg, Qd           |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>        | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------------------|--------------------|--------------------|-----------------|-----------------------------|----------------------|-----------------|--------------|----------------|
| 05-Jan-2017              | 13090186                   | EXPEDITED (15-DAY) |                    | OT              | FR-ANIPHARMA-2017-FR-000002 |                      | 82 YR           | Female       | FRA            |
| <u>Preferred Term</u>    | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Pemphigoid               | Risperidone (Non-Specific) |                    |                    | S               | Unknown                     |                      |                 | Not Reported |                |
|                          | Vildagliptin               |                    |                    | S               |                             |                      |                 | Not Reported |                |
|                          | Escitalopram               |                    |                    | S               |                             |                      |                 | Not Reported |                |
|                          | Metformin                  |                    |                    | C               |                             |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                         | <u>503B Facility</u>                                                                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|--------------------------------------------------------------|--------------------------------------------------------------------------------------|-----------------|--------------|----------------|
| 06-Jan-2017                                                                                                                             | 13070960       | EXPEDITED (15-DAY) |                    | HO, LT, OT      | IN-SUN<br>PHARMACEUTICAL<br>INDUSTRIES LTD-<br>2016R1-130339 |                                                                                      | 19 YR           | Female       | IND            |
| <u>Preferred Term</u>                                                                                                                   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                 | <u>Dosage Text</u>                                                                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Headache;<br>Hypoglycaemia;<br>Intentional Overdose;<br>Respiratory Rate<br>Increased; Suicidal<br>Ideation; Suicide Attempt | Clonazepam     |                    |                    | S               | Oral                                                         | 10 To 15 Tablets Of<br>Venlafaxine, Tablet<br>Escitalopram And Tablet<br>Clonazepam  |                 | Sun          |                |
|                                                                                                                                         | Clonazepam     |                    |                    | S               | Oral                                                         | Unk Unk, Qd                                                                          |                 | Sun          |                |
|                                                                                                                                         | Escitalopram   |                    |                    | S               | Oral                                                         | 10 To 15 Tablets Of<br>Venlafaxine, Tablet<br>Escitalopram, And Tablet<br>Clonazepam |                 | Not Reported |                |
|                                                                                                                                         | Escitalopram   |                    |                    | S               | Oral                                                         | Unk Unk, Qd                                                                          |                 | Not Reported |                |
|                                                                                                                                         | Escitalopram   |                    |                    | S               | Oral                                                         | Unk                                                                                  |                 | Not Reported |                |
|                                                                                                                                         | Escitalopram   |                    |                    | S               | Oral                                                         | Unk                                                                                  |                 | Not Reported |                |
|                                                                                                                                         | Venlafaxine    |                    |                    | S               | Oral                                                         | 10 To 15 Tablets Of<br>Venlafaxine, Tablet<br>Escitalopram, And Tablet<br>Clonazepam |                 | Sun          |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 06-Jan-2017              | 13083902      | EXPEDITED (15-DAY) |                    | DE, HO          | US-JNJFOC-20161226465 |                      | 74 YR      | Female     | USA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                            | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide;<br>Toxicity To Various Agents | Famotidine          |              | Y          | S           | Oral         |                    |                 | Not Reported |
|                                                  | Famotidine          |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Cetirizine          |              | Y          | S           | Oral         |                    |                 | Not Reported |
|                                                  | Cetirizine          |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Doxepin             |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Escitalopram        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Hydrocodone         |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Olmesartan          |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Alprazolam          |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Hydrochlorothiazide |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Pregabalin          |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Jan-2017              | 13091877      | EXPEDITED (15-DAY) |                    | OT              | IT-TEVA-726426ACC    |                      | 26 YR      | Female     | ITA            |

| <u>Preferred Term</u>           | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Abuse; Poisoning;<br>Sopor | Simvastatin              |              |            | S           | Oral         |                    |                 | Ivax         |
|                                 | Simvastatin              |              |            | S           | Oral         |                    |                 | Ivax         |
|                                 | Aspirina - Bayer S.P.A.  |              |            | S           |              |                    |                 | Not Reported |
|                                 | Rivotril - Roche S.P.A.  |              |            | S           | Oral         |                    |                 | Not Reported |
|                                 | Rivotril - Roche S.P.A.  |              |            | S           |              |                    |                 | Not Reported |
|                                 | Igroton - Amdipharm Ltd  |              |            | S           | Oral         |                    |                 | Not Reported |
|                                 | Igroton - Amdipharm Ltd  |              |            | S           |              |                    |                 | Not Reported |
|                                 | Deursil - Cheplapharm    |              |            | S           | Oral         |                    |                 | Not Reported |
|                                 | Arzneimittel Gmbh        |              |            |             |              |                    |                 |              |
|                                 | Deursil - Cheplapharm    |              |            | S           |              |                    |                 | Not Reported |
|                                 | Arzneimittel Gmbh        |              |            |             |              |                    |                 |              |
|                                 | Torvast - Pfizer Limited |              |            | S           | Oral         |                    |                 | Not Reported |
|                                 | Torvast - Pfizer Limited |              |            | S           |              |                    |                 | Not Reported |
| Entact - H. Lundbeck A/S        |                          |              | S          | Oral        |              |                    | Not Reported    |              |
|                                 | Entact - H. Lundbeck A/S |              |            | S           |              |                    |                 | Not Reported |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>   | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------|-----------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 06-Jan-2017                | 13091999        | EXPEDITED (15-DAY) |                    | DE              | US-JNJFOC-20161226353 |                      | 58 YR           | Female       | USA            |
| <u>Preferred Term</u>      | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Toxicity To Various Agents | Ibuprofen       |                    | Y                  | S               | Oral                  |                      |                 | Not Reported |                |
|                            | Ibuprofen       |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                            | Oxycodone       |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                            | Escitalopram    |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>   | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Jan-2017                | 13092219        | EXPEDITED (15-DAY) |                    | DE              | US-JNJFOC-20161226577 |                      | 53 YR           | Female       | USA            |
| <u>Preferred Term</u>      | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Toxicity To Various Agents | Diphenhydramine |                    | Y                  | S               | Oral                  |                      |                 | Not Reported |                |
|                            | Amitriptyline   |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                            | Escitalopram    |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                            | Ethanol         |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>   | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Jan-2017                | 13092284        | EXPEDITED (15-DAY) |                    | DE, HO          | US-JNJFOC-20161226578 |                      | 41 YR           | Male         | USA            |
| <u>Preferred Term</u>      | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Toxicity To Various Agents | Diphenhydramine |                    | Y                  | S               | Oral                  |                      |                 | Not Reported |                |
|                            | Escitalopram    |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                            | Ethanol         |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>   | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Jan-2017                | 13093578        | EXPEDITED (15-DAY) |                    | DE, OT          | US-JNJFOC-20170100749 |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>      | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                     |                |   |   |         |              |
|-------------------------------------------------------------------------------------|----------------|---|---|---------|--------------|
| Cardiac Arrest; Cardiac Disorder; Death; Drug Interaction;                          | Domperidone    |   | S | Unknown | Not Reported |
| Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication | Domperidone    |   | S | Unknown | Not Reported |
|                                                                                     | Domperidone    |   | S | Unknown | Not Reported |
|                                                                                     | Domperidone    |   | S | Unknown | Not Reported |
|                                                                                     | Domperidone    |   | S | Unknown | Not Reported |
|                                                                                     | Domperidone    |   | S | Unknown | Not Reported |
|                                                                                     | Domperidone    |   | S | Unknown | Not Reported |
|                                                                                     | Domperidone    |   | S | Unknown | Not Reported |
|                                                                                     | Domperidone    |   | S | Unknown | Not Reported |
|                                                                                     | Levofloxacin   |   | S | Unknown | Not Reported |
|                                                                                     | Risperidone    |   | S | Unknown | Not Reported |
|                                                                                     | Droperidol     |   | S | Unknown | Not Reported |
|                                                                                     | Itraconazole   |   | S | Unknown | Not Reported |
|                                                                                     | Ketoconazole   |   | S | Unknown | Not Reported |
|                                                                                     | Miconazole     | Y | S | Unknown | Not Reported |
|                                                                                     | Miconazole     | Y | S | Unknown | Not Reported |
|                                                                                     | Tetracycline   |   | S | Unknown | Not Reported |
|                                                                                     | Fluconazole    | Y | S | Unknown | Not Reported |
|                                                                                     | Haloperidol    |   | S | Unknown | Not Reported |
|                                                                                     | Lapatinib      |   | S | Unknown | Not Reported |
|                                                                                     | Diltiazem      |   | S | Unknown | Not Reported |
|                                                                                     | Metronidazole  |   | S | Unknown | Not Reported |
|                                                                                     | Aprepitant     |   | S | Unknown | Not Reported |
|                                                                                     | Nicardipine    |   | S | Unknown | Not Reported |
|                                                                                     | Norfloxacin    |   | S | Unknown | Not Reported |
|                                                                                     | Sertraline     |   | S | Unknown | Not Reported |
|                                                                                     | Verapamil      |   | S | Unknown | Not Reported |
|                                                                                     | Voriconazole   |   | S | Unknown | Not Reported |
|                                                                                     | Clarithromycin |   | S | Unknown | Not Reported |

**FDA Adverse Event Reporting System  
Freedom of Information Act (FOIA)  
Detailed Report**

|               |   |         |              |
|---------------|---|---------|--------------|
| Amiodarone    | S | Unknown | Not Reported |
| Isoniazid     | S | Unknown | Not Reported |
| Cyclosporine  | S | Unknown | Not Reported |
| Erythromycin  | S | Unknown | Not Reported |
| Desipramine   | S | Unknown | Not Reported |
| Clotrimazole  | S | Unknown | Not Reported |
| Lidocaine     | S | Unknown | Not Reported |
| Escitalopram  | S | Unknown | Not Reported |
| Ibutilide     | S | Unknown | Not Reported |
| Fluoxetine    | S | Unknown | Not Reported |
| Imipramine    | S | Unknown | Not Reported |
| Azithromycin  | S | Unknown | Not Reported |
| Methadone     | S | Unknown | Not Reported |
| Moxifloxacin  | S | Unknown | Not Reported |
| Nortriptyline | S | Unknown | Not Reported |
| Octreotide    | S | Unknown | Not Reported |
| Ondansetron   | S | Unknown | Not Reported |
| Perflutren    | S | Unknown | Not Reported |
| Propafenone   | S | Unknown | Not Reported |
| Quetiapine    | S | Unknown | Not Reported |
| Ranolazine    | S | Unknown | Not Reported |
| Citalopram    | S | Unknown | Not Reported |
| Sotalol       | S | Unknown | Not Reported |
| Clindamycin   | S | Unknown | Not Reported |
| Desipramine   | S | Unknown | Not Reported |
| Ciprofloxacin | S | Unknown | Not Reported |
| Doxepin       | S | Unknown | Not Reported |
| Dronedarone   | S | Unknown | Not Reported |
| Tacrolimus    | S | Unknown | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|               |   |         |              |
|---------------|---|---------|--------------|
| Flecainide    | S | Unknown | Not Reported |
| Amitriptyline | S | Unknown | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 06-Jan-2017              | 13093854      | EXPEDITED (15-DAY) |                    | HO              | US-ALLERGAN-1700386US |                      |            | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                            | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|--------------|------------|-------------|----------------|--------------------|-----------------|------------|
| Bradycardia; Crying; Electrocardiogram Qt Prolonged; Foetal Exposure During Pregnancy; High-Pitched Crying; Hypertonia; Hypopnoea; Irritability; Lethargy; Meconium Aspiration Syndrome; Posturing; Seizure; Tachycardia; Toxicity To Various Agents; Umbilical Cord Around Neck | Escitalopram Oxalate - Bp |              |            | S           | Transplacental | 20 Mg, Unk         |                 | Allergan   |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Jan-2017              | 13096987      | DIRECT           |                    | OT              |                      |                      | 64 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                 | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u> |
|---------------------------------------------------------------------------------------|--------------------|--------------|------------|-------------|--------------|-----------------------------------|-----------------|------------|
| Anger; Condition Aggravated; Depression; Drug Ineffective; Product Substitution Issue | Escitalopram 10 Mg |              |            | S           | Oral         | Quantity:1 Tablet(S); Daily; Oral |                 | Cipla      |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Jan-2017              | 13095154      | EXPEDITED (15-DAY) |                    | OT              | FR-ZYDUS-013270      |                      | 82 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Pemphigoid            | Metformin      |              |            | S           | Unknown      |                    |                 | Zyodus Pharm |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|              |   |         |              |
|--------------|---|---------|--------------|
| Risperidone  | S | Unknown | Zydus Pharm  |
| Escitalopram | S | Unknown | Zydus Pharm  |
| Vildagliptin | S | Unknown | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------------------------------------|----------------------|------------|------------|----------------|
| 09-Jan-2017              | 13096153      | EXPEDITED (15-DAY) |                    | DS, HO, OT      | DE-SUN<br>PHARMACEUTICAL<br>INDUSTRIES LTD-<br>2016RR-121894 |                      |            | Male       | DEU            |

| <u>Preferred Term</u>                                       | <u>Product</u>                             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------|--------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Akathisia; Dystonia;<br>Restlessness; Tardive<br>Dyskinesia | Escitalopram Basics 10 Mg<br>Filmtabletten |              |            | S           | Unknown      | 1/2-0-1/2          |                 | Not Reported |
|                                                             | Escitalopram Basics 10 Mg<br>Filmtabletten |              |            | S           | Unknown      | 1-0-1/2            |                 | Not Reported |
|                                                             | Escitalopram Basics 10 Mg<br>Filmtabletten |              |            | S           | Unknown      | 1-0-0              |                 | Not Reported |
|                                                             | Citalopram Basics                          |              |            | S           | Oral         | 15 Mg              |                 | Sun          |
|                                                             | Risperidon Atid Fta                        |              |            | S           | Unknown      | Up To 4 Mg         |                 | Not Reported |
|                                                             | Melperon Aristo                            |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                                                             | Quetiapine                                 |              |            | C           | Unknown      | Unk                |                 | Not Reported |
|                                                             | Olanzapine                                 |              |            | C           | Unknown      | Unk                |                 | Not Reported |
|                                                             | Mirtazapine                                |              |            | C           | Unknown      | Unk                |                 | Not Reported |
|                                                             | Akineton                                   |              |            | C           | Unknown      | Unk                |                 | Not Reported |
|                                                             | Parkopan                                   |              |            | C           | Unknown      | Unk                |                 | Not Reported |
|                                                             | Dociton                                    |              |            | C           | Unknown      | Unk                |                 | Not Reported |
|                                                             | Diazepam                                   |              |            | C           | Unknown      | Unk                |                 | Not Reported |
|                                                             | Folgamma                                   |              |            | C           | Unknown      | Unk                |                 | Not Reported |
|                                                             | Tetmodis                                   |              |            | C           | Unknown      | Unk                |                 | Not Reported |
|                                                             | Biolin                                     |              |            | C           | Unknown      | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------------------------|----------------------|------------|------------|----------------|
| 09-Jan-2017              | 13097987      | NON-EXPEDITED    |                    |                 | US-<br>GLAXOSMITHKLINE-<br>US2017GSK001151 |                      |            | Female     | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Drug Ineffective      | Wellbutrin     |              |            | S           |              |                    |                 | Glaxosmithkline |
|                       | Lexapro        |              |            | S           |              |                    |                 | Not Reported    |
|                       | Zoloft         |              |            | S           |              |                    |                 | Not Reported    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Jan-2017              | 9893763       | EXPEDITED (15-DAY) |                    | OT              | CA-FRI-1000054196    |                      | 48 YR      | Male       | CAN            |

| <u>Preferred Term</u>                                                                                                                                                               | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abnormal Dreams;<br>Anxiety; Feeling Jittery;<br>Hallucination;<br>Hyperhidrosis;<br>Hypervigilance; Injury;<br>Middle Insomnia; Mood<br>Altered; Restlessness;<br>Tremor; Vomiting | Escitalopram Oxalate Unk |              |            | S           | Oral         | 10 Mg, Qd          |                 | Allergan     |
|                                                                                                                                                                                     | Escitalopram Oxalate Unk |              |            | S           |              |                    |                 | Allergan     |
|                                                                                                                                                                                     | Cymbalta                 |              |            | S           | Oral         | 60 Mg, Qd          |                 | Not Reported |
|                                                                                                                                                                                     | Cymbalta                 |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                     | Asa                      |              |            | C           |              | 325 Mg, Qd         |                 | Not Reported |
|                                                                                                                                                                                     | Atenolol                 |              |            | C           |              | 25 Mg, Qd          |                 | Not Reported |
|                                                                                                                                                                                     | Dronedarone              |              |            | C           |              | 400 Mg, Qd         |                 | Not Reported |
|                                                                                                                                                                                     | Percocet                 |              |            | C           |              | Unk Unk, Tid       |                 | Not Reported |
|                                                                                                                                                                                     | Synthroid                |              |            | C           |              | .1 Mg, Qd          |                 | Not Reported |
|                                                                                                                                                                                     | Zopiclone                |              |            | C           |              | 7.5 Mg, Qd         |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Jan-2017              | 11850406      | EXPEDITED (15-DAY) |                    | HO              | FR-FRI-1000081668    |                      | 87 YR      | Female     | FRA            |

| <u>Preferred Term</u>              | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction;<br>Haemarthrosis | Escitalopram Oxalate Unk |              |            | S           | Oral         | 5 Mg, Qd           |                 | Allergan     |
|                                    | Plavix                   |              |            | S           | Oral         | 75 Mg, Qd          |                 | Not Reported |
|                                    | Atorvastatin             |              |            | C           | Unknown      | 50 Mg, Bid         |                 | Not Reported |
|                                    | Atacand                  |              |            | C           | Unknown      | 8 Mg, Qd           |                 | Not Reported |
|                                    | Stresam                  |              |            | C           | Unknown      | 1 Df, Bid          |                 | Not Reported |
|                                    | Lyrica                   |              |            | C           | Unknown      | 25 Mg, Tid         |                 | Not Reported |
|                                    | Zyprexa                  |              |            | C           | Unknown      | 5 Mg, Qd           |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|            |   |         |                   |              |
|------------|---|---------|-------------------|--------------|
| Levothyrox | C | Unknown | 50 Mg, Qd         | Not Reported |
| Theralene  | C | Unknown | 5 Mg, Qd          | Not Reported |
| Zymad      | C | Oral    | 80000 Iu, Q Month | Not Reported |
| Dafalgan   | C | Unknown | 500 Mg, Bid       | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|------------|------------|----------------|
| 10-Jan-2017              | 12496097      | EXPEDITED (15-DAY) |                    | OT              | DE-CIPLA LTD.-<br>2016DE08123 |                      |            | Unknown    | DEU            |

| <u>Preferred Term</u>                                                          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Depressed Mood;<br>Gambling; Nicotine<br>Dependence; Suicide<br>Attempt; Theft | Escitalopram   |              |            | S           | Unknown      | Unk                |                 | Invagen      |
|                                                                                | Escitalopram   |              |            | S           | Unknown      | Unk                |                 | Invagen      |
|                                                                                | Quetiapine     |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                                                                                | Ropinirole     |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                                                                                | Ropinirole     |              |            | S           | Unknown      | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 10-Jan-2017              | 12918075      | EXPEDITED (15-DAY) |                    | HO, LT          | FR-ALLERGAN-<br>1674835US |                      | 75 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                          | <u>Product</u>                                                    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------|-------------------------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cerebral Haematoma;<br>Drug Interaction; Subdural<br>Haematoma | Escitalopram Oxalate - Bp                                         |              |            | S           | Oral         | 20 Mg, Qd          |                 | Allergan     |
|                                                                | Plavix                                                            |              |            | S           | Oral         | 75 Mg, Qd          |                 | Not Reported |
|                                                                | Kardegic                                                          |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                                                                | Seresta                                                           |              |            | C           |              | 10 Mg, Bid         |                 | Not Reported |
|                                                                | Pantoprazole                                                      |              |            | C           |              | 20 Mg, Qd          |                 | Not Reported |
|                                                                | Pantoprazole                                                      |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                | Folinoral                                                         |              |            | C           |              | 5 Mg, Qd           |                 | Not Reported |
|                                                                | Duphalac                                                          |              |            | C           |              | Unk                |                 | Not Reported |
|                                                                | Dexeryl (Glycerol And White Soft<br>Paraffin And Liquid Paraffin) |              |            | C           |              | Unk                |                 | Not Reported |
|                                                                | Simvastatin                                                       |              |            | C           |              | 40 Mg, Qd          |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 10-Jan-2017              | 13086153      | EXPEDITED (15-DAY) |                    | OT              | IT-MYLANLABS-2016M1058947 |                      |            | Unknown    | ITA            |

| <u>Preferred Term</u>                  | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Abuse; Overdose; Poisoning; Sopor | Simvastatin          |              |            | S           | Oral         | 14 Df, Once        |                 | Not Reported |
|                                        | Simvastatin          |              |            | S           |              | 20 Df, Once        |                 | Not Reported |
|                                        | Acetylsalicylic Acid |              |            | S           |              | Unk                |                 | Not Reported |
|                                        | Rivotril             |              |            | S           | Oral         | 10 MI, Total       |                 | Mylan        |
|                                        | Igroton              |              |            | S           | Oral         | 15 Df, Total       |                 | Mylan        |
|                                        | Deursil              |              |            | S           | Oral         | 10 Df, Total       |                 | Mylan        |
|                                        | Torvast              |              |            | S           | Oral         | 8 Df, Total        |                 | Mylan        |
|                                        | Entact               |              |            | S           | Oral         | 28 Df, Total       |                 | Mylan        |
|                                        | Aspirina             |              |            | S           |              |                    |                 | Mylan        |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Jan-2017              | 13091008      | EXPEDITED (15-DAY) |                    | HO, LT, OT      | IN-ACCORD-047140     |                      | 19 YR      | Female     | IND            |

| <u>Preferred Term</u>                                                                                                    | <u>Product</u>                        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                          | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------|---------------------------------------|--------------|------------|-------------|--------------|-----------------------------------------------------------------------------|-----------------|--------------|
| Dizziness; Headache; Hypoglycaemia; Intentional Overdose; Respiratory Rate Increased; Suicidal Ideation; Suicide Attempt | Clonazepam                            |              |            | S           | Oral         | 10 To 15 Tablets Of Venlafaxine, Tablet Escitalopram, And Tablet Clonazepam |                 | Accord       |
|                                                                                                                          | Escitalopram                          |              |            | S           | Oral         | 10 To 15 Tablets Of Venlafaxine, Tablet Escitalopram, And Tablet Clonazepam |                 | Accord       |
|                                                                                                                          | Venlafaxine/Venlafaxine Hydrochloride |              |            | S           | Oral         | 10 To 15 Tablets Of Venlafaxine, Tablet Escitalopram, And Tablet Clonazepam |                 | Not Reported |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                           | <u>Case #</u>    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------|------------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| 10-Jan-2017                                                                                                                                        | 13100986         | EXPEDITED (15-DAY) |                    | HO              | IT-ASTRAZENECA-2017SE00880 |                      | 58 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                                                                                              | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Adjustment Disorder With Mixed Anxiety And Depressed Mood; Anhedonia; Insomnia; Labelled Drug-Drug Interaction Medication Error; Suicidal Ideation | Quetiapine       |                    |                    | S               | Oral                       |                      |                 | Zeneca       |                |
|                                                                                                                                                    | Venlafaxine      |                    |                    | S               | Unknown                    |                      |                 | Not Reported |                |
|                                                                                                                                                    | Clonazepam       |                    |                    | S               | Unknown                    |                      |                 | Not Reported |                |
|                                                                                                                                                    | Escitalopram     |                    |                    | S               | Unknown                    |                      |                 | Not Reported |                |
|                                                                                                                                                    | Alprazolam       |                    |                    | S               | Unknown                    |                      |                 | Not Reported |                |
|                                                                                                                                                    | Sodium Valproate |                    |                    | S               | Unknown                    |                      |                 | Not Reported |                |
|                                                                                                                                                    | Sodium Valproate |                    |                    | S               | Unknown                    | Doubled Dose         |                 | Not Reported |                |
|                                                                                                                                                    | Trazodone        |                    |                    | S               | Unknown                    |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                           | <u>Case #</u>    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Jan-2017                                                                                                                                        | 13101079         | EXPEDITED (15-DAY) |                    | OT              | HR-PFIZER INC-2017008938   |                      | 43 YR           | Female       | HRV            |
| <u>Preferred Term</u>                                                                                                                              | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Disorientation; Intentional Overdose; Somnolence; Suicide Attempt                                                                                  | Alprazolam       |                    |                    | S               | Oral                       | Unknown              |                 | Pfizer       |                |
|                                                                                                                                                    | Mirtazapine      |                    |                    | S               | Oral                       | Unknown              |                 | Not Reported |                |
|                                                                                                                                                    | Lamotrigin       |                    |                    | S               | Oral                       | Unknown              |                 | Not Reported |                |
|                                                                                                                                                    | Escitalopram     |                    |                    | S               | Oral                       | Unknown              |                 | Not Reported |                |
|                                                                                                                                                    | Ergometrin Lek   |                    |                    | S               | Oral                       | Unknown              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                           | <u>Case #</u>    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Jan-2017                                                                                                                                        | 13102985         | EXPEDITED (15-DAY) |                    | HO              | FR-SA-2017SA002932         |                      | 65 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                                                              | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Interstitial Lung Disease                                                                                                                          | Allopurinol      |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                                                                                                                    | Metformin        |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                |   |                                       |              |
|----------------|---|---------------------------------------|--------------|
| Stilnox        | S | Oral                                  | Not Reported |
| Xatral         | S | Oral                                  | Not Reported |
| Seroplex       | S | Oral                                  | Not Reported |
| Levothyrox     | S | Oral                                  | Not Reported |
| Keppra         | S | Oral                                  | Not Reported |
| Acetylcysteine | S | Oral                                  | Not Reported |
| Solumedrol     | S | Intravenous (not otherwise specified) | Not Reported |
| Erbix          | S | Intravenous (not otherwise specified) | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------|----------------------|------------|------------|----------------|
| 11-Jan-2017              | 12390763      | EXPEDITED (15-DAY) | HO                 |                 | BR-DSJP-DSE-2016-116525 |                      |            | Unknown    | BRA            |

| <u>Preferred Term</u>                                                                                                                                                                        | <u>Product</u>                                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Depression; Face Injury; Facial Bones Fracture; Fall; Insomnia; Rib Fracture; Sciatic Nerve Injury; Somnolence; Spinal Pain; Urinary Incontinence; Urinary Tract Infection; Weight Increased | Benicar 40 Mg Com Rev Ct BI AI/AI X 30        |              |            | S           | Oral         | 40 Mg, Qd          |                 | Daiichi      |
|                                                                                                                                                                                              | Scitalax 10 Mg Com Rev Ct BI AI Plas Inc X 28 |              |            | S           | Oral         | 10 Mg, Qd          |                 | Not Reported |
|                                                                                                                                                                                              | Scitalax 10 Mg Com Rev Ct BI AI Plas Inc X 28 |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                              | Lantus                                        |              |            | C           |              | Unk, Bid           |                 | Not Reported |
|                                                                                                                                                                                              | Janumet                                       |              |            | C           | Oral         | 50/1000 Mg, Bid    |                 | Not Reported |
|                                                                                                                                                                                              | Higroton                                      |              |            | C           | Oral         | 0.5 Df, Unk        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 11-Jan-2017              | 13027806      | EXPEDITED (15-DAY) | OT                 |                 | IT-PFIZER INC-2016578809 |                      | 26 YR      | Female     | ITA            |

| <u>Preferred Term</u>                              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Abuse; Intentional Overdose; Poisoning; Sopor | Torvast        |              |            | S           | Oral         | 8 Df, Total        |                 | Pfizer       |
|                                                    | Aspirina       |              |            | S           | Oral         | 20 Df, Total       |                 | Not Reported |
|                                                    | Simvastatin    |              |            | S           | Oral         | 14 Df, Total       |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |          |   |      |              |              |
|--|----------|---|------|--------------|--------------|
|  | Rivotril | S | Oral | 10 MI, Total | Not Reported |
|  | Entact   | S | Oral | 28 Df, Total | Not Reported |
|  | Deursil  | S | Oral | 10 Df, Total | Not Reported |
|  | Igroton  | S | Oral | 15 Df, Total | Not Reported |

| <u>FDA Received Date</u>           | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|------------------------------------|---------------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|------------|----------------|
| 11-Jan-2017                        | 13031019                  | EXPEDITED (15-DAY) |                    | OT              | IE-ALLERGAN-1680300US |                      | 32 YR           | Female     | IRL            |
| <u>Preferred Term</u>              | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Abortion Spontaneous;<br>Pregnancy | Escitalopram Oxalate - Bp |                    |                    | S               | Oral                  | 20 Mg, Qd            |                 | Allergan   |                |
|                                    | Escitalopram Oxalate - Bp |                    |                    | S               |                       |                      |                 | Allergan   |                |
|                                    | Escitalopram Oxalate - Bp |                    |                    | S               |                       |                      |                 | Allergan   |                |

| <u>FDA Received Date</u>        | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------|----------------|--------------------|--------------------|-----------------|--------------------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 11-Jan-2017                     | 13087461       | EXPEDITED (15-DAY) |                    | OT              | IT-SUN<br>PHARMACEUTICAL<br>INDUSTRIES LTD-<br>2016RR-130777 |                      | 26 YR           | Female       | ITA            |
| <u>Preferred Term</u>           | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Abuse; Poisoning;<br>Sopor | Simvastatin    |                    |                    | S               | Unknown                                                      | 14 Df, Total         |                 | Sun          |                |
|                                 | Aspirina       |                    |                    | S               | Unknown                                                      |                      |                 | Not Reported |                |
|                                 | Rivotril       |                    |                    | S               | Oral                                                         | 10 MI, Total         |                 | Not Reported |                |
|                                 | Entact         |                    |                    | S               | Oral                                                         | 28 Df, Total         |                 | Not Reported |                |
|                                 | Torvast        |                    |                    | S               | Oral                                                         | 8 Df, Total          |                 | Not Reported |                |
|                                 | Deursil        |                    |                    | S               | Oral                                                         | 10 Df, Total         |                 | Not Reported |                |
|                                 | Igroton        |                    |                    | S               | Oral                                                         | 15 Df, Total         |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 11-Jan-2017              | 13103684       | EXPEDITED (15-DAY) |                    | HO              | US-ACCORD-047274     |                      |                 | Male       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                     |                                   |   |                |              |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|---|----------------|--------------|
| Foetal Exposure During Pregnancy; Hypertonia; Hypoglycaemia; Hypothermia; Irritability; Maternal Drugs Affecting Foetus; Necrotising Enterocolitis Neonatal; Tremor | Escitalopram                      | S | Transplacental | Accord       |
|                                                                                                                                                                     | Bupropion/Bupropion Hydrochloride | S | Transplacental | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------|----------------------|------------|------------|----------------|
| 11-Jan-2017              | 13104115      | EXPEDITED (15-DAY) |                    | DE, OT          | US-APOTEX-2017AP005411 |                      | 64 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Amlodipine Besylate  |              |            | S           | Oral         | Unk                |                 | Apotex       |
|                       | Amlodipine Besylate  |              |            | S           | Parenteral   | Unk                |                 | Apotex       |
|                       | Enalapril            |              |            | S           | Oral         | Unk                |                 | Apotex       |
|                       | Enalapril            |              |            | S           | Parenteral   | Unk                |                 | Apotex       |
|                       | Escitalopram Oxalate |              |            | S           | Oral         | Unk                |                 | Apotex       |
|                       | Escitalopram Oxalate |              |            | S           | Parenteral   | Unk                |                 | Apotex       |
|                       | Tamsulosin           |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                       | Tamsulosin           |              |            | S           | Parenteral   | Unk                |                 | Not Reported |
|                       | Insulin              |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                       | Insulin              |              |            | S           | Parenteral   | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 11-Jan-2017              | 13104305      | EXPEDITED (15-DAY) |                    | DE              | US-PERRIGO-17US000192 |                      | 58 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Death                 | Ibuprofen      |              |            | S           | Oral         | Unknown, Unknown   |                 | Perrigo      |
|                       | Oxycodone      |              |            | S           | Oral         | Unknown, Unknown   |                 | Not Reported |
|                       | Escitalopram   |              |            | S           | Oral         | Unknown, Unknown   |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|-----------------------------|--------------------|--------------------|-----------------|------------------------|----------------------|-----------------|--------------|----------------|
| 11-Jan-2017              | 13104469                    | EXPEDITED (15-DAY) |                    | DE, HO, OT      | US-APOTEX-2017AP005252 |                      | 41 YR           | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide        | Tramadol Hydrochloride      |                    |                    | S               | Oral                   |                      |                 | Apotex       |                |
|                          | Clonazepam Tablets Usp      |                    |                    | S               | Oral                   |                      |                 | Apotex       |                |
|                          | Escitalopram Oxalate        |                    |                    | S               | Oral                   |                      |                 | Apotex       |                |
|                          | Alprazolam                  |                    |                    | S               | Oral                   |                      |                 | Apotex       |                |
|                          | Baclofen                    |                    |                    | S               | Oral                   |                      |                 | Not Reported |                |
|                          | Acetaminophen W/Hydrocodone |                    |                    | S               | Oral                   |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>  | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>                                           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------|-------------------------|--------------------|--------------------|-----------------|---------------------------------------|----------------------------------------------------------------|-----------------|--------------|----------------|
| 11-Jan-2017               | 13105880                | EXPEDITED (15-DAY) |                    | HO, OT          | FR-UCBSA-2017001177                   |                                                                |                 | Male         | FRA            |
| <u>Preferred Term</u>     | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>                                             | <u>Duration</u> | <u>Mfr</u>   |                |
| Interstitial Lung Disease | Keppra                  |                    |                    | S               | Oral                                  | 500 Mg, 2x/Day (Bid), 500 Mg In The Morning And In The Evening |                 | Ucb          |                |
|                           | Erbix                   |                    |                    | S               | Intravenous (not otherwise specified) | Unk Unk, Ev 2 Weeks(Qow)                                       |                 | Not Reported |                |
|                           | Solumedrol              |                    |                    | S               | Intravenous (not otherwise specified) | Unk Unk, Ev 2 Weeks(Qow)                                       |                 | Not Reported |                |
|                           | Acetylcysteine          |                    |                    | S               | Oral                                  | 200 Mg, 2x/Day (Bid)                                           |                 | Not Reported |                |
|                           | Allopurinol             |                    |                    | S               | Oral                                  | 200 Mg, Once Daily (Qd)                                        |                 | Not Reported |                |
|                           | Levothyrox              |                    |                    | S               | Oral                                  | 50 Mg, Once Daily (Qd)                                         |                 | Not Reported |                |
|                           | Metformine              |                    |                    | S               | Oral                                  | 500 Mg, 2x/Day (Bid)                                           |                 | Not Reported |                |
|                           | Seroplex                |                    |                    | S               | Oral                                  | 10 Mg In The Morning, 10 Mg, Once Daily (Qd)                   |                 | Not Reported |                |
|                           | Stilnox                 |                    |                    | S               | Oral                                  | 10 Mg In The Evening, 10 Mg, Once Daily (Qd)                   |                 | Not Reported |                |
|                           | Alfuzosin Hydrochloride |                    |                    | S               | Oral                                  | Strength-10 Mg, 10 Mg,                                         |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                 |                          |                    |                    |                 |                          |                              |                 |              |                |
|-----------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|--------------------------|------------------------------|-----------------|--------------|----------------|
| Omeprazole                                                      |                          | C                  |                    | Once Daily (Qd) |                          | Unk                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                        | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Jan-2017                                                     | 13106149                 | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2017008850 |                              | 40 YR           | Female       | USA            |
| <u>Preferred Term</u>                                           | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Headache; Insomnia; Pain; Peripheral Swelling; Weight Increased | Lyrica                   |                    |                    | S               |                          | 50 Mg, Once Daily            |                 | Pfizer       |                |
|                                                                 | Lyrica                   |                    |                    | S               |                          | 75 Mg, Unk                   |                 | Pfizer       |                |
|                                                                 | Lyrica                   |                    |                    | S               |                          | 100 Mg, Unk                  |                 | Pfizer       |                |
|                                                                 | Klonopin                 |                    |                    | S               | Oral                     | 1 Mg, 3x/Day                 |                 | Not Reported |                |
|                                                                 | Klonopin                 |                    |                    | S               |                          |                              |                 | Not Reported |                |
|                                                                 | Escitalopram             |                    |                    | S               | Oral                     | 20 Mg, Daily                 |                 | Not Reported |                |
|                                                                 | Osphena                  |                    |                    | C               |                          | 60 Mg, Unk                   |                 | Not Reported |                |
|                                                                 | Nortriptyline            |                    |                    | C               |                          | 25 Mg, Once A Day (At Night) |                 | Not Reported |                |
|                                                                 | Flexeril                 |                    |                    | C               |                          | Unk                          |                 | Not Reported |                |
|                                                                 | Treximet                 |                    |                    | C               |                          | Unk                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                        | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Jan-2017                                                     | 13106516                 | EXPEDITED (15-DAY) |                    | HO              | FR-ALLERGAN-1701047US    |                              | 45 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                           | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Coma; Respiratory Distress; Toxicity To Various Agents          | Escitalopram Oxalate Unk |                    |                    | S               | Oral                     | 20 Mg, Qd                    |                 | Allergan     |                |
|                                                                 | Escitalopram Oxalate Unk |                    |                    | S               | Oral                     | 9 Df, Single                 |                 | Allergan     |                |
| <u>FDA Received Date</u>                                        | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Jan-2017                                                     | 13106517                 | EXPEDITED (15-DAY) |                    | OT              | FR-ALLERGAN-1701048US    |                              | 4 YR            | Male         | FRA            |
| <u>Preferred Term</u>                                           | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                      |                          |   |                |              |
|----------------------|--------------------------|---|----------------|--------------|
| Behaviour Disorder;  | Escitalopram Oxalate Unk | S | Transplacental | Allergan     |
| Developmental Delay; | Rivotril                 | S | Transplacental | Not Reported |
| Speech Disorder      | Stilnox                  | S | Transplacental | Not Reported |

| <u>FDA Received Date</u>                            | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 11-Jan-2017                                         | 13106640                 | EXPEDITED (15-DAY) |                    | HO              | FR-ALLERGAN-1701049US |                      | 65 YR           | Female       | FRA            |
| <u>Preferred Term</u>                               | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Poisoning Deliberate;<br>Toxicity To Various Agents | Escitalopram Oxalate Unk |                    |                    | S               | Oral                  | 28 Df, Single        |                 | Allergan     |                |
|                                                     | Bromazepam               |                    |                    | S               | Oral                  | 30 Df, Single        |                 | Not Reported |                |
|                                                     | Metformine               |                    |                    | S               | Oral                  | 15 Df, Single        |                 | Not Reported |                |
|                                                     | Diamicron                |                    |                    | C               | Unknown               | Unk, Tid             |                 | Not Reported |                |
|                                                     | Stilnox                  |                    |                    | C               | Unknown               | Unk, Qd              |                 | Not Reported |                |

| <u>FDA Received Date</u>                        | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|-------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|------------|----------------|
| 11-Jan-2017                                     | 13106670                 | EXPEDITED (15-DAY) |                    | DE              | IE-ALLERGAN-1701058US |                      | 32 YR           | Female     | IRL            |
| <u>Preferred Term</u>                           | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Foetal Exposure During<br>Pregnancy; Stillbirth | Escitalopram Oxalate Unk |                    |                    | S               | Transplacental        | 20 Mg, Qd            |                 | Allergan   |                |

| <u>FDA Received Date</u>  | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------|---------------------------|--------------------|--------------------|-----------------|------------------------------------------|----------------------|-----------------|--------------|----------------|
| 11-Jan-2017               | 13106699                  | EXPEDITED (15-DAY) |                    | HO              | FR-ALLERGAN-1701077US                    |                      | 65 YR           | Male         | FRA            |
| <u>Preferred Term</u>     | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Interstitial Lung Disease | Escitalopram Oxalate - Bp |                    |                    | S               | Oral                                     |                      |                 | Allergan     |                |
|                           | Erbitux                   |                    |                    | S               | Intravenous (not<br>otherwise specified) |                      |                 | Not Reported |                |
|                           | Solumedrol                |                    |                    | S               | Intravenous (not<br>otherwise specified) |                      |                 | Not Reported |                |
|                           | Acetylcysteine            |                    |                    | S               | Oral                                     |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |             |   |      |              |
|--|-------------|---|------|--------------|
|  | Allopurinol | S | Oral | Not Reported |
|  | Keppra      | S | Oral | Not Reported |
|  | Levothyrox  | S | Oral | Not Reported |
|  | Metformine  | S | Oral | Not Reported |
|  | Stilnox     | S | Oral | Not Reported |
|  | Xatral Lp   | S | Oral | Not Reported |
|  | Omeprazole  | S |      | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 11-Jan-2017              | 13106739      | EXPEDITED (15-DAY) |                    | DE              | US-ABBVIE-17P-163-1836436-00 |                      | 41 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Acetaminophen/Hydrocodone |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Tramadol                  |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Baclofen                  |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Clonazepam                |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Escitalopram              |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Alprazolam                |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------------------------|----------------------|------------|------------|----------------|
| 12-Jan-2017              | 13107449      | EXPEDITED (15-DAY) |                    | HO, OT          | IT-MACLEODS PHARMACEUTICALS US LTD-MAC2016004162 |                      |            | Unknown    | ITA            |

| <u>Preferred Term</u>       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Haemolysis; Self-Medication | Escitalopram   |              |            | S           | Unknown      | Unk                |                 | Macleods   |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Jan-2017              | 13107637      | EXPEDITED (15-DAY) |                    | HO              | US-ACCORD-047272     |                      |            | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                       |              |   |                |                            |        |
|---------------------------------------------------------------------------------------------------------------------------------------|--------------|---|----------------|----------------------------|--------|
| Electrocardiogram Qt Prolonged; Foetal Exposure During Pregnancy; High-Pitched Crying; Hypertonia; Irritability; Pupil Fixed; Seizure | Escitalopram | S | Transplacental | 20 Mg Throughout Pregnancy | Accord |
|---------------------------------------------------------------------------------------------------------------------------------------|--------------|---|----------------|----------------------------|--------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 12-Jan-2017              | 13108836      | EXPEDITED (15-DAY) |                    | HO              | FR-ALLERGAN-1701171US |                      | 47 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                      | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Altered State Of Consciousness; Toxicity To Various Agents | Escitalopram Oxalate - Bp |              |            | S           | Oral         | Unk                |                 | Allergan     |
|                                                            | Prazepam                  |              |            | S           | Oral         | 10 Mg, Qd          |                 | Not Reported |
|                                                            | Seresta                   |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                                                            | Ipraalox                  |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                                                            | Ginkgo                    |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                                                            | Alcool                    |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                                                            | Menophytes                |              |            | C           |              | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------|----------------------|------------|------------|----------------|
| 12-Jan-2017              | 13109170      | EXPEDITED (15-DAY) |                    | DE              | US-LANNETT COMPANY, INC.-US-2017LAN000027 |                      | 41 YR      | Male       | USA            |

| <u>Preferred Term</u>                         | <u>Product</u>                        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------|---------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide; Toxicity To Various Agents | Baclofen (20mg) Lannett Company, Inc. |              |            | S           | Oral         | Unk                |                 | Lannett      |
|                                               | Escitalopram Oxalate                  |              |            | S           | Oral         | Unk                |                 | Lannett      |
|                                               | Tramadol                              |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                                               | Clonazepam                            |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                                               | Acetaminophen W/Hydrocodone           |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                                               | Alprazolam                            |              |            | S           | Oral         | Unk                |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|--------------------------|--------------------|--------------------|-----------------|------------------------|-----------------------|-----------------|--------------|----------------|
| 12-Jan-2017              | 13109172                 | EXPEDITED (15-DAY) |                    | DE, HO, OT      | US-APOTEX-2017AP005290 |                       | 51 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide        | Amlodipine Besylate      |                    |                    | S               | Oral                   | Ingestion + Unknown   |                 | Apotex       |                |
|                          | Escitalopram Oxalate     |                    |                    | S               | Oral                   | Ingestion + Unknown   |                 | Apotex       |                |
|                          | Ethanol                  |                    |                    | S               | Oral                   | Ingestion + Unknown   |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Jan-2017              | 13109227                 | EXPEDITED (15-DAY) |                    | OT              | FR-TEVA-728019ISR      |                       | 82 YR           | Female       | FRA            |
| <u>Preferred Term</u>    | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Pemphigoid               | Risperidone              |                    |                    | S               | Unknown                |                       |                 | Pliva        |                |
|                          | Escitalopram             |                    |                    | S               | Unknown                |                       |                 | Ivax         |                |
|                          | Metformin                |                    |                    | S               | Unknown                |                       |                 | Not Reported |                |
|                          | Vildagliptin             |                    |                    | S               | Unknown                |                       |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Jan-2017              | 13110327                 | DIRECT             |                    |                 |                        |                       | 22 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Restless Legs Syndrome   | Escitalopram             |                    |                    | S               | Oral                   | Quantity:1 Tablet(S); |                 | Not Reported |                |
|                          | Cetirizine               |                    |                    | C               |                        |                       |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Jan-2017              | 13111183                 | EXPEDITED (15-DAY) |                    | DE              | US-PERRIGO-17US000379  |                       | 74 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Death                    | Famotidine               |                    |                    | S               | Oral                   | Unk                   |                 | Perrigo      |                |
|                          | Cetirizine Hydrochloride |                    |                    | S               | Oral                   | Unk                   |                 | Perrigo      |                |

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|  |                     |   |      |     |              |
|--|---------------------|---|------|-----|--------------|
|  | Doxepin             | S | Oral | Unk | Not Reported |
|  | Escitalopram        | S | Oral | Unk | Not Reported |
|  | Hydrocodone         | S | Oral | Unk | Not Reported |
|  | Olmesartan          | S | Oral | Unk | Not Reported |
|  | Alprazolam          | S | Oral | Unk | Not Reported |
|  | Hydrochlorothiazide | S | Oral | Unk | Not Reported |
|  | Pregabalin          | S | Oral | Unk | Not Reported |

| <u>FDA Received Date</u>                                                                                                                                                                          | <u>Case #</u>                                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------|--------------------|--------------------|-----------------|----------------------------|-------------------------------------------|-----------------|--------------|----------------|
| 13-Jan-2017                                                                                                                                                                                       | 12285930                                              | EXPEDITED (15-DAY) |                    | DE, HO, OT      | IE-009507513-1604IRL011222 |                                           | 63 YR           | Female       | IRL            |
| <u>Preferred Term</u>                                                                                                                                                                             | <u>Product</u>                                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                        | <u>Duration</u> | <u>Mfr</u>   |                |
| Altered State Of Consciousness; Blood Test Abnormal;                                                                                                                                              | Zispin                                                |                    |                    | S               | Unknown                    | 15 Mg, Unknown                            |                 | Merck        |                |
| Coagulopathy; Completed Suicide; Contusion; Contusion;                                                                                                                                            | Zispin                                                |                    |                    | S               | Unknown                    | Total Daily Dose 30 Mg                    |                 | Merck        |                |
| Electrocardiogram Abnormal;                                                                                                                                                                       | Lexapro                                               |                    |                    | S               |                            | Unk                                       |                 | Not Reported |                |
| Electrocardiogram St Segment Elevation; Fall; Fall; Fear; Fear Of Death; Haemorrhage; Head Injury; Hepatic Enzyme Abnormal; Hyponatraemia; Negative Thoughts; Panic Reaction; Withdrawal Syndrome | Sertraline Hydrochloride                              |                    |                    | S               |                            | 100 Mg                                    |                 | Not Reported |                |
|                                                                                                                                                                                                   | Sertraline Hydrochloride                              |                    |                    | S               |                            | 100 Mg                                    |                 | Not Reported |                |
|                                                                                                                                                                                                   | Sertraline Hydrochloride                              |                    |                    | S               |                            | 50 Mg                                     |                 | Not Reported |                |
|                                                                                                                                                                                                   | Solpadeine (Acetaminophen\Caffeine\Codeine Phosphate) |                    |                    | C               |                            | Paracetamol 500mg, Cod 500/30/8 Milligram |                 | Not Reported |                |
|                                                                                                                                                                                                   | Temazepam                                             |                    |                    | C               |                            | 20 Mg                                     |                 | Not Reported |                |
|                                                                                                                                                                                                   | Diazepam                                              |                    |                    | C               |                            | 5 Mg, Reducing Dose                       |                 | Not Reported |                |
|                                                                                                                                                                                                   | Diazepam                                              |                    |                    | C               |                            | 2 Mg                                      |                 | Not Reported |                |
|                                                                                                                                                                                                   | Sudafed                                               |                    |                    | C               |                            |                                           |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|------------|----------------|
| 13-Jan-2017              | 12941895                  | EXPEDITED (15-DAY) |                    | DS, HO          | PT-ALLERGAN-1675711US |                      | 64 YR           | Female     | PRT            |
| <u>Preferred Term</u>    | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Blood Creatinine         | Escitalopram Oxalate - Bp |                    |                    | S               | Oral                  | 20 Mg, Qd            |                 | Allergan   |                |

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|                                                                                                                                                                                            |                               |   |      |  |            |              |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|---|------|--|------------|--------------|
| Increased; Chronic Kidney Disease; Flight Of Ideas; Gamma-Glutamyltransferase Increased; Hallucination, Visual; Insomnia; Major Depression; Mania; Psychomotor Hyperactivity; Tachyphrenia | Adt (Amitriptyline)           | S |      |  | 25 Mg, Qd  | Not Reported |
|                                                                                                                                                                                            | Levofloxacin                  | S | Oral |  |            | Not Reported |
|                                                                                                                                                                                            | Zilpen                        | S | Oral |  |            | Not Reported |
|                                                                                                                                                                                            | Zyloric                       | C | Oral |  | 300 Mg, Qd | Not Reported |
|                                                                                                                                                                                            | Zyloric                       | C | Oral |  |            | Not Reported |
|                                                                                                                                                                                            | Kainever                      | C | Oral |  | 2 Mg, Qd   | Not Reported |
|                                                                                                                                                                                            | Amlodipina                    | C | Oral |  | 5 Mg, Qd   | Not Reported |
|                                                                                                                                                                                            | Amlodipina                    | C | Oral |  |            | Not Reported |
|                                                                                                                                                                                            | Enalapril                     | C | Oral |  | 20 Mg, Qd  | Not Reported |
|                                                                                                                                                                                            | Enalapril                     | C | Oral |  |            | Not Reported |
|                                                                                                                                                                                            | Propranolol                   | C | Oral |  | 80 Mg, Qd  | Not Reported |
|                                                                                                                                                                                            | Furosemida                    | C | Oral |  | 20 Mg, Qd  | Not Reported |
|                                                                                                                                                                                            | Furosemida                    | C | Oral |  |            | Not Reported |
|                                                                                                                                                                                            | Adalgur N                     | C | Oral |  | 1 Df, Q8hr | Not Reported |
|                                                                                                                                                                                            | Domperidona                   | C | Oral |  |            | Not Reported |
|                                                                                                                                                                                            | Cipralext Film-Coated Tablets | S | Oral |  |            | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Jan-2017              | 13107524      | EXPEDITED (15-DAY) |                    | HO              | IT-ACCORD-047287     |                      | 33 YR      | Female     | ITA            |

| <u>Preferred Term</u>                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |
|-----------------------------------------------|----------------|--------------|------------|-------------|--------------|----------------------|-----------------|------------|
| Drug Abuse; Intentional Self-Injury; Retching | Escitalopram   |              |            | S           | Oral         | 10 Mg 10 Dosage Form |                 | Accord     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|------------|------------|----------------|
| 13-Jan-2017              | 13112371      | EXPEDITED (15-DAY) |                    | HO              | IT-AUROBINDO-AUR-APL-2017-00205 |                      | 33 YR      | Unknown    | ITA            |

| <u>Preferred Term</u> | <u>Product</u>                        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|---------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Drug Abuse; Retching  | Escitalopram Film-Coated Tablets 10mg |              |            | S           | Oral         | 100 Mg, Total      |                 | Aurobindo  |

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| <u>FDA Received Date</u>                                                                                                                                                                                                                                                     | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 13-Jan-2017                                                                                                                                                                                                                                                                  | 13114380                  | EXPEDITED (15-DAY) |                    | HO, OT          | FR-ALLERGAN-1701270US |                      | 87 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                        | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aortic Aneurysm;<br>Asthenia; Cytomegalovirus<br>Infection; Decreased<br>Appetite; Epstein-Barr<br>Virus Infection; Febrile<br>Bone Marrow Aplasia;<br>General Physical<br>Condition Abnormal; Lung<br>Disorder; Pancytopenia;<br>Systemic Inflammatory<br>Response Syndrome | Escitalopram Oxalate - Bp |                    |                    | S               | Oral                  | 1 Df, Qd             |                 | Allergan     |                |
|                                                                                                                                                                                                                                                                              | Tavanic                   |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                              | Esomeprazole              |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                              | Ofloxacin                 |                    |                    | C               |                       | Unk                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                              | Norfloxacin               |                    |                    | C               |                       | Unk                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                              | Amoxicillin               |                    |                    | C               |                       | Unk                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                              | Ceftriaxone               |                    |                    | C               |                       | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                     | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Jan-2017                                                                                                                                                                                                                                                                  | 13115024                  | EXPEDITED (15-DAY) |                    | OT              | TR-ALLERGAN-1701423US |                      | 20 YR           | Female       | TUR            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                        | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Overdose; Off<br>Label Use; Suicide<br>Attempt                                                                                                                                                                                                                   | Escitalopram Oxalate - Bp |                    |                    | S               | Oral                  | Unk                  |                 | Allergan     |                |
|                                                                                                                                                                                                                                                                              | Escitalopram Oxalate - Bp |                    |                    | S               | Oral                  | Ingested 18 Tablets  |                 | Allergan     |                |
|                                                                                                                                                                                                                                                                              | Insulin                   |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                     | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Jan-2017                                                                                                                                                                                                                                                                  | 13115048                  | EXPEDITED (15-DAY) |                    | OT              | CH-ALLERGAN-1701484US |                      | 29 YR           | Male         | CHE            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                        | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dyskinesia;<br>Extrapyramidal Disorder                                                                                                                                                                                                                                       | Escitalopram Oxalate Unk  |                    |                    | S               | Oral                  | 10 Mg, Unk           |                 | Allergan     |                |
|                                                                                                                                                                                                                                                                              | Clopidogrel               |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                              | Seroquel                  |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                              | Temesta Expidet           |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

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|                                                                                   |                |                    |                    |                 |                                            |                      |                 |                 |                |
|-----------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|--------------------------------------------|----------------------|-----------------|-----------------|----------------|
| Valium                                                                            |                |                    | C                  |                 | Oral                                       |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                          | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 13-Jan-2017                                                                       | 13115176       | EXPEDITED (15-DAY) |                    | OT              | US-<br>GLAXOSMITHKLINE-<br>US2017GSK003970 |                      | 74 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                             | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Drug Ineffective;<br>Electrocardiogram Qt<br>Prolonged; Therapy Non-<br>Responder | Olanzapine     |                    |                    | S               |                                            |                      |                 | Glaxosmithkline |                |
|                                                                                   | Iloperidone    |                    |                    | S               |                                            |                      |                 | Not Reported    |                |
|                                                                                   | Bupropion      |                    |                    | S               |                                            |                      |                 | Glaxosmithkline |                |
|                                                                                   | Escitalopram   |                    |                    | S               |                                            |                      |                 | Glaxosmithkline |                |
|                                                                                   | Amitriptyline  |                    |                    | S               |                                            |                      |                 | Glaxosmithkline |                |
|                                                                                   | Mirtazapine    |                    |                    | S               |                                            |                      |                 | Not Reported    |                |
|                                                                                   | Lorazepam      |                    |                    | S               |                                            |                      |                 | Glaxosmithkline |                |
|                                                                                   | Alprazolam     |                    |                    | S               |                                            |                      |                 | Not Reported    |                |
|                                                                                   | Quetiapine     |                    |                    | C               |                                            | 50 Mg, At Bedtime    |                 | Not Reported    |                |
|                                                                                   | Clonazepam     |                    |                    | C               |                                            | 1 Mg, Bid            |                 | Not Reported    |                |
|                                                                                   | Trazodone      |                    |                    | C               |                                            | 50 Mg, At Bedtime    |                 | Not Reported    |                |
|                                                                                   | Warfarin       |                    |                    | C               |                                            | 6 Mg, Qd             |                 | Not Reported    |                |
|                                                                                   | Propranolol    |                    |                    | C               |                                            | 160 Mg, Qd           |                 | Not Reported    |                |
|                                                                                   | Methimazole    |                    |                    | C               |                                            | 30 Mg, Bid           |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                          | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 15-Jan-2017                                                                       | 13115961       | EXPEDITED (15-DAY) |                    | DE              | US-ALVOGEN-2017-<br>ALVOGEN-091052         |                      | 58 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                             | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Completed Suicide                                                                 | Oxycodone      |                    |                    | S               | Oral                                       |                      |                 | Not Reported    |                |
|                                                                                   | Escitalopram   |                    |                    | S               | Oral                                       |                      |                 | Not Reported    |                |
|                                                                                   | Ibuprofen      |                    |                    | S               | Oral                                       |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                          | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 16-Jan-2017                                                                       | 12940920       | NON-EXPEDITED      |                    |                 | US-JNJFOC-<br>20161103436                  |                      |                 | Male            | USA            |

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| <u>Preferred Term</u>                                                                                                                                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abnormal Weight Gain;<br>Dry Mouth;<br>Gynaecomastia; Increased<br>Appetite; Off Label Use;<br>Product Use In<br>Unapproved Indication;<br>Somnolence | Risperdal      |              |            | S           | Oral         | 0.5 Mg To 1 Mg     |                 | Not Reported |
|                                                                                                                                                       | Risperdal      |              |            | S           | Oral         | 0.5 Mg To 1 Mg     |                 | Not Reported |
|                                                                                                                                                       | Abilify        |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                                       | Lexapro        |              |            | S           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 16-Jan-2017              | 13056525      | EXPEDITED (15-DAY) |                    | OT              | CH-ALLERGAN-<br>1681965US |                      | 73 YR      | Female     | CHE            |

| <u>Preferred Term</u>                                                          | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Bone Density Decreased;<br>Pelvic Fracture; Rebound<br>Effect; Spinal Fracture | Escitalopram Oxalate - Bp |              |            | S           | Oral         | 0.5-0-0            |                 | Allergan     |
|                                                                                | Prolia                    |              |            | S           | Subcutaneous | 60 Mg, Q Month     |                 | Not Reported |
|                                                                                | Prolia                    |              |            | S           | Subcutaneous |                    |                 | Not Reported |
|                                                                                | Pantoprazol Actavis       |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                | Bekunis Bisacodyl         |              |            | C           | Oral         | Unk Unk, Unknown   |                 | Not Reported |
|                                                                                | Metoprolol                |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                | Ponstan                   |              |            | C           | Oral         | Unk Unk, Unknown   |                 | Not Reported |
|                                                                                | Ponstan                   |              |            | C           |              | As Needed          |                 | Not Reported |
|                                                                                | Simvastatin               |              |            | C           | Oral         | Unk Unk, Unknown   |                 | Not Reported |
|                                                                                | Targin                    |              |            | C           | Oral         | Unk Unk, Unknown   |                 | Not Reported |
|                                                                                | Vi-De 3                   |              |            | C           | Oral         | Unk Unk, Unknown   |                 | Not Reported |
|                                                                                | Vi-De 3                   |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                | Losartan                  |              |            | C           | Oral         | 50 Mg, Unknown     |                 | Not Reported |
|                                                                                | Lexotanil                 |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                | Lexotanil                 |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                | Kalcipos-D3               |              |            | C           | Oral         | Unk Unk, Unknown   |                 | Not Reported |
|                                                                                | Cipralelex Tablets        |              |            | S           | Oral         | 0.5-0-0            |                 | Not Reported |

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| <u>FDA Received Date</u>                                             | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------|-------------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|-----------------|--------------|----------------|
| 16-Jan-2017                                                          | 13116280          | EXPEDITED (15-DAY) |                    | DE              | US-ALVOGEN-2017-ALVOGEN-091154 |                      | 59 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                                    | Bupropion         |                    |                    | S               | Oral                           |                      |                 | Not Reported |                |
|                                                                      | Duloxetine        |                    |                    | S               | Oral                           |                      |                 | Not Reported |                |
|                                                                      | Escitalopram      |                    |                    | S               | Oral                           |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                             | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Jan-2017                                                          | 13116475          | EXPEDITED (15-DAY) |                    | HO              | US-HETERO LABS LTD-1062035     |                      |                 | Male         | USA            |
| <u>Preferred Term</u>                                                | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Foetal Exposure During Pregnancy; Necrotising Enterocolitis Neonatal | Escitalopram      |                    |                    | S               | Transplacental                 |                      |                 | Hetero       |                |
|                                                                      | Bupropion         |                    |                    | C               | Transplacental                 |                      |                 | Not Reported |                |
|                                                                      | Ampicillin Sodium |                    |                    | C               | Transplacental                 |                      |                 | Not Reported |                |
|                                                                      | Gentamicin        |                    |                    | C               | Transplacental                 |                      |                 | Not Reported |                |
|                                                                      | Vancomycin Hcl    |                    |                    | C               | Transplacental                 |                      |                 | Not Reported |                |
|                                                                      | Metronidazole     |                    |                    | C               | Transplacental                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                             | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Jan-2017                                                          | 13116609          | EXPEDITED (15-DAY) |                    | DE              | US-ALVOGEN-2017-ALVOGEN-091173 |                      | 22 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                                    | Bupropion         |                    |                    | S               | Oral                           |                      |                 | Not Reported |                |
|                                                                      | Clonazepam        |                    |                    | S               | Oral                           |                      |                 | Not Reported |                |
|                                                                      | Escitalopram      |                    |                    | S               | Oral                           |                      |                 | Not Reported |                |
|                                                                      | Ethanol           |                    |                    | S               | Oral                           |                      |                 | Not Reported |                |
|                                                                      | Dexamfetamine     |                    |                    | S               | Oral                           |                      |                 | Not Reported |                |
|                                                                      | Amfetamine        |                    |                    | S               | Oral                           |                      |                 | Not Reported |                |



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| <u>FDA Received Date</u>                         | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|--------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 16-Jan-2017                                      | 13117226                      | EXPEDITED (15-DAY) |                    | DE              | US-LANNETT<br>COMPANY, INC.-US-<br>2017LAN000309 |                      | 51 YR           | Female       | USA            |
| <u>Preferred Term</u>                            | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                     | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Toxicity To Various Agents | Escitalopram Oxalate          |                    |                    | S               |                                                  | Unk                  |                 | Lannett      |                |
|                                                  | Amlodipine                    |                    |                    | S               |                                                  | Unk                  |                 | Not Reported |                |
|                                                  | Ethanol                       |                    |                    | S               |                                                  | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Jan-2017                                      | 13117229                      | EXPEDITED (15-DAY) |                    | DE              | US-LANNETT<br>COMPANY, INC.-US-<br>2017LAN000308 |                      | 41 YR           | Male         | USA            |
| <u>Preferred Term</u>                            | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                     | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Toxicity To Various Agents | Escitalopram Oxalate          |                    |                    | S               | Oral                                             | Unk                  |                 | Lannett      |                |
|                                                  | Diphenhydramine Hydrochloride |                    |                    | S               | Oral                                             | Unk                  |                 | Not Reported |                |
|                                                  | Ethanol                       |                    |                    | S               | Oral                                             | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Jan-2017                                      | 13117232                      | EXPEDITED (15-DAY) |                    | DE              | US-LANNETT<br>COMPANY, INC.-US-<br>2017LAN000307 |                      | 59 YR           | Female       | USA            |
| <u>Preferred Term</u>                            | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                     | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Toxicity To Various Agents | Escitalopram Oxalate          |                    |                    | S               | Oral                                             | Unk                  |                 | Lannett      |                |
|                                                  | Duloxetine                    |                    |                    | S               | Oral                                             | Unk                  |                 | Not Reported |                |
|                                                  | Bupropion                     |                    |                    | S               | Oral                                             | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Jan-2017                                      | 13117240                      | EXPEDITED (15-DAY) |                    | DE              | US-LANNETT<br>COMPANY, INC.-US-<br>2017LAN000310 |                      | 64 YR           | Male         | USA            |
| <u>Preferred Term</u>                            | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                     | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                  |                      |   |     |              |
|--------------------------------------------------|----------------------|---|-----|--------------|
| Completed Suicide;<br>Toxicity To Various Agents | Escitalopram Oxalate | S | Unk | Lannett      |
|                                                  | Amlodipine           | S | Unk | Not Reported |
|                                                  | Enalapril            | S | Unk | Not Reported |
|                                                  | Tamsulosin           | S | Unk | Not Reported |
|                                                  | Insulin              | S | Unk | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                    | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------------------------|----------------------|------------|------------|----------------|
| 16-Jan-2017              | 13117654      | EXPEDITED (15-DAY) |                    | OT              | HR-<br>GLAXOSMITHKLINE-<br>HR2017002042 |                      | 43 YR      | Female     | HRV            |

| <u>Preferred Term</u>                                                   | <u>Product</u>                      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|-------------------------------------------------------------------------|-------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Disorientation; Intentional<br>Overdose; Somnolence;<br>Suicide Attempt | Lamotrigine                         |              |            | S           | Oral         | Unknown            |                 | Glaxosmithkline |
|                                                                         | Escitalopram                        |              |            | S           | Oral         | Unknown            |                 | Glaxosmithkline |
|                                                                         | Mirtazapine                         |              |            | S           | Oral         | Unknown            |                 | Not Reported    |
|                                                                         | Ergometrin (Ergometrine<br>Maleate) |              |            | S           | Oral         | Unknown            |                 | Not Reported    |
|                                                                         | Alprazolam                          |              |            | S           | Oral         | Unknown            |                 | Not Reported    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 16-Jan-2017              | 13118877      | EXPEDITED (15-DAY) |                    | HO, OT          | FR-ALLERGAN-<br>1701650US |                      | 43 YR      | Male       | FRA            |

| <u>Preferred Term</u>      | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|----------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Hepatitis; Hospitalisation | Escitalopram Oxalate - Bp |              |            | S           | Oral         |                    |                 | Allergan   |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------------------------------|----------------------|------------|------------|----------------|
| 16-Jan-2017              | 13119277      | EXPEDITED (15-DAY) |                    | DE              | US-LEHIGH_VALLEY-<br>USA-<br>POI0580201700028 |                      | 58 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>         |
|-----------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------------|
| Completed Suicide     | Oxycodone Hcl Capsules |              |            | S           |              |                    |                 | Lehigh Valley Tech |
|                       | Escitalopram           |              |            | S           |              |                    |                 | Not Reported       |
|                       | Ibuprofen              |              |            | S           |              |                    |                 | Not Reported       |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|--------------------------------------------------------|----------------------|-----------------|----------------------|----------------|
| 16-Jan-2017                                                                                                                             | 13119461                 | EXPEDITED (15-DAY) |                    | HO, OT          | FR-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>BMS-2017-001857 |                      |                 | Male                 | FRA            |
| <u>Preferred Term</u>                                                                                                                   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Interstitial Lung Disease                                                                                                               | Metformin Hydrochloride  |                    |                    | S               | Oral                                                   | 500 Mg, Bid          |                 | Bristol Myers Squibb |                |
|                                                                                                                                         | Erbitux                  |                    |                    | S               | Intravenous (not<br>otherwise specified)               | Unk, Q2wk            |                 | Not Reported         |                |
|                                                                                                                                         | Levothyrox               |                    |                    | S               | Oral                                                   | 50 Mg, Qd            |                 | Not Reported         |                |
|                                                                                                                                         | Solumedrol               |                    |                    | S               | Intravenous (not<br>otherwise specified)               | Unk, Q2wk            |                 | Not Reported         |                |
|                                                                                                                                         | Acetylcysteine           |                    |                    | S               | Oral                                                   | 200 Mg, Bid          |                 | Not Reported         |                |
|                                                                                                                                         | Allopurinol              |                    |                    | S               | Oral                                                   | 200 Mg, Qd           |                 | Not Reported         |                |
|                                                                                                                                         | Keppra                   |                    |                    | S               | Oral                                                   | 500 Mg, Bid          |                 | Not Reported         |                |
|                                                                                                                                         | Seroplex                 |                    |                    | S               | Oral                                                   | 10 Mg, Qd            |                 | Not Reported         |                |
|                                                                                                                                         | Stilnox                  |                    |                    | S               | Oral                                                   | 10 Mg, Unk           |                 | Not Reported         |                |
|                                                                                                                                         | Xatral                   |                    |                    | S               | Oral                                                   | 10 Mg, Qd            |                 | Not Reported         |                |
|                                                                                                                                         | Omeprazole               |                    |                    | C               | Unknown                                                | Unk                  |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                                                                                | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 17-Jan-2017                                                                                                                             | 12771571                 | EXPEDITED (15-DAY) |                    | DE, HO          | FR-FRI-1000087591                                      |                      | 49 YR           | Female               | FRA            |
| <u>Preferred Term</u>                                                                                                                   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Acute Hepatic Failure;<br>Anuria; Bradycardia;<br>Cardiogenic Shock;<br>Intentional Overdose;<br>Multiple Organ<br>Dysfunction Syndrome | Escitalopram Oxalate Unk |                    |                    | S               | Oral                                                   | 70 Tablets           |                 | Allergan             |                |
|                                                                                                                                         | Propranolol Hcl Unk      |                    |                    | S               | Oral                                                   | 110 Tablets          |                 | Allergan             |                |
|                                                                                                                                         | Doliprane                |                    |                    | S               | Oral                                                   | 7 G, Unk             |                 | Not Reported         |                |
|                                                                                                                                         | Alprazolam               |                    |                    | S               | Oral                                                   | 100 Tablets          |                 | Not Reported         |                |
|                                                                                                                                         | Prazepam                 |                    |                    | S               | Oral                                                   | Unk                  |                 | Not Reported         |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                 | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u>                                                                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------|----------------------------|--------------------|--------------------|-----------------|-------------------------------|--------------------------------------------------------------------------------------|-----------------|--------------|----------------|
| 17-Jan-2017                                                                                              | 13087349                   | EXPEDITED (15-DAY) |                    | HO              | IN-CIPLA LTD.-<br>2016IN24348 |                                                                                      |                 | Unknown      | IND            |
| <u>Preferred Term</u>                                                                                    | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>                                                                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Headache;<br>Hypoglycaemia;<br>Intentional Overdose;<br>Suicidal Ideation; Suicide<br>Attempt | Escitalopram               |                    |                    | S               | Unknown                       | Unk Unk, Qd                                                                          |                 | Invagen      |                |
|                                                                                                          | Escitalopram               |                    |                    | S               | Oral                          | 10 To 15 Tablets Of<br>Venlafaxine, Tablet<br>Escitalopram, And Tablet<br>Clonazepam |                 | Invagen      |                |
|                                                                                                          | Venlafaxine                |                    |                    | S               | Unknown                       | Unk, Qd                                                                              |                 | Not Reported |                |
|                                                                                                          | Venlafaxine                |                    |                    | S               | Oral                          | 10 To 15 Tablets Of<br>Venlafaxine, Tablet<br>Escitalopram, And Tablet<br>Clonazepam |                 | Not Reported |                |
|                                                                                                          | Clonazepam                 |                    |                    | S               | Unknown                       | Unk, Qd                                                                              |                 | Not Reported |                |
|                                                                                                          | Clonazepam                 |                    |                    | S               | Oral                          | 10 To 15 Tablets Of<br>Venlafaxine, Tablet<br>Escitalopram, And Tablet<br>Clonazepam |                 | Not Reported |                |
|                                                                                                          |                            |                    |                    |                 |                               |                                                                                      |                 |              |                |
|                                                                                                          |                            |                    |                    |                 |                               |                                                                                      |                 |              |                |
| <u>FDA Received Date</u>                                                                                 | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u>                                                                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Jan-2017                                                                                              | 13119980                   | EXPEDITED (15-DAY) |                    | DE, HO, OT      | US-APOTEX-<br>2017AP005124    |                                                                                      | 22 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                    | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>                                                                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                                                                        | Bupropion Hydrochloride    |                    |                    | S               | Oral                          |                                                                                      |                 | Apotex       |                |
|                                                                                                          | Clonazepam Tablets Usp     |                    |                    | S               | Oral                          |                                                                                      |                 | Apotex       |                |
|                                                                                                          | Escitalopram Oxalate       |                    |                    | S               | Oral                          |                                                                                      |                 | Apotex       |                |
|                                                                                                          | Amfetamine W/Dexamfetamine |                    |                    | S               | Oral                          |                                                                                      |                 | Not Reported |                |
|                                                                                                          | Ethanol                    |                    |                    | S               | Oral                          |                                                                                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                 | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u>                                                                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Jan-2017                                                                                              | 13120073                   | EXPEDITED (15-DAY) |                    | DE, OT          | US-APOTEX-<br>2017AP005360    |                                                                                      | 58 YR           | Female       | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Escitalopram Oxalate |              |            | S           | Oral         |                    |                 | Apotex       |
|                       | Oxycodone            |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Ibuprofen            |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------------------------------------|----------------------|------------|------------|----------------|
| 17-Jan-2017              | 13120096      | EXPEDITED (15-DAY) |                    | HO              | FR-CONCORDIA<br>PHARMACEUTICALS<br>INC.-GSH201701-<br>000292 |                      | 65 YR      | Male       | FRA            |

| <u>Preferred Term</u>     | <u>Product</u>                             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                             | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|--------------------------------------------|--------------|------------|-------------|------------------------------------------|--------------------|-----------------|--------------|
| Interstitial Lung Disease | Alfuzosin Extended-Release<br>Tablet 10 Mg |              |            | S           | Oral                                     |                    |                 | Concordia    |
|                           | Allopurinol                                |              |            | S           | Oral                                     |                    |                 | Not Reported |
|                           | Metformin                                  |              |            | S           | Oral                                     |                    |                 | Not Reported |
|                           | Stilnox                                    |              |            | S           | Oral                                     |                    |                 | Not Reported |
|                           | Seroplex                                   |              |            | S           | Oral                                     |                    |                 | Not Reported |
|                           | Levothyrox                                 |              |            | S           | Oral                                     |                    |                 | Not Reported |
|                           | Keppra                                     |              |            | S           | Oral                                     |                    |                 | Not Reported |
|                           | Acetylcysteine                             |              |            | S           | Oral                                     |                    |                 | Not Reported |
|                           | Solumedrol                                 |              |            | S           | Intravenous (not<br>otherwise specified) | Every Cycle        |                 | Not Reported |
|                           | Erbix                                      |              |            | S           | Intravenous (not<br>otherwise specified) | Every Cycle        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 17-Jan-2017              | 13120141      | EXPEDITED (15-DAY) |                    | DE, HO, OT      | US-APOTEX-<br>2017AP005487 |                      | 74 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Completed Suicide     | Escitalopram Oxalate |              |            | S           | Oral         |                    |                 | Apotex     |
|                       | Alprazolam           |              |            | S           | Oral         |                    |                 | Apotex     |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |                                  |   |      |              |
|--|----------------------------------|---|------|--------------|
|  | Hydrochlorothiazide              | S | Oral | Apotex       |
|  | Famotidine Tablets Usp           | S | Oral | Apotex       |
|  | Cetirizine Hydrochloride Tablets | S | Oral | Apotex       |
|  | Doxepin                          | S | Oral | Not Reported |
|  | Hydrocodone                      | S | Oral | Not Reported |
|  | Olmesartan                       | S | Oral | Not Reported |
|  | Pregabalin                       | S | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>                                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------------------------------------------|--------------------|--------------------|-----------------|------------------------|----------------------|-----------------|------------|----------------|
| 17-Jan-2017              | 13120145                                          | EXPEDITED (15-DAY) |                    | DE, OT          | US-APOTEX-2017AP005466 |                      | 59 YR           | Female     | USA            |
| <u>Preferred Term</u>    | <u>Product</u>                                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Completed Suicide        | Duloxetine Hydrochloride Delayed-Release Capsules |                    |                    | S               | Oral                   |                      |                 | Apotex     |                |
|                          | Bupropion Hydrochloride                           |                    |                    | S               | Oral                   |                      |                 | Apotex     |                |
|                          | Escitalopram Oxalate                              |                    |                    | S               | Oral                   |                      |                 | Apotex     |                |

| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------------|--------------------|--------------------|-----------------|------------------------|----------------------|-----------------|--------------|----------------|
| 17-Jan-2017              | 13120149             | EXPEDITED (15-DAY) |                    | DE, OT          | US-APOTEX-2017AP005458 |                      | 53 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide        | Escitalopram Oxalate |                    |                    | S               | Oral                   |                      |                 | Apotex       |                |
|                          | Amitriptyline        |                    |                    | S               | Oral                   |                      |                 | Not Reported |                |
|                          | Diphenhydramine      |                    |                    | S               | Oral                   |                      |                 | Not Reported |                |
|                          | Ethanol              |                    |                    | S               | Oral                   |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 17-Jan-2017              | 13122332       | EXPEDITED (15-DAY) |                    | DE, OT          | US-MYLANLABS-2017M1002100 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                         |                                                           |                  |                                                                      |                                                       |
|---------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------|------------------|----------------------------------------------------------------------|-------------------------------------------------------|
| Cardiac Failure;<br>Cardiomyopathy; Foetal<br>Exposure During<br>Pregnancy; Human<br>Herpesvirus 6 Infection;<br>Multiple Organ<br>Dysfunction Syndrome | Ondansetron<br>Sertraline<br>Escitalopram<br>Progesterone | S<br>S<br>S<br>S | Transplacental<br>Transplacental<br>Transplacental<br>Transplacental | Not Reported<br>Not Reported<br>Not Reported<br>Mylan |
|---------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------|------------------|----------------------------------------------------------------------|-------------------------------------------------------|

| <u>FDA Received Date</u>                                                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u>                               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|-------------------------------|----------------------------------------------------|-----------------|--------------|----------------|
| 17-Jan-2017                                                                | 13122333       | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-<br>2017M1002099 |                                                    |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>                                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Human Herpesvirus 6<br>Infection; Maternal<br>Exposure During<br>Pregnancy | Ondansetron    |                    |                    | S               | Unknown                       |                                                    |                 | Not Reported |                |
|                                                                            | Sertraline     |                    |                    | S               | Unknown                       | Drug Was Administered<br>For First Two Trimesters. |                 | Not Reported |                |
|                                                                            | Escitalopram   |                    |                    | S               | Unknown                       | Was Administered In The<br>Last Trimester          |                 | Not Reported |                |
|                                                                            | Progesterone   |                    |                    | S               | Unknown                       | Initiated From Week 16                             |                 | Mylan        |                |

| <u>FDA Received Date</u>                                                                         | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>                                                          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|---------------------------|-------------------------------------------------------------------------------|-----------------|--------------|----------------|
| 17-Jan-2017                                                                                      | 13123156                  | EXPEDITED (15-DAY) |                    | OT              | DE-ALLERGAN-<br>1701795US |                                                                               | 1 DAY           | Male         | DEU            |
| <u>Preferred Term</u>                                                                            | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>                                                            | <u>Duration</u> | <u>Mfr</u>   |                |
| Foetal Exposure During<br>Pregnancy; Small For<br>Dates Baby; Temperature<br>Regulation Disorder | Escitalopram Oxalate - Bp |                    |                    | S               | Transplacental            | 5 Mg, Unk                                                                     |                 | Allergan     |                |
|                                                                                                  | Escitalopram Oxalate - Bp |                    |                    | S               | Transplacental            | 10 Mg/D Until Week 24+3<br>And From Unknown Date<br>Then 10mg/D Untildelivery |                 | Allergan     |                |
|                                                                                                  | Fluoxetine                |                    |                    | C               | Transplacental            |                                                                               |                 | Not Reported |                |
|                                                                                                  | Elevit                    |                    |                    | C               | Transplacental            |                                                                               |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------------------------------------|----------------------|------------|------------|----------------|
| 17-Jan-2017              | 13123625      | EXPEDITED (15-DAY) |                    | OT              | DE-MACLEODS<br>PHARMACEUTICALS<br>US LTD-<br>MAC2017004203 |                      |            | Unknown    | DEU            |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                   | <u>Duration</u> | <u>Mfr</u>   |                |
|-----------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|------------------------------------------------------|-----------------|--------------|----------------|
| Foetal Exposure During Pregnancy; Small For Dates Baby; Temperature Regulation Disorder | Escitalopram   |                    |                    | S               | Transplacental       | 10 Mg, Qd (From Gw18.6 Until Week 24+3 (2 Trimester) |                 | Macleods     |                |
|                                                                                         | Escitalopram   |                    |                    | S               | Transplacental       | 5 Mg, Qd                                             |                 | Macleods     |                |
|                                                                                         | Escitalopram   |                    |                    | S               | Transplacental       | 10 Mg, Qd (Until Delivery At Gw 39)                  |                 | Macleods     |                |
|                                                                                         | Fluoxetin      |                    |                    | C               | Transplacental       | 20 Mg, Qd (First Trimester)(0- 14.6 Gw)              |                 | Not Reported |                |
|                                                                                         | Eelvit         |                    |                    | C               | Transplacental       | Unk                                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Jan-2017                                                                             | 12696443       | EXPEDITED (15-DAY) |                    | HO              | FR-UCBSA-2016032839  |                                                      | 88 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyponatraemia                                                                           | Xyzall         |                    |                    | S               | Oral                 | Unk                                                  |                 | Ucb          |                |
|                                                                                         | Seroplex       |                    |                    | S               | Oral                 | 5 Mg, Once Daily (Qd)                                |                 | Not Reported |                |
|                                                                                         | Esomeprazole   |                    |                    | S               | Oral                 | 20 Mg, Once Daily (Qd)                               |                 | Not Reported |                |
|                                                                                         | Alprazolam     |                    |                    | S               | Oral                 | 0.5 Mg, Once Daily (Qd)                              |                 | Not Reported |                |
|                                                                                         | Amlor          |                    |                    | C               | Oral                 | 5 Mg, Once Daily (Qd)                                |                 | Not Reported |                |
|                                                                                         | Aprovel        |                    |                    | C               | Oral                 | 300 Mg, Once Daily (Qd)                              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Jan-2017                                                                             | 13124042       | EXPEDITED (15-DAY) |                    | OT              | CZ-ACCORD-047482     |                                                      | 54 YR           | Male         | CZE            |
| <u>Preferred Term</u>                                                                   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective; Sexual Dysfunction                                                    | Escitalopram   |                    |                    | S               |                      |                                                      |                 | Accord       |                |
|                                                                                         | Sertraline     |                    |                    | S               |                      |                                                      |                 | Accord       |                |
|                                                                                         | Warfarin       |                    |                    | C               |                      |                                                      |                 | Not Reported |                |
|                                                                                         | Zolpidem       |                    |                    | C               |                      |                                                      |                 | Not Reported |                |
|                                                                                         | Agomelatine    |                    |                    | C               |                      |                                                      |                 | Not Reported |                |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                   | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|--------------------|--------------------|-----------------|--------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 18-Jan-2017                                                                                                                                                                                | 13124578                   | EXPEDITED (15-DAY) |                    | CA, DE          | PHHY2017US004336                                 |                      | 4 DAY           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                      | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                     | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Failure;<br>Congestive<br>Cardiomyopathy; Foetal<br>Exposure During<br>Pregnancy; Human<br>Herpesvirus 6 Infection;<br>Hypersensitivity; Multiple<br>Organ Dysfunction<br>Syndrome | Ondansetron                |                    |                    | S               | Transplacental                                   |                      |                 | Novartis     |                |
|                                                                                                                                                                                            | Sertraline                 |                    |                    | S               | Transplacental                                   |                      |                 | Not Reported |                |
|                                                                                                                                                                                            | Progesterone               |                    |                    | S               | Transplacental                                   |                      |                 | Not Reported |                |
|                                                                                                                                                                                            | Escitalopram               |                    |                    | S               | Transplacental                                   |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                   | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Jan-2017                                                                                                                                                                                | 13125508                   | EXPEDITED (15-DAY) |                    | DE              | US-LANNETT<br>COMPANY, INC.-US-<br>2017LAN000138 |                      | 58 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                      | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                     | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Toxicity To Various Agents                                                                                                                                           | Oxycodone Hydrochloride    |                    |                    | S               | Oral                                             | Unk                  |                 | Lannett      |                |
|                                                                                                                                                                                            | Escitalopram               |                    |                    | S               | Oral                                             | Unk                  |                 | Not Reported |                |
|                                                                                                                                                                                            | Ibuprofen                  |                    |                    | S               | Oral                                             | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                   | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Jan-2017                                                                                                                                                                                | 13125586                   | EXPEDITED (15-DAY) |                    | DE              | US-LANNETT<br>COMPANY, INC.-US-<br>2017LAN000298 |                      | 74 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                      | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                     | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Toxicity To Various Agents                                                                                                                                           | Doxepin Hydrochloride      |                    |                    | S               | Oral                                             | Unk                  |                 | Lannett      |                |
|                                                                                                                                                                                            | Escitalopram Oxalate       |                    |                    | S               | Oral                                             | Unk                  |                 | Lannett      |                |
|                                                                                                                                                                                            | Hydrochlorothiazide (50mg) |                    |                    | S               | Oral                                             | Unk                  |                 | Lannett      |                |
|                                                                                                                                                                                            | Cetirizine Hydrochloride   |                    |                    | S               | Oral                                             | Unk                  |                 | Lannett      |                |
|                                                                                                                                                                                            | Hydrocodone                |                    |                    | S               | Oral                                             | Unk                  |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|            |   |      |     |              |
|------------|---|------|-----|--------------|
| Olmesartan | S | Oral | Unk | Not Reported |
| Alprazolam | S | Oral | Unk | Not Reported |
| Famotidine | S | Oral | Unk | Not Reported |
| Pregabalin | S | Oral | Unk | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 18-Jan-2017              | 13126990      | EXPEDITED (15-DAY) |                    | HO              | FR-ALLERGAN-1701941US |                      | 20 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                      | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Antipsychotic Drug Level Increased; Somnolence; Toxicity To Various Agents | Escitalopram Oxalate - Bp |              |            | S           | Oral         | 2 Blister Packs    |                 | Allergan     |
|                                                                            | Teralithe                 |              |            | S           | Oral         | 2 Blister Packs    |                 | Not Reported |
|                                                                            | Teralithe                 |              |            | S           | Oral         | 400 Mg, Tid        |                 | Not Reported |
|                                                                            | Tercian                   |              |            | C           | Unknown      | 25 Mg, Prn         |                 | Not Reported |
|                                                                            | Alprazolam                |              |            | C           | Unknown      | 0.25 Mg, Prn       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Jan-2017              | 13127043      | EXPEDITED (15-DAY) |                    | OT              | DE-TEVA-728609GER    |                      | 1 DAY      | Male       | DEU            |

| <u>Preferred Term</u>                                                                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u>                                                | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|-------------------------------------------------------------------|-----------------|--------------|
| Foetal Exposure During Pregnancy; Small For Dates Baby; Temperature Regulation Disorder | Escitalopram   |              |            | S           | Transplacental | 10 (Mg/D)/ Until Week 24 And 3: 5mg/D, Then 10mg/D Until Delivery |                 | Ivax         |
|                                                                                         | Fluoxetine     |              |            | C           | Transplacental | 20 Milligram Daily;                                               |                 | Not Reported |
|                                                                                         | Elevit         |              |            | C           | Transplacental |                                                                   |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 18-Jan-2017              | 13127656      | EXPEDITED (15-DAY) |                    | OT              | FR-ALLERGAN-1701942US |                      | 40 YR      | Male       | FRA            |

| <u>Preferred Term</u>                          | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|------------------------------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Agitation; Chills; Drug Intolerance; Serotonin | Escitalopram Oxalate - Bp |              |            | S           | Oral         |                    |                 | Allergan   |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Syndrome

| <u>FDA Received Date</u>                                                                    | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------|---------------------|--------------------|--------------------|-----------------|------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 18-Jan-2017                                                                                 | 13128331            | EXPEDITED (15-DAY) |                    | HO              | US-ALLERGAN-1701890US                          |                      | 64 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                       | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Angina Pectoris; Cellulitis; Depression; Electrolyte Imbalance; Hypertension; Hyponatraemia | Lexapro             |                    |                    | S               | Unknown                                        |                      |                 | Allergan     |                |
|                                                                                             | Humira              |                    |                    | S               | Subcutaneous                                   | 40 Mg, Q2weeks       |                 | Not Reported |                |
|                                                                                             | Humira              |                    |                    | S               |                                                |                      |                 | Not Reported |                |
|                                                                                             | Hydrochlorothiazide |                    |                    | S               | Oral                                           | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                    | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Jan-2017                                                                                 | 13128430            | EXPEDITED (15-DAY) |                    | DE              | US-ARBOR PHARMACEUTICALS, LLC-US-2017ARB000013 |                      | 22 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                       | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Toxicity To Various Agents                                               | Amphetamine Sulfate |                    |                    | S               | Oral                                           | Unk                  |                 | Arbor        |                |
|                                                                                             | Bupropion           |                    |                    | S               | Oral                                           | Unk                  |                 | Not Reported |                |
|                                                                                             | Clonazepam          |                    |                    | S               | Oral                                           | Unk                  |                 | Not Reported |                |
|                                                                                             | Escitalopram        |                    |                    | S               | Oral                                           | Unk                  |                 | Not Reported |                |
|                                                                                             | Ethanol             |                    |                    | S               | Oral                                           | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                    | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Jan-2017                                                                                 | 13128857            | EXPEDITED (15-DAY) |                    | HO              | SE-CIPLA LTD.-2017SE00693                      |                      |                 | Unknown      | SWE            |
| <u>Preferred Term</u>                                                                       | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Lethargy; Suicide Attempt; Toxicity To Various Agents                                       | Escitalopram        |                    |                    | S               | Oral                                           | Unk                  |                 | Invagen      |                |
|                                                                                             | Sobril              |                    |                    | S               | Oral                                           | Unk                  |                 | Not Reported |                |
|                                                                                             | Imovane             |                    |                    | S               | Oral                                           | Unk                  |                 | Not Reported |                |
|                                                                                             | Mirtazapine         |                    |                    | S               | Oral                                           | Unk                  |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                     | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|-----------------------------------------------|----------------------|-----------------|-----------------|----------------|
| 19-Jan-2017                                                                                                  | 13129618                  | EXPEDITED (15-DAY) |                    | OT              | PHHY2017HR003566                              |                      | 43 YR           | Female          | HRV            |
| <u>Preferred Term</u>                                                                                        | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Disorientation; Intentional Overdose; Somnolence; Suicide Attempt                                            | Ergometrin Lek            |                    |                    | S               | Oral                                          |                      |                 | Not Reported    |                |
|                                                                                                              | Lamotrigine               |                    |                    | S               | Oral                                          |                      |                 | Novartis        |                |
|                                                                                                              | Escitalopram              |                    |                    | S               | Oral                                          |                      |                 | Not Reported    |                |
|                                                                                                              | Mirtazapine               |                    |                    | S               | Oral                                          |                      |                 | Not Reported    |                |
|                                                                                                              | Alprazolam                |                    |                    | S               | Oral                                          |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                     | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 19-Jan-2017                                                                                                  | 13130312                  | NON-EXPEDITED      |                    |                 | US-GLAXOSMITHKLINE-US2017GSK006759            |                      |                 | Female          | USA            |
| <u>Preferred Term</u>                                                                                        | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Aggression; Depressed Mood; Diarrhoea; Drug Ineffective; Insomnia; Partner Stress; Psychomotor Hyperactivity | Wellbutrin Tablet         |                    |                    | S               |                                               | 10 Mg, Qd            |                 | Glaxosmithkline |                |
|                                                                                                              | Paxil Capsule             |                    |                    | S               |                                               | 50 Mg, Qd            |                 | Glaxosmithkline |                |
|                                                                                                              | Lexapro                   |                    |                    | S               |                                               | 10 Mg, Qd            |                 | Not Reported    |                |
|                                                                                                              | Zoloft                    |                    |                    | S               |                                               | 20 Mg, Unk           |                 | Not Reported    |                |
|                                                                                                              | Omeprazole                |                    |                    | C               |                                               | 40 Mg, Qd            |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                     | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 19-Jan-2017                                                                                                  | 13130337                  | EXPEDITED (15-DAY) |                    | DE, HO          | US-TARO PHARMACEUTICALS USA.,INC-2017SUN00012 |                      | 4 DAY           | Male            | USA            |
| <u>Preferred Term</u>                                                                                        | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Cardiac Failure; Congestive Cardiomyopathy; Drug Hypersensitivity; Foetal Exposure During Pregnancy; Human   | Escitalopram              |                    |                    | S               | Transplacental                                | Unk                  |                 | Taro            |                |
|                                                                                                              | Ondansetron Hydrochloride |                    |                    | S               | Transplacental                                | Unk                  |                 | Taro            |                |
|                                                                                                              | Progesterone              |                    |                    | S               | Transplacental                                | Unk                  |                 | Not Reported    |                |
|                                                                                                              | Progesterone              |                    |                    | S               |                                               |                      |                 | Not Reported    |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                    |            |   |                |     |              |
|--------------------------------------------------------------------|------------|---|----------------|-----|--------------|
| Herpesvirus 6 Infection;<br>Multiple Organ<br>Dysfunction Syndrome | Sertraline | S | Transplacental | Unk | Not Reported |
|--------------------------------------------------------------------|------------|---|----------------|-----|--------------|

| <u>FDA Received Date</u>                                    | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------|-------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
| 19-Jan-2017                                                 | 13131371          | EXPEDITED (15-DAY) |                    | OT              | DE-MYLANLABS-2017M1002775 |                      |                 | Unknown      | DEU            |
| <u>Preferred Term</u>                                       | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Small For Dates Baby;<br>Temperature Regulation<br>Disorder | Escitalopram      |                    |                    | S               | Transplacental            | 10 Mg, Qd            |                 | Not Reported |                |
|                                                             | Escitalopram      |                    |                    | S               | Transplacental            | 5 Mg, Unk            |                 | Not Reported |                |
|                                                             | Escitalopram      |                    |                    | S               |                           | 10 Mg, Qd            |                 | Not Reported |                |
|                                                             | Fluoxetine        |                    |                    | C               | Transplacental            | 20 Mg, Qd            |                 | Mylan        |                |
|                                                             | Elevit /01730301/ |                    |                    | C               | Transplacental            |                      |                 | Mylan        |                |

| <u>FDA Received Date</u>                         | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                              | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|---------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 19-Jan-2017                                      | 13131773                    | EXPEDITED (15-DAY) |                    | DE              | US-NORTHSTAR HEALTHCARE HOLDINGS-US-2017NSR000065 |                      | 41 YR           | Male         | USA            |
| <u>Preferred Term</u>                            | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                      | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Toxicity To Various Agents | Tramadol Hydrochloride      |                    |                    | S               | Oral                                              | Unk                  |                 | Northstar    |                |
|                                                  | Baclofen                    |                    |                    | S               | Oral                                              | Unk                  |                 | Northstar    |                |
|                                                  | Clonazepam                  |                    |                    | S               | Oral                                              | Unk                  |                 | Not Reported |                |
|                                                  | Acetaminophen W/Hydrocodone |                    |                    | S               | Oral                                              | Unk                  |                 | Not Reported |                |
|                                                  | Escitalopram                |                    |                    | S               | Oral                                              | Unk                  |                 | Not Reported |                |
|                                                  | Alprazolam                  |                    |                    | S               | Oral                                              | Unk                  |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>   | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|-----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 19-Jan-2017              | 13132873        | DIRECT           |                    |                 |                      |                      | 25 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>  | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Chest Discomfort;        | Generic Bactrim |                  |                    | S               | Oral                 |                      |                 | Not Reported |                |

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Delusion; Drug Interaction; Headache; Night Sweats; Nightmare      Generic Lexapro      S      Not Reported

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Jan-2017              | 13133217      | DIRECT           | Y                  | OT              |                      |                      |            | Male       | USA            |

| <u>Preferred Term</u>                                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|----------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Depression; Drug Ineffective; Product Substitution Issue | Escitalopram   |              |            | S           |              |                    |                 | Unknown    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------|----------------------|------------|------------|----------------|
| 20-Jan-2017              | 13132918      | EXPEDITED (15-DAY) |                    | OT              | US-APOTEX-2017AP005886 |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                                           | <u>Product</u>                        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------|---------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Hypersensitivity; Exposure During Pregnancy; Human Herpesvirus 6 Infection | Ondansetron Hydrochloride Tablets Usp |              |            | S           | Unknown      | Unk                |                 | Apotex       |
|                                                                                 | Sertraline Hydrochloride              |              |            | S           | Unknown      | Unk                |                 | Apotex       |
|                                                                                 | Escitalopram Oxalate                  |              |            | S           | Unknown      | Unk                |                 | Apotex       |
|                                                                                 | Progesterone                          |              |            | S           | Unknown      | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------|----------------------|------------|------------|----------------|
| 20-Jan-2017              | 13132957      | EXPEDITED (15-DAY) |                    | DE, OT          | US-APOTEX-2017AP005888 |                      | 4 DAY      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                 | <u>Product</u>                        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Cardiac Failure; Cardiomyopathy; Foetal Exposure During Pregnancy; Human Herpesvirus 6 Infection; Multiple Organ Dysfunction Syndrome | Ondansetron Hydrochloride Tablets Usp |              |            | S           | Transplacental | Unk                |                 | Apotex       |
|                                                                                                                                       | Sertraline Hydrochloride              |              |            | S           | Transplacental | Unk                |                 | Apotex       |
|                                                                                                                                       | Escitalopram Oxalate                  |              |            | S           | Transplacental | Unk                |                 | Apotex       |
|                                                                                                                                       | Progesterone                          |              |            | S           | Transplacental | Unk                |                 | Not Reported |

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| <u>FDA Received Date</u>                                                                       | <u>Case #</u>                                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>              | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>             | <u>Country</u> |
|------------------------------------------------------------------------------------------------|-----------------------------------------------|--------------------|--------------------|-----------------|-----------------------------------|----------------------|-----------------|------------------------|----------------|
| 20-Jan-2017                                                                                    | 13132988                                      | EXPEDITED (15-DAY) |                    | OT              | HR-TEVA-729235ACC                 |                      | 43 YR           | Female                 | HRV            |
| <u>Preferred Term</u>                                                                          | <u>Product</u>                                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                      | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>             |                |
| Disorientation; Intentional Overdose; Somnolence; Suicide Attempt                              | Mirtazapine                                   |                    |                    | S               | Oral                              | Unknown              |                 | Teva                   |                |
|                                                                                                | Escitalopram                                  |                    |                    | S               | Oral                              | Unknown              |                 | Not Reported           |                |
|                                                                                                | Lamotrigin                                    |                    |                    | S               | Oral                              | Unknown              |                 | Not Reported           |                |
|                                                                                                | Ergometrin Lek                                |                    |                    | S               | Oral                              | Unknown              |                 | Not Reported           |                |
|                                                                                                | Alprazolam                                    |                    |                    | S               | Oral                              | Unknown              |                 | Not Reported           |                |
| <u>FDA Received Date</u>                                                                       | <u>Case #</u>                                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>              | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>             | <u>Country</u> |
| 20-Jan-2017                                                                                    | 13133101                                      | EXPEDITED (15-DAY) |                    | OT              | US-FRESENIUS KABI-FK201700552     |                      |                 | Female                 | USA            |
| <u>Preferred Term</u>                                                                          | <u>Product</u>                                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                      | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>             |                |
| Exposure During Pregnancy; Human Herpesvirus 6 Infection; Product Use In Unapproved Indication | Progesterone Injection (Manufacturer Unknown) |                    |                    | S               | Unknown                           |                      |                 | Fresenius Medical Care |                |
|                                                                                                | Ondansetron (Manufacturer Unknown)            |                    |                    | S               | Unknown                           |                      |                 | Not Reported           |                |
|                                                                                                | Sertraline                                    |                    |                    | S               | Unknown                           |                      |                 | Not Reported           |                |
|                                                                                                | Escitalopram                                  |                    |                    | S               | Unknown                           |                      |                 | Not Reported           |                |
| <u>FDA Received Date</u>                                                                       | <u>Case #</u>                                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>              | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>             | <u>Country</u> |
| 20-Jan-2017                                                                                    | 13134124                                      | EXPEDITED (15-DAY) |                    | DE              | US-EGALET US INC-US-2017EGA000051 |                      | 58 YR           | Female                 | USA            |
| <u>Preferred Term</u>                                                                          | <u>Product</u>                                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                      | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>             |                |
| Completed Suicide; Toxicity To Various Agents                                                  | Oxycodone Hydrochloride                       |                    |                    | S               | Oral                              | Unk                  |                 | Egalet                 |                |
|                                                                                                | Escitalopram                                  |                    |                    | S               | Oral                              | Unk                  |                 | Not Reported           |                |
|                                                                                                | Ibuprofen                                     |                    |                    | S               | Oral                              | Unk                  |                 | Not Reported           |                |

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| <u>FDA Received Date</u>                                                                                                                                                                                                                       | <u>Case #</u>                                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                        | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------|--------------------|--------------------|-----------------|-------------------------------------------------------------|----------------------|-----------------|---------------------------|----------------|
| 20-Jan-2017                                                                                                                                                                                                                                    | 13134648                                         | EXPEDITED (15-DAY) |                    | CA, DE, OT      | US-FRESENIUS KABI-FK201700554                               |                      | 4 DAY           | Male                      | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                          | <u>Product</u>                                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                |                |
| Cardiac Failure;<br>Congenital Cardiovascular<br>Anomaly; Congestive<br>Cardiomyopathy; Human<br>Herpesvirus 6 Infection;<br>Maternal Drugs Affecting<br>Foetus; Multiple Organ<br>Dysfunction Syndrome;<br>Vertical Infection<br>Transmission | Progesterone Injection<br>(Manufacturer Unknown) |                    |                    | S               | Transplacental                                              |                      |                 | Fresenius Medical<br>Care |                |
|                                                                                                                                                                                                                                                | Ondansetron (Manufacturer<br>Unknown)            |                    |                    | S               | Transplacental                                              |                      |                 | Not Reported              |                |
|                                                                                                                                                                                                                                                | Sertraline                                       |                    |                    | S               | Transplacental                                              |                      |                 | Not Reported              |                |
|                                                                                                                                                                                                                                                | Escitalopram                                     |                    |                    | S               | Transplacental                                              |                      |                 | Not Reported              |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                       | <u>Case #</u>                                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                        | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                | <u>Country</u> |
| 20-Jan-2017                                                                                                                                                                                                                                    | 13135876                                         | EXPEDITED (15-DAY) |                    | HO, OT          | FR-NORTHSTAR<br>HEALTHCARE<br>HOLDINGS-FR-<br>2017NSR000093 |                      | 33 YR           | Female                    | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                          | <u>Product</u>                                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                |                |
| Abnormal Behaviour;<br>Agitation; Anxiety;<br>Depressive Symptom;<br>Fatigue; Feeling<br>Abnormal; Grandiosity;<br>Insomnia; Logorrhoea;<br>Mania; Prescribed<br>Overdose; Psychomotor<br>Hyperactivity;<br>Tachyphrenia                       | Baclofen                                         |                    |                    | S               |                                                             | 60 Mg, Qd            |                 | Northstar                 |                |
|                                                                                                                                                                                                                                                | Baclofen                                         |                    |                    | S               |                                                             | Gradual Increase     |                 | Northstar                 |                |
|                                                                                                                                                                                                                                                | Baclofen                                         |                    |                    | S               |                                                             | 270 Mg, Qd           |                 | Northstar                 |                |
|                                                                                                                                                                                                                                                | Baclofen                                         |                    |                    | S               |                                                             | 240 Mg, Unk          |                 | Northstar                 |                |
|                                                                                                                                                                                                                                                | Baclofen                                         |                    |                    | S               |                                                             | 210 Mg, Unk          |                 | Northstar                 |                |
|                                                                                                                                                                                                                                                | Baclofen                                         |                    |                    | S               |                                                             | 180 Mg, Unk          |                 | Northstar                 |                |
|                                                                                                                                                                                                                                                | Baclofen                                         |                    |                    | S               |                                                             | 150 Mg, Unk          |                 | Northstar                 |                |
|                                                                                                                                                                                                                                                | Escitalopram                                     |                    |                    | S               |                                                             | 10 Mg, Unk           |                 | Not Reported              |                |
|                                                                                                                                                                                                                                                | Escitalopram                                     |                    |                    | S               |                                                             | 20 Mg, Unk           |                 | Not Reported              |                |
|                                                                                                                                                                                                                                                | Escitalopram                                     |                    |                    | S               |                                                             | Decreased            |                 | Not Reported              |                |
|                                                                                                                                                                                                                                                | Escitalopram                                     |                    |                    | S               |                                                             | Unk                  |                 | Not Reported              |                |



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| <u>FDA Received Date</u>       | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>              | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------|--------------------------|--------------------|--------------------|-----------------|-----------------------------------|----------------------|-----------------|--------------|----------------|
| 23-Jan-2017                    | 9132152                  | EXPEDITED (15-DAY) |                    | HO              | DE-FRI-1000043006                 |                      | 47 YR           | Male         | DEU            |
| <u>Preferred Term</u>          | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                      | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alopecia; Arrhythmia;          | Escitalopram Oxalate Unk |                    |                    | S               | Oral                              | 10 Mg, Qd            |                 | Allergan     |                |
| Asthenia; Atrial Fibrillation; | Escitalopram Oxalate Unk |                    |                    | S               | Oral                              | 2.5 Mg, Qd           |                 | Allergan     |                |
| Blood Testosterone             |                          |                    |                    |                 |                                   |                      |                 |              |                |
| Decreased; Coronary            | Bisoprolol               |                    |                    | C               |                                   |                      |                 | Not Reported |                |
| Artery Disease;                | Bisoprolol               |                    |                    | C               | Unknown                           |                      |                 | Not Reported |                |
| Depressed Level Of             | Nebivolol                |                    |                    | C               |                                   |                      |                 | Not Reported |                |
| Consciousness; Diabetes        | Nebivolol                |                    |                    | C               | Unknown                           |                      |                 | Not Reported |                |
| Mellitus; Diffuse Alopecia;    |                          |                    |                    |                 |                                   |                      |                 |              |                |
| Disturbance In Attention;      |                          |                    |                    |                 |                                   |                      |                 |              |                |
| Dyslipidaemia;                 |                          |                    |                    |                 |                                   |                      |                 |              |                |
| Glycosylated Haemoglobin       |                          |                    |                    |                 |                                   |                      |                 |              |                |
| Increased; Hormone Level       |                          |                    |                    |                 |                                   |                      |                 |              |                |
| Abnormal; Hyperhidrosis;       |                          |                    |                    |                 |                                   |                      |                 |              |                |
| Libido Disorder; Lipid         |                          |                    |                    |                 |                                   |                      |                 |              |                |
| Metabolism Disorder;           |                          |                    |                    |                 |                                   |                      |                 |              |                |
| Lipoprotein (A) Increased;     |                          |                    |                    |                 |                                   |                      |                 |              |                |
| Migraine; Mood Swings;         |                          |                    |                    |                 |                                   |                      |                 |              |                |
| Obesity; Restlessness;         |                          |                    |                    |                 |                                   |                      |                 |              |                |
| Seborrhoeic Dermatitis;        |                          |                    |                    |                 |                                   |                      |                 |              |                |
| Supraventricular               |                          |                    |                    |                 |                                   |                      |                 |              |                |
| Extrasystoles; Ventricular     |                          |                    |                    |                 |                                   |                      |                 |              |                |
| Extrasystoles; Weight          |                          |                    |                    |                 |                                   |                      |                 |              |                |
| Increased                      |                          |                    |                    |                 |                                   |                      |                 |              |                |
| <u>FDA Received Date</u>       | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>              | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Jan-2017                    | 13136707                 | EXPEDITED (15-DAY) |                    | OT              | IN-CIPLA (EU) LIMITED-2017IN00837 |                      |                 | Unknown      | IND            |
| <u>Preferred Term</u>          | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                      | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Extrapyramidal Disorder        | Escitalopram             |                    |                    | S               |                                   | 5 Mg, Daily          |                 | Invagen      |                |
|                                | Clonazepam               |                    |                    | C               |                                   | 0.5 Mg, Nighttime    |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                                                                                         | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u>                                           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|--------------------|--------------------|-----------------|---------------------------------|----------------------------------------------------------------|-----------------|--------------|----------------|
| 23-Jan-2017                                                                                                                                      | 13137210          | EXPEDITED (15-DAY) |                    | OT              | DE-AUROBINDO-AUR-APL-2017-01366 |                                                                | 1 DAY           | Unknown      | DEU            |
| <u>Preferred Term</u>                                                                                                                            | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>                                             | <u>Duration</u> | <u>Mfr</u>   |                |
| Foetal Exposure During Pregnancy; Small For Dates Baby; Temperature Regulation Disorder                                                          | Escitalopram      |                    |                    | S               | Transplacental                  | 10 [Mg/D ]I Until Week 24+3: 5mg/D, Then 10mg/D Until Delivery |                 | Aurobindo    |                |
|                                                                                                                                                  | Fluoxetine 20 Mg  |                    |                    | S               | Transplacental                  | 20 Mg, Daily                                                   |                 | Aurobindo    |                |
|                                                                                                                                                  | Elevit /01730301/ |                    |                    | S               | Transplacental                  |                                                                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                         | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u>                                           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Jan-2017                                                                                                                                      | 13138992          | EXPEDITED (15-DAY) |                    | OT              | US-TEVA-731851USA               |                                                                |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                            | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>                                             | <u>Duration</u> | <u>Mfr</u>   |                |
| Exposure During Pregnancy; Human Herpesvirus 6 Infection                                                                                         | Ondansetron       |                    |                    | S               | Unknown                         |                                                                |                 | Teva         |                |
|                                                                                                                                                  | Progesterone      |                    |                    | S               | Unknown                         | Initiated From Week 16                                         |                 | Teva         |                |
|                                                                                                                                                  | Sertraline        |                    |                    | S               | Unknown                         | Drug Was Administered For First Two Trimesters.                |                 | Not Reported |                |
|                                                                                                                                                  | Escitalopram      |                    |                    | S               | Unknown                         | Was Administered In The Last Trimester                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                         | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u>                                           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Jan-2017                                                                                                                                      | 13139022          | EXPEDITED (15-DAY) |                    | CA, DE, OT      | US-TEVA-731852USA               |                                                                |                 | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                            | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>                                             | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Failure; Congestive Cardiomyopathy; Foetal Exposure During Pregnancy; Human Herpesvirus 6 Infection; Multiple Organ Dysfunction Syndrome | Ondansetron       |                    |                    | S               | Transplacental                  |                                                                |                 | Teva         |                |
|                                                                                                                                                  | Progesterone      |                    |                    | S               | Transplacental                  |                                                                |                 | Teva         |                |
|                                                                                                                                                  | Sertraline        |                    |                    | S               | Transplacental                  |                                                                |                 | Not Reported |                |
|                                                                                                                                                  | Escitalopram      |                    |                    | S               | Transplacental                  |                                                                |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------|--------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
| 23-Jan-2017               | 13140499                 | EXPEDITED (15-DAY) |                    | HO, OT          | IN-MYLANLABS-2017M1003268 |                      |                 | Unknown      | IND            |
| <u>Preferred Term</u>     | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Headache;      | Venlafaxine              |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
| Hypoglycaemia;            | Escitalopram             |                    |                    | S               | Oral                      | Once A Day           |                 | Not Reported |                |
| Overdose; Suicidal        | Clonazepam               |                    |                    | S               | Oral                      | Once A Day           |                 | Not Reported |                |
| Ideation; Suicide Attempt |                          |                    |                    |                 |                           |                      |                 |              |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Jan-2017               | 13141327                 | EXPEDITED (15-DAY) |                    | OT              | IT-ALLERGAN-1702573US     |                      | 37 YR           | Male         | ITA            |
| <u>Preferred Term</u>     | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyperchlorhydria; Nausea; | Escitalopram Oxalate Unk |                    |                    | S               | Oral                      | 10 Gtt, Qd           |                 | Allergan     |                |
| Palpitations; Strangury   |                          |                    |                    |                 |                           |                      |                 |              |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Jan-2017               | 13142134                 | EXPEDITED (15-DAY) |                    | DE              | US-PFIZER INC-2017026209  |                      | 51 YR           | Female       | USA            |
| <u>Preferred Term</u>     | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide         | Amlodipine Besilate      |                    |                    | S               |                           | Unk                  |                 | Pfizer       |                |
|                           | Escitalopram             |                    |                    | S               |                           | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Jan-2017               | 13099496                 | EXPEDITED (15-DAY) |                    | HO              | IT-MYLANLABS-2017M1000774 |                      |                 | Unknown      | ITA            |
| <u>Preferred Term</u>     | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Abuse; Intentional   | Escitalopram             |                    |                    | S               | Oral                      | 100 Mg, Total        |                 | Not Reported |                |
| Self-Injury; Overdose;    |                          |                    |                    |                 |                           |                      |                 |              |                |
| Retching                  |                          |                    |                    |                 |                           |                      |                 |              |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                    | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|-------------------------------|--------------------------|-----------------|--------------|----------------|
| 24-Jan-2017                                                                                                                                                                 | 13143862                | EXPEDITED (15-DAY) |                    | OT              | US-CIPLA LTD.-<br>2017US01061 |                          |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                                                                                                                       | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Abulia; Apathy; Drug Ineffective; Enuresis; Fatigue; Impulse-Control Disorder; Insomnia; Loss Of Consciousness; Memory Impairment; Substance Abuse; Treatment Noncompliance | Sertraline              |                    |                    | S               | Unknown                       | 25 Mg, Qd, Every Morning |                 | Invagen      |                |
|                                                                                                                                                                             | Sertraline              |                    |                    | S               | Unknown                       | 25 Mg, Bid               |                 | Invagen      |                |
|                                                                                                                                                                             | Escitalopram            |                    |                    | S               | Unknown                       | 20 Mg, Qd                |                 | Invagen      |                |
|                                                                                                                                                                             | Escitalopram            |                    |                    | S               |                               |                          |                 | Invagen      |                |
|                                                                                                                                                                             | Bupropion               |                    |                    | S               | Unknown                       | Unk                      |                 | Invagen      |                |
|                                                                                                                                                                             | Bupropion               |                    |                    | S               |                               |                          |                 | Invagen      |                |
|                                                                                                                                                                             | Effexor Xr              |                    |                    | S               | Unknown                       | 37.5 Mg, Qd              |                 | Not Reported |                |
|                                                                                                                                                                             | Effexor Xr              |                    |                    | S               | Unknown                       | 75 Mg, Qd                |                 | Not Reported |                |
|                                                                                                                                                                             | Effexor Xr              |                    |                    | S               | Unknown                       | 150 Mg, Qd               |                 | Not Reported |                |
|                                                                                                                                                                             | Prozac                  |                    |                    | S               | Unknown                       | Unk                      |                 | Not Reported |                |
|                                                                                                                                                                             | Prozac                  |                    |                    | S               |                               |                          |                 | Not Reported |                |
|                                                                                                                                                                             | Alcohol                 |                    |                    | S               | Unknown                       | Unk                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                    | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Jan-2017                                                                                                                                                                 | 13144160                | EXPEDITED (15-DAY) |                    | DE              | US-PFIZER INC-<br>2017026230  |                          | 41 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                       | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                                                                                                                                           | Alprazolam              |                    |                    | S               | Oral                          | Unk                      |                 | Pfizer       |                |
|                                                                                                                                                                             | Tramadol                |                    |                    | S               | Oral                          | Unk                      |                 | Not Reported |                |
|                                                                                                                                                                             | Baclofen                |                    |                    | S               | Oral                          | Unk                      |                 | Not Reported |                |
|                                                                                                                                                                             | Clonazepam              |                    |                    | S               | Oral                          | Unk                      |                 | Not Reported |                |
|                                                                                                                                                                             | Hydrocodone/Paracetamol |                    |                    | S               | Oral                          | Unk                      |                 | Not Reported |                |
|                                                                                                                                                                             | Escitalopram            |                    |                    | S               | Oral                          | Unk                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                    | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Jan-2017                                                                                                                                                                 | 13144381                | EXPEDITED (15-DAY) |                    | DE              | US-PFIZER INC-<br>2017029270  |                          | 47 YR           | Male         | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiac Arrest; Completed Suicide; Respiratory Arrest | Propanolol Hcl |              |            | S           | Oral         | Unk                |                 | Unknown      |
|                                                       | Gabapentin     |              |            | S           | Oral         | Unk                |                 | Pfizer       |
|                                                       | Ibuprofen      |              |            | S           | Oral         | Unk                |                 | Pfizer       |
|                                                       | Quetiapine     |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                                                       | Citalopram     |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                                                       | Acetaminophen  |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                                                       | Benzotropine   |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                                                       | Trazodone      |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                                                       | Escitalopram   |              |            | S           | Oral         | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 24-Jan-2017              | 13145340      | EXPEDITED (15-DAY) |                    | DE              | US-PFIZER INC-2017028849 |                      | 74 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Doxepin Hcl         |              |            | S           | Oral         | Unk                |                 | Pfizer       |
|                       | Alprazolam          |              |            | S           | Oral         | Unk                |                 | Pfizer       |
|                       | Pregabalin          |              |            | S           | Oral         | Unk                |                 | Pfizer       |
|                       | Escitalopram        |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                       | Hydrocodone         |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                       | Olmesartan          |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                       | Hydrochlorothiazide |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                       | Cetirizine          |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                       | Famotidine          |              |            | S           | Oral         | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 24-Jan-2017              | 13145589      | EXPEDITED (15-DAY) |                    | DE              | US-PFIZER INC-2017026211 |                      | 64 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                   |                     |   |     |              |
|-------------------|---------------------|---|-----|--------------|
| Completed Suicide | Amlodipine Besilate | S | Unk | Pfizer       |
|                   | Enalapril           | S | Unk | Not Reported |
|                   | Escitalopram        | S | Unk | Not Reported |
|                   | Tamsulosin          | S | Unk | Not Reported |
|                   | Insulin             | S | Unk | Not Reported |

| <u>FDA Received Date</u>                         | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 24-Jan-2017                                      | 13157693       | DIRECT           |                    | DS              |                      |                      | 72 YR           | Female     | USA            |
| <u>Preferred Term</u>                            | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Rash; Rash; Rash; Skin Lesion; Vulvovaginal Rash | Lexapro        |                  |                    | S               | Oral                 |                      |                 | Accord     |                |

| <u>FDA Received Date</u>       | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>                               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------|--------------------------|--------------------|--------------------|-----------------|-----------------------|----------------------------------------------------|-----------------|--------------|----------------|
| 25-Jan-2017                    | 13089979                 | EXPEDITED (15-DAY) |                    | HO              | IT-ALLERGAN-1700416US |                                                    | 33 YR           | Female       | ITA            |
| <u>Preferred Term</u>          | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>                                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Overdose; Retching | Escitalopram Oxalate Unk |                    |                    | S               | Oral                  | 10 Mg, 10 Tablets                                  |                 | Allergan     |                |
|                                | Escitalopram Tablets     |                    |                    | S               | Oral                  | The Patient Took 10 Tablets Of Escitalopram 10 Mg. |                 | Not Reported |                |

| <u>FDA Received Date</u>                 | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------|----------------------------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|-----------------|--------------|----------------|
| 25-Jan-2017                              | 13146299                         | EXPEDITED (15-DAY) |                    | HO              | IT-AUROBINDO-AUR-APL-2017-13213 |                      | 22 YR           | Female       | ITA            |
| <u>Preferred Term</u>                    | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Self-Injury; Overdose; Sopor | Escitalopram Film-Coated Tablets |                    |                    | S               | Oral                            | 400 Mg, Total        |                 | Aurobindo    |                |
|                                          | Depakin                          |                    |                    | S               | Oral                            | 3 G, Total           |                 | Not Reported |                |
|                                          | Lexotan                          |                    |                    | S               | Oral                            | 25 Mg, Total         |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 25-Jan-2017                                                                                                                                                                                              | 13147965       | EXPEDITED (15-DAY) |                    | CA, DE, OT      | DE-LUPIN<br>PHARMACEUTICALS<br>INC.-2017-00390 |                      | 4 DAY           | Male         | DEU            |
| <u>Preferred Term</u>                                                                                                                                                                                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Congenital Infection;<br>Congestive<br>Cardiomyopathy; Foetal<br>Exposure During<br>Pregnancy; Human<br>Herpesvirus 6 Infection;<br>Maternal Drugs Affecting<br>Foetus; Neonatal Multi-<br>Organ Failure | Escitalopram   |                    |                    | S               | Transplacental                                 |                      |                 | Not Reported |                |
|                                                                                                                                                                                                          | Sertraline     |                    |                    | S               | Transplacental                                 |                      |                 | Not Reported |                |
|                                                                                                                                                                                                          | Progesterone   |                    |                    | S               | Transplacental                                 |                      |                 | Not Reported |                |
|                                                                                                                                                                                                          | Ondansteron    |                    |                    | S               | Transplacental                                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Jan-2017                                                                                                                                                                                              | 13147994       | EXPEDITED (15-DAY) |                    | OT              | DE-LUPIN<br>PHARMACEUTICALS<br>INC.-2017-00391 |                      |                 | Female       | DEU            |
| <u>Preferred Term</u>                                                                                                                                                                                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Exposure During<br>Pregnancy; Human<br>Herpesvirus 6 Infection                                                                                                                                           | Escitalopram   |                    |                    | S               | Unknown                                        |                      |                 | Not Reported |                |
|                                                                                                                                                                                                          | Sertraline     |                    |                    | S               | Unknown                                        |                      |                 | Not Reported |                |
|                                                                                                                                                                                                          | Progesterone   |                    |                    | S               | Unknown                                        |                      |                 | Not Reported |                |
|                                                                                                                                                                                                          | Ondansetron    |                    |                    | S               | Unknown                                        |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Jan-2017                                                                                                                                                                                              | 13151969       | EXPEDITED (15-DAY) |                    | HO, OT          | TR-MYLANLABS-<br>2017M1003934                  |                      |                 | Unknown      | TUR            |
| <u>Preferred Term</u>                                                                                                                                                                                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Angle Closure Glaucoma;<br>Drug Interaction                                                                                                                                                              | Mirtazapine    |                    |                    | S               | Unknown                                        | 15 Mg/Day            |                 | Not Reported |                |
|                                                                                                                                                                                                          | Escitalopram   |                    |                    | S               | Unknown                                        | 10 Mg/Day            |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u>                                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|--------------------|--------------------|-----------------|----------------------------------|-----------------------------------------------------|-----------------|--------------|----------------|
| 25-Jan-2017                                                                                                                                                             | 13152439                   | EXPEDITED (15-DAY) |                    | OT              | US-MIDATECHPHARMA-2017-US-000785 |                                                     |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                   | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                     | <u>Dosage Text</u>                                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity; Human Herpesvirus 6 Infection; Multiple Organ Dysfunction Syndrome                                                                               | Ondansetron (Non-Specific) |                    |                    | S               | Unknown                          |                                                     |                 | Not Reported |                |
|                                                                                                                                                                         | Escitalopram               |                    |                    | S               | Unknown                          | Used In Final Trimester Of Pregnancy                |                 | Not Reported |                |
|                                                                                                                                                                         | Sertraline                 |                    |                    | S               | Unknown                          | Used In Initial Two Trimesters Of Pregnancy         |                 | Not Reported |                |
|                                                                                                                                                                         | Progesterone               |                    |                    | S               | Unknown                          | Used From 16th Week Of Pregnancy                    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u>                                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Jan-2017                                                                                                                                                             | 13152440                   | EXPEDITED (15-DAY) |                    | DE              | US-MIDATECHPHARMA-2017-US-000687 |                                                     | 4 DAY           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                   | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                     | <u>Dosage Text</u>                                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Failure; Congenital Cardiovascular Anomaly; Congenital Infection; Congestive Cardiomyopathy; Human Herpesvirus 6 Infection; Multiple Organ Dysfunction Syndrome | Ondansetron (Non-Specific) |                    |                    | S               | Intra-uterine                    |                                                     |                 | Not Reported |                |
|                                                                                                                                                                         | Escitalopram               |                    |                    | S               | Intra-uterine                    | Maternal Use In Final Trimester Of Pregnancy        |                 | Not Reported |                |
|                                                                                                                                                                         | Sertraline                 |                    |                    | S               | Intra-uterine                    | Maternal Use In Initial Two Trimesters Of Pregnancy |                 | Not Reported |                |
|                                                                                                                                                                         | Progesterone               |                    |                    | S               | Intra-uterine                    | Maternal Use From 16th Week Of Pregnancy            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u>                                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Jan-2017                                                                                                                                                             | 13152712                   | EXPEDITED (15-DAY) |                    | OT              | FR-009507513-1701FRA011329       |                                                     | 63 YR           | Unknown      | FRA            |
| <u>Preferred Term</u>                                                                                                                                                   | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                     | <u>Dosage Text</u>                                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Hepatocellular Injury                                                                                                                                                   | Keytruda                   |                    |                    | S               | Parenteral                       | 150 Mg, Every 3 Weeks                               |                 | Merck        |                |
|                                                                                                                                                                         | Perfalgan                  |                    |                    | S               | Parenteral                       | Unk                                                 |                 | Not Reported |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                       |   |                |              |
|-----------------------|---|----------------|--------------|
| Propofol              | S | Unk            | Not Reported |
| Sufentanil            | S | Unk            | Not Reported |
| Sevorane              | S | Unk            | Not Reported |
| Ketamine              | S | Unk            | Not Reported |
| Xylocaine (Lidocaine) | S | Unk            | Not Reported |
| Acupan                | S | Unk            | Not Reported |
| Cefazolin             | S | Parenteral     | 2 G, Unk     |
| Escitalopram          | S | Unk, If Needed | Not Reported |
| Xanax                 | C | Unk, If Needed | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-----------------------------------------------------------|----------------------|------------|------------|----------------|
| 26-Jan-2017              | 12676784      | NON-EXPEDITED    |                    |                 | US-VALIDUS<br>PHARMACEUTICALS<br>LLC-US-<br>2015VAL000481 |                      |            | Unknown    | USA            |

| <u>Preferred Term</u> | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Urinary Retention     | Benazepril Hydrochloride |              |            | S           | Oral         | Unk                |                 | Validus      |
|                       | Lioresal Intratecal      |              |            | S           | Intrathecal  | 39.95 Mg, Qd       |                 | Not Reported |
|                       | Magnesium (Nch)          |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                       | Pravastatin (Ngx)        |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                       | Warfarin (Ngx)           |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                       | Metformin /00082702/     |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                       | Tylenol /00020001/       |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                       | Vitamin D3               |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Lexapro                  |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Insulin Glargine         |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Insulin Lispro           |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Levothyroxine            |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                       | Aspirin (E.C.)           |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                       | Lotrisone                |              |            | S           | Topical      |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                      | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------|----------------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 26-Jan-2017                                                                   | 12824198                         | EXPEDITED (15-DAY) |                    | HO              | AT-ALLERGAN-1670884US    |                      | 40 YR           | Male         | AUT            |
| <u>Preferred Term</u>                                                         | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Intentional Overdose; Toxicity To Various Agents                   | Cipralext Tablets                |                    |                    | S               | Oral                     | 21 Tablets At Once   |                 | Allergan     |                |
| <u>FDA Received Date</u>                                                      | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Jan-2017                                                                   | 13014234                         | EXPEDITED (15-DAY) |                    | LT, OT          | HR-ALLERGAN-1679736US    |                      |                 | Female       | HRV            |
| <u>Preferred Term</u>                                                         | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Product Use In Unapproved Indication; Serotonin Syndrome; Withdrawal Syndrome | Escitalopram Oxalate - Bp        |                    |                    | S               | Unknown                  | Unk Unk, Unknown     |                 | Allergan     |                |
|                                                                               | Escitalopram Oxalate - Bp        |                    |                    | S               |                          |                      |                 | Allergan     |                |
|                                                                               | Deanxit/Flupentixol + Melitracen |                    |                    | C               | Unknown                  | Unk                  |                 | Not Reported |                |
|                                                                               | Cymbalta /Duloxetine             |                    |                    | C               | Unknown                  |                      |                 | Not Reported |                |
|                                                                               | Cymbalta /Duloxetine             |                    |                    | C               |                          |                      |                 | Not Reported |                |
|                                                                               | Clonazepam                       |                    |                    | C               | Unknown                  | 20 Mg, Unk           |                 | Not Reported |                |
|                                                                               | Fluoxetine                       |                    |                    | C               | Unknown                  | Unk Mg, Unk          |                 | Not Reported |                |
|                                                                               | Benadryl/Diphenhydramine         |                    |                    | C               | Unknown                  |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                      | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Jan-2017                                                                   | 13153302                         | NON-EXPEDITED      |                    |                 | US-TORRENT-00001320      |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                         | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Product Taste Abnormal                                                        | Escitalopram Tablets, Up         |                    |                    | S               |                          |                      |                 | Torrent      |                |
|                                                                               | Loestrin 24 Fe                   |                    |                    | C               |                          |                      |                 | Unknown      |                |
| <u>FDA Received Date</u>                                                      | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Jan-2017                                                                   | 13154182                         | EXPEDITED (15-DAY) |                    | DE, OT          | US-PFIZER INC-2017028947 |                      | 58 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                         | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                   |              |   |      |     |              |
|-------------------|--------------|---|------|-----|--------------|
| Completed Suicide | Ibuprofen    | S | Oral | Unk | Pfizer       |
|                   | Oxycodone    | S | Oral | Unk | Not Reported |
|                   | Escitalopram | S | Oral | Unk | Not Reported |

| <u>FDA Received Date</u>            | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------|---------------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 26-Jan-2017                         | 13156463                  | EXPEDITED (15-DAY) |                    | OT              | CA-ALLERGAN-1703044US |                      |                 | Unknown      | CAN            |
| <u>Preferred Term</u>               | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective; Suicidal Ideation | Escitalopram Oxalate - Bp |                    |                    | S               | Unknown               | Unk                  |                 | Allergan     |                |
|                                     | Escitalopram Oxalate - Bp |                    |                    | S               | Unknown               | Unk                  |                 | Allergan     |                |
|                                     | Trintellix                |                    |                    | S               | Unknown               |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>               | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------|----------------------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 26-Jan-2017                            | 13156569                         | EXPEDITED (15-DAY) |                    | DE, HO          | CH-ALLERGAN-1703063US |                      | 84 YR           | Female       | CHE            |
| <u>Preferred Term</u>                  | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cerebral Haematoma; Subdural Haematoma | Escitalopram Oxalate - Bp        |                    |                    | S               | Unknown               | 10 Mg, Qd            |                 | Allergan     |                |
|                                        | Pradaxa /Dabigatran              |                    |                    | C               | Unknown               | 110 Mg, Bid          |                 | Not Reported |                |
|                                        | Tebokan /Gingki Biloba           |                    |                    | C               | Unknown               | 80 Mg, Qd            |                 | Not Reported |                |
|                                        | Beloc Zok / Metoprolol Succinate |                    |                    | C               | Oral                  | 25 Mg, Qd            |                 | Not Reported |                |
|                                        | Digoxin / Digoxin                |                    |                    | C               | Oral                  | 0.125 Mg, Unk        |                 | Not Reported |                |
|                                        | Tirosint / Levothyroxine Sodium  |                    |                    | C               | Oral                  | 50 Mg, Qd            |                 | Not Reported |                |
|                                        | Calcimagon D3 / Colecalciferol   |                    |                    | C               | Oral                  |                      |                 | Not Reported |                |
|                                        | Omeprazole / Omeprazole          |                    |                    | C               | Oral                  | 20 Mg, Qd            |                 | Not Reported |                |
|                                        | Estradot / Estradiol             |                    |                    | C               | Transdermal           | 50 Mg, Unk           |                 | Not Reported |                |
|                                        | Madipar /Levodopa                |                    |                    | C               | Unknown               | 125 Mg, Tid          |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------|----------------------|------------|------------|----------------|
| 27-Jan-2017              | 12194537      | NON-EXPEDITED    |                    |                 | US-APOTEX-2016AP007117 |                      | 56 YR      | Male       | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Adverse Drug Reaction;     | Paxil Tablets  |              |            | S           |              | Unk                |                 | Apotex       |
| Adverse Drug Reaction;     | Paxil Tablets  |              |            | S           |              |                    |                 | Apotex       |
| Anxiety; Depression; Drug  | Wellbutrin     |              |            | S           |              | 150 Mg, Once Daily |                 | Not Reported |
| Ineffective; Ejaculation   | Wellbutrin     |              |            | S           |              |                    |                 | Not Reported |
| Failure; Emotional         | Cymbalta       |              |            | S           |              | 60 Mg, Unk         |                 | Not Reported |
| Distress; Feeling          | Cymbalta       |              |            | S           |              |                    |                 | Not Reported |
| Abnormal; Headache;        | Lexapro        |              |            | S           |              | Unk                |                 | Not Reported |
| Hypertension; Potentiating | Lexapro        |              |            | S           |              |                    |                 | Not Reported |
| Drug Interaction; Sexual   |                |              |            | S           |              |                    |                 | Not Reported |
| Dysfunction; Tinnitus;     |                |              |            | S           |              |                    |                 | Not Reported |
| Unevaluable Event          |                |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Jan-2017              | 13067596      | EXPEDITED (15-DAY) |                    | HO              | IT-TEVA-723434ACC    |                      | 58 YR      | Female     | ITA            |

| <u>Preferred Term</u>    | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|-------------------------|--------------|------------|-------------|--------------|----------------------|-----------------|--------------|
| Adjustment Disorder With | Quetiapine              |              |            | S           | Oral         | 200 Milligram Daily; |                 | Teva         |
| Mixed Anxiety And        | Venlafaxine             |              |            | S           | Oral         | 300 Milligram Daily; |                 | Teva         |
| Depressed Mood;          | Valproic Acid           |              |            | S           | Oral         | 300 Milligram Daily; |                 | Not Reported |
| Affective Disorder;      | Valproic Acid           |              |            | S           | Oral         | 600 Milligram Daily; |                 | Not Reported |
| Anhedonia; Anxiety;      | Alprazolam              |              |            | S           | Oral         | 1.5 Milligram Daily; |                 | Actavis      |
| Depressed Mood; Drug     | Trazodone Hydrochloride |              |            | S           | Oral         | 75 Milligram Daily;  |                 | Not Reported |
| Ineffective; Feeling     | Trazodone Hydrochloride |              |            | S           | Oral         | 150 Milligram Daily; |                 | Not Reported |
| Abnormal; Insomnia;      | Escitalopram            |              |            | S           | Oral         | 20 Milligram Daily;  |                 | Not Reported |
| Labelled Drug-Drug       | Clonazepam              |              |            | S           | Oral         | .5 Milligram Daily;  |                 | Not Reported |
| Interaction Medication   |                         |              |            |             |              |                      |                 |              |
| Error; Social Avoidant   |                         |              |            |             |              |                      |                 |              |
| Behaviour; Suicidal      |                         |              |            |             |              |                      |                 |              |
| Ideation; Tension        |                         |              |            |             |              |                      |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Jan-2017              | 13109234      | EXPEDITED (15-DAY) |                    | HO              | IT-TEVA-727838ACC    |                      | 33 YR      | Female     | ITA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Retching              | Escitalopram   |              |            | S           | Oral         |                    |                 | Ivax       |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                               | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 27-Jan-2017                                            | 13157214       | EXPEDITED (15-DAY) |                    | OT              | CA-TEVA-734119ACC                                  |                      | 62 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                       | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Contusion                                              | Escitalopram   |                    |                    | S               | Oral                                               | 5 Milligram Daily;   |                 | Ivax         |                |
| <u>FDA Received Date</u>                               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                               | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Jan-2017                                            | 13157243       | EXPEDITED (15-DAY) |                    | OT              | CA-TEVA-734123ACC                                  |                      | 61 YR           | Male         | CAN            |
| <u>Preferred Term</u>                                  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                       | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Feeling Abnormal; Negative Thoughts; Paranoia | Escitalopram   |                    |                    | S               | Oral                                               | 10 Milligram Daily;  |                 | Ivax         |                |
|                                                        | Ibuprofen      |                    |                    | C               |                                                    |                      |                 | Not Reported |                |
|                                                        | Lorazepam      |                    |                    | C               |                                                    |                      |                 | Not Reported |                |
|                                                        | Metformin      |                    |                    | C               |                                                    |                      |                 | Not Reported |                |
|                                                        | Rosuvastatin   |                    |                    | C               |                                                    |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                               | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Jan-2017                                            | 13157505       | NON-EXPEDITED      |                    | DE              | MX-TORRENT-00000084                                |                      | 6 YR            | Female       | MEX            |
| <u>Preferred Term</u>                                  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                       | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Ischaemic Stroke; Off Label Use                        | Olanzapine     |                    |                    | S               |                                                    |                      |                 | Torrent      |                |
|                                                        | Escitalopram   |                    |                    | S               |                                                    |                      |                 | Torrent      |                |
|                                                        | Losartan       |                    |                    | C               |                                                    |                      |                 | Unknown      |                |
| <u>FDA Received Date</u>                               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                               | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Jan-2017                                            | 13158327       | EXPEDITED (15-DAY) |                    | DS, OT          | ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2016R1-117747 |                      | 67 YR           | Female       | ESP            |
| <u>Preferred Term</u>                                  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                       | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blindness; Glaucoma                                    | Escitalopram   |                    |                    | S               | Unknown                                            | Unk                  |                 | Not Reported |                |
|                                                        | Gemfibrozil    |                    |                    | S               | Unknown                                            | Unk                  |                 | Sun          |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |                     |   |         |     |              |
|--|---------------------|---|---------|-----|--------------|
|  | Hydrochlorothiazide | S | Unknown | Unk | Sun          |
|  | Irbesartan          | S | Unknown | Unk | Not Reported |
|  | Pantoprazole        | S | Unknown | Unk | Sun          |
|  | Quetiapine          | S | Oral    | Unk | Sun          |
|  | Ropinirole          | C | Unknown | Unk | Not Reported |

| <u>FDA Received Date</u>                               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 27-Jan-2017                                            | 13160403       | EXPEDITED (15-DAY) |                    | OT              | PHHY2017AU009436     |                      |                 | Male         | AUS            |
| <u>Preferred Term</u>                                  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Ejection Fraction Decreased; Hepatic Function Abnormal | Olanzapine     |                    |                    | S               | Unknown              | 20 Mg, Unk           |                 | Novartis     |                |
|                                                        | Escitalopram   |                    |                    | S               | Unknown              | 40 Mg, Unk           |                 | Not Reported |                |
|                                                        | Paliperidone   |                    |                    | S               | Unknown              | 150 Mg, Unk          |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>       | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|---------------------|------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 30-Jan-2017              | 12398808            | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2016270731 |                      | 62 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>      | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity    | Celebrex            |                  |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                          | Zoloft              |                  |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                          | Spiriva             |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                          | Protonix            |                  |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                          | Venlafaxine Hcl     |                  |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                          | Codeine             |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                          | Doxycycline Hyclate |                  |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                          | Pristiq             |                  |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                          | Flagyl              |                  |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                          | Theo-Dur            |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                          | Lortab              |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                          | Reglan              |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|             |   |     |              |
|-------------|---|-----|--------------|
| Topamax     | S | Unk | Not Reported |
| Vioxx       | S | Unk | Not Reported |
| Paxil       | S | Unk | Not Reported |
| Vasotec     | S | Unk | Not Reported |
| Buspar      | S | Unk | Not Reported |
| Cipro       | S | Unk | Not Reported |
| Prozac      | S | Unk | Not Reported |
| Singulair   | S | Unk | Not Reported |
| K-Dur       | S | Unk | Not Reported |
| Lexapro     | S | Unk | Not Reported |
| Micardis    | S | Unk | Not Reported |
| Levaquin    | S | Unk | Not Reported |
| Bactrim     | S | Unk | Not Reported |
| Bystolic    | S | Unk | Not Reported |
| Lisinopril  | S | Unk | Not Reported |
| Simvastatin | S | Unk | Not Reported |
| Ultracet    | S | Unk | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------|----------------------|------------|------------|----------------|
| 30-Jan-2017              | 12464482      | NON-EXPEDITED    |                    |                 | US-APOTEX-2016AP006769 |                      | 36 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Adverse Event; Drug Ineffective; Product Complaint; Withdrawal Syndrome | Paxil Tablets  |              |            | S           | Unknown      | Unk                |                 | Apotex       |
|                                                                         | Lexapro        |              |            | S           | Unknown      | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Jan-2017              | 12921321      | EXPEDITED (15-DAY) |                    | HO              | GB-TEVA-704386ACC    |                      | 60 YR      | Female     | GBR            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                  |                             |   |         |                     |              |
|----------------------------------------------------------------------------------|-----------------------------|---|---------|---------------------|--------------|
| Feeling Jittery; Hot Flush;<br>Loss Of Consciousness;<br>Palpitations; Psoriasis | Propranolol                 | S | Oral    | 40 Milligram Daily; | Actavis      |
|                                                                                  | Escitalopram                | S | Unknown |                     | Ivax         |
|                                                                                  | Amlodipine                  | C | Unknown | 10 Milligram Daily; | Not Reported |
|                                                                                  | Capasal Therapeutic Shampoo | C | Unknown |                     | Not Reported |
|                                                                                  | Cetaben Cream               | C | Unknown |                     | Not Reported |
|                                                                                  | Dermol 200 Shower Emollient | C | Unknown |                     | Not Reported |
|                                                                                  | Dovobet Gel                 | C | Unknown |                     | Not Reported |
|                                                                                  | Loratadine                  | C | Unknown |                     | Not Reported |
|                                                                                  | Crepe Bandage Bp            | C |         |                     | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|--------------------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 30-Jan-2017              | 13160974       | EXPEDITED (15-DAY) |                    | DE              | US-SUN<br>PHARMACEUTICAL<br>INDUSTRIES LTD-<br>2017US-131864 |                      |                 | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide        | Loperamide     |                    |                    | S               | Unknown                                                      | Unk                  |                 | Ranbaxy      |                |
|                          | Escitalopram   |                    |                    | S               | Unknown                                                      | Unk                  |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 30-Jan-2017              | 13161006       | EXPEDITED (15-DAY) |                    | OT              | CA-TEVA-734134ACC    |                      | 75 YR           | Female       | CAN            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Glossodynia              | Escitalopram   |                    |                    | S               | Oral                 | 10 Milligram Daily;  |                 | Ivax         |                |
|                          | Pantoloc       |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|-------------------------------------|----------------------|-----------------|------------|----------------|
| 30-Jan-2017              | 13161047       | EXPEDITED (15-DAY) |                    | DE              | US-AUROBINDO-AUR-<br>APL-2017-28389 |                      | 59 YR           | Female     | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Completed Suicide        | Duloxetine     |                    |                    | S               | Oral                                |                      |                 | Aurobindo  |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|              |   |      |              |
|--------------|---|------|--------------|
| Escitalopram | S | Oral | Aurobindo    |
| Bupropion    | S | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|------------|------------|----------------|
| 30-Jan-2017              | 13161129      | EXPEDITED (15-DAY) |                    | DE              | US-AUROBINDO-AUR-APL-2017-28480 |                      | 64 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Escitalopram   |              |            | S           | Oral         |                    |                 | Aurobindo    |
|                       | Tamsulosin     |              |            | S           | Oral         |                    |                 | Aurobindo    |
|                       | Amlodipine     |              |            | S           | Oral         |                    |                 | Aurobindo    |
|                       | Enalapril      |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Insulin        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|------------|------------|----------------|
| 30-Jan-2017              | 13161610      | EXPEDITED (15-DAY) |                    | DE              | US-AUROBINDO-AUR-APL-2017-28397 |                      | 58 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Escitalopram   |              |            | S           | Oral         |                    |                 | Aurobindo    |
|                       | Oxycodone      |              |            | S           | Oral         |                    |                 | Aurobindo    |
|                       | Ibuprofen      |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Jan-2017              | 13162510      | EXPEDITED (15-DAY) |                    | DE              | CA-TEVA-734132ACC    |                      | 62 YR      | Male       | CAN            |

| <u>Preferred Term</u> | <u>Product</u>                   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Death                 | Escitalopram                     |              |            | S           | Unknown      |                    |                 | Ivax         |
|                       | Temazepam                        |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Tylenol With Codeine No. 3 - Tab |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Advair                           |              |            | C           |              |                    |                 | Not Reported |
|                       | Atrovent                         |              |            | C           |              |                    |                 | Not Reported |
|                       | Gabapentin                       |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| Naproxen                                          |                           | C                  |                    | Not Reported    |                            |                      |                 |              |                |
|---------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| Ranitidine                                        |                           | C                  |                    | Not Reported    |                            |                      |                 |              |                |
| <u>FDA Received Date</u>                          | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Jan-2017                                       | 13162658                  | EXPEDITED (15-DAY) |                    | OT              | HR-PFIZER INC-2017033644   |                      | 17 YR           | Female       | HRV            |
| <u>Preferred Term</u>                             | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Overdose; Somnolence; Suicide Attempt | Xanax                     |                    |                    | S               | Oral                       | Unk                  |                 | Pfizer       |                |
|                                                   | Citram                    |                    |                    | S               | Oral                       | Unk                  |                 | Not Reported |                |
|                                                   | Seroquel                  |                    |                    | S               | Oral                       | Unk                  |                 | Not Reported |                |
|                                                   | Risset                    |                    |                    | S               | Oral                       | Unk                  |                 | Not Reported |                |
|                                                   | Cymbalta                  |                    |                    | S               | Oral                       | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                          | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Jan-2017                                       | 13163792                  | NON-EXPEDITED      |                    | OT              | US-STI PHARMA LLC-1062511  |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                             | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypersensitivity                                  | Escitalopram              |                    |                    | S               | Oral                       |                      |                 | Sti Pharma   |                |
| <u>FDA Received Date</u>                          | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Jan-2017                                       | 13163926                  | EXPEDITED (15-DAY) |                    | DE              | US-MALLINCKRODT-T201607018 |                      | 41 YR           | Male         | USA            |
| <u>Preferred Term</u>                             | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                 | Hydrocodone/Acetaminophen |                    |                    | S               | Oral                       |                      |                 | Mallinckrodt |                |
|                                                   | Tramadol                  |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                   | Baclofen                  |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                   | Clonazepam                |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                   | Escitalopram              |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                   | Alprazolam                |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                       | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|---------------------------------|------------------------------|-----------------|--------------|----------------|
| 30-Jan-2017                                                                                    | 13165079                  | EXPEDITED (15-DAY) |                    | HO, LT, OT      | CA-TEVA-734146ACC               |                              | 18 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                                                          | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Dreams;<br>Aggression; Crying;<br>Intentional Self-Injury;<br>Psychotic Disorder      | Teva-Escitalopram         |                    |                    | S               | Oral                            | 10 Milligram Daily;          |                 | Ivax         |                |
|                                                                                                | Teva-Escitalopram         |                    |                    | S               |                                 |                              |                 | Ivax         |                |
|                                                                                                | Abilify                   |                    |                    | C               |                                 |                              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                       | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-Jan-2017                                                                                    | 13145670                  | EXPEDITED (15-DAY) |                    | HO, OT          | TR-ALLERGAN-1702566US           |                              | 54 YR           | Male         | TUR            |
| <u>Preferred Term</u>                                                                          | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Disorder; Drug Ineffective; Intentional Overdose; Serotonin Syndrome; Weight Increased | Escitalopram Oxalate - Bp |                    |                    | S               | Oral                            | 80 Mg, Qd                    |                 | Allergan     |                |
|                                                                                                | Escitalopram Oxalate - Bp |                    |                    | S               | Oral                            | 40 Mg, Qd                    |                 | Allergan     |                |
|                                                                                                | Escitalopram Oxalate - Bp |                    |                    | S               | Oral                            | 20 Mg, Qd                    |                 | Allergan     |                |
|                                                                                                | Trazodone                 |                    |                    | S               | Oral                            | 200-300 Mg Daily Irregularly |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                       | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-Jan-2017                                                                                    | 13165583                  | EXPEDITED (15-DAY) |                    | DE, HO, OT      | US-AUROBINDO-AUR-APL-2017-28683 |                              | 41 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                          | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Completed Suicide; Respiratory Arrest                                          | Diphenhydramine           |                    |                    | S               | Oral                            |                              |                 | Aurobindo    |                |
|                                                                                                | Escitalopram              |                    |                    | S               | Oral                            |                              |                 | Aurobindo    |                |
|                                                                                                | Ethanol                   |                    |                    | S               | Oral                            |                              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                       | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-Jan-2017                                                                                    | 13165641                  | EXPEDITED (15-DAY) |                    | DE, HO          | US-AUROBINDO-AUR-APL-2017-28844 |                              | 74 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                          | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                   |                     |   |      |              |
|-------------------|---------------------|---|------|--------------|
| Completed Suicide | Alprazolam          | S | Oral | Aurobindo    |
|                   | Escitalopram        | S | Oral | Aurobindo    |
|                   | Hydrochlorothiazide | S | Oral | Aurobindo    |
|                   | Doxepin             | S | Oral | Not Reported |
|                   | Olmesartan          | S | Oral | Not Reported |
|                   | Famotidine          | S | Oral | Not Reported |
|                   | Cetirizine          | S | Oral | Not Reported |
|                   | Pregabalin          | S | Oral | Not Reported |

| <u>FDA Received Date</u>      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------|----------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|-----------------|--------------|----------------|
| 31-Jan-2017                   | 13165826       | EXPEDITED (15-DAY) |                    | OT              | US-HETERO LABS<br>LTD-1062551 |                      |                 | Female       | USA            |
| <u>Preferred Term</u>         | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Human Herpesvirus 6 Infection | Escitalopram   |                    |                    | S               | Unknown                       |                      |                 | Hetero       |                |
|                               | Ondansetron    |                    |                    | S               | Unknown                       |                      |                 | Not Reported |                |
|                               | Sertraline     |                    |                    | S               | Unknown                       |                      |                 | Not Reported |                |
|                               | Progesterone   |                    |                    | S               | Unknown                       |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|-----------------|--------------|----------------|
| 31-Jan-2017                                                                                                                                                           | 13165937       | EXPEDITED (15-DAY) |                    | DE, HO, OT      | US-HETERO LABS<br>LTD-1062552 |                      | 4 DAY           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Failure;<br>Congestive<br>Cardiomyopathy; Foetal<br>Exposure During<br>Pregnancy; Human<br>Herpesvirus 6 Infection;<br>Multiple Organ<br>Dysfunction Syndrome | Escitalopram   |                    |                    | S               | Transplacental                |                      |                 | Hetero       |                |
|                                                                                                                                                                       | Ondansetron    |                    |                    | S               |                               |                      |                 | Not Reported |                |
|                                                                                                                                                                       | Sertraline     |                    |                    | S               | Transplacental                |                      |                 | Not Reported |                |
|                                                                                                                                                                       | Progesterone   |                    |                    | S               |                               |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                     | <u>Case #</u>                                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u>                                                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                                 | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------|--------------------|--------------------|------------------|----------------------------------------------------------------------|----------------------|-----------------|------------------------------------------------------------|----------------|
| 31-Jan-2017                                                                                                                                                                                  | 13165982                                                  | EXPEDITED (15-DAY) |                    | OT               | NL-ASTRAZENECA-2017SE09134                                           |                      | 58 YR           | Female                                                     | NLD            |
| <u>Preferred Term</u>                                                                                                                                                                        | <u>Product</u>                                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>                                                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                                 |                |
| Apnoea; Blood Cholesterol Increased; Blood Glucose Increased                                                                                                                                 | Quetiapine<br>Lexapro                                     |                    |                    | S<br>S           | Oral<br>Oral                                                         |                      |                 | Zeneca<br>Not Reported                                     |                |
| <u>FDA Received Date</u>                                                                                                                                                                     | <u>Case #</u>                                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u>                                                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                                 | <u>Country</u> |
| 31-Jan-2017                                                                                                                                                                                  | 13166022                                                  | EXPEDITED (15-DAY) |                    | OT               | DE-HETERO LABS LTD-1062554                                           |                      |                 | Unknown                                                    | DEU            |
| <u>Preferred Term</u>                                                                                                                                                                        | <u>Product</u>                                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>                                                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                                 |                |
| Foetal Exposure During Pregnancy; Small For Dates Baby; Temperature Regulation Disorder                                                                                                      | Escitalopram<br>Fluoxetine<br>Elevit                      |                    |                    | S<br>C<br>C      | Transplacental<br>Transplacental                                     |                      |                 | Hetero<br>Not Reported<br>Not Reported                     |                |
| <u>FDA Received Date</u>                                                                                                                                                                     | <u>Case #</u>                                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u>                                                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                                 | <u>Country</u> |
| 31-Jan-2017                                                                                                                                                                                  | 13166094                                                  | EXPEDITED (15-DAY) |                    | DE, OT           | US-ZYDUS-013463                                                      |                      | 4 DAY           | Male                                                       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                        | <u>Product</u>                                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>                                                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                                 |                |
| Cardiac Failure; Cardiomyopathy Neonatal; Dilatation Ventricular; Foetal Exposure During Pregnancy; Human Herpesvirus 6 Infection; Multiple Organ Dysfunction Syndrome; Systolic Dysfunction | Escitalopram<br>Sertraline<br>Ondansetron<br>Progesterone |                    |                    | S<br>S<br>S<br>S | Transplacental<br>Transplacental<br>Transplacental<br>Transplacental |                      |                 | Zydus Pharm<br>Zydus Pharm<br>Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                     | <u>Case #</u>                                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u>                                                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                                 | <u>Country</u> |
| 31-Jan-2017                                                                                                                                                                                  | 13166110                                                  | EXPEDITED (15-DAY) |                    | OT               | US-ZYDUS-013465                                                      |                      |                 | Female                                                     | USA            |
| <u>Preferred Term</u>                                                                                                                                                                        | <u>Product</u>                                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>                                                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                                 |                |

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|                          |              |   |         |              |
|--------------------------|--------------|---|---------|--------------|
| Exposure During          | Escitalopram | S | Unknown | Zydus Pharm  |
| Pregnancy; Human         | Sertraline   | S | Unknown | Zydus Pharm  |
| Herpesvirus 6 Infection; | Ondansetron  | S | Unknown | Not Reported |
| Hypersensitivity         | Progesterone | S | Unknown | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|-----------------|--------------|----------------|
| 31-Jan-2017              | 13166420       | EXPEDITED (15-DAY) |                    | DE, HO          | US-AUROBINDO-AUR-APL-2017-28604 |                      | 51 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide        | Amlodipine     |                    |                    | S               | Oral                            |                      |                 | Aurobindo    |                |
|                          | Escitalopram   |                    |                    | S               | Oral                            |                      |                 | Aurobindo    |                |
|                          | Ethanol        |                    |                    | S               | Oral                            |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|-----------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|-----------------|--------------|----------------|
| 31-Jan-2017              | 13166522        | EXPEDITED (15-DAY) |                    | DE              | US-AUROBINDO-AUR-APL-2017-28829 |                      | 53 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide        | Escitalopram    |                    |                    | S               | Oral                            |                      |                 | Aurobindo    |                |
|                          | Diphenhydramine |                    |                    | S               | Oral                            |                      |                 | Aurobindo    |                |
|                          | Amitriptyline   |                    |                    | S               | Oral                            |                      |                 | Not Reported |                |
|                          | Ethanol         |                    |                    | S               | Oral                            |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|------------------------------------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|-----------------|------------|----------------|
| 31-Jan-2017              | 13167014                                 | EXPEDITED (15-DAY) |                    | DE, HO          | US-AUROBINDO-AUR-APL-2017-29108 |                      | 41 YR           | Unknown    | USA            |
| <u>Preferred Term</u>    | <u>Product</u>                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Completed Suicide        | Tramadol                                 |                    |                    | S               | Oral                            |                      |                 | Aurobindo  |                |
|                          | Hydrocodone Bitartrate And Acetaminophen |                    |                    | S               | Oral                            |                      |                 | Aurobindo  |                |
|                          | Escitalopram                             |                    |                    | S               | Oral                            |                      |                 | Aurobindo  |                |

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|            |   |      |              |
|------------|---|------|--------------|
| Alprazolam | S | Oral | Aurobindo    |
| Clonazepam | S | Oral | Not Reported |
| Baclofen   | S | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------------------|----------------------|------------|------------|----------------|
| 31-Jan-2017              | 13167373      | EXPEDITED (15-DAY) |                    | HO, OT          | NL-<br>GLAXOSMITHKLINE-<br>TW2017GSK012770 |                      | 66 YR      | Female     | TWN            |

| <u>Preferred Term</u>                                                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|-------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Asthenia; Decreased<br>Appetite; Dyspnoea;<br>Lethargy; Pulmonary<br>Embolism | Olanzapine     |              |            | S           |              | Unk                |                 | Glaxosmithkline |
|                                                                               | Mirtazapine    |              |            | S           |              | Unk                |                 | Not Reported    |
|                                                                               | Escitalopram   |              |            | S           |              | Unk                |                 | Glaxosmithkline |
|                                                                               | Bupropion      |              |            | S           |              | Unk                |                 | Glaxosmithkline |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------------|----------------------|------------|------------|----------------|
| 31-Jan-2017              | 13170079      | EXPEDITED (15-DAY) |                    | HO, OT          | CA-PURDUE PHARMA-<br>CAN-2017-0007368 |                      | 23 YR      | Female     | CAN            |

| <u>Preferred Term</u>                                                                                                        | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                             | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|------------------------------------------|--------------------|-----------------|--------------|
| Cholelithiasis; Exposure<br>During Pregnancy; Fall;<br>Hidradenitis; Off Label<br>Use; Product Use Issue;<br>Skin Laceration | Morphine Sulfate     |              |            | S           | Unknown                                  |                    |                 | Purdue       |
|                                                                                                                              | Ativan               |              |            | S           | Unknown                                  |                    |                 | Not Reported |
|                                                                                                                              | Baclofen             |              |            | S           | Unknown                                  |                    |                 | Not Reported |
|                                                                                                                              | Ciprallex            |              |            | S           | Unknown                                  |                    |                 | Not Reported |
|                                                                                                                              | Diclectin            |              |            | S           | Unknown                                  |                    |                 | Not Reported |
|                                                                                                                              | Gravol               |              |            | S           | Unknown                                  |                    |                 | Not Reported |
|                                                                                                                              | Metamucil /00091301/ |              |            | S           | Unknown                                  |                    |                 | Not Reported |
|                                                                                                                              | Metformin            |              |            | S           | Unknown                                  |                    |                 | Not Reported |
|                                                                                                                              | Rabeprazole          |              |            | S           | Unknown                                  |                    |                 | Not Reported |
|                                                                                                                              | Remicade             |              |            | S           | Intravenous (not<br>otherwise specified) | 500 Mg, Q 6 Weeks  |                 | Not Reported |
|                                                                                                                              | Remicade             |              |            | S           | Intravenous (not<br>otherwise specified) | 300 Mg, Q 6 Weeks  |                 | Not Reported |

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|                              |   |                                       |                   |              |
|------------------------------|---|---------------------------------------|-------------------|--------------|
| Remicade                     | S | Intravenous (not otherwise specified) | 500 Mg, Q 6 Weeks | Not Reported |
| Prenatal Vitamins /01549301/ | C |                                       |                   | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|---------------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 31-Jan-2017              | 13170235                  | EXPEDITED (15-DAY) |                    | OT              | FR-ALLERGAN-1703561US |                      |                 | Female       | FRA            |
| <u>Preferred Term</u>    | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Open Angle Glaucoma      | Escitalopram Oxalate - Bp |                    |                    | S               | Oral                  |                      |                 | Allergan     |                |
|                          | Lumigan                   |                    |                    | C               | Ophthalmic            |                      |                 | Not Reported |                |
|                          | Larmabak                  |                    |                    | C               | Ophthalmic            |                      |                 | Not Reported |                |
|                          | Valdoxan                  |                    |                    | C               |                       |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|------------------------------------|--------------------|--------------------|-----------------|------------------------------|---------------------------------------------|-----------------|--------------|----------------|
| 31-Jan-2017              | 13170600                           | EXPEDITED (15-DAY) |                    | OT              | FR-ABBVIE-17P-056-1852908-00 |                                             | 63 YR           | Male         | FRA            |
| <u>Preferred Term</u>    | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Hepatocellular Injury    | Ultane                             |                    |                    | S               | Intrathecal                  |                                             |                 | Not Reported |                |
|                          | Pembrolizumab                      |                    |                    | S               | Intrathecal                  | 2 Mg/ Kg (150 Mg) With Well Being Tolerance |                 | Not Reported |                |
|                          | Propofol                           |                    |                    | S               | Unknown                      |                                             |                 | Not Reported |                |
|                          | Citrate Sufentanil                 |                    |                    | S               | Unknown                      |                                             |                 | Not Reported |                |
|                          | Lidocaine Chlrohydrate Monohydrate |                    |                    | S               | Unknown                      |                                             |                 | Not Reported |                |
|                          | Chlorhydrate Nefopam               |                    |                    | S               | Unknown                      |                                             |                 | Not Reported |                |
|                          | Oxalate Escitalopram               |                    |                    | S               | Unknown                      |                                             |                 | Not Reported |                |
|                          | Paracetamol                        |                    |                    | S               | Intrathecal                  |                                             |                 | Not Reported |                |
|                          | Sodium Cefazoline                  |                    |                    | S               | Intrathecal                  |                                             |                 | Not Reported |                |
|                          | Ketamine                           |                    |                    | S               | Unknown                      |                                             |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-Jan-2017              | 13170773      | NON-EXPEDITED    |                    |                 | US-ABBVIE-16K-163-   |                      |            | Female     | USA            |



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1676768-00

| <u>Preferred Term</u>                                             | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------|-------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Nausea; Respiratory Tract Congestion; Throat Irritation; Vomiting | Humira 40mg/0.8ml |              |            | S           | Subcutaneous |                    |                 | Not Reported |
|                                                                   | Trintellix        |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                   | Lexapro           |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                   | Lamictal          |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                   | Zyprexa           |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                   | Ativan            |              |            | C           |              |                    |                 | Not Reported |
|                                                                   | Prilosec          |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 01-Feb-2017              | 12957376      | EXPEDITED (15-DAY) |                    | DS, HO, OT      | US-ALLERGAN-1676612US |                      | 67 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Pressure Increased; Drug Ineffective; Gait Inability; Off Label Use; Oxygen Saturation Decreased; Weight Increased | Lexapro        |              |            | S           | Unknown      | Unk                |                 | Allergan     |
|                                                                                                                          | Lexapro        |              |            | S           |              |                    |                 | Allergan     |
|                                                                                                                          | Antivert       |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                          | Antivert       |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                          | Revert         |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                          | Revert         |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                          | Medrol         |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                          | Medrol         |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                          | Vicodin        |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                          | Vicodin        |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                          | Lyrica         |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                          | Lyrica         |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                          | Xanax          |              |            | C           |              | 0.5 Mg, Tid        |                 | Not Reported |
|                                                                                                                          | Xanax          |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                          | Alprazolam     |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                          | Hydrocodone    |              |            | C           |              | 7.5 Mg, Unk        |                 | Not Reported |

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| <u>FDA Received Date</u>     | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|------------------------------|-----------------|--------------------|--------------------|-----------------|------------------------------------|----------------------|-----------------|-----------------|----------------|
| 01-Feb-2017                  | 13159110        | NON-EXPEDITED      |                    |                 | US-GLAXOSMITHKLINE-US2017GSK010485 |                      |                 | Male            | USA            |
| <u>Preferred Term</u>        | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                       | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Anxiety; Bradyphrenia;       | Wellbutrin      |                    |                    | S               |                                    | Unk                  |                 | Glaxosmithkline |                |
| Decreased Interest;          | Wellbutrin      |                    |                    | S               |                                    | Unk                  |                 | Glaxosmithkline |                |
| Depressive Symptom;          | Lexapro         |                    |                    | S               |                                    | 10 Mg, Unk           |                 | Not Reported    |                |
| Distractibility; Disturbance | Lexapro         |                    |                    | S               |                                    | 20 Mg, Unk           |                 | Not Reported    |                |
| In Attention; Feelings Of    | Lexapro         |                    |                    | S               |                                    | 30 Mg, Unk           |                 | Not Reported    |                |
| Worthlessness; Impaired      | Lexapro         |                    |                    | S               |                                    | 20 Mg, Unk           |                 | Not Reported    |                |
| Work Ability; Irritability;  | Chantix         |                    |                    | S               |                                    | Unk                  |                 | Not Reported    |                |
| Memory Impairment;           |                 |                    |                    |                 |                                    |                      |                 |                 |                |
| Performance Status           |                 |                    |                    |                 |                                    |                      |                 |                 |                |
| Decreased; Social            |                 |                    |                    |                 |                                    |                      |                 |                 |                |
| Avoidant Behaviour;          |                 |                    |                    |                 |                                    |                      |                 |                 |                |
| Social Fear                  |                 |                    |                    |                 |                                    |                      |                 |                 |                |
| <u>FDA Received Date</u>     | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 01-Feb-2017                  | 13172716        | EXPEDITED (15-DAY) |                    | HO              | PHHY2017SE013739                   |                      | 34 YR           | Female          | SWE            |
| <u>Preferred Term</u>        | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                       | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Accidental Poisoning;        | Tegretol Retard |                    |                    | S               | Unknown                            |                      |                 | Novartis        |                |
| Anxiety; Tachycardia;        | Cipralex        |                    |                    | S               | Unknown                            | Unk                  |                 | Not Reported    |                |
| Toxicity To Various Agents   | Seroquel        |                    |                    | S               | Unknown                            | Unk                  |                 | Not Reported    |                |
|                              | Theralen        |                    |                    | C               | Unknown                            |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>     | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 01-Feb-2017                  | 13175433        | EXPEDITED (15-DAY) |                    | HO, LT          | US-PFIZER INC-2017044567           |                      | 59 YR           | Male            | USA            |
| <u>Preferred Term</u>        | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                       | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Condition Aggravated;        | Doxepin Hcl     |                    |                    | S               | Oral                               | 2 Df, Single         |                 | Pfizer          |                |
| Depression; Focal            | Rebif           |                    |                    | S               | Subcutaneous                       | 44 Ug, Three Times A |                 | Not Reported    |                |
| Dyscognitive Seizures;       |                 |                    |                    |                 |                                    | Week                 |                 |                 |                |
| Incorrect Dose               |                 |                    |                    |                 |                                    |                      |                 |                 |                |

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|                           |          |   |      |               |              |
|---------------------------|----------|---|------|---------------|--------------|
| Administered; Influenza;  | Lexapro  | S | Oral | 10 Mg, 1x/Day | Not Reported |
| Insomnia; Memory          | Lexapro  | S | Oral | 20 Mg, Single | Not Reported |
| Impairment; Overdose;     | Lexapro  | S | Oral | 10 Mg, 1x/Day | Not Reported |
| Seizure; Speech Disorder; | Dilantin | C |      |               | Not Reported |
| Therapy Non-Responder     | Depakote | C |      |               | Not Reported |
|                           | Ambien   | C |      |               | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------------------------|----------------------|------------|------------|----------------|
| 01-Feb-2017              | 13175743      | EXPEDITED (15-DAY) |                    | OT              | AU-LUPIN<br>PHARMACEUTICALS<br>INC.-2017-00465 |                      |            | Male       | AUS            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Ejection Fraction     | Olanzapine     |              |            | S           | Unknown      |                    |                 | Not Reported |
| Decreased; Hepatic    | Escitalopram   |              |            | S           | Unknown      |                    |                 | Not Reported |
| Function Abnormal     | Paliperidone   |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Clozapine      |              |            | C           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 01-Feb-2017              | 13176434      | EXPEDITED (15-DAY) |                    | LT              | US-PFIZER INC-<br>2017044432 |                      | 58 YR      | Male       | USA            |

| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Condition Aggravated;     | Doxepin Hcl    |              |            | S           | Oral         |                    |                 | Pfizer       |
| Depression; Drug          | Rebif          |              |            | S           |              | Unk                |                 | Not Reported |
| Ineffective; Focal        | Lexapro        |              |            | S           | Oral         | Unk                |                 | Not Reported |
| Dyscognitive Seizures;    | Dalmane        |              |            | C           |              |                    |                 | Not Reported |
| Generalised Tonic-Clonic  | Depakote       |              |            | C           |              |                    |                 | Not Reported |
| Seizure; Incoherent;      | Ambien         |              |            | C           |              |                    |                 | Not Reported |
| Incorrect Dose            | Dilantin       |              |            | C           |              |                    |                 | Not Reported |
| Administered; Insomnia;   |                |              |            |             |              |                    |                 |              |
| Memory Impairment;        |                |              |            |             |              |                    |                 |              |
| Mobility Decreased;       |                |              |            |             |              |                    |                 |              |
| Speech Disorder; Suicidal |                |              |            |             |              |                    |                 |              |
| Ideation; Viral Infection |                |              |            |             |              |                    |                 |              |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 02-Feb-2017              | 12325801       | NON-EXPEDITED    |                    |                 | ES-LUPIN<br>PHARMACEUTICALS<br>INC.-2015-04500 |                      | 71 YR           | Male         | ESP            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Epistaxis                | Quetiapine     |                  |                    | S               | Oral                                           |                      |                 | Not Reported |                |
|                          | Risperidone    |                  |                    | S               | Unknown                                        |                      |                 | Not Reported |                |
|                          | Escitalopram   |                  |                    | S               | Unknown                                        |                      |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Feb-2017              | 13180032       | NON-EXPEDITED    |                    |                 | IL-LUPIN<br>PHARMACEUTICALS<br>INC.-2015-04270 |                      | 25 YR           | Male         | ISR            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Sexual Dysfunction       | Escitalopram   |                  |                    | S               | Unknown                                        | 10 Mg                |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Feb-2017              | 13180038       | NON-EXPEDITED    |                    |                 | IL-LUPIN<br>PHARMACEUTICALS<br>INC.-2015-04282 |                      | 39 YR           | Male         | ISR            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Sexual Dysfunction       | Escitalopram   |                  |                    | S               | Unknown                                        | 40 Mg                |                 | Not Reported |                |
|                          | Simvastatin    |                  |                    | C               | Unknown                                        |                      |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Feb-2017              | 13180041       | NON-EXPEDITED    |                    |                 | IL-LUPIN<br>PHARMACEUTICALS<br>INC.-2015-04285 |                      | 41 YR           | Male         | ISR            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Sexual Dysfunction       | Escitalopram   |                  |                    | S               | Unknown                                        |                      |                 | Not Reported |                |

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| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>                  | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|------------------------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 02-Feb-2017                       | 13180052                | NON-EXPEDITED             |                             |                          | IL-LUPIN<br>PHARMACEUTICALS<br>INC.-2015-04291 |                               | 32 YR                    | Male                | ISR                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                          | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Sexual Dysfunction                | Escitalopram            |                           |                             | S                        | Unknown                                        |                               |                          |                     | Not Reported            |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>                  | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 02-Feb-2017                       | 13180055                | NON-EXPEDITED             |                             |                          | TR-LUPIN<br>PHARMACEUTICALS<br>INC.-2016-00482 |                               | 32 YR                    | Female              | TUR                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                          | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Galactorrhoea                     | Escitalopram            |                           |                             | S                        | Unknown                                        | 10 Mg                         |                          |                     | Not Reported            |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>                  | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 02-Feb-2017                       | 13180057                | NON-EXPEDITED             |                             | OT                       | ES-LUPIN<br>PHARMACEUTICALS<br>INC.-2015-04498 |                               | 71 YR                    | Male                | ESP                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                          | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Acute Psychosis                   | Olanzapine              |                           |                             | S                        | Oral                                           |                               |                          |                     | Not Reported            |
|                                   | Trazodone               |                           |                             | S                        | Unknown                                        |                               |                          |                     | Not Reported            |
|                                   | Escitalopram            |                           |                             | S                        | Unknown                                        |                               |                          |                     | Not Reported            |
|                                   | Levodopa + Carbidopa    |                           |                             | S                        | Unknown                                        |                               |                          |                     | Not Reported            |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>                  | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 02-Feb-2017                       | 13180058                | NON-EXPEDITED             |                             | HO                       | FR-LUPIN<br>PHARMACEUTICALS<br>INC.-2016-00881 |                               | 82 YR                    | Female              | FRA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                          | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Hyponatraemia                     | Escitalopram            |                           |                             | S                        | Unknown                                        |                               |                          |                     | Not Reported            |
|                                   | Citalopram              |                           |                             | S                        | Unknown                                        |                               |                          |                     | Not Reported            |

# FDA Adverse Event Reporting System

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### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u>                 | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|-------------------------------|------------------|--------------------|-----------------|------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 02-Feb-2017              | 13180059                      | NON-EXPEDITED    |                    |                 | US-LUPIN<br>PHARMACEUTICALS<br>INC.-2016-01711 |                      |                 | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>                | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypersensitivity         | Escitalopram Tablets Usp 10mg |                  |                    | S               | Unknown                                        |                      |                 | Lupin        |                |
| <u>FDA Received Date</u> | <u>Case #</u>                 | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Feb-2017              | 13180067                      | NON-EXPEDITED    |                    | OT              | CN-LUPIN<br>PHARMACEUTICALS<br>INC.-2016-02183 |                      | 70 YR           | Male         | CHN            |
| <u>Preferred Term</u>    | <u>Product</u>                | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Angle Closure Glaucoma   | Escitalopram                  |                  |                    | S               | Unknown                                        |                      |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>                 | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Feb-2017              | 13180071                      | NON-EXPEDITED    |                    |                 | TR-LUPIN<br>PHARMACEUTICALS<br>INC.-2016-02169 |                      | 44 YR           | Female       | TUR            |
| <u>Preferred Term</u>    | <u>Product</u>                | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alopecia                 | Escitalopram                  |                  |                    | S               | Unknown                                        |                      |                 | Not Reported |                |
|                          | Escitalopram                  |                  |                    | S               | Unknown                                        |                      |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>                 | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Feb-2017              | 13180080                      | NON-EXPEDITED    |                    | OT              | CN-LUPIN<br>PHARMACEUTICALS<br>INC.-2016-02185 |                      | 41 YR           | Female       | CHN            |
| <u>Preferred Term</u>    | <u>Product</u>                | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Angle Closure Glaucoma   | Escitalopram                  |                  |                    | S               | Unknown                                        |                      |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>                 | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Feb-2017              | 13180086                      | NON-EXPEDITED    |                    | OT              | CN-LUPIN<br>PHARMACEUTICALS<br>INC.-2016-02199 |                      | 67 YR           | Female       | CHN            |

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| <u>Preferred Term</u>                              | <u>Product</u>    | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|----------------------------------------------------|-------------------|------------------|--------------------|-----------------|------------------------------------------------|----------------------|-----------------|--------------|----------------|
| Angle Closure Glaucoma                             | Escitalopram      |                  |                    | S               | Unknown                                        |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                           | <u>Case #</u>     | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Feb-2017                                        | 13180088          | NON-EXPEDITED    |                    | OT              | CN-LUPIN<br>PHARMACEUTICALS<br>INC.-2016-02200 |                      | 61 YR           | Female       | CHN            |
| <u>Preferred Term</u>                              | <u>Product</u>    | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Angle Closure Glaucoma                             | Escitalopram      |                  |                    | S               | Unknown                                        |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                           | <u>Case #</u>     | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Feb-2017                                        | 13180091          | NON-EXPEDITED    |                    | OT              | US-LUPIN<br>PHARMACEUTICALS<br>INC.-2016-02417 |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                              | <u>Product</u>    | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective;<br>Headache; Major<br>Depression | Escitalopram      |                  |                    | S               | Unknown                                        |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                           | <u>Case #</u>     | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Feb-2017                                        | 13180094          | NON-EXPEDITED    |                    |                 | US-LUPIN<br>PHARMACEUTICALS<br>INC.-2016-02426 |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                              | <u>Product</u>    | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Burning Sensation; Chills;<br>Headache             | Escitalopram 5 Mg |                  |                    | S               | Oral                                           |                      |                 | Not Reported |                |
|                                                    | Escitalopram 5 Mg |                  |                    | S               | Oral                                           |                      |                 | Not Reported |                |
|                                                    | Escitalopram 5 Mg |                  |                    | S               | Oral                                           |                      |                 | Not Reported |                |
|                                                    | Valium            |                  |                    | C               | Oral                                           | At Night             |                 | Not Reported |                |
| <u>FDA Received Date</u>                           | <u>Case #</u>     | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Feb-2017                                        | 13180116          | NON-EXPEDITED    |                    | OT              | FR-LUPIN<br>PHARMACEUTICALS<br>INC.-2016-03298 |                      | 55 YR           | Female       | FRA            |
| <u>Preferred Term</u>                              | <u>Product</u>    | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

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|                           |                |   |         |       |              |
|---------------------------|----------------|---|---------|-------|--------------|
| Drug-Induced Liver Injury | Escitalopram   | S | Unknown | 10 Mg | Not Reported |
|                           | Chlorpromazine | S | Unknown |       | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------------------------|----------------------|------------|------------|----------------|
| 02-Feb-2017              | 13180117      | NON-EXPEDITED    |                    | OT              | US-LUPIN<br>PHARMACEUTICALS<br>INC.-2016-03432 |                      | 68 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Autoimmune Hepatitis  | Escitalopram   |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Escitalopram   |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Diazepam       |              |            | C           | Unknown      |                    |                 | Not Reported |
|                       | Lorazepam      |              |            | C           | Unknown      |                    |                 | Not Reported |
|                       | Zolpidem       |              |            | C           | Unknown      |                    |                 | Not Reported |
|                       | Fexofenadine   |              |            | C           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------------------------|----------------------|------------|------------|----------------|
| 02-Feb-2017              | 13180120      | NON-EXPEDITED    |                    |                 | SA-LUPIN<br>PHARMACEUTICALS<br>INC.-2016-03556 |                      | 28 YR      | Female     | SAU            |

| <u>Preferred Term</u>               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Alopecia; Gastrointestinal Disorder | Escitalopram   |              |            | S           | Unknown      | Up To 10 Mg        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------------------------|----------------------|------------|------------|----------------|
| 02-Feb-2017              | 13180121      | NON-EXPEDITED    |                    |                 | GB-LUPIN<br>PHARMACEUTICALS<br>INC.-2016-03861 |                      | 25 YR      | Female     | GBR            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Madarosis             | Escitalopram   |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Escitalopram   |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>        | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-----------------------------|----------------------|------------|------------|----------------|
| 02-Feb-2017              | 13180125      | NON-EXPEDITED    |                    | OT              | HR-LUPIN<br>PHARMACEUTICALS |                      | 53 YR      | Male       | HRV            |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

INC.-2016-04011

| <u>Preferred Term</u>          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Electrocardiogram Qt Prolonged | Quetiapine     |              |            | S           | Unknown      | 800 Mg             |                 | Not Reported |
|                                | Quetiapine     |              |            | S           | Unknown      | 400mg              |                 | Not Reported |
|                                | Quetiapine     |              |            | S           | Unknown      | 200mg              |                 | Not Reported |
|                                | Quetiapine     |              |            | S           | Unknown      | 100mg              |                 | Not Reported |
|                                | Escitalopram   |              |            | S           | Unknown      | 20mg               |                 | Not Reported |
|                                | Escitalopram   |              |            | S           | Unknown      | 10mg               |                 | Not Reported |
|                                | Escitalopram   |              |            | S           | Unknown      | 5mg                |                 | Not Reported |
|                                | Valproate      |              |            | C           | Unknown      | 1500 Mg            |                 | Not Reported |
|                                | Valproate      |              |            | C           |              |                    |                 | Not Reported |
|                                | Diazepam       |              |            | C           | Unknown      | 30 Mg              |                 | Not Reported |
|                                | Diazepam       |              |            | C           |              |                    |                 | Not Reported |
|                                | Zolpidem       |              |            | C           | Unknown      | 10 Mg              |                 | Not Reported |
|                                | Zolpidem       |              |            | C           |              |                    |                 | Not Reported |
|                                | Biperiden      |              |            | C           | Unknown      | 1 Mg               |                 | Not Reported |
|                                | Biperiden      |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------------------------|----------------------|------------|------------|----------------|
| 02-Feb-2017              | 13180128      | NON-EXPEDITED    |                    |                 | TR-LUPIN<br>PHARMACEUTICALS<br>INC.-2016-04034 |                      | 21 YR      | Male       | TUR            |

| <u>Preferred Term</u>                                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Decreased Appetite; Sleep Disorder; Urinary Incontinence | Mirtazapine    |              |            | S           | Unknown      | 30 Mg              |                 | Not Reported |
|                                                          | Escitalopram   |              |            | S           | Unknown      | 10 Mg              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------------------------|----------------------|------------|------------|----------------|
| 02-Feb-2017              | 13180136      | NON-EXPEDITED    |                    |                 | TW-LUPIN<br>PHARMACEUTICALS<br>INC.-2016-04219 |                      | 27 YR      | Male       | TWN            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                                                      | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|------------------------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|--------------------------------------------|----------------------|-----------------|--------------|----------------|
| Sexual Dysfunction                                                                                         | Escitalopram              |                    |                    | S               | Unknown                                    |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                   | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Feb-2017                                                                                                | 13180677                  | EXPEDITED (15-DAY) |                    | HO              | IT-ALLERGAN-1703912US                      |                      | 47 YR           | Male         | ITA            |
| <u>Preferred Term</u>                                                                                      | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Abuse; Intentional Overdose; Sopor                                                                    | Escitalopram Oxalate - Bp |                    |                    | S               | Oral                                       | 120 MI, Single       |                 | Allergan     |                |
|                                                                                                            | Lorazepam                 |                    |                    | S               | Oral                                       | 30 Df, Single        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                   | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Feb-2017                                                                                                | 11825505                  | NON-EXPEDITED      |                    |                 | US-LUPIN PHARMACEUTICALS INC.-E2B_00004503 |                      | 17 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                      | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dyspnoea; Nausea; Wrong Technique In Product Usage Process                                                 | Escitalopram              |                    |                    | S               | Oral                                       |                      |                 | Not Reported |                |
|                                                                                                            | Keppra                    |                    |                    | C               | Unknown                                    |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                   | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Feb-2017                                                                                                | 13168811                  | EXPEDITED (15-DAY) |                    | HO              | SE-ASTRAZENECA-2017SE10264                 |                      | 34 YR           | Female       | SWE            |
| <u>Preferred Term</u>                                                                                      | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Accidental Poisoning; Anxiety; Gastrointestinal Motility Disorder; Tachycardia; Toxicity To Various Agents | Seroquel                  |                    |                    | S               | Oral                                       |                      |                 | Not Reported |                |
|                                                                                                            | Tegretol Retard           |                    |                    | S               | Unknown                                    |                      |                 | Not Reported |                |
|                                                                                                            | Ciprallex                 |                    |                    | S               | Unknown                                    |                      |                 | Not Reported |                |
|                                                                                                            | Theralen                  |                    |                    | C               |                                            |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                   | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Feb-2017                                                                                                | 13182454                  | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2017044844                   |                      | 66 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                      | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                       |               |   |     |              |
|-----------------------|---------------|---|-----|--------------|
| Drug Hypersensitivity | Celebrex      | S | Unk | Pfizer       |
|                       | Effexor Xr    | S | Unk | Pfizer       |
|                       | Flagyl        | S | Unk | Pfizer       |
|                       | Gabapentin    | S | Unk | Pfizer       |
|                       | Zoloft        | S | Unk | Pfizer       |
|                       | Ciprofloxacin | S | Unk | Unknown      |
|                       | Bupropion     | S | Unk | Not Reported |
|                       | Amoxicillin   | S | Unk | Not Reported |
|                       | Cymbalta      | S | Unk | Not Reported |
|                       | Lamictal      | S | Unk | Not Reported |
|                       | Iodine        | S | Unk | Not Reported |
|                       | Lexapro       | S | Unk | Not Reported |
|                       | Plavix        | S | Unk | Not Reported |
|                       | Remeron       | S | Unk | Not Reported |
|                       | Vioxx         | S | Unk | Not Reported |
|                       | Wellbutrin Sr | S | Unk | Not Reported |
|                       | Zocor         | S | Unk | Not Reported |

| <u>FDA Received Date</u>                      | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------|----------------|------------------|--------------------|-----------------|------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 03-Feb-2017                                   | 13183076       | NON-EXPEDITED    |                    |                 | JP-LUPIN<br>PHARMACEUTICALS<br>INC.-2016-05394 |                      | 19 YR           | Female       | JPN            |
| <u>Preferred Term</u>                         | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Withdrawal<br>Syndrome; Muscle<br>Spasms | Escitalopram   |                  |                    | S               | Unknown                                        |                      |                 | Not Reported |                |
|                                               | Mirtazapine    |                  |                    | S               | Unknown                                        |                      |                 | Not Reported |                |
|                                               | Flunitrazepam  |                  |                    | S               | Unknown                                        |                      |                 | Not Reported |                |
|                                               | Zolpidem       |                  |                    | C               | Unknown                                        |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>        | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-----------------------------|----------------------|------------|------------|----------------|
| 03-Feb-2017              | 13183081      | NON-EXPEDITED    |                    |                 | MY-LUPIN<br>PHARMACEUTICALS |                      | 45 YR      | Male       | MYS            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

INC.-2016-04347

| <u>Preferred Term</u>                                                                                                                                      | <u>Product</u>                | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                     | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|------------------|--------------------|-----------------|--------------------------------------------------|----------------------|-----------------|--------------|----------------|
| Sexual Dysfunction                                                                                                                                         | Escitalopram                  |                  |                    | S               | Unknown                                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                   | <u>Case #</u>                 | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Feb-2017                                                                                                                                                | 13183084                      | NON-EXPEDITED    |                    |                 | IT-LUPIN<br>PHARMACEUTICALS<br>INC.-2016-05244   |                      | 81 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                                                                                                      | <u>Product</u>                | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                     | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Telangiectasia                                                                                                                                             | Escitalopram                  |                  |                    | S               | Unknown                                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                   | <u>Case #</u>                 | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Feb-2017                                                                                                                                                | 13183112                      | NON-EXPEDITED    |                    |                 | US-LUPIN<br>PHARMACEUTICALS<br>INC.-E2B_00004684 |                      | 82 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                      | <u>Product</u>                | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                     | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Discomfort;<br>Anxiety; Depressed Mood;<br>Diarrhoea; Drug<br>Ineffective; Fear; Feeling<br>Of Body Temperature<br>Change; Flatulence;<br>Nausea | Escitalopram Tablets Usp 10mg |                  |                    | S               | Oral                                             |                      |                 | Lupin        |                |
|                                                                                                                                                            | Metoprolol                    |                  |                    | C               | Oral                                             |                      |                 | Not Reported |                |
|                                                                                                                                                            | Ramipril                      |                  |                    | C               | Oral                                             |                      |                 | Not Reported |                |
|                                                                                                                                                            | Gabapentin                    |                  |                    | C               | Oral                                             |                      |                 | Not Reported |                |
|                                                                                                                                                            | Atorvastatin                  |                  |                    | C               | Oral                                             |                      |                 | Not Reported |                |
|                                                                                                                                                            | Allopurinol                   |                  |                    | C               | Oral                                             |                      |                 | Not Reported |                |
|                                                                                                                                                            | Xarelto                       |                  |                    | C               | Oral                                             |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                   | <u>Case #</u>                 | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Feb-2017                                                                                                                                                | 13183119                      | NON-EXPEDITED    |                    |                 | DE-LUPIN<br>PHARMACEUTICALS<br>INC.-E2B_00005128 |                      | 61 YR           | Male         | DEU            |
| <u>Preferred Term</u>                                                                                                                                      | <u>Product</u>                | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                     | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

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|                                     |                  |   |      |                    |              |
|-------------------------------------|------------------|---|------|--------------------|--------------|
| Gamma-Glutamyltransferase Increased | Citalopram 10 Mg | S | Oral | 10/20 Mg Tabletten | Not Reported |
|                                     | Escitalopram     | S | Oral | 10 Mg Tropfen      | Not Reported |
|                                     | Citalopram 20 Mg | S | Oral | 10/20 Mg Tabletten | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>                 | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|-------------------------------|------------------|--------------------|-----------------|--------------------------------------------------|----------------------|-----------------|------------|----------------|
| 03-Feb-2017              | 13183123                      | NON-EXPEDITED    |                    |                 | US-LUPIN<br>PHARMACEUTICALS<br>INC.-E2B_00005766 |                      | 33 YR           | Female     | USA            |
| <u>Preferred Term</u>    | <u>Product</u>                | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                     | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective         | Escitalopram Tablets Usp 10mg |                  |                    | S               |                                                  |                      |                 |            | Not Reported   |

| <u>FDA Received Date</u> | <u>Case #</u>                 | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|-------------------------------|------------------|--------------------|-----------------|--------------------------------------------------|----------------------|-----------------|------------|----------------|
| 03-Feb-2017              | 13183129                      | NON-EXPEDITED    |                    |                 | US-LUPIN<br>PHARMACEUTICALS<br>INC.-E2B_00005777 |                      | 34 YR           | Male       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>                | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                     | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective         | Escitalopram Tablets Usp 10mg |                  |                    | S               | Oral                                             |                      |                 |            | Not Reported   |

| <u>FDA Received Date</u>                                                       | <u>Case #</u>                 | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------------------------------------------------------------|-------------------------------|------------------|--------------------|-----------------|--------------------------------------------------|----------------------|-----------------|------------|----------------|
| 03-Feb-2017                                                                    | 13183131                      | NON-EXPEDITED    |                    |                 | US-LUPIN<br>PHARMACEUTICALS<br>INC.-E2B_00005825 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>                                                          | <u>Product</u>                | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                     | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Abdominal Discomfort;<br>Arthralgia; Dizziness;<br>Gluten Sensitivity; Myalgia | Escitalopram Tablets Usp 10mg |                  |                    | S               | Oral                                             |                      |                 |            | Lupin          |

| <u>FDA Received Date</u> | <u>Case #</u>                 | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|-------------------------------|------------------|--------------------|-----------------|--------------------------------------------------|----------------------|-----------------|------------|----------------|
| 03-Feb-2017              | 13183132                      | NON-EXPEDITED    |                    |                 | US-LUPIN<br>PHARMACEUTICALS<br>INC.-E2B_00005900 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>    | <u>Product</u>                | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                     | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Diarrhoea                | Escitalopram Tablets Usp 20mg |                  |                    | S               | Oral                                             |                      |                 |            | Not Reported   |

# FDA Adverse Event Reporting System

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### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|-------------------------------|--------------------|--------------------|-----------------|--------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 03-Feb-2017              | 13183135                      | NON-EXPEDITED      |                    | OT              | US-LUPIN<br>PHARMACEUTICALS<br>INC.-E2B_00006241 |                      | 58 YR           | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                     | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Seizure                  | Escitalopram Tablets Usp 10mg |                    |                    | S               | Oral                                             | 20mg                 |                 | Not Reported |                |
|                          | Bupropion                     |                    |                    | C               | Oral                                             |                      |                 | Not Reported |                |
|                          | Opdivo                        |                    |                    | C               | Unknown                                          |                      |                 | Not Reported |                |
|                          | Primodone                     |                    |                    | C               | Oral                                             |                      |                 | Not Reported |                |
|                          | Keppra                        |                    |                    | C               | Oral                                             |                      |                 | Not Reported |                |
|                          | Ibuprofen                     |                    |                    | C               | Oral                                             |                      |                 | Not Reported |                |
|                          | Lorazepam                     |                    |                    | C               | Oral                                             |                      |                 | Not Reported |                |
|                          | Biotin                        |                    |                    | C               | Oral                                             |                      |                 | Not Reported |                |
|                          | Melatonin                     |                    |                    | C               | Oral                                             |                      |                 | Not Reported |                |
|                          | Hydrocodone/Ibuprofen         |                    |                    | C               | Oral                                             |                      |                 | Not Reported |                |
|                          | Vitamin D3                    |                    |                    | C               | Oral                                             |                      |                 | Not Reported |                |
|                          | Fish Oil                      |                    |                    | C               | Oral                                             |                      |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Feb-2017              | 13184119                      | NON-EXPEDITED      |                    |                 | KR-LUPIN<br>PHARMACEUTICALS<br>INC.-2015-04460   |                      | 69 YR           | Female       | KOR            |
| <u>Preferred Term</u>    | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                     | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Parkinsonism             | Haloperidol                   |                    |                    | S               | Unknown                                          | 1.5mg                |                 | Not Reported |                |
|                          | Clonazepam                    |                    |                    | S               | Unknown                                          | 0.5mg                |                 | Not Reported |                |
|                          | Buspirone                     |                    |                    | S               | Unknown                                          | 10mg                 |                 | Not Reported |                |
|                          | Escitalopram                  |                    |                    | S               | Unknown                                          | 10mg                 |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Feb-2017              | 13184683                      | EXPEDITED (15-DAY) |                    | HO, OT          | IT-MYLANLABS-<br>2017M1006324                    |                      |                 | Unknown      | ITA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                              | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |                |
|--------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|-------------------------------------------|-----------------------------------|-----------------|--------------|----------------|
| Drug Abuse; Intentional Self-Injury; Overdose; Sopor                                 | Lorazepam                 |                    |                    | S               | Oral                                      | 30 Df, Total                      |                 | Not Reported |                |
|                                                                                      | Escitalopram              |                    |                    | S               | Oral                                      | 120 MI, Total                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                             | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                      | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Feb-2017                                                                          | 13185487                  | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2017045101                  |                                   |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                              | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity                                                                | Bacitracin                |                    |                    | S               |                                           | Unk                               |                 | Pfizer       |                |
|                                                                                      | Sertraline Hcl            |                    |                    | S               |                                           | Unk                               |                 | Pfizer       |                |
|                                                                                      | Lisinopril                |                    |                    | S               |                                           | Unk                               |                 | Not Reported |                |
|                                                                                      | Lexapro                   |                    |                    | S               |                                           | Unk                               |                 | Not Reported |                |
|                                                                                      | Codeine                   |                    |                    | S               |                                           | Unk                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                             | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                      | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Feb-2017                                                                          | 13185565                  | EXPEDITED (15-DAY) |                    | HO              | SE-ALLERGAN-1704085US                     |                                   | 34 YR           | Female       | SWE            |
| <u>Preferred Term</u>                                                                | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                              | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |                |
| Accidental Poisoning; Anxiety; Constipation; Tachycardia; Toxicity To Various Agents | Escitalopram Oxalate - Bp |                    |                    | S               | Unknown                                   |                                   |                 | Allergan     |                |
|                                                                                      | Tegretol Retard           |                    |                    | S               | Unknown                                   |                                   |                 | Not Reported |                |
|                                                                                      | Seroquel                  |                    |                    | S               | Unknown                                   |                                   |                 | Not Reported |                |
|                                                                                      | Theralen                  |                    |                    | C               | Unknown                                   |                                   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                             | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                      | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Feb-2017                                                                          | 13139320                  | EXPEDITED (15-DAY) |                    | DE, HO          | FR-LANNETT COMPANY, INC.-FR-2017LAN000403 |                                   | 63 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                              | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |                |
| Acute Hepatic Failure; Acute Kidney Injury; Cardiogenic Shock;                       | Escitalopram Oxalate      |                    |                    | S               | Oral                                      | 280 Mg, Single (Seroplex Tablets) |                 | Lannett      |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                                                                   |                           |   |      |                                                               |              |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|---|------|---------------------------------------------------------------|--------------|
| Hyperlactacidaemia;<br>Intentional Overdose; Left<br>Ventricular Dysfunction;<br>Loss Of Consciousness;<br>Metabolic Acidosis;<br>Multiple Organ<br>Dysfunction Syndrome;<br>Skin Necrosis; Toxicity To<br>Various Agents;<br>Vasoplegia Syndrome | Hydroxyzine Hydrochloride | S | Oral | 700 Mg, Single (Atarax<br>Tablets)                            | Lannett      |
|                                                                                                                                                                                                                                                   | Sevikar                   | S | Oral | 1290 Mg Of Amlodipine<br>And 5160 Mg Of<br>Olmesartan, Single | Not Reported |
|                                                                                                                                                                                                                                                   | Zolpidem                  | S |      | Unk                                                           | Not Reported |
|                                                                                                                                                                                                                                                   | Lysanxia                  | S | Oral | 420 Mg, Single                                                | Not Reported |

| <u>FDA Received Date</u>                                                                                        | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|--------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 06-Feb-2017                                                                                                     | 13188128                    | EXPEDITED (15-DAY) |                    | HO              | CA-GLENMARK<br>PHARMACEUTICALS-<br>2017GMK026179 |                      |                 | Unknown      | CAN            |
| <u>Preferred Term</u>                                                                                           | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                     | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated;<br>Dehydration; Dysphagia;<br>Mental Disorder; Product<br>Use In Unapproved<br>Indication | Gabapentin                  |                    |                    | S               | Oral                                             | 600 Mg, Bid          |                 | Glenmark     |                |
|                                                                                                                 | Gabapentin                  |                    |                    | S               | Oral                                             | 300 Mg, Od           |                 | Glenmark     |                |
|                                                                                                                 | Acetaminophen & Cod. Phosp. |                    |                    | S               | Oral                                             | 2 Df, Tid            |                 | Not Reported |                |
|                                                                                                                 | Clonazepam                  |                    |                    | S               | Oral                                             | 0.5 Mg, Tid          |                 | Not Reported |                |
|                                                                                                                 | Domperidone                 |                    |                    | S               | Oral                                             | 10 Mg, Bid           |                 | Not Reported |                |
|                                                                                                                 | Escitalopram                |                    |                    | S               | Oral                                             | 20 Mg, Unk           |                 | Not Reported |                |
|                                                                                                                 | Ferrous Sulfate             |                    |                    | S               | Unknown                                          | 300 Mg, Tid          |                 | Not Reported |                |
|                                                                                                                 | Temazepam                   |                    |                    | S               | Oral                                             | 30 Mg, Od            |                 | Not Reported |                |
|                                                                                                                 | Wellbutrin                  |                    |                    | S               | Oral                                             | 150 Mg, Bid          |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|-------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|--------------------------------------------|----------------------|-----------------|-----------------|----------------|
| 06-Feb-2017                                                                         | 13190574       | EXPEDITED (15-DAY) |                    | OT              | US-<br>GLAXOSMITHKLINE-<br>US2017GSK014787 |                      |                 | Female          | USA            |
| <u>Preferred Term</u>                                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Depression; Drug<br>Resistance; Hypomania;<br>Suicide Attempt; Therapy<br>Cessation | Lithium        |                    |                    | S               |                                            |                      |                 | Glaxosmithkline |                |
|                                                                                     | Aripiprazole   |                    |                    | S               |                                            |                      |                 | Not Reported    |                |
|                                                                                     | Clozapine      |                    |                    | S               |                                            |                      |                 | Glaxosmithkline |                |
|                                                                                     | Haloperidol    |                    |                    | S               |                                            |                      |                 | Not Reported    |                |



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|                 |   |                 |
|-----------------|---|-----------------|
| Risperidone     | S | Not Reported    |
| Bupropion       | S | Not Reported    |
| Duloxetine      | S | Glaxosmithkline |
| Lamotrigine     | S | Glaxosmithkline |
| Carbamazepine   | S | Glaxosmithkline |
| Lorazepam       | S | Glaxosmithkline |
| Quetiapine      | S | Glaxosmithkline |
| Ziprasidone     | S | Not Reported    |
| Chlorpromazine  | S | Not Reported    |
| Loxapine        | S | Not Reported    |
| Nefazodone      | S | Not Reported    |
| Citalopram      | S | Glaxosmithkline |
| Escitalopram    | S | Glaxosmithkline |
| Doxepine        | S | Not Reported    |
| Paroxetine      | S | Glaxosmithkline |
| Venlafaxine     | S | Glaxosmithkline |
| Trazodone       | S | Not Reported    |
| Trihexyphenidyl | S | Not Reported    |
| Benzotropine    | S | Not Reported    |
| Divalproex      | S | Not Reported    |
| Oxcarbazepine   | S | Not Reported    |
| Topiramate      | S | Glaxosmithkline |
| Chloral Hydrate | S | Not Reported    |
| Clonazepam      | S | Not Reported    |
| Diazepam        | S | Glaxosmithkline |
| Phenobarbital   | S | Glaxosmithkline |
| Temazepam       | S | Not Reported    |
| Triazolam       | S | Not Reported    |
| Alprazolam      | S | Not Reported    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------|----------------------|------------|------------|----------------|
| 07-Feb-2017              | 13125630      | EXPEDITED (15-DAY) |                    | HO, OT          | FR-TAKEDA-2017TUS001249 |                      | 52 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Ineffective; Product Use In Unapproved Indication; Suicide Attempt | Brintellix     |              |            | S           | Oral         | 10 Mg, Unk         |                 | Takeda       |
|                                                                         | Seroplex       |              |            | S           | Oral         | 20 Mg, Qd          |                 | Not Reported |
|                                                                         | Lexomil        |              |            | C           | Oral         | 6 Mg, Qd           |                 | Not Reported |
|                                                                         | Doliprane      |              |            | C           | Oral         | Unk, Tid           |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| 07-Feb-2017                                                                               | 13192177       | EXPEDITED (15-DAY) |                    | DS              | CA-TEVA-736094ACC          |                      | 44 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                                                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Mental Status Changes                                                            | Lorazepam      |                    |                    | S               | Unknown                    |                      |                 | Actavis      |                |
|                                                                                           | Escitalopram   |                    |                    | S               | Oral                       |                      |                 | Ivax         |                |
| <u>FDA Received Date</u>                                                                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Feb-2017                                                                               | 13192736       | EXPEDITED (15-DAY) |                    | HO              | IT-TEVA-737059ACC          |                      | 46 YR           | Male         | ITA            |
| <u>Preferred Term</u>                                                                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Abuse; Sopor                                                                         | Lorazepam      |                    |                    | S               | Oral                       |                      |                 | Actavis      |                |
|                                                                                           | Escitalopram   |                    |                    | S               | Oral                       |                      |                 | Ivax         |                |
| <u>FDA Received Date</u>                                                                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Feb-2017                                                                               | 13193470       | EXPEDITED (15-DAY) |                    | DE              | US-MALLINCKRODT-T201607182 |                      | 58 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                                                         | Roxicodone     |                    |                    | S               | Oral                       |                      |                 | Mallinckrodt |                |
|                                                                                           | Escitalopram   |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                                                           | Ibuprofen      |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Feb-2017                                                                               | 13195204       | DIRECT             | Y                  | OT              |                            |                      | 37 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Feeling Abnormal; Heart Rate Increased; Panic Attack; Product Substitution Issue | Lexapro        |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

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### Detailed Report

| <u>FDA Received Date</u>                                                                                        | <u>Case #</u>    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------|------------------|--------------------|--------------------|-----------------|------------------------|-----------------------|-----------------|--------------|----------------|
| 07-Feb-2017                                                                                                     | 13195840         | DIRECT             | Y                  | HO              |                        |                       | 80 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                           | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyponatraemia                                                                                                   | Lexapro          |                    |                    | S               | Oral                   |                       |                 | Not Reported |                |
|                                                                                                                 | Albuterol        |                    |                    | C               |                        |                       |                 | Not Reported |                |
|                                                                                                                 | Aspirin          |                    |                    | C               |                        |                       |                 | Not Reported |                |
|                                                                                                                 | Carvedilol       |                    |                    | C               |                        |                       |                 | Not Reported |                |
|                                                                                                                 | Warfarin         |                    |                    | C               |                        |                       |                 | Not Reported |                |
|                                                                                                                 | Tiotropium       |                    |                    | C               |                        |                       |                 | Not Reported |                |
|                                                                                                                 | Lactobacillus    |                    |                    | C               |                        |                       |                 | Not Reported |                |
|                                                                                                                 | Bupropion        |                    |                    | C               |                        |                       |                 | Not Reported |                |
|                                                                                                                 | Clonazepam       |                    |                    | C               |                        |                       |                 | Not Reported |                |
|                                                                                                                 | Diaepam          |                    |                    | C               |                        |                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                        | <u>Case #</u>    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Feb-2017                                                                                                     | 13205558         | DIRECT             |                    | OT              |                        |                       | 66 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                           | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated; Depression; Product Substitution Issue; Therapeutic Response Changed; Withdrawal Syndrome | Escitalopram     |                    |                    | S               | Oral                   | Quantity:3 Tablet(S); |                 | Unknown      |                |
|                                                                                                                 | Celexa           |                    |                    | C               |                        |                       |                 | Not Reported |                |
|                                                                                                                 | Lisinipril       |                    |                    | C               |                        |                       |                 | Not Reported |                |
|                                                                                                                 | Multi Vitamin    |                    |                    | C               |                        |                       |                 | Not Reported |                |
|                                                                                                                 | Fish Oil         |                    |                    | C               |                        |                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                        | <u>Case #</u>    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Feb-2017                                                                                                     | 12914090         | EXPEDITED (15-DAY) |                    | OT              | AU-APOTEX-2016AP013845 |                       | 38 YR           | Male         | AUS            |
| <u>Preferred Term</u>                                                                                           | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective; Liver Function Test Abnormal; Product Substitution Issue                                      | Apo-Escitalopram |                    |                    | S               | Oral                   | 20 Mg, Qd             |                 | Apotex       |                |

# FDA Adverse Event Reporting System

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### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 08-Feb-2017              | 13042163       | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2016586661 |                      | 17 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective         | Zoloft         |                  |                    | S               | Oral                     | 50 Mg, Unk           |                 | Pfizer       |                |
|                          | Lexapro        |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                          | Wellbutrin     |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                           | <u>Case #</u>              | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------|----------------------------|------------------|--------------------|-----------------|-------------------------|-------------------------|-----------------|--------------|----------------|
| 08-Feb-2017                                                                                                        | 13195188                   | NON-EXPEDITED    |                    |                 | US-BAXTER-2017BAX003346 |                         | 49 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                              | <u>Product</u>             | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Fibromyalgia;<br>Gastroesophageal Reflux<br>Disease; Neuropathy<br>Peripheral; Osteoarthritis;<br>Weight Increased | Fluconazole Injection, Usp |                  |                    | S               | Unknown                 | As Needed               |                 | Baxter       |                |
|                                                                                                                    | Pristiq                    |                  |                    | S               | Unknown                 |                         |                 | Not Reported |                |
|                                                                                                                    | Pristiq                    |                  |                    | S               | Unknown                 |                         |                 | Not Reported |                |
|                                                                                                                    | Pristiq                    |                  |                    | S               | Unknown                 |                         |                 | Not Reported |                |
|                                                                                                                    | Lexapro                    |                  |                    | S               | Unknown                 |                         |                 | Not Reported |                |
|                                                                                                                    | Buspirone                  |                  |                    | S               | Unknown                 |                         |                 | Not Reported |                |
|                                                                                                                    | Gabapentin                 |                  |                    | S               | Unknown                 |                         |                 | Not Reported |                |
|                                                                                                                    | Tramadol                   |                  |                    | S               | Unknown                 | 1/2 To 2 Needed Per Day |                 | Not Reported |                |
|                                                                                                                    | Meloxicam                  |                  |                    | S               | Unknown                 | 1 Per Day At Night      |                 | Not Reported |                |
|                                                                                                                    | Protonix                   |                  |                    | S               | Unknown                 |                         |                 | Not Reported |                |
|                                                                                                                    | Ativan                     |                  |                    | S               | Unknown                 | Dose: 1.0               |                 | Not Reported |                |
|                                                                                                                    | Robaxin                    |                  |                    | S               | Unknown                 | 1 To 3 Daily            |                 | Not Reported |                |
|                                                                                                                    | Trazodone                  |                  |                    | S               | Unknown                 | 1 To 2                  |                 | Not Reported |                |
|                                                                                                                    | Celexa                     |                  |                    | S               | Unknown                 |                         |                 | Not Reported |                |
|                                                                                                                    | Wellbutrin                 |                  |                    | S               | Unknown                 |                         |                 | Not Reported |                |
|                                                                                                                    | Cymbalta                   |                  |                    | S               | Unknown                 |                         |                 | Not Reported |                |
|                                                                                                                    | Zoloft                     |                  |                    | S               | Unknown                 |                         |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                         |                 |                    |                    |                 |                                             |                                            |                 |                  |                |
|-----------------------------------------------------------------------------------------------------------------------------------------|-----------------|--------------------|--------------------|-----------------|---------------------------------------------|--------------------------------------------|-----------------|------------------|----------------|
| Doxycycline                                                                                                                             |                 |                    | C                  |                 | Unknown                                     |                                            |                 | Not Reported     |                |
| <u>FDA Received Date</u>                                                                                                                | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u>                       | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 08-Feb-2017                                                                                                                             | 13197136        | EXPEDITED (15-DAY) |                    | DE              | TR-ELI_LILLY_AND_COMP<br>ANY-TR201702001961 |                                            | 51 YR           | Female           | TUR            |
| <u>Preferred Term</u>                                                                                                                   | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                | <u>Dosage Text</u>                         | <u>Duration</u> | <u>Mfr</u>       |                |
| Embolism Venous;<br>Haemorrhage; Toxicity To<br>Various Agents                                                                          | Olanzapine      |                    |                    | S               | Unknown                                     |                                            |                 | Eli Lilly And Co |                |
|                                                                                                                                         | Citalopram      |                    |                    | S               | Unknown                                     |                                            |                 | Not Reported     |                |
|                                                                                                                                         | Escitalopram    |                    |                    | S               | Unknown                                     |                                            |                 | Not Reported     |                |
| <u>FDA Received Date</u>                                                                                                                | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u>                       | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 08-Feb-2017                                                                                                                             | 13205998        | DIRECT             |                    | OT              |                                             |                                            | 15 YR           | Female           | USA            |
| <u>Preferred Term</u>                                                                                                                   | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                | <u>Dosage Text</u>                         | <u>Duration</u> | <u>Mfr</u>       |                |
| Abnormal Behaviour;<br>Depressed Mood;<br>Dyspnoea; Heart Rate<br>Increased; Speech<br>Disorder                                         | Lexapro         | Y                  |                    | S               | Oral                                        | Quantity:60 Tablet(S);                     |                 | Cadista          |                |
| <u>FDA Received Date</u>                                                                                                                | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u>                       | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 09-Feb-2017                                                                                                                             | 13065208        | EXPEDITED (15-DAY) |                    | HO, LT, OT      | IN-PFIZER INC-<br>2016596876                |                                            | 19 YR           | Female           | IND            |
| <u>Preferred Term</u>                                                                                                                   | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                | <u>Dosage Text</u>                         | <u>Duration</u> | <u>Mfr</u>       |                |
| Dizziness; Headache;<br>Hypoglycaemia;<br>Intentional Overdose;<br>Respiratory Rate<br>Increased; Suicidal<br>Ideation; Suicide Attempt | Venlafaxine Hcl |                    |                    | S               | Oral                                        | 37.5 Mg, Od Orally                         |                 | Pfizer           |                |
|                                                                                                                                         | Venlafaxine Hcl |                    |                    | S               | Oral                                        | 10 To 15 Tablets Of<br>Venlafaxine, Tablet |                 | Pfizer           |                |
|                                                                                                                                         |                 |                    |                    |                 |                                             | Escitalopram, And Tablet                   |                 |                  |                |
|                                                                                                                                         | Clonazepam      |                    |                    | S               | Oral                                        | 1 Df, 1x/Day                               |                 | Not Reported     |                |
|                                                                                                                                         | Clonazepam      |                    |                    | S               | Oral                                        | 10 To 15 Tablets Of<br>Venlafaxine, Tablet |                 | Not Reported     |                |

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|              |   |      |                                            |              |
|--------------|---|------|--------------------------------------------|--------------|
| Escitalopram | S | Oral | Escitalopram, And Tablet<br>Clonazepam     | Not Reported |
| Escitalopram | S | Oral | 1 Df, 1x/Day                               | Not Reported |
|              |   |      | 10 To 15 Tablets Of<br>Venlafaxine, Tablet |              |
|              |   |      | Escitalopram, And Tablet<br>Clonazepam     |              |

| <u>FDA Received Date</u>   | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------|---------------------|--------------------|--------------------|-----------------|--------------------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 09-Feb-2017                | 13202059            | EXPEDITED (15-DAY) |                    | HO              | IT-SUN<br>PHARMACEUTICAL<br>INDUSTRIES LTD-<br>2017RR-132698 |                      | 46 YR           | Male         | ITA            |
| <u>Preferred Term</u>      | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Abuse; Sopor          | Lorazepam           |                    |                    | S               | Oral                                                         | 30 Df Total          |                 | Sun          |                |
|                            | Escitalopram        |                    |                    | S               | Oral                                                         | 120 MI Total         |                 | Not Reported |                |
| <u>FDA Received Date</u>   | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Feb-2017                | 13208050            | EXPEDITED (15-DAY) |                    | DE, HO          | US-ALLERGAN-<br>1680857US                                    |                      | 15 YR           | Female       | USA            |
| <u>Preferred Term</u>      | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;         | Lexapro             |                    |                    | S               |                                                              | 20 Mg, Qam           |                 | Allergan     |                |
| Depression; Intentional    | Metformin           |                    |                    | C               |                                                              | 500 Mg, Bid          |                 | Not Reported |                |
| Self-Injury; Mood Swings;  | Iron Sulfate        |                    |                    | C               |                                                              | 325 Mg, Bid          |                 | Not Reported |                |
| Multiple Injuries; Stress; | Topamax             |                    |                    | C               |                                                              | 50 Mg, Bid           |                 | Not Reported |                |
| Suicidal Ideation          | Amoxicillin         |                    |                    | C               |                                                              | 500 Mg, Unk          |                 | Not Reported |                |
|                            | Doxycycline Hyclate |                    |                    | C               |                                                              | 100 Mg, Unk          |                 | Not Reported |                |
|                            | Escitalopram        |                    |                    | C               |                                                              | 20 Mg, Unk           |                 | Not Reported |                |
|                            | Alprazolam          |                    |                    | C               |                                                              | .5 Mg, Unk           |                 | Not Reported |                |
| <u>FDA Received Date</u>   | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Feb-2017                | 13209306            | NON-EXPEDITED      |                    |                 | US-PFIZER INC-<br>2017049684                                 |                      | 56 YR           | Female       | USA            |

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| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Hypersensitivity | Lipitor        |              |            | S           |              | Unk                |                 | Pfizer       |
|                       | Zithromax      |              |            | S           |              | Unk                |                 | Pfizer       |
|                       | Escitalopram   |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Lamictal       |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Keppra         |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Montelukast    |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Penicillin G   |              |            | S           |              | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 10-Feb-2017              | 13089478      | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-2016604616 |                      | 68 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Breast Cancer; Hernia | Xeljanz             |              |            | S           |              | 5 Mg, Unk          |                 | Pfizer       |
|                       | Xeljanz             |              |            | S           |              | 10 Mg, 2x/Day      |                 | Pfizer       |
|                       | Methotrexate Sodium |              |            | S           |              | Unk, 1x/Day (2.5)  |                 | Pfizer       |
|                       | Meloxicam           |              |            | S           |              | 15 Mg, 1x/Day      |                 | Not Reported |
|                       | Anastrozole         |              |            | S           |              | 1 Mg, 1x/Day       |                 | Not Reported |
|                       | Omeprazole          |              |            | S           |              | 20 Mg, 1x/Day      |                 | Not Reported |
|                       | Escitalopram        |              |            | S           |              | 10 Mg, 1x/Day      |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 10-Feb-2017              | 13156344      | EXPEDITED (15-DAY) |                    | HO              | FR-ALLERGAN-1703047US |                      | 51 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                             | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                           | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------|---------------------------|--------------|------------|-------------|--------------|----------------------------------------------|-----------------|--------------|
| Coma; Drug Ineffective; Overdose; Pneumonia; Pneumonia Aspiration | Escitalopram Oxalate - Bp |              |            | S           | Oral         | Overdose: 1 Box (Presumed Quantity)          |                 | Allergan     |
|                                                                   | Ketamine Panpharma        |              |            | S           | Unknown      | 4 Ampoules, Qd                               |                 | Not Reported |
|                                                                   | Ketamine Panpharma        |              |            | S           | Oral         | Overdose: 23 Boxes Of 5 Ampoules Of 50mg/5ml |                 | Not Reported |

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|                                                                | Laroxyl                   |                    | S                  | Oral            |                       | Unk, Single          |                 | Not Reported |                |
|----------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
|                                                                | Laroxyl                   |                    | S                  | Oral            |                       | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Feb-2017                                                    | 13210024                  | EXPEDITED (15-DAY) |                    | HO              | PT-JNJFOC-20170204655 |                      | 47 YR           | Female       | PRT            |
| <u>Preferred Term</u>                                          | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Catatonia; Off Label Use; Product Use In Unapproved Indication | Haloperidol               |                    |                    | S               | Unknown               | 5-15 Mg              |                 | Not Reported |                |
|                                                                | Pregabalin                |                    |                    | S               | Unknown               |                      |                 | Not Reported |                |
|                                                                | Olanzapine                |                    |                    | S               | Unknown               |                      |                 | Not Reported |                |
|                                                                | Escitalopram              |                    |                    | S               | Unknown               |                      |                 | Not Reported |                |
|                                                                | Lorazepam                 |                    |                    | S               | Unknown               | Up To 30 Mg          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Feb-2017                                                    | 13212563                  | EXPEDITED (15-DAY) |                    | DE              | CA-ALLERGAN-1704890US |                      | 82 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                          | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Death                                                          | Escitalopram Oxalate - Bp |                    |                    | S               | Unknown               | 10 Mg                |                 | Allergan     |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Feb-2017                                                    | 13212614                  | EXPEDITED (15-DAY) |                    | OT              | ES-ALLERGAN-1704889US |                      | 96 YR           | Female       | ESP            |
| <u>Preferred Term</u>                                          | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Seizure                                                        | Escitalopram Oxalate - Bp |                    |                    | S               | Oral                  | 3 Mg, Qd             |                 | Allergan     |                |
|                                                                | Escitalopram Oxalate - Bp |                    |                    | S               | Oral                  | 2 Mg, Qd             |                 | Allergan     |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Feb-2017                                                    | 13213966                  | EXPEDITED (15-DAY) |                    | DE              | CA-ALLERGAN-1705046US |                      | 54 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                          | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |



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|                                                        |                           |                    |                    |                  |                       |                      |                 |              |                |
|--------------------------------------------------------|---------------------------|--------------------|--------------------|------------------|-----------------------|----------------------|-----------------|--------------|----------------|
| Death                                                  | Escitalopram Oxalate - Bp | S                  | Unknown            | Unk Unk, Unknown | Allergan              |                      |                 |              |                |
| <u>FDA Received Date</u>                               | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Feb-2017                                            | 13214465                  | EXPEDITED (15-DAY) |                    | HO, OT           | US-ALLERGAN-1671455US |                      | 56 YR           | Female       | USA            |
| <u>Preferred Term</u>                                  | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Chronic Obstructive Pulmonary Disease                  | Lexapro                   |                    |                    | S                | Oral                  | 20 Mg, Qd            |                 | Allergan     |                |
|                                                        | Brexpiprazole             |                    |                    | S                |                       | 1 Mg, Qd             |                 | Not Reported |                |
|                                                        | Luaf41156                 |                    |                    | S                | Oral                  | 1 Mg, Qd             |                 | Not Reported |                |
|                                                        | Oxycodone                 |                    |                    | C                | Oral                  | 10/325 Mg, Unk       |                 | Not Reported |                |
|                                                        | Oxycodone                 |                    |                    | C                |                       |                      |                 | Not Reported |                |
|                                                        | Lisinopril                |                    |                    | C                | Oral                  | 5 Mg, Unk            |                 | Not Reported |                |
|                                                        | Albuterol                 |                    |                    | C                | Oral                  | Unk, 2 Puffs         |                 | Not Reported |                |
|                                                        | Symbicort                 |                    |                    | C                | Oral                  | Unk, 2 Puffs         |                 | Not Reported |                |
|                                                        | Amlodipine                |                    |                    | C                | Oral                  | 2.5 Mg, Unk          |                 | Not Reported |                |
|                                                        | Fentanyl Patch            |                    |                    | C                |                       |                      |                 | Not Reported |                |
|                                                        | Endocet                   |                    |                    | C                |                       |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                               | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Feb-2017                                            | 13219188                  | EXPEDITED (15-DAY) |                    | HO               | IT-ACCORD-048053      |                      | 47 YR           | Male         | ITA            |
| <u>Preferred Term</u>                                  | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Abuse; Intentional Self-Injury; Sopor             | Escitalopram              |                    |                    | S                | Oral                  |                      |                 | Accord       |                |
|                                                        | Lorazepam                 |                    |                    | S                | Oral                  |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                               | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Feb-2017                                            | 13220110                  | EXPEDITED (15-DAY) |                    | OT               | AU-TORRENT-00000041   |                      | 24 YR           | Male         | AUS            |
| <u>Preferred Term</u>                                  | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Ejection Fraction Decreased; Hepatic Function Abnormal | Olanzapine                |                    |                    | S                |                       |                      |                 | Unknown      |                |
|                                                        | Escitalopram              |                    |                    | S                |                       |                      |                 | Unknown      |                |
|                                                        | Paliperidone              |                    |                    | S                |                       |                      |                 | Unknown      |                |

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| <u>FDA Received Date</u>                                                                                                                                                                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|---------------------------------------|---------------------------------------------|-----------------|--------------|----------------|
| 12-Feb-2017                                                                                                                                                                                                         | 10715561       | EXPEDITED (15-DAY) |                    | DE              | US-JNJFOC-20150105346                 |                                             | 37 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Toxicity To Various Agents                                                                                                                                                                                          | Loperamide     |                    | Y                  | S               | Oral                                  |                                             |                 | Not Reported |                |
|                                                                                                                                                                                                                     | Loperamide     |                    |                    | S               | Oral                                  | 2 Mg Loperamide (10 Caplets)                |                 | Not Reported |                |
|                                                                                                                                                                                                                     | Escitalopram   |                    |                    | S               | Oral                                  | 20 Mg Escitalopram (30 Tablets Missing)     |                 | Not Reported |                |
|                                                                                                                                                                                                                     | Meloxicam      |                    |                    | S               | Oral                                  | 15 Mg Meloxicam (13 Tablets Missing)        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Feb-2017                                                                                                                                                                                                         | 12866268       | EXPEDITED (15-DAY) |                    |                 | BR-TAKEDA-2016TUS018860               |                                             |                 | Female       | BRA            |
| <u>Preferred Term</u>                                                                                                                                                                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective                                                                                                                                                                                                    | Vortioxetine   |                    |                    | S               | Unknown                               | 10 Mg, Qd                                   |                 | Takeda       |                |
|                                                                                                                                                                                                                     | Vortioxetine   |                    |                    | S               | Unknown                               | 10 Mg, Bid                                  |                 | Takeda       |                |
|                                                                                                                                                                                                                     | Escitalopram   |                    |                    | S               | Unknown                               | 20 Mg, Unk                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Feb-2017                                                                                                                                                                                                         | 13226134       | EXPEDITED (15-DAY) |                    | OT              | US-ACORDA-ACO_133605_2017             |                                             |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Adverse Event; Amnesia; Cognitive Disorder; Condition Aggravated; Confusional State; Deafness; Gallbladder Operation; Hemiparesis; Hemiplegia; Irritability; Lip Swelling; Somnolence; Tinnitus; Urticaria; Uterine | Ampyra         |                    |                    | S               | Unknown                               | Unk                                         |                 | Acorda       |                |
|                                                                                                                                                                                                                     | Tysabri        |                    |                    | S               | Intravenous (not otherwise specified) | 300 Mg, Infused Over One Hour Every 4 Weeks |                 | Not Reported |                |
|                                                                                                                                                                                                                     | Gilenya        |                    |                    | S               | Unknown                               | Unk                                         |                 | Not Reported |                |
|                                                                                                                                                                                                                     | Copaxone       |                    |                    | S               | Unknown                               | Unk                                         |                 | Not Reported |                |
|                                                                                                                                                                                                                     | Solumedrol     |                    |                    | S               | Unknown                               | Unk                                         |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|           |          |   |         |     |              |
|-----------|----------|---|---------|-----|--------------|
| Operation | Acthar   | S | Unknown | Unk | Not Reported |
|           | Lexapro  | S | Unknown | Unk | Not Reported |
|           | Cymbalta | S | Unknown | Unk | Not Reported |
|           | Nuvigil  | S | Unknown | Unk | Not Reported |

| <u>FDA Received Date</u>                                     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 13-Feb-2017                                                  | 13226442       | EXPEDITED (15-DAY) |                    | OT              | HR-JNJFOC-20170210805 |                      | 26 YR           | Male         | HRV            |
| <u>Preferred Term</u>                                        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Overdose;<br>Sopor; Suicide Attempt;<br>Vomiting | Tramal         |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                              | Q Pin          |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                              | Elicea         |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                              | Alprazolam     |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                              | Sulpirid       |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>             | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|---------------------------|------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| 14-Feb-2017              | 13232361                  | NON-EXPEDITED    |                    |                 | US-009507513-1702USA000340 |                      | 84 YR           | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u>            | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective         | Remeron                   |                  |                    | S               | Oral                       | Unk                  |                 | Merck        |                |
|                          | Fluoxetine                |                  |                    | S               |                            |                      |                 | Not Reported |                |
|                          | Citalopram                |                  |                    | S               |                            |                      |                 | Not Reported |                |
|                          | Escitalopram              |                  |                    | S               |                            |                      |                 | Not Reported |                |
|                          | Venlafaxine Hydrochloride |                  |                    | S               |                            |                      |                 | Not Reported |                |
|                          | Bupropion Hydrochloride   |                  |                    | S               |                            |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>      | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|-------------------------------|---------------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|------------|----------------|
| 15-Feb-2017                   | 13236973                  | EXPEDITED (15-DAY) |                    | HO              | FR-ALLERGAN-1705798US |                      | 84 YR           | Female     | FRA            |
| <u>Preferred Term</u>         | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Haematemesis;<br>Oesophagitis | Escitalopram Oxalate - Bp |                    |                    | S               | Oral                  | Unk, Unknown         |                 | Allergan   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                    |                           |                    |                    |                 |                           |                      |                 |              |                |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
| Kardegic                                                                                                                                                                           |                           |                    | S                  | Oral            | Unk, Unknown              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                           | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Feb-2017                                                                                                                                                                        | 13237178                  | EXPEDITED (15-DAY) |                    | OT              | FR-ALLERGAN-1705801US     |                      |                 | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                                                              | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Electrocardiogram Qt Prolonged; Off Label Use                                                                                                                                      | Escitalopram Oxalate - Bp |                    |                    | S               | Oral                      |                      |                 | Allergan     |                |
| <u>FDA Received Date</u>                                                                                                                                                           | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Feb-2017                                                                                                                                                                        | 13134348                  | EXPEDITED (15-DAY) |                    | HO              | FR-MYLANLABS-2016M1058466 |                      |                 | Unknown      | FRA            |
| <u>Preferred Term</u>                                                                                                                                                              | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anaphylactic Reaction; Hypersensitivity                                                                                                                                            | Escitalopram Mylan 5 Mg   |                    |                    | S               |                           | 1 Df, Qd             |                 | Mylan        |                |
|                                                                                                                                                                                    | Escitalopram Mylan 5 Mg   |                    |                    | S               |                           | Unk                  |                 | Mylan        |                |
|                                                                                                                                                                                    | Citalopram                |                    |                    | S               |                           | 5 Mg, Unk            |                 | Not Reported |                |
|                                                                                                                                                                                    | Monoprost                 |                    |                    | C               |                           | 1 Gtt, Tid           |                 | Mylan        |                |
|                                                                                                                                                                                    | Optive                    |                    |                    | C               |                           | 1 Gtt, Qd            |                 | Mylan        |                |
| <u>FDA Received Date</u>                                                                                                                                                           | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Feb-2017                                                                                                                                                                        | 13241035                  | EXPEDITED (15-DAY) |                    | OT              | PT-JNJFOC-20170209058     |                      |                 | Unknown      | PRT            |
| <u>Preferred Term</u>                                                                                                                                                              | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrial Fibrillation; Drug Interaction; Fatigue; Gastrointestinal Infection; Haematotoxicity; Haemorrhage; Hypertension; Myalgia; Pneumonitis Chemical; Respiratory Tract Infection | Ibrutinib                 |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                    | Ibrutinib                 |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                    | Ibrutinib                 |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                    | Isoniazid                 |                    |                    | S               | Unknown                   |                      |                 | Not Reported |                |
|                                                                                                                                                                                    | Amiodarone                |                    |                    | S               | Unknown                   |                      |                 | Not Reported |                |
|                                                                                                                                                                                    | Clarithromycin            |                    |                    | S               | Unknown                   |                      |                 | Not Reported |                |
|                                                                                                                                                                                    | Aliskiren                 |                    |                    | S               | Unknown                   |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|              |   |         |              |
|--------------|---|---------|--------------|
| Voriconazole | S | Unknown | Not Reported |
| Fluconazole  | S | Unknown | Not Reported |
| Sertraline   | S | Unknown | Not Reported |
| Escitalopram | S | Unknown | Not Reported |
| Paroxetine   | S | Unknown | Not Reported |
| Enoxaparin   | S | Unknown | Not Reported |
| Ibuprofen    | S | Unknown | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Feb-2017              | 13243195      | DIRECT           |                    | DS, HO, LT, OT  |                      |                      | 31 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|------------------------|-----------------|------------|
| Acoustic Neuroma      | Escitalopram   |              |            | S           | Oral         | Quantity:1 Capsule(S); |                 | Cipla      |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 17-Feb-2017              | 13248138      | EXPEDITED (15-DAY) |                    | OT              | US-ALLERGAN-1705782US |                      | 68 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Abdominal Discomfort;<br>Aortic Aneurysm; Apathy;<br>Blood Urine Present; Drug<br>Ineffective; Dysuria;<br>Malaise; Rash | Lexapro        |              |            | S           | Oral         | 20 Mg, Qd          |                 | Allergan   |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 20-Feb-2017              | 9885323       | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2014036696 |                      | 55 YR      | Female     | USA            |

| <u>Preferred Term</u>              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Hypersensitivity;<br>Insomnia | Celebrex       |              |            | S           |              | Unk                |                 | Pfizer       |
|                                    | Cymbalta       |              |            | S           |              | Unk                |                 | Not Reported |
|                                    | Lexapro        |              |            | S           |              | Unk                |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|------------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 20-Feb-2017                                                                                             | 13250805       | EXPEDITED (15-DAY) |                    | OT              | US-CIPLA LTD.-<br>2017US01995                        |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                                                   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Adverse Event                                                                                           | Escitalopram   |                    |                    | S               | Unknown                                              | Unk                  |                 | Invagen      |                |
| <u>FDA Received Date</u>                                                                                | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Feb-2017                                                                                             | 13251111       | EXPEDITED (15-DAY) |                    | OT              | US-CIPLA (EU)<br>LIMITED-2017US01951                 |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                                                   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Drug<br>Ineffective; Palpitations;<br>Panic Attack; Suicidal<br>Ideation                    | Escitalopram   |                    |                    | S               | Oral                                                 | 10 Mg, Qd            |                 | Invagen      |                |
|                                                                                                         | Clopidogrel    |                    |                    | C               | Unknown                                              | 10 Mg, Qd            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Feb-2017                                                                                             | 13252931       | EXPEDITED (15-DAY) |                    | OT              | US-ALLERGAN-<br>1705956US                            |                      | 36 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Amnesia; Cognitive<br>Disorder; Condition                                                               | Lexapro        |                    |                    | S               |                                                      |                      |                 | Allergan     |                |
| Aggravated; Confusional<br>State; Deafness; Drug<br>Ineffective; Gallbladder<br>Operation; Hemiparesis; | Ampyra         |                    |                    | S               |                                                      |                      |                 | Not Reported |                |
| Hemiplegia; Irritability; Lip<br>Swelling; Somnolence;<br>Tinnitus; Urticaria; Uterine<br>Operation     | Tysabri        |                    |                    | S               | Intravenous (not<br>otherwise specified)             | 300 Mg, Q4weeks      |                 | Not Reported |                |
|                                                                                                         | Gilenya        |                    |                    | S               |                                                      |                      |                 | Not Reported |                |
|                                                                                                         | Copaxone       |                    |                    | S               |                                                      |                      |                 | Not Reported |                |
|                                                                                                         | Solmedrol      |                    |                    | S               |                                                      |                      |                 | Not Reported |                |
|                                                                                                         | Acthar         |                    |                    | S               |                                                      |                      |                 | Not Reported |                |
|                                                                                                         | Cymbalta       |                    |                    | S               |                                                      |                      |                 | Not Reported |                |
|                                                                                                         | Nuvigil        |                    |                    | S               |                                                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Feb-2017                                                                                             | 13253483       | NON-EXPEDITED      |                    |                 | US-ACADIA<br>PHARMACEUTICALS<br>INC.-ACA-2017-001857 |                      | 61 YR           | Female       | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                 | <u>Product</u>                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                                                                               | <u>Duration</u> | <u>Mfr</u>                |                |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|--------------------|--------------------|-----------------|------------------------------|--------------------------------------------------------------------------------------------------|-----------------|---------------------------|----------------|
| Agitation; Anxiety;<br>Dizziness; Drug<br>Interaction                                                                                                                                                                                                                                 | Nuplazid                                    |                    |                    | S               | Oral                         | 34 Mg, Qd                                                                                        |                 | Acadia<br>Pharmaceuticals |                |
|                                                                                                                                                                                                                                                                                       | Lexapro                                     |                    |                    | S               |                              |                                                                                                  |                 | Not Reported              |                |
|                                                                                                                                                                                                                                                                                       | Azilect                                     |                    |                    | C               | Unknown                      | 0.5 Mg, Qd                                                                                       |                 | Not Reported              |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                              | <u>Case #</u>                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                                                                             | <u>Age</u>      | <u>Sex</u>                | <u>Country</u> |
| 20-Feb-2017                                                                                                                                                                                                                                                                           | 13256689                                    | DIRECT             |                    | OT              |                              |                                                                                                  | 20 YR           | Female                    | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                 | <u>Product</u>                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                                                                               | <u>Duration</u> | <u>Mfr</u>                |                |
| Akathisia; Confusional<br>State; Energy Increased;<br>Feeling Jittery;<br>Formication; Hypomania;<br>Impulsive Behaviour;<br>Mania; Restlessness;<br>Sleep Disorder                                                                                                                   | Aripiprazole (Generic Abilify)              |                    |                    | S               | Oral                         |                                                                                                  |                 | Not Reported              |                |
|                                                                                                                                                                                                                                                                                       | Escitalopram (Generic Lexapro)              |                    |                    | S               | Oral                         |                                                                                                  |                 | Not Reported              |                |
|                                                                                                                                                                                                                                                                                       | Fluoxetine (Generic For Prozac)             |                    |                    | C               |                              |                                                                                                  |                 | Not Reported              |                |
|                                                                                                                                                                                                                                                                                       | Gabapentin (Generic For<br>Neurontin)       |                    |                    | C               |                              |                                                                                                  |                 | Not Reported              |                |
|                                                                                                                                                                                                                                                                                       | Dexmethylphenidate (Generic<br>For Focalin) |                    |                    | C               |                              |                                                                                                  |                 | Not Reported              |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                              | <u>Case #</u>                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                                                                             | <u>Age</u>      | <u>Sex</u>                | <u>Country</u> |
| 21-Feb-2017                                                                                                                                                                                                                                                                           | 9688626                                     | EXPEDITED (15-DAY) |                    | OT              | BR-PFIZER INC-<br>2013314534 |                                                                                                  | 63 YR           | Female                    | BRA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                 | <u>Product</u>                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                                                                               | <u>Duration</u> | <u>Mfr</u>                |                |
| Agitation; Bradycardia;<br>Confusional State; Drug<br>Ineffective; Dry Mouth;<br>Extrasystoles; Fear;<br>Feeling Abnormal;<br>Headache; Loss Of<br>Consciousness; Migraine;<br>Orthostatic Hypotension;<br>Palpitations; Photopsia;<br>Retinal Tear; Somnolence;<br>Vitreous Disorder | Frontal                                     |                    |                    | S               | Oral                         | 1.5 Mg, Daily                                                                                    |                 | Pfizer                    |                |
|                                                                                                                                                                                                                                                                                       | Frontal                                     |                    |                    | S               | Oral                         | 1mg, Daily (Half Tablet<br>(0.5mg) At Lunch Time<br>And Another Half Tablet<br>(0.5mg) At Night) |                 | Pfizer                    |                |
|                                                                                                                                                                                                                                                                                       | Lexapro                                     |                    |                    | S               |                              |                                                                                                  |                 | Not Reported              |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                        | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|--------------------|--------------------|-----------------|---------------------------------------------|----------------------|-----------------|------------------|----------------|
| 21-Feb-2017                                                                                                                                                                                                     | 13135562                                  | EXPEDITED (15-DAY) |                    | HO              | IT-ABBVIE-17P-083-1847855-00                |                      | 22 YR           | Female           | ITA            |
| <u>Preferred Term</u>                                                                                                                                                                                           | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |
| Intentional Overdose;<br>Intentional Self-Injury;<br>Overdose; Sopor                                                                                                                                            | Depakine Chrono                           |                    |                    | S               | Oral                                        |                      |                 | Not Reported     |                |
|                                                                                                                                                                                                                 | Depakine Chrono                           |                    |                    | S               |                                             |                      |                 | Not Reported     |                |
|                                                                                                                                                                                                                 | Depakine Chrono                           |                    |                    | S               |                                             |                      |                 | Not Reported     |                |
|                                                                                                                                                                                                                 | Escitalopram Oxalate                      |                    |                    | S               | Oral                                        |                      |                 | Not Reported     |                |
|                                                                                                                                                                                                                 | Escitalopram Oxalate                      |                    |                    | S               |                                             |                      |                 | Not Reported     |                |
|                                                                                                                                                                                                                 | Escitalopram Oxalate                      |                    |                    | S               |                                             |                      |                 | Not Reported     |                |
|                                                                                                                                                                                                                 | Lexotan (Bromazepam) Oral Drops, Solution |                    |                    | S               | Oral                                        |                      |                 | Not Reported     |                |
|                                                                                                                                                                                                                 | Lexotan (Bromazepam) Oral Drops, Solution |                    |                    | S               |                                             |                      |                 | Not Reported     |                |
|                                                                                                                                                                                                                 | Lexotan (Bromazepam) Oral Drops, Solution |                    |                    | S               |                                             |                      |                 | Not Reported     |                |
|                                                                                                                                                                                                                 | Lexotan (Bromazepam) Oral Drops, Solution |                    |                    | S               |                                             |                      |                 | Not Reported     |                |
| <u>FDA Received Date</u>                                                                                                                                                                                        | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 21-Feb-2017                                                                                                                                                                                                     | 13255508                                  | EXPEDITED (15-DAY) |                    | HO, LT, OT      | TR-ELI_LILLY_AND_COMP<br>ANY-TR201702007439 |                      | 24 YR           | Female           | TUR            |
| <u>Preferred Term</u>                                                                                                                                                                                           | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |
| Acidosis; Coma;<br>Hypercapnia;<br>Hypernatraemia;<br>Hypocalcaemia;<br>Intentional Overdose;<br>Leukopenia; Respiratory Depression; Sinus Tachycardia; Somnolence; Suicide Attempt; Toxicity To Various Agents | Olanzapine                                |                    |                    | S               | Oral                                        | Unk, Unknown         |                 | Eli Lilly And Co |                |
|                                                                                                                                                                                                                 | Fluoxetine Hydrochloride                  |                    |                    | S               | Oral                                        | Unk, Unknown         |                 | Eli Lilly And Co |                |
|                                                                                                                                                                                                                 | Escitalopram                              |                    |                    | S               | Oral                                        | Unk, Unknown         |                 | Not Reported     |                |
|                                                                                                                                                                                                                 | Valproic Acid                             |                    |                    | S               | Oral                                        | Unk, Unknown         |                 | Not Reported     |                |
| <u>FDA Received Date</u>                                                                                                                                                                                        | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 21-Feb-2017                                                                                                                                                                                                     | 13255728                                  | EXPEDITED (15-DAY) |                    | OT              | FR-ASTRAZENECA-2017SE18910                  |                      | 31 YR           | Male             | FRA            |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                           | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
| Compulsive Shopping;<br>Diffuse Alopecia; Erection<br>Increased; Hypersexuality                 | Xeroquel                  |                    |                    | S               | Oral                      |                      |                 | Astrazeneca  |                |
|                                                                                                 | Seroplex                  |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                        | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Feb-2017                                                                                     | 13256325                  | DIRECT             | Y                  | HO, RI          |                           |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                                           | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Haematocrit Decreased;<br>Haemoglobin Decreased;<br>International Normalised<br>Ratio Increased | Warfarin                  |                    |                    | S               |                           |                      |                 | Not Reported |                |
|                                                                                                 | Escitalopram              |                    |                    | S               |                           |                      |                 | Not Reported |                |
|                                                                                                 | Atorvastatin              |                    |                    | S               |                           |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                        | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Feb-2017                                                                                     | 13257020                  | EXPEDITED (15-DAY) |                    | DE              | CA-ALLERGAN-<br>1706365US |                      | 54 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                                                           | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Death                                                                                           | Escitalopram Oxalate - Bp |                    |                    | S               | Unknown                   | 20 Mg                |                 | Allergan     |                |
| <u>FDA Received Date</u>                                                                        | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Feb-2017                                                                                     | 13257775                  | EXPEDITED (15-DAY) |                    | HO              | JP-ALLERGAN-<br>1706543US |                      |                 | Unknown      | JPN            |
| <u>Preferred Term</u>                                                                           | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Nausea; Overdose;<br>Pyrexia; Somnolence                                                        | Escitalopram Oxalate - Bp |                    |                    | S               | Oral                      | 28 Df, Unk           |                 | Allergan     |                |
| <u>FDA Received Date</u>                                                                        | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Feb-2017                                                                                     | 13257896                  | EXPEDITED (15-DAY) |                    | OT              | PHEH2017US004537          |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                           | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Amnesia; Cognitive<br>Disorder; Condition                                                       | Gilenya                   |                    |                    | S               | Unknown                   |                      |                 | Novartis     |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                               |            |   |                                       |                                                  |  |  |  |              |
|-------------------------------------------------------------------------------------------------------------------------------|------------|---|---------------------------------------|--------------------------------------------------|--|--|--|--------------|
| Aggravated; Confusional State; Deafness; Hemiparesis; Hemiplegia; Irritability; Lip Swelling; Somnolence; Tinnitus; Urticaria | Ampyra     | S | Unknown                               |                                                  |  |  |  | Not Reported |
|                                                                                                                               | Tysabri    | S | Intravenous (not otherwise specified) | 300 Mg Infused Over One Hour Every 4 Weeks (Qw4) |  |  |  | Not Reported |
|                                                                                                                               | Copaxone   | S | Unknown                               |                                                  |  |  |  | Not Reported |
|                                                                                                                               | Solumedrol | S | Unknown                               |                                                  |  |  |  | Not Reported |
|                                                                                                                               | Acthar     | S | Unknown                               |                                                  |  |  |  | Not Reported |
|                                                                                                                               | Lexapro    | S | Unknown                               |                                                  |  |  |  | Not Reported |
|                                                                                                                               | Cymbalta   | S | Unknown                               |                                                  |  |  |  | Not Reported |
|                                                                                                                               | Nuvigil    | S | Unknown                               |                                                  |  |  |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 21-Feb-2017              | 13258104      | EXPEDITED (15-DAY) |                    | HO              | FI-ALLERGAN-1706362US |                      | 45 YR      | Female     | FIN            |

| <u>Preferred Term</u>                                                              | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|------------------------------------------------------------------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Hereditary Angioedema; Swelling; Swelling Face; Swelling Of Eyelid; Swollen Tongue | Escitalopram Oxalate - Bp |              |            | S           | Oral         |                    |                 | Allergan   |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Feb-2017              | 13262995      | DIRECT           | Y                  | OT              |                      |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                    | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------|-------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Depression; Drug Ineffective; Product Substitution Issue | Escitalopram 20mg |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 22-Feb-2017              | 10453352      | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2014255004 |                      | 49 YR      | Female     | USA            |

| <u>Preferred Term</u>       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Drug Ineffective; Dry Skin; | Pristiq        |              |            | S           |              | 50 Mg, Unk         |                 | Pfizer     |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                         |                                                                                                                                                                                                                                               |                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                                      |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Feeling Abnormal;<br>Fibromyalgia;<br>Gastroesophageal Reflux<br>Disease; Inflammation;<br>Intentional Product<br>Misuse; Neuropathy<br>Peripheral; Osteoarthritis;<br>Skin Lesion; Weight<br>Increased | Pristiq<br>Pristiq<br>Fluconazole<br>Gabapentin<br>Protonix<br>Zoloft<br>Lexapro<br>Lexapro<br>Buspirone<br>Ativan<br><br>Robaxin<br>Robaxin<br>Trazodone<br>Celexa<br>Wellbutrin<br>Cymbalta<br>Tramadol<br><br>Meloxicam<br><br>Doxycycline | S<br>S<br>S<br>S<br>S<br>S<br>S<br>S<br>S<br>S<br><br>S<br>S<br>S<br>S<br>S<br>S<br>S<br><br>S<br><br>C | 100 Mg, Unk<br>100 Mg, 1x/Day<br>100 Mg, As Needed (1 In 1<br>As Required)<br>100 Mg, 3x/Day<br>40 Mg, 1x/Day<br>Unk<br>10 Mg, Unk<br>20 Mg, 1x/Day<br>7.5 Mg, 2x/Day<br>Unk, As Needed (1.0<br>(Units Not Reported) As<br>Needed)<br>Unk, Daily 500 Mg<br>(Muscles)<br>500 Mg, Unk (1 To 3 Daily)<br>50 Mg, Unk (1 To 2)<br>Unk<br>Unk<br>Unk<br>50 Mg, As Needed (1/2 To<br>2 Needed Per Day )<br>15 Mg, 1x/Day (1 Per Day<br>At Night ) (1 In 1 Pm)<br>100 Mg, Unk | Pfizer<br>Pfizer<br>Pfizer<br>Pfizer<br>Pfizer<br>Pfizer<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br><br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br><br>Not Reported<br><br>Not Reported |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u>   | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|-----------------|------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|------------|----------------|
| 22-Feb-2017              | 13259302        | NON-EXPEDITED    |                    |                 | US-PFIZER INC-<br>2017071143 |                      | 49 YR           | Female     | USA            |
| <u>Preferred Term</u>    | <u>Product</u>  | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Hypersensitivity    | Clindamycin Hcl |                  |                    | S               |                              | Unk                  |                 | Pfizer     |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                    |   |     |              |
|--------------------|---|-----|--------------|
| Vancomycin Hcl     | S | Unk | Pfizer       |
| Daptomycin         | S | Unk | Unknown      |
| Clarithromycin     | S | Unk | Not Reported |
| Zinacef /00454601/ | S | Unk | Not Reported |
| Lexapro            | S | Unk | Not Reported |
| Nortriptyline      | S | Unk | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Feb-2017              | 13264505      | DIRECT           |                    | OT              |                      |                      | 17 YR      | Female     | USA            |

| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|----------------|--------------|------------|-------------|--------------|-----------------------|-----------------|--------------|
| Abdominal Pain Upper;      | Zoloft         |              |            | S           | Oral         | Quantity:1 Tablet(S); |                 | Not Reported |
| Abnormal Behaviour; Drug   | Lexapro        |              |            | S           | Oral         | Quantity:1 Tablet(S); |                 | Not Reported |
| Ineffective; Feeding       | Probiotic      |              |            | C           |              |                       |                 | Not Reported |
| Disorder; Feeling          | Vitamin D3     |              |            | C           |              |                       |                 | Not Reported |
| Abnormal; Gastrointestinal |                |              |            |             |              |                       |                 |              |
| Disorder; Hallucination;   |                |              |            |             |              |                       |                 |              |
| Hyperhidrosis;             |                |              |            |             |              |                       |                 |              |
| Hyperphagia;               |                |              |            |             |              |                       |                 |              |
| Hypoaesthesia; Malaise;    |                |              |            |             |              |                       |                 |              |
| Muscle Twitching;          |                |              |            |             |              |                       |                 |              |
| Mydriasis; Nightmare;      |                |              |            |             |              |                       |                 |              |
| Palpitations; Vomiting;    |                |              |            |             |              |                       |                 |              |
| Weight Increased           |                |              |            |             |              |                       |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 23-Feb-2017              | 13266097      | EXPEDITED (15-DAY) |                    | HO              | FR-PFIZER INC-2017073739 |                      | 82 YR      | Male       | FRA            |

| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Condition Aggravated;     | Xanax          |              |            | S           | Oral         | 0.25 Mg, 1x/Day    |                 | Pfizer       |
| Decreased Appetite;       | Seroplex       |              |            | S           |              | Unk                |                 | Not Reported |
| Hypokinesia; Loss Of      | Anexate        |              |            | S           |              |                    |                 | Not Reported |
| Personal Independence In  | Digoxin        |              |            | S           |              |                    |                 | Not Reported |
| Daily Activities; Morose; |                |              |            |             |              |                    |                 |              |
| Mutism; Nausea;           |                |              |            |             |              |                    |                 |              |
| Overdose; Psychomotor     |                |              |            |             |              |                    |                 |              |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                       |                                  |                    |                    |                 |                      |                       |                 |              |                |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|--------------------|--------------------|-----------------|----------------------|-----------------------|-----------------|--------------|----------------|
| Skills Impaired                                                                                                                                                       |                                  |                    |                    |                 |                      |                       |                 |              |                |
| <u>FDA Received Date</u>                                                                                                                                              | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Feb-2017                                                                                                                                                           | 13267118                         | DIRECT             |                    | LT              |                      |                       | 37 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                 | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;<br>Dyspnoea; Gait Inability;<br>Hyperhidrosis; Muscle<br>Twitching; Mydriasis;<br>Paraesthesia; Tremor;<br>Visual Impairment                        | Lexapro                          |                    |                    | S               | Oral                 | Quantity:1 Tablet(S); |                 | Not Reported |                |
|                                                                                                                                                                       | Buspar                           |                    |                    | S               |                      |                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                              | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Feb-2017                                                                                                                                                           | 13269120                         | EXPEDITED (15-DAY) |                    | DE              | US-LPDUSPRD-20170195 |                       | 4 DAY           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                 | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Failure;<br>Congestive<br>Cardiomyopathy; Foetal<br>Exposure During<br>Pregnancy; Human<br>Herpesvirus 6 Infection;<br>Multiple Organ<br>Dysfunction Syndrome | Progesterone Injection (0750-01) |                    |                    | S               | Transplacental       | Dose Unknown          |                 | Luitpold     |                |
|                                                                                                                                                                       | Ondansetron Injection (4420-01)  |                    |                    | S               | Transplacental       | Dose Unknown          |                 | Luitpold     |                |
|                                                                                                                                                                       | Sertraline                       |                    |                    | S               | Transplacental       | Dose Unknown          |                 | Not Reported |                |
|                                                                                                                                                                       | Escitalopram                     |                    |                    | S               | Transplacental       | Dose Unknown          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                              | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Feb-2017                                                                                                                                                           | 13269457                         | EXPEDITED (15-DAY) |                    | OT              | US-LPDUSPRD-20170198 |                       |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                 | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Exposure During<br>Pregnancy; Human<br>Herpesvirus 6 Infection                                                                                                        | Progesterone Injection (0750-01) |                    |                    | S               | Unknown              | Dose Unknown          |                 | Luitpold     |                |
|                                                                                                                                                                       | Ondansetron Injection (4420-01)  |                    |                    | S               | Unknown              | Dose Unknown          |                 | Luitpold     |                |
|                                                                                                                                                                       | Sertraline                       |                    |                    | S               | Unknown              | Dose Unknown          |                 | Not Reported |                |
|                                                                                                                                                                       | Escitalopram                     |                    |                    | S               | Unknown              | Dose Unknown          |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>   | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                              | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------|-------------------------------|--------------------|--------------------|-----------------|---------------------------------------------------|------------------------|-----------------|--------------|----------------|
| 24-Feb-2017                | 13269944                      | NON-EXPEDITED      |                    |                 | US-IMPAX<br>LABORATORIES, INC-<br>2016-IPXL-01976 |                        | 39 YR           | Female       | USA            |
| <u>Preferred Term</u>      | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                      | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Discomfort;      | Mirtazapine Odt               |                    |                    | S               | Unknown                                           |                        |                 | Impax        |                |
| Abdominal Pain Upper;      | Baclofen                      |                    |                    | S               | Unknown                                           |                        |                 | Not Reported |                |
| Adverse Event; Burning     | Citalopram                    |                    |                    | S               | Unknown                                           |                        |                 | Not Reported |                |
| Sensation; Drug            | Eszopiclone                   |                    |                    | S               | Unknown                                           |                        |                 | Not Reported |                |
| Hypersensitivity; Fatigue; | Escitalopram                  |                    |                    | S               | Unknown                                           |                        |                 | Not Reported |                |
| Fatigue; Headache;         | Penicillin (Benzylpenicillin) |                    |                    | S               | Unknown                                           |                        |                 | Not Reported |                |
| Headache; Rash             | Trazodone                     |                    |                    | S               | Unknown                                           |                        |                 | Not Reported |                |
|                            | Zolpidem                      |                    |                    | S               | Unknown                                           |                        |                 | Not Reported |                |
|                            | Lyrica                        |                    |                    | S               | Unknown                                           | 200 Milligram Daily;   |                 | Not Reported |                |
|                            | Daypro                        |                    |                    | S               | Unknown                                           |                        |                 | Not Reported |                |
|                            | Levoxyl                       |                    |                    | S               | Unknown                                           |                        |                 | Not Reported |                |
|                            | Protonix /01263204/           |                    |                    | S               | Unknown                                           |                        |                 | Not Reported |                |
|                            | Zithromax                     |                    |                    | S               | Unknown                                           |                        |                 | Not Reported |                |
|                            | Synthroid                     |                    |                    | S               | Unknown                                           |                        |                 | Not Reported |                |
|                            | Tegretol                      |                    |                    | S               | Unknown                                           |                        |                 | Not Reported |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                              | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Feb-2017                | 13272574                      | DIRECT             |                    |                 |                                                   |                        | 52 YR           | Male         | USA            |
| <u>Preferred Term</u>      | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                      | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Pollakiuria; Somnolence;   | Escitalopram - 20mg           |                    |                    | S               | Oral                                              | Quantity:30 Tablet(S); |                 | Accord       |                |
| Tinnitus; Vision Blurred   |                               |                    |                    |                 |                                                   |                        |                 |              |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                              | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Feb-2017                | 11941084                      | EXPEDITED (15-DAY) |                    | OT              | US-ABBVIE-16K-163-<br>1543592-00                  |                        |                 | Male         | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                    | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|----------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Abdominal Pain Upper;<br>Abdominal Pain Upper;<br>Fatigue; Fatigue;<br>Gastrointestinal<br>Inflammation; Headache;<br>Pseudopolyp; Rectal<br>Haemorrhage | Humira                   |                    |                    | S               | Subcutaneous         |                      |                 | Not Reported |                |
|                                                                                                                                                          | Humira                   |                    |                    | S               | Subcutaneous         |                      |                 | Not Reported |                |
|                                                                                                                                                          | Humira                   |                    |                    | S               | Subcutaneous         |                      |                 | Not Reported |                |
|                                                                                                                                                          | Humira                   |                    |                    | S               | Subcutaneous         |                      |                 | Not Reported |                |
|                                                                                                                                                          | Escitalopram             |                    |                    | S               | Unknown              |                      |                 | Not Reported |                |
|                                                                                                                                                          | Escitalopram             |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                          | Cyproheptadine           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                          | Wellbutrin               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                          | Wellbutrin               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                          | Vitamin B12              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                          | Culturelle               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                          | Vitamin D3               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                          | Melatonin                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                          | Multivitamin             |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                          | Probiotic                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                          | Cyproheptad              |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                 | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Feb-2017                                                                                                                                              | 12925498                 | EXPEDITED (15-DAY) |                    | HO              | US-SA-2016SA159206   |                      | 73 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                    | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Failure; Chronic<br>Obstructive Pulmonary<br>Disease; Panic Attack;<br>Product Dose Omission;<br>Renal Disorder; Tremor                          | Praluent                 |                    |                    | S               | Unknown              |                      |                 | Not Reported |                |
|                                                                                                                                                          | Praluent                 |                    |                    | S               | Unknown              |                      |                 | Not Reported |                |
|                                                                                                                                                          | Praluent                 |                    |                    | S               | Unknown              |                      |                 | Not Reported |                |
|                                                                                                                                                          | Lexapro                  |                    |                    | S               | Unknown              |                      |                 | Not Reported |                |
|                                                                                                                                                          | Alirocumab Prefilled Pen |                    |                    | C               | Unknown              |                      |                 | Not Reported |                |
|                                                                                                                                                          | Alirocumab Prefilled Pen |                    |                    | C               | Unknown              |                      |                 | Not Reported |                |
|                                                                                                                                                          | Alirocumab Prefilled Pen |                    |                    | C               | Unknown              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                 | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Feb-2017                                                                                                                                              | 13110634                 | EXPEDITED (15-DAY) |                    | OT              | IT-TEVA-728395ACC    |                      |                 | Unknown      | FIN            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                | <u>Product</u>                                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
|------------------------------------------------------|------------------------------------------------------------|--------------------|--------------------|-----------------|-----------------------|-------------------------|-----------------|--------------|----------------|
| Speech Disorder                                      | Fluoxetine                                                 |                    |                    | S               |                       |                         |                 | Barr         |                |
|                                                      | Citalopram                                                 |                    |                    | S               |                       |                         |                 | Pliva        |                |
|                                                      | Sertraline                                                 |                    |                    | S               |                       |                         |                 | Not Reported |                |
|                                                      | Paroxetine                                                 |                    |                    | S               |                       |                         |                 | Not Reported |                |
|                                                      | Fluvoxamine                                                |                    |                    | S               |                       |                         |                 | Not Reported |                |
|                                                      | Escitalopram                                               |                    |                    | S               |                       |                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                             | <u>Case #</u>                                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Feb-2017                                          | 13145570                                                   | EXPEDITED (15-DAY) |                    | HO              | IT-ALLERGAN-1702569US |                         | 22 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                | <u>Product</u>                                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Self-Injury; Overdose; Sopor             | Escitalopram Oxalate - Bp                                  |                    |                    | S               | Oral                  | Overdose: Unknown Dose  |                 | Allergan     |                |
|                                                      | Depakin Chrono 300mg Comprese Rivestite/ Valproic Acid     |                    |                    | S               | Oral                  | Overdose: Unknown Dose. |                 | Not Reported |                |
|                                                      | Lexotan/ Bromazepam                                        |                    |                    | S               | Oral                  | Overdose: Unknown Dose. |                 | Not Reported |                |
|                                                      |                                                            |                    |                    |                 |                       |                         |                 |              |                |
| <u>FDA Received Date</u>                             | <u>Case #</u>                                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Feb-2017                                          | 13151170                                                   | EXPEDITED (15-DAY) |                    | HO              | IT-TEVA-732876ACC     |                         | 22 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                | <u>Product</u>                                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Self-Injury; Overdose; Sopor             | Escitalopram Oxalate                                       |                    |                    | S               | Oral                  | 400 Mg Total            |                 | Ivax         |                |
|                                                      | Depakin Chrono - 300 Mg Comprese Rivestite - Sanofi S.P.A. |                    |                    | S               | Oral                  | 3 G Total               |                 | Not Reported |                |
|                                                      | Lexotan - Roche S.P.A.                                     |                    |                    | S               | Oral                  | 25 Mg Total             |                 | Not Reported |                |
|                                                      |                                                            |                    |                    |                 |                       |                         |                 |              |                |
| <u>FDA Received Date</u>                             | <u>Case #</u>                                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Feb-2017                                          | 13180332                                                   | EXPEDITED (15-DAY) |                    | HO              | ES-ALLERGAN-1703894US |                         | 58 YR           | Male         | ESP            |
| <u>Preferred Term</u>                                | <u>Product</u>                                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Generalised Tonic-Clonic Seizure; Oculogyric Crisis; | Escitalopram Oxalate - Bp                                  |                    |                    | S               | Unknown               | Unk                     |                 | Allergan     |                |



## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                      |               |   |         |     |              |
|--------------------------------------|---------------|---|---------|-----|--------------|
| Partial Seizures; Systemic Infection | Carbamazepine | S | Unknown | Unk | Not Reported |
|                                      | Diazepam      | S | Unknown | Unk | Not Reported |
|                                      | Topiramate    | S | Unknown | Unk | Not Reported |
|                                      | Haloperidol   | S | Unknown | Unk | Not Reported |

| <u>FDA Received Date</u>        | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------|---------------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 27-Feb-2017                     | 13208137                  | EXPEDITED (15-DAY) |                    | OT              | JP-ALLERGAN-1704684US |                      |                 | Unknown      | JPN            |
| <u>Preferred Term</u>           | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain; Seizure; Tremor | Escitalopram Oxalate - Bp |                    |                    | S               | Oral                  | Unk                  |                 | Allergan     |                |
|                                 | Irinotecan Hydrochloride  |                    |                    | S               | Intravenous drip      | Unk                  |                 | Not Reported |                |

| <u>FDA Received Date</u>  | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---------------------------|---------------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|------------|----------------|
| 27-Feb-2017               | 13272270                  | EXPEDITED (15-DAY) |                    | DS              | CN-ALLERGAN-1706771US |                      |                 | Female     | CHN            |
| <u>Preferred Term</u>     | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Asthenia; Spinal Fracture | Escitalopram Oxalate - Bp |                    |                    | S               | Oral                  | 1 Df, Qd             |                 | Allergan   |                |

| <u>FDA Received Date</u>                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------|----------------|--------------------|--------------------|-----------------|-------------------------|----------------------|-----------------|--------------|----------------|
| 27-Feb-2017                              | 13273494       | EXPEDITED (15-DAY) |                    | OT              | ES-TAKEDA-2017TUS004259 |                      | 72 YR           | Male         | ESP            |
| <u>Preferred Term</u>                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Motor Dysfunction; Therapy Non-Responder | Brintellix     |                    |                    | S               | Oral                    | 5 Mg, Qd             |                 | Takeda       |                |
|                                          | Brintellix     |                    |                    | S               | Oral                    | 10 Mg, Qd            |                 | Takeda       |                |
|                                          | Escitalopram   |                    |                    | S               | Oral                    | 10 Mg, Qd            |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 27-Feb-2017              | 13273611       | NON-EXPEDITED    |                    | HO              | DE-TORRENT-00006232  |                      | 45 YR           | Female     | DEU            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                    |                   |   |              |
|--------------------|-------------------|---|--------------|
| Serotonin Syndrome | Quetiapine        | S | Unknown      |
|                    | Lithium Carbonate | S | Unknown      |
|                    | Escitalopram      | S | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 27-Feb-2017              | 13273992      | EXPEDITED (15-DAY) |                    | OT              | NL-ALLERGAN-1706968US |                      |            | Female     | NLD            |

| <u>Preferred Term</u>                           | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-------------------------------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Derealisation;<br>Electrocardiogram<br>Abnormal | Escitalopram Oxalate - Bp |              |            | S           | Oral         | Unk Mg, Unk        |                 | Allergan   |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------------------|----------------------|------------|------------|----------------|
| 27-Feb-2017              | 13274537      | EXPEDITED (15-DAY) |                    | OT              | US-ELI_LILLY_AND_COMP<br>ANY-US201702005908 |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                          | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>       |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|--------------|------------|-------------|---------------------------------------|-----------------------|-----------------|------------------|
| Amnesia; Cognitive Disorder; Condition Aggravated; Confusional State; Deafness; Hemiparesis; Hemiplegia; Irritability; Lip Swelling; Somnolence; Tinnitus; Urticaria | Cymbalta          |              |            | S           | Unknown                               | Unk, Unknown          |                 | Eli Lilly And Co |
|                                                                                                                                                                      | Ampyra            |              |            | S           | Unknown                               | Unk, Unknown          |                 | Not Reported     |
|                                                                                                                                                                      | Tysabri           |              |            | S           | Intravenous (not otherwise specified) | 300 Mg, Monthly (1/M) |                 | Not Reported     |
|                                                                                                                                                                      | Gilenya           |              |            | S           | Unknown                               | Unk, Unknown          |                 | Not Reported     |
|                                                                                                                                                                      | Copaxone          |              |            | S           | Unknown                               | Unk, Unknown          |                 | Not Reported     |
|                                                                                                                                                                      | Solumedrol        |              |            | S           | Unknown                               | Unk, Unknown          |                 | Not Reported     |
|                                                                                                                                                                      | Acthar /00005501/ |              |            | S           | Unknown                               | Unk, Unknown          |                 | Not Reported     |
|                                                                                                                                                                      | Lexapro           |              |            | S           | Unknown                               | Unk, Unknown          |                 | Not Reported     |
|                                                                                                                                                                      | Nuvigil           |              |            | S           | Unknown                               | Unk, Unknown          |                 | Not Reported     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Feb-2017              | 13275843      | DIRECT           |                    |                 |                      |                      | 57 YR      | Unknown    | USA            |

| <u>Preferred Term</u> | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|-------------------|--------------|------------|-------------|--------------|------------------------|-----------------|------------|
| Abnormal Faeces;      | Escitalopram 5 Mg |              |            | S           | Oral         | Quantity:30 Tablet(S); |                 | Lupin      |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                      |               |   |              |
|----------------------|---------------|---|--------------|
| Contusion; Faeces    | Multivitamins | C | Not Reported |
| Discoloured; Feeling | Vitamin B     | C | Not Reported |
| Abnormal; Gingival   | Vitamin C     | C | Not Reported |
| Bleeding; Middle     | Vitamin E     | C | Not Reported |
| Insomnia; Pain In    |               |   |              |
| Extremity; Pain In   |               |   |              |
| Extremity; Product   |               |   |              |
| Substitution Issue   |               |   |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Feb-2017              | 12611322      | EXPEDITED (15-DAY) |                    | OT              | CA-FRI-1000086501    |                      | 59 YR      | Female     | CAN            |

| <u>Preferred Term</u>           | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Eye Pain; Headache; Pain In Jaw | Escitalopram Oxalate - Bp |              |            | S           | Oral         | 5 Mg, Qd           |                 | Allergan     |
|                                 | Escitalopram Oxalate - Bp |              |            | S           | Oral         | 10 Mg, Qd          |                 | Allergan     |
|                                 | Zopiclone                 |              |            | C           |              | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 28-Feb-2017              | 13119912      | EXPEDITED (15-DAY) |                    | HO              | US-CIPLA LTD.-2017US00593 |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>                                        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Asthenia; Dizziness; Drug Ineffective; Loss Of Consciousness | Bupropion      |              |            | S           | Unknown      | Unk, Far Farm      |                 | Invagen      |
|                                                              | Bupropion      |              |            | S           | Oral         | 150 Mg, Qd         |                 | Invagen      |
|                                                              | Escitalopram   |              |            | S           | Unknown      | 10 Mg, Qd          |                 | Invagen      |
|                                                              | Losartan       |              |            | S           | Unknown      | 25 Mg, Qd          |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 28-Feb-2017              | 13266444      | EXPEDITED (15-DAY) |                    | DS              | IT-MYLANLABS-2017M1011711 |                      |            | Unknown    | ITA            |

| <u>Preferred Term</u>                                         | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---------------------------------------------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Depression; Product Quality Issue; Product Substitution Issue | Escitalopram Mylan Pharma |              |            | S           | Oral         | Unk                |                 | Mylan      |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                   | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------|---------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
| 28-Feb-2017                                | 13276939                  | NON-EXPEDITED      |                    | OT              | DE-TORRENT-00006251       |                      | 45 YR           | Female       | DEU            |
| <u>Preferred Term</u>                      | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Suicidal Behaviour                         | Escitalopram              |                    |                    | S               |                           |                      |                 | Unknown      |                |
|                                            | Mirtazapine               |                    |                    | S               |                           |                      |                 | Unknown      |                |
|                                            | Quetiapine                |                    |                    | S               |                           |                      |                 | Unknown      |                |
|                                            | Lorazepam                 |                    |                    | S               |                           |                      |                 | Unknown      |                |
|                                            | Ethanol                   |                    |                    | S               |                           |                      |                 | Unknown      |                |
| <u>FDA Received Date</u>                   | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Feb-2017                                | 13278455                  | EXPEDITED (15-DAY) |                    | OT              | ES-ALLERGAN-1707196US     |                      | 72 YR           | Male         | ESP            |
| <u>Preferred Term</u>                      | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective; Motor Dysfunction        | Escitalopram Oxalate - Bp |                    |                    | S               | Oral                      | 10 Mg, Qd            |                 | Allergan     |                |
|                                            | Vortioxetine              |                    |                    | S               | Oral                      | 10 Mg, Qd            |                 | Not Reported |                |
|                                            | Vortioxetine              |                    |                    | S               | Oral                      | 5 Mg, Qd             |                 | Not Reported |                |
| <u>FDA Received Date</u>                   | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Feb-2017                                | 13278458                  | EXPEDITED (15-DAY) |                    | OT              | TR-ALLERGAN-1707215US     |                      | 37 YR           | Female       | TUR            |
| <u>Preferred Term</u>                      | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Arrhythmia; Night Sweats; Weight Increased | Escitalopram Oxalate - Bp |                    |                    | S               | Oral                      | 20 Mg, Qd            |                 | Allergan     |                |
|                                            | Seroquel                  |                    |                    | C               | Unknown                   |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                   | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Feb-2017                                | 13278519                  | EXPEDITED (15-DAY) |                    | OT              | ES-MYLANLABS-2017M1011599 |                      |                 | Unknown      | ESP            |
| <u>Preferred Term</u>                      | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Sialoadenitis            | Ondansetron               |                    |                    | S               | Unknown                   |                      |                 | Not Reported |                |
|                                            | Escitalopram              |                    |                    | S               | Unknown                   |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|               |   |         |       |
|---------------|---|---------|-------|
| Temozolomide  | C | Unknown | Mylan |
| Levetiracetam | C | Unknown | Mylan |
| Dexamethasone | C | Unknown | Mylan |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 28-Feb-2017              | 13278695      | EXPEDITED (15-DAY) |                    | HO, OT          | IT-ABBVIE-17P-083-1890789-00 |                      | 46 YR      | Female     | ITA            |

| <u>Preferred Term</u>                                                                              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Abuse; Intentional Overdose; Lactic Acidosis; Metabolic Disorder; Neurological Decompensation | Depakin Chrono |              |            | S           | Oral         | Extended Release   |                 | Not Reported |
|                                                                                                    | Tegretol       |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                    | Ciprallex      |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                    | Seroquel       |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Feb-2017              | 13280026      | DIRECT           | Y                  | OT              |                      |                      | 50 YR      | Female     | USA            |

| <u>Preferred Term</u>                        | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------|-------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Panic Attack; Therapy Non-Responder | Escitalopram 10mg |              |            | S           | Oral         |                    |                 | Not Reported |
|                                              | Celexa 20mg       |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Mar-2017              | 12600703      | EXPEDITED (15-DAY) |                    |                 | CA-FRI-1000086484    |                      | 44 YR      | Female     | CAN            |

| <u>Preferred Term</u>               | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Heart Rate Irregular; Off Label Use | Escitalopram Oxalate - Bp |              |            | S           | Oral         | 10 Mg, Qd          |                 | Allergan     |
|                                     | Trazodone                 |              |            | C           | Unknown      | 25 Mg, Qhs         |                 | Not Reported |
|                                     | Valtrex                   |              |            | C           | Unknown      | 1000 Mg, Prn       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 01-Mar-2017              | 13082369      | EXPEDITED (15-DAY) |                    | LT              | IT-MYLANLABS-2016M1058666 |                      |            | Unknown    | ITA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|--------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Depressed Level Of Consciousness; Labelled Drug-Drug Interaction Medication Error; Musculoskeletal Stiffness; Rhabdomyolysis; Tremor | Escitalopram         |                    |                    | S               |                      | Unk                  |                 | Not Reported |                |
|                                                                                                                                      | Lithium              |                    |                    | S               |                      | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                             | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Mar-2017                                                                                                                          | 13160933             | EXPEDITED (15-DAY) |                    | HO              | IT-ACCORD-047632     |                      | 22 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                                                                                | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Self-Injury; Overdose; Sopor                                                                                             | Escitalopram         |                    |                    | S               | Oral                 |                      |                 | Accord       |                |
|                                                                                                                                      | Depakin Chrono       |                    |                    | S               | Oral                 | Strength: 300 Mg     |                 | Not Reported |                |
|                                                                                                                                      | Lexotan Roche        |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                             | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Mar-2017                                                                                                                          | 13282175             | EXPEDITED (15-DAY) |                    | OT              | BR-ROCHE-1899600     |                      | 18 YR           | Male         | BRA            |
| <u>Preferred Term</u>                                                                                                                | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Feeling Of Despair; Loss Of Consciousness; Mood Swings; Overdose; Suicide Attempt                                                    | Rivotril             |                    |                    | S               | Unknown              |                      |                 | Not Reported |                |
|                                                                                                                                      | Escitalopram Oxalate |                    |                    | S               | Unknown              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                             | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Mar-2017                                                                                                                          | 13286337             | EXPEDITED (15-DAY) |                    | OT              | PHHY2017BR027679     |                      |                 | Female       | BRA            |
| <u>Preferred Term</u>                                                                                                                | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Drug Ineffective; Fatigue; Incorrect Dose Administered; Pain; Tremor; Vertigo                                             | Razapina             |                    |                    | S               | Unknown              | 15 Mg, Unk           |                 | Novartis     |                |
|                                                                                                                                      | Citalopram           |                    |                    | S               | Unknown              |                      |                 | Not Reported |                |
|                                                                                                                                      | Amitriptyline        |                    |                    | S               | Unknown              | 75 Mg, Unk           |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| Exodus//Escitalopram Oxalate                                                                                                                                                 |                           |                    | S                  |                 | Unknown                               |                         |                 | Not Reported |                |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|---------------------------------------|-------------------------|-----------------|--------------|----------------|
| <u>FDA Received Date</u>                                                                                                                                                     | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Mar-2017                                                                                                                                                                  | 12600704                  | EXPEDITED (15-DAY) |                    | HO, OT          | CA-FRI-1000086487                     |                         | 28 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                                                                                                                                        | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Amniotic Fluid Volume Decreased; Drug Hypersensitivity; Gestational Diabetes; Gestational Hypertension; Haematochezia; Mucous Stools; Nausea; Pregnancy; Sinusitis; Vomiting | Escitalopram Oxalate - Bp |                    |                    | S               | Unknown                               | Unk                     |                 | Allergan     |                |
|                                                                                                                                                                              | Remicade                  |                    |                    | S               | Intravenous (not otherwise specified) | 400 Mg, Every Six Weeks |                 | Not Reported |                |
|                                                                                                                                                                              | Ergocalciferol            |                    |                    | C               | Unknown                               | Unk                     |                 | Not Reported |                |
|                                                                                                                                                                              | Progesterone              |                    |                    | C               | Unknown                               | Unk                     |                 | Not Reported |                |
|                                                                                                                                                                              | Vitamin B12               |                    |                    | C               | Other                                 | Unk                     |                 | Not Reported |                |
|                                                                                                                                                                              | Prometrium                |                    |                    | C               | Unknown                               |                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                     | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Mar-2017                                                                                                                                                                  | 13285819                  | NON-EXPEDITED      |                    |                 | US-FRI-1000085998                     |                         | 73 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                        | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Alopecia; Drug Ineffective                                                                                                                                                   | Viibryd                   |                    |                    | S               | Oral                                  | 10 Mg, Qd               |                 | Allergan     |                |
|                                                                                                                                                                              | Lexapro                   |                    |                    | S               | Oral                                  | 20 Mg, Qd               |                 | Allergan     |                |
|                                                                                                                                                                              | Paxil                     |                    |                    | C               | Oral                                  | Unk                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                     | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Mar-2017                                                                                                                                                                  | 13285886                  | NON-EXPEDITED      |                    |                 | US-FRI-1000086173                     |                         | 85 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                        | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Product Misuse; Pruritus Generalised; Pruritus Generalised                                                                                                       | Viibryd                   |                    |                    | S               | Oral                                  | 20 Mg, Qd               |                 | Allergan     |                |
|                                                                                                                                                                              | Viibryd                   |                    |                    | S               | Oral                                  | 20 Mg, Qd               |                 | Allergan     |                |
|                                                                                                                                                                              | Lexapro                   |                    |                    | S               | Oral                                  | 20 Mg, Qd               |                 | Allergan     |                |
|                                                                                                                                                                              | Lexapro                   |                    |                    | S               | Oral                                  | 20 Mg, Qd               |                 | Allergan     |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|               |   |      |             |              |
|---------------|---|------|-------------|--------------|
| Synthroid     | C | Oral | .1 Mg, Qd   | Not Reported |
| Verapamil     | C | Oral | 120 Mg, Qd  | Not Reported |
| Vitamin D Nos | C | Oral | Unk Unk, Qd | Not Reported |
| Iron          | C | Oral | Unk Unk, Qd | Not Reported |
| Metrx         | C |      | Unk Unk, Qd | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Mar-2017              | 13285938      | NON-EXPEDITED    |                    |                 | US-FRI-1000087560    |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|---------------------|-----------------|--------------|
| Arthralgia; Fatigue;<br>Hallucination;<br>Hypokinesia; Influenza<br>Like Illness; Limb<br>Discomfort; Night Sweats;<br>Off Label Use; Pain;<br>Paralysis; Sleep Terror | Viibryd        |              |            | S           | Oral         | 5 Mg - Tapered Dose |                 | Allergan     |
|                                                                                                                                                                        | Lexapro        |              |            | S           | Oral         | Unk                 |                 | Allergan     |
|                                                                                                                                                                        | Gabapentin     |              |            | C           | Ophthalmic   | Unk                 |                 | Not Reported |
|                                                                                                                                                                        | Synthroid      |              |            | C           | Oral         | Unk Unk, Qd         |                 | Not Reported |
|                                                                                                                                                                        | Lidoderm       |              |            | C           | Topical      | Unk, Prn            |                 | Not Reported |
|                                                                                                                                                                        | Oxycontin      |              |            | C           | Oral         | Unk                 |                 | Not Reported |
|                                                                                                                                                                        | Vicodin        |              |            | C           | Oral         | Unk Unk, Prn        |                 | Not Reported |
|                                                                                                                                                                        | Accufex        |              |            | C           | Unknown      | Unk                 |                 | Not Reported |
|                                                                                                                                                                        | Patanase       |              |            | C           | Nasal        | Unk                 |                 | Not Reported |
|                                                                                                                                                                        | Warfarin       |              |            | C           | Oral         | Unk                 |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 02-Mar-2017              | 13287901      | EXPEDITED (15-DAY) |                    | HO, OT          | US-ALLERGAN-1707583US |                      | 66 YR      | Female     | USA            |

| <u>Preferred Term</u>                       | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Arterial Disorder; Breast<br>Cancer; Hernia | Escitalopram Oxalate - Bp |              |            | S           |              | 10 Mg, Qd          |                 | Allergan     |
|                                             | Omeprazole                |              |            | S           |              | 20 Mg, Qd          |                 | Not Reported |
|                                             | Methotrexate              |              |            | S           |              | 2.5 Mg, Qd         |                 | Not Reported |
|                                             | Meloxicam                 |              |            | S           |              | 15 Mg, Qd          |                 | Not Reported |
|                                             | Xeljanz                   |              |            | S           |              | 10 Mg, Bid         |                 | Not Reported |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                                                                 | <u>Case #</u>                                                                                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>                               | <u>Mfr Control #</u>                                                       | <u>503B Facility</u>                                                                                                                    | <u>Age</u>      | <u>Sex</u>                                                                                                                       | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------|--------------------|--------------------|-----------------------------------------------|----------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------|-----------------|----------------------------------------------------------------------------------------------------------------------------------|----------------|
| 02-Mar-2017                                                                                                                                                                                                                                              | 13287906                                                                                                   | EXPEDITED (15-DAY) |                    | OT                                            | ES-IPCA<br>LABORATORIES<br>LIMITED-IPC201702-<br>000085                    |                                                                                                                                         | 28 YR           | Female                                                                                                                           | ESP            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                    | <u>Product</u>                                                                                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                                   | <u>Route</u>                                                               | <u>Dosage Text</u>                                                                                                                      | <u>Duration</u> | <u>Mfr</u>                                                                                                                       |                |
| Salivary Gland Calculus;<br>Sialoadenitis                                                                                                                                                                                                                | Ondansetron<br>Temozolomide<br>Dexamethasone<br>Escitalopram<br>Dexamethasone<br>Levetiracetam             |                    |                    | S<br>S<br>S<br>S<br>C<br>C                    |                                                                            |                                                                                                                                         |                 | Ipca<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported                                             |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                 | <u>Case #</u>                                                                                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>                               | <u>Mfr Control #</u>                                                       | <u>503B Facility</u>                                                                                                                    | <u>Age</u>      | <u>Sex</u>                                                                                                                       | <u>Country</u> |
| 02-Mar-2017                                                                                                                                                                                                                                              | 13288410                                                                                                   | EXPEDITED (15-DAY) |                    | OT                                            | US-MALLINCKRODT-<br>T201700673                                             |                                                                                                                                         |                 | Female                                                                                                                           | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                    | <u>Product</u>                                                                                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                                   | <u>Route</u>                                                               | <u>Dosage Text</u>                                                                                                                      | <u>Duration</u> | <u>Mfr</u>                                                                                                                       |                |
| Adverse Event; Amnesia;<br>Cognitive Disorder;<br>Condition Aggravated;<br>Confusional State;<br>Deafness; Gallbladder<br>Operation; Hemiparesis;<br>Hemiplegia; Irritability; Lip<br>Swelling; Somnolence;<br>Tinnitus; Urticaria; Uterine<br>Operation | H P Acthar<br>Ampyra<br>Tysabri<br><br>Gilenya<br>Copaxone<br>Solumedrol<br>Lexapro<br>Cymbalta<br>Nuvigil |                    |                    | S<br>S<br>S<br><br>S<br>S<br>S<br>S<br>S<br>S | <br><br>Unknown<br><br>Unknown<br>Unknown<br>Unknown<br>Unknown<br>Unknown | <br><br>300 Mg Infused Over One<br>Hour Every 4 Week,<br>Concentrate For Solution<br>For Infused<br><br>Unk<br>Unk<br>Unk<br>Unk<br>Unk |                 | Mallinckrodt<br>Not Reported<br>Not Reported<br><br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                 | <u>Case #</u>                                                                                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>                               | <u>Mfr Control #</u>                                                       | <u>503B Facility</u>                                                                                                                    | <u>Age</u>      | <u>Sex</u>                                                                                                                       | <u>Country</u> |
| 02-Mar-2017                                                                                                                                                                                                                                              | 13291192                                                                                                   | DIRECT             |                    | OT                                            |                                                                            |                                                                                                                                         | 70 YR           | Male                                                                                                                             | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                    | <u>Product</u>                                                                                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                                   | <u>Route</u>                                                               | <u>Dosage Text</u>                                                                                                                      | <u>Duration</u> | <u>Mfr</u>                                                                                                                       |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                     |                    |   |      |                        |              |
|-------------------------------------------------------------------------------------|--------------------|---|------|------------------------|--------------|
| Burning Sensation; Chest Discomfort; Hypertension; Palpitations; Serotonin Syndrome | Escitalopram 10 Mg | S | Oral | Quantity:30 Tablet(S); | Unknown      |
|                                                                                     | Metoprolol         | C |      |                        | Not Reported |
|                                                                                     | Fosonopril         | C |      |                        | Not Reported |
|                                                                                     | Aspirin            | C |      |                        | Not Reported |
|                                                                                     | Multi Vitamin      | C |      |                        | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 03-Mar-2017              | 12980497      | EXPEDITED (15-DAY) |                    | OT              | US-ALLERGAN-1677704US |                      | 73 YR      | Female     | USA            |

| <u>Preferred Term</u>                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Brain Injury; Cerebral Disorder; Seizure; Weight Decreased | Lexapro        |              |            | S           | Unknown      | 5 Mg, Qd           |                 | Allergan     |
|                                                            | Lexapro        |              |            | S           | Unknown      | 10 Mg, Qd          |                 | Allergan     |
|                                                            | Lexapro        |              |            | S           | Unknown      | 20 Mg, Qd          |                 | Allergan     |
|                                                            | Vesicare       |              |            | C           |              | 10 Mg, Qd          |                 | Not Reported |
|                                                            | Sertraline     |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 03-Mar-2017              | 13048172      | EXPEDITED (15-DAY) |                    | HO, OT          | PT-MYLANLABS-2016M1056321 |                      |            | Unknown    | PRT            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Carcinoid Syndrome    | Escitalopram   |              |            | S           | Unknown      | 10mg               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 03-Mar-2017              | 13277269      | EXPEDITED (15-DAY) |                    | HO              | IT-ASTRAZENECA-2017SE20183 |                      | 46 YR      | Female     | ITA            |

| <u>Preferred Term</u>                                                        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Abuse; Lactic Acidosis; Metabolic Disorder; Neurological Decompensation | Seroquel       |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                              | Seroquel       |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                              | Seroquel       |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                              | Seroquel       |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                              | Tegretol       |              |            | S           | Oral         |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|          |   |      |              |
|----------|---|------|--------------|
| Tegretol | S | Oral | Not Reported |
| Tegretol | S | Oral | Not Reported |
| Tegretol | S | Oral | Not Reported |
| Cipralex | S | Oral | Not Reported |
| Cipralex | S | Oral | Not Reported |
| Depakin  | S | Oral | Not Reported |
| Depakin  | S | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 03-Mar-2017              | 13289954      | EXPEDITED (15-DAY) |                    | HO, OT          | US-AMGEN-<br>USASP2017029638 |                      | 63 YR      | Male       | USA            |

| <u>Preferred Term</u>                        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Dyspnoea; Intentional Product Misuse; Nausea | Enbrel         |              |            | S           | Unknown      | Unk                |                 | Amgen        |
|                                              | Enbrel         |              |            | S           | Unknown      | Unk                |                 | Amgen        |
|                                              | Enbrel         |              |            | S           |              |                    |                 | Amgen        |
|                                              | Lexapro        |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                                              | Advair         |              |            | C           |              |                    |                 | Not Reported |
|                                              | Proair         |              |            | C           |              | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------------------------|----------------------|------------|------------|----------------|
| 03-Mar-2017              | 13293955      | EXPEDITED (15-DAY) |                    | DE              | US-LANNETT<br>COMPANY, INC.-US-<br>2017LAN000601 |                      | 4 DAY      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                   | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Congestive Cardiomyopathy; Drug Hypersensitivity; Foetal Exposure During Pregnancy; Multiple Organ Dysfunction Syndrome | Ondansetron          |              |            | S           | Transplacental | Unk                |                 | Lannett      |
|                                                                                                                         | Escitalopram Oxalate |              |            | S           | Transplacental | Unk                |                 | Lannett      |
|                                                                                                                         | Sertraline           |              |            | S           | Transplacental | Unk                |                 | Not Reported |
|                                                                                                                         | Progesterone         |              |            | S           | Transplacental | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|------------|------------|----------------|
| 03-Mar-2017              | 13294120      | EXPEDITED (15-DAY) |                    | OT              | US-LANNETT<br>COMPANY, INC.-US- |                      |            | Female     | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

2017LAN000623

| <u>Preferred Term</u>                                                     | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Hypersensitivity;<br>Exposure During<br>Pregnancy; Herpes<br>Simplex | Ondansetron          |              |            | S           |              | Unk                |                 | Lannett      |
|                                                                           | Escitalopram Oxalate |              |            | S           |              | Unk                |                 | Lannett      |
|                                                                           | Sertraline           |              |            | S           |              | Unk                |                 | Not Reported |
|                                                                           | Progesterone         |              |            | S           |              | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 03-Mar-2017              | 13294389      | EXPEDITED (15-DAY) |                    | HO              | FR-ALLERGAN-1707980US |                      | 78 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                   | <u>Product</u>                                     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------|----------------------------------------------------|--------------|------------|-------------|-----------------------------|--------------------|-----------------|--------------|
| Drug Interaction;<br>Haematemesis; Melaena;<br>Overdose | Escitalopram Oxalate Unk                           |              |            | S           | Oral                        | 15 Mg, Qd          |                 | Allergan     |
|                                                         | Previscan (Fluindione)                             |              |            | S           | Oral                        | 15 Mg, Qd          |                 | Not Reported |
|                                                         | Econazole                                          |              |            | S           | Topical                     |                    |                 | Not Reported |
|                                                         | Daivonex                                           |              |            | C           | Unknown                     |                    |                 | Not Reported |
|                                                         | Diffu K                                            |              |            | C           | Unknown                     |                    |                 | Not Reported |
|                                                         | Doliprane                                          |              |            | C           | Unknown                     |                    |                 | Not Reported |
|                                                         | Eludril (Chlorhexidine<br>Gluconate\Chlorobutanol) |              |            | C           | Oral                        |                    |                 | Not Reported |
|                                                         | Lasilix                                            |              |            | C           | Unknown                     |                    |                 | Not Reported |
|                                                         | Lorazepam                                          |              |            | C           | Oral                        |                    |                 | Not Reported |
|                                                         | Lysanxia                                           |              |            | C           | Oral                        |                    |                 | Not Reported |
|                                                         | Montelukast                                        |              |            | C           | Oral                        |                    |                 | Not Reported |
|                                                         | Oxycontin Lp                                       |              |            | C           | Oral                        |                    |                 | Not Reported |
|                                                         | Oxynormoro                                         |              |            | C           | Oral                        | 5 Mg, Bid          |                 | Not Reported |
|                                                         | Seretide Discus                                    |              |            | C           | Respiratory<br>(inhalation) | 500µg/50µg/Dose    |                 | Not Reported |
|                                                         | Soriatane                                          |              |            | C           | Oral                        |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                   |                          | Theralene          | C                  | Oral                     |                                 |                                     |                 | Not Reported |                |
|-----------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|--------------------------|---------------------------------|-------------------------------------|-----------------|--------------|----------------|
|                                                                                   |                          | Valaciclovir       | C                  | Oral                     |                                 |                                     |                 | Not Reported |                |
|                                                                                   |                          | Ventoline          | C                  | Respiratory (inhalation) | 2 Puffs Every 6 Hours As Needed |                                     |                 | Not Reported |                |
|                                                                                   |                          | Xylocaine          | C                  | Cutaneous                |                                 |                                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                          | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>          | <u>Mfr Control #</u>            | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Mar-2017                                                                       | 13295483                 | EXPEDITED (15-DAY) |                    | HO, LT, OT               | DE-ALLERGAN-1708010US           |                                     | 50 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                                             | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>              | <u>Route</u>                    | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrial Fibrillation; Ventricular Fibrillation                                     | Escitalopram Oxalate Unk |                    |                    | S                        | Unknown                         |                                     |                 | Allergan     |                |
| <u>FDA Received Date</u>                                                          | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>          | <u>Mfr Control #</u>            | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Mar-2017                                                                       | 13295491                 | EXPEDITED (15-DAY) |                    | HO                       | CH-ALLERGAN-1708068US           |                                     | 59 YR           | Male         | CHE            |
| <u>Preferred Term</u>                                                             | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>              | <u>Route</u>                    | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Delusion Of Grandeur; Euphoric Mood; Hostility; Mania; Sleep Disorder | Escitalopram Oxalate Unk |                    |                    | S                        | Oral                            | 20 Mg, Qd                           |                 | Allergan     |                |
|                                                                                   | Trittico                 |                    |                    | S                        | Oral                            |                                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                          | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>          | <u>Mfr Control #</u>            | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Mar-2017                                                                       | 13296138                 | EXPEDITED (15-DAY) |                    | OT                       | US-ACCORD-048633                |                                     | 34 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                             | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>              | <u>Route</u>                    | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Amenorrhoea; Pregnancy Test False Positive                                        | Escitalopram             |                    |                    | S                        |                                 | Started On Escitalopram 10 Mg Daily |                 | Accord       |                |
| <u>FDA Received Date</u>                                                          | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>          | <u>Mfr Control #</u>            | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Mar-2017                                                                       | 13194202                 | EXPEDITED (15-DAY) |                    | HO                       | JP-ALLERGAN-1704394US           |                                     | 23 YR           | Female       | JPN            |
| <u>Preferred Term</u>                                                             | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>              | <u>Route</u>                    | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                          |                                                        |   |      |           |              |
|--------------------------|--------------------------------------------------------|---|------|-----------|--------------|
| Hepatic Function         | Escitalopram Oxalate - Bp                              | S | Oral | 10 Mg, Qd | Allergan     |
| Abnormal; Off Label Use; | Yaz                                                    | C | Oral |           | Not Reported |
| Serotonin Syndrome       | Tsumura Yokukansan Extract<br>Granules For Ethical Use | C | Oral |           | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 06-Mar-2017              | 13298962       | EXPEDITED (15-DAY) |                    | HO              | DE-TEVA-743323GER    |                      |                 | Female       | DEU            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;        | Risperidon     |                    |                    | S               |                      |                      |                 | Teva         |                |
| Galactorrhoea            | Risperidon     |                    |                    | S               |                      |                      |                 | Teva         |                |
|                          | Cipralext      |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                          | Cipralext      |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                          | Aripiprazol    |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>   | <u>Case #</u>     | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------|-------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 06-Mar-2017                | 13301310          | DIRECT           |                    | HO              |                      |                      | 42 YR           | Female       | USA            |
| <u>Preferred Term</u>      | <u>Product</u>    | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Behaviour;        | Escitalopram      |                  |                    | S               | Oral                 |                      |                 | Lundbeck     |                |
| Contusion; Dry Skin; Dry   | Amlodipine        |                  |                    | C               |                      |                      |                 | Not Reported |                |
| Skin; Respiratory Failure; | Vitamin B Complex |                  |                    | C               |                      |                      |                 | Not Reported |                |
| Seizure; Skin Exfoliation; |                   |                  |                    |                 |                      |                      |                 |              |                |
| Thinking Abnormal;         |                   |                  |                    |                 |                      |                      |                 |              |                |
| Tongue Injury; Tremor;     |                   |                  |                    |                 |                      |                      |                 |              |                |
| Visual Impairment; Weight  |                   |                  |                    |                 |                      |                      |                 |              |                |
| Decreased                  |                   |                  |                    |                 |                      |                      |                 |              |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|-------------------------------------|----------------------|-----------------|--------------|----------------|
| 07-Mar-2017              | 12261822       | NON-EXPEDITED    |                    |                 | US-AUROBINDO-AUR-<br>APL-2015-09576 |                      |                 | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity    | Metformin      |                  |                    | S               | Unknown                             |                      |                 | Aurobindo    |                |
|                          | Lexapro        |                  |                    | S               | Unknown                             |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                     | <u>Case #</u>                                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------|---------------------------------------------------|--------------------|--------------------|-----------------|----------------------------|-----------------------|-----------------|--------------|----------------|
| 07-Mar-2017                                                                  | 13061928                                          | EXPEDITED (15-DAY) |                    | HO, OT          | PT-APOTEX-2016AP016121     |                       | 23 YR           | Female       | PRT            |
| <u>Preferred Term</u>                                                        | <u>Product</u>                                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Carcinoid Syndrome; Metastases To Liver                                      | Escitalopram Apotex<br>Comprimidol Orodipersiveis |                    |                    | S               | Unknown                    | 10 Mg, Unk            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                     | <u>Case #</u>                                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Mar-2017                                                                  | 13282251                                          | EXPEDITED (15-DAY) |                    | HO              | PHHY2017IT029673           |                       | 46 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                        | <u>Product</u>                                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Abuse; Lactic Acidosis; Metabolic Disorder; Neurological Decompensation | Tegretol                                          |                    |                    | S               | Oral                       | 90 Df, Unk (Total)    |                 | Novartis     |                |
|                                                                              | Depakin                                           |                    |                    | S               | Oral                       | 20 Df, Unk (Total)    |                 | Not Reported |                |
|                                                                              | Cipralext                                         |                    |                    | S               | Oral                       | 10 Df, Unk (Total)    |                 | Not Reported |                |
|                                                                              | Seroquel                                          |                    |                    | S               | Oral                       | 50 Df, Unk(Total)     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                     | <u>Case #</u>                                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Mar-2017                                                                  | 13301464                                          | EXPEDITED (15-DAY) |                    | HO              | FR-009507513-1703FRA002661 |                       | 77 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                        | <u>Product</u>                                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Acute Kidney Injury                                                          | Sevikar                                           |                    |                    | S               | Oral                       | Unk                   |                 | Not Reported |                |
|                                                                              | Furosemide                                        |                    |                    | S               | Oral                       | Unk                   |                 | Merck        |                |
|                                                                              | Acetaminophen                                     |                    |                    | S               | Oral                       | Unk                   |                 | Not Reported |                |
|                                                                              | Simvastatin                                       |                    |                    | S               | Oral                       | Unk                   |                 | Merck        |                |
|                                                                              | Esomeprazole Magnesium                            |                    |                    | S               | Oral                       | 20 Mg, Qd             |                 | Merck        |                |
|                                                                              | Esomeprazole Magnesium                            |                    |                    | S               | Oral                       | 20 Mg, In The Morning |                 | Merck        |                |
|                                                                              | Metformin                                         |                    |                    | S               | Oral                       | Unk                   |                 | Not Reported |                |
|                                                                              | Amlodipine                                        |                    |                    | S               | Oral                       | Unk                   |                 | Not Reported |                |
|                                                                              | Propranolol                                       |                    |                    | S               | Oral                       | Unk                   |                 | Not Reported |                |
|                                                                              | Naproxen                                          |                    |                    | S               | Oral                       | Unk                   |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                           |   |              |                               |              |
|---------------------------|---|--------------|-------------------------------|--------------|
| Pregabalin                | S | Oral         | Unk                           | Not Reported |
| Escitalopram              | S | Oral         | 10 Mg, Qd                     | Not Reported |
| Escitalopram              | S | Oral         | 10 Mg, In The Evening         | Not Reported |
| Lantus                    | C | Subcutaneous | Unk                           | Not Reported |
| Lantus                    | C | Subcutaneous | 30 Iu, In The Evening         | Not Reported |
| Loprazolam                | C |              | Unk                           | Not Reported |
| Lumirelax (Methocarbamol) | C |              | Unk                           | Not Reported |
| Desloratadine             | C |              | Unk                           | Merck        |
| Levothyrox                | C |              | Unk                           | Not Reported |
| Levothyrox                | C |              | 100 Microgram, In The Morning | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------------------------------------|----------------------|------------|------------|----------------|
| 07-Mar-2017              | 13302146      | EXPEDITED (15-DAY) |                    | DS, OT          | US-ARALEZ<br>PHARMACEUTICALS<br>RD INC.-ARA-TP-US-<br>2017-9 |                      | 77 YR      | Female     | USA            |

| <u>Preferred Term</u>                               | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                |
|-----------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|---------------------------|
| Cerebrovascular Accident;<br>Dysarthria; Hemiplegia | Metoprolol Succinate |              |            | S           | Oral         |                    |                 | Aralez<br>Pharmaceuticals |
|                                                     | Metoprolol Succinate |              |            | S           |              |                    |                 | Aralez<br>Pharmaceuticals |
|                                                     | Lisinopril           |              |            | S           | Oral         |                    |                 | Not Reported              |
|                                                     | Onglyza              |              |            | S           |              |                    |                 | Not Reported              |
|                                                     | Escitalopram         |              |            | S           | Oral         |                    |                 | Not Reported              |
|                                                     | Diltiazem            |              |            | C           | Oral         |                    |                 | Not Reported              |
|                                                     | Digoxin              |              |            | C           | Oral         |                    |                 | Not Reported              |
|                                                     | Furosemide           |              |            | C           | Oral         |                    |                 | Not Reported              |
|                                                     | Gabapentin           |              |            | C           | Oral         |                    |                 | Not Reported              |
|                                                     | Glimepiride          |              |            | C           | Oral         |                    |                 | Not Reported              |
|                                                     | Levothyroxine        |              |            | C           | Oral         |                    |                 | Not Reported              |
|                                                     | Metformin            |              |            | C           | Oral         |                    |                 | Not Reported              |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |                      |   |      |              |
|--|----------------------|---|------|--------------|
|  | Pradaxa              | C | Oral | Not Reported |
|  | Pravastatin          | C | Oral | Not Reported |
|  | Tramadol             | C | Oral | Not Reported |
|  | Potassium Chloride   | C | Oral | Not Reported |
|  | Levemir Flex Insulin | C |      | Not Reported |

| <u>FDA Received Date</u>                             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------|----------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
| 08-Mar-2017                                          | 13142898       | EXPEDITED (15-DAY) |                    | HO              | IT-MYLANLABS-2017M1003749 |                      |                 | Unknown      | ITA            |
| <u>Preferred Term</u>                                | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Abuse; Intentional Self-Injury; Overdose; Sopor | Escitalopram   |                    |                    | S               | Oral                      | 400 Mg, Total        |                 | Not Reported |                |
|                                                      | Depakin Chrono |                    |                    | S               | Oral                      | 3 G, Total           |                 | Mylan        |                |
|                                                      | Lexotan        |                    |                    | S               | Oral                      | 25 Mg, Total         |                 | Mylan        |                |

| <u>FDA Received Date</u>        | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------|----------------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|-----------------|--------------|----------------|
| 08-Mar-2017                     | 13305988             | EXPEDITED (15-DAY) |                    | HO              | DE-AUROBINDO-AUR-APL-2017-30649 |                      |                 | Female       | DEU            |
| <u>Preferred Term</u>           | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Galactorrhoea | Risperidone 4mg      |                    |                    | S               | Oral                            | 4 Mg, Daily          |                 | Aurobindo    |                |
|                                 | Risperidone 4mg      |                    |                    | S               | Oral                            | 2 Mg, Daily          |                 | Aurobindo    |                |
|                                 | Ciprallex /01588501/ |                    |                    | S               | Oral                            | 20 Mg, Daily         |                 | Not Reported |                |
|                                 | Ciprallex /01588501/ |                    |                    | S               | Oral                            | 25 Mg, Daily         |                 | Not Reported |                |
|                                 | Aripiprazol          |                    |                    | C               | Unknown                         | 10 Mg, Daily         |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|-----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 08-Mar-2017              | 13307308              | EXPEDITED (15-DAY) |                    | DE              | ZA-MYLANLABS-2017M1013957 |                      |                 | Unknown    | ZAF            |
| <u>Preferred Term</u>    | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Death                    | Mylan Oxybutynin 5 Mg |                    |                    | S               | Oral                      | 5 Mg, Unk            |                 | Mylan      |                |
|                          | Purgoxin              |                    |                    | S               | Oral                      | 0.25 Mg, Unk         |                 | Mylan      |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                             |   |      |             |       |
|-----------------------------|---|------|-------------|-------|
| Renitec [Enalapril Maleate] | S | Oral | 5 Mg, Unk   | Mylan |
| Carbilev                    | S | Oral | Unk         | Mylan |
| Ecotrin                     | S | Oral | 81 Mg, Unk  | Mylan |
| Celebrex                    | S | Oral | 200 Mg, Unk | Mylan |
| Puricos                     | S | Oral | 100 Mg, Unk | Mylan |
| Vesicare                    | S | Oral | 5 Mg, Unk   | Mylan |
| Lexamil                     | S | Oral | 5 Mg, Unk   | Mylan |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 08-Mar-2017              | 13307515      | EXPEDITED (15-DAY) | HO                 |                 | FR-ALLERGAN-1708877US |                      | 65 YR      | Male       | FRA            |

| <u>Preferred Term</u>                | <u>Product</u>                          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------|-----------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Eosinophilia; Rash<br>Maculo-Papular | Escitalopram Oxalate - Bp               |              |            | S           | Oral         | 20 Mg, Qd          |                 | Allergan     |
|                                      | Dalacine                                |              |            | S           | Oral         | 1800 Mg, Qd        |                 | Not Reported |
|                                      | Fucidine (Fusidic Acid)                 |              |            | S           | Oral         | 1500 Mg, Qd        |                 | Not Reported |
|                                      | Antivitamin-K                           |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                      | Discotrine                              |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                      | Amlor                                   |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                      | Tahor                                   |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                      | Inexium                                 |              |            | C           | Unknown      | Unk                |                 | Not Reported |
|                                      | Triatec (Codeine Phosphate/Paracetamol) |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                      | Lasilix                                 |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                      | Amiodarone                              |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                      | Acupan                                  |              |            | C           | Unknown      | Unk                |                 | Not Reported |
|                                      | Alprazolam                              |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                      | Keppra                                  |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                      | Diffu-K                                 |              |            | C           | Unknown      | Unk                |                 | Not Reported |
|                                      | Lantus                                  |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                      | Speciafoldine                           |              |            | C           | Unknown      |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|             |   |         |              |
|-------------|---|---------|--------------|
| Paracetamol | C | Unknown | Not Reported |
| Lovenox     | C | Unknown | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 08-Mar-2017              | 13326236      | EXPEDITED (15-DAY) |                    | OT              | GB-MYLANLABS-2017M1014024 |                      |            | Unknown    | GBR            |

| <u>Preferred Term</u>                       | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------|----------------------|--------------|------------|-------------|--------------|------------------------------------------|-----------------|--------------|
| Blister; Skin Exfoliation;<br>Skin Fissures | Escitalopram         |              |            | S           |              |                                          |                 | Not Reported |
|                                             | Canesten             |              |            | C           |              |                                          |                 | Mylan        |
|                                             | Citalopram           |              |            | C           |              |                                          |                 | Mylan        |
|                                             | Clobetasone Butyrate |              |            | C           |              | Apply 1-2 Times/Day.                     |                 | Mylan        |
|                                             | Clotrimazole         |              |            | C           |              | Use As Directed.                         |                 | Mylan        |
|                                             | Hydrocortisone       |              |            | C           |              |                                          |                 | Mylan        |
|                                             | Lactulose            |              |            | C           |              |                                          |                 | Mylan        |
|                                             | Naproxen             |              |            | C           |              | Maximum Three Times Daily.               |                 | Mylan        |
|                                             | Omeprazole           |              |            | C           |              |                                          |                 | Mylan        |
|                                             | Paracetamol          |              |            | C           |              | One To Two To Be Taken Four Times A Day. |                 | Mylan        |
|                                             | Quetiapine           |              |            | C           |              | Night.                                   |                 | Mylan        |
|                                             | Zerobase             |              |            | C           |              | Apply Liberally.                         |                 | Mylan        |
|                                             | Zopiclone            |              |            | C           |              | Take Half To One Tablet At Night.        |                 | Mylan        |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 09-Mar-2017              | 10340742      | EXPEDITED (15-DAY) |                    | HO, OT          | CA-GLAXOSMITHKLINE-B1016879A |                      | 182 DAY    | Female     | CAN            |

| <u>Preferred Term</u>                                                   | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|-------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Drug Level Increased;<br>Exposure Via Breast Milk;<br>Seizure; Vomiting | Bupropion            |              |            | S           | Transmammary |                    |                 | Glaxosmithkline |
|                                                                         | Escitalopram Oxalate |              |            | S           | Transmammary |                    |                 | Glaxosmithkline |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 09-Mar-2017              | 12698099      | NON-EXPEDITED    |                    |                 | US-JNJFOC-20160709705 |                      |            | Male       | USA            |

| <u>Preferred Term</u>                                                                               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Fatigue; Insomnia; Lethargy; Memory Impairment; Off Label Use; Product Use In Unapproved Indication | Risperdal      |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                     | Invega         |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                     | Lexapro        |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                     | Strattera      |              |            | S           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 09-Mar-2017              | 13243668      | EXPEDITED (15-DAY) |                    | HO              | SE-ALLERGAN-1706000US |                      | 84 YR      | Female     | SWE            |

| <u>Preferred Term</u>                                    | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Dizziness; Nausea; Product Administration Error; Syncope | Escitalopram Oxalate - Bp |              |            | S           | Oral         | Unk                |                 | Allergan     |
|                                                          | Citalopram Sandoz         |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                          | Normorix Mite             |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                          | Artrotec                  |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                          | Stesolid                  |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                          | Alvedon                   |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                          | Tromblyl                  |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                          | Metoprolol Orion          |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                          | Ovesterin                 |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                          | Daktacort                 |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                          | Loceryl                   |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                          | Nexium                    |              |            | C           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 09-Mar-2017              | 13301946      | EXPEDITED (15-DAY) |                    | OT              | IT-PFIZER INC-2017098062 |                      | 58 YR      | Female     | ITA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                             |                      |   |      |               |              |
|---------------------------------------------|----------------------|---|------|---------------|--------------|
| Bradyphrenia; Drug Abuse; Movement Disorder | Efexor Er            | S | Oral | 3 Df, Total   | Pfizer       |
|                                             | Tavor [Lorazepam]    | S | Oral | 2 Df, Total   | Pfizer       |
|                                             | Cipralext /01588501/ | S | Oral | 60 Df, Total  | Not Reported |
|                                             | Abilify              | S | Oral | 0.5 Df, Total | Not Reported |
|                                             | Talofen              | S | Oral | 5 Gtt, Total  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|------------|------------|----------------|
| 09-Mar-2017              | 13309679      | EXPEDITED (15-DAY) |                    | OT              | PT-AUROBINDO-AUR-APL-2017-30476 |                      | 42 YR      | Male       | PRT            |

| <u>Preferred Term</u>           | <u>Product</u>                             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------|--------------------------------------------|--------------|------------|-------------|--------------|-----------------------------------------------|-----------------|--------------|
| Loss Of Consciousness; Vomiting | Escitalopram Aurovitas Film-Coated Tablets |              |            | S           | Oral         | 5 Mg, Once A Day                              |                 | Aurobindo    |
|                                 | Bupropiom                                  |              |            | S           | Oral         | 150 Mg, Once A Day                            |                 | Not Reported |
|                                 | Levodopa-Carbidopa                         |              |            | C           | Unknown      | Unk                                           |                 | Not Reported |
|                                 | Levodopa-Carbidopa                         |              |            | C           |              | Medicação Concomitante Sem Dados Adicionais   |                 | Not Reported |
|                                 | Tizanidina                                 |              |            | C           | Unknown      | Terapêutica Concomitante Sem Outra Informação |                 | Not Reported |
|                                 | Tizanidina                                 |              |            | C           |              | Terapêutica Concomitante Sem Outra Informação |                 | Not Reported |
|                                 | Ropinirol                                  |              |            | C           | Unknown      | Unk                                           |                 | Not Reported |
|                                 | Ropinirol                                  |              |            | C           |              | Terapêutica Concomitante Sem Outra Informação |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 09-Mar-2017              | 13312894      | EXPEDITED (15-DAY) |                    | OT              | BE-ALLERGAN-1708915US |                      | 29 YR      | Female     | BEL            |

| <u>Preferred Term</u>                    | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|------------------------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Abortion Spontaneous; Anxiety; Pregnancy | Escitalopram Oxalate - Bp |              |            | S           | Unknown      | 5 Mg, Unk          |                 | Allergan   |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                             | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|--------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|----------------------|----------------|
| 09-Mar-2017                                                                          | 13312932                  | EXPEDITED (15-DAY) |                    | HO              | FR-ALLERGAN-1708907US                           |                      |                 | Female               | FRA            |
| <u>Preferred Term</u>                                                                | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Pregnancy; Premature Labour; Premature Rupture Of Membranes; Streptococcal Infection | Escitalopram Oxalate - Bp |                    |                    | S               | Unknown                                         | 10 Gtt, Qd           |                 | Allergan             |                |
| <u>FDA Received Date</u>                                                             | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 09-Mar-2017                                                                          | 13312935                  | EXPEDITED (15-DAY) |                    | OT              | DE-ALLERGAN-1708912US                           |                      | 16 YR           | Female               | DEU            |
| <u>Preferred Term</u>                                                                | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Bradycardia; Off Label Use; Syncope                                                  | Escitalopram Oxalate - Bp |                    |                    | S               |                                                 | 20 Mg, Qam           |                 | Allergan             |                |
| <u>FDA Received Date</u>                                                             | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 09-Mar-2017                                                                          | 13313294                  | EXPEDITED (15-DAY) |                    | HO, OT          | FR-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-019754 |                      | 36 YR           | Male                 | FRA            |
| <u>Preferred Term</u>                                                                | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Pancreatitis; Surgery                                                                | Abilify                   |                    |                    | S               | Oral                                            | Unk                  |                 | Bristol Myers Squibb |                |
|                                                                                      | Seroplex                  |                    |                    | S               | Oral                                            | Unk                  |                 | Not Reported         |                |
|                                                                                      | Innohep                   |                    |                    | C               | Unknown                                         | 0.8 MI, Qd           |                 | Not Reported         |                |
|                                                                                      | Gaviscon /00237601/       |                    |                    | C               | Unknown                                         | Unk, Tid             |                 | Not Reported         |                |
|                                                                                      | Ogastoro                  |                    |                    | C               | Unknown                                         | Unk, Qd              |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                             | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 09-Mar-2017                                                                          | 13313317                  | EXPEDITED (15-DAY) |                    | CA, HO, OT      | FR-ALLERGAN-1708884US                           |                      | 1 DAY           | Female               | FRA            |
| <u>Preferred Term</u>                                                                | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Congenital Nose                                                                      | Escitalopram Oxalate - Bp |                    |                    | S               | Transplacental                                  | 10 Gtt, Qd           |                 | Allergan             |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Malformation; Premature  
Baby

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 09-Mar-2017              | 13313330      | EXPEDITED (15-DAY) |                    | HO              | GB-ALLERGAN-1708936US |                      | 60 YR      | Female     | GBR            |

| <u>Preferred Term</u>                                                            | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------|---------------------------|--------------|------------|-------------|--------------|---------------------|-----------------|--------------|
| Feeling Jittery; Hot Flush;<br>Loss Of Consciousness;<br>Palpitations; Psoriasis | Escitalopram Oxalate - Bp |              |            | S           | Unknown      |                     |                 | Allergan     |
|                                                                                  | Propranolol               |              |            | S           | Oral         | 40 Milligram Daily; |                 | Not Reported |
|                                                                                  | Amlodipine                |              |            | C           | Unknown      | 10 Milligram Daily; |                 | Not Reported |
|                                                                                  | Capasal                   |              |            | C           | Unknown      |                     |                 | Not Reported |
|                                                                                  | Cetraben Emollient Cream  |              |            | C           | Unknown      |                     |                 | Not Reported |
|                                                                                  | Dermol Shampoo            |              |            | C           | Unknown      |                     |                 | Not Reported |
|                                                                                  | Dovobet                   |              |            | C           | Unknown      |                     |                 | Not Reported |
|                                                                                  | Loratadine                |              |            | C           | Unknown      |                     |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 09-Mar-2017              | 13313341      | EXPEDITED (15-DAY) |                    | OT              | CN-ALLERGAN-1708895US |                      | 83 YR      | Male       | CHN            |

| <u>Preferred Term</u>                                         | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Back Pain; Parkinson'S<br>Disease; Somnolence;<br>Spinal Pain | Escitalopram Oxalate - Bp |              |            | S           | Oral         | 5 Mg, Qd           |                 | Allergan     |
|                                                               | Escitalopram Oxalate - Bp |              |            | S           | Oral         | 2.5 Mg, Qd         |                 | Allergan     |
|                                                               | Diazepam                  |              |            | C           | Unknown      | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 09-Mar-2017              | 13313414      | EXPEDITED (15-DAY) |                    | HO              | CA-ALLERGAN-1709117US |                      | 50 YR      | Female     | CAN            |

| <u>Preferred Term</u>                                                      | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|----------------------------------------------------------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Aptyalism; Drug<br>Ineffective; Off Label Use;<br>Overdose; Panic Disorder | Escitalopram Oxalate - Bp |              |            | S           | Oral         | 30 Mg, Unknown     |                 | Allergan   |
|                                                                            | Escitalopram Oxalate - Bp |              |            | S           | Oral         | 30 Mg, Unknown     |                 | Allergan   |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|               |   |      |            |              |
|---------------|---|------|------------|--------------|
| Amitriptyline | S | Oral | 20 Mg, Qd  | Not Reported |
| Buspirone     | S | Oral | 5 Mg, Qd   | Not Reported |
| Zyprexa       | S | Oral | 2.5 Mg, Qd | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------|----------------------|------------|------------|----------------|
| 09-Mar-2017              | 13319974      | EXPEDITED (15-DAY) |                    |                 | US-LUNDBECK-DKLU2026430 |                      | 68 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                           | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Asthenopia; Dry Mouth; Feeling Abnormal; Feeling Jittery; Malaise; Nervousness; Palpitations; Visual Impairment | Escitalopram Oral Drops |              |            | S           | Oral         | 20 Mg, Unk         |                 | Not Reported |
|                                                                                                                 | Escitalopram Oral Drops |              |            | S           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Mar-2017              | 12666411      | EXPEDITED (15-DAY) |                    | LT              | JP-FRI-1000086879    |                      | 31 YR      | Female     | JPN            |

| <u>Preferred Term</u> | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Loss Of Consciousness | Escitalopram Oxalate - Bp |              |            | S           | Oral         | 5 Mg, Qd           |                 | Allergan   |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 10-Mar-2017              | 13094784      | EXPEDITED (15-DAY) |                    | OT              | JP-ALLERGAN-1700384US |                      | 88 YR      | Female     | JPN            |

| <u>Preferred Term</u>            | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Generalised Tonic-Clonic Seizure | Escitalopram Oxalate - Bp |              |            | S           | Oral         | 10 Mg, Qd          |                 | Allergan     |
|                                  | Rozerem                   |              |            | C           | Oral         |                    |                 | Not Reported |
|                                  | Belsomra                  |              |            | C           | Oral         | 15 Mg, Unk         |                 | Not Reported |
|                                  | Selenica R                |              |            | C           |              | 200 Mg, Unk        |                 | Not Reported |
|                                  | Reminyl                   |              |            | C           | Oral         | 8 Mg, Unk          |                 | Not Reported |
|                                  | Risperidone               |              |            | C           | Oral         | 0.5 Mg, Unk        |                 | Not Reported |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                    | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|-----------------|--------------|----------------|
| 10-Mar-2017                                                 | 13106469       | EXPEDITED (15-DAY) |                    | OT              | US-ALLERGAN-1700966US           |                      | 64 YR           | Female       | USA            |
| <u>Preferred Term</u>                                       | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Contusion; Fall; Loss Of Consciousness; Upper Limb Fracture | Lexapro        |                    |                    | S               | Oral                            | 10 Mg, Qd            |                 | Allergan     |                |
|                                                             | Clorazepate    |                    |                    | C               | Oral                            | 7.5 Mg, Qd           |                 | Not Reported |                |
|                                                             | Uloric         |                    |                    | C               | Oral                            | 80 Mg, Qd            |                 | Not Reported |                |
|                                                             | Probenecid     |                    |                    | C               | Oral                            | 500 Mg, Qid          |                 | Not Reported |                |
|                                                             | Colcrys        |                    |                    | C               | Oral                            | 0.6 Mg, Bid          |                 | Not Reported |                |
|                                                             | Flexeril       |                    |                    | C               |                                 | 10 Mg, Unk           |                 | Not Reported |                |
|                                                             | Topamax        |                    |                    | C               | Oral                            | 200 Mg, Bid          |                 | Not Reported |                |
|                                                             | Glucotrol      |                    |                    | C               | Oral                            | 5 Mg, Unk            |                 | Not Reported |                |
|                                                             | Welchol        |                    |                    | C               | Oral                            | 625 Mg, Bid          |                 | Not Reported |                |
|                                                             | Prevacid       |                    |                    | C               | Oral                            | 15 Mg, Qid           |                 | Not Reported |                |
|                                                             | Prevacid       |                    |                    | C               |                                 |                      |                 | Not Reported |                |
|                                                             | Prevacid       |                    |                    | C               |                                 |                      |                 | Not Reported |                |
|                                                             | K-Dur          |                    |                    | C               | Oral                            | 25 Meq, Unk          |                 | Not Reported |                |
|                                                             | Lasix          |                    |                    | C               | Oral                            | 40 Mg, Unk           |                 | Not Reported |                |
|                                                             | Coreg          |                    |                    | C               | Oral                            | 25 Mg, Bid           |                 | Not Reported |                |
|                                                             | Hydralazine    |                    |                    | C               | Oral                            | 25 Mg, Unk           |                 | Not Reported |                |
|                                                             | Synthroid      |                    |                    | C               | Oral                            | 125 Mg, Unk          |                 | Not Reported |                |
|                                                             | Premarin       |                    |                    | C               | Oral                            | 0.625 Mg, Unk        |                 | Not Reported |                |
|                                                             | Pataday        |                    |                    | C               | Ophthalmic                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                    | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Mar-2017                                                 | 13301475       | EXPEDITED (15-DAY) |                    | HO, LT, OT      | ES-AUROBINDO-AUR-APL-2017-30326 |                      | 49 YR           | Female       | ESP            |
| <u>Preferred Term</u>                                       | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bronchitis; Depression; Dyspnoea; Headache;                 | Escitalopram   |                    |                    | S               | Unknown                         | 5 Mg, Daily          |                 | Aurobindo    |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hyperhidrosis;  
Hyponatraemia;  
Inappropriate Antidiuretic  
Hormone Secretion;  
Nausea; Pancreatitis  
Chronic; Paraesthesia;  
Respiratory Alkalosis;  
Tremor; Vomiting

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|------------|------------|----------------|
| 10-Mar-2017              | 13315808      | EXPEDITED (15-DAY) |                    | OT              | GB-CIPLA LTD.-<br>2017GB02799 |                      |            | Unknown    | GBR            |

| <u>Preferred Term</u>                       | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                              | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------|----------------------|--------------|------------|-------------|--------------|-------------------------------------------------|-----------------|--------------|
| Blister; Skin Exfoliation;<br>Skin Fissures | Escitalopram         |              |            | S           | Unknown      | Unk                                             |                 | Invagen      |
|                                             | Canesten             |              |            | C           | Unknown      | 1 Df, Bid                                       |                 | Not Reported |
|                                             | Citalopram           |              |            | C           | Unknown      | 1 Df, Qd                                        |                 | Not Reported |
|                                             | Clobetasone Butyrate |              |            | C           | Unknown      | Unk, Apply 1-2 Times/Day                        |                 | Not Reported |
|                                             | Clotrimazole         |              |            | C           | Unknown      | Unk, Use As Directed                            |                 | Not Reported |
|                                             | Hydrocortisone       |              |            | C           | Unknown      | 1 Df, Bid                                       |                 | Not Reported |
|                                             | Lactulose            |              |            | C           | Unknown      | 15 Ml, Bid                                      |                 | Not Reported |
|                                             | Naproxen             |              |            | C           | Unknown      | 1 Df, Maximum Three<br>Times Daily              |                 | Not Reported |
|                                             | Omeprazole           |              |            | C           | Unknown      | 1 Df, Qd                                        |                 | Not Reported |
|                                             | Paracetamol          |              |            | C           | Unknown      | Unk, One To Two To Be<br>Taken Four Times A Day |                 | Not Reported |
|                                             | Quetiapine           |              |            | C           | Unknown      | 1 Df, Qd, Night                                 |                 | Not Reported |
|                                             | Zerobase             |              |            | C           | Unknown      | Unk, Apply Liberally                            |                 | Not Reported |
|                                             | Zopiclone            |              |            | C           | Unknown      | Unk, Take Half To One<br>Tablet At Night        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                    | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------------------------------|----------------------|------------|------------|----------------|
| 10-Mar-2017              | 13317879      | EXPEDITED (15-DAY) |                    | HO              | US-TARO<br>PHARMACEUTICALS<br>USA.,INC-<br>2017SUN00062 |                      |            | Unknown    | USA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u> |
|-------------------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|---------------------------------|-----------------|------------|
| Foetal Exposure During Pregnancy; Low Birth Weight Baby; Premature Baby | Escitalopram   |              |            | S           | Transplacental | Dose At 36 Week: 10             |                 | Taro       |
|                                                                         | Escitalopram   |              |            | S           | Transplacental | Dose Estimated From 36 Week: 10 |                 | Taro       |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 10-Mar-2017              | 13323525      | EXPEDITED (15-DAY) |                    | OT              | GB-ALLERGAN-1709166US |                      | 42 YR      | Female     | GBR            |

| <u>Preferred Term</u>                    | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------|---------------------------|--------------|------------|-------------|--------------|------------------------------------------|-----------------|--------------|
| Blister; Skin Exfoliation; Skin Fissures | Escitalopram Oxalate - Bp |              |            | S           |              |                                          |                 | Allergan     |
|                                          | Canesten                  |              |            | C           |              |                                          |                 | Not Reported |
|                                          | Clotrimazole              |              |            | C           |              | Use As Directed.                         |                 | Not Reported |
|                                          | Hydrocortisone            |              |            | C           |              |                                          |                 | Not Reported |
|                                          | Lactulose                 |              |            | C           | Unknown      |                                          |                 | Not Reported |
|                                          | Naproxen                  |              |            | C           |              | Maximum Three Times Daily.               |                 | Not Reported |
|                                          | Omeprazole                |              |            | C           |              |                                          |                 | Not Reported |
|                                          | Paracetamol               |              |            | C           |              | One To Two To Be Taken Four Times A Day. |                 | Not Reported |
|                                          | Quetiapine                |              |            | C           |              | Night.                                   |                 | Not Reported |
|                                          | Zopiclone                 |              |            | C           | Unknown      | Take Half To One Tablet At Night.        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 10-Mar-2017              | 13324461      | EXPEDITED (15-DAY) |                    | OT              | EG-ALLERGAN-1709155US |                      | 20 YR      | Female     | EGY            |

| <u>Preferred Term</u>  | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Retinal Vein Occlusion | Escitalopram Oxalate - Bp |              |            | S           | Unknown      | 10 Mg, Qd          |                 | Allergan   |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Mar-2017              | 13324683      | EXPEDITED (15-DAY) |                    | HO              | PHHY2016GB153148     |                      | 60 YR      | Female     | GBR            |

# FDA Adverse Event Reporting System

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| <u>Preferred Term</u>                                                                      | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|--------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|----------------------------------------------|----------------------|-----------------|--------------|----------------|
| Feeling Jittery; Hot Flush;<br>Loss Of Consciousness;<br>Palpitations; Psoriasis           | Propranolol               |                    |                    | S               | Oral                                         | 40 Milligram Daily   |                 | Novartis     |                |
|                                                                                            | Escitalopram              |                    |                    | S               | Unknown                                      | 5 Mg, Unk            |                 | Not Reported |                |
|                                                                                            | Amlodipine                |                    |                    | C               | Unknown                                      | 10 Milligram Daily;  |                 | Not Reported |                |
|                                                                                            | Capasal                   |                    |                    | C               | Unknown                                      | 250 Mg, Unk          |                 | Not Reported |                |
|                                                                                            | Cetraben                  |                    |                    | C               | Unknown                                      | 500 G, Unk           |                 | Not Reported |                |
|                                                                                            | Dermol                    |                    |                    | C               | Unknown                                      | 200 MI, Unk          |                 | Not Reported |                |
|                                                                                            | Dovobet                   |                    |                    | C               | Unknown                                      | 30 G, Unk            |                 | Not Reported |                |
|                                                                                            | Loratadine                |                    |                    | C               | Unknown                                      | 10 Mg, Unk           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                   | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Mar-2017                                                                                | 13325360                  | EXPEDITED (15-DAY) |                    | HO, LT          | FR-ALLERGAN-1709123US                        |                      | 82 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                      | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anaemia; Muscle<br>Haemorrhage; Periorbital<br>Haematoma                                   | Escitalopram Oxalate - Bp |                    |                    | S               | Oral                                         | 10 Mg, Qd            |                 | Allergan     |                |
|                                                                                            | Previscan (Fluindione)    |                    |                    | S               | Oral                                         | Unk, Unknown         |                 | Allergan     |                |
|                                                                                            | Lasilix                   |                    |                    | C               | Unknown                                      |                      |                 | Not Reported |                |
|                                                                                            | Levothyrox                |                    |                    | C               | Unknown                                      | Unk Unk, Unknown     |                 | Not Reported |                |
|                                                                                            | Tahor                     |                    |                    | C               | Unknown                                      | Unk Unk, Unknown     |                 | Not Reported |                |
|                                                                                            | Atenolol                  |                    |                    | C               | Unknown                                      | Unk, Unknown         |                 | Not Reported |                |
|                                                                                            | Speciafoldine             |                    |                    | C               | Unknown                                      | Unk, Unknown         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                   | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Mar-2017                                                                                | 13175838                  | EXPEDITED (15-DAY) |                    | HO, OT          | PT-LANNETT<br>COMPANY, INC.-PT-2017LAN000437 |                      | 23 YR           | Female       | PRT            |
| <u>Preferred Term</u>                                                                      | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Carcinoid Syndrome;<br>Metastases To Liver;<br>Metastases To Lymph<br>Nodes; Metastases To | Escitalopram Oxalate      |                    |                    | S               |                                              | 10 Mg Tablet Unk     |                 | Lannett      |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Ovary; Metastases To  
Peritoneum; Metastases  
To Spleen

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Mar-2017              | 13254672      | EXPEDITED (15-DAY) |                    | HO              | PHHY2017SE020858     |                      | 84 YR      | Female     | SWE            |

| <u>Preferred Term</u>                                          | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------|-------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Dizziness; Nausea;<br>Product Administration<br>Error; Syncope | Citalopram Sandoz |              |            | S           | Oral         | 20 Mg, Unk         |                 | Novartis     |
|                                                                | Ciprallex         |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                | Normorix Mite     |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                | Artrotec          |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                | Stesolid          |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                | Alvedon           |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                | Trombyl           |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                | Metoprolol Orion  |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                | Ovesterin         |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                | Daktacort         |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                | Loceryl           |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                | Nexium            |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                | Metoprolol        |              |            | C           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|------------|------------|----------------|
| 13-Mar-2017              | 13329200      | EXPEDITED (15-DAY) |                    | OT              | ES-HETERO LABS<br>LTD-1064174 |                      | 28 YR      | Female     | ESP            |

| <u>Preferred Term</u>              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction;<br>Sialoadenitis | Escitalopram   |              |            | S           | Unknown      |                    |                 | Hetero       |
|                                    | Ondansetron    |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                    | Temozolomide   |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                    | Levetiracetam  |              |            | S           | Unknown      |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| Dexamethasone                                                                                                                                                                   |                |                    | S                  |                 | Unknown                      |                                          |                 | Not Reported |                |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|------------------------------|------------------------------------------|-----------------|--------------|----------------|
| <u>FDA Received Date</u>                                                                                                                                                        | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Mar-2017                                                                                                                                                                     | 10957850       | EXPEDITED (15-DAY) |                    | OT              | PHHY2015BR032525             |                                          | 29 YR           | Female       | BRA            |
| <u>Preferred Term</u>                                                                                                                                                           | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>   |                |
| Anaemia; Asthenia;<br>Fatigue; Headache;<br>Hemiparesis; Influenza;<br>Lymphocyte Count<br>Decreased; Vision Blurred;<br>Vision Blurred; White<br>Blood Cell Count<br>Decreased | Gilenya        |                    |                    | S               | Oral                         | 0.5 Mg, Qd                               |                 | Novartis     |                |
|                                                                                                                                                                                 | Escitalopram   |                    |                    | S               | Unknown                      | 10 Mg, Unk                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                        | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Mar-2017                                                                                                                                                                     | 13257491       | NON-EXPEDITED      |                    |                 | US-PFIZER INC-<br>2017072673 |                                          | 43 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                           | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;<br>Dyspnoea; Fall; Irritability;<br>Mood Altered; Skin<br>Discolouration                                                                                      | Chantix        |                    |                    | S               |                              | Unk                                      |                 | Pfizer       |                |
|                                                                                                                                                                                 | Lexapro        |                    |                    | S               |                              | 20mg One Time A Day                      |                 | Not Reported |                |
|                                                                                                                                                                                 | Klonopin       |                    |                    | C               |                              | 1mg, 1 Tablet 2 Times A<br>Day As Needed |                 | Not Reported |                |
|                                                                                                                                                                                 | Amitriptyline  |                    |                    | C               | Oral                         | 10mg, 2 Tablets At<br>Bedtime            |                 | Not Reported |                |
|                                                                                                                                                                                 | Ambien         |                    |                    | C               |                              | 10 Mg, 1x/Day                            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                        | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Mar-2017                                                                                                                                                                     | 13330243       | EXPEDITED (15-DAY) |                    | OT              | GB-TEVA-746165ACC            |                                          | 42 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                                                                                                                           | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>   |                |
| Blister; Skin Exfoliation;<br>Skin Fissures                                                                                                                                     | Escitalopram   |                    |                    | S               |                              |                                          |                 | Ivax         |                |
|                                                                                                                                                                                 | Canesten       |                    |                    | C               |                              | 2 Dosage Forms Daily;                    |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                      |   |                                          |              |
|----------------------|---|------------------------------------------|--------------|
| Citalopram           | C | 1 Dosage Forms Daily;                    | Not Reported |
| Clobetasone Butyrate | C | Apply 1-2 Times/Day.                     | Not Reported |
| Clotrimazole         | C | Use As Directed.                         | Not Reported |
| Hydrocortisone       | C | 2 Dosage Forms Daily;                    | Not Reported |
| Lactulose            | C | 30 MI Daily;                             | Not Reported |
| Naproxen             | C | Maximum Three Times Daily.               | Not Reported |
| Omeprazole           | C | 1 Dosage Forms Daily;                    | Not Reported |
| Paracetamol          | C | One To Two To Be Taken Four Times A Day. | Not Reported |
| Quetiapine           | C | 1 Dosage Forms Daily;                    | Not Reported |
| Zerobase             | C | Apply Liberally.                         | Not Reported |
| Zopiclone            | C | Take Half To One Tablet At Night.        | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Mar-2017              | 13330946      | EXPEDITED (15-DAY) |                    | HO              | GB-ACCORD-045606     |                      | 60 YR      | Female     | GBR            |

| <u>Preferred Term</u>                                                                     | <u>Product</u>                                    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------|---------------------------------------------------|--------------|------------|-------------|--------------|---------------------|-----------------|--------------|
| Feeling Jittery; Hot Flush; Hyperhidrosis; Loss Of Consciousness; Palpitations; Psoriasis | Escitalopram                                      |              |            | S           | Oral         |                     |                 | Accord       |
|                                                                                           | Propranolol/Propranolol Hydrochloride/Propranolol |              |            | S           |              |                     |                 | Accord       |
|                                                                                           | Phenobarbital                                     |              |            |             |              |                     |                 |              |
|                                                                                           | Amlodipine                                        |              |            | C           |              |                     |                 | Not Reported |
|                                                                                           | Capasal                                           |              |            | C           |              | Therapeutic Shampoo |                 | Not Reported |
|                                                                                           | Cetraben                                          |              |            | C           |              | Emollient Cream     |                 | Not Reported |
|                                                                                           | Dermol                                            |              |            | C           |              | Shower Emollient    |                 | Not Reported |
|                                                                                           | Dovobet                                           |              |            | C           |              |                     |                 | Not Reported |
|                                                                                           | Loratadine                                        |              |            | C           |              |                     |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Mar-2017              | 13331232      | EXPEDITED (15-DAY) |                    | HO, OT          | ES-ZYDUS-014069      |                      | 49 YR      | Female     | ESP            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                                                       | <u>Product</u>                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|--------------------|--------------------|-----------------|-------------------------------|-----------------------------------|-----------------|--------------|----------------|
| Dyspnoea; Headache;<br>Hyperhidrosis;<br>Hyponatraemia;<br>Inappropriate Antidiuretic<br>Hormone Secretion;<br>Nausea; Paraesthesia;<br>Respiratory Alkalosis;<br>Seizure; Tremor; Vomiting | Escitalopram                               |                    |                    | S               | Unknown                       |                                   |                 | Zydus Pharm  |                |
|                                                                                                                                                                                             | Valeriana/Passion Flower/White<br>Hawthorn |                    |                    | C               | Unknown                       |                                   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                    | <u>Case #</u>                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Mar-2017                                                                                                                                                                                 | 13331249                                   | EXPEDITED (15-DAY) |                    | OT              | ES-ZYDUS-014071               |                                   | 28 YR           | Female       | ESP            |
| <u>Preferred Term</u>                                                                                                                                                                       | <u>Product</u>                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Salivary<br>Duct Obstruction;<br>Sialoadenitis                                                                                                                            | Escitalopram                               |                    |                    | S               | Unknown                       |                                   |                 | Zydus Pharm  |                |
|                                                                                                                                                                                             | Ondansetron                                |                    |                    | S               | Unknown                       |                                   |                 | Not Reported |                |
|                                                                                                                                                                                             | Temozolomide                               |                    |                    | S               | Unknown                       |                                   |                 | Not Reported |                |
|                                                                                                                                                                                             | Dexamethasone                              |                    |                    | S               | Unknown                       |                                   |                 | Not Reported |                |
|                                                                                                                                                                                             | Levetiracetam                              |                    |                    | C               | Unknown                       |                                   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                    | <u>Case #</u>                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Mar-2017                                                                                                                                                                                 | 13331266                                   | EXPEDITED (15-DAY) |                    | HO              | GB-CIPLA LTD.-<br>2017GB02807 |                                   |                 | Unknown      | GBR            |
| <u>Preferred Term</u>                                                                                                                                                                       | <u>Product</u>                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |                |
| Feeling Jittery; Hot Flush;<br>Loss Of Consciousness;<br>Palpitations; Psoriasis                                                                                                            | Escitalopram                               |                    |                    | S               | Unknown                       | 5 Mg, Unk                         |                 | Invagen      |                |
|                                                                                                                                                                                             | Propranolol                                |                    |                    | S               | Oral                          | 40 Mg, Qd (40 Milligram<br>Daily) |                 | Not Reported |                |
|                                                                                                                                                                                             | Amlodipine                                 |                    |                    | C               | Unknown                       | 10 Mg, Qd (10 Milligram<br>Daily) |                 | Not Reported |                |
|                                                                                                                                                                                             | Capasal                                    |                    |                    | C               | Unknown                       | 250 Mg, Unk                       |                 | Not Reported |                |
|                                                                                                                                                                                             | Cetaben Emollient Cream                    |                    |                    | C               | Unknown                       | 500 G, Unk                        |                 | Not Reported |                |
|                                                                                                                                                                                             | Dermol Shampoo                             |                    |                    | C               | Unknown                       | 200 MI, Unk                       |                 | Not Reported |                |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                                            |                           | Dovobet            | C                  | Unknown         | 30 G, Unk                       |                      |                 | Not Reported |                |
|----------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|-----------------|--------------|----------------|
|                                                                            |                           | Loratadine         | C                  | Unknown         | 10 Mg, Unk                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                   | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Mar-2017                                                                | 13332252                  | EXPEDITED (15-DAY) |                    | HO              | GB-AUROBINDO-AUR-APL-2017-30622 |                      | 60 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                      | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Feeling Jittery; Hot Flush; Loss Of Consciousness; Palpitations; Psoriasis | Escitalopram              |                    |                    | S               | Unknown                         | 5 Mg, Unk            |                 | Aurobindo    |                |
|                                                                            | Propranolol               |                    |                    | S               | Oral                            | 40 Mg, Once A Day    |                 | Not Reported |                |
|                                                                            | Amlodipine                |                    |                    | C               | Unknown                         | 10 Mg, Once A Day    |                 | Not Reported |                |
|                                                                            | Capasal                   |                    |                    | C               | Unknown                         | 250 Mg, Unk          |                 | Not Reported |                |
|                                                                            | Cetraben /01007601/       |                    |                    | C               | Unknown                         | 500 G, Unk           |                 | Not Reported |                |
|                                                                            | Dermol /00337102/         |                    |                    | C               | Unknown                         | 200 MI, Unk          |                 | Not Reported |                |
|                                                                            | Dovobet                   |                    |                    | C               | Unknown                         | 30 G, Unk            |                 | Not Reported |                |
|                                                                            | Loratadine                |                    |                    | C               | Unknown                         | 10 Mg, Unk           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                   | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Mar-2017                                                                | 13332883                  | EXPEDITED (15-DAY) |                    | HO              | FR-ALLERGAN-1709328US           |                      | 61 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                      | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrial Fibrillation                                                        | Escitalopram Oxalate - Bp |                    |                    | S               | Oral                            | 5 Mg, Qd             |                 | Allergan     |                |
|                                                                            | Zyloric                   |                    |                    | C               |                                 | Unk                  |                 | Not Reported |                |
|                                                                            | Inegy                     |                    |                    | C               |                                 | Unk                  |                 | Not Reported |                |
|                                                                            | Toviaz                    |                    |                    | C               |                                 | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                   | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Mar-2017                                                                | 13332945                  | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2017108983        |                      | 58 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                      | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective                                                           | Xanax                     |                    |                    | S               |                                 | Unk                  |                 | Pfizer       |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| Lexapro                                                                                                                                      |                    |                    | S                  |                 | Unk                        |                                  |                 | Not Reported |                |
|----------------------------------------------------------------------------------------------------------------------------------------------|--------------------|--------------------|--------------------|-----------------|----------------------------|----------------------------------|-----------------|--------------|----------------|
| <u>FDA Received Date</u>                                                                                                                     | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Mar-2017                                                                                                                                  | 13334663           | EXPEDITED (15-DAY) |                    | OT              | US-ASTRAZENECA-2017SE24246 |                                  | 44 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                        | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Arthropathy; Bronchitis; Dyspnoea; Fall; Hypotension; Insomnia; Mood Altered; Nephrolithiasis; Panic Attack; Skin Discolouration | Seroquel           |                    |                    | S               | Oral                       |                                  |                 | Zeneca       |                |
|                                                                                                                                              | Lexapro            |                    |                    | S               | Unknown                    |                                  |                 | Not Reported |                |
|                                                                                                                                              | Chantix            |                    |                    | S               | Unknown                    | Daily                            |                 | Not Reported |                |
|                                                                                                                                              | Corticosteroid Nos |                    |                    | S               | Unknown                    |                                  |                 | Not Reported |                |
|                                                                                                                                              | Klonopin           |                    |                    | C               |                            | 1 Tablet 2 Times A Day As Needed |                 | Not Reported |                |
|                                                                                                                                              | Amitriptyline      |                    |                    | C               | Oral                       |                                  |                 | Not Reported |                |
|                                                                                                                                              | Thyroxine          |                    |                    | C               |                            |                                  |                 | Not Reported |                |
|                                                                                                                                              | Vitamin D2         |                    |                    | C               |                            |                                  |                 | Not Reported |                |
|                                                                                                                                              | Vitamin D          |                    |                    | C               |                            |                                  |                 | Not Reported |                |
|                                                                                                                                              | Ambien             |                    |                    | C               |                            |                                  |                 | Not Reported |                |
|                                                                                                                                              | Ativan             |                    |                    | C               |                            |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                     | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Mar-2017                                                                                                                                  | 13336945           | EXPEDITED (15-DAY) |                    | OT              | GXKR2017DE001615           |                                  |                 | Unknown      | DEU            |
| <u>Preferred Term</u>                                                                                                                        | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Withdrawal Syndrome Neonatal; Small For Dates Baby                                                                                      | Bupropion          |                    |                    | S               | Transplacental             | 150 [Mg/D ]                      |                 | Novartis     |                |
|                                                                                                                                              | Escitalopram       |                    |                    | S               | Transplacental             | 25 [Mg/D ]                       |                 | Not Reported |                |
|                                                                                                                                              | L-Thyroxine        |                    |                    | C               | Transplacental             | 100 [Mg/D ]                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                     | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Mar-2017                                                                                                                                  | 13261610           | EXPEDITED (15-DAY) |                    | OT              | FR-ALLERGAN-1706544US      |                                  | 32 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                                                        | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                 |                             |                                       |                    |                 |                                     |                        |                 |              |                |
|---------------------------------------------------------------------------------|-----------------------------|---------------------------------------|--------------------|-----------------|-------------------------------------|------------------------|-----------------|--------------|----------------|
| Compulsive Shopping;<br>Diffuse Alopecia; Erection<br>Increased; Hypersexuality |                             | Escitalopram Oxalate - Bp<br>Xeroquel |                    | S               | Oral                                | 20 Mg, Qd              |                 | Allergan     |                |
|                                                                                 |                             |                                       |                    | S               | Oral                                | 150 Mg, Qd             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                        | <u>Case #</u>               | <u>Case Type</u>                      | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Mar-2017                                                                     | 13335965                    | EXPEDITED (15-DAY)                    |                    |                 | US-LUNDBECK-<br>DKLU2027679         |                        |                 | Male         | USA            |
| <u>Preferred Term</u>                                                           | <u>Product</u>              | <u>Comp.</u>                          | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                        | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Discomfort; Palpitations;<br>Tremor                                             | Lexapro Film-Coated Tablets |                                       |                    | S               | Unknown                             | Unk                    |                 | Forest       |                |
|                                                                                 | Lithium                     |                                       |                    | C               | Unknown                             | Unk                    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                        | <u>Case #</u>               | <u>Case Type</u>                      | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Mar-2017                                                                     | 13336425                    | EXPEDITED (15-DAY)                    |                    | OT              | GB-AUROBINDO-AUR-<br>APL-2017-30626 |                        | 33 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                           | <u>Product</u>              | <u>Comp.</u>                          | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                        | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Bradycardia; Fatigue;<br>Tinnitus                                               | Escitalopram                |                                       |                    | S               | Oral                                | 5 Mg, Unk              |                 | Aurobindo    |                |
|                                                                                 | Escitalopram                |                                       |                    | S               | Oral                                | 10 Mg, Unk             |                 | Aurobindo    |                |
|                                                                                 | Escitalopram                |                                       |                    | S               | Oral                                | 20 Mg, Unk             |                 | Aurobindo    |                |
| <u>FDA Received Date</u>                                                        | <u>Case #</u>               | <u>Case Type</u>                      | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Mar-2017                                                                     | 13337338                    | EXPEDITED (15-DAY)                    |                    | OT              | GB-AUROBINDO-AUR-<br>APL-2017-30689 |                        | 42 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                           | <u>Product</u>              | <u>Comp.</u>                          | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                        | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Blister; Skin Exfoliation;<br>Skin Fissures                                     | Escitalopram                |                                       |                    | S               | Unknown                             | Unk                    |                 | Aurobindo    |                |
|                                                                                 | Canesten                    |                                       |                    | C               | Unknown                             | 1 Df, Two Times A Day  |                 | Not Reported |                |
|                                                                                 | Citalopram                  |                                       |                    | C               | Unknown                             | 1 Df, Once A Day       |                 | Not Reported |                |
|                                                                                 | Clobetasone Butyrate        |                                       |                    | C               | Unknown                             | Apply 1-2 Times/Day.   |                 | Not Reported |                |
|                                                                                 | Clotrimazole                |                                       |                    | C               | Unknown                             | Use As Directed.       |                 | Not Reported |                |
|                                                                                 | Hydrocortisone              |                                       |                    | C               | Unknown                             | 1 Df, Two Times A Day  |                 | Not Reported |                |
|                                                                                 | Lactulose                   |                                       |                    | C               | Unknown                             | 15 Ml, Two Times A Day |                 | Not Reported |                |
|                                                                                 | Naproxen                    |                                       |                    | C               | Unknown                             | 1 Df, Maximum Three    |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                     |   |         |                                             |              |
|---------------------|---|---------|---------------------------------------------|--------------|
| Omeprazole          | C | Unknown | Times Daily.                                | Not Reported |
| Paracetamol         | C | Unknown | 1 Df, Once A Day                            | Not Reported |
| Quetiapine          | C |         | One To Two To Be Taken<br>Four Times A Day. | Not Reported |
| Zerobase /00103901/ | C | Unknown | 1 Df, Once A Day, At Night                  | Not Reported |
| Zopiclone           | C | Unknown | Apply Liberally.                            | Not Reported |
|                     |   |         | Take Half To One Tablet<br>At Night.        | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 16-Mar-2017              | 13284567      | EXPEDITED (15-DAY) |                    | HO              | PL-JNJFOC-<br>20170222386 |                      |            | Male       | POL            |

| <u>Preferred Term</u>                                                             | <u>Product</u>  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------|-----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Drug Ineffective;<br>Fear; Feeling Abnormal;<br>Hospitalisation; Tension | Risperidone     |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                   | Paroxetine      |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                   | Sertraline      |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                   | Olanzapine      |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                   | Doxepin         |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                   | Pregabalin      |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                   | Escitalopram    |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                   | Propranolol     |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                   | Aripiprazole    |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                   | Quetiapine      |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                   | Chlorprothixene |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                   | Mirtagen        |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                   | Venlafaxine     |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                   | Buspirone       |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                   | Flupentixol     |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                   | Amisulpride     |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                   | Hydroxyzine     |              |            | S           | Unknown      |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|            |   |         |              |
|------------|---|---------|--------------|
| Pridinol   | S | Unknown | Not Reported |
| Alprazolam | S | Unknown | Not Reported |
| Estazolam  | S | Unknown | Not Reported |
| Lorazepam  | S | Unknown | Not Reported |
| Lorazepam  | S | Unknown | Not Reported |
| Lorazepam  | S | Unknown | Not Reported |

| <u>FDA Received Date</u>                                                                                                                                                                                                               | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|----------------------|----------------|
| 16-Mar-2017                                                                                                                                                                                                                            | 13319661                | EXPEDITED (15-DAY) |                    | HO, LT, OT      | ES-TEVA-745163ISR    |                      | 49 YR           | Female               | ESP            |
| <u>Preferred Term</u>                                                                                                                                                                                                                  | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Bronchitis; Depression;<br>Dyspnoea; Headache;<br>Hyperhidrosis;<br>Hyponatraemia;<br>Inappropriate Antidiuretic<br>Hormone Secretion;<br>Nausea; Pancreatitis<br>Chronic; Paraesthesia;<br>Respiratory Alkalosis;<br>Tremor; Vomiting | Escitalopram<br>Enrelax |                    |                    | S<br>C          | Unknown              | 5 Milligram Daily;   |                 | Ivax<br>Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                                                                                                                                | <u>Case #</u>                                                                                                                                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>            | <u>Mfr Control #</u>                                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                                                           | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|--------------------|----------------------------|----------------------------------------------------------|----------------------|-----------------|--------------------------------------------------------------------------------------|----------------|
| 16-Mar-2017                                                                                                                                                                                                                                             | 13336965                                                                                                                                                   | EXPEDITED (15-DAY) |                    | HO, OT                     | FR-ALLERGAN-1709589US                                    |                      | 58 YR           | Male                                                                                 | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                   | <u>Product</u>                                                                                                                                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                | <u>Route</u>                                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                                                           |                |
| Abdominal Pain;<br>Dyskinesia; Dyspepsia;<br>Dysphagia; Energy<br>Increased; Fatigue;<br>Gastric Cyst;<br>Gastrointestinal Disorder;<br>Gastrointestinal Motility<br>Disorder; Hospitalisation;<br>Hyperhidrosis; Insomnia;<br>Loss Of Libido; Malaise; | Escitalopram Oxalate - Bp<br>Escitalopram Oxalate - Bp<br>Temesta (Lorazepam)<br>Seresta<br>Transilane (Potassium<br>Bicarbonate\Psyllium Husk)<br>Aprovel |                    |                    | S<br>S<br>C<br>C<br>C<br>C | Oral<br>Oral<br>Unknown<br>Unknown<br>Unknown<br>Unknown | Unk<br>Unk           |                 | Allergan<br>Allergan<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Movement Disorder;  
Paraesthesia;  
Prostatomegaly; Pyrexia;  
Renal Cyst; Serotonin  
Syndrome; Weight  
Decreased

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Mar-2017              | 13340488      | EXPEDITED (15-DAY) |                    | OT              | GB-ACCORD-048998     |                      | 42 YR      | Female     | GBR            |

| <u>Preferred Term</u>                       | <u>Product</u>                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------|--------------------------------|--------------|------------|-------------|--------------|---------------------------------------------|-----------------|--------------|
| Blister; Skin Exfoliation;<br>Skin Fissures | Escitalopram                   |              |            | S           |              |                                             |                 | Accord       |
|                                             | Canesten                       |              |            | C           |              |                                             |                 | Not Reported |
|                                             | Citalopram                     |              |            | C           |              |                                             |                 | Not Reported |
|                                             | Clobetasone                    |              |            | C           |              | Apply 1-2 Times/Day.                        |                 | Not Reported |
|                                             | Clotrimazole                   |              |            | C           |              | Use As Directed.                            |                 | Not Reported |
|                                             | Hydrocortisone                 |              |            | C           |              |                                             |                 | Not Reported |
|                                             | Lactulose                      |              |            | C           |              |                                             |                 | Not Reported |
|                                             | Naproxen                       |              |            | C           |              | Maximum Three Times<br>Daily.               |                 | Not Reported |
|                                             | Omeprazole                     |              |            | C           |              |                                             |                 | Not Reported |
|                                             | Paracetamol                    |              |            | C           |              | One To Two To Be Taken<br>Four Times A Day. |                 | Not Reported |
|                                             | Quetiapine/Quetiapine Fumarate |              |            | C           |              | Night.                                      |                 | Not Reported |
|                                             | Zerobase                       |              |            | C           |              | Apply Liberally.                            |                 | Not Reported |
|                                             | Zopiclone                      |              |            | C           |              | Take Half To One Tablet<br>At Night.        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Mar-2017              | 13341300      | EXPEDITED (15-DAY) |                    | HO              | PHHY2017FR035644     |                      | 67 YR      | Female     | FRA            |

| <u>Preferred Term</u>                  | <u>Product</u>                  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------|---------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Condition Aggravated;<br>Hyponatraemia | Amoxicilline/Acide Clavulanique |              |            | S           | Unknown      | 3 G, Qd            |                 | Novartis     |
|                                        | Sandoz<br>Seroplex              |              |            | S           | Oral         | 1 Df, Qd           |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                    |   |                          |          |              |
|--------------------|---|--------------------------|----------|--------------|
| Tenoretic          | S | Unknown                  | 1 Df, Qd | Not Reported |
| Ultibro Breezhaler | C | Respiratory (inhalation) |          | Not Reported |
| Timolol Maleate    | C | Ophthalmic               |          | Not Reported |
| Smecta             | C | Unknown                  | Unk      | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 16-Mar-2017              | 13343874                         | EXPEDITED (15-DAY) | HO                 |                 | FR-ALLERGAN-1710003US |                      | 91 YR           | Female       | FRA            |
| <u>Preferred Term</u>    | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Epilepsy                 | Escitalopram Oxalate - Bp        |                    |                    | S               | Oral                  |                      |                 | Allergan     |                |
|                          | Loxen (Nifedipine Hydrochloride) |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |
|                          | Bisocor                          |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |
|                          | Kardex                           |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |
|                          | Mobic                            |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |
|                          | Lexapro                          |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |
|                          | Naaxia                           |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |
|                          | Debridat                         |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |
|                          | Uvedose                          |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                  | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------|--------------------------|------------------|--------------------|-----------------|----------------------|------------------------|-----------------|--------------|----------------|
| 16-Mar-2017                                               | 13345239                 | DIRECT           |                    |                 |                      |                        | 54 YR           | Female       | USA            |
| <u>Preferred Term</u>                                     | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Blister; Eye Swelling; Eyelid Exfoliation; Vision Blurred | Escitalopram 10mg Tablet |                  |                    | S               | Oral                 | Quantity:30 Tablet(S); |                 | Accord       |                |
|                                                           | Levothroid               |                  |                    | C               |                      |                        |                 | Not Reported |                |
|                                                           | Zyrtec                   |                  |                    | C               |                      |                        |                 | Not Reported |                |
|                                                           | Cyclobenzaprine          |                  |                    | C               |                      |                        |                 | Not Reported |                |
|                                                           | Valacyclovir             |                  |                    | C               |                      |                        |                 | Not Reported |                |
|                                                           | Fluticasone              |                  |                    | C               |                      |                        |                 | Not Reported |                |
|                                                           | B-12                     |                  |                    | C               |                      |                        |                 | Not Reported |                |
|                                                           | Dramamine (Meclizine)    |                  |                    | C               |                      |                        |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                               | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|----------------------------------------------------|-------------------------|-----------------|--------------|----------------|
| 17-Mar-2017                                                                                                                                                                             | 13296288                  | EXPEDITED (15-DAY) |                    |                 | BR-009507513-1702BRA011636                         |                         | 73 YR           | Female       | BRA            |
| <u>Preferred Term</u>                                                                                                                                                                   | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                       | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Cough; Depression; Drug Interaction; Dry Mouth; Dyspepsia; Flatulence; Gastric Polyps; Gastritis; Gastrooesophageal Reflux Disease; Hiatus Hernia; Hypertension; Insomnia; Paraesthesia | Vytorin                   |                    |                    | S               | Oral                                               | 1 Tablet (10-20 Mg), Qd |                 | Merck        |                |
|                                                                                                                                                                                         | Vytorin                   |                    |                    | S               | Oral                                               | 1 Tablet (10-20 Mg), Qd |                 | Merck        |                |
|                                                                                                                                                                                         | Escitalopram              |                    |                    | S               |                                                    | Unk                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                               | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Mar-2017                                                                                                                                                                             | 13323511                  | EXPEDITED (15-DAY) |                    | OT              | CA-ALLERGAN-1709147US                              |                         | 57 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                                                                                                                                                   | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                       | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Hidradenitis                                                                                                                                                                            | Escitalopram Oxalate - Bp |                    |                    | S               | Unknown                                            | 20 Mg, Qd               |                 | Allergan     |                |
|                                                                                                                                                                                         | Methotrexate              |                    |                    | S               | Unknown                                            | Unk Unk, Unknown        |                 | Not Reported |                |
|                                                                                                                                                                                         | Sulfasalazine             |                    |                    | S               | Unknown                                            | Unk, Unknown            |                 | Not Reported |                |
|                                                                                                                                                                                         | Leflunomide               |                    |                    | C               | Unknown                                            |                         |                 | Not Reported |                |
|                                                                                                                                                                                         | Zantac                    |                    |                    | C               | Unknown                                            |                         |                 | Not Reported |                |
|                                                                                                                                                                                         | Tylenol W/Codeine         |                    |                    | C               | Unknown                                            | Unk, Unknown            |                 | Not Reported |                |
|                                                                                                                                                                                         | Butrans Opoids            |                    |                    | C               | Transdermal                                        | Unk, Unknown            |                 | Not Reported |                |
|                                                                                                                                                                                         | Zoledronic Acid           |                    |                    | C               | Unknown                                            | Unk, Unknown            |                 | Not Reported |                |
|                                                                                                                                                                                         | Plaquenil                 |                    |                    | C               | Unknown                                            | Unk, Unknown            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                               | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Mar-2017                                                                                                                                                                             | 13344329                  | EXPEDITED (15-DAY) |                    | OT              | NZ-CONCORDIA PHARMACEUTICALS INC.-GSH201703-001607 |                         | < 1 DAY         | Male         | NZL            |
| <u>Preferred Term</u>                                                                                                                                                                   | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                       | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                             |                |   |      |              |
|-------------------------------------------------------------|----------------|---|------|--------------|
| Drug Withdrawal Syndrome Neonatal; Nystagmus; Optic Atrophy | Clonidine      | S | Oral | Not Reported |
|                                                             | Gabapentin     | S | Oral | Not Reported |
|                                                             | Escitalopram   | S | Oral | Not Reported |
|                                                             | Allopurinol    | S | Oral | Not Reported |
|                                                             | Mercaptopurine | S | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Mar-2017              | 13345016      | NON-EXPEDITED    |                    | OT              | PHEH2017US007063     |                      |            | Female     | USA            |

| <u>Preferred Term</u>  | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------|-----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Psoriasis; Skin Plaque | Cosentyx              |              |            | S           | Subcutaneous | 300 Mg, Qw         |                 | Novartis     |
|                        | Cosentyx              |              |            | S           |              |                    |                 | Novartis     |
|                        | Lopressor             |              |            | S           | Unknown      |                    |                 | Not Reported |
|                        | Flecainide            |              |            | S           | Unknown      |                    |                 | Not Reported |
|                        | Protonix              |              |            | S           | Unknown      |                    |                 | Not Reported |
|                        | Lexapro               |              |            | S           | Unknown      |                    |                 | Not Reported |
|                        | Lyrica                |              |            | S           | Unknown      |                    |                 | Not Reported |
|                        | Vit D3                |              |            | S           | Unknown      |                    |                 | Not Reported |
|                        | Vitamin B1            |              |            | S           | Unknown      |                    |                 | Not Reported |
|                        | Vitamin C             |              |            | S           | Unknown      |                    |                 | Not Reported |
|                        | Klonopin              |              |            | C           | Unknown      | Unk Unk, Prn       |                 | Not Reported |
|                        | Melatonin             |              |            | C           | Unknown      | Unk Unk, Prn       |                 | Not Reported |
|                        | Hydrocodone           |              |            | C           | Unknown      | Unk Unk, Prn       |                 | Not Reported |
|                        | Ipratropium/Albuterol |              |            | C           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Mar-2017              | 13349535      | DIRECT           |                    |                 |                      |                      | 27 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Body Temperature      | Escitalopram   |              |            | S           | Oral         |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                       |                                               |                  |  |  |  |  |  |  |                                                              |
|---------------------------------------|-----------------------------------------------|------------------|--|--|--|--|--|--|--------------------------------------------------------------|
| Increased; Hyperhidrosis;<br>Vomiting | Xanax<br>Dicyclomine<br>Omeprazole<br>Imodium | C<br>C<br>C<br>C |  |  |  |  |  |  | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |
|---------------------------------------|-----------------------------------------------|------------------|--|--|--|--|--|--|--------------------------------------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>        | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------------|----------------------|------------|------------|----------------|
| 19-Mar-2017              | 13348255      | EXPEDITED (15-DAY) |                    |                 | US-LUNDBECK-<br>DKLU2025460 |                      | 40 YR      | Female     | USA            |

| <u>Preferred Term</u>                                     | <u>Product</u>                                     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>                   |
|-----------------------------------------------------------|----------------------------------------------------|--------------|------------|-------------|--------------|------------------------|-----------------|------------------------------|
| Cognitive Disorder;<br>Feeling Abnormal; Off<br>Label Use | Escitalopram Oral Drops<br>Escitalopram Oral Drops |              |            | S<br>S      | Oral<br>Oral | 30 Mg, Qd<br>10 Mg, Qd |                 | Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 20-Mar-2017              | 13299558      | EXPEDITED (15-DAY) |                    | DS, OT          | US-ALLERGAN-<br>1708499US |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                                               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Aphasia; Immobile;<br>Nausea; Paralysis;<br>Tinnitus; Wrong Product<br>Administered | Lexapro        |              |            | S           | Oral         | 20 Mg, Single      |                 | Allergan   |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Mar-2017              | 13348842      | NON-EXPEDITED    |                    |                 | US-TEVA-656308USA    |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Depressive Symptom;<br>Product Substitution Issue | Escitalopram   |              |            | S           | Unknown      |                    |                 | Ivax       |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Mar-2017              | 13348843      | NON-EXPEDITED    |                    |                 | US-TEVA-656789USA    |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Hypersensitivity      | Escitalopram   |              |            | S           |              |                    |                 | Ivax       |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 20-Mar-2017                       | 13348845                | NON-EXPEDITED             |                             |                          | US-TEVA-700341USA             |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Headache; Panic Reaction          | Escitalopram            |                           |                             | S                        | Unknown                       |                               |                          | Ivax                |                         |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 20-Mar-2017                       | 13348846                | NON-EXPEDITED             |                             |                          | US-TEVA-690857USA             |                               | 60 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Tinnitus                          | Escitalopram            |                           |                             | S                        | Unknown                       |                               |                          | Ivax                |                         |
|                                   | Xtandi                  |                           |                             | S                        | Oral                          | 160 Milligram Daily;          |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 20-Mar-2017                       | 13348847                | NON-EXPEDITED             |                             |                          | US-TEVA-648541USA             |                               | 42 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Mydriasis                         | Escitalopram            |                           |                             | S                        |                               |                               |                          | Ivax                |                         |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 20-Mar-2017                       | 13348848                | NON-EXPEDITED             |                             |                          | US-TEVA-698272USA             |                               |                          | Male                | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Dysgraphia; Dysstasia;            | Escitalopram            |                           |                             | S                        |                               |                               |                          | Ivax                |                         |
| Product Use In                    | Escitalopram            |                           |                             | S                        |                               |                               |                          | Ivax                |                         |
| Unapproved Indication;            |                         |                           |                             |                          |                               |                               |                          |                     |                         |
| Therapeutic Product Effect        |                         |                           |                             |                          |                               |                               |                          |                     |                         |
| Incomplete                        |                         |                           |                             |                          |                               |                               |                          |                     |                         |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 20-Mar-2017                       | 13348849                | NON-EXPEDITED             |                             |                          | US-TEVA-641850USA             |                               |                          | Female              | USA                     |

# FDA Adverse Event Reporting System

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### Detailed Report

| <u>Preferred Term</u>                                                                                            | <u>Product</u>          | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
|------------------------------------------------------------------------------------------------------------------|-------------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|----------------------|----------------|
| Drug Ineffective; Hot Flush; Insomnia                                                                            | Escitalopram            |                  |                    | S               | Unknown              |                      |                 | Ivax                 |                |
| <u>FDA Received Date</u>                                                                                         | <u>Case #</u>           | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 20-Mar-2017                                                                                                      | 13348850                | NON-EXPEDITED    |                    |                 | US-TEVA-640973USA    |                      | 14 YR           | Female               | USA            |
| <u>Preferred Term</u>                                                                                            | <u>Product</u>          | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Increased Appetite; Weight Increased                                                                             | Escitalopram            |                  |                    | S               | Unknown              |                      |                 | Ivax                 |                |
| <u>FDA Received Date</u>                                                                                         | <u>Case #</u>           | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 20-Mar-2017                                                                                                      | 13348851                | NON-EXPEDITED    |                    |                 | US-TEVA-642536USA    |                      |                 | Male                 | USA            |
| <u>Preferred Term</u>                                                                                            | <u>Product</u>          | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Agitation; Dizziness; Epistaxis; Feeling Abnormal; Inappropriate Schedule Of Product Administration; Nervousness | Escitalopram<br>Flonase |                  |                    | S<br>C          |                      |                      |                 | Ivax<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                                         | <u>Case #</u>           | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 20-Mar-2017                                                                                                      | 13348852                | NON-EXPEDITED    |                    |                 | US-TEVA-729396USA    |                      |                 | Male                 | USA            |
| <u>Preferred Term</u>                                                                                            | <u>Product</u>          | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Product Dispensing Error; Product Label On Wrong Product                                                         | Escitalopram            |                  |                    | S               |                      |                      |                 | Ivax                 |                |
| <u>FDA Received Date</u>                                                                                         | <u>Case #</u>           | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 20-Mar-2017                                                                                                      | 13348854                | NON-EXPEDITED    |                    |                 | US-TEVA-643939USA    |                      |                 | Male                 | USA            |
| <u>Preferred Term</u>                                                                                            | <u>Product</u>          | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                             |              |   |         |      |
|-------------------------------------------------------------|--------------|---|---------|------|
| Anxiety; Depression; Drug Ineffective; Heart Rate Increased | Escitalopram | S | Unknown | Ivax |
|-------------------------------------------------------------|--------------|---|---------|------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Mar-2017              | 13348855      | NON-EXPEDITED    |                    |                 | US-TEVA-678102USA    |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Anxiety; Blood Pressure Increased; Epistaxis; Feeding Disorder; Gingival Bleeding; Gingival Disorder; Headache; Hyperhidrosis; Oral Disorder; Thirst; Weight Increased; Wrong Technique In Product Usage Process | Escitalopram   |              |            | S           |              |                    |                 | Ivax       |
|                                                                                                                                                                                                                  | Escitalopram   |              |            | S           |              |                    |                 | Ivax       |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Mar-2017              | 13348856      | NON-EXPEDITED    |                    |                 | US-TEVA-691095USA    |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abnormal Dreams; Anxiety; Bone Pain; Drug Ineffective | Escitalopram   |              |            | S           | Unknown      |                    |                 | Ivax         |
|                                                       | Lorazepam      |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Mar-2017              | 13348857      | NON-EXPEDITED    |                    |                 | US-TEVA-740550USA    |                      |            | Male       | USA            |

| <u>Preferred Term</u>                                                                              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|----------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Confusional State; Decreased Appetite; Depression; Drug Ineffective; Feeling Abnormal; Mood Swings | Escitalopram   |              |            | S           | Unknown      |                    |                 | Ivax       |

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| <u>FDA Received Date</u>                                          | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 20-Mar-2017                                                       | 13348858       | NON-EXPEDITED    |                    |                 | US-TEVA-643087USA    |                      | 55 YR           | Female       | USA            |
| <u>Preferred Term</u>                                             | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Diarrhoea; Feeling Abnormal; Flatulence; Nausea; Weight Decreased | Escitalopram   |                  |                    | S               | Unknown              |                      |                 | Ivax         |                |
| <u>FDA Received Date</u>                                          | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Mar-2017                                                       | 13348859       | NON-EXPEDITED    |                    | OT              | US-TEVA-714482USA    |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                             | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Procedural Pain; Serotonin Syndrome                   | Escitalopram   |                  |                    | S               | Unknown              |                      |                 | Ivax         |                |
|                                                                   | Subsys         |                  |                    | S               | Unknown              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                          | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Mar-2017                                                       | 13348860       | NON-EXPEDITED    |                    |                 | US-TEVA-744291ACC    |                      |                 | Male         | USA            |
| <u>Preferred Term</u>                                             | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Malaise                                                           | Escitalopram   |                  |                    | S               | Unknown              |                      |                 | Ivax         |                |
| <u>FDA Received Date</u>                                          | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Mar-2017                                                       | 13348861       | NON-EXPEDITED    |                    |                 | US-TEVA-647832USA    |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                             | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Malaise                                                           | Escitalopram   |                  |                    | S               |                      |                      |                 | Ivax         |                |
| <u>FDA Received Date</u>                                          | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Mar-2017                                                       | 13348862       | NON-EXPEDITED    |                    |                 | US-TEVA-648626USA    |                      | 39 YR           | Female       | USA            |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                             | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|--------------|------------|-------------|--------------|----------------------|-----------------|--------------|
| Abdominal Discomfort;<br>Abdominal Pain Upper;<br>Adverse Event; Burning<br>Sensation; Drug<br>Hypersensitivity; Fatigue;<br>Fatigue; Headache;<br>Headache; Rash | Escitalopram                  |              |            | S           | Unknown      |                      |                 | Ivax         |
|                                                                                                                                                                   | Baclofen                      |              |            | S           | Unknown      |                      |                 | Ivax         |
|                                                                                                                                                                   | Citalopram                    |              |            | S           | Unknown      |                      |                 | Pliva        |
|                                                                                                                                                                   | Eszopiclone                   |              |            | S           | Unknown      |                      |                 | Teva         |
|                                                                                                                                                                   | Mirtazapine                   |              |            | S           | Unknown      |                      |                 | Teva         |
|                                                                                                                                                                   | Penicillin (Benzylpenicillin) |              |            | S           | Unknown      |                      |                 | Teva         |
|                                                                                                                                                                   | Trazodone                     |              |            | S           | Unknown      |                      |                 | Barr         |
|                                                                                                                                                                   | Zolpidem                      |              |            | S           | Unknown      |                      |                 | Teva         |
|                                                                                                                                                                   | Lyrica                        |              |            | S           | Unknown      | 200 Milligram Daily; |                 | Not Reported |
|                                                                                                                                                                   | Daypro                        |              |            | S           | Unknown      |                      |                 | Not Reported |
|                                                                                                                                                                   | Levoxyl                       |              |            | S           | Unknown      |                      |                 | Not Reported |
|                                                                                                                                                                   | Protonix                      |              |            | S           | Unknown      |                      |                 | Not Reported |
|                                                                                                                                                                   | Zithromax                     |              |            | S           | Unknown      |                      |                 | Not Reported |
|                                                                                                                                                                   | Synthroid                     |              |            | S           | Unknown      |                      |                 | Not Reported |
|                                                                                                                                                                   | Tegretol Xr                   |              |            | S           | Unknown      |                      |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Mar-2017              | 13348863      | NON-EXPEDITED    |                    |                 | US-TEVA-735961ACC    |                      |            | Female     | USA            |

| <u>Preferred Term</u>                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Abdominal Discomfort;<br>Anxiety; Insomnia | Escitalopram   |              |            | S           | Unknown      |                    |                 | Ivax       |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------|----------------------|------------|------------|----------------|
| 20-Mar-2017              | 13349738      | EXPEDITED (15-DAY) |                    | OT              | US-AUROBINDO-AUR-<br>APL-2014-00467 |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>                                                        | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------|-------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Back Pain; Dyspnoea;<br>Generalised Tonic-Clonic<br>Seizure; Hallucinations, | Escitalopram Tablets Usp 10mg |              |            | S           | Unknown      | Unk Unk,Unk,       |                 | Aurobindo    |
|                                                                              | Depakote                      |              |            | C           | Unknown      | Unk Unk,Unk,       |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Mixed; Muscle Rigidity;  
Muscle Spasms

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 20-Mar-2017              | 13350614      | EXPEDITED (15-DAY) |                    | HO              | FR-ALLERGAN-1710280US |                      | 97 YR      | Female     | FRA            |

| <u>Preferred Term</u>                        | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|----------------------------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Confusional State;<br>Hyponatraemia; Seizure | Escitalopram Oxalate - Bp |              |            | S           | Oral         | 10 Mg, Qd          |                 | Allergan   |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------|----------------------|------------|------------|----------------|
| 20-Mar-2017              | 13350820      | EXPEDITED (15-DAY) |                    |                 | US-LUNDBECK-DKLU2024398 |                      | 85 YR      | Female     | USA            |

| <u>Preferred Term</u>    | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|-----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hypersensitivity; Tremor | Lexapro Film-Coated Tablets |              |            | S           | Unknown      | 10 Mg, Daily       |                 | Forest       |
|                          | Ativan                      |              |            | C           | Unknown      | Unk                |                 | Not Reported |
|                          | Mavik                       |              |            | C           | Unknown      | Unk                |                 | Not Reported |
|                          | Synthroid                   |              |            | C           | Unknown      | Unk                |                 | Not Reported |
|                          | Fioricet                    |              |            | C           | Unknown      | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 20-Mar-2017              | 13351777      | EXPEDITED (15-DAY) |                    | HO, OT          | FR-PFIZER INC-2017109981 |                      | 53 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                                                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Coma Scale Abnormal;<br>Sinus Tachycardia;<br>Somnolence; Suicide<br>Attempt; Toxicity To<br>Various Agents | Xanax          |              |            | S           | Oral         | 1/2-1/2-1/2-2      |                 | Pfizer       |
|                                                                                                             | Xanax          |              |            | S           | Oral         | Unk, Single        |                 | Pfizer       |
|                                                                                                             | Seroplex       |              |            | S           | Oral         | 20 Mg, Unk         |                 | Not Reported |
|                                                                                                             | Seroplex       |              |            | S           | Oral         | Unk, Single        |                 | Not Reported |
|                                                                                                             | Solian         |              |            | S           | Oral         | 100 Mg, 1x/Day     |                 | Not Reported |
|                                                                                                             | Solian         |              |            | S           | Oral         | Unk, Single        |                 | Not Reported |
|                                                                                                             | Nozinan        |              |            | S           | Oral         | Between 0.5 And 1  |                 | Not Reported |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|         |   |      |                                     |              |
|---------|---|------|-------------------------------------|--------------|
| Nozinan | S | Oral | Dosage Form In The Evening          | Not Reported |
| Enbrel  | C |      | Unk, Single<br>One Injection Weekly | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------|----------------------|------------|------------|----------------|
| 21-Mar-2017              | 13353462      | EXPEDITED (15-DAY) |                    |                 | US-LUNDBECK-DKLU2026728 |                      |            | Unknown    | USA            |

| <u>Preferred Term</u> | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|-----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Off Label Use         | Lexapro Film-Coated Tablets |              |            | S           | Oral         | Unk                |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------|----------------------|------------|------------|----------------|
| 21-Mar-2017              | 13353465      | EXPEDITED (15-DAY) |                    |                 | US-LUNDBECK-DKLU2013746 |                      |            | Male       | USA            |

| <u>Preferred Term</u>                                                  | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|------------------------------------------------------------------------|-----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Depression; Weight Increased; Wrong Technique In Product Usage Process | Lexapro Film-Coated Tablets |              |            | S           | Oral         | 10 Mg, Bid         |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------------------------|----------------------|------------|------------|----------------|
| 21-Mar-2017              | 13353606      | EXPEDITED (15-DAY) |                    | OT              | DE-MACLEODS PHARMACEUTICALS US LTD-MAC2017004464 |                      |            | Unknown    | DEU            |

| <u>Preferred Term</u>                                                                                                                                                                             | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u>                                   | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|--------------|------------|-------------|----------------|------------------------------------------------------|-----------------|--------------|
| Agitation Neonatal; Bradycardia Neonatal; Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Hypertension Neonatal; Neonatal Gastrointestinal Disorder; Neonatal Hypoxia; Small | Escitalopram       |              |            | S           | Transplacental | 25 Mg/D (1 Trimester) (0.-39.4 Gestational Week)     |                 | Macleods     |
|                                                                                                                                                                                                   | Bupropion          |              |            | S           | Transplacental | 150 Mg/Day (1 Trimester) (0.-39.4 Gestational Wee)   |                 | Not Reported |
|                                                                                                                                                                                                   | L-Thyroxine Sodium |              |            | C           | Transplacental | 100 Mg/D Qd (1 Trimester) (0.-39.4 Gestational Week) |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

For Dates Baby; Tremor  
Neonatal

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------------------|----------------------|------------|------------|----------------|
| 21-Mar-2017              | 13354709      | EXPEDITED (15-DAY) |                    | OT              | DE-<br>GLAXOSMITHKLINE-<br>DE2017GSK037872 |                      | < 1 DAY    | Male       | DEU            |

| <u>Preferred Term</u>                                                                                                                                                                                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|-----------------|
| Agitation Neonatal;<br>Bradycardia; Drug<br>Withdrawal Syndrome<br>Neonatal; Gastrointestinal<br>Disorder; Hypertonia;<br>Oxygen Saturation<br>Decreased; Small For<br>Dates Baby; Tremor;<br>Tremor Neonatal | Bupropion      |              |            | S           | Transplacental | 150 Mg, Qd         |                 | Glaxosmithkline |
|                                                                                                                                                                                                               | Escitalopram   |              |            | S           | Transplacental | 25 G, Qd           |                 | Glaxosmithkline |
|                                                                                                                                                                                                               | L-Thyroxin     |              |            | S           | Oral           | 100 Ug, Qd         |                 | Not Reported    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|------------|------------|----------------|
| 21-Mar-2017              | 13356847      | EXPEDITED (15-DAY) |                    | OT              | ZA-MYLANLABS-<br>2017M1016951 |                      |            | Unknown    | ZAF            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Neck Surgery          | Mylan Alprazolam 1mg |              |            | S           |              | Unk                |                 | Mylan      |
|                       | Topzol (Tioconazole) |              |            | S           |              | Unk                |                 | Mylan      |
|                       | Lexamil              |              |            | S           |              | Unk                |                 | Mylan      |
|                       | Molipaxin            |              |            | S           |              | Unk                |                 | Mylan      |
|                       | Altosec              |              |            | S           |              | Unk                |                 | Mylan      |
|                       | Angeliq              |              |            | S           |              | Unk                |                 | Mylan      |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 22-Mar-2017              | 12898358      | EXPEDITED (15-DAY) |                    | LT              | JP-ALLERGAN-<br>1674184US |                      | 61 YR      | Male       | JPN            |

| <u>Preferred Term</u>  | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Anxiety; Bundle Branch | Escitalopram Oxalate - Bp |              |            | S           | Oral         | 20 Mg              |                 | Allergan   |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                   |                           |   |      |              |              |
|---------------------------------------------------|---------------------------|---|------|--------------|--------------|
| Block Right;<br>Electrocardiogram Qt<br>Prolonged | Escitalopram Oxalate - Bp | S | Oral | 10 Mg, Qd    | Allergan     |
|                                                   | Escitalopram Oxalate - Bp | S | Oral | 10 Mg, Qd    | Allergan     |
|                                                   | Magnesium Oxide           | C | Oral | 1.5 G, Qd    | Not Reported |
|                                                   | Reflex                    | C | Oral | 15 Mg, Qd    | Not Reported |
|                                                   | Meilax                    | C | Oral | 1 Mg, Qd     | Not Reported |
|                                                   | Januvia                   | C | Oral | Unk          | Not Reported |
|                                                   | Gliclazide                | C | Oral | Unk          | Not Reported |
|                                                   | Paxil Cr                  | C | Oral | 12.5 Mg, Unk | Not Reported |
|                                                   | Paxil Cr                  | C | Oral | 25 Mg, Unk   | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Mar-2017              | 13323791      | EXPEDITED (15-DAY) |                    | OT              | ES-TEVA-746229ROM    |                      | 28 YR      | Female     | ESP            |

| <u>Preferred Term</u>              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction;<br>Sialoadenitis | Ondansetron    |              |            | S           | Unknown      |                    |                 | Teva         |
|                                    | Escitalopram   |              |            | S           | Unknown      |                    |                 | Ivax         |
|                                    | Temozolomide   |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                    | Levetiracetam  |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                    | Dexamethasone  |              |            | C           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------|----------------------|------------|------------|----------------|
| 22-Mar-2017              | 13334202      | EXPEDITED (15-DAY) |                    | DS, OT          | CH-GILEAD-2017-0261671 |                      | 65 YR      | Male       | CHE            |

| <u>Preferred Term</u>               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hypertension; Nephritic<br>Syndrome | Harvoni        |              |            | S           | Oral         | 1 Df, Qd           |                 | Gilead       |
|                                     | Escitalopram   |              |            | S           | Oral         |                    |                 | Not Reported |
|                                     | Pantoprazol    |              |            | S           | Oral         |                    |                 | Not Reported |
|                                     | Paracetamol    |              |            | S           | Oral         | 2000 Mg, Prn       |                 | Not Reported |
|                                     | Etodolac       |              |            | S           | Oral         | 600 Unk, Unk       |                 | Not Reported |
|                                     | Vitamin D3     |              |            | C           | Oral         |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                  | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|---------------------------------------|------------------------------|-----------------|--------------|----------------|
| 22-Mar-2017                                                                               | 13358602                      | EXPEDITED (15-DAY) |                    | OT              | DE-TEVA-749636GER                     |                              | 1 DAY           | Male         | DEU            |
| <u>Preferred Term</u>                                                                     | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Small For Dates Baby | Escitalopram                  |                    |                    | S               | Transplacental                        | 25 Milligram Daily;          |                 | Ivax         |                |
|                                                                                           | Bupropion                     |                    |                    | S               | Transplacental                        | 150 Milligram Daily;         |                 | Not Reported |                |
|                                                                                           | L-Thyroxin                    |                    |                    | C               | Transplacental                        | 100 Microgram Daily;         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                  | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Mar-2017                                                                               | 13359233                      | EXPEDITED (15-DAY) |                    | LT, OT          | CH-ASTRAZENECA-2017SE27487            |                              | 85 YR           | Female       | CHE            |
| <u>Preferred Term</u>                                                                     | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Bradycardia; Haemoglobin Decreased; Loss Of Consciousness                                 | Carbostesin                   |                    |                    | S               | Intrathecal                           | 7.5 Mg, Then 2.5 Mg And 5 Mg |                 | Not Reported |                |
|                                                                                           | Atacand                       |                    |                    | S               | Oral                                  |                              |                 | Not Reported |                |
|                                                                                           | Escitalopram                  |                    |                    | S               | Oral                                  |                              |                 | Not Reported |                |
|                                                                                           | Metoprolol Succinate          |                    |                    | S               | Oral                                  |                              |                 | Not Reported |                |
|                                                                                           | Dexmedetomidine Hydrochloride |                    |                    | S               | Intravenous drip                      | 38.1 Ug, Dosing Unknown      |                 | Not Reported |                |
|                                                                                           | Phenylephrin                  |                    |                    | S               | Intravenous drip                      | 525 Ug, Dosing Unknown       |                 | Not Reported |                |
|                                                                                           | Sintrom                       |                    |                    | C               |                                       |                              |                 | Not Reported |                |
|                                                                                           | Aldactone                     |                    |                    | C               |                                       |                              |                 | Not Reported |                |
|                                                                                           | Omeprazol                     |                    |                    | C               |                                       |                              |                 | Not Reported |                |
|                                                                                           | Zoldorm                       |                    |                    | C               |                                       |                              |                 | Not Reported |                |
|                                                                                           | Lexotanil                     |                    |                    | C               |                                       |                              |                 | Not Reported |                |
|                                                                                           | Colecalciferol                |                    |                    | C               |                                       | 6 Drops Once Daily           |                 | Not Reported |                |
|                                                                                           | Zinacef                       |                    |                    | C               | Intravenous (not otherwise specified) | 1.5 G                        |                 | Not Reported |                |
|                                                                                           | Adrenaline                    |                    |                    | C               | Intravenous bolus                     | 0.5 Mg                       |                 | Not Reported |                |
|                                                                                           | Chirocaine                    |                    |                    | C               | Intra-articular                       | 20.0ml Unknown               |                 | Not Reported |                |
|                                                                                           | Tora Dol                      |                    |                    | C               | Intra-articular                       | 30.0mg Unknown               |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Nexium

C

Intravenous (not  
otherwise specified)

Not Reported

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 22-Mar-2017              | 13360460      | EXPEDITED (15-DAY) |                    | OT              | DE-ALLERGAN-1710905US |                      |            | Male       | DEU            |

| <u>Preferred Term</u> | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Colitis Ulcerative    | Escitalopram Oxalate - Bp |              |            | S           | Unknown      | 5 Mg, Qd           |                 | Allergan   |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 22-Mar-2017              | 13360729      | EXPEDITED (15-DAY) |                    | OT              | DE-ALLERGAN-1710677US |                      | 1 DAY      | Male       | DEU            |

| <u>Preferred Term</u>                                                                     | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------|---------------------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Small For Dates Baby | Escitalopram Oxalate - Bp |              |            | S           | Transplacental | 25 Mg, Qd          |                 | Allergan     |
|                                                                                           | Bupropion                 |              |            | S           | Transplacental | 150 Mg, Qd         |                 | Not Reported |
|                                                                                           | L-Thyroxin                |              |            | C           | Transplacental | 100 Mg, Qd         |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------|----------------------|------------|------------|----------------|
| 22-Mar-2017              | 13360746      | EXPEDITED (15-DAY) |                    | OT              | US-ALLERGAN-1000017118 |                      | 67 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|---------------------------------|-----------------|--------------|
| Abnormal Dreams; Dyspepsia; Hair Growth Abnormal; Headache; Nausea; Neoplasm Malignant; Nervousness; Paraesthesia | Lexapro        |              |            | S           | Oral         | 5 Mg, Qd                        |                 | Allergan     |
|                                                                                                                   | Lexapro        |              |            | S           | Oral         | 10 Mg, Qd                       |                 | Allergan     |
|                                                                                                                   | Lexapro        |              |            | S           | Oral         | 5 Mg, Qd                        |                 | Allergan     |
|                                                                                                                   | Lexapro        |              |            | S           | Oral         | 10 Mg, Qd                       |                 | Allergan     |
|                                                                                                                   | Lorazepam      |              |            | C           | Oral         | .5 Mg, Qid                      |                 | Not Reported |
|                                                                                                                   | Lorazepam      |              |            | C           |              |                                 |                 | Not Reported |
|                                                                                                                   | Prilosec       |              |            | C           | Oral         | Unk Unk, ,Freq Unit As Required |                 | Not Reported |
|                                                                                                                   | Vitamin D3     |              |            | C           |              | Unk                             |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                              | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|-------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|------------|----------------|
| 22-Mar-2017                                           | 13360748                  | EXPEDITED (15-DAY) |                    | HO              | AU-ALLERGAN-1710663US |                      | 29 YR           | Female     | AUS            |
| <u>Preferred Term</u>                                 | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Maternal Exposure During Pregnancy;<br>Polyhydramnios | Escitalopram Oxalate - Bp |                    |                    | S               | Oral                  | 20 Mg, Qd            |                 | Allergan   |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|--------------------------|-----------------------------------------------------|-----------------|--------------|----------------|
| 23-Mar-2017              | 13162182       | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2017038633 |                                                     | 56 YR           | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective         | Advil          |                  |                    | S               |                          | Unk                                                 |                 | Pfizer       |                |
|                          | Topiramate     |                  |                    | S               |                          | 50 Mg, 2x/Day(One In The Morning And One At Night ) |                 | Not Reported |                |
|                          | Escitalopram   |                  |                    | S               |                          | 1 Df, Daily                                         |                 | Not Reported |                |
|                          | Tylenol        |                  |                    | S               |                          | Unk                                                 |                 | Not Reported |                |
|                          | Fioricet       |                  |                    | S               |                          | Unk                                                 |                 | Not Reported |                |
|                          | Sumatriptan    |                  |                    | S               |                          | 100 Mg, As Needed                                   |                 | Not Reported |                |

| <u>FDA Received Date</u>                      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 23-Mar-2017                                   | 13348310       | EXPEDITED (15-DAY) |                    | OT              | PHHY2017AU036739     |                      | 28 YR           | Male         | AUS            |
| <u>Preferred Term</u>                         | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Dependence;<br>Product Prescribing Error | Ritalin        |                    |                    | S               | Unknown              | Unk                  |                 | Not Reported |                |
|                                               | Tramadol       |                    |                    | S               | Unknown              | Unk                  |                 | Novartis     |                |
|                                               | Methotrexate   |                    |                    | S               | Unknown              | Unk                  |                 | Not Reported |                |
|                                               | Paracetamol    |                    |                    | S               | Unknown              | Unk                  |                 | Not Reported |                |
|                                               | Pantoprazole   |                    |                    | S               | Unknown              | Unk                  |                 | Not Reported |                |
|                                               | Fentanyl       |                    |                    | S               | Unknown              | Unk                  |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                         |   |         |     |              |
|-------------------------|---|---------|-----|--------------|
| Zolpidem                | S | Unknown | Unk | Not Reported |
| Oxycodone Hydrochloride | S | Unknown | Unk | Not Reported |
| Alprazolam              | S | Unknown | Unk | Not Reported |
| Escitalopram            | S | Unknown | Unk | Not Reported |
| Naproxen                | S | Unknown | Unk | Not Reported |
| Pregabalin              | S | Unknown | Unk | Not Reported |
| Buprenorphine           | S | Unknown | Unk | Not Reported |
| Oxazepam                | S | Unknown | Unk | Not Reported |
| Dexamphetamine          | S | Unknown | Unk | Not Reported |
| Prednisolone            | S | Unknown | Unk | Not Reported |
| Folic Acid              | S | Unknown | Unk | Not Reported |
| Clonidine               | S | Unknown | Unk | Not Reported |
| Lorazepam               | S | Unknown | Unk | Not Reported |
| Cocaine                 | S | Unknown | Unk | Not Reported |
| Cannabis                | S | Unknown | Unk | Not Reported |
| Temazepam               | S | Unknown | Unk | Not Reported |
| Psilocybine             | S | Unknown | Unk | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------------------------|----------------------|------------|------------|----------------|
| 23-Mar-2017              | 13362270      | EXPEDITED (15-DAY) |                    | OT              | ES-LUPIN<br>PHARMACEUTICALS<br>INC.-2017-01308 |                      | 28 YR      | Female     | ESP            |

| <u>Preferred Term</u>              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction;<br>Sialoadenitis | Escitalopram   |              |            | S           |              | Unk                |                 | Lupin        |
|                                    | Ondansetron    |              |            | S           |              | Unk                |                 | Not Reported |
|                                    | Temozolomide   |              |            | C           |              | Unk                |                 | Not Reported |
|                                    | Levetiracetam  |              |            | C           |              | Unk                |                 | Not Reported |
|                                    | Dexamethasone  |              |            | C           |              | Unk                |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
| 23-Mar-2017                                                                               | 13362336             | NON-EXPEDITED      |                    |                 | US-TAKEDA-2017TUS005861   |                      |                 | Male         | USA            |
| <u>Preferred Term</u>                                                                     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Diarrhoea                                                                                 | Dexilant             |                    |                    | S               | Oral                      | 60 Mg, Qd            |                 | Takeda       |                |
|                                                                                           | Viberzi              |                    |                    | S               | Unknown                   | Unk                  |                 | Not Reported |                |
|                                                                                           | Bupropion            |                    |                    | C               | Oral                      | 150 Mg, Tid          |                 | Not Reported |                |
|                                                                                           | Tamsulosin           |                    |                    | C               | Oral                      | 0.4 Mg, Qd           |                 | Not Reported |                |
|                                                                                           | Finasteride          |                    |                    | C               | Oral                      | 5 Mg, Qd             |                 | Not Reported |                |
|                                                                                           | Methylphenidate      |                    |                    | C               | Oral                      | 20 Mg, Tid           |                 | Not Reported |                |
|                                                                                           | Escitalopram         |                    |                    | S               | Oral                      | 20 Mg, Unk           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Mar-2017                                                                               | 13363131             | EXPEDITED (15-DAY) |                    | HO              | FR-PFIZER INC-2017119194  |                      | 93 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Inappropriate Antidiuretic Hormone Secretion                                              | Amlor                |                    |                    | S               | Oral                      | 5 Mg, 1x/Day         |                 | Pfizer       |                |
|                                                                                           | Seroplex             |                    |                    | S               | Oral                      | 10 Mg, 1x/Day        |                 | Not Reported |                |
|                                                                                           | Zestril              |                    |                    | S               | Oral                      | 20 Mg, 1x/Day        |                 | Not Reported |                |
|                                                                                           | Stagid               |                    |                    | S               | Oral                      | 700 Mg, 2x/Day       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Mar-2017                                                                               | 13365099             | EXPEDITED (15-DAY) |                    | OT              | DE-MYLANLABS-2017M1017868 |                      |                 | Unknown      | DEU            |
| <u>Preferred Term</u>                                                                     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Small For Dates Baby | Escitalopram         |                    |                    | S               | Transplacental            | 25 [Mg/D ]           |                 | Not Reported |                |
|                                                                                           | Bupropion /00700502/ |                    |                    | S               | Transplacental            | 150 [Mg/D ]          |                 | Mylan        |                |
|                                                                                           | L-Thyroxin           |                    |                    | C               | Transplacental            | 100 [Microgram/D ]   |                 | Mylan        |                |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                              | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|--------------------|--------------------|-----------------|-------------------------------------|------------------------|-----------------|--------------|----------------|
| 23-Mar-2017                                                                                                                           | 13367331                              | DIRECT             |                    | DS              |                                     |                        | 48 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                 | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                        | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Systolic Hypertension                                                                                                                 | Escitalopram                          |                    |                    | S               | Oral                                | Quantity:30 Tablet(S); |                 | Not Reported |                |
|                                                                                                                                       | Xanax                                 |                    |                    | C               |                                     |                        |                 | Not Reported |                |
|                                                                                                                                       | Baby Aspirin                          |                    |                    | C               |                                     |                        |                 | Not Reported |                |
|                                                                                                                                       | Multivitamin                          |                    |                    | C               |                                     |                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                              | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Mar-2017                                                                                                                           | 13368040                              | DIRECT             | Y                  | OT              |                                     |                        | 66 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                 | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                        | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Behaviour;<br>Aggression; Agitation;<br>Drug Interaction;<br>Epistaxis; Logorrhoea                                           | Escitalopram 10mg Aurobindo<br>Pharma |                    |                    | S               | Oral                                |                        |                 | Aurobindo    |                |
| <u>FDA Received Date</u>                                                                                                              | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Mar-2017                                                                                                                           | 13360426                              | EXPEDITED (15-DAY) |                    | OT              | AU-ALLERGAN-<br>1710610US           |                        | 43 YR           | Female       | AUS            |
| <u>Preferred Term</u>                                                                                                                 | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                        | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Coordination Abnormal;<br>Depressed Level Of<br>Consciousness;<br>Disturbance In Attention;<br>Feeling Abnormal;<br>Memory Impairment | Escitalopram Oxalate - Bp             |                    |                    | S               | Unknown                             | Unk                    |                 | Allergan     |                |
| <u>FDA Received Date</u>                                                                                                              | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Mar-2017                                                                                                                           | 13366863                              | EXPEDITED (15-DAY) |                    | HO              | IT-AUROBINDO-AUR-<br>APL-2017-31575 |                        | 43 YR           | Male         | ITA            |
| <u>Preferred Term</u>                                                                                                                 | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                        | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                   |               |   |         |               |              |
|-------------------|---------------|---|---------|---------------|--------------|
| Drug Abuse; Sopor | Escitalopram  | S | Oral    | 270 Mg, Total | Aurobindo    |
|                   | Quetiapine    | S | Oral    | Unk           | Aurobindo    |
|                   | Carbolithium  | S | Oral    | 5 Df, Total   | Not Reported |
|                   | Etiltox       | S | Oral    | 9 Df, Total   | Not Reported |
|                   | Ethyl Alcohol | C | Unknown |               | Not Reported |

| <u>FDA Received Date</u>                                      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|-------------------------------------|----------------------|-----------------|--------------|----------------|
| 24-Mar-2017                                                   | 13366932       | EXPEDITED (15-DAY) |                    | OT              | DE-AUROBINDO-AUR-<br>APL-2017-31181 |                      | 1 DAY           | Male         | DEU            |
| <u>Preferred Term</u>                                         | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Withdrawal<br>Syndrome Neonatal; Small<br>For Dates Baby | Escitalopram   |                    |                    | S               | Transplacental                      | 25 Mg, Once A Day    |                 | Aurobindo    |                |
|                                                               | Bupropion      |                    |                    | S               | Transplacental                      | 150 Mg, Once A Day   |                 | Not Reported |                |
|                                                               | L-Thyroxin     |                    |                    | C               | Transplacental                      | 100 Mcg, Once A Day  |                 | Not Reported |                |

| <u>FDA Received Date</u>              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 24-Mar-2017                           | 13371202       | EXPEDITED (15-DAY) |                    | LT              | PHHY2017CH039123     |                      | 85 YR           | Female       | CHE            |
| <u>Preferred Term</u>                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bradycardia; Loss Of<br>Consciousness | Meto Zerok     |                    |                    | S               | Oral                 | 50 Mg, Bid           |                 | Not Reported |                |
|                                       | Escitalopram   |                    |                    | S               | Oral                 | 10 Mg, Qd            |                 | Not Reported |                |
|                                       | Atacand        |                    |                    | S               | Oral                 | 32 Mg, Qd            |                 | Not Reported |                |
|                                       | Dexdor         |                    |                    | S               | Intravenous drip     | 38.1 Ug, Unk         |                 | Not Reported |                |
|                                       | Phenylephrin   |                    |                    | S               | Intravenous drip     | 525 Ug, Unk          |                 | Not Reported |                |
|                                       | Carbostesin    |                    |                    | S               | Intrathecal          | 15 Mg, Unk           |                 | Not Reported |                |
|                                       | Sintrom        |                    |                    | C               | Unknown              |                      |                 | Not Reported |                |
|                                       | Aldactone      |                    |                    | C               | Unknown              |                      |                 | Not Reported |                |
|                                       | Omeprazol      |                    |                    | C               | Unknown              |                      |                 | Not Reported |                |
|                                       | Zoldorm        |                    |                    | C               | Unknown              |                      |                 | Not Reported |                |
|                                       | Lexotanil      |                    |                    | C               | Unknown              |                      |                 | Not Reported |                |
|                                       | Colecalciferol |                    |                    | C               | Unknown              |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |            |   |                   |             |              |
|--|------------|---|-------------------|-------------|--------------|
|  | Zinacef    | C | Unknown           | 1.5 G, Unk  | Not Reported |
|  | Adrenaline | C | Intravenous bolus | 0.5 Mg, Unk | Not Reported |
|  | Chirocaine | C | Unknown           |             | Not Reported |
|  | Tora Dol   | C | Unknown           | 30 Mg, Unk  | Not Reported |
|  | Nexium     | C | Unknown           | 40 Mg, Qd   | Not Reported |

| <u>FDA Received Date</u>                                                                                          | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 24-Mar-2017                                                                                                       | 13371342                  | EXPEDITED (15-DAY) |                    | HO              | FR-ALLERGAN-1711190US |                      | 53 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                             | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Coma Scale Abnormal;<br>Road Traffic Accident;<br>Sinus Tachycardia;<br>Somnolence; Toxicity To<br>Various Agents | Escitalopram Oxalate - Bp |                    |                    | S               | Oral                  | 20 Mg, Qd            |                 | Allergan     |                |
|                                                                                                                   | Nozinan                   |                    |                    | C               |                       |                      |                 | Not Reported |                |
|                                                                                                                   | Solian                    |                    |                    | C               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                                   | Xanax                     |                    |                    | C               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                                   | Enbrel                    |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|------------|----------------|
| 24-Mar-2017              | 13371349                  | EXPEDITED (15-DAY) |                    | OT              | CA-ALLERGAN-1711227US |                      | 53 YR           | Female     | CAN            |
| <u>Preferred Term</u>    | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Dependence          | Escitalopram Oxalate - Bp |                    |                    | S               | Unknown               | 10 Mg, Unk           |                 | Allergan   |                |
|                          | Escitalopram Oxalate - Bp |                    |                    | S               | Unknown               | 5 Mg, Unk            |                 | Allergan   |                |

| <u>FDA Received Date</u> | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|---------------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 24-Mar-2017              | 13371352                  | EXPEDITED (15-DAY) |                    | OT              | DE-ALLERGAN-1710683US |                      | 27 YR           | Female       | DEU            |
| <u>Preferred Term</u>    | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Pregnancy                | Escitalopram Oxalate - Bp |                    |                    | S               | Oral                  | 25 Mg, Qd            |                 | Allergan     |                |
|                          | Bupropion                 |                    |                    | S               | Oral                  | 150 Mg, Qd           |                 | Not Reported |                |
|                          | L-Thyroxin                |                    |                    | C               | Oral                  | 100 Mg, Qd           |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Mar-2017              | 13372277      | DIRECT           |                    |                 |                      |                      |            | Female     | USA            |

| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Migraine; Nausea; Vomiting | Escitalopram   |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Mar-2017              | 13030231      | EXPEDITED (15-DAY) |                    | HO              | FR-SA-2016SA228619   |                      | 90 YR      | Female     | FRA            |

| <u>Preferred Term</u>               | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Acute Cutaneous Lupus Erythematosus | Aprovel                |              |            | S           | Oral         |                    |                 | Not Reported |
|                                     | Loperamide             |              |            | S           | Oral         |                    |                 | Not Reported |
|                                     | Aerius (Desloratadine) |              |            | S           | Oral         |                    |                 | Not Reported |
|                                     | Aerius (Desloratadine) |              |            | S           | Oral         |                    |                 | Not Reported |
|                                     | Gaviscon               |              |            | S           | Oral         |                    |                 | Not Reported |
|                                     | Eliquis                |              |            | S           | Oral         |                    |                 | Not Reported |
|                                     | Inexium                |              |            | S           | Oral         |                    |                 | Not Reported |
|                                     | Seroplex               |              |            | S           | Oral         |                    |                 | Not Reported |
|                                     | Hemigoxine Nativelle   |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 27-Mar-2017              | 13099690      | EXPEDITED (15-DAY) |                    | HO              | FR-ABBVIE-17K-056-1827945-00 |                      | 54 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                                    | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------|-------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Actinomycosis; Headache; Hypoacusis; Osteomyelitis; Osteonecrosis Of Jaw | Humira 40mg/0.8ml |              |            | S           | Subcutaneous |                    |                 | Not Reported |
|                                                                          | Imeth             |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                          | Intelence         |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                          | Kivexa            |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                          | Nebivolol         |              |            | S           | Unknown      |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                       |   |         |              |
|-----------------------|---|---------|--------------|
| Escitalopram          | S | Unknown | Not Reported |
| Speciafoldine         | S | Unknown | Not Reported |
| Ketoprofene           | C |         | Not Reported |
| Omeprazole            | C |         | Not Reported |
| Candesartan Cilexetil | C |         | Not Reported |
| Fenofibrate           | C |         | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------------------------------------|----------------------|------------|------------|----------------|
| 27-Mar-2017              | 13281888      | EXPEDITED (15-DAY) |                    | OT              | ES-SUN<br>PHARMACEUTICAL<br>INDUSTRIES LTD-<br>2017RR-134628 |                      | 28 YR      | Female     | ESP            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Sialoadenitis         | Escitalopram   |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                       | Ondansetron    |              |            | S           | Unknown      | Unk                |                 | Natco Pharma |
|                       | Temozolomide   |              |            | C           | Unknown      | Unk                |                 | Not Reported |
|                       | Levetiracetam  |              |            | C           | Unknown      | Unk                |                 | Not Reported |
|                       | Dexamethasone  |              |            | C           | Unknown      | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------------------------------|----------------------|------------|------------|----------------|
| 27-Mar-2017              | 13335845      | EXPEDITED (15-DAY) |                    | OT              | IT-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>BMS-2017-021116 |                      | 58 YR      | Female     | ITA            |

| <u>Preferred Term</u>                                    | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>           |
|----------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------|
| Bradyphrenia; Drug Abuse; Hypokinesia; Movement Disorder | Abilify              |              |            | S           | Oral         | 1 Df, Unk          |                 | Bristol Myers Squibb |
|                                                          | Efexor               |              |            | S           | Oral         | 1 Df, Unk          |                 | Not Reported         |
|                                                          | Tavor /00273201/     |              |            | S           | Oral         | 1 Df, Unk          |                 | Not Reported         |
|                                                          | Cipralext /01588501/ |              |            | S           | Unknown      | 60 Mg, Unk         |                 | Not Reported         |
|                                                          | Talofen              |              |            | S           | Oral         | 5 Gtt, Unk         |                 | Not Reported         |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------------------|----------------------|------------|------------|----------------|
| 27-Mar-2017              | 13372406      | EXPEDITED (15-DAY) |                    | OT              | DE-SUN<br>PHARMACEUTICAL<br>INDUSTRIES LTD- |                      | 1 DAY      | Male       | DEU            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

2017RR-136485

| <u>Preferred Term</u>                                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Drug Withdrawal Syndrome Neonatal; Small For Dates Baby | Escitalopram   |              |            | S           | Transplacental | 25 Mg, Qd          |                 | Not Reported |
|                                                         | Bupropion      |              |            | S           | Transplacental | 150 Mg, Qd         |                 | Sun          |
|                                                         | L-Thyroxin     |              |            | C           | Transplacental | 100 Mg, Qd         |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 27-Mar-2017              | 13373909      | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2017131896 |                      | 72 YR      | Unknown    | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|-----------------------|-----------------|--------------|
| Neuralgia             | Lyrica         |              |            | S           |              | 50 Mg, Unk (At Night) |                 | Pfizer       |
|                       | Lyrica         |              |            | S           |              | 75 Mg, Unk            |                 | Pfizer       |
|                       | Clonazepam     |              |            | S           |              | Unk                   |                 | Not Reported |
|                       | Escitalopram   |              |            | S           |              | Unk                   |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                               | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------------------------------|----------------------|------------|------------|----------------|
| 27-Mar-2017              | 13375309      | EXPEDITED (15-DAY) |                    | LT, OT          | CH-ARALEZ PHARMACEUTICALS R&D INC.-ARA-TP-CH-2017- |                      | 85 YR      | Female     | CHE            |

| <u>Preferred Term</u>                                     | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>     | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>             |
|-----------------------------------------------------------|-------------------------------|--------------|------------|-------------|------------------|------------------------------|-----------------|------------------------|
| Bradycardia; Haemoglobin Decreased; Loss Of Consciousness | Metoprolol Succinate          |              |            | S           | Oral             |                              |                 | Aralez Pharmaceuticals |
|                                                           | Carbostesin                   |              |            | S           | Intrathecal      | 7.5 Mg, Then 2.5 Mg And 5 Mg |                 | Not Reported           |
|                                                           | Atacand                       |              |            | S           | Oral             |                              |                 | Not Reported           |
|                                                           | Escitalopram                  |              |            | S           | Oral             |                              |                 | Not Reported           |
|                                                           | Dexmedetomidine Hydrochloride |              |            | S           | Intravenous drip | 38.1 Ug, Dosing Unknown      |                 | Not Reported           |
|                                                           | Phenylephrin                  |              |            | S           | Intravenous drip | 525 Ug, Dosing Unknown       |                 | Not Reported           |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                      |   |                                       |              |
|----------------------|---|---------------------------------------|--------------|
| Sintrom              | C | Unknown                               | Not Reported |
| Aldactone            | C | Unknown                               | Not Reported |
| Omeprazole           | C | Unknown                               | Not Reported |
| Zoldem               | C | Unknown                               | Not Reported |
| Lexotanil            | C | Unknown                               | Not Reported |
| Colecalciferol       | C | Unknown                               | Not Reported |
| Zinacef              | C | Intravenous (not otherwise specified) | Not Reported |
| Adrenaline           | C | Intravenous bolus                     | Not Reported |
| Chirocaine           | C | Intra-articular                       | Not Reported |
| Toradol              | C | Intra-articular                       | Not Reported |
| Nexium For Injection | C | Intravenous (not otherwise specified) | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------|----------------------|------------|------------|----------------|
| 28-Mar-2017              | 12971631      | EXPEDITED (15-DAY) |                    | HO              | US-LUNDBECK-DKLU2022931 |                      | 34 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                                        | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Chest Pain; Dizziness; Dizziness Postural; Early Satiety; Muscular Weakness; Orthostatic Hypotension; Syncope; Urinary Tract Infection Pseudomonal; Vomiting | Northera                    |              |            | S           | Unknown      | Schedule B         |                 | Lundbeck   |
|                                                                                                                                                              | Northera                    |              |            | S           | Unknown      |                    |                 | Lundbeck   |
|                                                                                                                                                              | Northera                    |              |            | S           | Unknown      |                    |                 | Lundbeck   |
|                                                                                                                                                              | Northera                    |              |            | S           | Oral         | Schedule B         |                 | Lundbeck   |
|                                                                                                                                                              | Lexapro Film-Coated Tablets |              |            | S           | Unknown      |                    |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 28-Mar-2017              | 13375495      | EXPEDITED (15-DAY) |                    | HO, OT          | US-SUNOVION-2017SUN000087 |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Bipolar Disorder; Blood Glucose Increased; Drug Abuse; Drug Ineffective; | Latuda         |              |            | S           | Oral         | Unk                |                 | Sunovion   |
|                                                                          | Latuda         |              |            | S           | Oral         | Unk                |                 | Sunovion   |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                          |         |   |     |              |
|--------------------------|---------|---|-----|--------------|
| Heart Rate Increased;    | Lexapro | S | Unk | Not Reported |
| Sinus Disorder; Suicidal | Sudafed | S | Unk | Not Reported |
| Ideation                 | Abilify | S | Unk | Not Reported |

| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>             | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|-------------------------------------|----------------------|-----------------|------------------------|----------------|
| 28-Mar-2017                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 13376939       | EXPEDITED (15-DAY) |                    | DE, OT          | US-AUROBINDO-AUR-<br>APL-2014-07832 |                      | 45 YR           | Female                 | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>             |                |
| Blood Pressure Increased;<br>Brain Oedema; Cerebral<br>Infarction; Cerebral<br>Infarction; Clonus; Coma;<br>Condition Aggravated;<br>Confusional State; Death;<br>Decerebrate Posture;<br>Heart Rate Abnormal;<br>Hyperreflexia; Mental<br>Status Changes; Muscle<br>Rigidity; Muscle Rigidity;<br>Posterior Reversible<br>Encephalopathy<br>Syndrome; Pyrexia;<br>Reversible Cerebral<br>Vasoconstriction<br>Syndrome; Subarachnoid<br>Haemorrhage;<br>Tachycardia; Thunderclap<br>Headache | Escitalopram   |                    |                    | S               | Unknown                             | 10 Mg, Daily         |                 | Aurobindo              |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>             | <u>Country</u> |
| 28-Mar-2017                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 13380747       | DIRECT             |                    |                 |                                     |                      |                 | Female                 | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>             |                |
| Tinnitus                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Escitalopram   |                    |                    | S               |                                     |                      |                 | Bluepoint Laboratories |                |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------|----------------------------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| 29-Mar-2017                                             | 13026771                         | EXPEDITED (15-DAY) |                    | HO, OT          | FR-009507513-1612FRA006447 |                      | 90 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                   | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Acute Cutaneous Lupus Erythematosus                     | Aerius (Desloratadine)           |                    |                    | S               | Oral                       | Unk                  |                 | Merck        |                |
|                                                         | Aprovel                          |                    |                    | S               | Oral                       | Unk                  |                 | Not Reported |                |
|                                                         | Gaviscon Liquid Antacid          |                    |                    | S               | Oral                       | Unk                  |                 | Not Reported |                |
|                                                         | Eliquis                          |                    |                    | S               | Oral                       | 2.5 Mg, Bid          |                 | Not Reported |                |
|                                                         | Inexium (Esomeprazole Magnesium) |                    |                    | S               | Oral                       | 20 Mg, Qd            |                 | Not Reported |                |
|                                                         | Seroplex                         |                    |                    | S               | Oral                       | 5 Mg, Qd             |                 | Not Reported |                |
|                                                         | Hemigoxine Nativelle             |                    |                    | S               | Oral                       | Unk                  |                 | Not Reported |                |
|                                                         | Loperamide                       |                    |                    | S               | Oral                       | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Mar-2017                                             | 13181684                         | EXPEDITED (15-DAY) |                    | DE              | JP-ALLERGAN-1703914US      |                      | 70 YR           | Female       | JPN            |
| <u>Preferred Term</u>                                   | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Lung Neoplasm Malignant; Off Label Use                  | Escitalopram Oxalate - Bp        |                    |                    | S               | Oral                       | 10 Mg, Qd            |                 | Allergan     |                |
| <u>FDA Received Date</u>                                | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Mar-2017                                             | 13382898                         | EXPEDITED (15-DAY) |                    | OT              | FR-PFIZER INC-2017129205   |                      | 67 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                   | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Colitis Microscopic; Diarrhoea; Diverticulum Intestinal | Tahor                            |                    |                    | S               | Oral                       | Unk                  |                 | Pfizer       |                |
|                                                         | Coolmetec                        |                    |                    | S               | Oral                       | Unk                  |                 | Not Reported |                |
|                                                         | Seroplex                         |                    |                    | S               | Oral                       | 10 Mg, 1x/Day        |                 | Not Reported |                |
|                                                         | Valium                           |                    |                    | C               |                            |                      |                 | Not Reported |                |

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| <u>FDA Received Date</u>                  | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>     | <u>Country</u> |
|-------------------------------------------|---------------------------|--------------------|--------------------|-----------------|----------------------------------------------|----------------------|-----------------|----------------|----------------|
| 29-Mar-2017                               | 13384321                  | EXPEDITED (15-DAY) |                    | OT              | CN-ALLERGAN-1711916US                        |                      |                 | Unknown        | CHN            |
| <u>Preferred Term</u>                     | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>     |                |
| Gastric Cancer                            | Escitalopram Oxalate - Bp |                    |                    | S               | Unknown                                      | Unk                  |                 | Allergan       |                |
| <u>FDA Received Date</u>                  | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>     | <u>Country</u> |
| 29-Mar-2017                               | 13384767                  | NON-EXPEDITED      |                    |                 | US-PRINSTON PHARMACEUTICAL INC.-2016PRN00337 |                      | 20 YR           | Male           | USA            |
| <u>Preferred Term</u>                     | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>     |                |
| Drug Screen Positive; Feeling Abnormal    | Escitalopram              |                    |                    | S               | Oral                                         | 10 Mg, 1x/Day        |                 | Prinston       |                |
|                                           | Escitalopram              |                    |                    | S               |                                              |                      |                 | Pharmaceutical |                |
|                                           | Flax Seed Oil             |                    |                    | C               |                                              |                      |                 | Prinston       |                |
|                                           | Tramadol                  |                    |                    | C               |                                              |                      |                 | Pharmaceutical |                |
|                                           | Melatonin                 |                    |                    | C               |                                              |                      |                 | Not Reported   |                |
|                                           | Zyrtec D                  |                    |                    | C               |                                              |                      |                 | Not Reported   |                |
|                                           | Theraflu                  |                    |                    | C               |                                              |                      |                 | Not Reported   |                |
|                                           | Ibuprofen                 |                    |                    | C               |                                              |                      |                 | Not Reported   |                |
|                                           | Sinex Nose Spray          |                    |                    | C               |                                              |                      |                 | Not Reported   |                |
|                                           | Wellbutrin                |                    |                    | S               |                                              | Unk                  |                 | Not Reported   |                |
|                                           | Wellbutrin                |                    |                    | S               |                                              |                      |                 | Not Reported   |                |
| <u>FDA Received Date</u>                  | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>     | <u>Country</u> |
| 29-Mar-2017                               | 13385261                  | EXPEDITED (15-DAY) |                    | OT              | CN-ALLERGAN-1711921US                        |                      | 38 YR           | Female         | CHN            |
| <u>Preferred Term</u>                     | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>     |                |
| Pruritus Generalised; Rash Maculo-Papular | Escitalopram Oxalate - Bp |                    |                    | S               | Oral                                         | 10 Mg, Qd            |                 | Allergan       |                |
| <u>FDA Received Date</u>                  | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>     | <u>Country</u> |
| 29-Mar-2017                               | 13385270                  | EXPEDITED (15-DAY) |                    | OT              | DE-ALLERGAN-1711928US                        |                      | 82 YR           | Male           | DEU            |

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| <u>Preferred Term</u>                                                                                                                                                                                                                                     | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                           | <u>Dosage Text</u>                                                       | <u>Duration</u> | <u>Mfr</u>           |                |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|--------------------------------------------------------|--------------------------------------------------------------------------|-----------------|----------------------|----------------|
| Brain Hypoxia; Fall;<br>Hypotension; Loss Of<br>Consciousness                                                                                                                                                                                             | Escitalopram Oxalate - Bp |                    |                    | S               | Unknown                                                | 10 Mg, Qd                                                                |                 | Allergan             |                |
|                                                                                                                                                                                                                                                           | Trusopt S                 |                    |                    | C               | Ophthalmic                                             | 2 Gtt, Qam                                                               |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                  | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u>                                                     | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 30-Mar-2017                                                                                                                                                                                                                                               | 13038964                  | EXPEDITED (15-DAY) |                    | HO, OT          | FR-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>BMS-2016-106663 |                                                                          | 90 YR           | Female               | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                     | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                           | <u>Dosage Text</u>                                                       | <u>Duration</u> | <u>Mfr</u>           |                |
| Acute Cutaneous Lupus<br>Erythematosus                                                                                                                                                                                                                    | Eliquis                   |                    |                    | S               | Oral                                                   | 2.5 Mg, Bid                                                              |                 | Bristol Myers Squibb |                |
|                                                                                                                                                                                                                                                           | Aprovel                   |                    |                    | S               | Unknown                                                | 150 Mg, Qd                                                               |                 | Not Reported         |                |
|                                                                                                                                                                                                                                                           | Aerius /01398501/         |                    |                    | S               | Unknown                                                | Unk                                                                      |                 | Not Reported         |                |
|                                                                                                                                                                                                                                                           | Gaviscon                  |                    |                    | S               | Unknown                                                | Unk                                                                      |                 | Not Reported         |                |
|                                                                                                                                                                                                                                                           | Seroplex                  |                    |                    | S               | Oral                                                   | 5 Mg, Qd                                                                 |                 | Not Reported         |                |
|                                                                                                                                                                                                                                                           | Inexium /01479302/        |                    |                    | S               | Unknown                                                | 20 Mg, Qd                                                                |                 | Not Reported         |                |
|                                                                                                                                                                                                                                                           | Hemigoxine Nativelle      |                    |                    | S               | Oral                                                   | 0.125 Mg, Unk                                                            |                 | Not Reported         |                |
|                                                                                                                                                                                                                                                           | Loperamide                |                    |                    | S               | Unknown                                                | Unk                                                                      |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                  | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u>                                                     | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 30-Mar-2017                                                                                                                                                                                                                                               | 13243124                  | EXPEDITED (15-DAY) |                    | HO              | GR-ABBVIE-17P-066-<br>1878084-00                       |                                                                          | 70 YR           | Male                 | GRC            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                     | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                           | <u>Dosage Text</u>                                                       | <u>Duration</u> | <u>Mfr</u>           |                |
| Abnormal Dreams;<br>Aggression; Agitation;<br>Delusion; Fall;<br>Hallucination;<br>Hypotension; Irritability;<br>Nephrolithiasis; Psychotic<br>Disorder; Pyrexia; Staring;<br>Tremor; Unintentional<br>Medical Device Removal;<br>Urinary Tract Infection | Duodopa                   |                    |                    | S               | Other                                                  | Morning Dose:10.5 MI,<br>Extra Dose: 1.5 MI,<br>Continuous Rate:2.6 MI/H |                 | Not Reported         |                |
|                                                                                                                                                                                                                                                           | Duodopa                   |                    |                    | S               | Other                                                  |                                                                          |                 | Not Reported         |                |
|                                                                                                                                                                                                                                                           | Entact                    |                    |                    | S               | Unknown                                                |                                                                          |                 | Not Reported         |                |
|                                                                                                                                                                                                                                                           | Filicine                  |                    |                    | C               | Oral                                                   |                                                                          |                 | Not Reported         |                |
|                                                                                                                                                                                                                                                           | Omnice Tocas              |                    |                    | C               | Oral                                                   |                                                                          |                 | Not Reported         |                |
|                                                                                                                                                                                                                                                           | Stalevo                   |                    |                    | C               | Oral                                                   |                                                                          |                 | Not Reported         |                |

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| <u>FDA Received Date</u>                                                                                                                                  | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|------------------------------------------|----------------------|-----------------|------------------|----------------|
| 30-Mar-2017                                                                                                                                               | 13274430                  | EXPEDITED (15-DAY) |                    | HO              | IT-MYLANLABS-2017M1000888                |                      |                 | Unknown          | ITA            |
| <u>Preferred Term</u>                                                                                                                                     | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |
| Intentional Product Misuse; Off Label Use; Somnolence                                                                                                     | Escitalopram              |                    |                    | S               |                                          | Unk                  |                 | Not Reported     |                |
| <u>FDA Received Date</u>                                                                                                                                  | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 30-Mar-2017                                                                                                                                               | 13381552                  | EXPEDITED (15-DAY) |                    | OT              | ES-ALLERGAN-1711683US                    |                      |                 | Unknown          | ESP            |
| <u>Preferred Term</u>                                                                                                                                     | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |
| Osteomyelitis; Osteonecrosis                                                                                                                              | Escitalopram Oxalate - Bp |                    |                    | S               |                                          | 15 Gtt, Qd           |                 | Allergan         |                |
| <u>FDA Received Date</u>                                                                                                                                  | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 30-Mar-2017                                                                                                                                               | 13381567                  | EXPEDITED (15-DAY) |                    | HO, OT          | US-ALLERGAN-1711841US                    |                      | 34 YR           | Male             | USA            |
| <u>Preferred Term</u>                                                                                                                                     | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |
| Chest Pain; Dizziness; Dizziness Postural; Dyspepsia; Early Satiety; Muscular Weakness; Orthostatic Hypotension; Pseudomonas Infection; Syncope; Vomiting | Lexapro                   |                    |                    | S               | Unknown                                  |                      |                 | Allergan         |                |
|                                                                                                                                                           | Northera                  |                    |                    | S               | Oral                                     | 300 Mg, Tid          |                 | Not Reported     |                |
|                                                                                                                                                           | Northera                  |                    |                    | S               | Oral                                     | 1800 Mg, Qd          |                 | Not Reported     |                |
|                                                                                                                                                           | Northera                  |                    |                    | S               | Oral                                     | Unk Unk, Qd          |                 | Not Reported     |                |
|                                                                                                                                                           | Northera                  |                    |                    | S               | Oral                                     | 900 Mg, Qd           |                 | Not Reported     |                |
| <u>FDA Received Date</u>                                                                                                                                  | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 30-Mar-2017                                                                                                                                               | 13385763                  | EXPEDITED (15-DAY) |                    | OT              | US-ELI_LILLY_AND_COMP ANY-US201608000458 |                      |                 | Female           | USA            |
| <u>Preferred Term</u>                                                                                                                                     | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |
| Abnormal Behaviour; Affect Liability; Agitation;                                                                                                          | Cymbalta                  |                    |                    | S               | Oral                                     | 30 Mg, Qd            |                 | Eli Lilly And Co |                |

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|                                 |          |   |         |              |                  |
|---------------------------------|----------|---|---------|--------------|------------------|
| Anger; Anhedonia;               | Cymbalta | S | Oral    | 60 Mg, Qd    | Eli Lilly And Co |
| Anxiety; Arthralgia;            | Cymbalta | S | Oral    | 90 Mg, Qd    | Eli Lilly And Co |
| Asthenia; Back Pain;            | Cymbalta | S | Oral    | 120 Mg, Qd   | Eli Lilly And Co |
| Blood Cholesterol               | Cymbalta | S | Oral    | 30 Mg, Qd    | Eli Lilly And Co |
| Increased; Confusional          | Cymbalta | S | Oral    | 90 Mg, Qd    | Eli Lilly And Co |
| State; Diarrhoea;               | Cymbalta | S | Oral    | 60 Mg, Qd    | Eli Lilly And Co |
| Disturbance In Attention;       | Cymbalta | S | Oral    | 30 Mg, Qd    | Eli Lilly And Co |
| Dizziness; Drug                 | Cymbalta | S | Oral    | 30 Mg, Qd    | Eli Lilly And Co |
| Ineffective; Drug               | Cymbalta | S | Unknown | Unk, Unknown | Not Reported     |
| Withdrawal Syndrome;            | Lexapro  | S |         |              |                  |
| Dysphoria; Fatigue; Fear;       |          |   |         |              |                  |
| Headache; Hepatic Cyst;         |          |   |         |              |                  |
| Hyperhidrosis;                  |          |   |         |              |                  |
| Hypertension; Hypomania;        |          |   |         |              |                  |
| Injury; Insomnia; Irritability; |          |   |         |              |                  |
| Judgement Impaired;             |          |   |         |              |                  |
| Lethargy; Libido Disorder;      |          |   |         |              |                  |
| Lung Neoplasm; Memory           |          |   |         |              |                  |
| Impairment; Myalgia;            |          |   |         |              |                  |
| Nausea; Nausea; Nausea;         |          |   |         |              |                  |
| Nervousness; Nightmare;         |          |   |         |              |                  |
| Restless Legs Syndrome;         |          |   |         |              |                  |
| Sleep Disorder; Soliloquy;      |          |   |         |              |                  |
| Suicidal Ideation; Tinnitus;    |          |   |         |              |                  |
| Tremor; Vertigo; Visual         |          |   |         |              |                  |
| Impairment; Vomiting;           |          |   |         |              |                  |
| Weight Increased                |          |   |         |              |                  |

| <u>FDA Received Date</u> | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|---------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
| 30-Mar-2017              | 13386956                  | EXPEDITED (15-DAY) |                    | OT              | DE-ALLERGAN-1712260US     |                      | 73 YR           | Female       | DEU            |
| <u>Preferred Term</u>    | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrial Fibrillation;     | Escitalopram Oxalate - Bp |                    |                    | S               |                           | 20 Mg, Qd            |                 | Allergan     |                |
| Paroxysmal Arrhythmia    | Escitalopram Oxalate - Bp |                    |                    | S               |                           | 10 Mg, Qd            |                 | Allergan     |                |
|                          | Xarelto                   |                    |                    | C               |                           | 20 Mg, Qd            |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Mar-2017              | 13387382                  | EXPEDITED (15-DAY) |                    | OT              | AU-MYLANLABS-2017M1019137 |                      |                 | Unknown      | AUS            |

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| <u>Preferred Term</u>                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Dependence;<br>Product Prescribing Error | Tramadol       |              |            | S           |              | Unk                |                 | Not Reported |
|                                               | Paracetamol    |              |            | S           |              | Unk                |                 | Not Reported |
|                                               | Pantoprazole   |              |            | S           |              | Unk                |                 | Not Reported |
|                                               | Fentanyl       |              |            | S           |              | Unk                |                 | Not Reported |
|                                               | Zolpidem       |              |            | S           |              |                    |                 | Not Reported |
|                                               | Alprazolam     |              |            | S           |              | Unk                |                 | Not Reported |
|                                               | Escitalopram   |              |            | S           |              | Unk                |                 | Not Reported |
|                                               | Naproxen       |              |            | S           |              | Unk                |                 | Not Reported |
|                                               | Oxazepam       |              |            | S           |              | Unk                |                 | Not Reported |
|                                               | Folic Acid     |              |            | S           |              | Unk                |                 | Not Reported |
|                                               | Temazepam      |              |            | S           |              | Unk                |                 | Not Reported |
|                                               | Methotrexate   |              |            | S           |              | Unk                |                 | Mylan        |
|                                               | Ritalin        |              |            | S           |              |                    |                 | Mylan        |
|                                               | Oxycodone      |              |            | S           |              | Unk                |                 | Mylan        |
|                                               | Pregabalin     |              |            | S           |              | Unk                |                 | Mylan        |
|                                               | Buprenorphine  |              |            | S           |              | Unk                |                 | Mylan        |
|                                               | Dexamphetamine |              |            | S           |              | Unk                |                 | Mylan        |
|                                               | Prednisolone   |              |            | S           |              | Unk                |                 | Mylan        |
|                                               | Clonidine      |              |            | S           |              | Unk                |                 | Mylan        |
|                                               | Lorazepam      |              |            | S           |              | Unk                |                 | Mylan        |
|                                               | Cocaine        |              |            | S           |              | Unk                |                 | Mylan        |
|                                               | Cannabis       |              |            | S           |              | Unk                |                 | Mylan        |
|                                               | Psilocybine    |              |            | S           |              | Unk                |                 | Mylan        |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                              | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------------------------|----------------------|------------|------------|----------------|
| 30-Mar-2017              | 13388024      | EXPEDITED (15-DAY) |                    | DE, OT          | FR-IMPAX<br>LABORATORIES, INC-<br>2017-IPXL-00751 |                      | 53 YR      | Male       | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                  |              |   |         |     |              |
|------------------------------------------------------------------|--------------|---|---------|-----|--------------|
| Cardiac Arrest; Off Label Use; Overdose; Unresponsive To Stimuli | Baclofen     | S | Unknown | Unk | Impax        |
|                                                                  | Colchicine   | S | Unknown | Unk | Not Reported |
|                                                                  | Escitalopram | S | Unknown | Unk | Not Reported |
|                                                                  | Metoprolol   | S | Unknown | Unk | Not Reported |
|                                                                  | Perindopril  | S | Unknown | Unk | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------------------|----------------------|------------|------------|----------------|
| 30-Mar-2017              | 13388029      | EXPEDITED (15-DAY) |                    | DE, OT          | FR-IMPAX LABORATORIES, INC-2017-IPXL-00755 |                      | 41 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                        | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------|--------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Off Label Use; Poisoning Deliberate; Unresponsive To Stimuli | Baclofen           |              |            | S           | Unknown      | Unk                |                 | Impax        |
|                                                              | Acetaminophen      |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                                                              | Dextropropoxyphene |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                                                              | Escitalopram       |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                                                              | Valpromide         |              |            | S           | Unknown      | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 30-Mar-2017              | 13388404      | EXPEDITED (15-DAY) |                    | OT              | IT-MYLANLABS-2017M1019235 |                      |            | Unknown    | ITA            |

| <u>Preferred Term</u> | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Abuse            | Escitalopram      |              |            | S           |              | 10 Df, Total       |                 | Not Reported |
|                       | Tavor [Lorazepam] |              |            | S           |              | 2 Df, Total        |                 | Mylan        |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Mar-2017              | 13389412      | EXPEDITED (15-DAY) |                    | HO              | IT-TEVA-752802ACC    |                      | 43 YR      | Male       | ITA            |

| <u>Preferred Term</u> | <u>Product</u>                                            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|-----------------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Drug Abuse; Sopor     | Carbolithium - 300 Mg Capsule Rigide - Teva Italia S.R.L. |              |            | S           | Oral         | 5 Df Total         |                 | Barr       |
|                       | Escitalopram                                              |              |            | S           | Oral         | 270 Mg Total       |                 | Ivax       |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |                               |   |      |  |            |  |  |              |
|--|-------------------------------|---|------|--|------------|--|--|--------------|
|  | Quetiapine                    | S | Oral |  |            |  |  | Not Reported |
|  | Ettiltox - 200 Mg Compresse - | S | Oral |  | 9 Df Total |  |  | Not Reported |
|  | Afom Dipendenza S.R.L.        |   |      |  |            |  |  |              |
|  | Ethyl Alcohol                 | C |      |  |            |  |  | Not Reported |

| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------|----------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
| 31-Mar-2017               | 13095471       | EXPEDITED (15-DAY) |                    | HO              | AU-MYLANLABS-2016M1050143 |                      | 54 YR           | Male         | AUS            |
| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aspartate                 | Clozapine      |                    |                    | S               | Oral                      | 25 Mg, Unk           |                 | Not Reported |                |
| Aminotransferase          | Clozapine      |                    |                    | S               | Oral                      | Unk                  |                 | Not Reported |                |
| Increased; Blood Creatine | Clozapine      |                    |                    | S               | Oral                      | 350 Mg, Qd           |                 | Not Reported |                |
| Phosphokinase Increased;  | Clozapine      |                    |                    | S               | Oral                      | 775 Mg, Qd           |                 | Not Reported |                |
| Blood Lactate             | Clozapine      |                    |                    | S               | Oral                      | 400 Mg, Bid          |                 | Not Reported |                |
| Dehydrogenase             | Amisulpride    |                    |                    | S               | Oral                      | 20 Mg, Qd            |                 | Not Reported |                |
| Increased; Blood Sodium   | Escitalopram   |                    |                    | S               | Oral                      | 30 Mg, Tid           |                 | Not Reported |                |
| Decreased; Neuroleptic    | Oxazepam       |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
| Malignant Syndrome;       |                |                    |                    |                 |                           |                      |                 |              |                |
| White Blood Cell Count    |                |                    |                    |                 |                           |                      |                 |              |                |
| Increased                 |                |                    |                    |                 |                           |                      |                 |              |                |

| <u>FDA Received Date</u> | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|---------------------|--------------------|--------------------|-----------------|--------------------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 31-Mar-2017              | 13389628            | EXPEDITED (15-DAY) |                    | HO              | IT-SUN<br>PHARMACEUTICAL<br>INDUSTRIES LTD-<br>2017RR-136773 |                      | 43 YR           | Male         | ITA            |
| <u>Preferred Term</u>    | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Abuse; Sopor        | Escitalopram        |                    |                    | S               | Oral                                                         | 270 Mg Total         |                 | Not Reported |                |
|                          | Quetiapine          |                    |                    | S               | Oral                                                         | Unk                  |                 | Sun          |                |
|                          | Carbolithium 300 Mg |                    |                    | S               | Oral                                                         | 5 Df Total           |                 | Not Reported |                |
|                          | Ettiltox 200 Mg     |                    |                    | S               | Oral                                                         | 9 Df Total           |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|------------------------|----------------------|-----------------|------------|----------------|
| 31-Mar-2017              | 13393624       | EXPEDITED (15-DAY) |                    | HO, OT          | IT-APOTEX-2017AP009118 |                      | 43 YR           | Male       | ITA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                   |                             |   |         |               |              |
|-------------------|-----------------------------|---|---------|---------------|--------------|
| Drug Abuse; Sopor | Quetiapina Doc Generici     | S | Oral    |               | Apotex       |
|                   | Comprese Rivestite Con Film |   |         |               |              |
|                   | Escitalopram                | S | Oral    | 270 Mg, Total | Not Reported |
|                   | Carbolithium                | S | Oral    | 5 Df, Total   | Not Reported |
|                   | Etilton                     | S | Oral    | 9 Df, Total   | Not Reported |
|                   | Ethyl Alcohol               | C | Unknown | Unk           | Not Reported |

| <u>FDA Received Date</u>                                      | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|------------------------|----------------------|-----------------|--------------|----------------|
| 31-Mar-2017                                                   | 13393888                  | EXPEDITED (15-DAY) |                    | OT              | DE-ALLERGAN-1000082554 |                      | 70 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                         | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Nausea; Urinary Retention; Weight Increased | Escitalopram Oxalate - Bp |                    |                    | S               | Unknown                | 10 Mg, Qd            |                 | Allergan     |                |
|                                                               | Escitalopram Oxalate - Bp |                    |                    | S               |                        | 5 Mg, Qd             |                 | Allergan     |                |
|                                                               | Valsartan                 |                    |                    | S               | Unknown                | 120 Mg, Qd           |                 | Not Reported |                |
|                                                               | Diclofenac                |                    |                    | S               |                        |                      |                 | Not Reported |                |
|                                                               | L-Thyroxin                |                    |                    | C               |                        |                      |                 | Not Reported |                |
|                                                               | Baldrian-Dispert          |                    |                    | C               |                        |                      |                 | Not Reported |                |
|                                                               | Homeopathic Preparation   |                    |                    | C               |                        |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>       | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------|---------------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 31-Mar-2017                    | 13393889                  | EXPEDITED (15-DAY) |                    | OT              | FR-ALLERGAN-1712510US |                      | 67 YR           | Female       | FRA            |
| <u>Preferred Term</u>          | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Colitis Microscopic; Diarrhoea | Escitalopram Oxalate - Bp |                    |                    | S               | Oral                  | 10 Mg, Qd            |                 | Allergan     |                |
|                                | Coolmetec                 |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                | Tahor                     |                    |                    | S               | Oral                  | Unk                  |                 | Not Reported |                |
|                                | Valium                    |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|------------|----------------|
| 03-Apr-2017              | 13047375       | EXPEDITED (15-DAY) |                    | HO              | FR-ALLERGAN-1681364US |                      | 90 YR           | Female     | FRA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                     |                           |   |      |             |              |
|-------------------------------------|---------------------------|---|------|-------------|--------------|
| Acute Cutaneous Lupus Erythematosus | Escitalopram Oxalate - Bp | S | Oral | 5 Mg, Qd    | Allergan     |
|                                     | Seroplex                  | S | Oral | 5 Mg, Qd    | Not Reported |
|                                     | Aprovel                   | S | Oral | Unk         | Not Reported |
|                                     | Aerius (Desloratadine)    | S | Oral | Unk         | Not Reported |
|                                     | Gaviscon                  | S | Oral | Unk         | Not Reported |
|                                     | Eliquis                   | S | Oral | 2.5 Mg, Bid | Not Reported |
|                                     | Inexium                   | S | Oral | 20 Mg, Qd   | Not Reported |
|                                     | Hemigoxine Nativelle      | S | Oral | Unk         | Not Reported |
|                                     | Loperamide                | S | Oral | Unk         | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|------------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|-----------------|--------------|----------------|
| 03-Apr-2017              | 13395914         | EXPEDITED (15-DAY) |                    | OT              | IT-AUROBINDO-AUR-APL-2017-31676 |                      | 44 YR           | Female       | ITA            |
| <u>Preferred Term</u>    | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Abuse               | Escitalopram     |                    |                    | S               | Unknown                         | 10 Df, Unk           |                 | Aurobindo    |                |
|                          | Tavor /00273201/ |                    |                    | S               | Unknown                         | Unk                  |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                             | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 03-Apr-2017                                                                                                                                          | 13397478                  | EXPEDITED (15-DAY) |                    | HO, OT          | FR-ALLERGAN-1712676US |                      | 72 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                                | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Pressure Increased; Cerebrovascular Accident; Dizziness; Headache; Insomnia; Irritability; Nervousness; Nodule; Palpitations; Tremor; Vomiting | Escitalopram Oxalate - Bp |                    |                    | S               | Oral                  | 10 Mg, Qd            |                 | Allergan     |                |
|                                                                                                                                                      | Escitalopram Oxalate - Bp |                    |                    | S               | Oral                  | 5 Mg, Qd             |                 | Allergan     |                |
|                                                                                                                                                      | Escitalopram Oxalate - Bp |                    |                    | S               | Oral                  | 15 Mg, Qd            |                 | Allergan     |                |
|                                                                                                                                                      | Escitalopram Oxalate - Bp |                    |                    | S               | Oral                  | 10 Mg, Qd            |                 | Allergan     |                |
|                                                                                                                                                      | Escitalopram Oxalate - Bp |                    |                    | S               | Oral                  | 15 Mg, Qd            |                 | Allergan     |                |
|                                                                                                                                                      | Lexomil                   |                    |                    | S               | Oral                  | 0.25 Df, Single      |                 | Not Reported |                |
|                                                                                                                                                      | Tenoretic                 |                    |                    | C               | Unknown               | 50/12.5mg            |                 | Not Reported |                |
|                                                                                                                                                      | Kenzen                    |                    |                    | C               | Unknown               | Unk                  |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                       | <u>Case #</u>    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------|------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 03-Apr-2017                                                    | 13397757         | EXPEDITED (15-DAY) |                    | DE, LT, OT      | JP-PFIZER INC-2017137368 |                      | 55 YR           | Female       | JPN            |
| <u>Preferred Term</u>                                          | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Brain Death; Cardio-Respiratory Arrest; Chest Pain; Somnolence | Effexor 37.5mg   |                    |                    | S               | Oral                     | Unk                  |                 | Pfizer       |                |
|                                                                | Effexor 37.5mg   |                    |                    | S               | Oral                     | 37.5 Mg, Daily       |                 | Pfizer       |                |
|                                                                | Lexapro          |                    |                    | S               | Oral                     | 20 Mg, Daily         |                 | Not Reported |                |
|                                                                | Lamictal         |                    |                    | S               | Oral                     | 400 Mg, Daily        |                 | Not Reported |                |
|                                                                | Abilify          |                    |                    | S               | Oral                     | 3 Mg, Daily          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Apr-2017                                                    | 13397981         | EXPEDITED (15-DAY) |                    | OT              | FR-DSJP-DSE-2017-109416  |                      |                 | Unknown      | FRA            |
| <u>Preferred Term</u>                                          | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Colitis Microscopic; Diarrhoea                                 | Coolmetec        |                    |                    | S               | Oral                     | Unk                  |                 | Daiichi      |                |
|                                                                | Tahor            |                    |                    | S               | Oral                     | Unk Unk, Qd          |                 | Not Reported |                |
|                                                                | Seroplex         |                    |                    | S               | Oral                     | 10 Mg, Qd            |                 | Not Reported |                |
|                                                                | Valium           |                    |                    | C               |                          | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Apr-2017                                                    | 13398813         | EXPEDITED (15-DAY) |                    | CA              | CA-TEVA-755466ACC        |                      | 31 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                          | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Trisomy 21                                                     | Act Escitalopram |                    |                    | S               | Oral                     | 10 Milligram Daily;  |                 | Ivax         |                |
|                                                                | Act Escitalopram |                    |                    | S               |                          |                      |                 | Ivax         |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Apr-2017                                                    | 13399586         | DIRECT             | Y                  | OT              |                          |                      | 29 YR           | Female       | USA            |
| <u>Preferred Term</u>                                          | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                     |                   |                    |                    |                    |                                           |                                   |                 |              |                |
|-------------------------------------------------------------------------------------|-------------------|--------------------|--------------------|--------------------|-------------------------------------------|-----------------------------------|-----------------|--------------|----------------|
| Nausea; Product Substitution Issue                                                  |                   | Escitalopram       |                    | S                  | Oral                                      |                                   | 90 DAY          |              | Exelan         |
| <u>FDA Received Date</u>                                                            | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>    | <u>Mfr Control #</u>                      | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Apr-2017                                                                         | 13399458          | EXPEDITED (15-DAY) |                    | OT                 | DE-HETERO LABS LTD-1064957                |                                   | 45 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                                               | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>        | <u>Route</u>                              | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Drug Ineffective; Serotonin Syndrome; Suicidal Behaviour                | Lithium           |                    |                    | S                  | Unknown                                   |                                   |                 | Hetero       |                |
|                                                                                     | Escitalopram      |                    |                    | S                  | Unknown                                   |                                   |                 | Not Reported |                |
|                                                                                     | Quetiapine        |                    |                    | S                  | Unknown                                   |                                   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                            | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>    | <u>Mfr Control #</u>                      | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Apr-2017                                                                         | 13399528          | EXPEDITED (15-DAY) |                    | OT                 | IT-ACCORD-049739                          |                                   | 44 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                               | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>        | <u>Route</u>                              | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Abuse                                                                          | Escitalopram      |                    |                    | S                  |                                           | 10 Df Total                       |                 | Not Reported |                |
|                                                                                     | Tavor [Lorazepam] |                    |                    | S                  |                                           | 2 Df Total                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                            | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>    | <u>Mfr Control #</u>                      | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Apr-2017                                                                         | 13400372          | EXPEDITED (15-DAY) |                    | OT                 | US-GLENMARK PHARMACEUTICALS-2017GMK026982 |                                   |                 | Female       | USA            |
| <u>Preferred Term</u>                                                               | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>        | <u>Route</u>                              | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |                |
| Human Herpesvirus 6 Infection; Hypersensitivity; Maternal Exposure During Pregnancy | Ondansetron       |                    |                    | S                  | Unknown                                   | Unk                               |                 | Glenmark     |                |
|                                                                                     | Sertraline        |                    |                    | S                  | Unknown                                   | Unk,For The Initial Two Trimester |                 | Not Reported |                |
|                                                                                     | Escitalopram      |                    |                    | S                  | Unknown                                   | Unk,For The Final Trimester       |                 | Not Reported |                |
|                                                                                     | Progesterone      |                    |                    | S                  | Unknown                                   | Unk,High-Dose                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                            | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>    | <u>Mfr Control #</u>                      | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Apr-2017                                                                         | 13400404          | EXPEDITED (15-DAY) |                    | CA, DE, HO, LT, OT | US-GLENMARK PHARMACEUTICALS-              |                                   | 4 YR            | Male         | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

2017GMK026983

| <u>Preferred Term</u>                                                                                                                                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Cardiac Failure;<br>Cardiomyopathy; Foetal<br>Exposure During<br>Pregnancy; Human<br>Herpesvirus 6 Infection;<br>Multiple Organ<br>Dysfunction Syndrome | Ondansetron    |              |            | S           | Transplacental | Unk                |                 | Glenmark     |
|                                                                                                                                                         | Sertraline     |              |            | S           | Transplacental | Unk                |                 | Not Reported |
|                                                                                                                                                         | Escitalopram   |              |            | S           | Transplacental | Unk                |                 | Not Reported |
|                                                                                                                                                         | Progesterone   |              |            | S           | Transplacental | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 04-Apr-2017              | 13401899      | EXPEDITED (15-DAY) |                    | OT              | US-ALLERGAN-1712712US |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                                                                 | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Exposure During<br>Pregnancy; Human<br>Herpesvirus 6 Infection;<br>Hypersensitivity; Off Label<br>Use | Progesterone Unk         |              |            | S           | Unknown      | Unk Unk, Unknown   |                 | Allergan     |
|                                                                                                       | Escitalopram Oxalate Unk |              |            | S           | Unknown      | Unk                |                 | Allergan     |
|                                                                                                       | Sertraline               |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                       | Ondansetron              |              |            | S           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 04-Apr-2017              | 13401907      | EXPEDITED (15-DAY) |                    | DE              | US-ALLERGAN-1712723US |                      | 4 DAY      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                                                 | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Cardiac Failure;<br>Congestive<br>Cardiomyopathy; Foetal<br>Exposure During<br>Pregnancy; Human<br>Herpesvirus 6 Infection;<br>Multiple Organ<br>Dysfunction Syndrome | Progesterone Unk         |              |            | S           | Transplacental |                    |                 | Allergan     |
|                                                                                                                                                                       | Escitalopram Oxalate Unk |              |            | S           | Transplacental |                    |                 | Allergan     |
|                                                                                                                                                                       | Sertraline               |              |            | S           | Transplacental |                    |                 | Not Reported |
|                                                                                                                                                                       | Ondansetron              |              |            | S           | Transplacental |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------|----------------|--------------------|--------------------|-----------------|-----------------------------------------------|----------------------|-----------------|--------------|----------------|
| 05-Apr-2017                                           | 13028220       | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2016566548                      |                      | 72 YR           | Female       | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity                                 | Calan          |                    |                    | S               |                                               | Unk                  |                 | Pfizer       |                |
|                                                       | Tessalon       |                    |                    | S               |                                               | Unk                  |                 | Pfizer       |                |
|                                                       | Lexapro        |                    |                    | S               |                                               | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Apr-2017                                           | 13404035       | EXPEDITED (15-DAY) |                    | HO, OT          | US-TORRENT-00002641                           |                      | 46 YR           | Male         | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Catatonia; Delirium; Serotonin Syndrome               | Escitalopram   |                    |                    | S               |                                               |                      |                 | Unknown      |                |
|                                                       | Lithium        |                    |                    | S               |                                               |                      |                 | Unknown      |                |
|                                                       | Trazodone      |                    |                    | S               |                                               |                      |                 | Unknown      |                |
|                                                       | Paliperidone   |                    |                    | S               |                                               |                      |                 | Unknown      |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Apr-2017                                           | 13404929       | EXPEDITED (15-DAY) |                    | OT              | DE-BAYER-2017-061458                          |                      | 28 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cervicitis; Haematoma; Metrorrhagia; Thrombocytopenia | Mirena         |                    |                    | S               | Intra-uterine                                 | 20 Mcg/24hr, Cont    |                 | Bayer        |                |
|                                                       | Escitalopram   |                    |                    | S               |                                               | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Apr-2017                                           | 13406258       | EXPEDITED (15-DAY) |                    | CA, DE, OT      | DE-IPCA LABORATORIES LIMITED-IPC201703-000332 |                      | 4 DAY           | Unknown      | DEU            |
| <u>Preferred Term</u>                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Congestive Cardiomyopathy; Foetal                     | Ondansetron    |                    |                    | S               |                                               |                      |                 | Ipca         |                |
|                                                       | Sertraline     |                    |                    | S               |                                               |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                               |                              |        |                              |
|-----------------------------------------------------------------------------------------------|------------------------------|--------|------------------------------|
| Exposure During Pregnancy; Human Herpesvirus 6 Infection; Multiple Organ Dysfunction Syndrome | Escitalopram<br>Progesterone | S<br>S | Not Reported<br>Not Reported |
|-----------------------------------------------------------------------------------------------|------------------------------|--------|------------------------------|

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>    | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|---------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 05-Apr-2017                       | 13406705                  | EXPEDITED (15-DAY)        |                             | HO                       | FR-ALLERGAN-1713133US         |                               | 91 YR                    | Male                | FRA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a>   | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Anaemia; Melaena                  | Escitalopram Oxalate - Bp |                           |                             | S                        | Oral                          | 5 Mg, Qd                      |                          | Allergan            |                         |
|                                   | Pradaxa                   |                           |                             | S                        | Oral                          | 150 Mg, Bid                   |                          | Not Reported        |                         |
|                                   | Bisoprolol                |                           |                             | C                        |                               | 5 Mg, Qd                      |                          | Not Reported        |                         |
|                                   | Simvastatine              |                           |                             | C                        |                               | 20 Mg, Qd                     |                          | Not Reported        |                         |
|                                   | Valsartan                 |                           |                             | C                        |                               | Unk                           |                          | Not Reported        |                         |

| <a href="#">FDA Received Date</a>                                                                                   | <a href="#">Case #</a>    | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|---------------------------------------------------------------------------------------------------------------------|---------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 05-Apr-2017                                                                                                         | 13407269                  | EXPEDITED (15-DAY)        |                             | OT                       | SE-ALLERGAN-1713422US         |                               | 37 YR                    | Female              | SWE                     |
| <a href="#">Preferred Term</a>                                                                                      | <a href="#">Product</a>   | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Arrhythmia; Contusion; Daydreaming; Diarrhoea; Dizziness; Fatigue; Hyperhidrosis; Off Label Use; Pruritus; Vomiting | Escitalopram Oxalate - Bp |                           |                             | S                        | Oral                          | 5 Mg, Qd                      |                          | Allergan            |                         |

| <a href="#">FDA Received Date</a>                                      | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>              | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|--------------------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 05-Apr-2017                                                            | 13407406                | EXPEDITED (15-DAY)        |                             | OT                       | US-IMPAX LABORATORIES, INC-2017-IPXL-00803 |                               | 33 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>                                         | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                      | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Cyanosis; Depressed Level Of Consciousness; Toxicity To Various Agents | Alprazolam Er           |                           |                             | S                        | Unknown                                    | Unk                           |                          | Impax               |                         |
|                                                                        | Buspirone Hydrochloride |                           |                             | S                        | Unknown                                    | Unk                           |                          | Impax               |                         |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                           |                |                  |                    |                 |                      |                      |                       |                 |                |  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------------|-----------------|----------------|--|
| Escitalopram                                                                                                                                              |                |                  | S                  |                 | Unknown              |                      | Unk                   |                 | Not Reported   |  |
| <u>FDA Received Date</u>                                                                                                                                  | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>            | <u>Sex</u>      | <u>Country</u> |  |
| 05-Apr-2017                                                                                                                                               | 13408490       | DIRECT           |                    | OT              |                      |                      | 31 YR                 | Female          | USA            |  |
| <u>Preferred Term</u>                                                                                                                                     | <u>Product</u> |                  | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>          | <u>Route</u>         | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>     |  |
| Condition Aggravated;<br>Dizziness; Impaired Work<br>Ability; Palpitations;<br>Paraesthesia; Product<br>Substitution Issue; Product<br>Substitution Issue | Escitalopram   |                  |                    |                 | S                    | Oral                 | Quantity:1 Tablet(S); |                 | Accord         |  |
|                                                                                                                                                           | Paxil          |                  |                    |                 | C                    |                      |                       |                 | Not Reported   |  |
|                                                                                                                                                           | Xanax          |                  |                    |                 | C                    |                      |                       |                 | Not Reported   |  |

|                                                                                                                      |                |                  |                    |                 |                           |                      |                    |                 |                |
|----------------------------------------------------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|---------------------------|----------------------|--------------------|-----------------|----------------|
| <u>FDA Received Date</u>                                                                                             | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |
| 06-Apr-2017                                                                                                          | 11817837       | NON-EXPEDITED    |                    |                 | US-JNJFOC-<br>20151116078 |                      |                    | Male            | USA            |
| <u>Preferred Term</u>                                                                                                | <u>Product</u> |                  | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>               | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>     |
| Emotional Distress;<br>Gynaecomastia; Off Label<br>Use; Product Use In<br>Unapproved Indication;<br>Weight Increased | Risperdal      |                  |                    |                 | S                         | Oral                 |                    |                 | Not Reported   |
|                                                                                                                      | Risperdal      |                  |                    |                 | S                         | Oral                 |                    |                 | Not Reported   |
|                                                                                                                      | Risperdal      |                  |                    |                 | S                         | Oral                 |                    |                 | Not Reported   |
|                                                                                                                      | Risperdal      |                  |                    |                 | S                         | Oral                 |                    |                 | Not Reported   |
|                                                                                                                      | Risperidone    |                  |                    |                 | S                         | Oral                 |                    |                 | Not Reported   |
|                                                                                                                      | Focalin        |                  |                    |                 | S                         |                      |                    |                 | Not Reported   |
|                                                                                                                      | Lexapro        |                  |                    |                 | S                         |                      | 10-20 Mg           |                 | Not Reported   |
|                                                                                                                      | Strattera      |                  |                    |                 | S                         |                      |                    |                 | Not Reported   |

|                                                                             |                |                  |                    |                 |                           |                      |                    |                 |                |
|-----------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|---------------------------|----------------------|--------------------|-----------------|----------------|
| <u>FDA Received Date</u>                                                    | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |
| 06-Apr-2017                                                                 | 11818361       | NON-EXPEDITED    |                    |                 | US-JNJFOC-<br>20150812399 |                      | 13 YR              | Male            | USA            |
| <u>Preferred Term</u>                                                       | <u>Product</u> |                  | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>               | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>     |
| Abnormal Weight Gain;<br>Gynaecomastia; Insomnia;<br>Off Label Use; Product | Risperdal      |                  |                    |                 | S                         | Oral                 |                    |                 | Not Reported   |
|                                                                             | Risperdal      |                  |                    |                 | S                         | Oral                 |                    |                 | Not Reported   |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                              |           |   |         |              |
|------------------------------|-----------|---|---------|--------------|
| Use In Unapproved Indication | Risperdal | S | Oral    | Not Reported |
|                              | Lexapro   | S | Unknown | Not Reported |

| <u>FDA Received Date</u>                                                       | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 06-Apr-2017                                                                    | 11819317       | NON-EXPEDITED    |                    |                 | US-JNJFOC-20150923181 |                      |                 | Male         | USA            |
| <u>Preferred Term</u>                                                          | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Weight Gain;                                                          | Risperdal      |                  |                    | S               | Oral                  | 1 And 2 Mg           |                 | Not Reported |                |
| Gynaecomastia;                                                                 | Risperdal      |                  |                    | S               | Oral                  |                      |                 | Not Reported |                |
| Hyperprolactinaemia; Off Label Use; Pain; Product Use In Unapproved Indication | Risperidone    |                  |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                | Lexapro        |                  |                    | S               | Oral                  |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>         | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|----------------------------------|---------------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|------------|----------------|
| 06-Apr-2017                      | 12867614                  | EXPEDITED (15-DAY) |                    | HO              | JP-ALLERGAN-1673145US |                      | 47 YR           | Male       | JPN            |
| <u>Preferred Term</u>            | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Disease Recurrence; Pericarditis | Escitalopram Oxalate - Bp |                    |                    | S               | Oral                  | Unk, Unknown         |                 | Allergan   |                |

| <u>FDA Received Date</u>                  | <u>Case #</u>   | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------|-----------------|------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 06-Apr-2017                               | 12881333        | NON-EXPEDITED    |                    | OT              | US-JNJFOC-20161003689 |                      | 35 YR           | Male         | USA            |
| <u>Preferred Term</u>                     | <u>Product</u>  | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Breast Disorder Male; Hyperprolactinaemia | Risperdal       |                  |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                           | Risperdal       |                  |                    | S               | Oral                  | 2-4mg                |                 | Not Reported |                |
|                                           | Risperdal       |                  |                    | S               | Oral                  | 2-4mg                |                 | Not Reported |                |
|                                           | Risperdal       |                  |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                           | Risperdal M-Tab |                  |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                           | Lexapro         |                  |                    | S               | Unknown               |                      |                 | Not Reported |                |
|                                           | Lexapro         |                  |                    | S               | Unknown               |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>    | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|--------------------|--------------------------------|----------------------|-----------------|--------------|----------------|
| 06-Apr-2017                                                                                             | 13161498                  | EXPEDITED (15-DAY) |                    | CA, DE, HO, LT, OT | US-DRREDDYS-USA/USA/17/0086577 |                      | 4 DAY           | Male         | USA            |
| <u>Preferred Term</u>                                                                                   | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>        | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Failure;                                                                                        | Ondansetron               |                    |                    | S                  | Transplacental                 |                      |                 | Not Reported |                |
| Congenital Cardiovascular Anomaly; Congestive                                                           | Sertraline Hydrochloride  |                    |                    | S                  | Transplacental                 |                      |                 | Not Reported |                |
| Cardiomyopathy; Foetal                                                                                  | Escitalopram              |                    |                    | S                  | Transplacental                 |                      |                 | Not Reported |                |
| Exposure During Pregnancy; Human                                                                        | Progesterone              |                    |                    | S                  | Transplacental                 |                      |                 | Not Reported |                |
| Herpesvirus 6 Infection; Multiple Organ Dysfunction Syndrome                                            |                           |                    |                    |                    |                                |                      |                 |              |                |
| <u>FDA Received Date</u>                                                                                | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>    | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Apr-2017                                                                                             | 13194980                  | EXPEDITED (15-DAY) |                    | DE                 | JP-ALLERGAN-1704425US          |                      | 70 YR           | Female       | JPN            |
| <u>Preferred Term</u>                                                                                   | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>        | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Death                                                                                                   | Escitalopram Oxalate - Bp |                    |                    | S                  | Oral                           | Q                    |                 | Allergan     |                |
|                                                                                                         | Rohypnol                  |                    |                    | C                  |                                |                      |                 | Not Reported |                |
|                                                                                                         | Tetramide                 |                    |                    | C                  |                                | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>    | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Apr-2017                                                                                             | 13247455                  | EXPEDITED (15-DAY) |                    | OT                 | US-ALLERGAN-1705822US          |                      | 47 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                   | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>        | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Appendix Disorder; Depression; Drug Ineffective;                                               | Lexapro                   |                    |                    | S                  | Oral                           | 20 Mg, Qd            |                 | Allergan     |                |
| Gallbladder Disorder; Musculoskeletal Discomfort; Nerve Compression; Spinal Disorder; Suicidal Ideation | Embeda                    |                    |                    | C                  | Oral                           | 20 Mg, Qd            |                 | Not Reported |                |
|                                                                                                         | Valium                    |                    |                    | C                  | Oral                           | 10 Mg, Bid           |                 | Not Reported |                |
|                                                                                                         | Valium                    |                    |                    | C                  |                                |                      |                 | Not Reported |                |
|                                                                                                         | Lyrica                    |                    |                    | C                  | Oral                           | 150 Mg, Bid          |                 | Not Reported |                |
|                                                                                                         | Lyrica                    |                    |                    | C                  | Oral                           | 75 Mg, Bid           |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|               |   |      |            |              |
|---------------|---|------|------------|--------------|
| Levothyroxine | C | Oral | 125 Mg, Qd | Not Reported |
| Ambien        | C | Oral | 10 Mg, Prn | Not Reported |
| Baclofen      | C |      | Unk        | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 06-Apr-2017              | 13301263      | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2017092556 |                      | 51 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Ineffective      | Effexor Xr     |              |            | S           |              | 300 Mg, 1x/Day     |                 | Pfizer       |
|                       | Gabapentin     |              |            | S           |              |                    |                 | Pfizer       |
|                       | Zoloft         |              |            | S           |              | Unk                |                 | Pfizer       |
|                       | Wellbutrin     |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Prozac         |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Cymbalta       |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Lexapro        |              |            | S           |              | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Apr-2017              | 13409181      | DIRECT           | Y                  |                 |                      |                      |            | Female     | USA            |

| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Product Dispensing Error | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Apr-2017              | 13410123      | EXPEDITED (15-DAY) |                    | OT              | DE-TORRENT-00006328  |                      | 1 DAY      | Male       | DEU            |

| <u>Preferred Term</u>             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Agitation; Bradycardia;           | Bupropion      |              |            | S           |              |                    |                 | Unknown    |
| Drug Withdrawal                   | Escitalopram   |              |            | S           |              |                    |                 | Unknown    |
| Syndrome Neonatal;                | L-Thyroxin     |              |            | C           |              |                    |                 | Unknown    |
| Foetal Exposure During Pregnancy; |                |              |            |             |              |                    |                 |            |
| Gastrointestinal Disorder;        |                |              |            |             |              |                    |                 |            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Hypertension; Neonatal  
Hypoxia; Small For Dates  
Baby; Tremor

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 06-Apr-2017              | 13415728      | EXPEDITED (15-DAY) |                    | HO              | FR-JNJFOC-20170405561 |                      | 88 YR      | Female     | FRA            |

| <u>Preferred Term</u>                     | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Facial Bones Fracture;<br>Fall; Haematoma | Tramadol Hydrochloride |              |            | S           | Oral         |                    |                 | Not Reported |
|                                           | Seresta                |              |            | S           | Oral         |                    |                 | Not Reported |
|                                           | Seroplex               |              |            | S           | Oral         |                    |                 | Not Reported |
|                                           | Amlodipine             |              |            | S           | Oral         |                    |                 | Not Reported |
|                                           | Imovane                |              |            | S           | Oral         |                    |                 | Not Reported |
|                                           | Simvastatine           |              |            | S           | Oral         |                    |                 | Not Reported |
|                                           | Omeprazole             |              |            | S           | Oral         |                    |                 | Not Reported |
|                                           | Kardegic               |              |            | S           | Oral         |                    |                 | Not Reported |
|                                           | Tardyferon             |              |            | S           | Oral         |                    |                 | Not Reported |
|                                           | Doliprane              |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                           | Uvedose                |              |            | C           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 06-Apr-2017              | 13416441      | EXPEDITED (15-DAY) |                    | CA, OT          | FR-ALLERGAN-1713418US |                      |            | Unknown    | FRA            |

| <u>Preferred Term</u>                                                                                | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------|---------------------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Coarctation Of The Aorta;<br>Congenital Nose<br>Malformation; Foetal<br>Exposure During<br>Pregnancy | Escitalopram Oxalate - Bp |              |            | S           | Transplacental | 15 Mg, Qd          |                 | Allergan     |
|                                                                                                      | Seresta                   |              |            | S           | Transplacental | 10 Mg, Qd          |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 06-Apr-2017              | 13416512      | EXPEDITED (15-DAY) |                    | OT              | DE-ALLERGAN-1713425US |                      | 17 YR      | Male       | DEU            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                     | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                           | <u>Dosage Text</u>                               | <u>Duration</u> | <u>Mfr</u>           |                |
|-----------------------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|--------------------------------------------------------|--------------------------------------------------|-----------------|----------------------|----------------|
| Abdominal Pain Upper;<br>Growth Retardation;<br>Hypothyroidism; Off Label<br>Use; Weight Increased        | Escitalopram Oxalate - Bp |                    |                    | S               | Oral                                                   | 15 Mg, Unk                                       |                 | Allergan             |                |
|                                                                                                           | Escitalopram Oxalate - Bp |                    |                    | S               | Oral                                                   | Unk                                              |                 | Allergan             |                |
|                                                                                                           | EutYROX                   |                    |                    | C               |                                                        | Unk                                              |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                                                  | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u>                             | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 06-Apr-2017                                                                                               | 13416764                  | EXPEDITED (15-DAY) |                    | OT              | SE-TEVA-757386ISR                                      |                                                  | 19 YR           | Female               | SWE            |
| <u>Preferred Term</u>                                                                                     | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                           | <u>Dosage Text</u>                               | <u>Duration</u> | <u>Mfr</u>           |                |
| Hypersomnia                                                                                               | Escitalopram              |                    |                    | S               | Oral                                                   |                                                  |                 | Ivax                 |                |
| <u>FDA Received Date</u>                                                                                  | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u>                             | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 06-Apr-2017                                                                                               | 13416855                  | EXPEDITED (15-DAY) |                    | OT              | PL-TEVA-756598ISR                                      |                                                  | 93 YR           | Female               | POL            |
| <u>Preferred Term</u>                                                                                     | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                           | <u>Dosage Text</u>                               | <u>Duration</u> | <u>Mfr</u>           |                |
| Choking; Dyspnoea;<br>Incorrect Product<br>Administration Duration;<br>Oral Mucosal Eruption              | Escitalopram Actavis      |                    |                    | S               |                                                        | 10 Milligram Daily; The<br>Patient Took 1 Tablet |                 | Ivax                 |                |
| <u>FDA Received Date</u>                                                                                  | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u>                             | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 07-Apr-2017                                                                                               | 13418022                  | EXPEDITED (15-DAY) |                    | OT              | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>BMS-2017-029267 |                                                  |                 | Female               | USA            |
| <u>Preferred Term</u>                                                                                     | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                           | <u>Dosage Text</u>                               | <u>Duration</u> | <u>Mfr</u>           |                |
| Breech Presentation;<br>Foetal Exposure During<br>Pregnancy;<br>Hypoglycaemia Neonatal;<br>Premature Baby | Aripiprazole              |                    |                    | S               | Transplacental                                         | 5 Mg, Unk                                        |                 | Bristol Myers Squibb |                |
|                                                                                                           | Lexapro                   |                    |                    | S               | Transplacental                                         | Unk                                              |                 | Not Reported         |                |
|                                                                                                           | Wellbutrin                |                    |                    | S               | Transplacental                                         | Unk                                              |                 | Not Reported         |                |
|                                                                                                           | Zofran /00955301/         |                    |                    | S               | Transplacental                                         | Unk                                              |                 | Not Reported         |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                          | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|-------------------------------|---------------------------------------|-----------------|--------------|----------------|
| 08-Apr-2017                                                                                       | 13418487       | EXPEDITED (15-DAY) |                    | CA, DE, HO      | US-CIPLA LTD.-<br>2017US05073 |                                       |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                                             | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Failure;<br>Congestive                                                                    | Sertraline     |                    |                    | S               | Transplacental                | Unk                                   |                 | Invagen      |                |
| Cardiomyopathy; Foetal                                                                            | Escitalopram   |                    |                    | S               | Transplacental                | Unk                                   |                 | Invagen      |                |
| Exposure During<br>Pregnancy; Human                                                               | Ondansetron    |                    |                    | S               | Transplacental                | Unk                                   |                 | Cipla        |                |
| Herpesvirus 6 Infection;<br>Multiple Organ<br>Dysfunction Syndrome                                | Progesterone   |                    |                    | S               | Transplacental                | Unk                                   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                          | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Apr-2017                                                                                       | 13418490       | EXPEDITED (15-DAY) |                    | OT              | US-CIPLA LTD.-<br>2017US05075 |                                       |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                                             | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Exposure During<br>Pregnancy; Human                                                               | Sertraline     |                    |                    | S               | Unknown                       | Unk, For The Initial Two<br>Trimester |                 | Invagen      |                |
| Herpesvirus 6 Infection;<br>Hypersensitivity                                                      | Escitalopram   |                    |                    | S               | Unknown                       | Unk, For The Final<br>Trimester       |                 | Invagen      |                |
|                                                                                                   | Ondansetron    |                    |                    | S               | Unknown                       | Unk                                   |                 | Cipla        |                |
|                                                                                                   | Progesterone   |                    |                    | S               | Unknown                       | Unk                                   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                          | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Apr-2017                                                                                       | 13422446       | DIRECT             |                    | DS              |                               |                                       | 40 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                             | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Cognitive<br>Disorder; Disease<br>Recurrence; Memory<br>Impairment; Therapy<br>Cessation | Escitalopram   |                    |                    | S               | Oral                          | Quantity:1 Tablet(S);                 |                 | Not Reported |                |
|                                                                                                   | Lexapo         |                    |                    | C               |                               |                                       |                 | Not Reported |                |
|                                                                                                   | Multi Vitamin  |                    |                    | C               |                               |                                       |                 | Not Reported |                |
|                                                                                                   | Vitamin D Nos  |                    |                    | C               |                               |                                       |                 | Not Reported |                |
|                                                                                                   | Claritin       |                    |                    | C               |                               |                                       |                 | Not Reported |                |
|                                                                                                   | Melatonin      |                    |                    | C               |                               |                                       |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                 | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------------|--------------------|--------------------|--------------------|-----------------|---------------------------------|------------------------------------|-----------------|--------------|----------------|
| 10-Apr-2017                                                                                                                              | 13036375           | EXPEDITED (15-DAY) |                    | OT              | US-FERRINGPH-2016FE06513        |                                    |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                                                                                    | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Human Herpesvirus 6 Infection; Hypersensitivity; Maternal Exposure During Pregnancy; Off Label Use; Product Use In Unapproved Indication | Sertraline         |                    |                    | S               | Unknown                         | For The Initial Two Trimester      |                 | Not Reported |                |
|                                                                                                                                          | Ondansetron        |                    |                    | S               | Unknown                         | Unk                                |                 | Not Reported |                |
|                                                                                                                                          | Escitalopram       |                    |                    | S               | Unknown                         | For The Final Trimester            |                 | Not Reported |                |
|                                                                                                                                          | Progesterone       |                    |                    | S               | Unknown                         | High-Dose                          |                 | Ferring      |                |
| <u>FDA Received Date</u>                                                                                                                 | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Apr-2017                                                                                                                              | 13188020           | EXPEDITED (15-DAY) |                    | OT              | US-AUROBINDO-AUR-APL-2017-29211 |                                    |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                    | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Human Herpesvirus 6 Infection; Hypersensitivity; Maternal Exposure During Pregnancy                                                      | Sertraline         |                    |                    | S               | Unknown                         | Unk, For The Initial Two Trimester |                 | Aurobindo    |                |
|                                                                                                                                          | Escitalopram       |                    |                    | S               |                                 | Unk, For The Final Trimester       |                 | Aurobindo    |                |
|                                                                                                                                          | Ondansetron        |                    |                    | S               | Unknown                         |                                    |                 | Aurobindo    |                |
|                                                                                                                                          | Progesterone       |                    |                    | S               | Unknown                         |                                    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                 | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Apr-2017                                                                                                                              | 13295478           | EXPEDITED (15-DAY) |                    | HO              | JP-ALLERGAN-1707900US           |                                    | 53 YR           | Male         | JPN            |
| <u>Preferred Term</u>                                                                                                                    | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Liver Disorder; Metabolic Acidosis; Nausea; Vomiting                                                                                     | Lexapro            |                    |                    | S               | Oral                            | 10 Mg, Qd                          |                 | Allergan     |                |
|                                                                                                                                          | Reflex             |                    |                    | S               | Oral                            | 30 Mg, Qd                          |                 | Not Reported |                |
|                                                                                                                                          | Reflex             |                    |                    | S               | Oral                            | 15 Mg, Qd                          |                 | Not Reported |                |
|                                                                                                                                          | Sodium Picosulfate |                    |                    | S               | Unknown                         | 10 Gtt, Qd                         |                 | Not Reported |                |
|                                                                                                                                          | Remeron            |                    |                    | C               |                                 | Unk                                |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|--------------------------------------------------------|----------------------|-----------------|----------------------|----------------|
| 10-Apr-2017              | 13315214       | NON-EXPEDITED    |                    |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>BMS-2017-019682 |                      | 33 YR           | Male                 | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Sexual Dysfunction       | Abilify        |                  |                    | S               | Unknown                                                | Unk                  |                 | Bristol Myers Squibb |                |
|                          | Lexapro        |                  |                    | S               | Unknown                                                |                      |                 | Not Reported         |                |

| <u>FDA Received Date</u>                                                                                                              | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|-------------------------------------|----------------------|-----------------|------------|----------------|
| 10-Apr-2017                                                                                                                           | 13421069                      | EXPEDITED (15-DAY) |                    | OT              | US-AUROBINDO-AUR-<br>APU-2015-06206 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>                                                                                                                 | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Anger; Anxiety; Crying;<br>Depression; Fatigue;<br>Feeling Abnormal;<br>Headache; Insomnia;<br>Nausea; Suicidal Ideation;<br>Vomiting | Escitalopram Tablets Usp 20mg |                    |                    | S               | Unknown                             | 20 Mg, Unk           |                 | Aurobindo  |                |

| <u>FDA Received Date</u>               | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|----------------------------------------|-------------------------------|--------------------|--------------------|-----------------|-------------------------------------|----------------------|-----------------|------------|----------------|
| 10-Apr-2017                            | 13421073                      | EXPEDITED (15-DAY) |                    | HO              | US-AUROBINDO-AUR-<br>APU-2015-06220 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>                  | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Anxiety; Drug Ineffective;<br>Dyspnoea | Escitalopram Tablets Usp 10mg |                    |                    | S               | Unknown                             | 10 Mg, Unk           |                 | Aurobindo  |                |

| <u>FDA Received Date</u>                                                                                 | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|-------------------------------------|----------------------|-----------------|------------|----------------|
| 10-Apr-2017                                                                                              | 13421078                      | EXPEDITED (15-DAY) |                    | DS, OT          | US-AUROBINDO-AUR-<br>APU-2015-06208 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>                                                                                    | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Depression; Fatigue;<br>Feeling Abnormal; Loss Of<br>Personal Independence In<br>Daily Activities; Pain; | Escitalopram Tablets Usp 20mg |                    |                    | S               | Unknown                             | 20 Mg, Unk           |                 | Aurobindo  |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Product Substitution Issue;  
Speech Disorder; Suicidal  
Ideation

| <u>FDA Received Date</u>                                                                                                                                | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>       | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------------|----------------------|----------------------|-----------------|--------------|----------------|
| 10-Apr-2017                                                                                                                                             | 13421470       | EXPEDITED (15-DAY) |                    | CA, DE, HO, LT,<br>OT | US-ACCORD-049936     |                      | 4 YR            | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>           | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Failure;<br>Cardiomyopathy; Foetal<br>Exposure During<br>Pregnancy; Human<br>Herpesvirus 6 Infection;<br>Multiple Organ<br>Dysfunction Syndrome | Escitalopram   |                    |                    | S                     | Transplacental       |                      |                 | Accord       |                |
|                                                                                                                                                         | Ondansetron    |                    |                    | S                     | Transplacental       |                      |                 | Accord       |                |
|                                                                                                                                                         | Sertraline     |                    |                    | S                     | Transplacental       |                      |                 | Accord       |                |
|                                                                                                                                                         | Progesterone   |                    |                    | S                     | Transplacental       |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------------------|-----------------|--------------|----------------|
| 10-Apr-2017                                                                                  | 13421495       | EXPEDITED (15-DAY) |                    | OT              | US-ACCORD-049937     |                                  |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Human Herpesvirus 6<br>Infection; Hypersensitivity;<br>Maternal Exposure During<br>Pregnancy | Escitalopram   |                    |                    | S               |                      | For The Final Trimester          |                 | Accord       |                |
|                                                                                              | Sertraline     |                    |                    | S               |                      | For The Initial Two<br>Trimester |                 | Accord       |                |
|                                                                                              | Ondansetron    |                    |                    | S               |                      |                                  |                 | Accord       |                |
|                                                                                              | Progesterone   |                    |                    | S               |                      | High Dose                        |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 10-Apr-2017              | 13423946                  | EXPEDITED (15-DAY) |                    | DE              | CA-ALLERGAN-<br>1713843US |                      | 76 YR           | Male       | CAN            |
| <u>Preferred Term</u>    | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Death                    | Escitalopram Oxalate - Bp |                    |                    | S               | Unknown                   | 10 Mg                |                 | Allergan   |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 10-Apr-2017              | 13423964      | EXPEDITED (15-DAY) |                    | OT              | GB-ALLERGAN-<br>1713602US |                      | 27 YR      | Female     | GBR            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                                                                                                                 | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|-----------------------|-----------------------|-----------------|--------------|----------------|
| Asthenia; Decreased Appetite; Dizziness; Fatigue; Female Orgasmic Disorder; Headache; Heart Rate Increased; Heart Rate Irregular; Hyperhidrosis; Hypotension; Mydriasis; Nausea; Pyrexia; Restlessness; Somnolence; Tremor; Weight Decreased; Yawning | Escitalopram Oxalate - Bp |                    |                    | S               | Oral                  | 10 Mg, Qd             |                 | Allergan     |                |
|                                                                                                                                                                                                                                                       | Diclofenac Sodium         |                    |                    | C               | Unknown               | One Dosage Form Daily |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                              | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Apr-2017                                                                                                                                                                                                                                           | 13423985                  | EXPEDITED (15-DAY) |                    | HO              | NL-ALLERGAN-1713809US |                       | 20 DAY          | Male         | NLD            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                 | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Asterixis; Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Mood Swings; Restlessness; Tachypnoea; Tremor                                                                                                                         | Escitalopram Oxalate - Bp |                    |                    | S               | Transplacental        | 10 Mg, Qd             |                 | Allergan     |                |
|                                                                                                                                                                                                                                                       | Remeron Tablet            |                    |                    | C               | Transplacental        | 15 Mg, Unknown        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                              | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Apr-2017                                                                                                                                                                                                                                           | 13425930                  | DIRECT             |                    | OT              |                       |                       | 77 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                 | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Gait Disturbance; Headache; Insomnia; Muscle Spasms; Muscle Spasms                                                                                                                                                                                    | Escitalopram Oxalate      |                    |                    | S               | Oral                  | Quantity:1 Tablet(S); |                 | Cipla        |                |
|                                                                                                                                                                                                                                                       | Wellbutrin Hcl XI         |                    |                    | C               |                       |                       |                 | Not Reported |                |
|                                                                                                                                                                                                                                                       | Acyclovir                 |                    |                    | C               |                       |                       |                 | Not Reported |                |
|                                                                                                                                                                                                                                                       | Allegra D                 |                    |                    | C               |                       |                       |                 | Not Reported |                |
|                                                                                                                                                                                                                                                       | Biotin                    |                    |                    | C               |                       |                       |                 | Not Reported |                |
|                                                                                                                                                                                                                                                       | Vit B-12                  |                    |                    | C               |                       |                       |                 | Not Reported |                |
|                                                                                                                                                                                                                                                       | Vit D 10                  |                    |                    | C               |                       |                       |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                    | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------|-----------------|--------------------|--------------------|-----------------|----------------------|--------------------------------|-----------------|--------------|----------------|
| 11-Apr-2017                                                                                 | 9929955         | EXPEDITED (15-DAY) |                    | OT              | PHHY2014US022507     |                                |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                       | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Exposure Via Father;<br>Fatigue; Frustration<br>Tolerance Decreased;<br>Psychiatric Symptom | Fluoxetine      |                    |                    | S               | Unknown              | Fetal Drug Exposure Via Father |                 | Novartis     |                |
|                                                                                             | Citalopram      |                    |                    | S               | Unknown              | Fetal Drug Exposure Via Father |                 | Not Reported |                |
|                                                                                             | Escitalopram    |                    |                    | S               | Unknown              | Fetal Drug Exposure Via Father |                 | Not Reported |                |
|                                                                                             | Sertraline      |                    |                    | S               | Unknown              | Fetal Drug Exposure Via Father |                 | Not Reported |                |
|                                                                                             | Bupropion       |                    |                    | S               | Unknown              | Fetal Drug Exposure Via Father |                 | Not Reported |                |
|                                                                                             | Olanzapine      |                    |                    | S               | Unknown              | Fetal Drug Exposure Via Father |                 | Not Reported |                |
|                                                                                             | Amitriptyline   |                    |                    | S               | Unknown              | Fetal Drug Exposure Via Father |                 | Not Reported |                |
|                                                                                             | Valproic Acid   |                    |                    | S               | Unknown              | Fetal Drug Exposure Via Father |                 | Not Reported |                |
|                                                                                             | Venlafaxine     |                    |                    | S               | Unknown              | Fetal Drug Exposure Via Father |                 | Not Reported |                |
|                                                                                             | Risperidone     |                    |                    | S               | Unknown              | Fetal Drug Exposure Via Father |                 | Not Reported |                |
|                                                                                             | Zolpidem        |                    |                    | S               | Unknown              | Fetal Drug Exposure Via Father |                 | Not Reported |                |
|                                                                                             | Quetiapine      |                    |                    | S               | Unknown              | Fetal Drug Exposure Via Father |                 | Not Reported |                |
|                                                                                             | Trazodone       |                    |                    | S               | Unknown              | Fetal Drug Exposure Via Father |                 | Not Reported |                |
|                                                                                             | Diphenhydramine |                    |                    | S               | Unknown              | Fetal Drug Exposure Via Father |                 | Not Reported |                |
|                                                                                             | Prazosin        |                    |                    | S               | Unknown              | Fetal Drug Exposure Via        |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Eszopiclone S Unknown Father Fetal Drug Exposure Via Father Not Reported

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>    | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|--------------------|---------------------------------|----------------------|------------|------------|----------------|
| 11-Apr-2017              | 13187936      | EXPEDITED (15-DAY) |                    | CA, DE, HO, LT, OT | US-AUROBINDO-AUR-APL-2017-29456 |                      | 4 YR       | Male       | USA            |

| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Cardiac Failure;         | Sertraline     |              |            | S           | Transplacental | Unk                |                 | Aurobindo    |
| Cardiomyopathy;          | Escitalopram   |              |            | S           | Transplacental | Unk                |                 | Aurobindo    |
| Dilatation Ventricular;  | Escitalopram   |              |            | S           | Transplacental | Unk                |                 | Aurobindo    |
| Endocardial              | Ondansetron    |              |            | S           | Transplacental | Unk                |                 | Aurobindo    |
| Fibroelastosis; Foetal   | Progesterone   |              |            | S           | Transplacental | Unk                |                 | Not Reported |
| Exposure During          | Progesterone   |              |            | S           | Transplacental | Unk                |                 | Not Reported |
| Pregnancy; Human         |                |              |            |             |                |                    |                 |              |
| Herpesvirus 6 Infection; |                |              |            |             |                |                    |                 |              |
| Multiple Organ           |                |              |            |             |                |                    |                 |              |
| Dysfunction Syndrome;    |                |              |            |             |                |                    |                 |              |
| Myocardial Fibrosis;     |                |              |            |             |                |                    |                 |              |
| Myocarditis; Oedema      |                |              |            |             |                |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 11-Apr-2017              | 13399201      | EXPEDITED (15-DAY) |                    | HO              | US-CIPLA LTD.-2017US04877 |                      |            | Unknown    | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Catatonia             | Escitalopram   |              |            | S           | Unknown      | Unk                |                 | Invagen      |
|                       | Lithium        |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                       | Trazodone      |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                       | Paliperidone   |              |            | S           | Unknown      | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------|----------------------|------------|------------|----------------|
| 11-Apr-2017              | 13425452      | EXPEDITED (15-DAY) |                    |                 | US-LUNDBECK-DKLU2028232 |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|